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New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Significant Adverse Drug Events

1. A 79-year-old female patient with glaucoma was prescribed a new prescription for brimonidine/timolol; however, dorzolamide/timolol was dispensed at the point of sale. After using the incorrect medication for an unspecified amount of time, the patient reported eye stinging and irritation. The pharmacist attributes the error to look-alike, sound-alike medications. The pharmacist required review of standard operating procedures for all staff involved.
2. A 78-year-old female patient with depression was prescribed a new prescription for Zoloft®; however, the technician entering the prescription confused sertraline with Seroquel®. As a result of the mix-up, quetiapine was dispensed. After taking the incorrect medication for approximately three months, the patient did not report an adverse reaction to the medication; however, she required a follow-up visit with the prescriber for monitoring during discontinuation of the quetiapine. The pharmacist attributes the error to look-alike, sound-alike medications and increased distractions/workload considerations. The pharmacist recommends increasing the number of staff; updating the pharmacy computer system to insert a hard stop on all look-alike, sound-alike medications; and reinforcing the use of the "search generic" function during data entry.
3. A two-year-old female patient was prescribed via telephone a new prescription for Ciprodex® for otitis media. The patient's mother asked for a different medication at the point of sale due to cost considerations. The pharmacist mistook the mother (who is not a licensed health care professional) as the prescriber, due to having the same last name as the prescriber and changed the medication according to the mother's suggestion of neomycin/polymyxin/hydrocortisone. After using four to five doses of the medication, the patient required follow-up as neomycin/polymyxin/hydrocortisone can potentially cause ototoxicity due to patient's tympanostomy tubes. The pharmacist attributes the error to workload considerations; there were multiple cars in the drive-through behind the patient. The pharmacist recommends that anytime there is a question regarding a change in a verbal prescription order at the point of sale, the patient/prescriber should be directed to go inside the store for further assistance and verification of prescribing credentials.
4. A 48-year-old male patient's wife was given another patient's carbamazepine ER 400 mg at the point of sale, in addition to the refills she intended to pick up for her husband. The pharmacist stated that both patients' first and last names were identical. After taking 24 doses of the incorrect medication, the patient reported that he stopped because it made him feel drowsy and awful. The pharmacist attributes the error to a break in procedure as the address and phone number were not verified on all patient packages (of which there were multiple). The pharmacist recommends retraining technicians to follow procedures for verifying all packages being dispensed/sold.
5. A 14-year-old male patient was reported to have experienced a needlestick with a used needle while in the process of receiving an influenza (flu) vaccination. The pharmacist reported that two doses of flu vaccine were requested simultaneously by the guardians of two different patients, and the pharmacist tried to multitask by preparing and completing the vaccinations within short succession of one another. The pharmacist recapped a syringe after vaccine administration and proceeded to draw a second flu vaccine dose using the same syringe. As a result, the patient was stuck with a needle that had already been used to administer a flu vaccine to a different patient. The pharmacist recommends the following: 1) utilizing retractable syringes; 2) keeping a sharps container nearby during administration; 3) workflow procedures that do not allow for multiple vaccines (for different patients) to be prepared/staged in the same area or tote; 4) designating a dedicated vaccine area; and 5) reviewing procedures on the prohibition of recapping syringes once used.

Disclaimer: These suggestions are made by the pharmacist submitting the Significant Adverse Drug Event Report. *Newsletter* publications of recommendations are not an indication of endorsement by the New Mexico Board of Pharmacy.

Crisis Standards of Care COVID-19

During the December 8, 2020 meeting, the Board approved a resolution regarding "Crisis Standards of Care" related to the coronavirus disease 2019 (COVID-19): For the duration of the current public health emergency, it will not be considered a violation for organized medical staff, acting by and through its medical executive committee, to authorize and direct pharmacists and pharmacist clinicians to serve as COVID-19 providers, and provide health care services to patients of the hospital where they serve. Such services, which may be beyond an individual pharmacist's usual scope of practice, must still fall within the pharmacist's scope of practice for their license. The Board further approved a template pharmacist clinician protocol to provide pharmaceutical care to hospitalized patients during the declared COVID-19 public health emergency.

National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

Disciplinary Actions

Douglas Chan – RP6764. License revocation. The license may be reinstated upon demonstrations that respondent is in compliance with the Board's decision and order dated April 15, 2020.

Cheyenne Ntiforo – IN4239, PT9979. Suspension of license. Respondent had her license(s) suspended for a period of seven months and until further order of the Board. The respondent must comply with Monitored Treatment Program. The order from April 15, 2020, related to this respondent is still in effect.

Philip Rodriguez – CS225303. Voluntary surrender. The Board accepted the surrender of respondent's controlled substance registration. The respondent must pay investigative costs in the amount of $2,509 within 90 days.

Shannon M. Saltclah – RP8098, PC253. Settlement agreement. Respondent was ordered to pay a $1,000 fine and a $100 investigative cost, totaling $1,100 within 90 days. The respondent must also complete any deficient continuing education (CE) within 90 days.

Steve Nguyen – RP6530, PC255. Settlement agreement. Respondent was ordered to pay a $1,000 fine and a $100 investigative cost, totaling $1,100 within 90 days. Respondent completed deficient CE as required.

Corine Martinez – PT12421. Summary suspension. Respondent's technician registration was suspended until further order of the Board.

2021 Law Update Schedule

- Upcoming Albuquerque, NM Pharmacy Law Lecture Dates:
  - March 5, 2021
    (Webinar. Registration closes on March 3)
  - April 2, 2021
    (Webinar. Registration closes on March 31)
  - May 7, 2021
  - June 4, 2021
  - July 9, 2021
  - August 6, 2021
  - September 10, 2021
  - October 1, 2021
  - November 5, 2021
  - December 3, 2021
- Upcoming Pharmacy Law Lecture Dates (Outside of Albuquerque):
  - **March 23, 2021**
    Webinar
    Silver City, NM
  - **May 18, 2021**
    San Juan College
    (Tentative location due to COVID-19)
    Farmington, NM
  - **June 22, 2021**
    Toney Anaya Building
    Rio Grande Room
    Santa Fe, NM
  - **August 31, 2021**
    Eastern New Mexico University
    Roswell Occupational Technology Center
    Room 20
    Roswell, NM
  - **September 14, 2021**
    Blackwater Coffee Co
    Clovis, NM
  - **September 28, 2021**
    Holy Cross Hospital
    Taos, NM
  - **October 26, 2021**
    Alta Vista Regional Hospital
    Las Vegas, NM
  - **November 16, 2021**
    Lea Regional Medical Center
    Hobbs, NM
  - **November 29, 2021**
    MountainView Regional Medical Center
    Las Cruces, NM
  - **November 30, 2021**
    Memorial Medical Center
    Las Cruces

Because of COVID-19 restrictions, some of the law update reviews may be held as webinars. The most up-to-date information on review format and the full list of law updates can be found on the Board website.

Reminders

Pharmacists, be sure that you are completing the required CE prior to relicensure. The Board conducts audits on a monthly basis. Some things to keep in mind when completing your CE:

- The patient safety and safe/appropriate use of opioid requirements can be combined if CE is appropriate to cover both topics.
- Your New Mexico law CE credits do not count toward your 10-hour live CE requirement.
- CE credits required to maintain pharmacist prescriptive authority do not count toward your 30-hour CE requirement.

Failure to comply with all requirements may result in a fine of up to $1,000 and disciplinary action against your license.

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