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Pilots Using Over-the-Counter, Prescription, and Illicit Drugs (15-04-484)

This article was created, and its publication in the Newsletter *requested, by the NTSB.*

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs. The study found significantly increasing trends in pilots' use of all drugs, potentially impairing drugs (those with a Food and Drug Administration warning about sedation or behavior changes in routine use), controlled substances (CS), and illicit drugs (those listed in Schedule I by Drug Enforcement Administration). The final report, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment,* is available on the NTSB's Safety Studies web page under report number SS-14-01.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 years old to 57 years old over the study period. Over the course of the study, the following was found:

- The proportion of pilots testing positive for at least one drug increased from 10% to 40%.
- More than 20% of all pilots from 2008-2012 were positive for a potentially impairing drug, and 6% of all pilots were positive for more than one potentially impairing drug.
- Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine.
- During the most recent five years studied, 8% of all pilots tested positive for CS; hydrocodone and diazepam each accounted for 20% of the positive findings.
- The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

These results highlight the importance of routine discussions between health care providers, including pharmacists, and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.

Renewal of Pharmacy Technician Certificates (15-04-485)

The renewal cycle for pharmacy technicians will open on May 1 and conclude on June 30. The Louisiana Board of Pharmacy no longer mails renewal application forms; instead, the Board will mail a renewal reminder mailer just prior to May 1. The mailer will remind you of the three options you have to renew your certificate:

1. Visit the Board's website at *www.pharmacy.la.gov* and renew your certificate using a credit card;
2. Visit the same website to download and print an application form, then complete and mail the application form with the appropriate fee using a check or money order; or
3. Send a written request to the Board office (mail, fax, or email) with your name, certificate number, and current mailing address, requesting the Board to mail a paper application form to you.

Any address changes received at the Board office after April 17, 2015, will not be reflected on your renewal reminder mailer. In the event the postal service fails to deliver your renewal reminder mailer by May 15, 2015, then it becomes your responsibility to obtain an application form or renew your certificate online. Certificates renewed online will be mailed within one or two business days; certificates renewed using paper application

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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forms will be mailed within two to four weeks, depending on the volume of paper application forms received for processing.

The online renewal function of the website is programmed to activate at 12:01 AM on May 1, and to deactivate at midnight on June 30. While the Board makes every effort to maintain this online convenience during the renewal cycle, the Board's service provider may experience weather-related or other unforeseen technical difficulties from time to time. You have 60 days to renew your certificate, and it is your choice as to when to complete that duty. If you choose to wait until the last day and the website is not available, then you will be responsible for the consequences of your failure to renew your certificate in a timely manner. The Board does not waive late fees in that situation. Why take a chance? Please do not wait until the last minute of the last day.

All technician certificates shall expire on June 30, regardless of the date of issue. You may not practice with an expired certificate. The fee for the timely renewal of an active certificate is $50. The renewal of an expired certificate will incur an additional $25 penalty as well as an additional $200 reinstatement fee. Applications bearing a postal service mark of July 1 or later must be accompanied by the additional fees or the application package will be returned to the sender unprocessed. If it is important to you to know if or when the Board receives your paper application form, the Board suggests you use the mail tracking service of your choice. With over 6,000 certificates to be renewed, the staff will not be able to respond to your request to confirm mail deliveries.

Renewal of Other Credentials (15-04-486)

In addition to the pharmacy technician cycle, the Board will also be renewing other credentials this spring and summer:

- Automated Medication System (AMS) registrations expire June 30.
- Emergency Drug Kit (EDK) permits expire June 30.
- Durable Medical Equipment (DME) permits expire August 31.

The AMS and EDK credentials must be renewed using paper application forms. The Board will mail those pre-printed application forms just prior to May 1, and timely renewals must be accomplished on or before June 30; penalties will apply to the renewal of expired credentials.

The DME permits may be renewed either online or using paper application forms. The Board will mail the renewal reminder mailer just prior to July 1, and timely renewals must be accomplished on or before August 31; penalties will apply to the renewal of expired credentials.

Disciplinary Actions (15-04-487)

During its February 2015 meeting, the Board took final action in the following matters.

Louisiana CVS Pharmacy, LLC, dba CVS Pharmacy No. 5330 (PHY.005862): For permitting a technician to practice with an expired certificate for approximately six weeks, the Board assessed a fine of $2,500 plus administrative costs.

Louisiana CVS Pharmacy, LLC, dba CVS Pharmacy No. 3730 (PHY.006329): For its failure to designate a replacement pharmacist-in-charge (PIC) for approximately 23 months, the Board assessed a fine of $25,000 plus administrative and investigative costs.

Institutional Pharmacy Solutions, LLC, dba Institutional Pharmacy Solutions (PHY.006424-IR): For its failure to designate a replacement PIC in a timely manner as well as for its improper closure, the Board revoked the pharmacy permit.

Institutional Pharmacy Solutions, LLC, dba Institutional Pharmacy Solutions (PHY.006801-HOS): For its failure to designate a replacement PIC in a timely manner, for its authorizing another pharmacy to improperly use its automated medication system, and for its improper closure, the Board revoked the pharmacy permit.

George Joseph Hebert III dba Hebert's Pharmacy (PHY.002260): For permitting a pharmacist to practice with an expired license for approximately two years, the Board assessed a fine of $10,000 plus administrative and investigative costs.

Shantrell Trineese Landry (CPT.010019): For her admission to the theft of hydrocodone and alprazolam from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate.

BesScription, Inc, dba BesScription (PHY.006712): For its failure to properly report its eligible prescription transactions to the Louisiana Prescription Monitoring Program for approximately 10 months, the Board assessed a fine of $5,000 plus administrative and investigative costs.

Kmart Corporation dba Kmart Pharmacy No. 3016 (PHY.002058): For its failure to designate a replacement PIC for approximately four months, the Board assessed a fine of $10,000 plus administrative and investigative costs.

John Henry Cunningham (PST.016578): For his failure to obtain a Medication Administration Registration from the Board prior to administering medications to patients, the Board issued a letter of reprimand, and further, assessed a fine of $500 plus administrative and investigative costs.

Richard Jeffrey Gaude (PST.015640): Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective December 11, 2014.

Matthew Marston Lane (PST.018065): Board granted his request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years, effective February 25, 2015, subject to certain terms enumerated in the consent agreement.

Joseph Percy Ricard, Jr (PST.016310): For conduct that prompted the Texas State Board of Pharmacy to place his Texas pharmacist license on probation, the Board suspended his Louisiana pharmacist license for four years, three months, and 12 days and stayed the execution of the suspension, then placed the license on probation for the suspensive period, terminating on June 6, 2019, subject to certain terms enumerated in the consent agreement.

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Charles Jude Mitchell, Jr (PST.016284): Board granted his request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years, effective February 25, 2015, subject to certain terms enumerated in the consent agreement.

Thadrian Marquis Johnson (PST.013542): Board granted her request for reinstatement of the previously lapsed license, conditioned upon the satisfaction of certain requirements identified in the consent agreement, and further, suspended the license and any other temporary credentials for five years and stayed the execution thereof, then placed the license and any other temporary credentials on probation for five years, effective February 25, 2015, subject to certain terms enumerated in the consent agreement.

Lydia Nicole Wallace (CPT.010431): For her alleged diversion of CS from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate.

Yasheka Deann Bolton (CPT.011798): For her alleged diversion of CS from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate.

Amberlyn Jaree Reney (PTC.020713): For her alleged diversion of CS from her employer pharmacy, the Board revoked the registration, and further, permanently prohibited the acceptance of any future application for the reinstatement of the registration.

Gene Raymond Lachney (PST.016415): For conduct that prompted the Florida Board of Pharmacy to place his Florida pharmacist license on probation, the Board suspended his Louisiana pharmacist license for six months and 15 days and stayed the execution of the suspension, then placed the license on probation for the suspensive period, terminating on September 9, 2015, subject to certain terms enumerated in the consent agreement.

Appling Enterprises, LLC, dba Denton Prescription Shop (PHY.006778): For conduct that prompted the Texas State Board of Pharmacy to place its resident Texas pharmacy permit on probation, the Board suspended the Louisiana pharmacy permit for one year, six months, and 11 days and stayed the execution of the suspension, then placed the permit on probation for the suspensive period, terminating on September 5, 2016, subject to certain terms enumerated in the consent agreement.

Aaron Wayne Nash (PST.010983): Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective December 18, 2014.

Lara Lindsey Deeane Thomas (CPT.011941): Board accepted the voluntary surrender, resulting in the active suspension of the certificate for an indefinite period of time, effective December 31, 2014.

Ashley Elizabeth Reynolds (PST.020382): Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective January 23, 2015.

Majeste's St. Claude Pharmacy, Inc, dba St. Claude Pharmacy (CDS.039058-PHY): Board accepted the voluntary surrender, resulting in the active suspension of the license for an indefinite period of time, effective February 6, 2015.

Jessica Renee Chantel Bowen (PTC.019957): For her failure to furnish information legally requested by the Board, the Board suspended the registration for an indefinite period of time, and further, assessed administrative, investigative, and hearing costs, and further, conditioned the acceptance of any future reinstatement application upon the satisfaction of certain requirements identified in the order.

Dana Elizabeth Berchtold (CPT.011810): For her admission to the theft of CS from her employer pharmacy, the Board suspended the certificate for five years and stayed the execution thereof, then placed the certificate on probation for five years, effective February 25, 2015, subject to certain terms enumerated in the order.

During the same meeting, the Board granted (1) one request for the reinstatement of a controlled dangerous substances (CDS) license for a pharmacy, (2) conditional approval for the reinstatement of an expired certificate for one technician, pending satisfaction of certain requirements identified in the technician's consent agreement, and (3) one request for modification of previous orders by removing a restriction that prohibited the pharmacist from serving as the PIC of a pharmacy. The Board also issued letters of reprimand to three pharmacists and a letter of warning to one pharmacy permit owner. Finally, the Board suspended the CDS license for one physician whose medical license was suspended by the Louisiana State Board of Medical Examiners.

Calendar Notes (15-04-488)

The Board office will be closed on April 3, in observance of Good Friday; May 25, in observance of Memorial Day; and July 3, in observance of Independence Day.

Special Note (15-04-489)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. The Board encourages you to keep them in the back of the *Louisiana Pharmacy Law Book* for future reference.

The *Louisiana Board of Pharmacy News* is published by the Louisiana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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