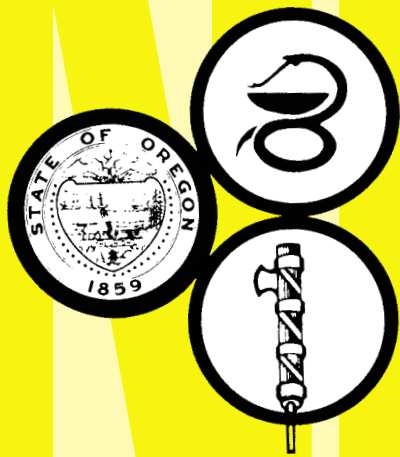


August 2004



Oregon State Board of Pharmacy

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No. 362: New Board Members

Lee Howard, a resident of Redmond, has been appointed by Governor Ted Kulongoski to serve a four-year term as a public member of the Oregon State Board of Pharmacy. Mr Howard will fill the position vacated by former public member and retired registered nurse Lynn Talton. Mr Howard has worked as an associate professor at Southern Oregon State University and as project manager for PacificCare/Secure Horizons. His term began in January of 2004 and expires in June of 2007, at which time he may be eligible for reappointment to another four-year term. He is a graduate of San Jose State University and holds a master of arts degree in Health and Physical Education. Lynn Talton leaves after 10 and one-half years of service as a public member of the Board. She was first appointed to serve the two years left on a vacant, unexpired term and then continued on to serve two full terms plus an additional six months while her replacement was recruited. That makes Ms Talton the longest serving public member and, we believe, the longest serving Board member in the history of the Oregon State Board of Pharmacy.

Pharmacist Ann Zweber of Corvallis has been appointed to serve a four-year term on the Board to fill the position being vacated by Allan Dulwick. Her appointment was confirmed by the Oregon State Senate, as required, on June 21, 2004, and her term expires in June of 2008. She will attend her first meeting as a Board member in August. Ms Zweber is a graduate of the University of Wisconsin and the Oregon State University (OSU) College of Pharmacy. She is currently a member of the faculty at OSU College of Pharmacy and is an instructor in the Department of Pharmacy Practice. Her pharmacy experience spans a variety of settings, including hospital, long-term care, home infusion, and community pharmacy. She is a certified instructor for pharmacy-based immunization delivery and a consultant to the OSU Student Health Service. Allan Dulwick, manager of the Kaiser Permanente Pharmacy in Beaverton, leaves the Board after eight years of distinguished service.

No. 363: Staff Changes

A number of changes have occurred over the past year in the composition of Board of Pharmacy staff. Inspector Nicolle King and Chief Inspector Larry "Chief" Martin have left the Board to take on new career challenges. Ms King started as an inspector with the Compliance staff in April of 2000 and left in September of 2003 to continue her career in long-term care pharmacy. Chief Martin started with the Board in 1990 and worked in Compliance

until his departure in March of 2004. He will also work in the area of long-term care pharmacy practice. The loss of his nearly 15 years of institutional memory and experience on the Board's staff is already being missed.

Two new inspectors have been hired to replace Chief Martin and Ms King. Inspector Michele Cale, a 1976 graduate of Northwest Louisiana University College of Pharmacy, is a pharmacist with 14 years of current experience at Oregon Health and Science University. Inspector Gary Miner, a 1973 graduate of Oregon State University College of Pharmacy, has 26 years of experience as director of pharmacy for Woodland Park Hospital and, for nine of those years, he was also director of pharmacy for Eastmoreland Hospital. Miner directed and oversaw the closure and disposition of both pharmacies when those hospitals recently closed. Inspectors Miner and Cale have had to "hit the ground running" and both are demonstrating their varied talents.

The Compliance section also recruited Annette Gearhart from her long-time position as the Board's licensing secretary to serve in the position of compliance secretary with new and expanded responsibilities. The newly upgraded Licensing section is now staffed by three knowledgeable and motivated individuals, including Michael Hunt, Tzetz Backardjieva, and Chrisy Hennigan. The License 2000[®] computer licensing and data base system has been implemented to assist the Licensing and Compliance staff with operations, record keeping, and reporting, and is expected to help increase efficiency and productivity. An accelerated orientation and training program has been completed by the staff.

No. 364: Dispensing Errors

The most common complaint received in the Board office regarding pharmacies or pharmacists continues to be dispensing errors. The complainant states that the pharmacy dispensed the wrong drug or dose, or dispensed a drug to the wrong patient. Following are examples of the types of dispensing errors received in 2004.

1. A prescription for **amoxicillin 125 mg/5 ml** was reconstituted and dispensed with rubbing alcohol (isopropyl alcohol) instead of water. The error was discovered prior to ingestion of the suspension.
2. **Tambocor[™] 100 mg** was dispensed to a five-year-old patient when his prescription was for Tenex[®] 1 mg. The patient took the Tambocor 100 mg tablets for approximately seven days and suffered side effects requiring hospitalization following discovery of the error.

Continued on page 4



National Pharmacy C

(Applicability of the contents of articles in the National Pharmacy Compliance and can only be ascertained by examining the

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 interpretive 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.

Continued from page 1

3. A prescription for **furosemide liquid** was refilled with fluoxetine liquid for a two-pound, 12-year-old Pomeranian dog. The incorrect medication was administered for seven to 10 days prior to discovery of the error. The veterinarian believes this error resulted in the dog's death.
4. A **morphine sulfate 30 mg** prescription was dispensed to the wrong patient with a similar name. The patient consumed two tablets before discovering the error.
5. **Zantac® syrup** was erroneously dispensed for a Zyrtec® syrup prescription. The patient took three doses prior to discovering the error.
6. A **Celexa™ 20 mg** prescription was refilled with estradiol 1 mg. The patient discovered the error and did not take any of the wrong medication.
7. A **prednisone 10 mg** prescription was erroneously labeled and dispensed with another patient's name.
8. A prescription written for **Neurontin® 800 mg** was refilled with both **Neurontin 800 mg** tablets and Guaifenes® GP tablets.
9. **Ciprofloxacin 250 mg** tablets were dispensed for a prescription that was written for Ciprofloxacin 500 mg.
10. A prescription written for **propoxyphene-and-APAP 100/650** to dispense a quantity of 150 was dispensed with a quantity of 100.
11. A prescription for **Evista 60 mg** labeled for a patient was mistakenly dispensed to the wrong person.
12. **Pravastatin 80 mg** was dispensed to a patient when the prescription was written for pravastatin 40 mg. The patient discovered the error before taking any of the wrong dosage.

Multiple factors contribute to the incidence of dispensing errors, and vigilance alone is an insufficient response. A human being incapable of making a mistake has yet to be discovered, and mistakes will occur when an individual is required to perform repetitive tasks for hours at a time. Our goal is to encourage and facilitate the establishment of systems with redundancies, safety and accuracy checks, and technology to ensure that the inevitable human mistake does not result in a patient receiving the wrong drug or dose, or the wrong information.

No. 365: Board Recognizes 50-Year Pharmacists

Once each year, the Board of Pharmacy recognizes and honors a number of pharmacists who have been licensed in the state for 50 years. The Board is grateful to them for their many years of service and contribution to the profession and to the citizens of Oregon. These individuals, who are pharmacists still actively licensed in Oregon, deserve the acknowledgement and recognition of their profession. When you see them on the job or around the state at various professional functions, be sure and take a moment to congratulate them. Fifty years is a really long time!

Robert F. Barclay, Eugene
R. Dareld Brown, Springfield
Charles W. Deer, Eugene
Leon F. Gordon, Salem
Elsie A. Hatch, Beaverton
Wayne M. Hatch, Beaverton
Sherman O. Hess, Portland
Yoshio Inahara, Portland
Philip B. Kaser, Roseburg
Robert L. Lammers, Eugene
Jack C. Means, Portland
Roderick L. Newland, Winston
William D. Peterson, Sunny Valley
Clifford D. "Bud" Rose, Bend
L. Lane "Skip" Thornton, Lakeview
Shigeru Yuzuriha, Portland

This list of names and their location in Oregon has been generated from the Board of Pharmacy's current computer records. If you are aware of any inaccuracy, please contact the Board office so the information may be corrected.

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