PUBLIC HEARING
State of Addiction

Tuesday, October 2, 2018
Senate Majority Caucus Room
Room 156, Main Capitol Building
Harrisburg, PA

AGENDA

10:00 AM Welcome and Opening Comments
Senator Gene Yaw, Chairman, The Center for Rural Pennsylvania

10:10 AM Dr. Bradley Miller, UPMC Susquehanna

10:50 AM Dr. Rachel Levine, Secretary of the Pennsylvania Department of Health and Pennsylvania Physician General

11:20 AM Dr. William Santoro, Public Policy Chair, Pennsylvania Society of Addiction Medicine
Dr. Frederic Baurer, President, Pennsylvania Society of Addiction Medicine

11:50 AM Closing Comments
Senator Gene Yaw

12:00 PM Adjournment
OPIOIDS 101

Communities in Crisis: PA’s Opioid Epidemic
Center for Rural Pennsylvania
Harrisburg, PA
02 October 2018
Bradley J Miller, DO, FAAFP
Disclosures

• There are no disclosures.
Objectives

• Brief history of opioid use
• History of opioid crisis development
• Define addiction as a chronic illness
• Overview of current treatment strategies
• What can you do?


2013


2014


WHAT ARE OPIOIDS?
• Natural opiates (from poppy plant)
  – heroin, morphine, codeine

• Synthetic/semi-synthetic opioids (chemically synthesized in lab)
  – Prescription pain medications ("painkillers")
    • OxyContin, Percocet, Vicodin, Dilaudid, Fentanyl, Methadone, etc
  – Addiction Treatments:
    • Methadone
    • Buprenorphine (Suboxone, Subutex)

• **NOT** OTC pain medications (NSAIDs or acetaminophen)
HOW DID WE GET HERE?

About five thousand years ago.....
Oxycodone consumption, mg/capita

Despite a decline in recent years, U.S. per capita opioid consumption remains much higher than oxycodone consumption in Europe.

1996: OxyContin Marketed in US

Source: The International Narcotics Control Board / THE CONVERSATION, CC-BY-ND
National Trends

Figure 6. Past Month Nonmedical Use of Pain Relievers among People Aged 12 or Older, by Age Group: Percentages, 2002-2014

Drugs Involved in U.S. Overdose Deaths - Among the more than 72,000 drug overdose deaths estimated in 2017, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with nearly 30,000 overdose deaths. Source: CDC WONDER.
Common scenario

- Acute pain → Prescriptions for opioid → Addiction → Prescription Ends → Heroin

- One of the major causes of opioid addiction is the use of legitimately prescribed opioid medications
HOW ARE HEROIN AND PRESCRIPTION PAIN MEDICATIONS SIMILAR/DIFFERENT?
Prescription opioid pain medications and heroin affect the brain in the same way and same place

- Any differences in effect are due to:
  - **POTENCY**: How powerful is it?
  - **DOSE**: How much of it was taken?
  - **METHOD OF ADMINISTRATION**: How was it taken? (Oral, Inhaled, Nasal, Intravenous)
WHAT IS ADDICTION?
IS NOT

Physical Dependence

Withdrawal symptoms
- Opioid withdrawal is rarely fatal, but awful enough to do almost anything to avoid
- Can be experienced after only 6-8 hours of no use

Tolerance
The need for more and more of the substance to get the same effect

IS

Behavior

Compulsive use despite consequences

Cannot stop despite repeated attempts

Significantly disrupts functioning and relationships—time spent finding, taking, and recovering from substance
- Can result in unethical/illegal activities
HOW CAN ONE TELL PHYSICAL DEPENDENCE FROM ADDICTION?
OFTEN, ONE CAN’T…. HUGE DILEMMA FOR PRESCRIBERS
DRUGS OF ABUSE TARGET THE BRAIN’S PLEASURE CENTER

Brain reward (dopamine) pathways

These brain circuits are important for natural rewards such as food, music, and sex.

Drugs of abuse increase dopamine

Typically, dopamine increases in response to natural rewards such as food. When cocaine is taken, dopamine increases are exaggerated, and communication is altered.

*National Institute of Drug Abuse:
https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drugs-brain
Opioid Dependence Causes Changes in Brain

PET scan images

The lack of red in the opioid-dependent brain shows that chronic opioid use has reduced dopamine receptor concentration.

PET=Positron Emission Tomography
The evolution of dopamine reward...

• The midbrain of the human is almost identical to that of an amphibian.
  – All animals have the same basic reward wiring.
  – Behaviors that are rewarding:
    • Warm Body
    • Eating → Full Belly
    • Reproductive activity
  – The brain provides a reward of “well being” to reinforce these behaviors that are positively associated with SURVIVAL.

• 2. Physiologic Range of reward is on a scale of 1-50. Food → Sex
• 3. Supra-physiologic range of reward with drugs and alcohol.
  – Range of 50-10,000.
  – DEEP IMPRINT for Reward behaviors = Difficult to forget
Short Definition of Addiction
Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.”

HOW LONG/ HOW MUCH DOES IT TAKE TO BECOME ADDICTED?
(WHAT IS SAFE?)
Length of Initial Opioid Rx

* Days’ supply of the first prescription is expressed in days (1–40) in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days’ supply was considered the first prescription.
DOES EVERYONE WHO TAKES OPIOIDS FOR “TOO LONG” BECOME ADDICTED?
OF COURSE NOT. PHYSICAL DEPENDENCE, HOWEVER, WILL OCCUR.
WHY IS THE CONCEPT “ADDICTION IS A CHRONIC DISEASE” IMPORTANT?
Characteristics of Chronic Disease

• Chronic = no known cure; must be managed over time
  – long-lasting chemical changes in the brain regardless of detoxification

• Relapsing
  – with and without treatment, craving and compulsive, pathological pursuit of substance can return

• Progressive
  – gets worse over time; high fatality rates for addiction specifically
Management of a Chronic Disease

**Chronic Disease**

(Short-term)
- Acute Stabilization
- Hospitalization

(Long-term)
- Medication Treatments
- Psychosocial Treatments/Behavior Change

**Addiction**

(Short-term)
- Detoxification
- Rehabilitation

(Long-term)
- Medication Treatments
- Psychosocial Treatments/Behavior Change
WHY IS THE CONCEPT “ADDICTION IS A CHRONIC DISEASE” CONTROVERSIAL?
WHAT ARE THE TREATMENTS?
• Historically, a great divide between:

  – Abstinence-oriented treatment
    • AA, NA – Twelve-step-based
    • Use of no psychoactive substances, often including prescribed medications

  – Disease-oriented treatment
    • Medication-assisted treatment; reduce harmful symptoms physiologically
    • Recommended in conjunction with psychosocial treatment
Medication Treatments for Opioid Use

**Full Agonist**: (high intrinsic activity) (Oxycodone, Heroin, Methadone)

**Partial Agonist**: (low intrinsic activity) (Buprenorphine)

**Antagonist**: (no intrinsic activity) (Naloxone/Naltrexone/Vivitrol)

Nutt&Langford, 2008, *Brit Jl Pharm*
Why are opioid medications used to treat opioid addictions?

• Long-term (permanent?) changes to opioid receptor system.

• Changed receptors may require an opioid to function normally.

• Effective! Opioid treatment medications reduce symptoms; promote remission.

• Long-term (for some, lifelong) medication treatment works best.
“Medication treatment is just replacing one addiction with another”

Really? Are these the same?

<table>
<thead>
<tr>
<th>With Substance</th>
<th>With Medication</th>
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<tbody>
<tr>
<td>Unable to function well or at all in daily responsibilities</td>
<td>Able to function in daily responsibilities</td>
</tr>
<tr>
<td>Loss of job, school</td>
<td>Job, School</td>
</tr>
<tr>
<td>Broken relationships</td>
<td>Relationship repair</td>
</tr>
<tr>
<td>Crime, deceit</td>
<td>Pre-addiction self</td>
</tr>
<tr>
<td>Sense of desperation</td>
<td>Sense of normalcy</td>
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WHY ARE METHADONE AND BUPRENORPHINE CONTROVERSIAL AND DIFFICULT TO ACCESS?
What about naltrexone (Vivitrol)?

• 30-Day Injection form - Promising, but scant data
  – Longer-term outcomes/issues not yet fully researched
  – (Oral form – Dismal failure for most)
• Definitely an important part of the toolbox
• Until more is known, population best served may be those who have been abstinent for a significant length of time, but are at high risk of relapse
  – Completion of incarceration
  – No opioids for some length of time
WHY CAN’T PEOPLE JUST WEAN OFF OR GO THROUGH DETOX AND STOP?
Detoxification is not Treatment

• Detoxification does NOT “reset” the brain’s baseline

• Relapse after detoxification alone is the norm – upwards of 95%

• Can increase risk of overdose and death

• If someone is detoxified:
  – Withdrawal should be medically assisted
  – Medication treatment should be started immediately
WHAT ARE THE DILEMMAS PRESCRIBERS FACE WHEN PRESCRIBING OPIOIDS FOR PAIN?
WHAT ARE THE INITIATIVES COMMUNITIES ARE DOING?
• Heroin Task Forces
• Increased access to Medication Assisted Treatments
• Narcan rescue kits
• Prescriber education
• Medication take-back boxes
HOW CAN YOU HELP?
Discontinue Stigmatizing Language

Instead of saying:

- **Addict** – how about “opioid use disorder” or “person with an addiction”? 
- **Drug-seeker** – how about “may have a substance use disorder” or “may be experiencing cravings” or “needs to be evaluated for pain”?
- **Clean/Dirty** – how about “negative/positive”; or “in remission” and “in active use”??
Beliefs that may *increase* overdose and fatalities

**MYTH**

– People who have developed a substance use disorder are
  
  • Bad
  
  • Unworthy of our respect and care
Beliefs that may *increase* overdose and fatalities

**MYTH**

Agonist medication *treatment* is just replacing one addiction with another
Beliefs that may increase overdose and fatalities

MYTH

Recovering from the disease of addiction without agonist medication is somehow reflective of being “better,” “stronger,” “more successful” than recovering with medication...that medication is a “crutch”
Beliefs that may increase overdose and fatalities

MYTH

Once someone has achieved abstinence/recovery with the use of treatment medications, then he or she should be able to stop the medication.
QUESTIONS?

Brad Miller, DO
millerbj10@upmc.edu
570-321-2340
Center for Rural Pennsylvania
Senator Yaw
October 2, 2018

Rachel Levine, MD
Secretary of Health
Good Morning Chairman Yaw, Vice Chair Everett, members of the Center for Rural Pennsylvania, as well as members and guests who are here today. On behalf of myself and Governor Wolf, I would like to thank you for the opportunity today to provide an update on our efforts dealing with the heroin and opioid crisis here in the Commonwealth.

Before I discuss our Medical Marijuana Program and its potential place in fighting this epidemic, I want to bring the committee up to speed with our efforts thus far. The Department of Health recently received $5.1 million from the Centers for Disease Control and Prevention as part of a cooperative agreement for emergency response to continue to fight the opioid crisis. This funding is in addition to the $55.9 million in SAMHSA funding awarded to the Department of Drug and Alcohol Programs.

The $5.1 million in funding will assist the Opioid Operational Command Center in ensuring the entire commonwealth is working to address this crisis. Much of this funding will be used to strengthen the state’s data collection and analysis, which will help us as we engage with local municipalities and other key stakeholders to address the opioid crisis. Some of our specific areas of focus will include pharmacy outreach and education; public information campaigns conducted by local health departments; hiring epidemiologists and data staff to continue to assist in data collection; enhancing data collection with additional data sources; working to collect fatal overdose data from our county coroners; increasing syndromic surveillance to monitor and track opioid overdoses; training for first responders and physicians; and outreach regarding Hepatitis and HIV.

Since Gov. Wolf signed the first 90-day Heroin and Opioid Disaster Declaration in January, numerous initiatives have been put in place, including:

- Expanded access to the Prescription Drug Monitoring Program (PDMP) to other commonwealth departments for clinical decision-making purposes. Numerous local and state departments have already gained access to the database, and 17 states are now connected to Pennsylvania’s PDMP.
- Creation of prescribing guidelines for workers’ compensation, bringing the total number of guidelines to eleven.
- Waived fees for birth certificates for individuals with opioid use disorders, allowing them definitive identification and thus access to treatment and benefits. To date, 761 birth certificates fees have been waived through this process to help get people into treatment faster. The waiving of a 20-dollar fee may not seem like a big deal as we sit here, but to someone trying to get into treatment and in need of identification, this has the potential to be lifesaving.
- Implementing – at the request of various EMS agencies and public health entities – a Naloxone leave behind program which allows EMS providers to leave this critical medication behind with family or friends after reversing an opioid overdose. To date, hundreds of doses have been left behind on emergency scenes.
- Added non-fatal overdoses and neonatal abstinence syndrome (NAS) as reportable conditions. Close to 85 percent of our hospitals and birthing centers in the state are now reporting with more with 1,449 NAS cases reported to date. Note that some may be not be reporting because they have no cases, which is the preferred circumstance.
• Waived annual licensing requirements for high-performing drug and alcohol treatment facilities and have already seen 289 eligible facilities apply for and receive two-year licenses, ensuring continued, high-quality treatment for OUD sufferers.

The Governor’s Opioid Data Dashboard was created to help the public gain access to information about what resources are available locally, and where those resources need to be deployed.

Most recently, the Opioid Command center has implemented what we refer to as “EpiCenter alerts” to communicate unusually high numbers of emergency room visits for overdoses to state and local partners, including first responders, hospitals, county drug and alcohol staff, etc.

Now let’s look at where our Medical Marijuana Program may be of assistance in our efforts. The medical marijuana program was signed into law by Governor Tom Wolf on April 17, 2016. More than 70,000 patients in Pennsylvania have registered to participate, with nearly 44,000 having been certified for the program. More than 1,200 physicians have registered and nearly 800 of have been approved as practitioners. Patients and practitioners in Pennsylvania may see this program as a viable alternative to the highly addictive prescription opioid course of action.

Act 16 of 2016 Chapter 12, establishes the Medical Marijuana Advisory Board. The Board, which I have the pleasure of Chairing, was responsible for submitting a written report to the Governor, the Senate and the House of Representatives. The report was to include recommendations and findings on several topics. One of the topics addressed was whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this act. Section 1202 states that after receiving the report of the advisory board, at the discretion of the secretary, myself, the Department may promulgate regulations to effectuate recommendations made by the Board.

The Board completed their final report and adopted it unanimously at a public meeting held April 9, 2018 in accordance with the Act. There was a total of 21 recommendations and the Wolf Administration announced on April 16, 2018, that the Department would implement all of the recommendations made by the Board. I issued notice in the Pennsylvania Bulletin on May 12, 2018, that those recommendations would take effect May 17, 2018.

As a result of promulgating the regulations, effective May 17, 2018, the list of serious medical conditions for which a patient may be certified to use medical marijuana has expanded to include: Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.

I strongly agree with this recommendation because being able to conduct research on the use of medical marijuana for addiction treatment is a top priority, particularly in light of the current opioid crisis. In Pennsylvania, research under Chapter 20 of the Act will be designed to study the efficacy and utility of medical marijuana as medication for the qualifying serious medical conditions. Current data correlate well with patient’s individual experiences; however, formal controlled research trials are often requested as an outcome of observational studies but are very challenging to undertake based on Marijuana’s federal classification The Commonwealth’s
Chapter 20 research initiative provides a unique opportunity for us to thoroughly research the effects of medical marijuana.

In addition to using medical marijuana as part of a treatment strategy for opioid use disorder, medical marijuana for pain relief can keep some patients away from opioids entirely. Studies show that states with medical marijuana programs are seeing a reduction in the use of opioids, and patients are reporting relief from their symptoms, most notably in the area of pain management. It’s worth noting that nearly half of Pennsylvania’s registered patient population have a pain-based certification.

In summary, opioid use disorder as a new serious medical condition not only provides another tool in the toolbox for practitioners, it also puts Pennsylvania at the forefront for conducting cutting edge research at a time when physicians are looking for alternatives to addictive opioids.
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

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 pharmacologic 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.