CO*RE NEWS

inform | connect | share

Summer 2017 | AAFP State Chapters Update

CA AFP Continues to Provide Live CO*RE Education at AAFP Chapters

Working with our Collaborative for REMS Education (CO*RE) partners over the past seven years, CAFP has provided primary care physicians with evidence-based education on the safe use of opioids for chronic pain. This includes education about inappropriate uses of opioids and alternative pain therapies. The education meets the FDA's Risk Evaluation and Mitigation Strategy (REMS) requirements and addresses the latest guidelines from the Centers for Disease Control. The



CAFP has presented CO*RE's content across the country.

curriculum also includes information on immediate release opioids (covering the FDA's most recent REMS), non-pharmacological options for treating pain and state-specific information. The latest activity trains stopped in Alaska, Michigan and Florida.

If your members have missed the live activities, we hope you will help promote Medscape's free online CO*RE REMS two-hour activity at:

http://www.medscape.org/clinicaladvances/long-acting-opioids-cafp

FDA Update

At a July 10th FDA meeting on abuse-deterrent formulations, FDA Commissioner Dr. Scott Gottlieb said the FDA would require drug manufacturers to provide and pay for training for prescribers of immediate-release (IR) opioid medications. In the US, 90 percent of all opioid prescriptions are for IR formulations, amounting to some 200 million prescriptions annually. The FDA will start notifying IR manufacturers of the new requirements over the next few weeks. All IR formulations now will be subject to the same Risk Evaluation and Mitigation Strategy (REMS) program as extended release opioids. The FDA's Opioids



CO*RE NEWS

1

<u>Action Plan</u> aims to promote abuse-deterrent formulations of opioid drugs by helping drug makers through the regulatory process. A lack of data on abuse-deterrent formulations and concerns about safety, however, also have spurred research into alternative approaches such as genetic engineering.

New CDC Statistics Reported

A new CDC <u>report</u> on 2015 statistics indicates opioid painkillers prescribed in the United States peaked in 2010 with prescriptions for higher, more dangerous doses dropping by 41 percent by 2015. But the analysis also found the prescribing rate in 2015 remained three times as high as in 1999 and pointed to dramatic regional differences in prescribing and abuse numbers. This *New York Times* (*NYT*) <u>article</u> provides an overview of the report.

More Numbers Tell the Story's Past and Future

At least 59,000 Americans died from drug overdose in 2016 and deaths increased 19 percent from 52,404 a year earlier, according to an *NYT* <u>analysis</u> of data from state health departments, county coroners and medical examiners. Increasing use of fentanyl is one factor, but prescription pain drugs also contribute. Close to 100 Americans are killed by opioids each day, a figure that could rise to 250 – or more than 650,000 over the next decade – if potent synthetic compounds such as fentanyl and carfentanil continue to proliferate, according to this <u>STAT News analysis</u>. Experts predict that mortality will not stabilize until after 2020, because it will take several years to see if government interventions are effective.



A <u>report</u> from the HHS Office of Inspector General found that more than 500,000 Medicare Part D subscribers – a figure that excludes those with cancer or in hospice care – received more than 120 milligrams of morphine equivalent dose (MED) in opioids daily for three months or more last year, a dose that exceeds CDC-recommended levels for most patients and puts them at risk of addiction and overdose. Almost 70,000 beneficiaries got an equivalent of 240 mg MED or more daily for 12 months, while more than 22,000 appeared to have been "doctor shopping."



Pharma News

About a month after the FDA started the <u>process</u> to have Opana ER withdrawn from the market because of "public health consequences of abuse," <u>Endo International</u> said it will stop selling its long-lasting opioid painkiller in the US. The firm said it will work with the FDA on a timeline for the withdrawal to minimize treatment disruption in patients.

Drug company researchers are hurrying to develop <u>alternatives</u> to opioid pain medications as scrutiny increases on usage and prescribing and the federal government has started to block sales of some drugs. Researchers are studying



CO*RE NEWS 2

capsaicin, cannabis, genetics and snail toxins in search of alternative pain medications, while some companies have focused efforts on developing opioids that are safer and less addictive.

This NYT <u>article</u> chronicles the scrutiny under which the marketing of the opioid addiction treatment drug Vivitrol has recently come. According to the NYT, despite limited evidence to prove its drug works, the maker of Vivitrol has used political connections and marketing to push for its use for detoxing. Sorrento Therapeutics' investigational new drug application for <u>resiniferatoxin</u>, a naturally occurring chemical found in the resin spurge plant as a treatment for patients with chronic pain, received FDA <u>approval</u>. The non-opioid drug reduced patients' pain and dependence on opioids, according to the preliminary results of an early-stage trial.

FREE CME Course: Research-Based Clinical Strategies to Prevent and Address Adolescent Substance Use and Prescription Medication Misuse - Being Part of the Solution

With drug overdose deaths reaching epidemic proportions, and one in twenty teens experiencing a substance use (SU) disorder, now is the time to tackle the issue from all angles, including during all clinical visits with adolescents.

To help clinicians do that, the CAFP, together with the Coalition of Health



<u>Care Providers on Adolescent Substance Use</u>, has launched a continuing medical education (CME) course covering all aspects of discussing SU and prescription medication misuse with adolescent patients. The course, <u>Research-Based Clinical Strategies to Prevent and Address Adolescent Substance Use and Prescription Medication Misuse—Being Part of the Solution</u>, features brief videos of fellow clinicians offering helpful insights and strategies for identifying and addressing SU in teen patients. The course is offered in two parts—each worth .5 AAFP Prescribed CME credits.

Teens who receive early interventions for substance use (SU) can achieve positive outcomes¹ and adolescents *want* clinicians to bring up sensitive issues like this one.¹ Given that, family physicians are in a prime position to have a positive impact on patients by addressing SU before it leads to addiction. Don't wait—take this CME course today! #NIDAMED

Noteworthy links for more information:

- US Opioid use, by county, from the latest CDC published data. Check out yours: Opioid Use by County
- Empathy in an Epidemic ... "Every day, 91 people overdose on opioids..." Opioids and Empathy
- You Draw It: Just How Bad Is the Drug Overdose Epidemic? https://www.nytimes.com/interactive/2017/04/14/upshot/drug-overdose-epidemic-you-draw-it.html? r=4

CO*RE NEWS

3

<u>an</u>

¹ Brown JD, Wissow LS. Discussion of sensitive health topics with youth during primary care visits: relationship to youth perceptions of care. *J Adolesc Health*. 2009;44(1):48-54.