Vermont Pharmacist Association
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Building One Voice for Pharmacy!

## August 2014

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# Vermont News

## DEA Classifies Tramadol a Controlled Substance

The pain reliever tramadol is now classified as a Schedule IV controlled substance (CS). Starting August 18, 2014, the Drug Enforcement Administration (DEA) will require manufacturers to print the "C-IV" designation on all labels that contain tramadol. Tramadol is already a Schedule IV in New York.

## Ask the Board of Pharmacy:


**On August 18th tramadol will become a Class IV controlled substance. For prescriptions written before August 18th that were originally written for more than five refills, are patients eligible to fill refills past #5?**

**Answer:** The Federal Drug Enforcement Administration (DEA) has enacted final regulations making Tramadol a Schedule IV Controlled Substance. The regulation takes effect August 18, 2014.

Before opening for business on August 18, 2014, every pharmacy must inventory its stocks of Tramadol and accurately record same. The results of this inventory are to be added or attached to the pharmacy's last controlled substances Biennial inventory.

As of August 18, 2014 all prescriptions received for Tramadol are to be treated as a Schedule IV Controlled Substance prescription subject to all the rules pertaining to Schedule IV Controlled Substances. Prescriptions issued for Tramadol prior to August 18 may continue to be refilled, if there are authorized refills remaining on the prescription. In no case may such a prescription be filled more than six (6) times, (original fill plus five refills) regardless of the number of refills authorized on the original prescription. As of August 18, a prescription issued for Tramadol expires six months after the date of issue, regardless of how many authorized refills remain on the prescription.

## VPA Student Scholarship Application

Applications for the 2014-15 Vermont Pharmacists Association student scholarships are available on the student section of the VPA website.

## Upcoming Board of Pharmacy Meeting

The next meeting of the Board of Pharmacy is scheduled for **August 27th** at 9 AM. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

# National Pharmacy News

## Abuse-Deterrent Opioid Approved by FDA

Targiniq ER (oxycodone/naloxone, Purdue) has been approved by the FDA to treat severe pain requiring around-the-clock, long-term treatment. This combination will help deter abuse of oxycodone, as naloxone blocks the euphoric effects when the drug is snorted or injected. Targiniq ER can still be abused when taken orally. Approved indications for Targiniq ER are pain management for individuals whom alternative treatments are ineffective, not tolerated, or otherwise inadequate according to the FDA. The drug is not approved for as-needed pain management. Safety and efficacy were evaluated in a trial involving 601 individuals with chronic lower back pain, and safety evaluated in more than 3000 individuals treated with the drug. Purdue is required to conduct post-marketing studies evaluating risks of misuse, abuse, increased sensitivity to pain, addiction, overdose, and death beyond 12 weeks of use.

## Crackdown on Florida Pill-Mills Reduces Overdose Deaths

According to a CDC report, Florida's crackdown on pill mills and doctor shoppers resulted in a 23% reduction in prescription drug deaths in Florida from 2010 to 2012. Florida has become known for pill mills in recent years, with effects reaching other states including Vermont. In response, Florida has passed laws and increased law enforcement efforts to expose phony medical clinics and doctors. The full report can be found on the CDC website.

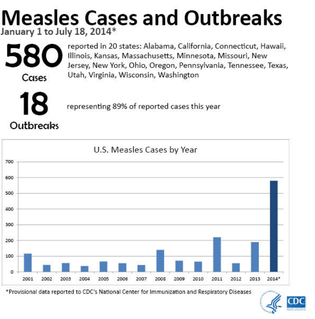
## CDC Launches Tobacco Cessation Webpage for Pharmacists

As part of the national tobacco education campaign Tips From Former Smokers, a new tool for pharmacists to help patients quit smoking is now available. The Pharmacists: Help Your Patients Quit Smoking webpage consolidates helpful links to FAQs for healthcare professionals, downloadable "Talk With Your Pharmacist" posters for use in pharmacies, a printable pocket-sized card listing the 5 As for reference, and toll-free numbers for help quitting. The Tips From Former Smokers campaign is the first paid national tobacco education program, and features stories of former smokers living with smoking-related diseases and non-smokers who have experienced complications resulting from second-hand smoke.

## 2014 US Measles Cases Alarmingly High

According to the CDC, 580 confirmed cases of measles have been reported so far in 2014, from January to July 18th. This represent the largest number of cases reported in a 5-month period (January-May) in the past 20 years and surpasses the highest reported yearly total of measles, 220 cases in 2011, since the disease was declared eliminated in 2000. Since this elimination was declared, secondary measles cases continue to occur in the US when individuals travel to areas of the world where measles is endemic. Cases have been reported in a total of 20 states and New York City, with no report cases to date in Vermont. Almost all the cases in 2014 have been associated with international travel by unvaccinated individuals – only 10% occurred in vaccinated individuals. Most cases were reported from Ohio (138 cases, ongoing outbreak in Amish community), California (60 cases), and New York City (26 cases). Patients ranged in age from 2 weeks to 65 years old, with 52% of reported cases 20 years and older. According to the CDC, the high number of cases this year highlights the need for health care workers to have a heightened awareness of the signs and symptoms of measles, and the importance of measles vaccination to prevent the disease.

Patients presenting with both fever and rash, combined with cough, inflammation of the mucous membrane in the nose, and/or conjunctivitis may have measles. Healthcare professionals are advised to ask these patients about international travel and vaccinations, and diagnosis of measles can be confirmed if symptoms match and international travel has occurred. Diagnosis of measles may also be confirmed with laboratory results. For more information about measles, visit the CDC Measles Homepage and the page specifically for Healthcare Professionals.




*source: http://www.cdc.gov/measles/cases-outbreaks.html*

## Flonase OTC Sales Approved

The FDA has approved over-the-counter sales of the nasal spray Flonase (fluticasone propionate, GlaxoSmithKline) for allergy treatment. The labeled indications for the product will be temporary relief of nasal and eye-related allergy symptoms, including runny nose, sneezing, nasal congestion, and watery itchy eyes. According to the manufacturer, the product is expected to be available for sale in early 2015 with the same dosage as the prescription product.

## Vorapaxar Receives FDA Approval

Vorpaxar (Zontivity, Merck) is the first drug to be approved in a new class called protease-activated receptor-1 (PAR-1) antagonists. Indications are decreasing the risk of heart attack, stroke, and need for procedures to restore blood flow to the heart in patients with a history of adverse cardiovascular events. Vorapaxar inhibits the PAR-1 pathway, the primary receptor for thrombin and an activator of platelets. Vorapaxar is novel because this pathway is not targeted by aspirin or other antiplatelet drugs like clopidogrel, and should be used in combination with either drug.

Safety and efficacy of Vorapaxar was studied in a clinical trial involving 26,449 individuals. Participants were given either Vorapaxar and aspirin/clopidogrel or placebo. The group treated with the drug combination showed a 17% relative risk reduction over the 3-year duration of the study for adverse cardiovascular events compared to the placebo group. Like other drugs that prevent blood clotting, patients treated with Vorapaxar have an increased risk of bleeding shown in trials. The drug should not be used in patients with a history of stroke, transient ischemic attack, or bleeding in the head. Vorapaxar will be available in the third quarter of 2014 according to Merck.

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