



Arkansas State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Arkansas State Board of Pharmacy Policy Statement Regarding a Public Health Issue

The Arkansas State Board of Pharmacy has been made aware that some pharmacists and technicians use their hands to count pills in the prescription filling process. During the February 2007 Board meeting, the Board of Pharmacy discussed this issue and views this practice as a potential health risk to the public due to the potential for contamination of medications. Furthermore, the Board has instructed Board inspectors to investigate this practice during pharmacy inspections. Inspectors will note this practice as a deficiency on inspection reports when discovered. This deficiency will result in the issuance of warning notices or further potential action if not immediately corrected.

Smoking in Pharmacies

After receiving reports of pharmacists smoking while filling prescriptions or pharmacy patrons smoking in pharmacies, the Arkansas State Board of Pharmacy would like to pass along the following information:

The Arkansas Indoor Clean Air Act of 2006, Ark. Code Ann. §20-27-1801, et seq, prohibits smoking in all public places, including all retail service establishments and retail stores. **None of the exceptions to the law will allow smoking in a pharmacy or drugstore that is open to the public by anyone including owners, pharmacists, or patrons.** The Arkansas State Board of Health's rules and regulations provide that persons/establishments violating the law will be subject to a civil penalty of up to \$1,000 for each day of violation.

Arkansas Act 128 of 2007

The Arkansas State Board of Pharmacy has received copies of several contracts that have been offered to Arkansas pharmacies to act as fulfillment pharmacies for companies that allege they are either trying to "help the bottom line" of the local pharmacy or that they have "too much business and need help fulfilling orders." While these contracts may seem lucrative it is important to note that any prescriptions filled in Arkansas must comply with this new law or the pharmacy and pharmacist will be charged with violations of the pharmacy practice act.

AN ACT TO PROHIBIT INTERNET SALES INTO ARKANSAS OF PRESCRIPTION DRUGS IF THE PATIENT HAS NOT ACTUALLY CONSULTED A PRESCRIBING PRACTITIONER.

- (c) A pharmacist practicing within or outside Arkansas may not fill a prescription order to dispense a prescription-only drug to a patient if the pharmacist knows or reasonably should have known under the circumstances that the prescription order was issued:
 - (1) On the basis of:
 - (A) An Internet questionnaire;
 - (B) An Internet consultation; or
 - (C) A telephonic consultation; and

- (2) Without a valid prior patient-practitioner relationship.

- (d)(1) An Internet broker operating within or outside Arkansas may participate in the sale of a prescription-only drug in this state only if the internet broker knows that the pharmacist who dispenses the drug has complied with the requirements of subsection (c) of this section.
- (2) The board shall report to the Attorney General any violations of subdivision (d)(1) of this section.

Regulation Changes from the February Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulation at the February 2007 Board Meeting.

Regulation 4: Pharmacy

The changes to Regulation 4 will help to explain the chain of responsibility for individual pharmacists involved in the prescription filling process related to the ability of the pharmacy computer to track each step in the prescription filling process.

In a pharmacy system that can delineate the individual steps in the prescription filling process, the pharmacist overseeing each step would be specifically responsible for that part of the process.

In a system that is not capable of delineating the individual steps in the prescription filling process, the pharmacist(s) involved in the process will share a corresponding liability for each prescription filled.

The pharmacist-in-charge is responsible for ensuring that pharmacy staff has been appropriately trained to follow the pharmacy's policies and procedures.

Regulation 8: Wholesale Distribution

The changes to Regulation 8 add language in the regulation to allow for the issuance of a limited use wholesale distributor license for entities that only engage in the wholesale distribution of medical gas.

Regulation 9: Pharmaceutical Care/Patient Counseling

Changes to Regulation 9 require that cardiopulmonary resuscitation (CPR) or basic cardiac life support (BCLS) certification for immunizing pharmacists must be accredited by the American Heart Association and must contain a live component where proficiency is tested.

The updated regulations may be viewed in their entirety in the pharmacy law book section of our Web site at www.arkansas.gov/asbp.

Methadone: An Unlikely Candidate for Drug Abuse

This article regarding the abuse of methadone was written by Sue Ellen Wilkerson, PD, who is a University of Arkansas for

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at www.fda.gov/medwatch/report/hcp.htm. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.


During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger

than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.

Changes in Medication Appearance Should Prompt Investigation

 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.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.



After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**[®] (letrozole) but instead received the estrogen replacement product **femhrt**[®] (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at www.connectlive.com/events/fdamedwatch. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at www.fda.gov/cder/learn/CDER-Learn/default.htm.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at www.buprenorphine.samhsa.gov.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at <https://nppes.cms.hhs.gov>.

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Medical Sciences (UAMS) College of Pharmacy graduate and has worked as the pharmacist-in-charge at UAMS' Substance Abuse Treatment Clinic (SATC) since 2001. While working at SATC, she has discovered what a nationwide problem methadone abuse has become and has focused on increasing both pharmacist and public awareness of this issue.

There is a trend among teens and young adults in our country today: a deadly trend. At an alarming rate, more and more individuals are experimenting recreationally with prescription drugs. In many cases the end result is death. One of the more surprising of the misused drugs is methadone. According to the National Center for Health Statistics, of all the narcotics mentioned in poisoning deaths, methadone has had the largest relative increase from 1999-2004.¹

Methadone, a drug rarely talked about, is a synthetic narcotic. Since the beginning of methadone maintenance therapy (MMT) in the 1960s, it has helped millions of people participate in a recovery program for narcotic dependence. Methadone has been proven to be safe and effective in MMT, but since it is a potent drug, misuse can be harmful and even fatal. It has a slow onset of action and a long half-life, of which most people are not aware. When it is misused for recreational purposes, that quick "high" is not delivered so the individual will ingest more. Most of the time other drugs such as Xanax®, Valium®, Klonopin®, and alcohol are used with methadone creating a lethal combination. Methadone can be toxic to anyone who is not tolerant of opioids (narcotics) and a single dose could be life threatening. The primary toxic effect of excessive methadone in the "opiate naive" is respiratory depression.

Methadone is also used to treat chronic pain. It is widely used for pain management due to its low cost and effectiveness. Studies have indicated that most of the methadone that is diverted illegally to the illicit drug market primarily comes from pain management, not from methadone treatment clinics. Recently, Food and Drug Administration issued a public health advisory concerning methadone use for pain control as well as a black box warning.

In Arkansas, in 2004, 49 deaths were attributed to methadone.² In Maine, in 2005, for the first time drug-related deaths outnumbered deaths from car crashes. The number one drug in those deaths was methadone.³ There were 133 deaths from methadone in Florida in 2002. In fact, the Florida Office of Drug Control issued a safety alert in an attempt to warn their citizens about the dangers of misusing methadone.⁴

Every day most pharmacists probably dispense methadone without giving much thought to the dangers methadone could pose to an individual who is not tolerant to opioids. Knowing that

the increased prevalence of prescription drug abuse is on the rise, we need to direct our efforts and attention to this serious issue. As pharmacists, we can help to address this problem, especially with this particular drug, which is rarely mentioned. We can be proactive by informing, educating, and warning our patients and the public. Taking that time could possibly save a life.

1. National Center for Health Statistics. Increases in Methadone Related Deaths: 1999-2004. Lois Fingerhut. Office of Analysis and Epidemiology.
2. Brooks J. Arkansas Center for Health Statistics, *Arkansas Democrat Gazette*. September 25, 2006.
3. Surprising Kids Killer: Methadone. April 10, 2006. Available at: www.cbsnews.com.
4. Narconon of Southern California, Inc. Available at: www.methadoneaddiction.net/m-overdose.htm

Tramadol to be Placed in Schedule IV

Please note that all prescription products containing the active ingredient tramadol will become Schedule IV controlled substances per Act 558 of 2007 sponsored by Representative Tommy Dickenson, and Act 585 sponsored by Senator Percy Malone, effective 90 days after the "sine die" for the legislative session. To quote the Drug Enforcement Administration Pharmacist's Manual, "When a drug not previously controlled is scheduled, the drug must be inventoried as of the effective date of scheduling." This is also addressed in the Code of Federal Regulations 21 CFR §1304.11 Inventory Requirements.

**Arkansas Pharmacy Support Group Help Line
870/636-0923**

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