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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

April 29, 2015

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?"

On Friday, May 1st, at 9:00 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing titled "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?" The hearing will focus on federal efforts to address the opioid abuse epidemic, and it is the third in a series.

I. BACKGROUND

The Centers for Disease Control and Prevention (CDC) has called prescription drug abuse in the United States an epidemic and has found drug overdose to be the leading cause of injury death in the United States.[1] Between 1999 and 2010, the death rate from prescription opioids more than quadrupled, and in 2010 alone, prescription opioids were involved in 16,651 overdose deaths.[2] In 2013, over 50% of all drug overdose deaths were related to prescription pharmaceuticals. More than 70% of these overdoses involved opioid pain relievers.[3]

The rate of heroin overdoses has also increased dramatically in recent years. In 2010, approximately 3,000 drug-poisoning deaths were connected to heroin. In 2013, the number

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[1] Office of National Drug Control Policy, *Prescription Drug Abuse* (online at www.whitehouse.gov/ondcp/prescription-drug-abuse) (accessed Mar. 17, 2015).

[2] Nora D. Volkow et. al., *Medication-Assisted Therapies – Tackling the Opioid Overdose Epidemic,* New England Journal of Medicine (May 29, 2014).

[3] Centers for Disease Control and Prevention, *Prescription Drug Overdose in the United States: Fact Sheet* (Mar. 2, 2015).

jumped to a total of 8,000 overdose deaths.[4] Some evidence suggests that individuals switch to heroin when prescription drugs are harder to obtain, due to cost or limited supply. For example, a 2012 New England Journal of Medicine study found that heroin use nearly doubled after the introduction of an abuse-deterrent formulation of Oxycontin.[5]

Increased opioid consumption over the past few decades has been driven largely by its greater use by patients for chronic non-cancer pain. The Substance Abuse and Mental Health Services Administration (SAMHSA) found that between 2000 and 2010, there was a fourfold increase in the prescribing of opioids for treating pain.[6] Notwithstanding these increases, there is limited scientific evidence supporting the safety and efficacy of opioids for chronic non-cancer pain.[7]

The opioid abuse epidemic is also having downstream public health consequences. According to the CDC, there was a 150% increase in reports of hepatitis C between 2010 and 2013, which is believed to be attributable to injectable drug use. The opioid epidemic has also been linked to a recent outbreak of HIV in Indiana. The CDC has issued an advisory to health departments to alert them of the possibility of HIV outbreaks and to provide guidance to assist in the identification and prevention of such outbreaks.[8]

The Subcommittee held hearings on March 26, 2015, at which state and local experts offered their perspectives on the opioid epidemic, and on April 23, 2015, at which medical experts offered their perspectives on opioid abuse treatment and prevention.[9] At both hearings, witnesses offered the consensus view that the most effective treatment to combat opioid addiction is a combination of medication-assisted treatment (MAT) and behavioral treatment (e.g. counseling and other supportive services). They also agreed that serious impediments to widespread access to treatment persist, including a shortage of substance abuse treatment

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[4] National Institute on Drug Abuse, *Overdose Death Rates* (online at www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates) (accessed Apr. 24, 2015).

[5] Thomas J. Cicero, Matthew S. Ellis, and Hilary L. Surrat, *Effect of Abuse-Deterrent Formulation of OxyContin,* New England Journal of Medicine (July 2012).

[6] Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Prevention Toolkit* (2014).

[8] Andrew Kolodny et. al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction,* Annual Review of Public Health (Jan. 12, 2015); Gary M. Franklin, *Opioids for Chronic Noncancer Pain: A Position Paper of the American Academy of Neurology,* Neurology (Sept. 30, 2014).

[8] Centers for Disease Control, *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs* (Apr. 24, 2015) (online at emergency.cdc.gov/han/han00377.asp).

[9] House Committee on Energy and Commerce, *Hearing on Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives*, 114th Cong. (Mar. 26, 2015); House Committee on Energy and Commerce, *Hearing on Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives*, 114th Cong. (Apr. 23, 2014).

providers, a shortage of treatment beds, high costs, and difficulty getting insurers to cover behavioral health treatment services. Additional information relating to these hearings is available online here and here.

II. FEDERAL RESPONSE TO PRESCRIPTION DRUG AND HEROIN ABUSE

The Department of Health and Human Services is leading the federal response to the opioid abuse epidemic. In March of 2015, the Secretary of Health and Human Services announced an initiative to combat the opioid abuse epidemic. This new initiative focuses broadly on three areas: 1) opioid prescribing practices; 2) the expanded use of naloxone to treat opioid overdoses; and 3) expanded use of MATs to treat opioid abuse disorders.[10] Additional detail on HHS's new initiative as well as other federal programs to address the opioid abuse epidemic are provided below:

Substance Abuse and Mental Health Services Administration (SAMHSA): The Secretary's opioid abuse initiative proposes increased SAMHSA funding for the expanded use of naloxone. Currently, states may use some of their substance abuse block grant funds to purchase naloxone and provide training on its use. The President's FY 2016 budget proposes $12 million in SAMHSA grants to states to purchase naloxone, equip first responders in high-risk communities, and provide education.

The Secretary's opioid abuse initiative also proposes expanding SAMHSA support for MATs. In FY 2015, SAMHSA will provide $12 million to grantees in 39 states through a demonstration program to expand treatment services for opioid dependence. Grantees will provide accessible, effective, comprehensive, coordinated and evidence-based medication-assisted treatment and recovery support services including the use of methadone, buprenorphine, and naltrexone. The FY 2016 President's Budget proposes an additional $13 million expansion of this program to increase the number of states that would receive targeted funding.

SAMHSA administers a number of additional grant programs to address prescription drug and heroin abuse. Through the Substance Abuse Prevention and Treatment Block Grant, states can obtain funding for overdose prevention education and training.[11] The Strategic Prevention Framework (SPF) State Incentive Grant Program provides funding to grantees to prevent prescription drug misuse and abuse. The President's FY2016 budget requests an increase of $10 million to fund the SPF Prescription Drugs (SPF-Rx) program, which would

[10] Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* (Mar. 26, 2015).

[11] Senate Caucus on International Narcotics Control, Testimony of H. Westley Clark, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse* 113th Cong. (Mar. 26, 2014).

provide funds to states to use data from state prescription drug monitoring programs (PDMPs) to develop targeted prevention programs.[12]

In conjunction with the Drug Enforcement Agency (DEA), SAMHSA is also involved in the regulation of methadone clinics and licensure of physicians to dispense buprenorphine.

Centers for Disease Control and Prevention (CDC): The Secretary's opioid abuse initiative also proposes increasing CDC funding to address the epidemic. CDC received $20 million in FY2015 and has launched the Prescription Drug Overdose (PDO) Prevention for States program, which provides grants to states to expand state-level interventions focused on improving opioid prescribing practices and enhancing state PDMPs.[13] The President's FY 2016 budget requests an additional increase of $48 million to expand the PDO Prevention program to all 50 states, as well as fund monitoring and evaluation efforts.[14] To improve clinical decision-making and reduce inappropriate prescribing, the CDC is also developing guidelines for opioid prescribing for chronic pain.[15]

The Office of National Drug Control Policy (ONDCP)*:* ONDCP coordinates drug-control activities and related funding across the federal government. In 2011, ONDCP developed the nation's first Prescription Drug Abuse Prevention Action Plan, which called for action in four areas: education for the general population and medical practitioners; monitoring through state prescription drug monitoring programs; proper medication disposal; and efforts to eliminate improper prescribing, illicit diversion, and unscrupulous pain management clinics.[16]

The National Institute on Drug Abuse (NIDA)*:* NIDA is currently supporting 90 projects related to MAT, including research into the development of new pharmacological therapies to treat opioid use disorders, incorporating MAT into comprehensive addiction treatment services, utilizing MAT within the criminal justice system and its impact on retention in treatment and recidivism, and recovery outcomes for extended-release naltrexone versus

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[12] Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *FY2016 Justification of Estimates for Appropriations Committees* (online at www.samhsa.gov/sites/default/files/samhsa-fy2016-congressional-justification.pdf).

[13] Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* (Mar. 26, 2015).

[14] Department of Health and Human Services, Centers for Disease Control and Prevention, *FY 2016 Justification of Estimates for Appropriation Committees* (online at www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2016_CDC_CJ_FINAL.pdf).

[15] *Id.*

[16] Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (Apr. 19, 2011) (online at www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf).

buprenorphine for opioid treatment.[17] NIDA is also conducting research into the efficacy of prescribing take-home naloxone for individuals at a high risk of opioid overdose.

The Centers for Medicare & Medicaid Services (CMS): CMS has taken steps to combat prescription drug abuse by strengthening oversight of drug utilization in the Medicare Part D program. The agency has implemented the Medicare Part D Overutilization Monitoring System, in which CMS analyzes prescription drug data and provides quarterly reports to plan sponsors on beneficiaries with potential opioid overuse issues; plan sponsors are required to respond within 30 days. Furthermore, it has adopted an HHS-OIG recommendation to require that all prescribers of Part D drugs enroll in Medicare. Finally, it has strengthened the agency's authorities to permit revocation of Medicare enrollment for abusive prescribing practices and patterns, or based upon a suspension or revocation of the prescriber's DEA certificate or state authority to prescribe drugs.[18]

The Food and Drug Administration (FDA): FDA has taken a number of actions to address the prescription opioid abuse epidemic, including: 1) encouraging the development of medications to treat opioid abuse, such as buprenorphine and naloxone; 2) encouraging development of abuse-deterrent formulations of opioid medications; and 3) requiring manufacturers to offer education to physicians on the proper prescribing and safe use of opioid medications through the risk evaluation and mitigation strategy (REMS) requirement for extended-release and long-acting opioids.[19]

III. THE AFFORDABLE CARE ACT (ACA) AND PARITY

According to the Department of Health and Human Services, since the ACA's coverage provisions have taken effect, approximately 16.4 million uninsured people have gained health insurance coverage.[20] The ACA expands access to affordable care and treatment for individuals fighting substance abuse disorders primarily through the provision of subsidies on the state and federal healthcare exchanges, allowing children to remain on their parents' health insurance until the age of 26, and Medicaid expansion. The ACA also improves coverage for treatment of substance abuse disorders by requiring all non-grandfathered plans in the individual and small group markets to offer mental health and substance abuse disorder benefits through the Essential Health Benefits package.

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[17] National Institute for Drug Abuse, *NIDA Research on Medication-Assisted Treatment (MAT)* (Apr. 20, 2015).

[18] Center for Medicare and Medicaid Services, *CMS Strategy to Combat Medicare Part D Prescription Drug Fraud Abuse* (online at www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-01-06-2.html) (accessed Apr. 27, 2015).

[19] Food and Drug Administration, *FDA Commissioner Margaret A. Hamburg Statement on Prescription Opioid Abuse* (Apr. 3, 2014).

[20] Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Health Insurance Coverage and the Affordable Care Act* (Mar. 16, 2015).

The ACA extends the reach of the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. MHPAEA prohibited large group insurance plans offering coverage for mental health or substance-use disorders from imposing treatment limitations and financial requirements that are more restrictive than the corresponding requirements applied to medical benefits under the plan. Under the ACA, parity was extended further, across plans in the individual and small group market, as well as to Medicaid Alternative Benefit plans for the Medicaid expansion population.[21] The final regulation implementing MHPAEA in individual and group health plans became effective January 13, 2014, and generally applies to plan years beginning on or after July 1, 2014.[22] Earlier this month, HHS promulgated a proposed rule applying parity requirements to Medicaid Alternative Benefit Plans as well as the Children's Health Insurance Program, and Medicaid managed care plans.[23]

V. WITNESSES

The following witnesses have been invited to testify:

Mr. Michael Botticelli
Acting Director
Office of National Drug Control Policy

Dr. Richard Frank
Assistant Secretary for Planning and Evaluation
Department of Health and Human Services

Dr. Debra Houry
Director
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Nora D. Volkow
Director
National Institute on Drug Abuse
National Institutes of Health

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[21] Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Affordable Care Act Expands Mental Health and Substance Use Disorder Benefits and Federal Parity Protections for 62 Million Americans* (Feb. 20, 2013).

[22] Centers for Medicare and Medicaid Services, *The Mental Health Parity and Addiction Equity Act* (accessed Mar. 19, 2015).

[23] Department of Health and Human Services, *Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance program (CHIP), and Alternative Benefit Plans* (Apr. 10, 2015).

Dr. Douglas Throckmorton
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
Food and Drug Administration

Dr. Pam Hyde
Administrator
Substance Abuse and Mental Health Services Administration

Dr. Patrick Conway
Deputy Administrator for Innovation & Quality
Centers for Medicare and Medicaid Services