

Health News: December 13, 2020

- In a dangerous product mix-up, **ED pills** and **sleeping pills** were packaged together in the same bottles. Both were 100 mg tablets inadvertently packaged together during bottling at a 3rd party facility. Check FDA site for expiration dates and lot numbers. [FDA Link](#)



AVKARE packaging for trazodone (Source:FDA)

- On December 4, weight loss drug **Saxenda** had four safety-related labeling changes approved by the FDA.

[FDA Label Change for Saxenda](#)

- A post-marketing clinical study of **Pfizer's injectable birth control drug Depo-Provera** and **adolescents** looked at whether **bone mass density (BMD)** recovers after the discontinuation of the drug. As a result, its **boxed warning** was modified to reflect that results showed that **BMD did not fully recover** after 5 years of discontinuation in patients who were treated for more than 2 years. It is unknown if use of Depo-Provera will reduce peak bone mass and increase the risk for osteoporotic fracture in later life. Because of these risks to bone health, Depo-Provera is not recommended as a long-term (i.e., longer than 2 years) birth control method. Safety-related label change:

[FDA Label Change for Depo-Provera](#)

- Read examples of [patient experiences](#) with Depo-Provera (medroxyprogesterone), an intramuscular birth control drug administered by injection every three months. **Pfizer's Depo-SubQ** is a subcutaneous injection version of the drug (injected in skin instead of the muscle), but like Depo-Provera requires administration by a health care professional, and has a boxed warning for risk of bone density loss.

- **Teens** who are unhappy with their **physical appearance** are at much higher risk of **depression** by the time they reach early adulthood, reveals a UK study published online in the *Journal of Epidemiology & Community Health*. The size of the increased risk ranges from 50% to 285%, with boys more likely to experience severe depression than girls.

<https://www.sciencedaily.com/releases/2020/12/201207195131.htm>

Opioid Crisis and Research

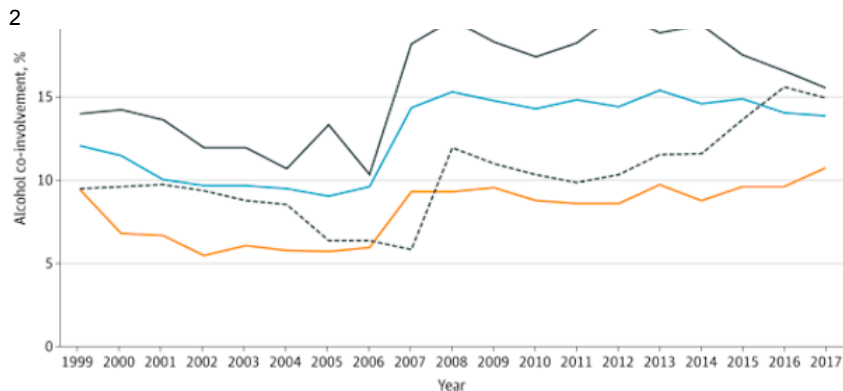
The opioid pandemic has only intensified in the midst of the Covid-19 pandemic. **Drug overdoses** have jumped in many areas compared with previous years, and while 2020 is not over yet, signs point to record-setting levels of fatal overdoses this year. Here are some examples of cities, states, and regions both large and small affected by the crisis in the U.S. and Canada:

- **Virginia:** Drug overdoses are now the state's worst year on record. ([Daily Press](#))
- **Minnesota:** Drug overdoses jumped 30% in the first half of 2020 compared with 2019. ([MSN.com](#))
- **Cook County, Illinois:** Cook County sees record opioid deaths in midst of pandemic. ([NBC Chicago](#))
- **Salt Lake City:** Pandemic within a pandemic data suggests opioid-related overdoses on the rise along Wasatch front. ([KSL.com](#))
- **London, Ontario:** Opioid-related deaths steady, outreach agencies report rise in overdoses in London. ([GlobalNews](#))
- **Central Florida:** Guest commentary on the opioid epidemic in central Florida. ([Orlando Sentinel](#))
- **Lancaster, South Carolina:** South Carolina city ravaged by opioid crisis during pandemic puts naloxone in holiday gift bags. ([WMUR.com](#))
- **Philadelphia:** Overdoses rise among restaurant workers in Philly as pandemic surges. ([Mccall.com](#))
- **Toronto:** October 2020 was the worst month ever for drug overdoses in Toronto. ([Toronto.com](#))

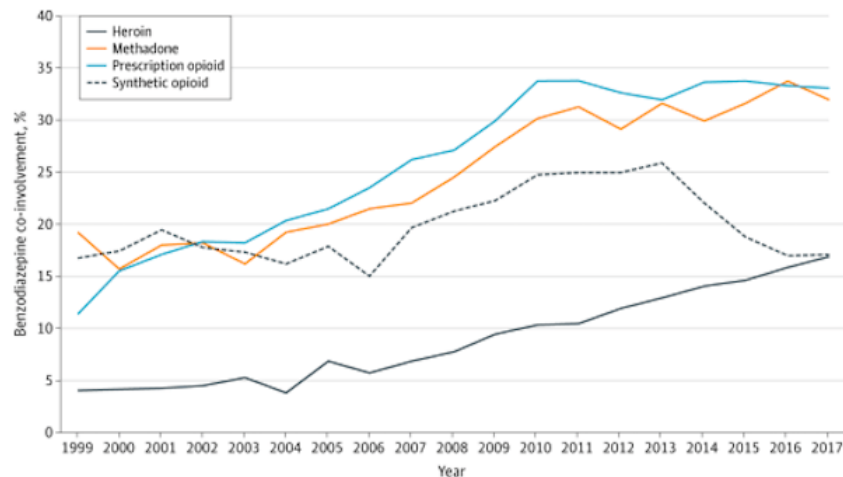
- Boston University researchers studied the co-involvement of **alcohol** and **benzodiazepines** (prescription drug for anxiety or as muscle relaxant) in over 400,000 U.S. **opioid overdose deaths** between 1999 and 2017. This is the first study of its kind to look at each type of opioid, including heroin, methadone, prescription, and synthetic (fentanyl). **Prescription opioids** were more likely to be co-involved with benzos, while **heroin** was the type of opioid most likely to be co-taken with alcohol. Deaths from opioid overdoses involving benzodiazepines increased by more than 10-fold in the time period, and those involving alcohol increased 5.5-fold, reaching 14.7% for alcohol and 21.0% for benzodiazepines in 2017.

Here are the four opioid types along with associated alcohol co-involvement:





Here are the four opioid types along with associated benzo co-involvement:



Source: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764233>

- CDC's Opioid **overdose tip card** with signs and symptoms and what to do if you think someone is overdosing on any kind of opioid:

<https://www.cdc.gov/drugoverdose/pdf/patients/Preventing-an-Opioid-Overdose-Tip-Card-a.pdf>

- **Methadone** is frequently prescribed to treat opioid addiction, but is itself addictive. In October 2019, the methadone [drug label was modified](#) to include a drug interaction warning with muscle relaxants (benzodiazepines).

Read examples of the more than 200 [Methadone reviews](#) by patients.

- University of Pennsylvania researchers suggest a possible **novel treatment** for opioid addiction that doesn't involve an addictive substitute drug. **GLP-1R agonists**, which are FDA-approved for treating **diabetes** and **obesity** (like Victoza/liraglutide or Byetta), have been shown to reduce voluntary drug taking and seeking in preclinical models of cocaine used disorder. Additionally, separate studies conducted on animals have found that GLP-1 receptor agonists can reduce voluntary alcohol drinking.

<https://www.nursing.upenn.edu/live/news/1793-novel-anti-craving-mechanism-discovered-to-treat>

Covid News and Statistics

- In a 17-4 vote, with one abstention, a panel of advisers to the Food and Drug Administration recommended that the **COVID-19 vaccine** developed by **Pfizer and BioNTech** be authorized for emergency use for age 16 and older. Those that voted against recommendation wanted it approved only for age 18 and up, because of lack of test data for younger teenagers. On Friday, the vaccine received **Emergency Use Authorization** from the FDA, and shipment of this **first vaccine** authorized for preventing COVID-19 is now in full swing across the U.S.

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

More on the vaccine approval:

<https://khn.org/morning-breakout/fda-panel-endorses-pfizer-vaccine-for-those-16-and-older/>

- Starting with the elderly and frontline workers, Britain began mass vaccinating its population with Pfizer/BioNtech's new vaccine. Its medicine regulator recommends that those people with a **prior anaphylactic reaction** to a drug or vaccine NOT get this vaccine.

<https://www.nytimes.com/2020/12/11/health/Covid-Pfizer-vaccine-allergies.html>

- The **European Medicines Agency** (EMA), the EU regulatory body in charge of approving COVID-19 vaccines, said it was the victim of a **cyberattack**. Some documents relating to the regulatory submission for Pfizer and BioNtech's COVID-19 vaccine candidate were unlawfully

accessed. Researchers from IBM X-Force warned that threat actors are targeting organizations associated with the COVID-19 vaccine cold-storage supply chain using phishing campaigns.

<https://www.bleepingcomputer.com/news/security/pfizer-covid-19-vaccine-documents-accessed-in-ema-cyberattack/>

- The U.S. Food and Drug Administration (FDA) is informing patients and health care providers that patients may be injured if they wear **face masks** (such as surgical or non-surgical masks and respirators) with **metal parts** and coatings during a Magnetic Resonance Imaging (**MRI**) exam. Metal parts, like nose pieces sometimes called nose clips or wires, nanoparticles (ultrafine particles), or antimicrobial coating that may contain metal (such as silver or copper), may become hot and burn the patient during an MRI.

<https://www.fda.gov/medical-devices/safety-communications/wear-face-masks-no-metal-during-mri-exams-fda-safety-communication>

- University of North Carolina health researchers compared **particle-blocking masks** and showed that some masks were as much as 79 percent effective at blocking particles that could carry the virus. These were masks made of two layers of woven nylon and fit snug against the wearer's face. Unmodified medical procedure masks with ear loops - also known as surgical masks and have the blue and white sides - offered 38.5 percent filtration efficacy, but when the ear loops were tied in a specific way to tighten the fit, the efficacy improved to 60.3 percent.

<https://www.eurekalert.org/multimedia/pub/251456.php>

- Cases continue to spike across the U.S., with a surge in hospitalizations in parts of the country. This chart shows the **number of patients admitted to a U.S. hospital each day** for the last two months, from October 14 through December 11. (October 23 had an anomaly in the data (catch-up numbers of more than 15,000 admissions), so is not included in the chart.) On December 12, **5,444 patients** were admitted to a hospital for Covid treatment in the U.S., contributing to a total of more than **108,000 patients in the hospital** on Saturday, December 12.

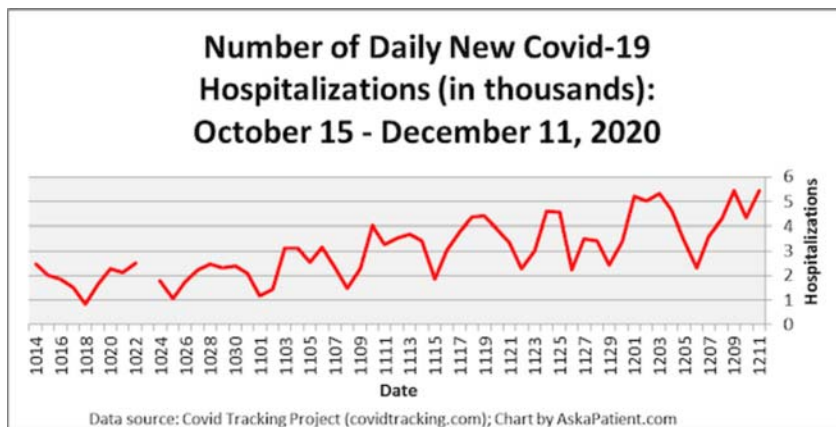


Chart by Ask a Patient using Data Source: [CovidTracking Project](https://covidtracking.com)

Updated Statistics for Sunday, December 13, 2020:

Worldwide totals: 71.83 million cases and over 1.6 million deaths.

United States totals: 16 million cases and more than 297,000 deaths. Daily cases in the U.S. have surged and averaged over 200,000 each day this week, with an all-time high of 231,000 cases recorded in one day on December 11.

India has recorded over 9.8 million cases, but daily case numbers are decreasing to about 32,000 a day down from a peak of close to 96,000 cases in September.

Brazil has the third-highest number of cases globally with over 6.8 million cases, with daily cases increasing, averaging more than 50,000 new cases per day this week.

Source: Johns Hopkins University [Coronavirus Dashboard](https://coronavirus.jhu.edu)

Ask a Patient Weekly Newsletter: December 13, 2020

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[2020-2021 Flu Vaccine Information](#)

[Patient Guide to Coronavirus Information Websites](#)

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Contact with questions, comments, and suggestions: admin@askapatient.com

The *AskaPatient Newsletter* will be on break until the year-end issue.