March 2016

# North Dakota State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## Tanya Schmidt Appointed to Board

Tanya Schmidt, PharmD, RPh, was appointed to serve on the North Dakota State Board of Pharmacy by Governor Jack Dalrymple on August 20, 2015. Tanya will fill the vacant seat caused by the expiring term of Laurel Haroldson, RPh.

Tanya resides in Fargo, ND, where she is the director of central operations for Thrifty White Pharmacy. Tanya is a graduate of North Dakota State University College of Pharmacy. Tanya brings an extensive background to the Board with her work experience and being licensed in many jurisdictions across the United States.

The Board welcomes Tanya and thanks Laurel for her 10 years of service to the profession of pharmacy by serving on the Board.

## Drug Disposal Program Opportunity for North Dakota Licensed Pharmacies

The Board has developed a partnership with the Yellow Jug Old Drugs Program to provide an option for the safe disposal of a patient's prescription drug medications. The Board has generously decided to provide these systems and containers to any pharmacy eligible and willing to participate in the program. This will be free of charge and, depending upon the impact and scope of the program, the Board hopes to continue funding for future years.

The collection of unused controlled substances (CS) from the public is a new initiative based on a rule recently passed by Drug Enforcement Administration (DEA) that allows certain DEA registrants, such as pharmacies, to be eligible to register as a disposal location and provide that service to the public in the registrants' area. North Dakota now has over 50 pharmacies participating in the program and, in conjunction with the North Dakota Attorney General's take-back program, has made those sites available to the public at *www.ag.nd.gov/PDrugs/TakeBackProgram.htm*.

Information on the procedures for registering with DEA as a disposal site was sent to pharmacies, along with instructions on how and where they would need to place the secure container within the pharmacy so it is accessible to the public. If you need this information, please contact the Board office.

The goal of providing this program to our citizens in an accessible manner is to decrease the number of prescription drug medications left in medicine cabinets waiting to be discovered by an individual who will divert them for misuse. National data show 71% of people misusing prescriptions first obtain them from friends or relatives, which is why it is important for pharmacies to provide this service and to inform patients of this program.

All pharmacies in North Dakota should have received forms to complete in order to participate in the program. Once a form is submitted to the Yellow Jug Old Drugs Program, the pharmacy will receive a container as soon as one is available. Of course, participation is voluntary and a service you can choose to offer. The Board hopes that you will agree to provide this important service by becoming a disposal location for your patients and the public.

## New Rules With Estimated Effective Date in April 2016

During the November Board meeting, the Board put its final approval on five rule changes that will likely be effective on April 1, 2016. The final version of the rules are found on the Board's website or can be obtained by calling the Board office for copies. They include:

- A new standard requiring that all pharmacies have a continuous quality improvement program in place to track and prevent quality-related events and/or errors;
- Updated terminology on procedures for transfer of pharmacists' licensure;
- Updated regulations on Clinical Laboratory Improvement Amendments-waived tests to the current practice standards. Also expanded the lists of tests that a pharmacist may conduct to those applicable to current practice expectations;
- A new process for pharmacists to have prescriptive authority to distribute naloxone rescue kits to appropriate individuals to treat narcotic overdoses; and
- Revised collaborative agreement standards to be consistent with the legislative changes currently in effect.

## Electronic Prescriptions for Controlled Substances Reminder

DEA issued a rule change in 2010 allowing for electronic prescriptions for controlled substances (EPCS). North Dakota law also allows for electronic prescription transmission of all prescriptions, including CS. The DEA rule requires providers and pharmacies to have certifications in place for their electronic prescribing/dispensing system. This certification ensures safeguards are in place for authorized prescriptions to be received and transmitted. For pharmacies, much of this work is done by the dispensing software systems. The Board continues to see a rapid escalation in the number of providers and pharmacies that

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## Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

## Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

*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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

**6) Compounded Pain Creams: High Profit Margin and Danger**

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

**7) Clear Care: Still Causing Severe Eye Injuries Five Years Later**

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

## Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

## US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

## FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

## Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

## MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

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are approved to transmit EPCS. If you are not accepting EPCS, the Board encourages you to work with your vendor to make the adjustment, as this adds a tremendous amount of efficiency to both the pharmacy and the provider. As always, it is important to verify the integrity of a CS prescription when a red flag presents itself, and also to work with the provider should there be any questions or concerns.

## *Individual License and Registration Renewals*

Pharmacist license and technician registration renewals were due by March 1. Any delinquent renewals need to be processed as soon as possible. Pharmacists-in-charge, please ensure that your employees have current licenses and registrations posted in the pharmacy; if there are any individuals who have not renewed, they should not be allowed to work until they can provide a current license/registration. You can verify or reprint your license at any time on the Board website at *www.nodakpharmacy.com*.

## *North Dakota Pharm-Assist Committee*

The North Dakota Pharm-Assist Program is a voluntary program for impaired pharmacists, interns, technicians, and pharmacy students who are in need of support and assistance for either alcohol or chemical abuse, or other stressors.

Through this program, members of the pharmacy community can receive help from caring colleagues in a confidential, non-coercive, and non-punitive manner.

Impaired individuals can be helped with the following:

- ♦ Substance abuse education
- ♦ Awareness of factors leading to impairment
- ♦ Understanding the warning signs of impairment
- ♦ Help from the North Dakota Pharm-Assist Program

The goals of the North Dakota Pharm-Assist Program include: providing continual support and assistance to the pharmacist, intern, technician, or pharmacy student; preventing the loss of a professional career; preserving the pharmacist's, intern's, or technician's professional reputation; and restoring the individual's ability to practice competent and professional pharmacy.

### How It Works

1. Once a committee member from the Pharm-Assist Program receives a request for assistance, one of the co-chairs will initiate steps to verify expressed concerns.
2. If there is sufficient reason for concern, the co-chair will arrange for a personal visit with the person and other involved individuals.
3. The pharmacist, intern, technician, or pharmacy student will be encouraged to seek help voluntarily. An initial evaluation to assess the need for treatment will be provided at no charge to the person.
4. A program member will assist the pharmacist, intern, technician, or pharmacy student in entering treatment. He or she will maintain contact and provide encouragement and support during and after treatment.
5. The program will provide support after treatment and during re-entry into practice.

### Pharmacy Professionals Helping Pharmacy Professionals

Committee members have a genuine concern about the welfare of their colleagues seeking assistance.

If a person has direct knowledge about an impaired pharmacist, intern, technician, or pharmacy student and is concerned, that person should contact the North Dakota Pharm-Assist Program. That person could be a colleague, spouse, family member, employer, employee, concerned citizen, or even the impaired pharmacist, intern, or technician himself/herself.

The Board **is not** contacted when a pharmacist, intern, or technician becomes involved with the program. **All** information is kept strictly confidential.

A pharmacist, intern, technician, or pharmacy student in need of assistance who refuses to seek help is a danger to the health and welfare of the community. In such cases, the program **must** notify the Board Investigating Committee, but not the Board itself.

Contact information of the program's committee members may be found on the Board's website under Pharm-Assist.



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