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Vermont Pharmacist Association
Building One Voice for Pharmacy!

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Marci Wood, Editor

Vermont News

Spring Conference Information

The VPA Spring CE Conference will be held on **Sunday, April 27** from 7 AM to 3 PM at the Holiday Inn on Route 7 in Rutland. View or download the brochure here.

Upcoming Board of Pharmacy Meeting

The next meeting of the Board of Pharmacy is scheduled for **April 30th** at 9 AM. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

Federal Provider Status Update

The VPA encourages pharmacists to contact Peter Welch's office, call 888-605-7270 and request him to support HR 4190. On March 11th, HR 4190 was introduced in the US House of Representatives to recognize pharmacists as providers under Medicare Part B. The current legislation, introduced by Representatives Brett Guthrie (R-KY), G.K. Butterfield (D-NC), and Todd Young (R-IN), will enable patient access to, and reimbursement for, Medicare Part B services by state-licensed pharmacists in medically underserved communities. Pharmacists, as the most accessible health care professionals, are uniquely positioned to provide patients in medically underserved communities, access to health care services that are already within their scope of practice. By providing for a payment mechanism under Medicare Part B, the bill will allow pharmacists to help fill the gaps in care that have been created by shortages of health care professionals and increases in the number of Americans who are now eligible to gain health insurance under the Patient Protection and Affordable Care Act.
Although provider status has been a profession-wide goal for many years, activity began picking up in early 2013 and has come to a head with the formation of the Patient Access to Pharmacists' Care Coalition (PAPCC). The coalition currently represents over 20 organizations and is continuing to grow. Members include organizations representing patients, pharmacists, pharmacies, and other interested stakeholders. This coalition is focused on developing and helping to enact a federal policy proposal that will enable patient access to, and payment for, Medicare Part B services by state-licensed pharmacists in medically underserved communities. Their primary goal is to expand medically underserved patients' access to pharmacist services consistent with state scope of practice law.

Getting HR 4190 passed may be a long term effort (possibly even multiple years) that will require grassroots advocacy from all pharmacists. Get ready for action alerts asking you to send letters and emails and make phone calls to your legislators! The VPA will keep you up to date on the progress of HR 4190 and PAPCC.

April 26th is National Prescription Drug Take-Back Day

The next National prescription drug take-back day is scheduled for **April 26th**. Collection sites will be posted online on April 1st.

National Pharmacy News

Ibrutinib (Imbruvica) FDA Approved For MCL and CLL

By Derek Peterson

Ibrutinib is a novel first in class oral Bruton's kinase inhibitor. The Bruton kinase of the B-cell receptor-signaling pathway has been implicated as a mediator of B-cell malignancies and therefore recently has been FDA approved for treatment of chronic lymphocytic leukemia (CLL) and mantel cell lymphoma (MCL). Ibrutinib is available as 140 mg capsules and is dosed once daily at 560 mg (4 capsules) orally for MCL treatment and 420 mg (3 capsules) orally for CLL treatment. Each dose should be taken with a full glass of water without respect to meals. Common adverse effects seen with Ibrutinib include thrombocytopenia, infection, myelosuppression, fatigue, and GI upset. Rare adverse effects include increased risk of hemorrhage and renal failure. Due to significant p450 drug interactions and rare bleeding risks, patients should be counseled to avoid foods/juices containing grapefruit or Seville orange (the bitter orange used in orange marmalade) and to consult their doctor before taking aspirin, NSAIDs, or herbal supplements. Patients should be encouraged to report all OTC, Rx, and herbal medications to their community pharmacist since this product is only available at mail order specialty pharmacies at this time.

Research conducted by Derek Peterson & Dr. Joanna Schwartz
Derek is a 3rd professional year pharmacy student at Albany College of Pharmacy – Vermont campus (ACPHS-VT). Dr. Schwartz, PharmD, BCOP, currently practices at Fletcher Allen/University of Vermont Medical School Vermont Cancer Center as well as an assistant professor in the department of pharmacy practice at ACPHS-VT.

New Cholesterol Guidelines May Increase Statin Prescriptions

The new cholesterol guidelines released by the American Heart Association in November would qualify 12.8 million new adults as candidates for statin therapy, according to a study published in the *New England Journal of Medicine*. This study utilized data from 3773 patients collected in 2005 and 2010 for the National Health and Nutrition Examination Surveys. The study authors compared the statin recommendations for these patients under the new cholesterol guidelines to prior recommendations, and extrapolated the results to the population of US adults ages 40-75 (115.4 million people).

The study found the largest change in statin therapy recommendation in men and women ages 65-70 without cardiovascular disease. Under the previous recommendations, 30.4% of men and 21.2% of women were eligible for statin therapy. If the new guidelines are followed, these percentages will increase to 87.4% of men and 53.6 percent of women. The authors attribute the drastic increase mostly to the new recommendations based on a patient's 10-year risk of a cardiovascular event, including adults expected to have adverse health effects in the future – some which may not have future events. The new recommendations also include more patients with hypertension, but lower the levels of LDL cholesterol necessary to require statin recommendation. Percentages of adults ages 40 to 60 recommended statin therapy remained similar (29.7% for new guidelines and 27% for previous guidelines). Need for statin therapy was calculated using the American Heart Association's new risk calculator.

In response to these criticisms of the new cholesterol guidelines, Neil Stone (chair of the committee that issued the guidelines) stated the risk calculator was intended for use by doctors and patients as a predictor of potential need for treatment, not a determinant of statin therapy necessity.

Debate Over E-cigarette Safety Continues

Use of electronic cigarettes (e-cigarettes) continues to rise rapidly, especially among adolescents. These battery-operated devices look like regular cigarettes and deliver nicotine to the user while vaporizing a liquid, such as propylene glycol. Many questions regarding the safety and long-term effects of e-cigarettes remain unanswered, making their use controversial. Authors of a recent article in the *New England Journal of Medicine* expressed concern that the marketing of e-cigarettes might shift public perspective on tobacco use. The CDC has documented the rise of e-cigarette use in teens, raising concern that teens may begin smoking actual cigarettes due to their use of e-cigarettes. Caution to supporting e-cigarette use in teens is expressed by a study published in the *Journal of American Medical Association Pediatrics* that found an association between use of e-cigarettes in middle and high-school students and increased use of conventional cigarettes.

Supporters of e-cigarettes highlight their potential to aid in smoking cessation, however strong evidence to support this is currently lacking. In addition, a longitudinal study found that use of e-cigarettes did not help current smokers quit or smoke less traditional cigarettes. This study lacked participants that were actively trying to quit smoking, which may be an important factor in their success as a smoking cessation therapy. This study also highlighted the need for more regulation of e-cigarettes, which the FDA plans to fulfill through control similar to that of traditional cigarettes. Overall, more research is needed to fully assess the risks and benefits of e-cigarette use.

Diet Drug alli Recalled Over Tampering

GlaxoSmithKlein Consumer Healthcare announced on March 27th their voluntary recall of all nonprescription diet drug orlistat (alli) in the United States and Puerto Rico. The recall comes after reports by consumers of OTC alli containing tablets and capsules that were not orlistat (a turquoise capsule with a dark blue band that says "60 Orlistat"). According to GlaxoSmithKlein, there were reports of a "range of tablets and capsules of various shapes and colors" discovered inside bottles of alli. Other reports detail other issues with the product, inclusing bottles missing the outer carton or with non-authentic tamper-evident seals. So far, reports have been received from Alabama, Florida, Louisiana, Mississippi, New York, North Carolina, and Texas.

Bottles with the lot numbers and expiration date listed below have been reported as containing foreign products according to GlaxoSmithKlein. Patients with questions about the authenticity of their product should be advised not to take it, and can call GlaxoSmithKlein at 800-671-2554 for further instructions.

Carton Lot	Expiration Date
14372	February 28, 2016
14395	February 28, 2016
14124	September 30, 2015
14267	January 31, 2016
14442	April 30, 2016

Topamax Receives Approval for Adolescent Migraine Prophylaxis

Topamax 100 mg (topiramate, Janssen) has received FDA approval for migraine phophylaxis in children aged 12-17, making it the first drug available for migraine prevention in this age group. The efficacy and safety of Topamax in adolescents was established in a clinical trial of 103 participants. In this study, Topamax treatment reduced migraine frequency by 72%, compared to a decrease of 44% in patients given placebo. Common adverse reactions included parasthesia, upper respiratory infection, loss of appetite, and abdominal pain. Topamax is already approved for migraine prophylaxis in adults, as well as the prevention of seizures.

Otezla Approved to Treat Psoriatic Arthritis

The FDA has announced its approval of Otezla (apremilast, Celgene Corporation) for the treatment of active psoriatic arthritis in adults. Otezla, a phosphodiesterase-4 inhibitor, is the only FDA-approved oral therapy for psoriatic arthritis. The recommended starting dosage of Otezla is 10 mg in the morning to reduce risk of GI side effects, to be increased over 5 days to the recommended maintenance dosage of 30 mg twice daily. This maintenance dosage is the recommendation for patients with a creatinine clearance of less than 30 mL/min. Approval is based on results of three clinical studies involving 1,493 patients with active psoriatic arthritis that showed improvement of these patients' signs and symptoms compared to placebo. The most common adverse effects of Otezla during these studies were diarrhea, nausea, and headache. An increase in reports of depression in patients compared to placebo was also reported. Otezla will be available in 10, 20, and 30 mg tablets soon through a network of specialty pharmacies, according to the manufacturer.

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