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New Jersey Board of Pharmacy

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www.state.nj.us/lps/ca/boards.htm

Published to promote voluntary compliance of pharmacy and drug law.

Erratum

An error appeared in the January 2006 New Jersey Board of Pharmacy *Newsletter* article titled "Labeling Requirements for Dispensed Retail Prescription Drug Containers." According to the provisions of New Jersey Administrative Code 13:39-7.12, the "use by" date, if the drug is dispensed in any package other than the manufacturer's original package, is either of the following dates (whichever comes first):

- one year from the dispensing date; or
- the expiration date on the manufacturer's original package.

The January 2006 *Newsletter* erroneously described part (b) as "One year from the expiration date on the manufacturer's original package."

New Board Member

Peter Halecky, RPh, was appointed to the New Jersey Board of Pharmacy on December 22, 2005. Mr Halecky is a 1990 graduate of St John's University College of Pharmacy and co-owner of Hudackos Pharmacy in Bayonne, NJ, with his father, John Halecky, and uncle John Hudacko. Hudackos Pharmacy specializes in compounding, including pediatric and veterinary prescriptions. Mr Halecky replaced Ira Katz, who served as a Board member for 10 years. The Board would like to thank Mr Katz for 10 years of dedicated service to the state of New Jersey.

Changes in the Prescribing of Controlled Dangerous Substances by Advanced Practice Nurses

The law (NJSA 45:11-49) regarding prescriptions issued by advanced practice nurses (APN) was amended, effective November 9, 2004, and resulted in modifications being made to the design of New Jersey Prescription Blanks (NJPBs), which may be issued by APNs. Pursuant to the amended statute, an APN may now prescribe controlled dangerous substances (CDS) in all medically appropriate settings, as long as joint protocols between the APN and his or her collaborating physician permit the same. In addition, if an APN wants to prescribe CDS, he or she must complete six contact hours of continuing education (CE) in pharmacology related to controlled substances. The prior restriction that APNs may only prescribe CDS under three specific sets of circumstances is no longer in effect. The NJPB format for APNs, since April 18, 2005, has been modified so that it is consistent with the amended statute. The previous version NJPB, which has three boxes to check to indicate if it is a reissue dosage change, or consistent with the statute, will be phased out. Until further notice, pharmacies may continue to accept CDS prescriptions from APNs written on the

previous version NJPB without requiring that a box be checked off to indicate the rationale for prescribing. In addition, the prescribing APN is no longer required to list the Drug Enforcement Administration (DEA) number of the collaborating physician. Please note that the Board of Pharmacy's October 2005 *Newsletter* indicated that pharmacies would no longer be allowed to accept previous version NJPBs from APNs after December 31, 2005. The cutoff date has been extended until further notice.

Return to Practice by an Inactive Licensee

Pharmacists registered in the state of New Jersey who have chosen inactive status may not practice pharmacy. To return to active practice an inactive licensee must apply to the Board based on one of the following criteria:

- If the licensee has maintained an active license in another state and practiced for a minimum of 1,000 hours during the two years immediately preceding the application, he or she must submit a biennial renewal fee of \$140;
- If the licensee has maintained an active license in another state but practiced for less than 1,000 hours during the two years immediately preceding the application, he or she must submit proof of 30 hours of CE (including 10 didactic hours and three hours related to pharmacy law) during the two years immediately preceding the application in addition to the biennial renewal fee; or
- If the licensee has not practiced pharmacy in another state during the inactive license period, he or she must submit proof of 15 hours of CE per year (to a maximum of 75 hours), with at least 30 hours completed within the two years immediately prior to the application and meeting the requirements described in (2) above, in addition to the biennial renewal fee.

Continuing Education Programs Qualifying for Law Credit

New Jersey pharmacy licensure requires a total of three hours of CE related to pharmacy law during each biennial registration period. Acceptable programs are those accredited by the Accreditation Council for Pharmacy Education (ACPE) that have a program number ending with the digits 03. Please note that the letter preceding these two digits indicates how the program was taken ("L" for live or didactic, "H" for home study, or "C" for a combination of the two). For example, the New Jersey Law Review, sponsored June 1, 2005, by the Ernest Mario School of Pharmacy, had the program number 038-999-05-002-L03. This program, with the "L03" designation, would therefore count as

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben[®], a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien[®], a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as

reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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both law and didactic CE. Any non-ACPE-accredited source of law CE must be granted prior approval by the Board to satisfy the CE requirement.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site at www.state.nj.us/lps/ca/boards.htm or by calling the License Verification Line at 973/273-8090.

License Suspensions/Surrenders/Revocations

EZRX, LLC – Respondent is a pharmacy and retail permit holder in the state of New Jersey. Respondent dispensed CDS without ensuring legitimate medical purpose of prescriptions pursuant to valid patient-physician relationship. On November 29, 2004, respondent's permit was revoked by DEA. As of June 15, 2005, respondent's permit to operate a pharmacy in the state of New Jersey is revoked. (Filed on June 20, 2005.)

Abdul-Hameed Anayoor, RPh – Respondent pled guilty to one (1) count of Medicaid Fraud in Monmouth County and entered into a Consent Agreement with the Division of Medical Assistance and Health Services to pay restitution and fines in the amount of \$2,000. Respondent shall immediately surrender his license to practice pharmacy, which is deemed a revocation, with no right to reinstatement prior to the termination of criminal probation or supervised release. Respondent shall not be a permit holder nor be related by consanguinity or marriage to a permit holder, nor to a business entity in which any such related individual has a financial interest in a pharmacy in the state of New Jersey. (Filed on June 22, 2005.)

Richard DiGiovanni, RPh – Respondent was convicted of one (1) count of Conspiracy to commit theft in excess of \$500, and from June 2002 to August 2004, respondent diverted OxyContin®, a Schedule II CDS from his workplace, Happy Harry's, a pharmacy in the state of Maryland. Pursuant to the Consent Order set forth, respondent's license to practice pharmacy has been revoked with prejudice to requesting reinstatement for four (4) years from entry of this Order, or upon completion of the criminal probation, whichever occurs later. Respondent shall cease and desist from engaging in the practice of pharmacy. Upon application of reinstatement, respondent shall appear before the

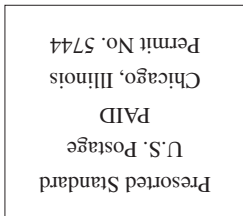
Board or a committee upon request and submit documentation satisfactory to the Board inclusive of, but not limited to weekly, random, witnessed urine screens; complete treatment records of all diagnostic and rehabilitative therapy; and an in-depth, current evaluation from a Board approved psychiatrist or psychologist upon any application. (Filed on July 6, 2005.)

Reinstatements

Mark Pesotski, RPh – History: On or about June 3, 2004, respondent agreed to the voluntary surrender of his pharmacy license due to substance abuse issues. In connection with an application for reinstatement of his license to practice pharmacy in the state of New Jersey, respondent appeared before the Board on June 8, 2005, to testify of past substance abuse treatment and present efforts to maintain sobriety. After respondent has submitted documentation of his successful completion of thirty (30) CE credits, ten (10) of which must be didactic, and has paid all required fees, his license to practice pharmacy shall be reinstated and placed on a probationary status for three (3) years. If the respondent violates any of the provisions outlined in the Order, the Board may initiate proceedings to revoke his license to practice pharmacy. (Filed on June 9, 2005.)

The *New Jersey Board of Pharmacy News* is published by the New Jersey 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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