June 2012

Vermont Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Vermont Secretary of State, Office of Professional Regulation, Board of Pharmacy
National Life Building, North, FL 2 • Montpelier, VT 05620-3402 • *www.vtprofessionals.org*

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; **Aprille Morrison,** licensing board specialist, phone: 802/828-2373, e-mail: amorris@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 Licensing Board Specialist

Please note the following staff changes. Kristy Pirie, the licensing board specialist for the OPR has accepted a position at the Secretary's Office at the Agency of Human Services.

Kristy has been providing administrative support for the Board of Pharmacy since July 2008. She has done a tremendous job providing support and communications to the Board, and the Board will miss her services.

Please direct future correspondence, inquiries, e-mails, etc, to Aprille Morrison. Her contact information is as follows: phone: 802/828-2373, e-mail: amorris@sec.state.vt.us, mailing address: Office of Professional Regulation, 1 National Life Drive, North Fl 2, Montpelier, VT 05620-3402.

Institutional Chart Orders Not Valid for Outpatients

It has come to the Board's attention that some pharmacists have been filling off of chart orders faxed to them from the provider of medical services for Vermont's correctional facilities. This has been occurring when an individual is released from a correctional facility. These chart orders have been signed by a licensed practical nurse, not a physician. Licensed practical nurses do not have prescriptive authority and are not allowed to sign/authorize prescriptions. It is not acceptable to fill prescriptions off of chart orders from a medical institution for a patient who has been discharged from a hospital, nursing home, or correctional facility. Chart orders are valid only while the patient is a resident of that facility. Upon discharge, prescriptions may be issued, following standards set forth in Board of Pharmacy Rule 9.1, in one of three ways:

1. Signed by an authorized prescriber to present at a retail pharmacy.
2. Signed by an authorized prescriber and then faxed or electronically sent to a retail pharmacy.
3. Upon direction of a prescriber, a prescription order by the authorized prescriber may be telephoned to a retail pharmacy by a nurse licensed by the Vermont State Board of Nursing.

Pharmacy Administrative Rules

The Board will again begin the task of reviewing the state's Administrative Rules for the Board of Pharmacy. The Board invites comments from licensees. If you have any suggestions on an area of pharmacy practice that needs to be addressed in order to protect the health, safety, or welfare of the public, or if you are aware of an outdated rule that should be updated or removed, please contact the Board. Send your comments to Peter Comart at peter.comart@sec.state.vt.us.

Vermont Board of Pharmacy Encourages Participation in the CPE Monitor Service

The Vermont Board of Pharmacy encourages its licensees to visit *www.MyCPEmonitor.net* to create their National Associa-

continued on page 4

DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

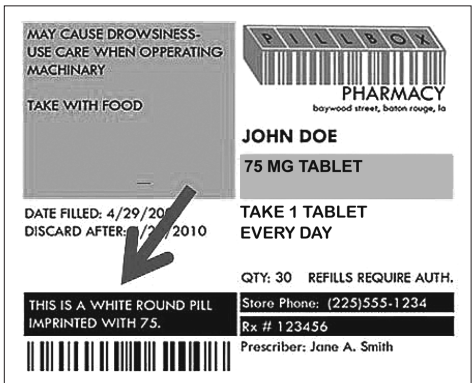
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

continued from page 1

tion of Boards of Pharmacy® (NABP®) e-Profile and complete CPE Monitor™ registration in order to obtain their NABP e-profile ID. To date more than 143,000 pharmacists and 67,000 pharmacy technicians nationwide have set up their NABP e-Profiles to prepare for the shift to electronic tracking of all their Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) units. The CPE Monitor process will eventually eliminate the need for all hard copy statements of credit taken from the ACPE-accredited providers. Soon all ACPE-accredited CPE providers will require the e-Profile ID, along with the licensee's date of birth (MMDD), in order to receive credit for all ACPE-accredited CPE activities. To ensure that your CPE is accurately recorded in your e-Profile through the CPE Monitor service, it is important that you submit the correct e-Profile ID and date of birth to the provider when registering for a CPE activity. Currently the Vermont Board of Pharmacy will not be using the electronic tracking system to verify CPE during an audit. Hard copies will still be required for verification of all completed CPE. Statements of credit for CPE recorded through CPE Monitor will be available for print from your e-Profile. For approval for non-ACPE-accredited CPE, visit the Board's Web site to obtain the necessary form for submission.

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/searchdiscipline.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 January of 2012.

Respondent/Licensee: Southwestern Vermont Medical Center (Pharmacy). License Type: Pharmacy. Violation: Allowing unregistered technician(s) to work. Sanction: Warning and $2,000 administrative penalty.

Respondent/Licensee: Rite Aid Pharmacy #10320. License Type: Pharmacy. Violation: Dispensing errors. Sanction: Reprimand and $4,000 administrative penalty.

Web Site

Please visit the OPR Web site at *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 1,462 licensed pharmacists, 176 of whom are registered preceptors (867 resident and 595 nonresident); 1,311 registered pharmacy technicians (1,223 resident and 88 nonresident); 286 registered pharmacy interns (194 resident and 92 nonresident); 72 registered telepharmacists; 142 retail pharmacies; 16 institutional pharmacies; zero institutional long-term care pharmacies; two investigation and research project pharmacies; two home infusion pharmacies; three remote pharmacy pilot projects; 556 wholesalers, manufacturers, etc; and 365 nonresident pharmacies.

Annual Report

For more statistics including complaint data, financial information, and more, visit the Board's Web site, *www.vtprofessionals.org*, 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.

Vermont Board of Pharmacy
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Communications Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

VERMONT BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744