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

April 29, 2015

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

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

On Friday, May 1, 2015, at 9:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?" The purpose of this hearing is to confer with the relevant Federal agencies regarding their ongoing efforts to combat the opioid abuse epidemic and explore how Federal policies can most effectively incentivize the development and broaden use of evidence-based practices and treatments. Subcommittee members will hear testimony from senior officials representing the full range of multi-disciplinary activities comprising the Federal response to this epidemic.

WITNESSES

- Michael Botticelli, Director, Office of National Drug Control Policy, Executive Office of the President;
- Richard G. Frank, Ph.D., Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services;
- Nora D. Volkow, MD, Director, National Institute on Drug Abuse, National Institutes of Health;
- Douglas Throckmorton, M.D., Deputy Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration;
- Debra Houry, M.D., M.P.H., Director of the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention;
- The Honorable Pamela S. Hyde, Administrator, The Substance Abuse and Mental Health Services Administration; and
- Patrick Conway, M.D., M.Sc., Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer, Centers for Medicare & Medicaid Services.

BACKGROUND

This hearing follows up on the April 23, 2015, Subcommittee hearing on "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives." At that hearing, the Subcommittee heard from a panel of professional and academic witnesses that provided insights and findings, drawn from clinical practice and research—as well as constructive policy recommendations—from some of the nation's foremost experts on opioid abuse. The Subcommittee heard testimony on treatment options currently available, as well as new and emerging evidence-based practices supporting individuals living with opioid abuse and addiction.

At the March 26, 2015 Subcommittee hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives," 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

The trends related to prescription drug misuse and overdoses involving opioids are alarming. Drug overdose death rates have increased five-fold since 1980.[1] From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics, or pain medications, nearly quadrupled.[2] By 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes for the first time. Abuse of opioid pain relievers claimed over 16,600 lives in 2010, resulting in over 400,000 emergency department visits in 2011, and cost health insurers an estimated $72 billion annually in medical costs.[3] Deaths related to heroin, an illicit opioid, also have increased sharply since 2010, including a 39 percent increase between 2012 and 2013.[4] Mortality data show that there was a 6 percent increase in overall drug overdose deaths between 2012 and 2013

[1] M. Warner, et al, Drug poisoning deaths in the United States, 1980-2008, CDC National Center for Health Statistics data brief, no. 81 (CDC National Center for Health Statistics 2011).
[2] 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.
[3] CDC FY 2015 Budget Justification at 9.
[4] 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.

and approximately 37 percent of those deaths involved prescription opioids.[5] The mortality rate from heroin overdose increased each year from 2010 to 2013.[6] 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.[7] Heroin and prescription opioid abuse also can 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.[8] On average, heroin addicts lose about 18 years of life expectancy, and the mortality rate for injection users is roughly 2 percent per year.[9]

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 shift from the abuse of prescription pain relievers to heroin as a more potent, readily available, and cheaper alternative to prescription opioids.[10] In fact, nearly half of young people who inject heroin surveyed in three recent studies reported abusing prescription opioids before starting to use heroin.[11] Among those who began abusing opioids in the 2000s, 75 percent of individuals indicated they initiated their abuse with prescription opioids.[12] 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.[13]

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[5] Centers for Disease Control and Prevention. Wide Ranging Online Data for Epidemiologic Research (CDC WONDER). Available at: http://wonder.cdc.gov/.
[6] *Id.*
[7] *Id.*
[8] 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.
[9] B. Smyth, et al., Years of potential life lost among heroin addicts 33 years after treatment, 44 Preventive Medicine 369 (2007).
[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] 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.
[12] 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.
[13] 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.

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.[14] 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.[15] 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.[16]

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 receive evidence-based treatment.[17] 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.[18] Many counties lack substance abuse treatment facilities that accept Medicaid.[19] A 2007 SAMHSA analysis of workforce issues noted that more than 50 percent of U.S. counties in rural areas lack practicing psychiatrists, psychologists, or social workers.[20]

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.[21] Scientific research has established that MAT increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.[22]

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

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[14] 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 .
[15] *Id.*
[16] 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/.
[17] http://www.casacolumbia.org/addiction-research/reports/addiction-medicine.
[18] 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).
[19] SAMHSA Budget Justification FY2016 at 5.
[20] *Id.*
[21] NIDA Topics in Brief. Medication-Assisted Treatment for Opioid Addiction. April 2012. https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf.
[22] *Id.*

regulation.[23] 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.[24] 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.[25]

Notably, the Department of Health and Human Services (HHS) 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.[26] 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.[27]

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.[28] Dr. Robert DuPont, the first Director of NIDA, President of the Institute for Behavioral Health, and a witness at the April 23rd 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.[29]

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

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[23] 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.
[24] *Id.*
[25] *Id.*
[26] 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.
[27] 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.
[28] *Id.*
[29] 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).

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 treat pain effectively, 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.[30] 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.[31] 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.[32] Moreover, the FDA, the CDC, the American Academy of Pain Medicine, and the American Society of Interventional Pain Physicians have recommended that methadone not be used as a first-line therapy for chronic pain.[33]

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 potentially are 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 D.C. program are operational.[34] 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.[35] Another concern related to neonatal doctors not knowing

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[30] The Pew Charitable Trust, "Prescription Drug Abuse Epidemic: Spotlight on Methadone," August 2014.
[31] http://www.cdc.gov/vitalsigns/MethadoneOverdoses/.
[32] The Pew Charitable Trusts' Prescription Drug Abuse Project, Undated handout (provided to committee staff, March 20, 2015).
[33] 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.
[34] PDMP Training and Technical Assistance center, PDMP Frequently Asked Questions. http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.
[35] Testimony of Fred Wells Brason II, Executive Director, Project Lazarus, Moravian Falls, North Carolina. (Unofficial hearing transcript, 40).

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 while the mother and baby are receiving opioid medication to treat the addiction.[36]

Federal Agencies

- **Office of National Drug Control Policy:** The Office was established by the Anti-Drug Abuse Act of 1988. ONDCP is responsible for developing a national drug control policy, developing and applying specific goals and performance measurements to evaluate the effectiveness of national drug control policy and programs, overseeing and coordinating the implementation of the national drug control policy and assessing and certifying the adequacy of the budget for National Drug Control Programs.

- **Assistant Secretary for Planning and Evaluation (HHS):** The Assistant Secretary for Planning and Evaluation (ASPE), who advises the Secretary of HHS on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy, is spearheading recent HHS efforts to address the opioid abuse problem.

  On March 26, 2015, HHS Secretary Sylvia Burwell announced a targeted initiative aimed at reducing prescription opioid and heroin related overdose, death, and dependence. The President's Fiscal Year (FY 2016) budget includes expenditures to intensify efforts to reduce opioid misuse and abuse, including $133 million in new funding to address this issue. The Secretary's initiative targets three priority areas to combat opioid abuse:

  (1) Helping health professionals make informed prescribing decisions –

  - Teaching medical professionals how and when to prescribe opioids by working with lawmakers on bipartisan legislation requiring specific training for safe opioid prescribing and establishing new opioid prescribing guidelines for chronic pain.
  - Supporting data sharing for safe prescribing by facilitating PDMP and health information technology integration and further adoption of electronic prescribing practices.
  - Increasing investments in State-level prevention interventions, including PDMPs, to track opioid prescribing and support appropriate pain management.

  (2) Increasing use of naloxone –

  - Supporting the development, review, and approval of new naloxone products and delivery options.
  - Promoting State use of Substance Abuse Block Grants funds to purchase naloxone.
  - Implementing the Prescription Drug Overdose grants program for States to purchase naloxone and train first responders on its use.

  3) Expanding use of Medication-assisted Treatment (MAT) –

[36] *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).

- Launching a grant program in FY 2015 to improve access to MAT services through education, training, and purchase of MAT medications for treatment of prescription opioid and heroin addiction.
- Exploring bipartisan policy changes to increase use of buprenorphine and develop the training to assist prescribing.[37]

- **National Institute on Drug Abuse:** The Institute, a part of the National Institutes of Health (NIH), supports research to prevent and treat drug abuse and addiction and mitigate their impacts. NIDA's efforts include identifying the characteristics and patterns of drug abuse and developing more effective strategies to prevent people from abusing drugs and from progressing to addiction. Their work also includes developing successful treatments for drug abuse and addiction and improving treatment accessibility and implementation.

- **Center for Drug Evaluation and Research (FDA):** Under the Food Drug and Cosmetic Act, the FDA is responsible for the approval and marketing of drugs for medical use and for monitoring products for continued safety after they are in use, including controlled substances used to treat pain. FDA is committed to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely manner and monitoring products for continued safety after they are in use. FDA aims to ensure that patients who require opioids for legitimate, medical pain control purposes maintain appropriate access to them through informed providers, while limiting misuse, abuse, and diversion of these products.[38]

- **National Center for Injury Prevention and Control (CDC):** The National Center, a center within the CDC, researches ways to enhance State prescription drug monitoring programs, which track prescriptions for controlled substances, such as prescription painkillers. It also tracks and evaluates State policies and programs, like those to prevent "doctor shopping" and "pill mills" involved in painkiller misuse and overdose, while ensuring access to safe and effective pain treatment for those who need it. Additionally, the Center works to ensure that health care providers follow science-based guidelines for safe and effective prescribing of painkillers. Identifying health care providers who prescribe painkillers inappropriately could reduce overdoses and misuse, as the increase in overdose deaths parallels a sharp rise in the sale of prescription painkillers. Building off the infrastructure of the Prevention Boost and Core Violence and Injury Prevention programs, CDC received $20 million in FY 2015 and will launch the Prescription Drug Overdose Prevention for States program, which fund expansion of State-level interventions including enhancements to PDMPs.[39] Another $65 million is proposed in the FY 2016 budget to expand the program to all 50 States and Washington, D.C.[40] The PDMP component of this program is designed to advance broad adoption of universal, real-time, actively managed PDMPs.

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[37] HHS Press Release, HHS takes strong steps to address opioid-drug related overdoses and deaths, March 26, 2015.
[38] Statement of Robert J. Meyer, M.D., FDA's Role in Preventing Prescription Drug Abuse http://www.fda.gov/NewsEvents/Testimony/ucm112718.htm.
[39] HHS ASPE Issue Brief, note 26 at 6 (March 26, 2015).
[40] *Id.*

- **SAMHSA:** SAMHSA's mission is to reduce the impact of substance abuse on America's communities. With respect to opioid abuse, SAMHSA spent more than $8.7 million on opioid treatment programs and regulatory activities in FY 2014. SAMHSA's Budget Request for FY 2016 proposes a total of $25 million of spending for MAT, including a $12 million request for a new community-based program to prevent prescription drug and opioid overdose-related deaths and proposed increased funding of $13 million for medication assisted treatment. The new community-based program will provide grants to 10 States to reduce significantly the number of opioid overdose-related deaths. Funding will help States purchase naloxone, equip first responders in high-risk communities, support education on the use of naloxone, and other overdose death prevention strategies. The MAT program request would increase the number of States from 11 to 22 that receive funding to expand services that address prescription drug misuse and heroin use in high-risk communities. The new funding is expected to serve an additional 24 high-risk communities. The FY 2016 budget also requests $118.3 million, an increase of $8.8 million from FY 2015 enacted level, for the Strategic Prevention Framework (SPF-Rx) program. The aim of SPF-Rx is to raise public awareness about the dangers of sharing medications and to work with pharmaceutical and medical communities to raise awareness on the risks of overprescribing.

- **Centers for Medicare & Medicaid Services:** The Centers for Medicare and Medicaid Services are responsible for administering the Medicare Part D drug program, and the Medicaid program, which significantly impacts the opioid epidemic program through coverage and funding of beneficiaries and providers. In 2014, CMS committed to take the problem seriously and begin actions to protect Medicare beneficiaries and the Medicare Trust Fund against Part D fraud and abuse.[41] CMS is targeting Part D enrollees who use opioids to see if they have overutilization issues and physicians who may overprescribe. CMS focuses its fraud and abuse strategy on the validation and analysis of Part D claims data it receives from Part D sponsors. With regard to Medicaid, the 2013 study by the American Society of Addiction Medicine (ASAM) found that Medicaid coverage of, and patient and practitioner access to, opioid dependence treatment medications demonstrated important coverage and use limitations.[42] Critically needed medications that could reduce the opioid overdose epidemic were substantially underutilized by State Medicaid programs. Moreover, ASAM practitioners reported Medicaid coverage, utilization management, financing, reimbursement, and regulatory issues as significant obstacles. A witness testifying at last week's hearing[43] and the Senate Caucus on International Narcotics Control[44] have raised questions over whether CMS quality measures may contribute to the overprescribing of opioid medications.

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[41] CMS Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse (January 6, 2014), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-01-06-2.html.
[42] S. Rinaldo and D. Rinaldo, The Avisa Group, "Availability Without Accessability? State Medicaid Coverage and Authorization Requirements For Opioid Dependence Medications," report prepared for the American Society of Addiction Medicine (June 2013).
[43] Written testimony of Anna Lembke, M.D., before the House Energy and Commerce Subcommittee on Oversight and Investigations, Hearing on "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives," April 23, 2015.
[44] June 23, 2014 letter from the Senate Caucus on International Narcotics Control (Co-chairmen Senator Charles E. Grassley and Senator Dianne Feinstein) to The Honorable Marilyn Tavenner, Administrator, CMS.

ISSUES

The following issues may be examined at the hearing:

- What Federal programs have been effective in combatting opioid abuse and why?
- What Federal programs have not been effective in combatting opioid abuse and why?
- Are Federal health programs combatting opioid abuse adequately coordinated?
- Are Federal agencies collecting and evaluating the best data to determine the effectiveness of medication-assisted treatment programs?
- How can Federal policy better support efforts to develop new and promising treatments for opioid addiction?
- What are the best practices for treating opioid addiction, and how can Federal policy better incentivize these practices?

In addition, the following policy ideas or areas were mentioned in last week's Subcommittee hearing and could be raised for further exploration with the witnesses:

1. Changes to 42 CFR privacy regulations may be needed to update standards for integrating physical and behavioral medicine.
2. Addiction-treatment physicians should have all available tools "in their quiver" of treatment options, including the array of FDA-approved medications to treat opioid dependency.
3. Patients and sponsoring family members must be given more information regarding the probability of success for various treatment approaches. This will allow them to seek informed choices on which treatment approaches to consider.
4. Improve communication between pharmacies and physicians.
5. Define recovery – not in terms of today, but longer term – 5 years – so we see addiction as a chronic disease and see treatments as meeting chronic care.
6. Ensure physicians treating patients with pain have sufficient information and resources.
7. Make sure insurance parity is being enforced and that insurance companies are not arbitrarily discontinuing coverage for treatment at a certain time.

8. Increase the number of providers who are trained and experienced for mental illness, serious mental illness, and addiction.

9. Increase the number of in-patient beds for detoxification and in-depth treatment that meets the needs of patients.

10. Increase the number of physicians that can prescribe MAT in regions of the country where opioid abuse/dependency is high and where medical services are sparse.

11. MAT alone or psychotherapy alone are rarely sufficient; make sure patient needs are met with all available treatment.

12. Ensuring drug courts allow treatment with MAT.

13. Combining the funding for mental health and substance abuse for dual diagnosis

14. Stop State Medicaid plan reimbursement policies from incentivizing the prescribing of methadone as first-line therapy for pain.

15. Making naloxone (narcan) available over-the-counter.

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.