



# Montana Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Tips from Your Compliance Officer:**

Bill Sybrant, our compliance officer, reminds you that he will always check the following during routine compliance visits:

- ◆ Every license and renewal to ensure they are signed, current, and posted.
- ◆ Check for Pharmacist-in-charge designation including non-owner Pharmacist-in-charge agreement if **the owner is not a pharmacist**
- ◆ Who has power of attorney (signed and current).
- ◆ If technicians are employed, the technician utilization plan, training module being used, and technician files all with current and up-to-date information.
- ◆ Institutional policy and procedures manual (current and up-to-date).
- ◆ The current biennial controlled substance inventory (CII and CIII-V signed and dated properly).

These and other things that Bill may check are all spelled out in *Federal and State Law and State Administrative Rules*. He suggests that you and all staff members know where these items are filed. Thanks to those of you that have done so and keep up the good work. To those of you who need or want help, Bill is only a phone call away.

## **Pseudoephedrine Status**

The Montana Board of Pharmacy is proposing rule wording for public comment that would effectively make pseudoephedrine-containing products a “third class of drug” to be sold only by a pharmacist. The Board does not have the option of placing pseudoephedrine into CIV or CV as some states have done, as Montana law prohibits scheduling an over-the-counter drug product. **Tentative** draft rule wording follows:

1. Any non-legend drug product containing pseudoephedrine, the salts, isomers or salts of isomers of pseudoephedrine shall be sold or otherwise transferred only in a licensed pharmacy from a secure area accessible only by a pharmacist on duty.

2. No more than 9 Grams of pseudoephedrine, the salts, isomers or salts of isomers of pseudoephedrine may be sold in a single transaction.
3. Any pharmacy selling a pseudoephedrine product must require the purchaser to produce a valid photo identification issued by a government or a school before completing the sale.
4. This rule does not apply to the sale or transfer of a pseudoephedrine product:
  - (a) To a veterinarian, physician, pharmacist, pharmacy, wholesaler, manufacturer, [warehouseperson] or common carrier or an agent of any of these in the regular course of lawful business activities;
  - (b) That has been determined by the Board to present no significant risk of use in the clandestine manufacture of methamphetamine.

The above wording, if approved, would become an **administrative (Board) rule**. At least two pseudoephedrine-related bills appear to be in drafting for introduction during the upcoming legislative session, and could restrict pseudoephedrine sales by **statute (law)** as well. The Montana Pharmacy Association is actively working with sponsors of at least one of these bills. Therefore, it is likely that within the upcoming months, Montana will join the growing number of states that have elected to tighten controls on pseudoephedrine in an effort to stem the spiraling methamphetamine epidemic. Critics of such legislation decry such efforts as temporary “stop-gap measures” that would inconvenience legitimate users of such products without addressing the related problems of drug abuse and addiction. The majority of methamphetamine within the United States is supplied by clandestine super labs (labs producing more than 10 pounds of methamphetamine in one 24-hour cycle) located both within the US and in countries such as Mexico. The Board agrees that the best approach is an inclusive approach, and feels that **all** meth labs regardless of size pose a significant public safety risk. Tightening controls on methamphetamine

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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/pandemic-plan](http://www.hhs.gov/nvpo/pandemic-plan). 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](http://www.fda.gov/oc/opacom/hottopics/flu.html).

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – [www.cdc.gov/flu](http://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](http://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](http://www.pfizer.com) as well as FDA's distributed a press release that is now available at [www.fda.gov](http://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](http://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](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).*

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](http://www.ismp.org/Pages/FDAVideos.htm) for videos related to medication errors. See [www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm](http://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](http://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](mailto: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](mailto:custserv@nabp.net) or call 847/391-4406.

## Register Now for NABP's 101<sup>st</sup> Annual Meeting

Register now for NABP's 101<sup>st</sup> 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](http://www.nabp.net), or contact NABP at 847/391-4406 or [custserv@nabp.net](mailto:custserv@nabp.net).

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precursors such as pseudoephedrine should not appreciably affect legitimate use or sales, and will hopefully hamper methamphetamine production, trafficking, and abuse within our state. It is a good start toward the solution of a menacing problem.

### **Upcoming Legislative Topics**

In addition to pseudoephedrine and methamphetamine-related bills, it appears that bills addressing drug importation, drug costs, pain management, and child medication safety will also be introduced. The Board considers the public safety impact of these bills while steering clear of issues such as economic impact.

### **CII Prescriptions, DEA, and You: Important Changes**

Drug Enforcement Administration (DEA) has published an interim statement of policy entitled "Dispensing of Controlled Substances for the Treatment of Pain" in the Federal Register on November 16, 2004 (69 FR 67170). The Interim Policy is available at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) (look under "What's New"). Excerpts from that site follow.

**SUMMARY:** In August 2004, DEA published on its Office of Diversion Control Web site a document entitled: "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (August 2004 FAQ). The August 2004 FAQ was not published in the Federal Register and was not an official statement of the agency. DEA subsequently withdrew the document because it contained misstatements.

Refills of . . . [CII] prescriptions – The August 2004 FAQ stated: "[CII] prescriptions may not be refilled; however, *a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.*" (Italics added.) The first part of this sentence is correct, as the [Controlled Substances Act] expressly states: "No prescription for a controlled substance in CII

may be refilled." 21 U.S.C. 829 (a). However, the second part of the sentence (italicized above) is incorrect. For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a [CII] controlled substance . . . It is worth noting here that the DEA regulations setting forth the requirements for the issuance of a controlled substance prescription are set forth in 21 CFR 1306.01-1306.27.

The Board has addressed this practice in two previous *Newsletters*, and has a letter on file from Patricia Good of DEA supporting the practice as well, so we greeted this news with a collective sigh and the realization that, "Some days you're the dog, some days you're the hydrant." This practice has been working well to the best of the Board's knowledge, and has undoubtedly saved many patients the time and expense of returning to their doctor's office every month for a handwritten CII prescription. It is difficult to understand how this practice could be considered to be any different than if a patient returns to a prescriber's office to receive a subsequent identical prescription for the same item, and if an original signature is written on separate blanks it is certainly **not** a refill by conventional definition. Nevertheless, this is a change that will be in effect until DEA further defines its policy. Comments on this topic can be sent to William J. Walker, deputy assistant administrator, Office of Diversion Control of DEA.

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