February 2008

Ohio State Board of Pharmacy

77 S High St, Room 1702, Columbus, OH 43215-6126
Tel: 614/466-4143 Fax: 614/752-4836
www.pharmacy.ohio.gov

Published to promote voluntary compliance of pharmacy and drug law.

Do You Have Your New Terminal Distributor's License?

Please check the terminal distributor of dangerous drugs (TDDD) license at your facility to be sure you have received your 2008 TDDD license from the Ohio State Board of Pharmacy. The TDDD license is the license required for all pharmacies, hospitals, clinics, emergency medical service squads, etc. If you have not renewed or received your 2008 TDDD license, please call the Board office immediately. The 2007 TDDD licenses expired on December 31, 2007.

Continuing Pharmacy Education Note

The Board's annual Jurisprudence Quiz is included as part of this *Newsletter*. The questions in the quiz relate to the topics covered in this *Newsletter* as well as the May, August, and November 2007 issues. If needed, copies of the previous *Newsletters* can be found on the Board Web site at *www.pharmacy.ohio.gov* by clicking on "C.P.E. News and S.B.N."

Please note that the deadline for submission of the completed quiz is **March 31, 2008**. Any answer sheets postmarked after March 31 will not be accepted.

Final CPE Reminder

This is a final reminder to those pharmacists whose license numbers begin with 03-2. This is the year for you to report your continuing pharmacy education (CPE). It will be due in the Board of Pharmacy office **no later than May 15, 2008**. The CPE report forms should be arriving in your mail sometime early in March while your renewal forms will not be arriving until midsummer. If you have not received your CPE reporting form by the end of March, please notify us at the Board office so we can get you a replacement. The CPE reporting form is also available on the Board's Web page under **"Forms."** The Web page form can be filled out online and then you can print it, sign it, and mail it to the Board office.

You will need to show a total of six continuing education units (CEU) (60 hours) of CPE credit of which 0.3 CEUs (three hours) must be in Board-approved jurisprudence. Please make sure that the jurisprudence courses are Board approved as there are a lot of courses coded as law that are not approved by the Board for use in meeting this requirement. The other 57 hours may be in any approved category that you wish.

You may use certificates dated on or after March 1, 2005, that you did not use when reporting in 2005. In addition, please be sure that you have the certificates in hand before you enter the number on the form. Every year, we have a few pharmacists who put numbers down before they receive their certificates from the CPE provider. Sometimes, that certificate then fails to arrive because the pharmacist did not pass the examination. Falsifying the CPE reporting form is not something that the Board takes lightly. As long as you have the originals in your possession when you complete the reporting form, you should have no problem with this reporting period. If you fail to submit a CPE form in a timely manner, you will be subject to Board action on your license. Rule 4729-7-02(C) states:

> *A pharmacist shall be subject to further action of the board if the continuing pharmacy education report forms are not filed by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete.*

Is Filling Internet Prescriptions a Good Idea (Yet)?

Last February, the *Newsletter* contained an article warning pharmacists about some scams involving Internet prescriptions, doctors, and pharmacies. Before that article was written, pharmacists were being bombarded with offers from these Internet sites. Nothing has changed in the last 12 months. The offers continue. They seem to be primarily targeting independent pharmacies, probably knowing that many of them are suffering financially due to the initial problems with Medicare Part D, Medicaid reimbursement cuts, insurance cuts, etc. Unfortunately, a few pharmacists have given in to the temptation of higher than usual dispensing fees and have agreed to do business with these types of pharmacies. We have had one Board hearing already and we have a few others coming. The first hearing on this Internet prescription issue resulted in the revocation of both the pharmacist's license and the pharmacy's license. While this is not necessarily indicative of what will happen in future cases, since each situation is viewed independently, it does point out the Board's concern about pharmacists who engage in this type of behavior.

In addition to pharmacists being recruited to break the law, now the Internet drug dealers are also targeting consumers, businesses, schools, and others (apparently anyone with a fax number could be a target). The initial wave of unsolicited faxes, offering dangerous drugs without a prescription through Internet Web sites, first appeared in mid-June 2007. A second wave hit the state in mid-October 2007. Most people seem to recognize that this is indeed illegal activity, and many have been forwarding the faxes to the Board office to keep us informed. It seems that these faxes are going to any telephone number able to accept faxes, thus not only consumers but also health care professionals and other businesses are receiving them.

Continued on page 6

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.

JURISPRUDENCE QUIZ

(covering May 2007, August 2007, November 2007, and February 2008 issues of the State Board Newsletter)

No credit can be granted for Answer Sheets postmarked **after March 31, 2008.**
Certificates will be mailed to those receiving a passing score of 75 or better.

1. The deadline for submitting continuing pharmacy education (CPE) report forms is May 15th of the year you are required to report.

   A. True B. False

2. Which of the following are true regarding physician assistant (PA) prescribing in Ohio?

   A. The PA may prescribe most Schedule III through V controlled substances.
   B. The PA may not prescribe any Schedule II controlled substance.
   C. The PA will have to obtain his or her own Drug Enforcement Administration (DEA) license prior to prescribing a controlled substance.
   D. The PA's DEA license number will begin with the letter "M."
   E. All of the above.

3. All in-patient IV admixtures must have a complete label that includes the pharmacy name and address.

   A. True B. False

4. Which is true regarding the issuance of a written prescription that is handled to the patient?

   A. The prescription must have an original manual signature.
   B. For non-controlled prescriptions, a nurse may sign the prescriber's name.
   C. The use of a rubber stamp is acceptable for non-controlled substances.
   D. An electronic signature is acceptable.

5. Isotretinoin has been identified as a drug that is being sold illegally on the Internet.

   A. True B. False

6. The restriction for the number of patients a physician may treat for substance abuse from his or her office with Subutex® or Suboxone® is now?

   A. 35
   B. 50
   C. 60
   D. 75
   E. 100

7. The Centers for Disease Control and Prevention has issued an article addressing the overdose deaths of three infants due to cough and cold medications. The main ingredient causing the deaths was?

   A. Ephedrine
   B. Pseudoephedrine
   C. Ibuprofen
   D. Acetaminophen

8. Legislation has been introduced to change the laws regarding the practice of optometry. These changes would remove the formulary and limit the drugs to those used within their scope of practice.

   A. True B. False

9. All Medicaid prescriptions must be written on tamper–resistant paper by which of the following dates?

   A. March 1, 2008
   B. April 1, 2008
   C. July 1, 2008
   D. October 1, 2008

[Questions continued on reverse side > > >]

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JURISPRUDENCE REQUIREMENT FOR CPE

To receive a certificate of credit, please complete this form and mail it to the address below with a check for **$4** payable to **Justice Data Management.** A certificate will be mailed to those receiving a passing score of 75 or better.

JURISPRUDENCE CPE; JUSTICE DATA MANAGEMENT; PO BOX 43056; CINCINNATI, OH 45243-0056

Program Evaluation:
[1=Poor / 2=Fair / 3=Satisfactory / 4=Good / 5=Excellent]
(Please rate this program in the following areas)

- ♦ Quality of information 1 2 3 4 5
- ♦ Usefulness to my practice 1 2 3 4 5
- ♦ Readability and presentation 1 2 3 4 5

State Board Newsletter (February 2008) Answer Sheet:
(Please fill in your answer to each question)

	A	B	C	D	E
1.	☐	☐			
2.	☐	☐	☐	☐	☐
3.	☐	☐			
4.	☐	☐	☐	☐	
5.	☐	☐			
6.	☐	☐	☐	☐	☐
7.	☐	☐	☐	☐	
8.	☐	☐			
9.	☐	☐	☐	☐	
10.	☐	☐	☐	☐	☐
11.	☐	☐	☐	☐	
12.	☐	☐	☐	☐	
13.	☐	☐			
14.	☐	☐	☐	☐	☐
15.	☐	☐	☐	☐	☐
16.	☐	☐	☐	☐	

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Certificates will be mailed to those receiving a passing score of 75 or better.

10. Food and Drug Administration (FDA) has issued a final rule requiring current good manufacturing practices for dietary supplements. This requires manufacturers to evaluate their dietary supplements for which of the following?

    A. Identity
    B. Purity
    C. Strength
    D. Composition
    E. All of the above

11. Which of the following issues were raised at a public hearing on the use of medication guides?

    A. Lack of a standard distribution system
    B. Make them easier to read and understand
    C. Move toward electronic distribution
    D. All of the above

12. Illegal Internet sites are identifiable by which of the following?

    A. Use of a medical questionnaire in lieu of a physician-patient relationship
    B. Advertise "cheap" prices but the prices are actually expensive
    C. Unsolicited offers being made by an unknown company
    D. All of the above

13. FDA has notified health care professionals to cease manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

    A. True B. False

14. The Health Insurance Portability and Accountability Act required pharmacists to start using the National Provider Identifier (NPI) on which date?

    A. March 23, 2007
    B. May 23, 2007
    C. September 23, 2007
    D. March 23, 2008
    E. May 23, 2008

15. Senate Bill 58 as passed by the Ohio legislature expands the list of immunizations that a pharmacist may administer. The new immunizations include which of the following?

    A. Meningitis
    B. Diphtheria
    C. Pertussis
    D. Influenza to 14 years or older by a pharmacist
    E. All of the above

16. Senate Bill 58 allows for the administration of which of the following drugs?

    A. Epinephrine in an emergency situation
    B. Diphenhydramine in an emergency
    C. Influenza by an intern to adults only
    D. All of the above

[End of Questions]

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CITY:	STATE:	ZIP CODE:

JUSTICE DATA MANAGEMENT; PO BOX 43056; CINCINNATI, OH 45243-0056 (513/272-3265)

No credit can be granted for Answer Sheets postmarked after March 31, 2008.

Continued from page 1

All the faxes sent to us are similar, promoting the ability to acquire medication without a prescription after answering questions on the Web site. Although each site advertises that it has the cheapest prescription drugs on the Internet, the prices are the same and are much more expensive than what the patient would pay at an Ohio pharmacy. Pharmacists report that customers on chronic prescription medications who have received these faxes say that they are tempted because they would not have to visit their physicians. Blanket prices on the faxes state, "All 90 qty for $51.99 and $84.99 for 180 qty." Actual prices can be different on the Web site, and there is usually a shipping cost of $19.99 or $28.

What we have learned:

- The Web sites promoted in the June and July faxes were linked to *MyPharmaNow.com* whose IP address was on a server in Hong Kong, China, with the registrants mostly based in the Philippines. One commonality was "Homer Smith" who is recognized as bogus on several chat sites that recommend "Call your local Postal Inspector for a sting for the sale of prescriptionless pharmaceuticals. This is part of the Alliance Health Group/myfirstpharma outfit." Web sites include: *MyPharma1.net*, *AmericaPharmacyWorld.com*, *MyPharmaCentral.com*, and *MyPharmastop.net*.
- The Web sites promoted in the October faxes all had the exact same screen content with the exception of the name of each site. They referred to "Your Safe Med" online pharmacy as part of the Hardy Healthcare Group and were all registered on October 11 by various people in Singapore. All these Web sites are located on the same server in Hong Kong as the *MyPharmaNow.com* sites. Web sites include: *Directdoclink.com*, *Ezmedlink.com*, *Ezdoclink.com*, *Medhaven.net,* and *YourSafeMed.com*.
- Other site names that have recently come to our attention include: *Myfirstpharma.com*, *Suredoclink.com*, *Ezdoconline.com*, *Medicaltouch.net*, and *Ezpharmalink.com*. There will certainly be others in the future.
- All these sites target the United States and require credit card information (the only choice is VISA) including the three-digit security pin on the back of the card.

It appears that as domain names become available, these foreign Web sites are snatching them up and adding them to their Internet network of sites. As the Ohio State Board of Pharmacy has no jurisdiction internationally, we try to forward the Web site information to the National Association of Boards of Pharmacy® and/or Food and Drug Administration. As none of these sites appear to be offering to sell controlled substances, Drug Enforcement Administration does not have any jurisdiction.

We expect that this type of criminal activity will continue in the future. Please help educate the public in your area that they are at risk of identity theft, credit card theft, receiving counterfeit drugs, etc, when ordering drugs without local physicians and legitimate pharmacies involved. Any Internet site that is marketing prescription drugs to individuals by unsolicited fax is probably illegal and dangerous.

Disciplinary Actions

Anyone with a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, *www.dental.ohio.gov*
State Medical Board – 614/466-3934, *www.med.ohio.gov*
State Nursing Board – 614/466-3947, *www.nursing.ohio.gov*
State Optometry Board – 614/466-5115, *www.optometry.ohio.gov*
State Pharmacy Board – 614/466-4143, *www.pharmacy.ohio.gov*
State Veterinary Medical Board – 614/644-5281, *www.ovmlb.ohio.gov*
Drug Enforcement Administration – 1-800/230-6844, *www.deadiversion.usdoj.gov*

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William T. Winsley, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

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

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