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Oregon State Board of Pharmacy News

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No. 535: A Message from the Board's New Executive Director, Marc Watt, RPh

To my fellow Oregon pharmacy colleagues:

It is my honor to assume the duties of executive director of your Oregon State Board of Pharmacy. My service began on February 3, of this year. I am extremely fortunate to be inheriting an agency that is well run and staffed with highly competent individuals. Gary Schnabel is to be commended for leaving behind an agency that functions at such a high level.

For those of you who do not know me, I have been a pharmacist in Oregon since 1977, and have spent the majority of my time in retail pharmacy, with a recent three-year period working in a specialty pharmacy. I have held positions from staff pharmacist to pharmacy manager along with a number of management positions in several different companies. I served as an appointed member of the Board from 2000 to 2008. I am a member of the Oregon State Pharmacy Association (OSPA), and also served on the Board of Directors of OSPA for a period of time.

I have the utmost admiration for all the pharmacists who are in the trenches of health care every day. I am constantly impressed with your dedication to your patients and your profession and how well you perform under the pressures of the modern medical system.

One of the things that I have always admired about the Board is its philosophy of "Compliance through Education." For as long as I can remember, the Board has attempted to communicate to its licensees at a high enough level so that it can avoid having to take disciplinary action on a licensee if at all possible. I intend to continue this philosophy. I also have strong feelings about operating in a transparent and collaborative manner and will do my best to make sure the Board does so whenever possible.

No. 536: Recent FDA Actions Related to Acetaminophen-Containing Products and Codeine

Food and Drug Administration (FDA) has made two recent actions relevant to daily pharmacy practice that licensees should be aware of and understand. First, manufacturers of acetaminophen (APAP)-containing products are required to reduce the total dose of APAP per unit to no more than 325 mg. Please see the *National Pharmacy Compliance News* article entitled "FDA Issues Alert on Acetaminophen Products" on pages two and three of this *Newsletter* for additional information. Second, FDA has declared that certain prescription drug products containing codeine sulfate, codeine phosphate, and dihydrocodeine are not FDA approved and must be removed from pharmacy shelves. Please see the listserv e-mail article sent to licensees on March 24, 2014, entitled "FDA Update: Codeine and Dihydrocodeine Products" for additional information.

These changes in the landscape present the perfect opportunity for pharmacists to discuss drug therapy regimens and choices with patients. Pharmacists are encouraged to take the proactive approach to initiate the conversations for recommendation of appropriate alternatives to prescribers and patients. Also, consider visiting the website *www.knowyourdose.com,* which has valuable information for practitioners and patients regarding judicious APAP prescribing.

No. 537: Update on the PDMP – Are You Using the System?

By Oksana Khrapach, 2014 PharmD Candidate and Nicole O'Kane, PharmD

The Oregon Prescription Drug Monitoring Program (PDMP) was created in 2011 because of the increased number of deaths associated with controlled substance (CS) prescriptions. One mission of the program is for all health care practitioners, including pharmacists, to use the PDMP to support the appropriate use of prescription medications. Among Schedule II through IV CS reported to the PDMP, opioids are by far the class most often prescribed, with benzodiazepines being the second. Commonly these two classes are prescribed together, greatly increasing the risk of overdose. The pharmacist has a unique role in identifying and addressing these types of drug utilization review issues. A systematic approach should be used when dispensing and monitoring the use of CS, and the PDMP is a cornerstone of this approach. The Board recommends that pharmacists use the PDMP along with other available

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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes 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. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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information, first, to ensure patients are receiving the safest, most effective treatments, and second, to ensure public safety by screening for potential drug diversion.

The program receives data from Oregon-licensed pharmacies dispensing CS to Oregon residents. Pharmacies are required to report this data within seven days. According to the *2013 Annual Report to the PDMP Advisory Commission,* close to 100% of the pharmacies required to report had uploaded data by December 31, 2013. Unfortunately, only 1,636 pharmacists currently have active PDMP accounts to access this data. This is a small percentage of the total number of pharmacists practicing in the state. If you are not currently a registered user, sign up today using the following steps:

- Go to *www.orpdmp.com*
- Click the PDMP User Access & Registration link in the left-hand menu
- Open and read the Terms & Conditions
- Click the Registration link
- When prompted to log in, type in the following:
  - Username: newacct
  - Password: welcome
- Complete the required fields on the form
- Print and sign the form and then have it notarized
- Mail the completed form to:
  Oregon Prescription Monitoring Program – IPE
  PO Box 14450
  Portland, OR 97293-0450

As a user of the Oregon PDMP system, it is important to understand the following:

- Though health care providers and pharmacists are not required to obtain information about their patients' medications from the PDMP, it is highly recommended that it be utilized as a health care tool. Utilization can assist pharmacists caring for patients and in recognition of the pharmacist's corresponding responsibility to properly dispense CS (see 21 CFR 1306.04). Individual company requirements may expand these responsibilities.
- If the PDMP system is offline or unavailable, pharmacists are prohibited from refusing to dispense CS to patients solely based on this reason.
- It is against the law to access information of individuals not under your direct care.
- Patients can request a list of who has accessed their data.
- Information obtained from the PDMP is okay to discuss with other health care providers if it involves patient care.

Recent changes to the PDMP:

- Pharmacists and health care providers may authorize staff – known as a delegate – to access information from the PDMP. The practitioner must acknowledge a delegate and he or she is responsible for search queries done by the delegate. The delegate will have his or her own login information and will be required to input the authorizing provider's information upon each log in. The process of creating a delegate involves the same steps listed above, but under license type, choose "delegate."
- Neighboring states (California, Idaho, and Washington) now have access to the Oregon PDMP for their Oregon patients.

Currently, the Board does not require pharmacists to use the PDMP. However, the use of the system is in line with the Board's mission to promote, preserve, and protect the public health, safety, and welfare. Every pharmacist dispensing and monitoring CS treatments is encouraged to use this program. For more information on this topic, please visit *www.orpdmp.com/*.

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