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Center for Rural Pennsylvania
Public Hearing: State of Addiction
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Addiction is a chronic, relapsing, often fatal medical disease of the brain. Addiction is not a moral failing, nor is it a choice. There are over 23 million people in the United States who meet criteria for the diagnosis of substance use disorder. There are approximately 5 million people misusing prescription opiates in the United States. There are over 2 million people who are using opiates at a level that would classify them as opiate dependent. Of these, half of them are dependent on prescription opiates and half are dependent on illicit opiates such as heroin or fentanyl.

Increasing non-medical, illicit use of prescription opiates has been driving up overdose rates and emergency department visits. Since 2009, the non-medical, illicit use of prescription drugs has outpaced use of all street drugs except for marijuana. In 2015, there were 53,000 overdose deaths in the U.S and in 2016 the overdose deaths in the U.S jumped to 64,000. Opiates account for 66 percent of the overdose deaths. In 2017, there were over 72,000 overdose deaths in the United States, showing that we have yet to turn the corner or even level off this crisis. This translates into 180 deaths per day in 2016 and 200 deaths per day in 2017. But numbers by themselves do not always translate into empathy for the human lives lost. I am reminded that 58,000 American soldiers died in the Vietnam War. I am also struck by the fact that there are 180 passenger seats in a typical 737 airplane. We need to ask ourselves if we would tolerate a 737 airplane crashing with no survivors every day.

Because of these overdose deaths there has been a decrease in the life expectancy of a person born in the United States. Maybe we need an anti-drug movement similar to the anti-war movement of the 1960's.

In 2010 there were 254 million prescriptions written for opiates in the U.S. This is enough medication to medicate every man, woman and child in the United States for one month. The prescription writing of opiates has decreased each year since 2010. In 2017 there were less than 200 million prescriptions written for opiates. The decrease in the number of prescription opioids and the number of times a prescription drug monitoring program query was placed are in direct inverse proportion. As the queries for prescription drug-monitoring programs increased from 2010 until 2017 the number of prescriptions for opioids has correspondingly decreased.

Addiction is not new and those suffering from it are not unique. Like cancer, polio, depression and any other disease, the disease of addiction has a history. In order to truly appreciate the unseen destruction of this epidemic we need to see how it has evolved, and in many ways how it has remained the same. The face of addiction's differences and similarities are startling.

The History of Opioid Addiction

Opioid addiction first emerged as a serious problem in the United States after the Civil War, when opioids were widely prescribed to alleviate acute and chronic pain. Iatrogenic addiction was by far the most common form of addiction (White 1998). By the late 19th century, two-thirds of those addicted to opioids were middle- and upper-class white women, a fact Brecher and the editors of Consumer Reports (1972, p. 17) attribute to "the widespread medical custom of prescribing opiates for menstrual and menopausal discomfort, and the many proprietary opiates prescribed for 'female troubles.'" Only one-third of those addicted to opioids at that time became addicted due to non-medical opioid use mainly among Chinese immigrants and members of the Caucasian "underground" such as prostitutes, gamblers, and petty criminals.

The chronic nature of opioid addiction soon became evident, however, because many people who entered sanatoriums for a cure relapsed to addictive opioid use after discharge. By the end of the 19th century, doctors became more cautious in prescribing morphine and other opioids, and the prevalence of opioid addiction decreased. Most Americans regarded opioid abuse as socially

irresponsible and immoral. It is noteworthy, however, that heroin, introduced in 1898 as a cough suppressant, also began to be misused for its euphoric qualities, gradually attracting new types of users. This development, along with the improvement of the hypodermic needle in 1910-1920 had a profound effect on opioid use and addiction in the 20th century (Courtwright 2001).

The Harrison Narcotic Tax Act of 1914 is often cited as the beginning of the change from treating addiction as a disease to treating it in the courts. It states, "An Act to provide for the registration of, with collectors of internal revenue, and to impose a special tax on all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations, and for other purposes." Although the Act permitted physicians to prescribe or dispense opioids as long as they kept the required records, the Treasury interpreted the Act as a prohibition on physicians' prescribing opioids to persons with addictions to maintain their addictions. The Treasury was the agency responsible for enforcing the Harrison Act as well as prohibition laws. The Treasury's position appeared to be that addiction was not a disease and the person with an addiction, therefore, was not a patient. It followed that any physician prescribing or dispensing opioids to this type of individual was not doing so in the “course of his professional practice” (White 1998). In 1919, the United States Supreme Court upheld the Treasury's interpretation. Until the 1960’s this interpretation and enforcement of the Harrison Act effectively eliminated any legitimate role for the general medical profession in medication-assisted treatment for Americans who had a drug addiction (White 1998). Moving the treatment of addiction from the hands of physicians to those of law enforcement perpetuated and worsened the stigmatization of this disease.

The size and composition of the U.S. opioid-addicted population began to change in the early 20th century with the arrival of waves of European immigrants. Most people addicted to opioids in this period were young men in their 20’s described as “down-and-outs” of recent-immigrant European descent who were crowded into tenements and ghettos and acquired their addiction during adolescence or early adulthood. They often resorted to illegal means to obtain their opioids, usually from non-medical sources and specifically for the euphoric effects.

The initial treatment response in the early 20th century continued to involve the prescriptive administration of short-acting opioids. By the 1920’s, morphine was prescribed or dispensed in

numerous municipal treatment programs (Courtwright, et al. 1989). At around the same time addiction to opium, cocaine, and heroin, along with drug-related crime, especially in poor urban communities started drawing the concerns of political, religious and social leaders. The tolerance and empathy shown toward Civil War veterans and middle-aged women evaporated. Negative attitudes toward -- and discrimination against -- new immigrants likely worsened the stigma of addiction. Immigrants and others addicted to drugs were viewed as a threat. Society's response was to turn from early forms of treatment to law enforcement (Brecher and Editors 1972; Courtwright 2001; Courtwright et al. 1989).

The shift in the composition of opioid-addicted groups coincided with hardening attitudes toward these groups, leading some researchers to conclude that stigmatization of people with addiction disorders and their substances of abuse reflected, at least in part, class and ethnic biases. A portion of U.S. society appeared to view with disdain and fear the poor White, Asian, African-American, and Hispanic people with addiction disorders who lived in the inner-city ghettos (Courtwright 2001, et al. 1989).

By the mid-1960's, the number of middle-class, young White Americans using heroin was on the rise, as was addiction-related crime. This corresponded to the U.S. military involvement in Vietnam where 25 to 50 percent of American enlisted men in Vietnam were believed to have used or become addicted to heroin. Serendipitously, the fear that the majority of these Vietnam veterans would return home and continue to abuse heroin did not come to fruition.

The Advent of Pharmacologic Treatment

In 1962, Dr. Vincent P. Dole, a specialist at The Rockefeller University, became chair of the Narcotics Committee of the Health Research Council of New York City. He received a grant to establish a research unit to investigate the feasibility of opioid maintenance. In preparing for this research, he read "The Drug Addict as a Patient" by Dr. Marie E. Nyswander (Nyswander 1956), a psychiatrist with extensive experience treating patients who were addicted to opioids. She was convinced that these individuals could be treated within general medical practice. She also believed that many would have to be maintained on opioids because a significant number of people who attempted abstinence without medication relapsed, in spite of detoxifications, hospitalizations, and

psychotherapy (Brecher and editors 1972; Courtwright, et al. 1989). The research of Brecher and Courtwright represented a groundbreaking shift in drug addiction treatment.

By the 1980's, an estimated 500,000 Americans were using illicit opioids (mainly heroin); and were mostly poor, young minority men and women in the inner cities. Although this number represented a 66 percent increase over the estimated number of late 19th-century Americans with opioid addiction, the per capita rate was much less than in the late 19th century because the population had more than doubled (Courtwright, et al. 1989). Nevertheless, addiction became not only a major medical problem but also an explosive social issue (Courtwright 2001; Courtwright, et al. 1989).

How We Got Here

A confluence of factors have led to the steady expansion of opioid prescription:

In the past 15 years, and until recently, physicians have been encouraged to treat pain aggressively and not to "undertreat." This meant prescribing more opioids-- not less.

Pain was codified as the "fifth vital sign" by JCAHO, the accrediting body for all medical facilities. Physicians were admonished for not addressing patients' pain levels adequately, further encouraging physicians to prescribe more aggressively.

Pharmaceutical companies rolled out stronger and more addicting pain medication and marketed these aggressively. There was a widely held myth that opioid/narcotic medications are safe and won't cause addiction unless one is already addicted. This is patently false.

Prescription opioids became widely available across socio-economic and geographic lines, thus carving a path to an explosion in opioid addiction. Heroin and then fentanyl followed this path, leading to the opioid epidemic (cheap heroin) and then the overdose epidemic (even cheaper fentanyl.)

Fentanyl has become increasingly easier to obtain and is being cut into heroin sold on the streets across the United States. Being 50 to 100 times more potent than heroin, fentanyl is easier to smuggle across the borders. Based on a lethal dose being 2 mg, a supply of fentanyl weighing 1 gram, the average weight of a typical business card, is the equivalent of 500 lethal doses.

What Do We Do?

Traditional 12-step based approaches to addiction, while effective for alcohol addiction and addiction generally, are mostly not sufficient to deal with current opioid addiction. Most patients need medication assistance. Fortunately, we have three potent pharamacologic approaches to aid in the treatment of opioid addiction: methadone, buprenorphine (Suboxone), and extended release naltrexone (Vivitrol). None of these "cure" addiction and none is appropriate for all patients; but as with any medical treatment, the availability of treatment approaches that can be tailored to the individual gives patients suffering from opioid addiction a real chance to overcome this deadly disease. Medication assisted treatment is now considered to be the gold standard in treating opioid addiction because of its demonstrated superior efficacy. The following paragraphs will briefly explain these three pharmacologies.

Methadone was created in the 1940's and, like heroin, is a full opioid agonist. After Dole, Nyswander and Kreek completed their groundbreaking study of this medication it was approved for use in the United States. Methadone has been successfully used to treat opioid use disorder since the 1970's. It is scientific and has numerous studies backing its use as reducing death and morbidity. Methadone is tightly regulated for reasons of safety and risk of diversion, but the downside of this is that access is limited and requirements for maintaining on methadone are arduous for many.

Buprenorphine (Suboxone) has been available since 2003 with the passage of the DATA-2000. Unlike methadone, buprenorphine is a partial agonist to the mu-opioid receptors in the brain. In simple terms, buprenorphine gives a limited positive sensation to the patient without allowing a complete activation of the mu receptors. Because of its higher affinity to the receptors, it blocks the ability of other, more potent, agonists to activate the receptors fully. Its property of low (partial) activation, strong affinity and long half-life makes for a very powerful tool in the fight against opioid use disorder.

Buprenorphine has two huge practical advantages. Under DATA-2000, buprenorphine prescription is subject to federal regulation, but not nearly as restrictive as those for methadone, allowing many

more patients to access treatment. In addition, because of its pharmacologic profile it is much safer, and overdose is rare.

Diversion of buprenorphine is a legitimate concern but should not be confused with the opioid epidemic. People are not dying from buprenorphine, as buprenorphine overdose is rare and counterbalanced by a ceiling effect of this medication. Patients with opioid use disorder, to stave off withdrawal until their drug of choice is available, commonly use diverted buprenorphine. Many others use diverted buprenorphine because access to treatment is limited due to the limited number of physicians capable of prescribing it (Brazazi et. al. 2011). Treating buprenorphine as a problem needing further restriction will only serve to restrict one of the most potent weapons outpatient physicians have in treating this crisis.

Naltrexone first gained approval in 1984 as an oral medication to help in the treatment of opioid use disorder. Naltrexone is a full mu opioid antagonist. This means that it does not activate the receptors at all, a property that is a shortcoming to the medication. On the other hand, being a full antagonist means that it binds to the receptor, without activating, and blocks the ability of other substance to activate the receptor. The oral route of administration limited its effectiveness as patients often discontinued the medication, opting to use illicit substances. In 2010 Naltrexone was approved as an injectable medication, but only for alcohol use disorder. In 2014 Naltrexone injectable was approved for opioid use disorder, making it a third viable option for medication-assisted treatment.

Each of these three medications has its benefits and shortcomings. In the proper hands, administered to the proper patients, each medication is invaluable to the treatment of this illness. What many in the field of addiction fear is that legislation will worsen the access of care by convincing more physicians that getting and utilizing a buprenorphine waiver is costly and may result in unwarranted physician reprimands.

The goal of coming here today is to help better inform people who have a stake in addressing the opioid epidemic. Physicians understand that oversight is necessary and, to that end, would like to be active participants in creating the oversight. The hope is that discussions like this will further the conversation, helping ethical physicians continue to practice good medicine without additional

regulatory barriers, while protecting the public from the few unscrupulous practitioners. As board certified experts in addiction medicine and leaders in our field, we are here to engage with you in this dialogue and this process.