

October 2006



# New Jersey Board of Pharmacy

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[www.state.nj.us/lps/ca/boards.htm](http://www.state.nj.us/lps/ca/boards.htm)

Published to promote voluntary compliance of pharmacy and drug law.

## **Marinol Storage Requirements**

Marinol® (dronabinol) is an orally active cannabinoid indicated for treatment of chemotherapy-induced emesis, and anorexia associated with acquired immunodeficiency syndrome (AIDS). Marinol is classified as a Schedule III controlled dangerous substance (CDS) and is available as 2.5 mg, 5 mg, and 10 mg gelatin capsules containing dronabinol solution in sesame oil. Improper storage of Marinol capsules can result in reduced potency. Marinol should be stored in a well-closed container in a "cool environment," defined by the manufacturer as a temperature between 8°C and 15°C (46°F to 59°F). Marinol can be safely refrigerated but must not be frozen. Importantly, Marinol should never be stored at room temperature for prolonged time periods. The proper storage conditions for Marinol should be carefully explained to patients when the drug is dispensed.

## **Storage of Filled Prescriptions in "Will Call" Bins Prior to Dispensing**

A frequent complaint to the New Jersey Board of Pharmacy involves the dispensing of prescriptions, which have not been stored or compounded properly, resulting in the dispensing of a misbranded medication. A number of these events likely occur when the prescription is taken from the "will call" bin and dispensed by a technician without a final pharmacist check. For example, a recent complaint involved the dispensing of an injectable drug requiring refrigeration that had been left in the "will call" bin at room temperature for several hours. Another example involved the dispensing of an oral antibiotic powder that had not been reconstituted. To reduce the potential for error, prescriptions that require special storage conditions or additional compounding prior to dispensing should not be placed in the "will call" bin.

## **Record of Pharmacist Filling a Prescription**

As a reminder, the printed daily prescription log or document log that the dispensing pharmacist manually signed or initialed is no longer required. NJAC 13:39-7.6(a-e) permits the pharmacist's personal identifier to be directly entered into the electronic data processing system. NJAC 13:39-7.6(a) states that "[a] registered pharmacist who fills or compounds a prescription or supervises the filling or compounding of a prescription by an extern, intern, or pharmacy technician shall place his or her signature or readily identifiable initials or other personal identifier on the original prescription or in the electronic data processing system." All prescription records must be maintained for at least five years, with the most recent year immediately retrievable and readable, and the oldest four years retrievable and readable within two weeks.

## **Proposed Regulations for Registration of Pharmacy Technicians**

The proposed regulations for the registration of pharmacy technicians were published in the August 7, 2006 edition of the *New Jersey Register*. The public is welcome to submit comments until October 6, 2006. The *New Jersey Register* can be accessed from the New Jersey Board of Pharmacy Web site at [www.state.nj.us/oag/ca/proposal/pharmpro87.htm](http://www.state.nj.us/oag/ca/proposal/pharmpro87.htm).

## **Documentation of Inactive Licensure Status**

Any pharmacist who chooses inactive licensure status should procure written documentation to avoid any subsequent confusion. Acceptable documentation can include a written letter from the Board of Pharmacy confirming inactive status, or a printout of the pharmacist's license page in the Licensee Directory on the New Jersey Board of Pharmacy Web site. There is no current mechanism for a pharmacist with an inactive licensure status to continue receiving mailings or licensure updates from the Board.

## **Special Exceptions on Narcotic Prescriptions for Chronic Pain Management**

A regulation of the New Jersey Board of Medical Examiners permits practitioners to exceed the normal 120 dosage unit or 30-day supply limit (whichever is shorter) when prescribing Schedule II CDS for the management of chronic pain, and thereby for pharmacists to fill and dispense such prescriptions. NJAC 13:35-7.6 allows the normal limits to be exceeded for the chronic management of cancer pain, intractable pain, or terminal illness, so long as the practitioner meets certain criteria. The practitioner is permitted to exceed the 120 dosage unit limit provided that a treatment plan is designed that includes written treatment objectives and criteria for evaluating treatment success. The 30-day limit may be exceeded if an implantable infusion device is used; in which case, the prescription can be written for a 90-day supply of drug so long as the practitioner evaluates and documents the continued need for the medication every 30 days. If chronic pain management in a given patient extends beyond three months, the practitioner must review the treatment plan and patient progress toward meeting treatment objectives, and consider appropriate alternative treatment options.

Importantly, the dispensing pharmacist should understand that he or she bears a corresponding liability. NJAC 8.65-7.5 addresses the information that must be included on all prescriptions for CDS, and states that "[a] corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules." With respect to chronic pain management, if the prescription

*Continued on page 4*



## **FDA Launches Consumer Educational Program on the Safe Use of OTCs**

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- ◆ the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- ◆ read the label and follow the directions carefully and correctly;
- ◆ two medicines with the same active ingredient should not be used at the same time; and
- ◆ measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at [www.fda.gov/medsinmyhome](http://www.fda.gov/medsinmyhome).

## **HHS Warns Public of Heroin and Fentanyl Deadly Combo**

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl

may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at [Kenneth.Hoffman@samhsa.hhs.gov](mailto:Kenneth.Hoffman@samhsa.hhs.gov).

## **Pharmacy Technicians and Medication Error Prevention**



*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](http://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](mailto:ismpinfo@ismp.org).*

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm*. October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an



error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

## **One or Both Nostrils?**

*Submitted by ISMP*

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical**<sup>®</sup>, **Micalcin**<sup>®</sup>) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP**<sup>®</sup>), sumatriptan (**Imitrex**<sup>®</sup>), and zolmitriptan (**Zomig**<sup>®</sup>).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

## **FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations**

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit [www.fda.gov/cder/drug/MedErrors](http://www.fda.gov/cder/drug/MedErrors).

## **DEA Provides Retail Training Materials**

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing

ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov), under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

## **FDA Announces Release of Guidance on Useful Written Consumer Medication Information**

In the July 18, 2006 *Federal Register*, FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at [www.fda.gov/cder/guidance/7139fnl.htm](http://www.fda.gov/cder/guidance/7139fnl.htm).

## **2007 Survey of Pharmacy Law Available Soon**

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors<sup>™</sup> accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from [www.nabp.net](http://www.nabp.net) and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. 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](mailto:custserv@nabp.net).

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does not include an indication as described above, the pharmacist should contact the prescriber, confirm the indication, and document the indication on the original prescription.

### Disciplinary Actions

The actions listed below include only those in which 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 or by calling the License Verification Line at 973/273-8090.

### Revocations

**Narendra Dalal, RPh** – On September 28, 2004, respondent was convicted of a one (1)-count felony superceding Indictment charging Conspiracy to Defraud the United States, to buy and sell unlawfully prescription drug samples, and to misbrand prescription drugs in violation of 18 United States Code §371, in the United States District Court. Respondent was sentenced and placed on probation for a term of three (3) years and ordered to pay a fine of \$10,000. **Ordered:** Respondent's license to practice pharmacy has been revoked. Respondent may request reinstatement no earlier than the conclusion of the three (3) year period of probation imposed by the US District Court, District of New Jersey. (Filed on January 26, 2006.)

### Reinstatements

**Joseph DeMarinis, RPh** – Pursuant to a Modified Order of Reinstatement filed on January 24, 2003, respondent was reinstated as a provider of services in the programs administered in whole or in part by the Division of Medical Assistance and Health Services. On January 22, 2004, a modified order was issued subjecting his license to two limitations: (1) respondent shall not act as the pharmacist-in-charge or own or have an ownership interest in any pharmacy, and (2) respondent shall present a copy of the 2004 modified order to any future employer. **Ordered:** Respondent has been granted an unrestricted license to practice pharmacy. (Filed on January 12, 2006.)

**Thomas Clancy, RPh** – Pursuant to a Consent Order filed on September 13, 2004, respondent voluntarily surrendered his license to practice pharmacy in New Jersey. Specifically, respondent diverted CDS from his employer. **Ordered:** Respondent's license to practice pharmacy has been reinstated on a conditional basis. Respondent shall abstain from the use of alcohol and all psychoactive substances and shall undergo random urine monitoring for a minimum of two (2) times per week for the first six (6) months of his return

to practice and then a minimum of one (1) time per week for the next six months. Respondent must continue participation with the Professional Assistance Program (PAP) and have monthly "face-to-face" contacts with representatives from that program for the first six (6) months of his licensure and then at a frequency determined by PAP, and he must attend support groups, including Narcotics Anonymous or Alcoholics Anonymous, for a minimum of three (3) times per week. (Filed on January 12, 2006.)

**Jong Pak, RPh** – Pursuant to a Consent Order filed on May 12, 2004, respondent had surrendered his license to practice pharmacy, based on allegations he had diverted CDS from the active drug stock of his employer. **Ordered:** Respondent's license to practice has been reinstated on a conditional basis. Respondent shall undergo random urine monitoring for a minimum of two (2) times per week at a laboratory facility approved by the Board for the next six (6) months, and then one (1) time per week for the subsequent twelve (12) months. (Filed on January 26, 2006.)

**Thomas Togno, RPh** – Respondent's license expired on April 30, 2003, due to his failure to renew said license with the Board. Subsequent to the expiration, the Board learned that respondent had become impaired as a pharmacist due to the admitted substance abuse problem. **Ordered:** In support of his application for reinstatement, respondent has represented that he has not practiced pharmacy since April 2004, has maintained sobriety since January 2005, has submitted documentation demonstrating successful completion of the Pre-Trial Intervention Program, and has satisfied the court as to fines and restitution. Therefore, respondent's license has been reinstated and placed on probation for three (3) years to commence on the filing date of this order. Respondent must submit to directly witnessed, random urine monitoring for a minimum of two (2) times per week for the first six (6) months and a minimum of one (1) time per week for the subsequent twelve (12) months thereafter. (Filed on January 30, 2006.)

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