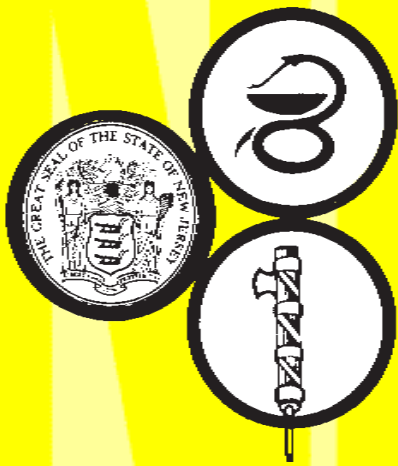


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New Jersey Board of Pharmacy

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PO Box 45013
124 Halsey St, 6th Floor
Newark, NJ 07101
www.state.nj.us/lps/ca/boards.htm

DEA Update – Multiple Prescription Rule

Even though the change in Drug Enforcement Administration regulations (21 CFR §1306.12) effective December 19, 2007, which allows a practitioner the ability to provide multiple prescriptions for the same Schedule II item, to the same patient, to be filled at a later date up to a 90-day supply, New Jersey Controlled Drug Substances regulation 8:65-7.5(a) specifically requires that “all prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued.” Because existing New Jersey state regulations for controlled dangerous substances are more restrictive than the new federal rule, New Jersey licensed practitioners issuing prescriptions, and New Jersey pharmacies filling prescriptions (including prescriptions written out of state) must continue to follow current New Jersey regulations.

Newsletter Going Online

Beginning with this edition, the *New Jersey Board of Pharmacy Newsletter* will only be available online. A printed version will no longer be mailed to licensees. Each time a new issue is published, subscribers to the notification listing will receive an e-mail containing a link to the current issue. Licensees may subscribe to the notification listing by clicking the “Subscribe” link at the following address: www.nabp.net/indexnjbop.asp, or by sending an e-mail to NewJerseyBOPNewsletter@nabp.net with the word “Subscribe” in both the subject heading and body of the e-mail. A link will be added to the New Jersey Board of Pharmacy Web site under Online Services.

Telephone Prescriptions from an “Agent”

There continues to be some confusion regarding telephone authorization for prescription renewals. N.J.A.C. 13:39-7.3 addresses authorization for prescription renewals, and 13:39-7.3(b) states, “When the renewals listed on

the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the prescriber as provided in N.J.S.A. 45:14-58a, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription.” Questions to the Board have specifically addressed the common scenario in which a pharmacist telephones a doctor’s office to renew a prescription by telephone and speaks to a nurse or receptionist. The New Jersey Board of Pharmacy does not interpret 13:39-7.3(b) to mean that the pharmacist must speak directly to the prescriber. In practice, when a pharmacist calls a doctor’s office for authorization to renew a prescription the pharmacist often speaks to a nurse, receptionist, or other “agent” acting on behalf of the prescriber. The pharmacist can reasonably assume that the agent has obtained authorization directly from the prescriber before passing this authorization to the pharmacist by telephone. It is recommended that any time authorization is received from anyone other than the prescriber that the pharmacist record the date and time of the telephone call and the full name and title of the prescriber’s agent on the prescription.

Senate Bill 1195 Signed by Governor Corzine

Senate Bill 1195 was signed by Governor Jon Corzine on November 2, 2007, establishing a pharmacy’s duty to fill a prescription for in-stock medications or devices without delay, notwithstanding sincerely held moral, philosophical, or religious beliefs of a pharmacist. The text of the act is given below:

AN ACT concerning the dispensing of medications and supplementing P.L.2003, c.280 (C.45:14-40 et seq.).

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

45:14-67.1 Duty of pharmacy to fill certain prescriptions
1.a. A pharmacy practice site has a duty to properly

Continued on page 4



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 drug 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 L.P. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

fill lawful prescriptions for prescription drugs or devices that it carries for customers, without undue delay, despite any conflicts of employees to filling a prescription and dispensing a particular prescription drug or device due to sincerely held moral, philosophical or religious beliefs.

b. If a pharmacy practice site does not have in stock a prescription drug or device that it carries, and a patient presents a prescription for that drug or device, the pharmacy practice site shall offer:

- (1) to obtain the drug or device under its standard expedited ordering procedures; or
- (2) to locate a pharmacy (of the patient's choice) that is reasonably accessible to the patient and has the drug or device in stock, and transfer the prescription there in accordance with the pharmacy practice site's standard procedures.

The pharmacy practice site shall perform the patient's chosen option without delay. If the patient so requests, the pharmacist shall return an unfilled prescription to the patient.

c. If a pharmacy practice site does not carry a prescription drug or device, and a patient presents a prescription for that drug or device, the pharmacy practice site shall offer to locate a pharmacy that is reasonably accessible to the patient and has the drug or device in stock.

d. A person who believes that a violation of this section has occurred may report the violation to the New Jersey State Board of Pharmacy.

2. This act shall take effect immediately.

Registration of Certified Pharmacy Technicians

The New Jersey Division of Consumer Affairs is currently finalizing the application process by which certified pharmacy technicians will register with the Board of Pharmacy. The Board office will notify pharmacies directly when applications are available. As a reminder, pharmacy students are counted in the pharmacist-to-technician ratio unless they are present in the pharmacy as part of a college of pharmacy-related externship.

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New Jersey Board of Pharmacy - State News Editor
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National Association of Boards of Pharmacy Foundation, Inc
1600 Fehanhville Drive
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