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Arkansas State Board of Pharmacy

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Wholesale Distributors of List I Chemicals

All wholesalers licensed by the Arkansas State Board of Pharmacy, both wholesale drug distributors of legend/controlled substances and wholesale distributors of List I Chemicals, who sell pseudoephedrine, ephedrine, or phenylpropanolamine, are required to report suspicious orders for those products to the Arkansas State Board of Pharmacy office. The criteria for determining a suspicious order are listed in *Regulation 08-02-0008 – Suspicious Orders for List I Chemicals,* and can be found on the Board of Pharmacy Web site at www.arkansas.gov/asbp. This requirement applies to sales of traditional and non-traditional retail outlets, as well as to pharmacies.

During the June 2004 Arkansas State Board of Pharmacy meeting, two wholesale distributors of List I Chemicals appeared before the Board pursuant to an Order and Notice of Hearing alleging failure to report suspicious orders. One respondent was fined $175,000 and its List I Chemical license was suspended for three years; and the other respondent was fined $163,000 and its List I Chemical license was suspended for one year. Failure to report suspicious orders can result in a ready supply of List I Chemical precursors used in the illicit manufacture of methamphetamine.

Methamphetamine is a principal drug threat to Arkansas, primarily because of the drug's ready availability, the devastating impact methamphetamine addiction has on our citizens and communities, and the violence and environmental harm that result from methamphetamine production and abuse. Both children and adults are adversely affected by exposure to toxic chemicals when methamphetamine laboratories are operated in or near their homes. Production of one pound of methamphetamine yields five to seven pounds of toxic waste. In addition, children are subject to abuse and neglect from meth addicts and meth lab operators. According to the Little Rock resident Drug Enforcement Administration (DEA) office, approximately 90% of the clandestine labs, located in private residences, had children either on site or present at the time of seizure.

The Arkansas State Crime Lab reports that 1,208 meth labs were seized in Arkansas in 2003. In 2004, 617 labs had been seized by mid-June. The Crime Lab estimates that the average yield of methamphetamine from pseudoephedrine for these labs is 80% – such that 5 grams of pseudoephedrine can be converted by lab operators to 4 grams of methamphetamine.

The percentage of federal sentences that are methamphetamine related in Arkansas is more than twice the national percentage. According to the Federal-wide Drug Seizure System federal law enforcement officials in Arkansas and the Arkansas State Police seized 15.5 kg of methamphetamine in 2001 and 51.8 kg in 2002. This is just the tip of the iceberg. According to the DEA New Orleans Division, methamphetamine is selling for $10,000 per pound, $1,000 to $1,600 per ounce, and $100 per gram in Fayetteville, Little Rock, and Fort Smith. The Fayetteville Police Department reports that the most common quantity sold on the street in Fayetteville is an "8-ball" (one-eighth ounce) that sells for $250.

The Arkansas State Board of Pharmacy will continue to monitor suspicious sales of List I Chemicals by subpoena of sales records from wholesalers to traditional retail outlets, nontraditional retail outlets, and pharmacies. However, it is becoming increasingly clear that we must consider a more restrictive distribution system for List I Chemicals used as precursors for methamphetamine.

Over-the-Counter Sales of Pseudoephedrine

Act 1209 of 2001 requires all over-the-counter sales of pseudoephedrine tablets to be in a form that is unit dose, blister packaged from the manufacturer. Sale of the 100-count, or larger stock bottle packages, of the 30 mg or 60 mg products can **only** be dispensed pursuant to a prescription by a physician. Even though pseudoephedrine is a non-prescription

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FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretative rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

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, and 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.

According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of

Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

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product, **it cannot be sold in loose form, in any amount,** to walk-in customers requesting pseudoephedrine.

Surrender of Unwanted Controlled Substances

A new regulation by the Arkansas Department of Health (ADH) requires that controlled substances, submitted for destruction by pharmacies, hospitals, long-term care facilities, or related facilities occur **at least quarterly**. In addition, discontinued or unwanted controlled substances must be submitted each time there is a **change in the licensed person responsible** for the controlled substances at the facility. There is no change in the requirement that the discontinued or unwanted controlled substances must be identified in such a manner as to determine the exact location in the facility where the controlled substances were last recorded in the accountability record, to determine what person or persons had access to, or administered, such controlled substances during the time they were in the controlled substance inventory in the facility.

All controlled substances submitted for destruction, which are no longer usable because of deterioration, or expired date, or are unwanted, shall be delivered in person, by registered mail or by other means of shipment (with a return receipt) to: Arkansas Department of Health, Division of Pharmacy Services and Drug Control, 4815 W Markham, Slot 25, Little Rock, AR 72205, and be accompanied by all completed copies of Report of Drugs Surrendered (Form PhA:DC-1) furnished by the Department of Health. Drug surrender forms can be obtained by calling the ADH at 501/661-2325.

Reverse Distributors

Regulation 08-00-0001(m) requires all reverse distributors to be licensed with the Board. Before using one of these businesses for the return of, or the destruction of, drugs, confirm that it is licensed with the Board.

Specialty Pharmacy Permit – Student Health Clinic Pharmacy

Following a public hearing on June 11, 2004, the Arkansas State Board of Pharmacy promulgated a *regulation (04-03-0003)* defining a "Specialty Pharmacy Permit" for Student Health Clinics. A Student Health Clinic Pharmacy means a pharmacy located on a university or college campus for the purpose of filling prescriptions for students or employees or their spouses or dependents. The pharmacist-in-charge (PIC) of said pharmacy must provide written policies, procedures, and protocols for the operation of the pharmacy and obtain approval of the aforementioned by the Board of Pharmacy prior to operation of the pharmacy. In addition, the pharmacy's minimum operating hours must be approved by the Board. A pharmacist must be on duty during all hours of operation and the PIC must work a minimum of fifty-percent (50%) of the hours of operation. The Regulation became effective July 15, 2004.

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