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Vermont Board of Pharmacy News

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Board Members

The members of the Vermont Board of Pharmacy and their term expiration dates are as follows: **Julie A. Eaton, RPh,** chair, Rutland, VT (December 2013); **Jeffrey P. Firlik, RPh,** vice chair, Williston, VT (December 2014); **Steven M. Vincent, RPh,** Newport, VT (December 2013); **Larry L. Labor, RPh,** Morgan, VT (December 2015); **Earl W. Pease, PharmD,** Essex, VT (December 2012); **Conrad Boucher** (public member), Montpelier, VT (December 2012); and **Judith Wernecke,** secretary (public member), Berlin, VT (December 2015).

Board members may be contacted by writing to the Vermont Board of Pharmacy, c/o Office of Professional Regulation, National Life Building, North, FL 2, Montpelier, VT 05620-3402. The phone number to the main office is 802/828-1505.

Staff: **Christopher D. Winters, Esq,** director of the Office of Professional Regulation (OPR); **Peter Comart,** licensing administrator, phone: 802/828-2808, e-mail: peter.comart@sec.state.vt.us; **Larry S. Novins,** legal counsel; **Jamie Palmisano,** chief investigator; **Kristy Pirie,** licensing board specialist, phone: 802/828-2373, e-mail: kristy.pirie@sec.state.vt.us; and **Carla Preston,** case manager, phone: 802/828-2875, e-mail: cpreston@sec.state.vt.us.

Web Site: *www.vtprofessionals.org*.

New Public Member

The Board was sorry to receive the resignation of long-time public member, Emma Pudvah last fall.

Her replacement, Conrad Boucher, attended his first meeting in January 2012. Conrad Boucher is a native Vermonter who lives in Montpelier with his 15-year-old daughter. He was a state probation and parole officer for many years before becoming a licensed private investigator and starting his own business, Vermont Legal Support Services. One of the reasons he applied to be on the Pharmacy Board was because he heard it was interesting and challenging. After his first meeting, he does not think he will be disappointed.

Reminders/Updates

1. A pharmacy's refrigerator must be maintained at a temperature between 36°F and 46°F. Unless a pharmacy's refrigerator temperature is electronically monitored, the temperature must be manually monitored and the temperature documented at least once a month. (Rule 8.13(b))
2. All pharmacy technicians must be registered with the Board of Pharmacy. See Rule 5.1 to clarify who is considered a pharmacy technician. The Board is continuing to find violations resulting in disciplinary action regarding this matter.
3. A pharmacist manager/owner must report to the Board within 10 days if disciplinary action, including termination of employment, has been taken against a pharmacist, pharmacy intern, or pharmacy technician due to any violation of the rules or statutes governing pharmacy practice. (Rule 6.3(h))
4. Effective January 11, 2012, carisoprodol (Soma®) is now a Schedule IV controlled substance. Do not refill any previously existing prescription for carisoprodol more than five times within six months from the date written.
5. As was stated in the Board's September 2009 *Newsletter,* in lieu of mandating a perpetual inventory of all hydrocodone products, the Board urges all pharmacist managers to complete a monthly review of hydrocodone purchases to determine if there is a change in the purchasing history and if so, to investigate the reason for this change. If the pharmacy keeps computerized counts, it is recommended to verify these counts against the actual physical count. The Board feels that this more stringent monitoring will act as a deterrent for internal diversion or alert the pharmacist managers to any problems in a timely manner.
6. All Schedule II controlled substances must be physically **inventoried and documented** at least one time per month. (Rule 9.33)

Case Manager

Carla Preston is case manager for all professions except nursing. You may reach Ms Preston at 802/828-2875 or via e-mail at cpreston@sec.state.vt.us.

Disciplinary Actions

The OPR issues press releases of all disciplinary actions taken during the month. The full text of decisions can be accessed for reading or printing from the OPR Web site noted below. The direct link to the search page is *http://vtprofessionals.org/opr1/search discipline.htm*. Disciplinary actions range from a warning, a finding of unprofessional conduct with an administrative penalty, to revocation. The Board took action against the following licensees since September 2011.

Respondent/Licensee: Albert E. Crease. License Type: Pharmacist. Violation: Drug diversion. Sanction: Pursuant to a September

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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/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.

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28, 2011 stipulation and consent order, the Board indefinitely suspended the respondent's license.

Respondent/Licensee: College Pharmacy, Inc. License Type: Nonresident pharmacy. Violation: Discipline in other jurisdiction(s). Sanction: Pursuant to a September 28, 2011 stipulation and consent order, the Board conditioned the respondent's license and ordered the respondent to successfully complete and adhere to all obligations and conditions required by the federal government and all other jurisdictions in which the respondent's license was conditioned, placed on probation, or disciplined in any way.

Respondent/Licensee: Kaylee M. Perkins. License Type: Pharmacy technician. Violation: Drug diversion. Sanction: Pursuant to a September 28, 2011 stipulation and consent order, the Board indefinitely suspended the respondent's registration.

Respondent/Licensee: Lakeside Pharmacy and John W. McAvoy. License Type: Pharmacy and pharmacist. Violation: Failure to maintain perpetual inventory, and so forth. Sanction: Pursuant to a November 7, 2011 stipulation and consent order, the Board imposed a $1,500 penalty on each respondent, reprimanded and conditioned the respondents' licenses, requiring four successful inspections of the perpetual inventory.

Respondent/Licensee: Aetna Specialty Pharmacy LLC. License Type: Nonresident pharmacy. Violation: Discipline in other jurisdiction(s). Sanction: Pursuant to a December 7, 2011 stipulation and consent order, the Board conditioned the respondent's license and ordered the respondent to successfully complete and adhere to all obligations and conditions required by the other jurisdiction(s), and notify the Vermont Board within 10 business days of any charges of unprofessional conduct or discipline imposed upon it in any jurisdiction, or any charges that it violated any probation or conditions.

Respondent/Licensee: Glenn Myer. License Type: Pharmacist. Violation: Request for reinstatement. Decision: Pursuant to a December 8, 2011 stipulation and consent order, the Board reinstated the respondent's license with conditions.

Respondent/Licensee: Erica L. Lemire. License Type: Pharmacy technician. Violation: Drug diversion. Sanction: Pursuant to a December 7, 2011 default order, the Board revoked the respondent's registration.

Respondent/Licensee: Marble Works Pharmacy. License Type: Pharmacy. Violation: Allowing unregistered technician to work. Sanction: Pursuant to a January 25, 2012 stipulation and consent order, the Board imposed a warning and administrative penalty of $500 on the respondent's license.

Respondent/Licensee: Bandana Trading Company. License Type: Nonresident wholesale drug outlet. Violation: Discipline in other jurisdiction(s). Sanction: Pursuant to a January 25, 2012 order, the Board imposed a $250 penalty and conditioned the respondent's license, requiring the respondent to successfully complete probation in other jurisdiction(s) and notify the Board within 60 days of any new charges or discipline in any other jurisdiction.

Web Site

Please visit the OPR Web site: *http://vtprofessionals.org/opr1/pharmacists/.*

You will find statutes, rules, applications, disciplinary actions, announcements, frequently asked questions, and more for pharmacy and other professions. In addition, you can also check the status of a license.

Statistics

The Board currently has 994 licensed pharmacists, 162 of whom are registered preceptors (519 resident and 475 nonresident); 1,252 registered pharmacy technicians (1,170 resident and 82 nonresident); 220 registered pharmacy interns (157 resident and 63 nonresident); 71 registered telepharmacists; 141 retail pharmacies; 17 institutional pharmacies; zero institutional long-term care pharmacies; two investigation and research project pharmacies; two home infusion pharmacies; three remote pharmacy pilot projects; 527 wholesalers, manufacturers, etc; and 341 nonresident pharmacies.

Annual Report

For more statistics including complaint data, financial information, and more, visit the Board's Web site and click on Annual Report.

The *Vermont Board of Pharmacy News* is published by the Vermont 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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