**April 2019 Newsletter**

**Prepared by Van Scoyoc Associates**

**CHINA AGREES TO TIGHTEN CURBS ON FENTANYL**

China announced tightened curbs on the painkiller fentanyl after the U.S. blamed Chinese imports for fueling the opioid crisis. Read more [here](https://www.scmp.com/news/china/diplomacy/article/3004136/china-agrees-tighten-curbs-fentanyl-after-us-calls-action-over).

**FDA HEARING ON CANNABIS-RELATED PRODUCTS**

The Food and Drug Administration set a public hearing to discuss safety and marketing for cannabis and cannabis-derived products for May 31 from 8 a.m. to 6 p.m. Submit requests to make oral presentations and comments at the public hearing by May 10, 2019. Read more [here](https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-06436.pdf).

**FDA COMMISSIONER STATEMENT ON NEW STEPS TO ADVANCE EVALUATION FOR CANNABIS-CONTAINING AND DERIVED PRODUCTS**

On April 2, FDA Commissioner Scott Gottlieb made a statement on new steps FDA is taking to advance the agency’s continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products. Read more [here](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635048.htm?utm_campaign=040219_Statement_FDA%20announces%20new%20steps%20on%20cannabis-related%20products&utm_medium=email&utm_source=Eloqua).

**BILL TO AUTHORIZE SANCTIONS ON DRUG MAKERS IN CHINA INTRODUCED**

A bipartisan group of senators including Senate Democratic leader Chuck Schumer introduced a bill that would authorize sanctions on drug makers in China who knowingly provide synthetic opioids to traffickers or groups that bring them into the U.S., as well as financial institutions that help them. Read more [here](https://www.schumer.senate.gov/newsroom/press-releases/schumer-reveals-chinese-traffickers-opioid-assembly-line-relies-on-jfks-mail-processing-facility-and-usps-to-keep-rolling-illicit-drugs-that-escape-detection-at-jfk-end-up-on-the-streets-of-nyc_li-senator-pushes-new--needed-fed-funds-to-add-detectors-other-protections-at-jfk-that-put-a-wrench-in-chinas-supply-chain--complement-new-sanctions).

**FDA REVAMPS OPIOID LABELING TO ADDRESS TAPERING DOSAGES**

On April 9, the FDA announced new requirements for opioid labels to help health care providers safely decrease the dose in patients who are physically dependent on the pain medications. Read more [here](https://www.fda.gov/Drugs/DrugSafety/ucm635038.htm).

**HOUSE LAWMAKERS UNVEIL BILL TARGETING CHINESE FENTANYL TRAFFICKING**

Reps. Vern Buchanan (R-FL) and Seth Moulton (D-MA) introduced a bill to imposes sanctions on China-based drug manufacturers that knowingly ship synthetic opioids to drug traffickers and authorizes $500 million for law enforcement to combat international opioid trafficking. Read more [here](https://buchanan.house.gov/media-center/press-releases/buchanan-moulton-introduce-bill-combat-chinese-opioids).

**OPIOIDS AND CANCER TREATMENT**

The Centers for Disease Control and Prevention’s 2016 guidelines on opioid prescriptions are not intended to deny clinically appropriate opioid therapy to any patients who suffer acute or chronic pain from conditions such as cancer and sickle cell disease, the agency said in a letter released on April 10. Read more [here](https://www.nccn.org/professionals/meetings/oncology_policy_program/pdf/2019_CDC_letter_to_NCCN_ASCO_ASH.pdf).

**NIH GRANTS FOR ADDICTION, PREVENTION AWARDED**

On April 18, HHS awarded $350 million in grants to institutions in Kentucky, Massachusetts, New York and Ohio to fund a pilot program that seeks to integrate addiction prevention and treatment into primary care settings, mental health services and the criminal justice system in targeted communities. Read more [here](https://www.nih.gov/news-events/news-releases/nih-funds-study-four-states-reduce-opioid-related-deaths-40-percent-over-three-years).

**GENERIC NALOXONE NASAL SPRAY GETS APPROVAL**

On April 19, FDA granted approval to Teva's generic naloxone nasal spray for reversing opioid overdoses, making it the first generic available for use by individuals without medical training. Read more [here](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636333.htm).

**PRESIDENT, FIRST LADY ADDRESS RX DRUG ABUSE & HEROIN SUMMIT**

Speaking at the Rx Drug Abuse & Heroin Summit in Atlanta, the president suggested that his policies are working to end the opioid crisis. Read more [here](https://markets.businessinsider.com/news/stocks/president-trump-first-lady-address-rx-drug-abuse-heroin-summit-1028136696).

**CDC: MISINTERPRETING OPIOID GUIDELINES PUT PATIENTS AT RISK**

In an article published on April 24 in the *New England Journal of Medicine*, CDC officials say any misinterpretation of the agency's recommendations for safe opioid prescribing could put people at risk and make it difficult for chronic pain and cancer patients to get their medications. Read more [here](https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html).

**FDA SCHEDULES MEETING TO GET FEEDBACK ON HIGHER-STRENGTH OPIOIDS**

The FDA will hold a public meeting on June 11 and 12 to discuss safety concerns raised by the prescribing and use of more powerful opioids. Read more [here](https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-public-meeting-discuss-safety-and-utility-higher-dose-opioid-analgesics).

**OPIOID PRICES AND OVERDOSE DEATHS**

The gradual decline in the cost of opioids fueled the rise in overdose deaths in the U.S., according to a report released by the White House on April 29. Read more [here](https://www.whitehouse.gov/wp-content/uploads/2019/04/The-Role-of-Opioid-Prices-in-the-Evolving-Opioid-Crisis.pdf).

**HOUSE LABOR HHS BILL APPROVED BY SUBCOMMITTEE**

The House Labor, Health and Human Services Appropriations Subcommittee approved their Fiscal 2020 bill on April 30. Read more [here](https://appropriations.house.gov/news/press-releases/appropriations-subcommittee-approves-fiscal-year-2020-labor-hhs-education).