

July 2017 Newsletter
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OPIOID COMMISSION INTERIM REPORT

On July 31, the President's Commission on Combating Drug Addiction and the Opioid Crisis released its [interim report](#). Comments may be submitted on the interim report to commission@ondcp.eop.gov. The final report is due out by October 1, 2017. In the report, the Commission urged a "national emergency" declaration and more federal funding to address the crisis. Read more [here](#).

HHS ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE

On August 3, the Senate approved the nomination of Dr. Elinore McCance-Katz to be HHS Assistant Secretary for Mental Health and Substance Use. The approval by unanimous consent came after a [hearing](#) on the nominations at the Senate Health, Education, Labor and Pensions (HELP) Committee on August 1 and Committee approval of the nominations by voice vote on August 2.

HOUSE JUDICIARY CONSIDERS SYNTHETIC ANALOGUES ACT

On July 12, the House Judiciary Committee passed by voice vote H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues Act, as amended. Rep. Goodlatte's substitute amendment adds a new subsection to the federal statute governing registration, provides an exemption for researchers of schedule A substances, and directs the DEA to register researchers in a timely fashion. A webcast and a copy of the legislation can be found [here](#).

COLLINS AND VOLKOW HIGHLIGHT NIH EFFORTS TO ADDRESS OPIOID EPIDEMIC

On July 27, NIH Director Francis Collins, MD, PhD, and National Institute on Drug Abuse (NIDA) Director Nora Volkow, MD [authored](#) a special report published in the New England Journal of Medicine on how the NIH is working with other stakeholders to address the opioid epidemic.

HOUSE COMMITTEE INCLUDES INCREASE FOR NIH

On July 19, the House Appropriations Committee [approved](#) their fiscal 2018 Labor, Health and Human Services bill. The bill provides a total of \$35.2 billion for NIH, an increase of \$1.1 billion above the fiscal year 2017 enacted level and \$8.6 billion above the President's budget request. The bill includes \$1.107 billion for the National Institute on Drug Abuse, a \$16.6 million or 1.5% increase over FY17.

OPIOID PRESCRIPTIONS FALL, BUT PROBLEMS PERSIST

The number of opioid prescriptions in the U.S. peaked in 2010, but according to new [CDC data](#) overdose death rates linked to prescription painkillers continue to rise. Read more [here](#).

FDA IMPLEMENTATION PLANS FOR 21ST CENTURY CURES ACT

On July 7th, FDA Commissioner Scott Gottlieb, M.D. posted a [blog](#) detailing the agency's plans to implement the [21st Century Cures Act](#), as well as updates on individual initiatives within the bill.

STUDY: ADDICTION PATIENTS' RISK OF DEATH RISES WHEN BUPRENORPHINE STOPPED

The mortality rate for patients taking buprenorphine was nearly thirty times lower than when patients stopped taking this medication for a period of time. The data from a seven-year study of more than 700 patients in France was published in the [Annals of Family Medicine's July/August issue](#).

FDA REQUIREMENTS FOR IMMEDIATE-RELEASE OPIOIDS

On July 10, the FDA required that all immediate-release opioids come under a special safety regime known as a risk evaluation and mitigation strategy (REMS). As part of the REMS expansion, FDA is also updating its blueprint for current voluntary training programs, so prescribers are briefed on non-drug and drug options to manage pain, as well as non-opioid pain medications. In addition, training options will need to be available for other providers, including nurses and pharmacists who work with opioids. Read more [here](#).

OPIOID BUSTS

On July 13, the Justice Department launched a crackdown that in large part focuses on fraudulent opioid treatment programs. Attorney General Jeff Sessions described the effort as the largest of its kind in U.S. history, charging 412 people, including 56 physicians, with defrauding the federal government of \$1.3 billion. Read more [here](#).

NATIONAL ACADEMIES REPORT ON OPIOID CRISIS

On July 13, the National Academies Sciences, Engineering, and Medicine issued a report requested by the FDA detailing an expert committee's findings on how the country should combat the opioid epidemic. Read the full report [here](#).

OIG REPORT ON OPIOID USE

On July 13, a report on opioid use was released by the Office of Inspector General (OIG) for the Department of Health and Human Services. According to the [report](#), one-third of beneficiaries in Medicare Part D received opioids in 2016, with one in 10 receiving opioids on a regular basis. Overall, they said about 90,000 Part D patients are "at serious risk of opioid misuse or overdose" because they received extreme amounts of opioids or appeared to be doctor-shopping for more drugs.

FIGHTING THE OPIOID CRISIS EVENT

On July 13, CQ Roll Call hosted an event sponsored by Cigna entitled, "Fighting the Opioid Crisis," focused on the opioid epidemic facing the United States with a special emphasis on veterans. Members of Congress and stakeholders were asked to consider how the federal government can address the growing opioid crisis, including for the veteran community. A webcast of the event can be seen [here](#).

HEARING ON OPIOID CRISIS IN THE STATES

On July 12, the House Energy and Commerce Committee Oversight Subcommittee held a hearing entitled, "Combating the Opioid Crisis: Battles in the States." Full witness statements are available [here](#). Some of the key issues raised at the hearing included naloxone, Medication Assisted Treatment (MAT), 42 CFR Part II rules and the Affordable Care Act (ACA).

ONDCP REAUTHORIZATION HEARING

On July 26, the House Oversight and Government Reform Committee held a hearing on reauthorization of the White House Office of National Drug Control Policy (ONDCP). Full witness testimony is available [here](#).

MANDATORY EDUCATION FOR PRESCRIBERS OF OPIOIDS

On July 14th Senator Edward Markey (D-MA) introduced legislation with Senators Richard Blumenthal (D-CT), Elizabeth Warren (D-MA), Dianne Feinstein (D-CA), and Joe Manchin (D-WV) that requires any prescriber of opioid medication to undergo mandatory education on safe prescribing practices. Specifically, the Safe Prescribing of Controlled Substances Act (S.1554) requires that all prescribers that

are applying for a federal license to prescribe controlled substances, such as prescription painkillers, complete mandatory education that will help encourage responsible prescribing practices. Read more [here](#).

CMS INNOVATION CENTER ANNOUNCEMENT

The week of July 17th, the CMS Innovation Center announced they are developing a new payment model for Medicare, Medicaid, and CHIP for behavioral health services, including substance use disorders. The agency will host an industry meeting on September 8th in Baltimore to garner input. The announcement can be found [here](#).

PATIENT PRIVACY LEGISLATION

On August 3, the Senate approved an amended version of [Jessie's Law](#) (S. 581) that directs the Department of Health and Human Services to develop best practices for sharing substance use disorder patient history if the patient requests that it be displayed.