Vermont Pharmacist Association
877.483.2646
Building One Voice for Pharmacy!

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Marci Wood, Editor

Vermont News

VPA Fall Conference: October 25th

Mark your calendars for the upcoming Fall CE meeting! It will be held Sunday, October 25th at the ACPHS-VT campus in Colchester. Watch your email for more information.

VPA Treasurer and Office Manager Positions

Dear Members: VPA Treasurer Lynne Vezina is retiring after a Decade plus involved in VPA's success. Also Sandy Pecor, our excellent office manager, is going in another direction and leaving the VPA. Please contact Jim Marmar at 877-483-2646 (home office) or at my day job 802-457-1306 (Woodstock Pharmacy) if you would like to volunteer and help out the VPA.

New Law Changes Reporting Procedures For Pharmacists

The Vermont legislature recently enacted Act 60 (formerly known as S.9). This new law, which came into effect July 1, 2015, changed mandated reporting procedures, some child abuse definitions, and information sharing across the system.

Mandated reporters of child abuse/neglect now include any health care professional, including pharmacists. The new reporting standard is:
Any mandated reporter who reasonably suspects abuse or neglect of a child shall report in accordance with the provisions of section 4914 of this title within 24 hours of the time information regarding the suspected abuse or neglect was first received or observed (33 VSA § 4913(c)).

A training for all mandated reporters is in the process of being developed, and is expected to be available online this fall. In the meantime, please direct any training requests to your local Family Services District Office. Detailed information about Act 60 can be found at mandatedreporters.vt.gov. The Act 60 changes are summarized in this memo. Please contact Lindsay Barron at Lindsay.Barron@state.vt.us if you have questions

Save the Date: Vermont Legislative Day

Next year's Vermont Pharmacists Day will be held on January 22nd at the Statehouse in Montpelier.

Upcoming Board of Pharmacy Meeting

The May meeting of the Board of Pharmacy will be held at 9 AM on August 23rd. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

2015 Membership Reminder

The Vermont Pharmacists Association would like to thank all those that have sent in their memberships for 2015, and remind everyone that your membership is critically important to our ongoing efforts to increase our professional voice throughout Vermont and is greatly appreciated. The VPA works diligently to support pharmacy in Vermont and get information out to all pharmacists on upcoming legislation and happenings that affect the pharmacy profession. We are working on dates for upcoming Continuing Education meetings and will get that information out to you when we get dates confirmed. Membership forms are available through our website using PayPal at www.vtpharmacists.com. Click on the menu link in the upper right hand corner, then "membership" from the drop down menu. Alternatively, check or money order can be sent to P.O. Box 818, Milton VT, 05468.

National Pharmacy News

FDA Approves flibanserin, First Approved HSDD Treatment

The FDA has approved Addyi (flibanserin Sprout Pharmaceuticals) to treat acquired generalized hypoactive sexual desire disorder (HSDD) in premenopausal women. Addyi is the first approved treatment for sexual desire disorder.

Addyi is a serotonin 1A receptor agonist and serotonin 2A receptor antagonist, but the precise mechanism that improves sexual desire in women is unknown. The drug is taken once daily at bedtime to decrease risk of adverse effects from hypotension, syncope, and CNS depression. Efficacy of 100 mg Addyi was studied in three 24-week randomized, double blind, placebo-controlled trials. Approximately 2,400 premenopausal women with an average age of 36 years were included in these trials.

Serious side effects highlighted by a Boxed Warning include severe hypotension and syncope, with increased incidence in patients that consume alcohol or take medications that inhibit moderately to severely inhibit CYP3A4. Use is contraindicated in patients that consume alcohol or have liver impairment. The drug will only be available through certified practices and pharmacies.

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Teen E-cigarette Use Leads to Tobacco Smoking, FDA Delays Packaging Ruling

A recently published study has associated e-cigarette use in adolescents with future use of other nicotine products. The study surveyed 14-year-olds, asking if he or she had used e-cigarettes at baseline. Follow up after 6 and 12-months from baseline was conducted to assess if cigarettes, cigars, and/or hookahs were used. Baseline use of e-cigarettes was associated with a greater likelihood to use other tobacco products.

In other e-cigarette news, the FDA has extended time for public comments until September 30th. People are invited to remark on what should be included on e-cigarette labels, the wording of these labels, and how childproof packaging should be stated. The FDA has been urged to provide restrictions on e-cigarette, but the agency has yet to finalize any regulations.

Second PCSK9 Inhibitor Granted Approval

The FDA has approved Repatha (evolocumab, Amgen) injection for treatment of certain patients with high LDL cholesterol. This is the second proprotein convertase subtilisin kextin type 9 (PCSK9) inhibitor to be approved, following the approval of Praluent (alirocumab, Sanofi-Aventis) last month.

Like Praluent, Repatha is approved for use in adult patients who have familial hypercholesterolemia or cardiovascular disease and require additional LDL lowering. Use of these PCSK9 inhibitors have been studied in addition to diet and the highest tolerated dose of statin therapy. The approved doses of Repatha are 140 mg injected subcutaneously every 2 weeks or 420 mg injected subcutaneously once monthly.

The most common side effects of Repatha therapy seen in clinical trials were nasopharyngitis, upper respiratory tract infections, flu, back pain, and injection site reactions.

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Oral GLP-1 Moves to Phase III Trials

Novo Nordisk has released a statement that it plans to begin studying semaglutide, a long-acting GLP-1 analog, in a Phase III trial. Plans to continue studying this drug, which is an oral medication unlike the other GLP-1 injections currently available, come after “encouraging” results in prior trials. The company released a statement detailing plans to begin the first trial in early 2016. According to this statement, semaglutide doses of 3 mg, 7 mg, and 14 mg will be compared to once-daily doses of stiagliptin 100 mg.

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High Dose Vitamin D Not Associated with Better Outcomes in Some Postmenopausal Women

A recently published randomized, double-blind clinical trial compared the effects of low-dose or high-dose vitamin D to placebo on calcium absorption, bone mineral density, muscle mass, and time to complete standardized exercises in postmenopausal women after one year. A total of 230 women 75 years or younger with baseline vitamin D levels of 14 to 27 ng/mL were included in the study. Exclusion criteria included women with osteoporosis, diabetes, diseases that may affect vitamin D absorption, kidney stones, or cancer in the past 5 years. Women that used bone-active medications, including bisphosphonates, estrogens, calcitonin, teriparatide, oral corticosteroids, anticonvulsants, or vitamin D doses of >400 IU/dose in the past 6 months were also excluded. After 1 year, calcium absorption was increased by 1% in the patients receiving high-dose (50,000 IU cholecalciferol twice monthly) group, decreased 2% in the low-dose (800 IU cholecalciferol once daily) group, and decreased 1.3% in the placebo group. However, researchers found no differences in bone mineral density, muscle mass, or timed exercise scores. There were also no differences seen in the number of falls, physical activity, or functional ability between the three groups. Researchers concluded these data do not support current recommendations to maintain vitamin D levels above 30 ng/mL in postmenopausal women. However, these results are not applicable to postmenopausal women with disease states that were excluded from the study, including osteoporosis and diabetes.

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