**February 2019 Newsletter**

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**WHO EXPERTS RECOMMEND RESCHEDULING MARIJUANA**

A World Health Organization committee is calling for marijuana to be removed from the most restrictive international drug category in order to drive more medical use and research. Read more [here](https://www.forbes.com/sites/tomangell/2019/02/01/world-health-organization-recommends-rescheduling-marijuana-under-international-treaties/).

**OPIOIDS STUDY**

The number of people who die each year from an opioid overdose will increase to 81,700 a year by 2025—a 72 percent jump—without more treatment-based interventions, according to a medical journal article released on February 1. Read more [here](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405).

**MEDICAL MARIJUANA USE RISES ALONG WITH PRESCRIPTIONS FOR QUESTIONABLE USES**

Medical marijuana use has risen dramatically across the countrybut so have prescriptions for conditions the substance hasn't been shown to effectively treat, according to a *Health Affairs* study. Read more [here](https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05266).

**WHITE HOUSE RELEASES NATIONAL DRUG CONTROL STRATEGY**

ONDCP recently released the [National Drug Control Strategy](https://www.whitehouse.gov/briefings-statements/white-house-releases-national-drug-control-strategy/). Read more [here](https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf).

**U.S. ATTORNEY SUES TO BLOCK SAFE INJECTION SITE**

A federal prosecutor sued to block a Philadelphia nonprofit from opening the nation's first supervised injection facility. Read more [here](https://www.npr.org/sections/health-shots/2019/02/06/691746907/u-s-prosecutors-sue-to-stop-nation-s-first-supervised-injection-site).

**FDA FINALIZES BUPRENORPHINE GUIDE TO SPUR DEVELOPMENT, COVERAGE**

On February 6, the FDA finalized guidance detailing the types of clinical studies and novel endpoints that can be used to support approval of depot buprenorphine products and how sponsors should design efficacy trials. Read more [here](https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm630847.htm).

**NEW CANNABIS GROUP WILL FOCUS ON LIFTING RESTRICTIONS ON MEDICAL RESEARCH**

Some of the country's biggest cannabis companies have created a new organization to lobby for loosening federal laws, including removing restrictions on medical research. Read more [here](https://nationalcannabisroundtable.org/).

**FDA SENDS WARNING TO OPIOID MAKER**

On February 7, FDA told big drug wholesaler McKesson to tighten its controls over prescription opioids after pain pills were found to have been lost or tampered with before reaching pharmacies. Read more [here](https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm631088.htm).

**E&C REPUBLICANS REQUEST CONTINUATION OF BIPARTISAN WORK TO COMBAT THE OPIOID CRISIS**

On February 11, Energy and Commerce Committee Republican Leader Greg Walden (R-OR) and Subcommittee on Health Republican Leader Michael Burgess, M.D. (R-TX), and Subcommittee on Oversight and Investigations Republican Leader Brett Guthrie (R-KY) sent a [letter](http://r20.rs6.net/tn.jsp?f=001nNXs8njlw91VTQzxspmdZeeg0gaVK_-MXYK-UPG5Pt88Qil7x_JOqwPOzOv1obyITyibjR0Wn6699uN0aq-VHgxuc56vQvQSFrrLJ_Bk92rQqlI0aZkQ4B61Bn_y33pdrTm6KEVZ37b7j5voP63F7aYLHAQx-djqkmFITlgJ7ACO3qEggAW-mzWZBiqgpLYFDgAxtvVc_EVuNBTMofhklrjnB00Uti-gSboKCSGT4V2wN4qfUQqGtyIJqTbly7PV&c=78ulbWJEa4EsXXhKAji0yrkchhbEDPqM5znlg_1vQcPCiIntkaRY4w==&ch=7HfANIb0xD-VLzUs8xhDlnJrbjiXUf_0g-AV18u3zTLhuHdWz4tCbw==) to Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ), Subcommittee on Health Chair Anna Eshoo (D-CA), and Subcommittee on Oversight and Investigations Chair Diana DeGette (R-CO), requesting the committee continue its bipartisan work to help combat the opioid crisis. Read more [here](https://republicans-energycommerce.house.gov/news/ec-republicans-request-continuation-of-bipartisan-work-to-combat-the-opioid-crisis/).

**LAWMAKERS ASK INSURERS TO COVER NON-OPIOID PAIN TREATMENTS**

In a February 12 hearing, lawmakers called for better research into, and insurance coverage for, non-opioid pain management options. Learn more [here](https://www.help.senate.gov/hearings/managing-pain-during-the-opioid-crisis).

**CHINA HOLDS FENTANYL CARDS IN TRADE TALKS**

President Donald Trump hopes trade negotiations between the United States and China will not only reduce the U.S. trade deficit but also cut off the main source of fentanyl shipments. Read more [here](https://www.politico.com/newsletters/morning-trade/2019/02/12/china-holds-fentanyl-card-in-us-trade-talks-509833).

**MEDICARE MONITORING SYSTEM FAILS TO IDENTIFY HIGH-RISK OPIOID PATIENTS**

A new paper from the Journal of the American Medical Association (JAMA) looked at a monitoring system that CMS set up in 2013 requiring Medicare Part D plans to identify patients who were at high risk of prescription opioid addiction and implement interventions, finding that the plans missed the majority of patients with opioid addiction or who overdosed. Read more [here](https://jamanetwork.com/journals/jama/article-abstract/2724180).

**FDA SAFETY PROGRAM FAILED TO RESTRICT ACCESS TO DEADLY OPIOIDS**

The FDA and opioid manufacturers allowed potentially deadly prescriptions to go through when they dropped the ball on monitoring a small class of highly potent opioids, according to a JAMA study published on Feb. 19. Read more [here](https://jamanetwork.com/journals/jama/article-abstract/2725233).

**SUPREME COURT REFUSES TO BLOCK GENERIC SUBOXONE**

U.S. Chief Justice John Roberts cleared the way for Dr. Reddy’s Laboratories Ltd. to resume selling a generic version of Indivior Plc’s opioid addiction treatment Suboxone Film. Read more [here](https://www.reuters.com/article/us-usa-court-indivior/us-top-court-rejects-bid-to-block-indivior-opioid-drug-copycat-idUSKCN1Q8221).

**FDA ERRED IN OPIOID APPROVAL EX-COMMISSIONER SAYS**

During a 60 Minutes interview, former FDA commissioner David Kessler said the FDA shouldn’t have approved opioids for long-term use and never should have allowed OxyContin and other drugs like it to be broadly marketed for chronic pain patients. Read more [here](https://www.cbsnews.com/news/former-fda-commissioner-says-agency-erred-in-allowing-drug-companies-to-promote-opioids-for-long-term-use-60-minutes/).

**FDA TAKES FRESH LOOK AT OPIOIDS EFFECTIVENESS FOR CHRONIC PAIN**

The FDA will soon require drug companies to study whether prescription opioids already on the market are effective in managing chronic pain. Read more [here](https://www.washingtonpost.com/national/health-science/fda-takes-fresh-look-at-whether-opioids-are-effective-for-chronic-pain/2019/02/25/227a5fe6-3917-11e9-a06c-3ec8ed509d15_story.html?noredirect=on&utm_term=.fc22cc5c76db).

**UTAH GOV. CALLS FOR EASING MARIJUANA RESEARCH RESTRICTIONS**

**On February 22** Utah Gov. Gary Herbert said that federal officials should remove marijuana from the list of Schedule I drugs so it can be studied for medicinal purposes — and, if proven effective, prescribed to patients for various ailments. Watch clip [here](https://www.c-span.org/video/?c4781743/utah-governor-discusses-medical-marijuana).

**UPDATED OPIOID PRESCRIPTION TRACKING TOOL INCLUDES MEDICAID DATA**

CMS has released an updated version of its opioid mapping tool, including for the first-time data on Medicaid prescription rates. Read more [here](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html).

**NY TIMES EXPLORES CBD OIL**

The New York Times explores the popularity of CBD oil, despite little research on its long-term effects. Read more [here](https://www.nytimes.com/2019/02/25/well/live/cbd-cannabidiol-marijuana-medical-treatment-therapy.html).

**FDA WANTS GUIDANCE FROM LAWMAKERS ON CBD REGS**

The FDA is interested in talking to Congress about alternative approaches for overseeing cannabidiol, FDA Commissioner Scott Gottlieb said during remarks February 26 at the National Association of State Departments of Agriculture's annual policy meeting. Read more [here](https://www.marijuanamoment.net/fda-is-exploring-alternative-approaches-to-cbd-regulation-commissioner-says/).

**AZAR LAUDS PROGRESS ON DRUG PRICES, OPIOID ADDICTION IN ADDRESS TO WORKERS**

HHS Secretary Alex Azar lauded the agency's employees for a "remarkable" 2018 in an address at HHS headquarters on February 22. In particular, Azar cited progress on reducing drug prices and combating the opioid crisis as top achievements. Read more [here](https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/2019-state-of-the-department-address.html).

**FDA OUTLINES OPIOID 2019 PLANS**

On February 26, the FDA outlined steps to build on 2018 plans, which include mandating new short-duration packaging for certain drugs, developing disposal techniques such as mail back pouches for unused drugs, expanding the use of medication-assisted treatment and naloxone, boosting research into non-addictive pain treatments and sharing data with U.S. Customs and Border Protection to crack down on illicit drug flows to the country. Read more [here](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632067.htm).

**CONTEST SEEKS SOLUTIONS FOR CURBING ILLICIT OPIOIDS**

The Trump administration is launching a $1.55 million competition to solicit ideas for curbing illicit opioids from entering the United States. The submission deadline for the Opioid Detection Challenge is April 24. Read more [here](https://www.opioiddetectionchallenge.com/).

**GOTTLIEB PLANS CBD MEETING TO CLEAR UP REGULATORY CONFUSION**

FDA Commissioner Scott Gottlieb on February 27 said the agency will hold a public meeting in April on regulation of cannabidiol products and emphasized that he wants to balancedemand in the food and supplement sectors with a desire to protect pharmaceutical industry research incentives. More [here](https://appropriations.house.gov/legislation/hearings/food-and-drug-administration-status-of-operations).

**BOOKER REINTRODUCES MARIJUANA JUSTICE ACT**

On February 28, Senator Cory Booker (D-NJ), Rep. Barbara Lee (D-CA), and Rep. Ro Khanna (D-CA) reintroduced the Marijuana Justice Act to end the federal prohibition on marijuana. Read more [here](https://www.booker.senate.gov/?p=press_release&id=892).

**APPROPRIATORS SEE MORE WORK AHEAD ON OPIOIDS**

On February 28, the Senate Labor-HHS Appropriations Subcommittee held a hearing on the opioid misuse and overdose epidemic titled, “*Review of the Opioid Epidemic in America*.” Read more [here](https://www.appropriations.senate.gov/hearings/review-of-the-opioid-epidemic-in-america).