U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

April 21, 2015

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing on "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

On Thursday, April 23, 2015, at 10:15 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives." The purpose of this hearing is to solicit insights and findings, drawn from clinical practice and research—as well as constructive policy recommendations—from some of the nation's foremost professional and academic experts on opioid abuse. Subcommittee members will hear testimony on treatment options currently available as well as new and emerging evidence-based practices supporting individuals living with opioid abuse and addiction.

WITNESSES

- Robert L. DuPont MD, President, Institute For Behavior and Health;
- Marvin D. Seppala, MD, Chief Medical Officer, Hazelden Betty Ford Foundation;
- Laurence M. Westreich, MD, President, American Academy of Addiction Psychiatry;
- Anna Lembke, MD, Assistant Professor of Psychiatry and Behavioral Sciences, Stanford University Medical Center, Psychiatry Department;
- Adam Bisaga, MD, Columbia University Medical Center, NYS Psychiatric Institute; and
- Patrice Harris, MD, American Medical Association

BACKGROUND

This hearing follows up on the March 26, 2015 Subcommittee hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives." At that hearing, the Subcommittee heard from a panel of witnesses offering a "boots on the ground"

perspective addressing the opioid abuse epidemic at the state and local levels, aiming to inform and improve the effectiveness of the federal public health response to this nationwide problem. Last year, on April 29, 2014, the Subcommittee held a hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse." At that hearing, the Subcommittee heard from a federal panel of witnesses from the Office of National Drug Control Policy (ONDCP), the National Center for Injury Prevention and Control (CDC), the Office of Diversion Control (DEA), the National Institute on Drug Abuse (NIDA), and the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA).

Origins and breadth of the problem

From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics, or pain medications, nearly quadrupled.[1] Deaths related to heroin, an illicit opioid, have also increased sharply since 2010, including a 39 percent increase between 2012 and 2013.[2] Mortality data show that there was a 6 percent increase in overall drug overdose deaths between 2012 and 2013 and approximately 37 percent of those deaths involved prescription opioids.[3] The mortality rate from heroin overdose increased each year from 2010 to 2013.[4] Deaths due to heroin overdoses increased by 39 percent from 2012 to 2013 alone and constituted as much as 19 percent of all drug overdose deaths in 2013.[5] Heroin and prescription opioid abuse can also result in other health consequences such as neonatal abstinence syndrome, increased risk of transmission of HIV and Hepatitis C, and bone fractures in older adults due to falls.[6] On average, heroin addicts lose about 18 years of life expectancy, and the mortality rate for injection users is roughly 2 percent per year.[7]

Although heroin use in the general population is low, the number of people beginning to use heroin has been steadily rising since 2007. According to NIDA, this may be due in part to a

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[1] Centers for Disease Control and Prevention. QuickStats: Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics – United States, 1999-2013. MMWR Weekly. Retrieved from: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm.
[2] Hedegaard H, Chen LH, Warner M.; National Center for Health Statistics (NCHS). Drug-poisoning deaths involving heroin: States, 2000-2013. NCHS data brief, no190. Retrieved from: http://www.cdc.gov/nchs/data/databriefs/db190.pdf.
[3] Centers for Disease Control and Prevention. Wide Ranging Online Data for Epidemiologic Research (CDC WONDER). Available at: http://wonder.cdc.gov/.
[4] *Id.*
[5] *Id.*
[6] Creanga AA, SabelJC, Ko JY, Wasserman CR, Shapiro-Medoza CK, Taylor P, Barfield W, et al. Maternal drug use and its effect on neonates: a population-based study in Washington State. Obstet Gynecol. 2012; 199(5):924-933.; Zibell JE, Hart-Mallory R, Barry J, Fan L, Flanigan C. Risk Factors for HCV infection among young adults in rural New York who inject prescription opioid analgesics. Am J Public Health. 2014 Nov;104(11):2226-32. Doi: 10.2105/AJPH.2014.302142. Epub 2014 Sep 11.; Mateu-Gelabert P1, Guarino H2, Jessel L2, Teper A2. Injection and sexual HIV/HCV risk behaviors associated with nonmedical use of prescription opioids among young adults in New York City. J Subst Abuse Treat. 2015 Jan;48(1):13-20. Doi: 10.1015/j.jsat.2014.07.002. Epub 2014 Jul 11.; Rolita L, Spegman A, Tang X, Cronstein BN. Greater number of narcotic analgesic prescriptions for osteoarthritis is associated with falls and fractures in elderly adults. J Am Geriatr Soc. 2013;61(3):335-340.; Miller M, Sturmer T, Azrael D, Levin R, Solomon DH. Opioid analgesics and the risk of fractures in older adults with arthritis. J Am Geriatr Soc. 2011;59(3):430-438.
[7] B. Smyth, et al., Years of potential life lost among heroin addicts 33 years after treatment, 44 Preventive Medicine 369 (2007).

shift from the abuse of prescription pain relievers to heroin as a more potent, readily available, and cheaper alternative to prescription opioids.[8] In fact, nearly half of young people who inject heroin surveyed in three recent studies reported abusing prescription opioids before starting to use heroin.[9] Among those who began abusing opioids in the 2000s, 75 percent of individuals indicated they initiated their abuse with prescription opioids.[10] Although the available literature indicates that abuse of prescription opioids is a risk factor for future heroin use, only a small fraction, roughly 4 percent of opioid abusers, transition to heroin use within five years of initiating opioid abuse.[11]

Overprescribing of painkillers has been a significant driver of our present opioid and heroin epidemic. Since 1997, the number of Americans seeking treatment for addiction to painkillers has increased by 900 percent.[12] The prevalence of opioid addiction started rising as long-term prescribing of opioids for chronic pain, a practice encouraged by opioid manufacturers, became more common.[13] As a result, many states started to make extensive use of their prescription drug monitoring programs as a tool to monitor prescription sales of controlled substances.[14]

President Obama's FY 2016 Budget includes an increase of $99 million over FY 2015 levels for targeted efforts to reduce opioid-related morbidity and mortality and the prevalence and impact of opioid use disorders. In response to the opioid abuse epidemic, in the FY 2016 budget, CDC requested an increase of $54 million to fund prescription drug overdose and heroin prevention efforts.

Paths to recovery

There is a wide consensus among experts that medical best practice demands a full menu of behavioral, pharmacological and psychosocial treatments be made available to individuals with opioid addiction. This is especially critical, as the Center for Addiction and Substance Abuse at Columbia University, in a five-year study, found that only 1 in 10 people with alcohol or drug addiction other than nicotine receive any form of treatment, and of those only 10 percent

[8] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry 2014;71:821-6.
[9] NIDA Report Series, "Heroin," NIH publication number 15-0165, 3 (November 2014, rev.). Some data have higher estimates. Data from SAMHSA shows that 81 percent of people who started using heroin from 2008 to 2010 had previously abused prescription drugs. Amy Pavuk, Rx for Danger: Oxycodone crackdown drives addicts to other drugs, Orlando Sentinel, July 28, 2012, http://articles.orlandosentinel.com/2012-07-28/health/os-oxycodone-drug-shift-dilaudid-20120728_1_oxycodone-prescription-drugs-dilaudid-pills.
[10] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry 2014;71:821-6.
[11] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013. Retrieved from: http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf.
[12] Science Daily, "Opioid and heroin crisis triggered by doctors overprescribing painkillers," Brandeis University, February 4, 2015. http://www.sciencedaily.com/releases/2015/02/150204125945.htm .
[13] *Id.*
[14] Ileana Arias, et al., Prescription Drug Overdose: State Health Agencies Respond, Association of State and Territorial Health Officials, 2008, http://www.astho.org/Programs/Prevention/Injury-and-Violence-Prevention/_Materials/Prescription-Drug-Overdose/.

receive evidence-based treatment.[15] Nearly 80 percent of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care.[16]

In particular, the data suggests that medication-assisted treatment (MAT) is effective in treating opioid addiction and reducing overdose deaths. As drug abuse changes the way the brain works, resulting in compulsive behavior focused on drug seeking and use, medications can be helpful in treating the symptoms of withdrawal during detoxification – which often prompt relapse – as well as become part of an ongoing treatment plan.[17] Scientific research has established that MAT increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.[18]

At present, the Food and Drug Administration (FDA) has approved only three medications for the treatment of opioid dependence. Methadone, a Schedule II controlled substance used as maintenance treatment for documented opioid addiction for over 40 years, may only be dispensed by clinics, certified by SAMHSA, and subject to both federal and state regulation.[19] Buprenorphine, a Schedule III controlled substance – which may be offered, under certain circumstances, by methadone treatment clinics – is a more recently introduced synthetic opioid treatment medication approved as an outpatient physician-prescribed treatment for opioid addiction.[20] Naltrexone is a physician-prescribed clinician-administered injectable medication for the prevention of relapse of opioid dependence after detoxification, commonly known by the brand name Vivitrol.[21]

Notably, the Department of Health and Human Services includes expansion of MAT to reduce opioid use disorders and overdose among Secretary Burwell's top three priority areas to combat opioid abuse, announced on March 26, 2015.[22] While MAT is a critical component of opioid addiction treatment, concerns have been raised that substance use disorders, as chronic conditions like diabetes or heart disease, demand a treatment model where long-term, sustained recovery – including extended engagement following formal periods of treatment – takes the place of what is too often the episodic, largely unsupervised prescription of medication followed by relapse to old habits.[23]

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[15] http://www.casacolumbia.org/addiction-research/reports/addiction-medicine

[16] C.L. Arfken, et al, Expanding treatment capacity for opioid dependence with buprenorphine: National surveys of physicians, 39 Journal of Substance Abuse Treatment 96 (2010).

[17] NIDA Topics in Brief. Medication-Assisted Treatment for Opioid Addiction. April 2012. https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf

[18] *Id.*

[19] The American Society of Addiction Medicine. Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final

[20] *Id.*

[21] *Id.*

[22] HHS Office of Assistant Secretary for Planning and Evaluation. Issue Brief, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. March 26, 2015. http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf

[23] McGovern, John P. Insitute for Behavior and Health, Inc. The New Paradigm for Recovery: Making Recovery – and not Relapse – the Expected Outcome of Addiction Treatment. March 2014. http://ibhinc.org/pdfs/NewParadigmforRecoveryReportMarch2014.pdf

With the aim of recovery in mind, long-term monitoring, both during and after episodes of MAT, is necessary to screen for the concurrent use of alcohol, illicit drugs, or the non-medical use of other prescription opioids that readily interfere with evidence-based treatments.[24] Dr. Robert DuPont, the first Director of NIDA, President of the Institute for Behavioral Health, and a witness at this hearing has argued that widespread acceptance of "harm reduction" as the ultimate goal of MAT, has often undermined efforts to frame recovery, as opposed to relapse — or simply maintenance — as the expected outcome of addiction treatment.[25]

At the March 26, 2015 hearing, the Subcommittee received testimony on the need for greater oversight of MAT and the need for standards on how these programs should be run. Professor Sarah Melton of East Tennessee University testified that "in Tennessee and southwest Virginia some buprenorphine programs have become pill mills where the physicians charge them high prices, they come in and get their medication, and they leave." She also confirmed the "devastating" trend of medication-assisted programs providing methadone or buprenorphine in cash transactions and being incentivized to become pill mills. She also testified that there is a "dearth of access to good treatment, and by 'good treatment,' I mean patients being seen frequently, getting urine drug screens at nearly every visit, if not every visit, requiring 12-step programs, group counseling, and not co-prescribing with other drugs of addiction such as benzodiazepines."

Other issues

Use of methadone for pain. In addition to the overprescribing of prescription painkillers, public health risks have worsened by the increased prescribing of methadone for pain (as opposed to use in addiction treatment). The use of methadone as a treatment for pain has expanded in recent years. Although methadone can effectively treat pain, it carries outsized risks due to its unique pharmacologic properties, such as a long half-life, short analgesic window relative to respiratory-depressant effect, and potential for drug-drug interactions.[26] While methadone from methadone clinics is in liquid form which addicts drink on-site, methadone prescribed for pain is in pill form, making it easier to divert and misuse. In contrast to the regulation of methadone clinics, no special licensing or monitoring is required to prescribe methadone in pill form. Methadone accounts for two percent of opioid prescriptions for pain control, but is responsible for one-third of overdose deaths, according to a 2012 CDC Vital Signs report.[27] Most state Medicaid programs encourage the prescribing of methadone as a first line treatment for pain, often due to its low cost, even though safer therapies are available.[28] Moreover, the FDA, the CDC, the American Academy of Pain Medicine, and the American

[24] *Id*.
[25] L. Merlo, M. Campbell, G. Skipper, C. Shea, and R. DuPont, "Recovery from Opioid Dependence: Lessons from the Treatment of Opioid-Dependent Physicians," (Study supported by the Robert Wood Johnson Foundation, submitted for publication and currently under review) (2015).
[26] The Pew Charitable Trust, "Prescription Drug Abuse Epidemic: Spotlight on Methadone," August 2014.
[27] http://www.cdc.gov/vitalsigns/MethadoneOverdoses/
[28] The Pew Charitable Trusts' Prescription Drug Abuse Project, Undated handout (provided to committee staff, March 20, 2015).

Society of Interventional Pain Physicians have recommended that methadone not be used as a first-line therapy for chronic pain.[29]

Prescription Drug Monitoring Programs. Prescription drug monitoring programs (PDMPs) are state-run electronic databases of prescriptions for controlled substances. PDMPs can provide a prescriber or pharmacist with information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially abusing medications. Currently, 49 states, the District of Columbia, and Guam have legislation authorizing the creation and operation of a PDMP and all but the DC program are operational.[30] While there is evidence indicating the potential of PDMPs to identify high-risk patients and impact prescribing behaviors, the effectiveness of PDMPs is constrained by the lack of timely data in some states and limited interoperability with other PDMPs. Witnesses at the March 26, 2015 Subcommittee hearing also testified about their concerns over methadone clinics not being required to report methadone dispensing to PDMPs. One witness said it was "a very serious situation" because if these patients do not disclose their methadone treatment to their primary care providers and the providers do not know about it from accessing the PDMP, other opioids or benzodiazepines could be prescribed leading to death.[31] Another concern related to neonatal doctors not being able to know about methadone treatment for pregnant women who are drug-addicted, which poses potential problems for the mother and the life of the fetus if the methadone is being increased during the same time the mother and baby are receiving opioid medication to treat the addiction.[32]

ISSUES

The following issues may be examined at the hearing:

- What evidence-based treatments are currently available to treat individuals suffering from opioid addiction?
- What is medication-assisted treatment, and what are its strengths and limitations?
- What can be done to increase levels of individual compliance with opioid addiction treatments and boost the chances of long-term recovery?
- How can federal policy better support efforts to develop new and promising treatments?

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[29] American Society of Interventional Pain Physicians, Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance, 15 Pain Physician Journal S67 (2012), http://www.painphysicianjournal.com/2012/july/2012;%2015;S67-116.pdf

[30] PDMP Training and Technical Assistance center, PDMP Frequently Asked Questions. http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

[31] Testimony of Fred Wells Brason II, Executive Director, Project Lazarus, Moravian Falls, North Carolina. (Unofficial hearing transcript, 40).

[32] *See* testimony of Stefan R. Maxwell, MD, Chair, West Virginia Perinatal Partnership, MEDNAX Medical Group, Director NICU, Charleston Area Medical Center, Charleston, West Virginia. (Unofficial hearing transcript, 90).

- What are the best practices for treating opioid addiction, and how can federal policy better incentivize these practices?

STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Sam Spector, or Brittany Havens of the Committee staff at (202) 225-2927.