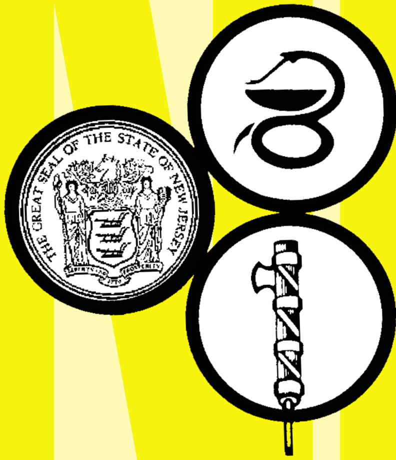
January 2005



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.

Importing Controlled Substances from Canada and Other Foreign Countries

Drug Enforcement Administration (DEA) recently published a notice to reiterate current federal law and DEA regulations on importing controlled substances from Canada and other foreign countries. Current regulations, as described in the Controlled Substance Act, which DEA administers, require that persons who have controlled substances sent from foreign countries into the United States and be registered with DEA as importers of controlled substances and must have satisfied the requirements for importation. Persons who import controlled substances into the US without being properly registered with DEA are subject to prosecution for violation of federal drug laws.

DEA published this notice as a result of an increasing number of Internet Web sites and "brick and mortar" businesses that claim to assist individual consumers in purchasing controlled substances from Canada and other foreign countries.

Discounting Still Not Allowed

Discounting prescription prices is only permitted in New Jersey for patients 60 years of age or older (N.J.S.A. 45:14-65e). In addition, the waiving or discounting of a copay is generally not allowed at any age. You should check your third-party contracts to verify this.

Furthermore, a permit holder cannot waive or discount the copay of a prescription when a patient has a complaint or there is an error unless you also reverse the charge to the third-party payer. Please check with your legal advisors before making a decision that might be considered a discount.

Centralized Prescription Handling

New regulations (N.J.A.C. 13:39-5.10) became effective in October 2004 that outline the procedures to follow when two or more licensed pharmacies share the responsibility for performing the intake, processing, fulfillment, and dispensing functions of handling a prescription. Such pharmacies must have a contractual agreement if they do not have the same owner and they must make an application to the New Jersey Board of Pharmacy and receive Board approval to engage in central prescription handling. Additional requirements address the audit trail, record storage, labeling, policies and procedures, and technology requirements. The full text of the regulation may be found on the Board of Pharmacy's Web site at www.state.nj.us/lps/ca/medical/pharmacy.htm.

Anyone who is interested in applying to the Board of Pharmacy for approval to operate as a centralized pharmacy will be able to obtain an application on the Board Web site. This should be sometime in early 2005 when the Board finalizes the form and process.

New Labeling Requirements

Effective April 2, 2005, there are new requirements (N.J.A.C. 13:39-5.9) for labeling all retail prescription medications (excluding sterile admixture and radiopharmaceutical products). The name of the pharmacist-in-charge (PIC) will no longer be required on the label as of this date. The strength of the medication, where applicable, and the quantity dispensed as well as a "use by" date must be on each label. In addition, the patient's name, the brand or generic name of the medication, and the directions for use must be bolded or be a larger font or a different color than the other information on the label. The full text of this requirement may be found on the Board of Pharmacy's Web site at www.state.nj.us/lps/ca/medical/pharmacy.htm.

New Appearance of DEA Controlled Substance Registration Certificate

As of October 1, 2004, DEA's Office of Diversion Control has changed the style and appearance of the DEA Controlled Substance Registration Certificate. It will now consist of two parts: one that can be displayed on the wall and a smaller, wallet-sized version. The certificate will have an embedded watermark logo, which will provide authentication of the certificate and also deter counterfeiting.

Registrants who are currently allowed to renew their DEA registration via the Diversion Control Program's Web site (ie, retail pharmacies, hospitals, practitioners, mid-level practioners, and teaching institutions) may print their Certificate of Registration upon completion of the registration renewal process as long as no changes have been made to their registration since their last renewal. The Diversion Control Program's Web site may be accessed at www.DEAdiversion.usdoj.gov. DEA will continue to send Certificates of Registration via the US Postal Service to all new registrants and all other DEA registrants renewing their DEA registration.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered,

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The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- Persons aged 65 years or older;
- Children six to 23 months of age;
- Residents of long-term care facilities and nursing homes;
- Persons two to 64 years of age with chronic medical conditions;
- Health care workers involved in direct patient care;
- Household contacts and out-of-home caregivers of children less than six months of age;
- Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- Washing your hands frequently to avoid the spread of viruses and bacteria;
- Avoiding contact with people who may be sick;
- Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- Covering your mouth and nose when coughing or sneezing;
- Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemicplan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

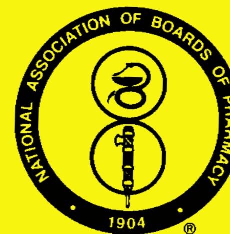
FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.



Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.

Diabetes or Alzheimer's Disease?

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.

Several reports of mix-ups have been reported in which the antidiabetic agent **AMARYL®** (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication **REMINYL®** (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's *2005 Survey of Pharmacy Law* CD-ROM is now available. Eight new questions were added to this year's *Survey;* topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

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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 (see above) or by calling the License Verification Line at 973/273-8090.

License Revocations

Ronald Hyman, RPh – On March 9, 2004, respondent was convicted in the Federal District Court of Pennsylvania for his involvement in the unlawful distribution of 200 Roxicet® tablets. Pursuant to the Final Order set forth, the respondent's license to practice pharmacy was revoked with no right to request reinstatement for three (3) years from the date of entry of this Order. (Filed on August 25, 2004)

License Suspensions/Surrenders

Mark Tyrell, RPh – Diverted Controlled Dangerous Substances while serving as a pharmacy consultant to a health care facility and has admitted to having a substance abuse problem. Respondent's license to practice pharmacy was surrendered. (Filed on May 13, 2004)

Mark Pesotski, RPh – Filled fraudulent prescriptions to obtain Percocet®, Lortab®, and Valium®, all Controlled Dangerous Substances, for his own consumption and has admitted to having a substance abuse problem. Respondent's license to practice pharmacy was surrendered. (Filed on June 2, 2004)

Georgeann Boulos-Pludowski, RPh – On November 3, 2002, respondent dispensed a chemotherapy drug (methotrexate) instead of the prescribed blood pressure medication (minoxidil). Respondent failed to inform the patient's family member of the serious nature of this error, failed to advise family member to take patient to his physician, and failed to notify the prescribing physician of the situation. Pursuant to the Consent Order set forth, respondent's license to practice pharmacy in the State of New Jersey was suspended for five years. The first three years shall be active and the last two shall be stayed and served as period of probation. During her active suspension, respondent shall not engage in the practice of pharmacy. Respondent shall successfully complete the "Pharmsafety.net" self-study modules 1-4 which shall not serve to satisfy any continuing education (CE) credit for next license renewal. She shall pay costs of $3,975 and $4,125 and a civil penalty of $5,000 to the Board. Respondent shall appear before the Board at the end of her active suspension to determine if any additional conditions should be imposed. (Filed on July 29, 2004)

Judith H. Leonard, RPh – Respondent diverted Phrenilin® from her work place, Food Circus Super Market, for her personal use. The respondent's license to practice pharmacy was suspended. Upon application for reinstatement, respondent shall submit documentation satisfactory to the Board which shall include weekly, random witnessed urine screens, complete treatment records of all therapy and a current in-depth evaluation from a Board-approved psychiatrist/psychologist. (Filed on August 25, 2004)

License Reinstatements

Michael Vallerini, RPh – After the Board has received documentation of respondent's successful completion of 60 hours of CE, payment of all biennial and reinstatement fees, and an acceptable criminal history background check, the license of respondent to practice pharmacy shall be reinstated and placed on a probationary status for one year from the date he begins dispensing as a pharmacist. Respondent shall be under the immediate personal supervision of a licensee of the Board for the first three months that he commences work as a pharmacist. The Respondent must comply with specific monitoring and oversight requirements of the Board and he shall not be a PIC for the first 12-consecutive-month period he commences work in a pharmacy. (Filed on April 19, 2004)

Chakkarin Burudpakee, RPh – After the Board has received documentation of respondent's successful completion of 30 hours of CE, the license of respondent to practice pharmacy shall be reinstated and placed on a probationary status for two years. The Respondent must comply with specific monitoring and oversight requirements of the Board and he shall not be a PIC for a five-year period from the entry of this order and shall be barred forever from being a permit holder either directly or indirectly. (Filed on May 12, 2004)

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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