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Madeline Ciccone, Editor

Vermont Pharmacy News



PABLO MARTINEZ MONSIVAIS / AP

Congressman Welch Meets With President

Congressmen Peter Welch, of Vermont, and Elijah Cummings, of Maryland, met with President Trump and his newly appointed Health and Human Services (HHS) secretary, Tom Price, to discuss the combat against rising prescription drug prices.

The meeting consisted of a

House bill pitch that would expand the federal government's ability to negotiate drug prices. According to a statement made by the president on [twitter](#), he is "working on a new system where there will be competition in the Drug Industry." The [proposed legislation](#) would enable the HHS Secretary to negotiate for lower prices with drug manufacturers under Medicare Part D, which provides coverage for prescription drugs. This bill would allow the HHS Secretary to establish a formulary, and utilize the government's purchasing power to gain "leverage" with drug manufacturers that participate in Medicare Part D. The HHS Secretary's established formulary may grant the ability to obtain significant discounts in negotiations with drug manufacturers. Douglas Holtz-Eakin, a former director of the Congressional Budget Office and current president of the American Action Forum states that this bill concept is "completely unrealistic," and "won't work" because the Medicare Part D program is already holding prescription drug costs down because of the negotiating ability of the drug plans. According to drug industry lobbying group PhRMA, price negotiation is already happening.

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Mid-West Pharmacy Company Acquires New England Mail Order Pharmacy

Serve You Custom Prescription Management Inc., of Wisconsin, has expanded into the Green Mountain State, adopting the New England Mail Order Pharmacy, based in Middlebury, Vermont. The New England Mail Order Pharmacy operations and staff in Middlebury will remain in place. The purpose of the addition is to better serve the mail order pharmacy needs of its growing members in New England states.

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Pharmacy Manufacturing Facility Expands in Colchester

Edge Pharmacy Services, a pharmaceuticals manufacturing facility that specializes in a wide variety of compounded pharmaceuticals is set to expand its area in Colchester, Vermont, upgrading with an additional 20,000 square foot space. Edge Pharmacy Services is a sterile and nonsterile 503B Outsourcing Facility, with specific focuses in “operating room anesthesia, medications for ophthalmic surgery, dermatology, ENT, and allergy treatment.” With the rising demand of its products, Edge is investing over \$1.5 million into expanding production capacity – with an estimated production increase of 5 times what it is today. “With the new FDA and state 503B Outsourcing laws, the pharmaceutical industry is in a transitional period, since it is no longer legal to purchase many medications from traditional compounding pharmacies for office or hospital use,” officials stated. Edge has been compliant with current rules and regulations implemented by the Vermont Board of Pharmacy, the FDA, USP-797, and USP-797, and has remained up-to-date with inspections.

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Vermont Board of Pharmacy Meeting

April 26th, 9:00am to 3:00pm

89 Main St., Montpelier, VT
Large Conference Room A

National Pharmacy News

Evolocumab Reduces LDL Cholesterol and Risk of CV Outcomes

By: Marci Wood, Pharm. D. Candidate Class of 2017

The first trial to focus on the PCSK9 inhibitor evolocumab (Repatha, Amgen) and its role in cardiovascular risk was recently published in the New England Journal of Medicine. Proprotein convertase subtilisin–kexin type 9 (PCSK9) inhibitors are an injectable class of medications approved in 2015 for use in patients with familial hypercholesterolemia or patients with clinical ASCVD on maximally tolerated statin who require additional lowering of LDL cholesterol, however their benefit on cardiovascular risk has previously been unknown.

The randomized, double-blind, placebo-controlled study included a large sample size of over 27,000 patients who had a history of ASCVD and a LDL of 70 mg/dL or higher. The results of this study showed that evolocumab, when added to maximally tolerated statin therapy, significantly reduced the likelihood of some cardiovascular events as well as LDL cholesterol to around 30 mg/dL. The primary outcome of this study was a composite of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization risk. Evolocumab treatment significantly reduced this composite endpoint compared to placebo, with a relative risk reduction 15% and an absolute risk reduction of 1.5%. Importantly, differences in cardiovascular death and hospitalizations were not statistically significant as individual outcomes between the evolocumab and placebo groups. Therefore, effects of the drug on these endpoints should still be considered exploratory. As evolocumab has an approximate yearly cost of \$14,000, it remains unclear if the benefits seen in this trial justify use of this costly drug in the average patient with dyslipidemia.

[Read more](#)

New England Compounding Center Pharmacist Acquitted of Murder Charges

Barry Cadden, the head pharmacist at New England Compounding Center out of Framingham, MA, was convicted of conspiracy, fraud and racketeering, but acquitted of murder charges against him. In the summer of 2012, the New England Compounding Center had shipped vials of tainted methylprednisolone acetate across the country. The vials were contaminated with a fungus that caused more than 60 deaths and hundreds of meningitis-related illnesses. Next to murder charges, Cadden was also acquitted on charges that he “sought to mislead customers by providing them with adulterated drugs,” charges that he “knowingly mislabeled drugs,” and charges that he sought to defraud the FDA by “treating his center as a pharmacy instead of a manufacturing center,” which would have led to the business facing greater federal scrutiny. This month, the New England Compounding supervising pharmacist, Glen A. Chin, will be placed on trial for his role in the outbreak. Several other workers, including pharmacists at the site, are slated to go on trial as well.

[Read more](#)

FDA Approves Parkinson’s Disease Treatment

Xadago (safinamide) tablets are now approved by the Food and Drug Administration as an adjunct therapy for patients with Parkinson’s disease currently taking Sinemet (carbidopa/levodopa) and experiencing a lapse in treatment, known as an “off” episode. “Off” episodes are defined as a time when a patient’s medications are not working well, causing an increase in Parkinson’s symptoms like tremors or difficulty walking. In a clinical trial of 645 participants who were presently taking levodopa and experiencing “off” episodes, those receiving Xadago experienced more beneficial reductions in Parkinson’s symptoms compared to those receiving placebo. In another clinical trial of 549 participants, the participants adding Xadago to their levodopa treatment had more “on” time without troublesome, uncontrolled involuntary movement compared to those taking placebo, and experienced better motor function scores on assessments during “on” time than before treatment. Contraindications to Xadago include those with severe liver problems. Additionally, those taking particular antidepressants, dextromethorphan, opiates, or cyclobenzaprine should avoid this medication. Common adverse events reported include uncontrolled involuntary movement, falls, nausea, and trouble sleeping or falling asleep. Rare but serious side effects include exacerbated high blood pressure and serotonin syndrome.

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Fungal Infection Spreads to United States

A new strain of drug-resistant *Candida* known as *Candida auris* has been found in nearly three-dozen patients in the United States. Originally found in Japan, this new pathogen has been seen in a dozen countries on five continents from its emergence in 2009. The CDC reports the largest number of infections were seen in New York, with 28 cases, but has spread to other states, including Massachusetts. Those at risk for infection are long-term ICU patients or those on ventilators or central line catheters. Serious bloodstream infections have been reported with those infected with *Candida auris*. Some strains are reported to be resistant to all three major classes of antifungal drugs, but the strains seen in the United States have shown to be treatable with existing drugs. Health officials state that this microbe is among a group of newly emerging drug-resistant threats.

[Read more](#)

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