



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Seasons Greetings

The members and staff of the Oklahoma State Board of Pharmacy would like to join in wishing everyone happiness and all the best for the coming year.

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Board Spotlight: Oklahoma Pharmacist Dr Kasey Thompson

Oklahoma pharmacist Dr Kasey Thompson was raised in Muskogee, OK, and currently serves as vice president for Policy, Planning, and Communications at the American Society of Health-System Pharmacists (ASHP) in Bethesda, MD. Kasey is a 1999 graduate of the University of Oklahoma (OU) College of Pharmacy and a 1995 graduate of Northeastern State University in Tahlequah, OK.

During his time at OU he developed a passion for advancing pharmacy practice at the state and national level, and sought opportunities through student government and state and national associations. Kasey attributes his interests and opportunities to exceptional mentorship by numerous faculty members and alumni of the OU College of Pharmacy, especially the late Carl Lyons, who was responsible for introducing him to ASHP and the ASHP Executive Residency in Association Management and Leadership.

After graduating, Kasey completed the Executive Residency at ASHP, a program designed to train individuals to lead and manage associations. Following the residency he was hired by ASHP to lead the newly formed Center on Patient Safety. Kasey was promoted in 2002 to lead the Practice Standards and Quality Division at ASHP, and was made assistant director for Policy, Planning, and Communications in 2006. In 2008, he was promoted to vice president, and now has oversight responsibilities for Government Affairs, Public Relations, Practice Standards Development, and Strategic Planning for ASHP. He serves as a national media spokesperson for ASHP, and frequently appears on television, on radio, in newspapers, and in other print and electronic media. He often testifies at hearings of federal agencies, and has served as an expert witness in testimony before the United States Congress.

Kasey has lived and worked in Washington, DC, for over 12 years, but he notes that he will always consider Oklahoma home and strongly believes that he would not have had the opportunities he has been given to represent pharmacists on the national stage had it not been for his upbringing in Oklahoma, and the many relatives, friends, and mentors that helped him along the way. Kasey is married to Christina Le Thompson, a 1996 graduate of the OU College of Pharmacy, and has two children, three-year-old Alex and six-year-old Sidney. He is currently completing a master's degree in information technology with specialization in informatics and a master of business administration at the University of Maryland University College. Kasey looks forward to spending the rest of his career helping pharmacists achieve their full potential as patient care providers, and to continuing to forge relation-

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that “inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration.” Further, FDA clarifies its October 21, 2011 communication “to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector.” FDA also notes the following:

- ◆ Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- ◆ Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- ◆ At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit www.cdc.gov/flu.

‘Tell Back’ Works Best to Confirm Patient Understanding



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported

by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at

www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? *Ann Emerg Med*. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of “Tell Back-Collaborative Inquiry” to Assess Understanding of Medical Information. *J Am Board Fam Med* 2008;21(1):24-30). Researchers tested three types of inquiry about the patient’s understanding:

- ◆ Yes-No
- ◆ Tell Back-Directive
- ◆ Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: “I’ve given you a lot of information. Do you understand?”) The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: “It’s really important that you do this exactly the way I explained. What do you understand?”) The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I’ve given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers’ reluctance to put patients “on the spot” with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider’s care and concern for them personally, or evidence of the provider’s attention to detail and competence. So, when counseling patients about their medications, instead of asking “Do you have any questions?” or “Do you understand?” ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address “processing integrity” as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-



tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at www.deadiversion.usdoj.gov/e-comm/e_rx/thirdparty.htm#approved. Detailed background information is provided in the Federal Register Notice, available for download at www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at www.ScriptYourFuture.org. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- ◆ Make a list of the medications they take
- ◆ Keep their medication list with them at all times
- ◆ Know the name of each medication, why they are taking it, how much to take, and when to take it
- ◆ Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement

liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at <http://rxpatrol.org/TrainingVideos.aspx>.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life-threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for \$195 by visiting the NABP Web site at www.nabp.net/publications.

The *Survey*, produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

ships with public policy decision makers and leaders in other health care professions and patient groups to help make the pharmacy practice model in all pharmacy practice settings focused on providing direct patient care, and to ensuring that the medication-use process is safe and effective.

From The Inspector's Desk

◆ **12.01. Technicians Cannot Counsel:** Counseling patients regarding their medications is a hallmark of a pharmacist's practice of pharmacy and is encoded in rule and law. The requirement that a pharmacist provide counseling is stated in Board rule 535:10-9-2. In addition, **Board rules 535:15-5-7.5.(6) and 535:15-13-7(7) specifically forbid pharmacy technicians from counseling patients.** Federal legislation in the Omnibus Budget Reconciliation Act of 1990 requires that dispensing pharmacists offer to counsel each Medicaid recipient when filling prescriptions for them. The Board has received reports of technicians who are attempting to counsel patients. In some cases, the technicians may have received information in an academic or certificate "technician training program" that led them to believe they are qualified to provide counseling. **In all cases this is not legal in Oklahoma.** Pharmacy Technician Certification Board Certification or any other academic or training programs do **not** qualify a technician to counsel patients. The Board will exercise strict enforcement in situations where technicians have counseled patients. The technician, the pharmacist at the pharmacy when the situation took place, the pharmacist-in-charge, and the pharmacy license are all responsible for, and subject to, disciplinary action by the Board in these cases. Additional enforcement action by Centers for Medicare and Medicaid Services/Medicaid, and/or payment recovery by insurers against the pharmacy, may occur. It is very important that pharmacists-in-charge ensure that technicians understand the rules and regulations regarding counseling and all other technician-related rules, and that all pharmacists ensure technician compliance with the state and federal statutes and rules. Encourage your technicians to **read** the pharmacy law book.

◆ **12.02. Investigational Drug Compounding:** Food and Drug Administration (FDA) defines the term "investigational new drug" as meaning an unapproved drug or biological drug that may be used in a clinical investigation study. The term may also include a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" (IND) are deemed to be synonymous for purposes of this part. (from 52 FR 8831, March 19, 1987, as amended at 64 FR 401, January 5, 1999; 64 FR 56449, October 20, 1999; 73 FR 22815, April 28, 2008). According to a communication dated October 13, 2009, from Stanley Shepperson, PharmD, MS (CDR, USPHS, Regulatory Operations Officer, FDA/Center for Drug Evaluation and Research/Office of Compliance/Division of New Drugs and Labeling Compliance/Compounding Team), "[d]rugs listed as 'investigational' by FDA **must be prescribed or ordered by a licensed prescriber who has an FDA-sanctioned IND for a recipient/patient who is also part of the IND study.**" State practitioner licensure boards may not consider a prescription order from a licensed practitioner who is not part of an investigational study for an "investigational only" drug written for a pa-

tient who is not a part of an investigational study to be a valid prescription. In addition to possible Board action, a pharmacy and/or pharmacist found to be compounding and dispensing such prescriptions shall be referred to the FDA enforcement office. Practitioners who are not part of an investigational study that are found on prescription audits to have prescribed investigational-only drugs will be referred to their practitioner licensing boards. FDA policy requires that in order for a patient to gain access to an investigational drug outside of a clinical trial, **the drug manufacturer and the patient's doctor must make special arrangements to obtain the drug for the patient. These arrangements must be authorized by FDA.** These safeguards are in place to avoid exposing patients to unnecessary risks.

Disciplinary Actions

For more information you may view hearing minutes at www.pharmacy.ok.gov.

12.03. September 29, 2011 Board Hearing

- Sydney Blackwell, Tech #10160 – Case 1057:** Revoked.
- Tamesha Odamtten, Tech #15560 – Case 1053:** Revoked.
- Nicholas Cleland, Tech #14821 – Case 1048:** Revoked. (Agreed Order)
- Ashley Bingham, Tech #11320 – Case 1051:** Revoked.
- Jill Nguyen, Tech #13150 – Case 1052:** Revoked. (Agreed Order)
- Derek L. Radford, Tech #15314 – Case 1054:** Revoked.
- Marcy Hebblethwaite, Tech #10751 – Case 1055:** Revoked. (Agreed Order)
- Maria Scott, Tech #5999 – Case 1056:** Revoked.
- Susan Henderson, Tech #6893 – Case 1059:** Revoked.
- Brandi M. Jewell, Tech #15348 – Case 1060:** Revoked. (Agreed Order)
- Samantha Westbrook, Tech #14467 – Case 1050:** Revoked.
- Ashley Carder, DPh, #13769 – Case 1064:** \$500 fine. 2011 continuing education (CE) requirements must include 15 hours CE plus four hours of live CE. (Agreed Order)
- Jon Mitchell Madden, DPh, #10164 – Case 1062:** Fifteen years suspension. \$10,000 fine. Must attend 2012 and 2013 law seminar in addition to completing the required 15 hours of CE. All CE completed during suspension must be live CE. (Agreed Order)

12.04. November 16, 2011 Board Hearing

- Cheri Catron, Tech #3149 – Case 1066:** Revoked. (Agreed Order)
- Amy Chandler, Tech #15110 – Case 1067:** Revoked. (Agreed Order)
- Oscar Obregon, Tech #15240 – Case 1068:** Revoked. (Agreed Order)
- Tosh Williams, Tech #14853 – Case 1049:** Revoked.
- William Fecteau, Tech #11333 – Case 1069:** Revoked.
- Lisa Miller, Tech #14155 – Case 1070:** Revoked.
- Sheila Royse, Tech #14102 – Case 1071:** Revoked.
- Dena Johnson, Tech #15414 – Case 1072:** Revoked.

Lecora Watley, Tech #14975 – Case 1058: Revoked.

Melissa Arthur, Tech #10361 – Case 1073: Revoked.
(Agreed Order)

Susan Livingston, Tech #13483 – Case 1074: Revoked.
(Agreed Order)

Mark Stowers, DPh, #11918 – Case 1061: Revoked.

John Watson, DPh, #8466 – Case 1077: \$5,000 fine. Must attend law seminar by December 31, 2012, in addition to completing the required 15 hours of CE. Must relinquish pharmacist-in-charge position by December 1, 2011.

Impaired Intern #6973 – Case 1076: Indefinite suspension with Oklahoma Pharmacists Helping Pharmacists (OPHP) contract.

ANewRx, #99-1462 – Case 1065: \$12,000 fine. (Agreed Order)

Respiratory Care & Home Medical Equipment, LLC, #2-D-1370 – Case 1078: \$2,000 fine. Revoked.

CE Update

The CPE Monitor™ service is a collaborative effort by the Accreditation Council for Pharmacy Education (ACPE) and the National Association of Boards of Pharmacy® (NABP®) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits.

In the near future, pharmacists who complete ACPE-accredited CPE programs will **not** receive a printed CPE certificate from CPE providers. To receive CPE credit, those pharmacists will first need to register and create an NABP e-Profile with CPE Monitor, if they have not done so already, and provide their unique e-Profile ID and date of birth (mmdd) to the ACPE-accredited CPE provider. The provider will then electronically report the information to ACPE, which will forward the information to NABP in order to record within CPE Monitor. They will then have electronic access to documentation of the credit(s) earned. If pharmacists wish to receive credit for ACPE-accredited programs, they must register at www.MyCPEmonitor.net for their unique e-Profile ID. The ID number is a requirement of ACPE, not the Oklahoma State Board of Pharmacy.

Sponsors providing Oklahoma State Board of Pharmacy-approved CE (non ACPE-accredited CE) will continue to provide a certificate of completion to pharmacists for CE programs.

The Board will accept CE approved by any of the following states without requiring OSBP CE Committee review: Mississippi, Alabama, Louisiana, Tennessee, Arkansas, Georgia, North Carolina, Florida, Kentucky, South Carolina, Kansas, Missouri, and Texas.

CE approved by other states (not listed above) and which is not ACPE accredited must be submitted to the OSBP CE Committee for review to receive Board approval. The CE submission form may be found at this link: www.ok.gov/OSBP/documents/ce.pdf.

Oklahoma pharmacists will still be required to enter their CE information upon renewal of their license (program, ACPE number or sponsor, date, hours). If it is necessary to verify the license renewal information for Board CE audit

purposes, documentation of any ACPE-accredited courses will be available online in the CPE Monitor section of the individual's e-Profile.

Prescription Monitoring Program Changes Effective January 1, 2012

All controlled prescriptions must be submitted to the prescription monitoring program within five minutes of selling (not filling) them to the customer. The pharmacy must submit the ID information of both the recipient and the recipient's agent, if someone other than the patient is picking up the prescription. If a patient is a resident of a nursing home or a hospice patient and does not have an ID card, the pharmacy may use the Social Security number for the patient. If you have further questions, please call the Bureau of Narcotics at 405/521-2885.

Calendar Notes

The Board will meet on **January 18, March 7, and April 26**. The Board will be closed Monday, **January 2**, in observance of New Year's Day; Monday, **January 16**, for Martin Luther King, Jr, Day; and Monday, **February 20**, for Presidents' Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the April *Newsletter*.

Change of Address or Employment?

All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About The Newsletter

The Oklahoma State Board of Pharmacy *Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext 5773. All calls are confidential.

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