February 2012

News

Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Alabama State Board of Medical Examiners

Effective January 20, 2012, the Alabama State Board of Medical Examiners is adding to its rules Chapter 540-X-17, which provides guidelines and standards for licensed medical doctors and doctors of osteopathy who determine that the use of a controlled substance as an adjunct for a weight reduction regimen is medically appropriate for a patient.

You can review the rules at their Web site, *www.albme.org/csforweight.html.*

Alabama Responds

Alabama Responds is an online database that allows the Department of Public Health to register volunteer pharmacists to assist during public health threats and emergencies. For more information, please visit the Board Web site at *www.albop.com,* then click on Pharmacy Links, Pharmacy Related Web Sites, Alabama Department of Public Health, Pharmacist's Opportunity to Volunteer, and read more.

New Concentration of Tamiflu

Manufacturer Genentech has made changes to the influenza drug, Tamiflu®, to reduce chances of medication errors stemming from prescribing or dosing confusion. The concentration has been changed from 12 mg/mL to 6 mg/mL. In addition, compounding instructions for pharmacies have been revised to prepare a 6 mg/mL oral suspension from Tamiflu capsules. This will be beneficial if an emergency situation exists where the commercially manufactured Tamiflu for oral suspension is unavailable. Genentech began distributing Tamiflu in the new concentration in July 2011.

Rule Changes Effective January 20, 2012

680-X-2-.22 Code of Professional Conduct

This rule was amended to include **pharmacy/pharmacies.**

680-X-2-.29. Score Transfer

The sentence "The board of pharmacy shall recognize only those schools and colleges of pharmacy which are accredited by the American Council on Pharmaceutical Education and are members of the American Association of Colleges of Pharmacy" in its entirety was deleted.

FDA Alert Regarding Errors Resulting From Confusion Between Risperidone and Ropinirole

Food and Drug Administration (FDA) is alerting health care providers and patients that a number of medication errors, in which patients were given risperidone (Risperdal®) instead of ropinirole (Requip®) and vice versa, have been reported. Some cases have resulted in patient hospitalization. FDA notes that four factors have contributed to confusion between the two medications:

1. Similarities of both the brand (propriety) and generic (established) names
2. Similarities of the container labels and carton packaging
3. Illegible handwriting on prescriptions
4. Overlapping product characteristics, such as the drug strengths, dosage forms, and dosing intervals

FDA advises pharmacists to physically separate the stocks of these two drugs on the shelf or wherever they are stored, and to confirm the drug name with prescribers if the prescription is not legible or the drug name is not clearly stated.

Change of Employment

Per the laws and/or rules of the Alabama State Board of Pharmacy, **all** pharmacists and technicians shall notify the Board in writing within 10 days on change of employment. The notice shall contain his or her name, license/registration number, the name of the pharmacy where formerly employed, and the name of the pharmacy where currently employed.

Calls to Board Office

When calling the Board office, please have your license/registration number available.

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/ecomm/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.

ACPE-Accredited Continuing Education

Pharmacists and/or pharmacy technicians can go to the Accreditation Council for Pharmacy Education (ACPE) Web site at *www.acpe-accredit.org* to find all available continuing education (CE) programs.

- **Home Page: Information for Pharmacists**
  1. Select CE programs
  2. Click on the "Search P.L.A.N.® Now" link located along the top of the page
- **Home Page: Information for Pharmacy Technicians**
  1. Select Education and Training
  2. Click on the "What programs are available to me? Search P.L.A.N.® now!" link (this link is found at bottom of page)

On the P.L.A.N. search page both pharmacists and technicians should follow instructions and use drop down boxes as needed to customize for their specific needs.

Or

- **Visit *www.albop.com***
  1. Select "Continuing Education"
  2. Scroll down on right until you see heading "External links for Continuing Education"
  3. Select *www.acpe-accredit.org/pdfwebtool/plan/searchplan.aspx*

CPE Monitor Service

The CPE Monitor™ service is a national online continuing pharmacy education (CPE) tracking service that will authenticate and store data for completed CPE units received by pharmacists and pharmacy technicians from the ACPE-accredited provider.

ACPE-accredited CPE providers are currently beginning to integrate CPE Monitor into their systems, with the majority anticipated to have completed the transition by mid-year. As providers implement the system, pharmacists and technicians registering for ACPE-accredited CPE with that provider will be required to provide their NABP e-Profile ID, plus their birth date (mmdd), to receive credit for completed CPE. Participation data will then be sent electronically from the provider to ACPE, then to the National Association of Boards of Pharmacy® (NABP®) for recording into the matching e-Profile. This will eventually eliminate paper forms and the need to submit paper copies of CPE statements of credit for ACPE-accredited activities in Alabama.

Pharmacists and technicians, visit *MyCPEmonitor.net* to create your NABP e-Profile and obtain your e-Profile ID. Failure to set up an e-Profile or inaccuracies in an e-Profile may result in unrecorded or mis-recorded CPE, with possible adverse consequences for licensees/registrants when renewing their licenses/registrations.

Reminder

Please notify the Board, in writing, of any change of address or employment.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help-line at 205/981-2273. All calls are confidential.

The *Alabama State Board of Pharmacy News* is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

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