June 2017 Newsletter Prepared by Van Scoyoc Associates

COLLINS TO STAY AT NIH

On June 6 the White House announced that they have decided to keep Francis Collins as director of the NIH. As you know, there has long been speculation about whether Trump would keep Collins on to oversee the medical research agency. Rep. Andy Harris (R-MD) had also been in the running to be NIH chief. Read more here.

NIH GRANT SUPPORT INDEX

On June 8, NIH <u>announced</u> that after soliciting feedback over the last month, they will not be moving forward with the "Grant Support Index" point system it announced on May 2. NIH will instead take a bolder, more focused approach to increase the number of NIH-funded early-stage and mid-career investigators and stabilize the career trajectory of researchers; an effort they are calling the <u>Next Generation Researchers Initiative</u>. Feedback can be provided on this topic through <u>Dr. Michael Lauer's Open Mike blog</u>, or by sending an email to <u>publicinput@od.nih.gov</u>.

WHITE HOUSE OPIOID COMMISSION

On June 16, the White House Opioid Commission held their first meeting with stakeholders to discuss recommendations in addressing the opioid epidemic. An <u>executive order</u> that established the commission had set a 90-day deadline for the completion of a preliminary report meant to outline federal strategies to curb the epidemic, but no report was filed by the due date and a commission teleconference originally scheduled for June 26 was <u>rescheduled</u> for July 17. The commission has not changed its goal of submitting a final report to Trump by Oct. 1. Read more here.

OPIOID COMMISSION MAY PROPOSE CHANGING HIPPA RULES

On June 12 Governor Chris Christie said the presidential opioid commission may propose changing patient privacy regulations so there are clear exemptions for overdose cases. Christie said the commission could recommend a retooling of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, so physicians can notify close relatives when a patient's overdose is reversed with the drug Narcan. Read more here.

MEDICAL MARIJUANA BILL REINTRODUCED

On June 15, Senators Kirsten Gillibrand (D-NY), Cory Booker (D-NJ), Rand Paul (R-KY), Lisa Murkowski (R-AK), Al Franken (D-MN), and Mike Lee (R-UT) <u>reintroduced</u> the Compassionate Access, Research Expansion and Respect States (CARERS) Act that would allow Americans to access medical marijuana in states where it is legal without fear of federal prosecution. The CARERS Act bill text can be viewed <u>here</u> and a one-pager can be viewed <u>here</u>.

SYNTHETIC ANALOGUES LEGISLATION

On June 27 the House Judiciary Subcommittee on Crime, Terrorism, Homeland Security, and Investigations held a hearing on <u>H.R. 2851</u>, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act. A webcast of the hearing and opening statements can be found <u>here</u>. CPDD sent a letter expressing the organization's views on H.R. 2851 to all members of the House Judiciary Committee ahead of the hearing. Similar <u>legislation</u> has been introduced in the Senate.

SENATE DELAYS VOTE ON HEALTH CARE REPEAL BILL

On June 27, Senate leaders announced they were delaying a vote on their repeal and replace discussion bill, the <u>Better Care Reconciliation Act of 2017</u> (BCRA), until after the July 4th recess to allow time for further negotiations on the package. On June 28 it was announced that \$45 billion to address the opioid misuse and overdose epidemic would be added to the package in an attempt to get members like Portman (R-OH) and Capito (R-WV) on board. Read more here.

PRICE TESTIFIES ON FISCAL YEAR 2018 HHS BUDGET

June 15, HHS Secretary Tom Price testified before the Senate Labor HHS Appropriations Subcommittee on the Department of Health and Human Services fiscal 2018 budget request. Secretary Price's statement and a webcast of the hearing can be found here

SENATE NATIONAL INSTITUTES OF HEALTH BUDGET HEARING

On June 22, the Senate Labor, Health and Human Services Appropriations Subcommittee held a hearing to review the FY18 budget request from the National Institutes of Health. NIH Director Dr. Francis Collins testified along with five other institute directors, including NIDA Director Dr. Nora Volkow. Opening statements and a webcast of the hearing can be found here.

ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE

President Trump sent his nomination for assistant secretary for mental health to the Senate. Dr. Elinore McCance-Katz is expected to get a hearing in the HELP Committee sometime after lawmakers return from the July Fourth recess. The administration announced its intent to nominate Katz in April.

PAINKILLER PULLED FROM MARKET

On June 8 the FDA told Endo Pharmaceuticals to pull its painkiller Opana ER from the market — the first time the agency has taken such an action because of an opioid's potential for abuse. An agency review of postmarket surveillance data found "a significant shift" in the way the reformulated drug was being abused — from snorting to crushing and injecting it. The decision follows an advisory board vote in March that the drug's benefits no longer outweigh its risks. Read FDA Commissioner Scott Gottlieb announcement here.

FDA PUBLIC MEETING AND ISSUE PAPER ON OPIOID DETERRENCE

FDA Commissioner Scott Gottlieb <u>announced</u> a July 10-11 public meeting to help assess opioid drugs with abuse-deterrent properties. FDA released a related <u>issues paper</u>.