Vermont Pharmacist Association
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Building One Voice for Pharmacy!

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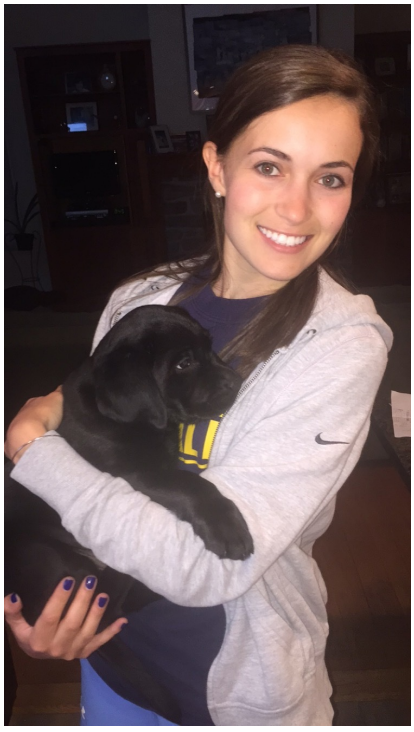
Marci Wood, Editor

Vermont News

New VPA Student Chapter President Elected



Janelle Puleo was elected to the position of VPA Student Chapter President for the 2016-2017 academic year. Janelle is an Essex Junction local who is entering her P3 year at ACPHS-Vermont Campus. She attended Essex High School and then went on to graduate from Saint Michael's College with a Bachelor of Science in Pre-Pharmacy. Prior to being elected as president, Janelle was a member of VPA during her P1 year and served as Vice President for VPA as a P2 student. In addition to being a Student Ambassador, she also has held the position of Community Service Chair and this year will be the secretary for the American Pharmacists Association - Academy of Student Pharmacists. Janelle looks forward to working with student members as well as VPA pharmacists this coming year and plans to encourage participation in events such as community screenings and Legislative Day!

Upcoming Lake Monsters ACPHS Alumni Event

ACPHS invites alumni and members of the college community to enjoy a Vermont Lake Monsters game on Friday, August 12 at 7:00 p.m. The event will be located at Centennial Field in Burlington.

If you are interested in tickets, please contact the Office of Institutional Advancement at 518.694.7393 or email alumni@acphs.edu by Friday, August 5. Limited tickets are available.

Upcoming Board of Pharmacy Meeting

The next meeting of the Board of Pharmacy will be held at 9 AM on Wednesday, August 24th. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

National Pharmacy News

American Heart Association Warns of Drugs that can Worsen Heart Failure

The American Heart Association has released a statement cautioning that certain prescription and OTC medications can precipitate or worsen heart failure. Many of the medications listed in this publication were previously known to be problematic in heart failure patients, however this is the first published statement by the AHA reviewing published data on medications and providing guidance about their use in HF. Case reports, case series, package inserts, meta-analyses, and prospective and observational trials were utilized to provide a list of clinically relevant drug issues for heart failure patients. Some of the medications included in this statement are NSAIDs due to risk of causing sodium and fluid retention, OTC cough/cold products such as Dayquil and Nyquil that are high in sodium, diabetes medications like metformin, and many more. Complementary and alternative medication use is cautioned due to potential interactions with common HF medications like digoxin, vasodilators, and beta blockers. Ephedra-like products are not recommended for patients with HF due to increases in blood pressure and heart rate.
Heart failure patients on average have five or more different medical problems, and are at high risk of drug-drug interactions. Recommend that patients keep an updated list of all their medications and discuss any changes with a health care professional.

Study Finds LABA Plus ICS Safer than ICS Alone for Asthma

A recent randomized, double-blind controlled trial funded by GlaxoSmithKline due to safety concerns of LABA use in asthma patients found no increased risk of serious asthma-related events associated with the drug. A total of 11,751 patients with moderate to severe asthma who had experienced at least one exacerbation in the previous year that required systemic steroids or hospitalizations, but no such episode in the previous month, were included in the trial. Patients were randomized to receive fluticasone-salmeterol or fluticasone alone twice daily. The dose of fluticasone in both groups was stratified into 3 subgroups based on disease severity: 100 mcg, 250 mcg, or 500 mcg. Patients in the combination group received 50 mcg of salmeterol. An intent to treat analysis was utilized and members of the research team were blinded to treatment assignment. The primary efficacy endpoint was the first severe asthma exacerbation, defined as the use of systemic steroids for at least 3 days, asthma-related hospitalization, or an emergency department visit resulting in systemic steroid administration. The results of the study showed patients in the combination group had fewer exacerbations than those in the group that received fluticasone alone (8% vs 10%; $P < .001$; NNT = 50 over 26 weeks) with similar safety outcomes between the groups. The conclusion of this study was that use of the LABA-ICS combination of salmeterol and fluticasone was associated with fewer severe asthma exacerbations and no increased risk of serious asthma-related events compared to patients who only received fluticasone.

Drug Makers Rush to Make “Smart” Inhalers

Drug manufacturers like GlaxoSmithKline, AstraZeneca, and Novartis are working with manufacturers of smart inhalers with the goals of improving health outcomes and increasing profits. Clip-on sensors are available as add-ons to inhalers already, however drug manufacturers are looking at further innovation in this field. Smart inhalers with built-in sensors utilize wireless technology to monitor if the device is being used correctly. AstraZeneca plans to begin a year-long clinical trial in August designed to study adherence in 400 COPD patients using a smart inhaler device made by the company Adherium. A smaller study performed using the same device in New Zealand last year in children with asthma showed increased adherence from 30 to 84 percent. Novartis is working with another smart inhaler company, Qualcomm, and aims to develop the first inhaler with an integrated sensor to launch by 2019. The opportunity to improve adherence in the 500 million people affected by asthma and COPD could save an estimated $19 billion a year in healthcare costs, according to a Coldman Sachs analysts estimate report, providing incentive for the use of these devices if studies can show they improve adherence.

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New Treatment for Dry Eyes Approved

The FDA has approved lifitegrast ophthalmic solution (Xiidra—Shire) for the treatment of signs and symptoms of dry eye disease. Xiidra is a lymphocyte function-associated antigen 1 (LFA-1) antagonist, the first drug to be approved in this class. Dry eye disease includes multiple conditions that involve the eye not making enough tears or tears that are not of correct consistency. The prevalence of these diseases increases with age, and if not treated can lead to complications such as pain and ulcers or scars on the cornea. Safety and efficacy of lifitegrast were evaluated in four separate randomized controlled trials that included over a thousand patients ages 19 to 97 years. Patients were randomized to be treated with lifitegrast or placebo twice a day for twelve weeks. Patients treated with lifitegrast showed improvement in signs and symptoms of dry eye disease compared to those that received placebo. The most common side effects reported in these trials were eye irritation, eye discomfort, blurred vision, and an unusual taste in the mouth.

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FDA Approves OTC Adapalene Gel

The FDA has announced its approval of adapalene (Differin Gel 0.1%—Galderma Laboratories) for the OTC treatment of acne, the first retinoid agent to be available without a prescription. The once-daily topical gel is approved for use in individuals aged 12 years and older. Consumer studies performed showed that a majority of consumers understood the information provided on the OTC label. This label indicates that pregnant or breastfeeding women should consult with their doctor prior to using adapalene gel. Although there are no reports of adapalene causing birth defects in humans, retinoids have been shown to cause teratogenicity in animals. Label instructions for use are to apply a thin layer on affected skin once daily, and that the product should not be used on sunburned or damaged skin.

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FDA Approves New GLP-1 Drug for T2DM

The FDA has announced its approval of another glucagon-like peptide-1 (GLP-1) receptor antagonist, lixisenatide (Adlyxin – Sanofi), for the treatment of type 2 diabetes as a once-daily subcutaneous injection. The product's starting dose is 10 mcg injected once daily, which is increased to 20 mcg after 14 days. This drug has already been marketed under the trade name Lyxumia in over 40 countries, including the European Union, Japan, Brazil, Mexico, and India. The approval is based on safety and efficacy data from 11 clinical trials involving more than 11,000 patients, including a trial evaluating cardiovascular outcomes. This trial showed lixisenatide did not increase risk of CV events, but did not show cardiovascular benefit. This may limit the drug's marketability, especially since the recently published LEADER trial associated improved CV outcomes with liraglutide (Victoza – Novo Nordisk).

However, this approval of lixisenatide may help pave the way for Sanofi's planned combination of the drug with insulin glargine. This product, which contains fixed doses of these medications in a pen device, was recommended for approval by an FDA advisory committee in May.

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