



# Minnesota Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions against **pharmacists** between the dates of December 19, 2013 and April 16, 2014:

**Mach, Daniel S., License #118941.** Dr Mach certified a prescription for amoxicillin, which was dispensed to and taken by the patient, even though the patient's profile indicated an allergy to penicillin. He admitted that he routinely overrode allergy alerts and simply put a note on the prescription receipt to discuss the allergy with the patient. However, the caretaker for the patient did not receive counseling. Consequently, the Board adopted a stipulation and consent order at its January 28, 2014 meeting that reprimanded Dr Mach and required him to pay a civil penalty in the amount of \$1,000.

**Cary, Erin M., License #118659.** Dr Cary incorrectly certified a prescription for sertraline as being accurately filled even though the prescription vial contained warfarin. She did not check the contents of the manufacturer's stock bottle or compare it with the contents of the prescription vial when certifying the prescription, in violation of Minnesota Rules 6800.3100, Subp. 3(c). Instead, she only compared the National Drug Code numbers of the manufacturer's stock bottle and the prescription vial. Consequently, the Board adopted a stipulation and consent order at its March 12, 2014 meeting that reprimanded Dr Cary and required her to pay a civil penalty in the amount of \$1,000.

Between the dates of December 19, 2013 and April 16, 2014, the Board administratively revoked the registrations of the following **pharmacy technicians** after receiving notification from the Minnesota Department of Revenue that they owed \$500 or more in delinquent taxes, penalties, or interest, or have not filed returns: **Khan, Lovern, #727277; Luevano, Rebecca, #726279; Pool, Lauren, #727672; Sheikh-Mohamed, Sadia, #727154; Williams, David, #727487; Williams, Melissa, #727581; Garvey, Patricia, #701877** (later reinstated, see below); and **Her, Yeev, #716282** (later reinstated, see below).

Between the dates of September 19, 2013 and April 16, 2014, the Board issued reinstatement orders for the following **pharmacy technicians** upon receiving notification from the Minnesota Department of Revenue that they had satisfactorily

resolved their tax-related cases: **Baracaldo, Camilo, #715788; Zarate, Alicia, #727893; Garvey, Patricia, #701877; and Her, Yeev, #716282.**

## Compounding – Federal Drug Quality and Security Act

On November 27, 2013, President Barack Obama signed the Drug Quality and Security Act (DQSA) into federal law. The DQSA contains two Titles – Title I concerns the compounding of drug products, while Title II has provisions related to the distribution of drugs. Many of the drug compounding provisions in Title I became effective immediately upon enactment of the law. Per Minnesota Rules 6800.2250, it is unprofessional conduct for a pharmacist or pharmacy to violate any federal, state, or local statute, rule, or ordinance involving the practice of pharmacy. Consequently, the Board expects pharmacies and pharmacists to be in compliance with this new federal law.

The following are the main provisions related to compounding in the DQSA:

- ◆ Creates a new type of entity that will be directly regulated by the United States Food and Drug Administration (FDA) and known as an outsourcing facility, which is defined as a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of the new federal law.
- ◆ Exempts outsourcing facilities from the requirements to get FDA approval before marketing a drug and to label products with adequate directions for use. However, such facilities are not exempt from following current Good Manufacturing Practices.
- ◆ Allows outsourcing facilities to be registered by FDA. If thus registered, these facilities will be subject to FDA inspections. Outsourcing facilities may, in addition, be licensed as a pharmacy if permitted under state law. (Minnesota will allow outsourcing facilities to be licensed as pharmacies.) Regardless of whether or not they are registered as pharmacies, the compounding operations of outsourcing facilities must be under the supervision of a licensed pharmacist.

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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](http://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](http://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](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto: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 "benazpryl." 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](http://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 Med-Watch Safety Information and Adverse Event Reporting Program. More information is available at [www.fda.gov/Safety/Recalls/ucm382076.htm](http://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](http://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](http://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](mailto:nwatson@nabp.net).



**Pharmacists & Technicians:**  
Don't Miss Out on Valuable CPE Credit.  
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.*

- ◆ Requires outsourcing facilities to report to FDA information about the products that it compounds, including a list of all of the products it compounded during the previous six months, and other information about the compounded products, such as the source of the ingredients used to compound. Such facilities must report adverse events to FDA and must label compounded products with certain information.
- ◆ Removes provisions from Section 503a of the Food, Drug, and Cosmetic Act (FD&C Act) that were found to be unconstitutional, but reinstates the remaining provisions. Pharmacies may compound drugs without being subject to the new drug approval, labeling, and current Good Manufacturing Practices requirements of the FD&C Act only if they meet the requirements of Section 503a. Those requirements are described in detail in a draft guidance document that FDA issued in December 2013. Pharmacists engaged in compounding would be well advised to review that guidance document, which can be found at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf).

### **Compounding 'For Office Use'**

Pharmacists should note that facilities licensed only as pharmacies are not allowed to compound for office use (ie, pharmacies are **not** allowed to sell a supply of a compounded drug at wholesale to clinics, hospitals, or to the offices of practitioners such as physicians, physician assistants, nurse practitioners, dentists, podiatrists, veterinarians, or optometrists). Compounding for office use, by pharmacies, appears to be prohibited under the new federal law (note that the DQSA does not apply to veterinary drugs, but existing federal law may prohibit compounding for veterinary office use). All compounding for office use is prohibited by existing state law. Under state law, all compounding must be done pursuant to a patient-specific prescription received in the pharmacy in advance of the dispensing of the compounded drug.

In the past, the Board has issued state manufacturing licenses to certain pharmacies that had received letters from FDA in which that agency stated that it would not require the pharmacies to be registered as manufacturers. In those cases, the Board did consider the production of a drug for office use to be a form of manufacturing, not compounding. Given the enactment of the DQSA, the Board is reassessing the issuance of manufacturing licenses in such circumstances. The Board did develop legislation that, among other things, would allow the Board to engage in rulemaking for the purpose of allowing compounding for office use in certain circumstances. That legislation is currently making its way through the Minnesota State Legislature.

However, FDA may very well interpret the DQSA to entirely prohibit an entity licensed only as a pharmacy from compounding a drug without receiving a patient-specific prescription in advance of the dispensing. If that is the FDA interpretation, the Board will not be able to allow compounding for office use by a pharmacy, even if the state legislation passes. That means that the Board would no longer issue manufacturing licenses to pharmacies unless those pharmacies were registered by FDA as manufacturers or as outsourcing facilities. Pharmacies that the Board currently licenses as manufacturers, but that are not

registered by FDA, should have contingency plans in place in case they are no longer allowed to compound for office use under a state manufacturing license. Board staff continues to work with FDA to seek clarification in this area, and the Board will work with affected pharmacies on a transition process if it becomes necessary to do so.

### **Requirement for Unique Identifiers**

In 2011, the Board adopted a package of rule changes that, among other things, defined the term "unique identifier" to mean (emphasis added) "a manual signature or initials, a biometric identifier, or a **board-approved electronic means of identifying only one individual.**" That term is now used in several parts of the rule, including Minnesota Rules 6800.3100, Subp. 3a, which states:

For prescriptions filled in a pharmacy, the unique identifier of each pharmacist, pharmacist-intern, or pharmacy technician who performs any portion of the prescription filling process must be documented, with the documentation maintained for a minimum of two years. The documentation must indicate which portion of the prescription filling process each pharmacist, pharmacist-intern, or pharmacy technician completed . . . This subpart does not waive the requirement for an individual pharmacist, practitioner, or pharmacist-intern to certify a filled prescription drug order according to subpart 3.

This rule was not adopted only to aid in Board investigations of complaints involving dispensing errors. It is very important for pharmacies to have a continuous quality improvement (CQI) program in place that tries to determine the cause of errors so that policies and procedures can be refined in order to minimize the risk of future errors. When conducting CQI, it is important to know who completed various portions of the dispensing process. Unique identifiers help track the individuals who complete portions of the dispensing process.

Inspections and complaint investigations have revealed that some pharmacies are not in compliance with the unique identifier requirements of the rules because they are relying on an electronic means of identifying staff that has not been approved by the Board. In particular, systems that rely on a simple login to a computer are not Board approved. Unless such systems automatically log off after a very brief period of inactivity (preferably less than a couple of minutes), anyone else in the pharmacy can use the computer while another staff person is logged in. Board investigations commonly find that an individual who supposedly worked on a portion of the dispensing process was not even on duty at the time the prescription was filled. Pharmacists-in-charge should assess their pharmacy's use of unique identifiers and make sure that the pharmacy is in compliance, including having Board approval for electronic unique identifiers. Questions can be directed to the Board's surveyors at 651/201-2825 or by e-mail at [pharmacy.board@state.mn.us](mailto:pharmacy.board@state.mn.us).