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Iowa Board of Pharmacy News

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Board Member Reappointed

Congratulations to pharmacist **Edward McKenna** of Storm Lake, IA, on his reappointment to the Iowa Board of Pharmacy by Governor Terry Branstad. Ed's new term began on May 1, 2015, and will end on April 30, 2018.

New Board Member Appointed

Congratulations to pharmacist **Jason Hansel** of Bettendorf, IA. Jason has been appointed to a three-year term on the Board by Governor Branstad effective May 1, 2015. Jason is a district pharmacy supervisor for Walgreens and is a doctor of pharmacy graduate of the University of Iowa College of Pharmacy. The Board welcomes Jason and looks forward to working with him.

Board Retirements

Pharmacist **Susan Frey** of Villisca, IA, retired from the Board on April 30, 2015. Susan served nine years on the Board, beginning on May 1, 2006. While on the Board, Susan also served on the Board's Rules Committee, various task force and advisory groups, and as chairperson of the Board.

Executive Director **Lloyd K. Jessen** retired from the Board on March 27, 2015. Lloyd served as the Board's director since January 1990. Prior to serving as director, he was the Board's chief investigator from 1987 to 1990. Lloyd was a member of the National Association of Boards of Pharmacy® (NABP®) Executive Committee for seven years, from 2006 to 2013.

The Board extends its sincere thanks to Susan and Lloyd for their many contributions and their dedicated public service.

Summary of Board Activities

The Board currently oversees the activities of approximately 35,500 licensees and registrants, including pharmacies, drug wholesalers, pharmacists, pharmacist interns, pharmacy technicians, pharmacy support persons, precursor vendors and recipients, Internet pharmacy sites, and controlled substance (CS) registrants. The Board conducts routine inspections of pharmacies and drug wholesalers and investigates complaints relating to all licensees and registrants. In addition to its licensing and registration programs, the Board has maintained and operated the Iowa Prescription Monitoring Program (PMP) since its implementation in 2009.

The Board is entirely self-supported through the ongoing collection and retention of licensing and registration fees. The Board receives no money from the state's General Fund, pursuant to Iowa Code §147.82. The Iowa PMP is funded exclusively through the use of fees collected by the Board, without any additional funding and without any additional costs to pharmacists and prescribers. Every fiscal year since the fiscal year beginning July 1, 2007, actual Board revenues have exceeded anticipated income, while Board expenditures have been less than projected and far below revenues. The Board reviews all fees and expenditures at least annually and adjusts fees accordingly. The Board reduced all fees by a minimum of 10% effective January 16, 2013. This decrease in fees provided a direct economic benefit to all Board licensees and registrants. No fees have been increased since the fee reduction was implemented in 2013.

Since 2010, the Board has experienced a significant increase in its workload. There has been a continual rise in the number of Board disciplinary cases each decade. The 1980s saw an average of 11 cases per year; the 1990s saw an average of 28 cases per year; and the 2000s saw an average of 31 cases per year. The most recent five-year period (2010 through 2014) shows a dramatic increase in disciplinary actions, with the Board taking action in an average of 74 cases per year. A record number of 109 cases came before the Board for resolution in 2013.

In 2012-2013, the Board oversaw the inspection of 538 nonresident (out-of-state) pharmacies licensed to do business in Iowa. This special project was undertaken in response to the pharmacy compounding tragedy in Massachusetts that killed 64 people and sickened hundreds of others across the country with fungal meningitis in the fall of 2012.

In 2013-2014, the Board issued 515 official documents as follows: 135 Board orders or settlement agreements; 112 statements of charges; 135 letters of education; 93 administrative warnings; 16 show cause orders relating to CS registrations; 11 confidential orders for evaluation; 10 combined charges and settlement agreements; and three emergency orders.

In addition to its regular duties, the Board sponsored and managed the following special advisory committees, task forces, and other meetings between 2012 and 2015: the Iowa

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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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Pharmacy Workplace and Patient Safety Task Force; the Iowa Telepharmacy Advisory Committee; the Iowa Pharmacy Compounding Task Force; the Iowa Pharmacist-In-Charge/ Pharmacy Owner Task Force; and the Iowa PMP Conference.

Since 1990, the Board has collected $777,702 in fines and civil penalties from licensees and registrants as part of the Board's formal disciplinary process. This money goes to the state's General Fund for the economic benefit of all Iowans. It is not used to support the Board's mission or programs. As a result, the Board generates revenue for the state of Iowa while protecting the health and safety of Iowans by effectively and efficiently using its resources to regulate the practice of pharmacy and the distribution of prescription drugs and devices.

The following table is a summary of disciplinary actions and civil penalties imposed by the Board, by decade, since 1980.

	1980-1989	1990-1999	2000-2009	2010-2014 (Five Years)
Total cases with disciplinary action	116	285	315	370
Total cases involving civil penalty	28	83	72	188
Percentage of cases involving civil penalty	24	29	23	51
Total civil penalties	$26,250	$262,502	$154,200	$334,750
Annual average penalties	$2,625	$26,250	$15,420	$66,950
Average civil penalty per case	$938	$3,163	$2,142	$1,781

The mission of the Board is to promote, preserve, and protect the public health, safety, and welfare though the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized, pursuant to Iowa Code §155A.2.

The Board's vision is to lead by promoting the provision of safe and effective pharmaceutical care to all Iowans. The Board achieves this by maintaining and enforcing minimum standards of practice, educating licensees and registrants, sponsoring pharmacy outreach programs, conducting pilot projects, building creative health care alliances, encouraging pharmacist empowerment and innovative pharmacy practice, supporting collaborative practice among pharmacists and other health care providers, and reducing the incidence of prescription drug abuse in Iowa.

The Board received the 2010 NABP Fred T. Mahaffey Award during the NABP 106th Annual Meeting for exceptional contributions to the protection of the public health and welfare and furthering the mission of NABP.

Board Website

Please visit the Board's website at *www.state.ia.us/ibpe* for more information.

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