



North Carolina Board of Pharmacy

Published to promote compliance of pharmacy and drug law

6015 Farrington Rd, Suite 201 • Chapel Hill, NC 27517 • Tel: 919/246-1050
Fax: 919/246-1056 • www.ncbop.org

Item 2262 – Continuing Update on Pharmacy Compounding Matters

Item 2252 of the January 2013 *Newsletter* and Item 2259 of the April 2013 *Newsletter* updated pharmacists on compounding regulation matters. The North Carolina Board of Pharmacy's Compounding Working Group reported its initial recommendations to the Board in April. That report may be found here: www.ncbop.org/PDF/CompoundingWorkGroupRecommendationsApril2013.pdf.

Many of the Compounding Working Group's data collection and training recommendations have already been implemented by Board staff or are in the process of implementation. Other recommendations for rule amendments are presently under consideration by the Board.

Legislative activity concerning pharmacy compounding continues apace at the federal level. S 959, the Pharmaceutical Compounding Quality and Accountability Act, was introduced in the United States Senate on May 15, 2013. The bill may be found here: <http://thomas.loc.gov/cgi-bin/query/z?c113:S.959>. The bill's chief proposal is to categorize "compounding manufacturers," which would be regulated primarily and exclusively by Food and Drug Administration (FDA). A compounding manufacturer is defined as a facility that either:

- (1) compounds any sterile drug product without receiving a prescription order for such sterile drug product prior to beginning compounding and distributes or offers to sell such compounded product in interstate commerce; or
- (2) repackages any preservative-free sterile product or pools any such sterile drug products (with some exceptions).

Observers expect the US House of Representatives to introduce its own legislation concerning pharmacy compounding, but no bill had been introduced at the time of this writing.

In late May, reports again surfaced of potentially contaminated preservative-free methylprednisolone acetate injections, this time from the Main Street Family Pharmacy in Newbern, TN. Board staff sought and obtained a surrender of Main Street Family Pharmacy's out-of-state pharmacy permit, and worked with the North Carolina Department of Health and Human Services to identify and contact clinics and patients who had received the potentially contaminated products. Main Street Family Pharmacy initiated a voluntary recall of all compounded sterile products. At the time of this writing, several adverse event reports have been collected from a handful of states. State and federal authorities are cooperating in the investigation, and twice-weekly updates may be found here: www.cdc.gov/hai/outbreaks/tn-pharmacy/index.html?mobile=nocontent.

In April, the Board issued a partial summary suspension of the pharmacy permit held by Stewart Pharmaceuticals in Fayetteville, NC, stemming from concerns over sterility control measures. Stewart Pharmaceuticals subsequently issued a voluntary recall of all sterile products. More information on the recall may be found here: www.ncbop.org/PDF/StewartRecallNotice041213.pdf.

Item 2263 – Congratulations to Pharmacists Continuously Licensed by the Board for 60 Years

Board members and staff extend their warmest congratulations to the following pharmacists who have been continuously licensed in North Carolina for 60 years. They are a select group, and the Board thanks them for their service to North Carolina pharmacy.

Pinckney Hugo Heaton, Clinton, NC.....February 27, 1953
Alfred Franklin Cole, Roxboro, NC.....June 29, 1953
Herman Hallet Daniels, Ahoskie, NC.....June 29, 1953
William James Miller, Statesville, NC.....June 29, 1953
Carson Meade Keys, West Jefferson, NC.....September 18, 1953

Item 2264 – Keeping Track of Emergency Contraception Developments

Board staff has received several calls expressing confusion over the current state of over-the-counter (OTC) (or behind-the-counter) access to emergency contraception products. Such confusion is understandable, owing to various developments in a federal court case, as well as changes approved by FDA.

FDA approved behind-the-counter status for Plan B® in 2009. Initially, FDA restricted behind-the-counter sales of Plan B (the two-pill version) to purchasers aged 18 or older. But, as a result of a lawsuit filed against FDA challenging the method by which that age limit was established, FDA reconsidered. In 2011, FDA determined that Plan B should be available without a prescription regardless of age. Kathleen Sebelius, secretary of the Department of Health and Human Services, however, disagreed with this decision. Secretary Sebelius modified FDA's determination and ordered that Plan B be available behind-the-counter (without prescription) to purchasers aged 17 or older.

Secretary Sebelius's decision precipitated another lawsuit against FDA, again charging that political considerations, not scientific evidence, were the predominant grounds for setting the age criterion.

On April 4, 2013, US District Court Judge Edward Korman issued a ruling that overturned this age restriction and ordered FDA to make Plan B and its generic equivalents available OTC without an age restriction.

Further confusion followed when, on April 30, 2013, FDA decided to make Plan B One-Step available OTC to any individual
continued on page 4



Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.

ISMP Study on Targeted Mandatory Patient Counseling

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert![®] Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
 - ◇ fentanyl patches
 - ◇ hydrocodone with acetaminophen
 - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
 - ◇ warfarin
 - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
 - ◇ Humalog[®] (insulin lispro)
 - ◇ NovoLog[®] (insulin aspart)
 - ◇ Levemir[®] (insulin detemir)
 - ◇ Lantus[®] (insulin glargine)
 - ◇ Apidra[®] (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
 - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at www.ismp.org/AHRQ/default.asp?link=ha.

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,

Compliance News



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of www.nabp.net.

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancil-

lary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of www.nabp.net.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in NABPLAW® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. NABPLAW Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about NABPLAW Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at www.nabp.net/programs/member-services/nabplaw/.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

continued from page 1

over the age of 15 who can verify his or her age by presenting a valid, government-issued form of identification. Per FDA's decision, Plan B One-Step is also no longer required to be kept behind the pharmacy counter. FDA's decision applied only to the single dose, 1.5 mg levonorgestrel tablet formulation of Plan B manufactured by Teva Pharmaceuticals. It did not apply to any other formulation of Plan B or to any other type of emergency contraceptive.

In the meantime, the US Department of Justice appealed Judge Korman's ruling and asked the US Court of Appeals for the Second Circuit for a stay to that ruling pending appeal. On June 5, 2013, the Second Circuit issued an order. It stayed Judge Korman's ruling where Plan B One-Step is concerned. It did **not** stay Judge Korman's ruling where the two-pill Plan B formulation is concerned. The Second Circuit directed that the merits of the appeal be heard on "an expedited schedule."

In response to the Second Circuit ruling, on June 11, 2013, FDA announced its intention to withdraw its appeal of Judge Korman's ruling and submit a proposal to Judge Korman. On June 14, 2013, Judge Korman approved a plan whereby, upon receipt of a supplemental new drug application from Teva, FDA will "without delay" approve Plan B One-Step for all-age purchasers OTC. FDA will not make changes to the availability of the two-pill Plan B formulation.

Accordingly, as of this writing (June 14, 2013), the state of emergency contraceptive availability is as follows:

- ◆ Plan B One-Step: Per FDA's April 30, 2013 decision, the Teva-manufactured product is available for purchase without a prescription by a person aged 15 or older. The purchaser must provide a valid, government-issued identification prior to purchase. This product does not have to be kept behind the pharmacy counter.

Per Judge Korman's June 12, 2013 order, however, Plan B One-Step will in the near future be made available without age restriction on an OTC basis. Board staff will update pharmacists when this change occurs.

- ◆ Two-pill Plan B formulations: Per Judge Korman's June 12, 2013 order, there will be no immediate changes to the two-dose Plan B formulation's availability. It remains available without a prescription to purchasers age 17 or older and available with a prescription to purchasers under age 17.

Board staff will update pharmacists on any further changes on this rapidly evolving topic through the Board's Web site at www.ncbop.org.

Item 2265 – Board Publishes Proposed Amendments to Rules Governing Automated Dispensing Devices

On April 19, 2013, the Board published proposed amendments to the rules governing automated dispensing devices. Written comments on the proposed rules will be accepted through September 10, 2013. Such comments should be addressed to Jay Campbell, Executive Director, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517. The Board will hold a public hearing on the proposed amendments Tuesday, September 10, 2013, 5 PM, at the Board's office. Pharmacists, members of the public, and other interested parties are invited and encouraged to share their comments on the proposed amendments in writing or at the public hearing.

The text of the proposed amendments may be found here: www.ncbop.org/LawsRules/3400AutomatedDispensingRuleForNoticeCommentRevMay2013.pdf. More background information on the proposed amendments may be found here: www.ncbop.org/LawsRules/3400AutomatedDispensingRuleNoticeOfText041913.pdf.

Item 2266 – Another Reminder of Pharmacist Duties Where Illegitimate Prescriptions for Controlled Substances Are Concerned

Pharmacists are again reminded to take heed of Item 2247 in the Board's October 2012 *Newsletter* (found at www.ncbop.org/Newsletters/Oct2012.pdf) concerning illegitimate prescriptions for controlled substances (CS) and, more specifically, the legal and ethical requirements governing pharmacists when dispensing CS prescriptions. Failure to act with due diligence has led to discipline of North Carolina pharmacists and pharmacies. Board staff continues to work closely with Drug Enforcement Administration and other law enforcement agencies on these matters.

Item 2267 – Xylitol is Toxic to Dogs

Editor's note – Thanks to Gigi Davidson and Amanda Groppe for this item.

Xylitol is an artificial sweetener commonly used to sweeten human medications, gums, mouthwashes, and candies. While not toxic to humans, exposure in even small amounts can be rapidly fatal to dogs.

Xylitol is not absorbed from the gastrointestinal tract of humans, but is easily absorbed in dogs. Once in the bloodstream, xylitol acts like glucose, stimulating insulin secretion, which lowers serum glucose concentrations but does not affect plasma concentrations of xylitol. Xylitol continues to stimulate insulin secretion, which causes life-threatening hypoglycemia. Profound hypoglycemia can last for one to two hours in dogs following ingestion of 0.1 g/kg of xylitol, and has frequently caused death. Doses of 0.5 g/kg can cause serious hepatic damage to dogs.

Many commercially available drugs labeled for humans contain xylitol as an inactive ingredient, and all human medications used in dogs should be scrutinized for xylitol content. Pharmacists can play a valuable role in preventing xylitol-poisoning by educating clients to avoid all xylitol-containing foods in their pets. Upon receiving queries about xylitol exposure in dogs (eg, ingestion of virtually any sugar-free human product), pharmacists should recognize this as a life-threatening veterinary emergency and immediately refer the pet owner to the nearest veterinary clinic. It is not currently known if xylitol is toxic in cats, but for the present, xylitol should be assumed to be toxic in this species. For more information, search "xylitol" at www.aspc.org.

Item 2268 – Congratulations to Executive Director Jay Campbell

Board President Gene Minton, along with members of the Board and its staff, extend their warmest congratulations to Executive Director Jay Campbell for his recent receipt of the Lester E. Hosto Distinguished Service Award, bestowed upon him by the National Association of Boards of Pharmacy® (NABP®). The Board is extraordinarily proud of Jay's many accomplishments during his tenure at the North Carolina Board. The Board looks forward to working with him in the future to protect and serve the citizens of North Carolina, and through its affiliations, the general population of the US, in furthering the practice of pharmacy.

Jay's full biography and nomination is available in the May 2013 *NABP Newsletter*, which may be accessed in the Publications section of the NABP Web site.

Page 4 – July 2013

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 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

Deborah Zak - Communications Manager