Testimony of Marvin D. Seppala, MD
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Summary

My name is Marvin D. Seppala, MD, and I am the Chief Medical Officer at the Hazelden Betty Ford Foundation, the nation's largest nonprofit addiction treatment provider, with a legacy that began in 1949 and includes the 1982 founding of the Betty Ford Center.

My written statement below discusses the following main points:

- The Hazelden Betty Ford Foundation's experience with the epidemic of opioid misuse and how it drove us to develop a new treatment protocol called the Comprehensive Opioid Response with 12 Steps, or COR-12, program; and

- The dangers of opioid over-prescribing, which has unfortunately been fueled by a lack of prescriber and consumer education.

The misuse of opioids, the class of drugs that includes prescription pain medications and heroin, has reached crisis levels, with resulting overdoses ravaging families and communities throughout the country. This crisis deserves the attention you are providing today, and I am honored to offer my thoughts and expertise.

Written Statement

Chairman Murphy and Ranking Member DeGette, thank you very much for inviting me to participate in this important hearing. I am grateful to you and the other Members of the Subcommittee for your leadership in addressing the crisis of addiction to opioids in this country.

My name is Marv Seppala, and I am the Chief Medical Officer at the Hazelden Betty Ford Foundation. I attended the Mayo Medical School, and I have been practicing in the addiction treatment field since completing psychiatric training and an addiction fellowship at the University of Minnesota 27 years ago. On a personal note, I am also a person in long-term recovery from addiction; I've been sober since age 19.

The mission of the Hazelden Betty Ford Foundation is to help people reclaim their lives from the disease of addiction. We are the nation's largest nonprofit addiction treatment provider, with a legacy that began in 1949 and includes the 1982 founding of the Betty Ford Center. With 16 sites in nine states, we offer prevention and recovery solutions nationwide and across the entire continuum of care for youth and adults.

My testimony today will focus on two key points:

1. The Hazelden Betty Ford Foundation's experience with the epidemic of opioid misuse and how it drove us to develop a new treatment protocol called the Comprehensive Opioid Response with 12 Steps, or COR-12, program; and

2. The dangers of opioid over-prescribing, which has unfortunately been fueled by a lack of prescriber and consumer education.

The misuse of prescription painkillers and heroin has ravaged our nation's families and communities, to the point that the Centers for Disease Control and Prevention (CDC) has labeled the overdose deaths caused by these drugs an epidemic. Here at the Hazelden Betty Ford Foundation, there has been a pronounced increase in the number of patients with opioid use disorders. Opioid dependence among residential treatment admissions in our youth program, for example, increased from 15 percent in 2001 to 42 percent in 2014.

Individuals who are dependent on opioids face unique challenges that often undermine their ability to remain in treatment and ultimately achieve long-term abstinence. They are hypersensitive to real or imagined physical and psychic pain and are more vulnerable to stressful events, putting them at greater risk of relapse. They are more likely than other patients to leave treatment before completing it. And they are at higher risk of death from accidental overdose during relapse because of their reduced tolerance levels. Deaths can occur after treatment and a period of abstinence when people relapse and return to using the same doses they were taking prior to treatment, for which the body no longer has tolerance, causing respiratory depression.

Anxiety, depression and intense craving for these drugs can continue for months, even years, after getting free of opioid use. Those who are dependent on opioids experience a strong desire to feel "normal" again, to escape this seemingly permanent state of dysphoria, which puts them at a high risk of relapse, accidental overdose and death during relapse.

Our clinical response

In 2012, we launched a new treatment protocol designed to address this grim reality that more Americans were becoming addicted to opioids and dying from overdose.

Our new program – the Comprehensive Opioid Response with 12 Steps, or COR-12 as we call it – embraces the latest and best addiction treatment research and includes changes to traditional group therapy, additional patient education about opioids and the option of medication assistance. The research indicates certain medications improve recovery outcomes for people with opioid use disorders, so we integrated two medications – extended release naltrexone (Vivitrol®) and buprenorphine/naloxone (Suboxone®) – into our world-class Twelve Step Facilitation model to form the foundation of a unique new approach that we believe gives those with opioid dependence the best chance for lifelong recovery.

We use medications to engage our opioid dependent patients long enough to allow them to complete treatment and become established in solid Twelve Step recovery. The highest risk period for relapse is the first 12 to 18 months after treatment, so we prefer to have our patients remain on medication and involved in outpatient care throughout this period. Our goal is to discontinue the medication as our patients become established in long-term recovery.

Addiction is a complex brain disease that alters reward, motivation, memory and related circuitry. These alterations manifest in biological, psychological, social and spiritual dysfunction. Medication only treats the biological aspects of this illness, and patients using medication alone will not achieve the full gains of broad treatment using all the methods that we consider necessary for people entering recovery. Psychotherapies, abstinence from all addictive substances and a strong Twelve

Step orientation build a foundation that supports lasting recovery by improving psychosocial functioning, enriching relationships and fostering a healthier lifestyle. COR-12 attends to all of these aspects of recovery using a long-term approach for this chronic brain disease.

Our COR-12 team consists of medical, clinical and research professionals whose collective goal is to improve the lives of those suffering from opioid addiction. After thorough evaluation, they recommend to our admitting opioid dependent patients one of three COR-12 treatment paths: no medications, the use of Suboxone®, or the use of Vivitrol®. These evidence-based medications reduce the risk of overdose death, increase engagement in treatment and are extremely beneficial in preventing opioid use.

Those who opt for the non-medication pathway participate in all other aspects of the COR-12 program, including specialized group therapy and education that continues in the outpatient setting for 6-24 months. The Vivitrol® pathway includes the same psychotherapeutic endeavors with a monthly injection. Vivitrol® blocks opioid receptors in the brain, preventing the individual from experiencing intoxication from opioids. This medication has no euphoric effects and does not cause dependence, withdrawal or respiratory depression. The third group uses Suboxone® on a daily basis. Suboxone® is a partial opioid agonist, meaning it partially stimulates opioid receptors. It is used for opioid detoxification, as a maintenance treatment of opioid dependence, and for pain. It can be misused to get intoxicated and is sometimes diverted for nonmedical use, although most often to self-detoxify or to get by when the preferred opioid is unavailable.

While our clinicians make recommendations, the final decision on medication use is up to the patient. Of our COR-12 patients, approximately 33 percent choose the no medication pathway, 29 percent use Suboxone®, and 42 percent opt for Vivitrol®.

The COR-12 program has resulted in more patients completing residential treatment and a reduction in overdose deaths after treatment. While the research study of COR-12 is ongoing and we do not have full results yet, we do know our "atypical discharge" rates have dropped dramatically among opioid dependent patients. Many patients leave treatment earlier than recommended for a variety of reasons, which we call atypical discharges. The atypical discharge rate for our general population is 13.5 percent. For those with opioid dependence who are not involved in COR-12, it is 22 percent. Those in COR-12 are much more likely to complete residential treatment with an atypical discharge rate of about 7.5 percent, less than even the general treatment population.

Patients experience the same joy and heartache of early recovery, whether on medications or not, and in the treatment setting, it is not even perceptible which patients are on these medications. While a small group of our patients may need to remain on these medications for an extended period, our goal is to use the medications long enough to get patients solidly grounded in a Twelve Step lifestyle that ultimately allows them to discontinue the medication safely. Recovery is taking place every day in our outpatient settings as these patients dramatically change their attitudes, start to witness the real gifts of recovery and transition off medications.

Some see medication assistance and abstinence as diametrically opposed, and we have been criticized by those who support an abstinence-only approach for altering our program in this manner. We do not see a conflict. Even when medications are part of our protocol, abstinence is still the objective.

The medication, in those cases, is simply a part of the path to abstinence. We call it COR-12. But one might also call it the "Third Way" because it strikes a reasonable, common-sense balance, grounded in the Twelve Steps and based on abstinence, while also utilizing the safest, life-saving medications to keep patients engaged in recovery long enough to achieve lasting sobriety.

We have chosen to use everything at our disposal to treat opioid addiction. We remain absolutely committed to Twelve Step recovery, in fact even more so, having witnessed our COR-12 patients reclaim their lives. We hope our research can inform the addiction field on how best to combine therapies and utilize the most appropriate medications. Based on our early positive results, we plan to continue paving the way for others to use both scientific and spiritual solutions to engage more people in treatment, save lives and ultimately help more people get into long-term recovery.

Overprescribing Opioids

I would also like to emphasize the need to educate our wider culture about the dangers of opioid overprescribing, use and misuse, as well as the perilous transition that many users make from pills to heroin. Over the past two decades, the use of opioids has escalated dramatically in this country, with enormous human and financial costs to individuals, families and communities.

The Hazelden Betty Ford Foundation sees the devastating effects of opioid addiction every day at our 16 locations, and our observations have been consistent with a wave of sobering statistics that reveal a public health crisis the CDC calls the worst drug addiction epidemic in U.S. history.

For starters, the CDC reports that prescription painkiller overdoses more than quadrupled in the U.S. from 1999 to 2011, and heroin overdoses more than doubled, leading to about a half million emergency department visits in 2010 alone. While CDC data show prescription drug deaths dipping slightly in 2012, heroin deaths shot up even more. And deaths from drug overdose still outnumber those caused by car accidents, with an average of 110 overdose deaths per day in America and more than half of those involving opioids, according to the CDC. If any other major medical illness caused such devastation, there would have been an unprecedented response from the medical community, but we are dealing with a poorly understood illness that remains overtly stigmatized.

Not surprisingly, opioid use disorders are also on the rise. Data from the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2012 showed a 500 percent increase in treatment admissions for prescription drug disorders nationwide since 2001. The National Institute on Drug Abuse estimates 2.6 million Americans had an opioid addiction in 2012. Millions more, while not addicted, also reported nonmedical use of prescription painkillers, according to the CDC.

These alarming increases in overdose deaths, addiction and misuse parallel, as one might suspect, a skyrocketing rate of prescriptions for opioids. The CDC says prescriptions for opioid painkillers have tripled in the past two decades. In 2012, 259 million opioid prescriptions were written, enough for every American adult to have a bottle of pills. Today, despite having only 4.6 percent of the world's population, the U.S. consumes 80 percent of the world's supply of painkillers, according to the American Society of Interventional Pain Physicians.

These troubling trends began to emerge in the late 1990s, after the U.S. Food and Drug Administration (FDA) approved OxyContin and allowed it to be promoted to primary care doctors for treatment of common aches and pains. Physician organizations loosened standards governing opioid prescribing and then many began advocating for increased use of opioids to address what was perceived to be a widespread problem of undertreated pain.

Education campaigns, often funded by opioid manufacturers, minimized risks, especially the risk of addiction, and exaggerated benefits of using opioids long-term for common problems. In fact, there is no substantial evidence to support the long-term use of opioids for chronic pain. When prescribed on a short-term basis to treat moderate to severe acute pain, opioids can be helpful. In fact, they are the best medicines we have. But when these highly addictive medications are taken around-the-clock, for weeks, months and years, they may actually produce more harm than healing. An increasing body of research suggests that for many chronic pain patients, opioids may be neither safe nor effective. Over time, patients often develop tolerance, leading them to require higher and higher doses, which ultimately can lead to quality-of-life issues and functional decline, not to mention addiction. In some cases, opioids can even make pain worse, a phenomenon called hyperalgesia.

Increased opioid prescribing has established a new generation of opioid dependent individuals. Opioid prescription standards in the U.S. are so flexible now that patients sometimes get opioids even when they don't have significant pain. A 2014 study by the George Washington University School of Medicine showed a 10 percent increase in opioid prescriptions written for people visiting the emergency room yet only a 4 percent increase in people coming to the ER complaining about pain. Doctors need to become aware of the serious risk of overdose, dependence and addiction associated with opioid pain medications.

Many people associate prescription painkillers with older adults, and that certainly is a significant population affected by the current crisis, especially given the other sedating medications that older adults are sometimes prescribed.

Youth are increasingly at risk too, especially with opioids available in the medicine cabinets of so many homes. Young people are particularly vulnerable because their brains aren't fully developed until the mid-20s. Teens think the drugs are safe because a doctor prescribed them. But opioids can cause lasting changes to the brain. When abused, painkillers can be as life-threatening as heroin. According to the Foundation for a Drug-Free World, 2,500 American youths abuse a prescription pain reliever for the first time every day. In the 2012 National Survey of American Attitudes on Substance Abuse, 34 percent of teenagers reported they could get prescription drugs within a day. Furthermore, the National Institute on Drug Abuse (NIDA) says 70 percent of 12th graders reported obtaining prescription opioids from a friend or relative and that adolescent abuse of prescription drugs frequently is associated with other risky behavior.

According to Leonard Paulozzi, a physician and researcher with the CDC, about 75 percent of heroin users say they started out by using prescription opioids. That is consistent with what we hear from our young patients. They often report a relatively swift path from medicine bottle to heroin needle. As prescription supplies dry up and doctor-shopping options run out, heroin becomes the cheaper and more available alternative. That progression is scary considering that teenage abuse of prescription drugs has become so prevalent the Partnership for Drug-Free Kids refers to this age group as "Generation Rx."

Opioid problems are affecting every area of the country, devastating an entire generation in some hard hit communities like Staten Island, NY, where someone died of an opioid overdose every five days, on average, in 2012. Many of the lost are young people and some are parents. And many of those who escape death spend time incarcerated or are unfit to raise children because their addiction remains untreated.

This is a crisis that demands our attention and commitment, and at the center of this problem is overprescribing. Doctors didn't start overprescribing opioids out of malicious intent, but rather out of a desire to relieve pain more compassionately. The No. 1 reason people visit a physician is pain. Doctors were mistakenly informed beginning in the 1990s that treating all pain with opioids was safe. Physician visits are shorter. Non-prescription related health support services for pain patients have been fragmented and underutilized. Pressure to make decisions and provide quick solutions add to the doctor's dilemma. Reimbursement tied to patient satisfaction surveys also intensifies the pressure to prescribe opioid painkillers in hospital emergency departments. Often it is easier for a physician to write a prescription to maintain the 'status quo' than to ask the difficult question,

"Should I change how I am treating this patient?" Physicians need to limit opioid medication to the treatment of moderate to severe acute pain, and rarely use them for chronic pain.

We have a culture that seeks opioid medication for pain relief, and not just for physical pain, but also to numb psychic pain. Some of these patients have a significant risk for the development of addiction in a culture that promotes 'quick-fixes,' instant gratification and escapism.

Medical professionals need further education about the proper use of opioid medications and their risks. The general public also needs education to improve recognition of the risks and limitations of these powerful, dangerous medications. It's time for new education campaigns and new policies to help recalibrate and find a better balance – one that addresses opioid overprescribing and overuse without stigmatizing pain, in whatever imperfect but thoughtful ways we can. This crisis deserves the attention you are providing today and requires a substantial response not only from the federal government, but from all of medicine as well. The opioid crisis is too diverse for a single entity to solve; we need leadership and action from multiple sources.

We welcome your efforts to improve access to addiction treatment and improve the efficacy of treatment programs. The Hazelden Betty Ford Foundation will continue to do everything we can to contribute, but we need your help, we need physicians' help and we need the help of researchers and treatment programs across the country to develop a consensus regarding the solutions to this crisis.

Thanks again for having me here and for your leadership on this important topic. I look forward to answering your questions.

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