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Pharmacy Alarm Systems

Alarm systems are vital for ensuring the security of stocked prescription medication. There has been some misunderstanding as to what represents an acceptable security system, especially regarding the backup component of the unit. New Jersey State Board of Pharmacy regulations stipulate the following:

- All entrances to the pharmacy or pharmacy department are capable of being locked and are connected to a monitored security system that transmits an audible, visual, or electronic signal warning of intrusion;
- **The security system shall be equipped with a backup mechanism to ensure notification or continued operation if the security system is tampered with or is disabled; and**
- Only the pharmacist-in-charge (PIC) shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department. It is incumbent upon all pharmacies to check with their alarm company to be sure that their current alarm system is compliant with these state board regulations.

Pharmacy Technician Renewals

The Board office would like to remind all PICs and permit holders that all active pharmacy technician registrations in New Jersey will expire on August 31, 2016. Renewal notices will be mailed to all pharmacy technicians holding an active registration approximately 60 days prior to this date. Please remind your staff to notify the Board in writing immediately if they need to update their address, or else they may not receive a renewal notification. Also remember that performing the duties of a pharmacy technician without maintaining an active registration (or working beyond the 180-day period for an initial registration, as outlined in N.J.A.C. 13:39-6.6(c)) constitutes unlicensed practice and may subject the applicant/licensee and their supervisors to discipline if deemed appropriate by the Board.

Biosimilars – An Overview

The Board wishes to thank Sandhya Balachandar for volunteering to author this article. Ms Balachandar is a third-year pharmacy student at the Ernest Mario School of Pharmacy at Rutgers University. The article contains the work and opinions of the author and is not expressly endorsed or approved by the New Jersey State Board of Pharmacy.

The prevalence of biologic drugs has led to the demand for "generic" alternatives of these products. The concept of a biosimilar drug, however, is not directly comparable to a generic drug, because of the manufacturing process and the nature of the products themselves. Compared to small-molecular compounds, which are synthesized chemically, biologics are much more complex and are often manufactured from living cells using advanced biotechnological methods.[1] Small changes in those processes can potentially cause immunogenic reactions in patients, an issue that is much more prevalent with biologics. Therefore, Food and Drug Administration (FDA) and state regulations of pharmacist-led substitution of biosimilars are more stringent than those of generics.

In assessing newly approved biosimilar products, it is important to recognize the distinction between the two applicable designations: biosimilarity and interchangeability. According to FDA, a product with biosimilarity "is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences . . . in terms of safety, purity and potency of the product."[2] However, to be considered biosimilar **and** interchangeable, there must be evidence that the product 1) is expected to produce the same clinical result as the reference product in any given patient, and 2) demonstrates that the safety or reduced efficacy risk of alternating or switching is not greater than the risk of using the reference product. Therefore, biosimilarity and interchangeability are not equivalent; a drug can qualify as biosimilar but not interchangeable, the latter designation

Continued on page 4

FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc*. 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med*. 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Continued from page 1

requiring more appraisal. FDA states that "an interchangeable product may be substituted for the reference product without the [original prescriber's] intervention . . . "[2] This stipulation – that a product can be deemed biosimilar but not necessarily interchangeable – is crucial in determining whether a product can be automatically substituted by the pharmacist. Products deemed biosimilar **and** interchangeable by FDA can be automatically substituted, but those that are only considered biosimilar cannot.[2]

The New Jersey Legislature passed a statute that went into effect January 1, 2016, describing the scope of pharmacist authority in this area. The statute states that a pharmacist may substitute a biological product for a prescribed biological product when 1) the authorized prescriber has not indicated that there shall be no substitution, and 2) the biological product to be substituted is FDA-approved to be interchangeable with or therapeutically equivalent to the prescribed biological product. Pharmacists will then be required to 1) notify the patient in writing that the biological product dispensed has been approved by FDA as an interchangeable biosimilar biological product for the prescribed biological reference product; 2) notify the prescriber (via written, telephonic, or electronic notification), within five business days, of the specific product provided to the patient, including the name of the product and the manufacturer; and 3) record on the prescription label and record of dispensing the product name and manufacturer of the biological product dispensed, followed by the words "Substituted for" and the name of the prescribed biologic.[3] Pharmacists who meet these requirements in dispensing and substituting a biological product for its reference product would incur no greater liability for dispensing the substituted product than would be incurred for dispensing the prescribed product.[3]

Currently, the only approved biosimilar is Zarxio™, intended to be a substitute for filgrastim (reference product Neupogen®), and is manufactured by Sandoz. However, Zarxio is not interchangeable and cannot be automatically substituted by the pharmacist. As the field of biosimilars evolves, it will be increasingly important for the pharmacist to be aware of FDA rules on biosimilarity and interchangeability.

References

1. Industry (biologics). FDA website. www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Industry. Updated December 5, 2014.
2. Background information: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations (purple book). FDA website. www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsAreDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411424.htm. Updated March 5, 2015.
3. Biological Products, Title 24, Subtitle 1, N.J.S.A. 24:6K-1, et seq (2015).

Compounding of Domperidone

It has come to the Board's attention that some pharmacists may be compounding domperidone. According to FDA, domperidone is currently not approved for human use in the United States. Although there are restrictions on domperidone, FDA recognizes that there are patients with severe gastrointestinal motility disorders refractory to standard treatment who might benefit from domperidone and in whom the benefits of the drug may outweigh its risks. Domperidone is currently available to these patients through FDA's Expanded Access to Investigational New Drug (IND) program. This Expanded Access IND program ensures that the appropriate safeguards are in place to protect patients treated with domperidone from the drug's serious adverse effects, including QT prolongation and cardiac arrhythmias. Information on this Expanded Access IND program can be found at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsAreDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm368736.htm.*

The compounding of domperidone without utilizing FDA's Expanded Access IND program is a direct violation of Board regulations N.J.A.C. 13:39-7.5, N.J.A.C. 13:39-6.2(f)(9), and N.J.A.C. 13:39-4.18(a) and may result in the Board imposing disciplinary action against pharmacies and pharmacists participating in this unauthorized activity.

Sale of Dextromethorphan to Minors

An act concerning the sale of dextromethorphan to minors, P.L. 2015, c. 114, became effective on February 1, 2016. It states:

> N.J.S.A 2A:170-51.7 Sale of dextromethorphan to persons under 18 prohibited; violations, penalties.
>
> 1. a. No person shall sell or offer for sale, either directly or indirectly by an agent or employee, any product containing dextromethorphan as an active ingredient to a person under 18 years of age.
>
> b. The establishment of all of the following shall constitute a defense to any prosecution brought pursuant to subsection a. of this section:
>
> (1) that the purchaser of the product falsely represented, by producing either a driver's license or non-driver identification card issued by the New Jersey Motor Vehicle Commission, a similar card issued pursuant to the laws of another state or the federal government or Canada, or a photographic identification card issued by a county clerk, that the purchaser was of legal age to make the purchase;

Continued on page 5

Continued from page 4

(2) that the appearance of the purchaser of the product was such that an ordinary prudent person would believe the purchaser to be of legal age to make the purchase; and

(3) that the sale of the product was made in good faith, relying upon the production of the identification set forth in paragraph (1) of this subsection, the appearance of the purchaser, and the reasonable belief that the purchaser was of legal age to make the purchase.

c. A person who violates the provisions of subsection a. of this section, including an employee of a retail establishment who actually sells a product containing dextromethorphan as an active ingredient to a person under 18 years of age, shall be liable to a civil penalty of not more than $750. In the case of a retail establishment that is part of a chain with two or more locations in the State, the violation shall be assessed against the particular retail establishment and not the chain. The civil penalty shall be collected pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.), in a summary proceeding before the municipal court having jurisdiction. An official authorized by statute or ordinance to enforce the State or local health codes or a law enforcement officer having enforcement authority in that municipality may issue a summons for a violation of the provisions of subsection a. of this section, and may serve and execute all process with respect to the enforcement of this section consistent with the Rules of Court. A penalty recovered under the provisions of this subsection shall be recovered by and in the name of the State by the local health agency. The penalty shall be paid into the treasury of the municipality in which the violation occurred for the general uses of the municipality.

d. The provisions of this act shall not apply to any prescription medication containing dextromethorphan as an active ingredient that is dispensed by a pharmacist pursuant to a valid prescription. [emphasis added]

N.J.S.A 2A:170-51.8 Listing of products containing dextromethorphan on Internet website.

2. The Department of Health shall include on its Internet website a comprehensive list of products that contain dextromethorphan as an active ingredient. This requirement may be satisfied by including on the Department of Health website a link to the list of products containing dextromethorphan as an active ingredient that is published by the National Institutes of Health, provided that such list is current and accurate.

2015 Pharmacist CE Audit

In February, the Board initiated a continuing education (CE) audit of approximately 2,000 pharmacists who renewed their license during the April 2015 renewal cycle. The participants were randomly selected from a pool of approximately 16,000 active pharmacists. The Board reminds all pharmacists that they are required to maintain documentation indicating completion of CE in accordance with N.J.A.C. 13:39-3A.4(b), which states: "A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request." The Board encourages all pharmacists to register for CPE Monitor® through the National Association of Boards of Pharmacy® (NABP®). CPE Monitor is a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers to allow pharmacists to electronically track their completed continuing pharmacy education (CPE) credits in one location. To ensure that your CPE information is available in the event of an audit, be sure to enter your New Jersey license information accurately when registering for CPE Monitor. Please visit *www.nabp.net* for additional information on utilizing CPE Monitor.

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