



# North Dakota State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Shane Wendel, RPh, is Appointed by Governor Dalrymple to Board of Pharmacy**

Shane Wendel, RPh, was appointed to serve on the North Dakota State Board of Pharmacy by Governor Jack Dalrymple on May 8, 2012. Pharmacist Wendel will fill the vacant seat caused by the expiring term of Rick Detwiller, RPh.

Shane resides in Carrington, ND, where he owns and operates Central Pharmacy in Carrington and New Rockford, ND. Shane is a 1994 graduate of the North Dakota State University College of Pharmacy.

The Board welcomes Shane and thanks Rick for his 10 years of service to the profession of pharmacy by serving on the Board.

## **Certificate to Administer Immunizations or Other Injectable Medications**

As we get closer to flu shot season, please remember to check to ensure your immunization/injectable certificate from the Board is current. The application to obtain or renew your immunization/injectable certificate is available on the Board's Web site under Applications/Forms.

With more and more requests to obtain the certificate, the Board will move to an online renewal process on the Board's Web site. The Board anticipates that this will be fully functional by the end of the year.

As a reminder, the North Dakota Legislature approved legislation related to pharmacist administered immunizations and vaccinations. It removed the 18 years or older age restriction for pharmacists in providing immunizations. This legislation lowers the age restrictions to at least 11 years of age for all immunizations and vaccinations. It also provides for the administration of influenza vaccination by injection or by "live" for an individual who is at least five years of age.

North Dakota Legislature clearly indicated that improving the immunization rate is a goal for North Dakota and pharmacists are at the forefront to providing this service across the state. The Board believes it is essential for its pharmacists to capitalize on this opportunity and show what a crucial part of the health care team we are.

## **Pharmacist Intern License and Registration**

Members of the National Association of Boards of Pharmacy® (NABP®)/American Association of Colleges of Pharmacy District 5, which includes the jurisdictions of Iowa, Minnesota, Nebraska, North Dakota, and South Dakota and the provinces of Manitoba and Saskatchewan, are working toward a system which could eventually issue a uniform internship registration/license to pharmacy interns in their jurisdiction. The first phase of the program, known as Pharmacist Intern License and Registration (PILAR), was released in late August. In Phase 1, prospective pharmacy interns in Iowa and North Dakota may register for an internship license/registration with their specific board of pharmacy online and, after the registration has been reviewed by NABP for disciplinary actions, the board of pharmacy approves the

internship license/registration online. Currently, North Dakota and Iowa are the only District 5 states participating in the program and the license/registration is not transferrable between the two states.

Future goals of PILAR are to allow interns to register online for a single pharmacy internship license that will be accepted in multiple states within District 5. In addition, the program would further plan to allow data sharing between the schools and colleges of pharmacy and the boards of pharmacy. This includes the ability for schools and colleges to manage their interns and approve their interns' practice experience online. The boards of pharmacy within District 5 would also have access to this information.

Once fully implemented, PILAR would offer the following benefits:

1. With a single online registration, a pharmacy intern could acquire and obtain internship credit for practice experience in any of the participating District 5 jurisdictions.
2. The complete record of an intern's practice experience would be available electronically to each state in District 5. This would decrease paperwork, expedite the licensing/registration process, and simplify the transfer or certification of internship hours within District 5 jurisdictions.
3. The new program would expand practice experience opportunities, decrease paperwork, and decrease costs for interns in District 5 jurisdictions while decreasing administrative tasks and costs for colleges and boards of pharmacy in District 5 jurisdictions.

## **Pharmacy Inspections**

It is the time of the year for pharmacy inspections to occur. By the time this *Newsletter* gets to you, inspections for most pharmacies will be complete. For those of you still waiting, as a reminder, the emphasis of the inspections this year will include:

- ◆ Use and compliance of Prescription Drug Monitoring Program
- ◆ Counseling or offer to counsel on **all** prescriptions by the pharmacist
- ◆ CII controlled substance audit: one done before the inspector arrives and one during inspection
- ◆ Information on new hospital first dose review rule effective June 2015
- ◆ Information on new compounding rules effective January 2015

## **Product Substitutions**

The Board often gets questions about the allowable substitution of medical devices, medical food, or other products that may require a prescription but are not contained in the *Orange Book*. One common example is the substitution between spacer devices used for inhalers: OptiChamber (which is covered by North Dakota Medicaid) vs Aero-Chamber. Often, the root of these tends to be third-party coverage or cost differences.

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## **FDA Warned Medical Practices About Counterfeits in US and Risks to Patients**

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm), may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm).

### **Rethink the Vial**



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid pre-

scriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request Parents' Guide to Understanding Prescription Drug Abuse brochures for distribution to your patients, visit [www.SafeguardMyMeds.org](http://www.SafeguardMyMeds.org).

### **Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports**

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at [www.abbott.com/vicodin-consumer-alert.htm](http://www.abbott.com/vicodin-consumer-alert.htm). Abbott advises that anyone who has the counterfeit ver-





Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at [www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm](http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

## **PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits**

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at [www.safemedicines.org/resources-for-healthcare-professionals.html](http://www.safemedicines.org/resources-for-healthcare-professionals.html). Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

## **FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches**

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm). Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at [www.fda.gov/Drugs/DrugSafety/ucm300747.htm](http://www.fda.gov/Drugs/DrugSafety/ucm300747.htm). Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARE<sub>x</sub>E<sup>®</sup> Web site at [www.awarerx.org/informedSiteMap.php](http://www.awarerx.org/informedSiteMap.php).

## **Providers Asked to Advise Patients of Acetaminophen Safe Use Steps**

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWARE<sub>x</sub>E Web site at [www.awarerx.org/OTCMedUse.php](http://www.awarerx.org/OTCMedUse.php). The AWARE<sub>x</sub>E consumer protection program and the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) are part of the Acetaminophen Awareness Coalition.



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

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your 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.*

The Board expects that the pharmacist, in coordination with the prescribing practitioner, will use his or her professional judgment in making these substitutions. It is always imperative that we work together for the patient to provide the care the patient needs to get the best outcomes.

### CPE Monitor

CPE Monitor™ is a national online continuing pharmacy education (CPE) tracking service that will authenticate and store data for completed CPE units received by pharmacists and pharmacy technicians.

Many Accreditation Council for Pharmacy Education (ACPE)-accredited providers have already begun requiring pharmacists and technicians to provide their NABP e-Profile ID, plus their birth date (MMDD), to receive credit for completing CPE, and the remaining providers continue to transition their systems throughout 2012. Participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching e-Profile. This will eventually eliminate paper forms and the need to submit paper copies of CPE statements of credit to the North Dakota State Board of Pharmacy.

Pharmacists and technicians, visit *MyCPEmonitor.net* to register for CPE Monitor and to obtain your e-Profile ID by creating your e-Profile. Any errors in an individual's e-Profile may result in unrecorded or mis-recorded CPE, so be sure to keep your e-Profile accurate and up to date.

### 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 family 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

Pharm-Assist Committee members have a genuine concern about the welfare of its colleagues seeking assistance.

If a person has direct knowledge about an impaired pharmacist, intern, technician, or pharmacy student and he or she is concerned, he or she 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 contacting the program.

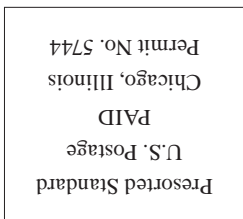
The Board of Pharmacy **is not** contacted when a pharmacist, intern, or technician becomes involved with the program. **All** information is kept strictly confidential.

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 of Pharmacy Investigating Committee, but not the Board of Pharmacy itself.

Contact information of the members is found at the Board of Pharmacy's Web site under Pharm-Assist Committee.

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