

HOW TO UNDERSTAND THE OPIOID EPIDEMIC

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Is there really such a thing as an opioid epidemic? Or it is just another hyperbolic term that is trending on social media? In order to answer this question, it may be helpful to understand what is meant by the term *epidemic*.

What is an epidemic?

The Centers for Disease Control and Prevention (CDC; 2012, p. 1) provides definitions of some closely related terms in the field of epidemiology:

Epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. **Outbreak** carries the same definition of epidemic, but is often used for a more limited geographic area. **Cluster** refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known. **Pandemic** refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people. (CDC, 2012, p. 1)

According to Mike Stobbe (2017), Medical Writer for the Associated Press, “There were fewer than 3,000 overdoses in 1970, when a heroin epidemic was raging in U.S. cities. There were fewer than 5,000 recorded in 1988, around the height of the crack epidemic” (p. 1). These figures pale in comparison to today’s death toll, when over 5,000 people per month die from overdoses. For example, the CDC reported that more than 64,000 Americans died from drug overdoses in 2016. Sixty percent (60%) of these deaths were from prescribed opioids, and 83% of heroin users started with abuse of prescription opioids. The National Institute on Drug Abuse (NIDA; 2018a) estimated more than 72,000 drug overdose deaths in 2017, with the sharpest increase occurring among deaths related to fentanyl and fentanyl analogs (synthetic opioids) with nearly 30,000 overdose deaths attributed to these drugs. For this same reporting period (2017), NIDA estimated 15,958 overdose deaths associated with heroin, 14,556 deaths associated with cocaine, and 10,684 deaths associated with benzodiazepines.

Historical Time Line Leading to the Opioid Epidemic

The opioid epidemic may not reach its peak for several years. For this reason, it may be helpful to take a historical perspective in order to understand the current trajectory into the future. A brief review of the time line leading to this epidemic illustrates some contributing factors, some of which are accompanied by this author’s (WFD) comments.

1960: Paul Janssen, a Belgian physician and founder of Janssen Pharmaceutica, and his team developed the fentanyl family of drugs as well as other anesthesia-related drugs (Stanley, 1992). With an effect 100 times more potent than morphine and up to 50 times stronger than heroin, fentanyl was introduced as a surgery anesthetic without the side effect of nausea (Davis & Dibble, 2018).

1968: Fentanyl was approved for medical use in the U.S. (Stanley, 1992).

1986: Russell Portney and Kathleen Foley’s article on chronic opioid use can be used as a starting point. Thirty-eight patients maintained on opioid analgesics for non-malignant pain were retrospectively evaluated to determine the indications, course, safety and efficacy of this therapy. As a result of their study of these 38 patients, Portenoy and Foley (1986, p. 171) drew the following conclusion: “We conclude that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse.” Three decades later, many non-psychiatric physicians are still quick to describe opioids as safe.

1990: Managed care companies restrict access to treatment. Although Kaiser Permanente, one of the largest integrated managed care consortiums in the U.S., was founded in Oakland, California, in 1945, the influence of managed care was not noticed as significantly on the East coast and in the Southern U.S. until the late 1980s and 1990s. The increasing *biologicalization* of the field of psychiatry sees an emergence of a managed care model that replaces treatment. In effect, “If you can’t get treated, at least get medicated.”

1995: The U.S. Food and Drug Administration (FDA) approves Purdue Pharmaceutical’s Oxycotin[®], and states to physicians that the drug “would result in less abuse potential.” It was the first

formulation of the drug that allowed dosing every 12 hours instead of every 4 to 6 hours.

- 1995:** In his Presidential Address to the American Pain Society (APS), James Campbell, M.D. (1995) presented the idea of evaluating pain as a vital sign. Where is a pain, there is a pill.
- 1996:** The American Pain Society (APS), an organization partially funded by pharmaceutical companies, introduced the phrase “pain as the 5th vital sign.” This initiative encouraged clinicians to take action when patients report pain.
- 1998:** FDA approves Actiq[®] (fentanyl), which was the first pain medicine approved to treat breakthrough pain associated with cancer.
- 1997:** FDA revokes 21 CFR 329.10 labeling requirements for habit-forming drugs (i.e., “Warning—May be habit forming”).
- 1998:** The Federation of State Medical Boards (FSMB) issued guidelines to physicians who prescribe opioids, saying they could be “essential” for treatment of chronic pain.
- 1999:** By the late 1990s, the idea of “pain as a 5th vital sign” had rapidly caught on nationally and was been adopted by the Veterans Health Administration (VHA; 2000) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO; now called simply The Joint Commission).
- 2000:** The Joint Commission recommended that pain be assessed in all patients (JCAHO Standard PE1.4, 2000).
- 2000:** Chronic pain is reported by 100 million Americans, 25% of whom say that it limits their quality of life.
- 2000s:** 20+ states passed laws and regulations expanding opiate prescription, requiring doctors to inform patients of the drugs’ availability and making it more difficult to prosecute physicians who prescribed them liberally.
- 2000s:** FDA approves ever more powerful opioids for long-term use based only on evidence of short-term safety.
- 2000s:** Reports of overdose and death from prescription pain drugs, especially OxyContin[®], began to rise sharply.
- 2003:** FDA issued a Warning Letter to OxyContin’s[®] manufacturer for making misleading advertisements.
- 2005:** The first major wave of illicit fentanyl-laced heroin was introduced in the U.S. around 2005 and 2006 (David & Dibble, 2018).
- 2007:** Opioid makers provided the Federation of State Medical Boards (FSMB) with \$586,620.00 to help publish a book version of the FSMB guidelines that said opioid pain treatment was essential.
- 2007:** Purdue Pharma paid out one of the largest fines ever levied against a pharmaceutical firm for mislabeling its product OxyContin[®], and three executives were found guilty of criminal charges.
- 2012:** The so-called “abuse deterrent” drug Opana[®] drug generated \$1.16 billion a year in sales for Purdue Pharma from 2008-2012). By 2017, the drug was found to be so highly addictive that the FDA asked the manufacturer to remove its reformulated, extended-release drug from the U.S. market.
- 2012:** On December 10, in a 11-2 vote (with one abstention) against approval, a panel of experts assembled by the FDA said that while the drug’s maker, Zogenix, had met narrow targets for safety and efficacy, the painkiller Zohydro[®] could be used by people addicted to other opioids, including oxycodone. Zohydro[®] contains the opioid hydrocodone. Unlike some hydrocodone products such as Vicodin[®], Zohydro[®] does not contain acetaminophen.
- 2013:** In January, FDA released draft guidance to assist manufacturers in developing abuse-deterrent opioids, 1 month after Zogenix presented Zohydro ER[®] to the FDA advisory committee that advised against approval. According to Andrew Kolodny, Co-Director of the Opioid Policy Research Collaborative at the Heller School for Social Policy and Management at Brandeis University, “this may be the first time in history that the FDA will allow a drug to be released despite a landslide vote to keep it off the market” (Kolodny, 2014, p. 1).
- 2013:** On April 15—the day the patent for the original OxyContin[®] was expiring—FDA approved new labeling for Purdue Pharma’s 2010 reformulation of OxyContin[®] and also rescinded its approval of the original OxyContin. This action had the effect

of preventing generic pharmaceutical companies from getting generic copies of the non-abuse-deterrent version of OxyContin[®] approved by FDA (Controversy surrounds FDA approval of Zohydro, 2013).

Zohydro[®] is an easily crushed capsule that contains up to 50 milligrams of pure hydrocodone—10 times more hydrocodone than a regular Vicodin[®]. An adult lacking a tolerance to opioids could overdose from taking just two capsules, and only one capsule of Zohydro[®] can kill a child.

If you are concerned about FDA approval of Zohydro, then you are in good company. On February 26, 2014, a letter signed by more than 40 organizations was sent to FDA Commissioner Hamburg, urging her to keep Zohydro off the market. The organizations include some of the most prominent addiction-treatment agencies in the country, including Hazelden, Caron, and Phoenix House. Other co-signers include CASAColumbia, the American Society of Addiction Medicine, Blue Cross Blue Shield, the consumer advocacy group Public Citizen, and dozens of community-based addiction-prevention organizations.

2013: On October 25, the FDA approved hydrocodone bitartrate extended-release capsules (Zohydro ER[®]—Zogenix), a single-ingredient opioid product with no abuse-deterrent features. The decision to approve Zohydro ER[®] without such controls went against the 2012 recommendation of the FDA's own advisory committee and came just a day after FDA announced its intent to recommend that U.S. Drug Enforcement Agency (DEA) move combination hydrocodone products from Schedule III to Schedule II (American Pharmacists Association, 2013).

2014: FDA changed rules for prescribing the following drugs, the generic versions of which are listed in bold: **codeine**, **fentanyl** (Fentora[®], Duragesic[®], and Actiq[®]), **hydrocodone** (Vicodin[®], Norco[®], Lortab[®], and Lorcet[®]), **hydromorphone** (Exalgo[®], Dilaudid[®]), **meperidine** (Demerol), **methadone** (Methadose[®], Dolophine[®]), **morphine** (Ora-Morph SR[®], MS Contin[®], Kadian[®], and Avinza[®]), and **oxycodone** (OxyContin[®], Percocet[®], and Roxicodone[®]).

The new rules apply to all of the patch, extended release (ER), and long-acting (LA) versions of the drugs. The FDA is not changing rules for the fast-acting versions of these drugs.

2015: FDA has not approved an abuse-deterrent labeling claim for Zohydro ER[®].

2015: Pharmaceutical corporations misleadingly market opiates as “abuse deterrent” (e.g., Opana[®]). The drug had generated \$1.16 billion a year in sales for Purdue from 2008-2012). In contrast, the costs of prescription opioid misuse in the U.S. comes out to \$78.5 billion a year (NIDA, 2018b).

2016: Fentanyl-type drugs alone were responsible for killing nearly 20,000 people in the U.S. (CDC, 2018). (Davis & Dibble, 2018).

2017: Fentanyl became the most widely used synthetic opioid in medicine (National Institutes of Health, 2017).

2017: In June, the FDA asked the manufacturer (Endo Pharmaceuticals) to remove its so-called “abuse deterrent” drug, Opana[®] (e.g, oxymorphone ER), from the U.S. market due to rates of IV abuse. The FDA concluded that the highly addictive drug’s risks outweighed its benefits (FDA to drugmaker, (2017).

2017 (March): Fentanyl and carfentanil (aka, carfentanyl) became scheduled drugs in China, although the drugs are still manufactured and marketed there. Most U.S. law enforcement experts consider China to be the main source from which Mexican cartels obtain these drugs, which are smuggled across the U.S. border and mixed with virtually everything. Based on seizures of these drugs, the DEA indicates that China supplies lower volumes of high-purity fentanyl and Mexico supplies higher volumes of fentanyl that is lower in purity.

The potency of illicit forms of fentanyl is difficult to imagine, with fentanyl 30 to 50 times more potent than heroin and 50 to 100 times more potent than morphine. In contrast, carfentanil is up to 10,000 times more potent than morphine. The DEA estimates that the amount of illicit fentanyl it takes to induce respiratory depression, arrest, and even death is about 2 to 3 milligrams—the equivalent to 5 to 7 individual grains of table salt (Garza, 2018).

2017 (June): FDA asked the Purdue Pharma to remove its so-called “abuse deterrent” drug, Opana[®], from the U.S. market due to rates of IV abuse.

2017 (August): 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 (NIDA, 2018a).

2018 (July): Two well-established pipelines have been feeding the U.S. opioid epidemic: (1) One fentanyl distribution route runs north through the Mexican cartel, with 80% of the drug funneled through San Diego border, (2) One pipeline flows east from Chinese laboratories to U.S. customers via hard-to-detect mail packages that are sometimes as small as envelopes (Davis & Dibble, 2018).

2018 (July): The CDC (2018) issued a Health Alert Network update for emergency preparedness and response to the increasing number of deaths associated with the use of drugs classified as fentanyl analog/synthetic opioids such as carfentanil, furanylfentanyl, 3-methylfentanyl, acrylfentanyl, and U-47700.

2019 (July): The American Pain Society filed Chapter 7 bankruptcy and their 2019 meeting was cancelled. The bankruptcy action was in response to the myriads of law suits targeting big Pharma for the opioid crisis. The litigation is apparently throwing out a wide net of liability, with the reasoning being that professional societies such as APS acted as fronts for big Pharma in promoting dangerous overprescribing of opioids. In reality, the American Pain Society was the flagship professional organization in the field of multidisciplinary pain management for the past 40 years. It published a world class refereed research journal *The Journal of Pain*, which included quality research publication ranging from psychological/behavioral studies to basic science things like brain structures, neurochemistry, and even rat tail flicks. Ironically, the loss of this multidisciplinary organization represents a loss for safe, psychological, and non-addictive approaches to pain management.

2019 (September): Purdue Pharma is expected to file for bankruptcy protection now that settlement talks over its role in the nation's opioid crisis have hit a standstill. Purdue and owners, the Sackler family, offered to settle some 2,000 lawsuits against the company for a reported \$10–\$12 billion, but discussions stalled and the Sacklers reportedly rejected two proposals and refused to offer any additional solutions. There are lawsuits filed against the company by local governments across the country and in nearly every state. According to state attorneys general negotiating with Purdue, the Sackler family rejected a demand that they

give up \$4.5 billion of their personal wealth to settle opioid claims against the company, As a consequence, the attorneys general predicted that the company will file for bankruptcy protection “imminently.”

2019 (November): Physician Kenneth Sun, M.D., 58, pleaded guilty to taking \$140,000.00 in bribes and kickbacks from Insys sales representatives to prescribe Subsys®. The product is a fentanyl sublingual (under the tongue) spray opioid pain medication that is used to treat “breakthrough” cancer pain that is not controlled by other medicines.

2020: John Kapoor, 76, the founder and former head of a specialty pharmaceutical company was sentenced to 5½ years in federal prison for overseeing a criminal conspiracy that involved bribing a network of doctors to peddle highly addictive and deadly opioids for purposes for which they were never intended. It was reported that Kapoor built a personal fortune of over \$3 billion at the same time that more than 8,000 people died of overdoses after taking Subsys®, a drug his company produced. “This was an offense of greed,” U.S. District Court Judge Allison D. Burroughs said before sentencing Alec Burlakoff, 46, former vice-president of sales at Insys. Burlajoff was sentenced to 20 months in prison; several other Insys managers were also sentenced.

How does addiction impact our community?

The level of drug use in the U.S. is believed to be the highest in the industrialized world (Perkinson, 2012, p. 12). Although heroin is often described as the most addictive drug, prescription pain killers account for the majority of opiates used by those who are addicted in the U.S. The CDC (2015) reports that since 1999 the amount of prescription painkillers prescribed and sold in the U.S. has nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report. The International Narcotics Control Board (INCB) reports some staggering statistics. With only 5% of the world's population in 2007, the U.S. accounted for over 99% of global consumption of hydrocodone (e.g., Vicodin®, Lorcet®), and 83% of global consumption of oxycodone (INCB, 2009, p. 20). According to the INCB (2013), the U.S. annually consumes approximately 124 tons of thebaine-based opiates such as oxycodone (e.g., OxyContin®) and oxymorphone (e.g., Opana®). Although some columnists such as Roger Chriss (2018) dispute these numbers, Statistica (2018) reports that in 2015 the U.S. consumed 30.1% of the world's supply of prescription fentanyl, with the U.S. far exceeding the consumption rates other countries in the top 10: Germany (19.8%), Spain

(6.4%), United Kingdom (5.8%), France (4.8%), Canada (4.6%), Netherlands (2.9%), Italy (2.5%), Belgium (2.2%), and Japan (2.1%). Even Chriss (2018) admits that in 2015 the U.S. comprised about 4.4% of the world's population yet consumed about 30% of the world's opioid medication.

Opioid addiction. Although crystal methamphetamine is often described as the most deadly drug, the leading cause of accidental death is prescription drug overdose, resulting in more deaths than crystal meth, cocaine, and heroin combined (CDC, 2015). With one overdose death every 14 minutes, since 2009 prescription drug overdoses have surpassed motor vehicle accidents as the major cause of accidental deaths (Warner, Chen, & Makuc, 2009). According to preliminary data compiled by *The New York Times*, opioid deaths in 2016 most likely exceeded 59,000, representing 19% more than the previous year and the largest annual jump ever recorded in the U.S. (Katz, 2017).

Alcohol addiction. Although drug overdoses are the leading cause of death among Americans under age 50, the number of drug-addicted Americans is exceeded ten-fold by those addicted to America's most popular legal substance—alcohol. According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA; 2017), alcohol is the substance with the highest prevalence of use during the month prior to when the SAMSHA survey was conducted. Although caffeine is actually the most widely used psychoactive substance in the U.S. (Barlow, Durand, & Hofmann, 2018), SAMHSA is concerned with substance use disorders (i.e., abuse and dependence), and thus caffeine (e.g., coffee) is not included in SAMSHA annual surveys.

Nicotine addiction. In contrast to sex, drugs, and rock-n-roll, smoking is still America's most wanted killer. According to Nora D. Volkow, M.D., Director of the National Institute on Drug Abuse (NIDA), tobacco use is still the leading preventable cause of death in the United States (NIDA, 2009). Although the CDC reports that there has been a decline of almost 50% in tobacco use since 1965, tobacco use results in more deaths than any other drug in the U.S., with one in every five U.S. deaths annually resulting from smoking. On average, tobacco smokers die 10 years earlier than nonsmokers. In fact, tobacco kills more Americans than alcohol, cocaine, heroin, homicide, suicide, car accidents, fire, and AIDS combined (NIDA, 2009). The Office of Smoking and Health (National Center for Chronic Disease Prevention and Health Promotion, 2014) estimates that cigarette smoking is responsible for more than 480,000 deaths per year in the U.S., including more than 41,000 deaths resulting from second hand smoke exposure.

What are HHS and NIH doing about it?

The National Institutes of Health (NIH), a component of the U.S. Department of Health and Human Services (HHS), is the nation's leading medical research agency helping solve the opioid crisis by discovering new and better ways to prevent opioid misuse, treat opioid use disorders, and manage pain. In response to the opioid crisis, HHS and NIH are focusing their efforts on five major goals:

1. Improve access to treatment and recovery services.
2. Promote use of overdose-reversing drugs.
3. Strengthen our understanding of the epidemic through better public health surveillance.
4. Provide support for cutting-edge research on pain and addiction.
5. Advance better practices for pain management.

How can opioid addiction be prevented?

Thinking about strategies of prevention requires understanding the three levels of prevention:

1. *Primary prevention* involves reducing factors that lead to a prevalence of a disease in the first place.
2. *Secondary prevention* involves early identification and detection of a disease in order to prevent it from getting worse.
3. *Tertiary prevention* focuses on accurate diagnosis and evidence-based treatments that have been shown to reduce symptoms and improve the quality of one's life.

Primary prevention will require a shift in the U.S. culture's drug-taking mentality (e.g., "When there's a problem, take a pill") as well as a shift in focus of both government and private industry's funding of the easy distribution of painkillers. An article in *The Guardian* contained the observation that "drug money is coursing through the veins of Congress—contributing directly to an epidemic that kills thousands of Americans each year" (McGreal, 2017, p. 1). In the last decade, drug makers have spent \$2.3 billion lobbying the U.S. Congress (Chon, 2016), whose legislative efforts have shown the pharmaceutical industry a good return on their investments. The level of drug use in the U.S. has been reported to be the highest in the industrialized world (Perkinson, 2012, p. 18). In other words, the complex origins of the U.S. opioid epidemic seem to involve supply and demand.

Secondary prevention must focus on supply, beginning with the sources from which most people receive their supplies—which are not professional drug dealers. Drug dealers are obviously the source of illegal drugs such as heroin and various forms of fentanyl that are not available by prescription. Data from SAMHSA (2014, 2017) indicate that when it comes to prescription opioids, drug

dealers play a limited role in the supply chain. At least 50% of non-medical users of prescription opioids get them from friends or relatives, and 25% of people get them by prescription from physicians. Despite the often cited problem of people obtaining prescriptions from multiple prescribers, most people receive their prescriptions from one physician. In contrast, fewer than 10% of opioids are purchased from drug dealers or other strangers. We have met the dealer—and he is us.

Tertiary prevention focuses on diagnosis and treatment. Addiction affects 23.2 million Americans—a number roughly equivalent to the entire population of Texas—of whom only about 10% are receiving the treatment they need. This *treatment gap* means that almost 20 million Americans do not receive the treatment they need. Yet two National Institute of Health institutes—the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA)—have revealed startling new advances in the fight against alcohol and other drug addiction. The SAMHSA (2015) National Registry of Evidence-based Programs and Practices (NREPP) includes 356 interventions, dozens of which have application in the treatment of addiction. Three of the most widely-used evidence-based psychological treatments are Motivational Enhancement Therapy, Twelve Step Facilitation Therapy, and Cognitive Behavioral Skills Training (e.g., Cocaine-Specific Coping Skills Training). Because opioids are primarily used for pain management, it makes sense to use less lethal means of managing pain, such as some of the cognitive-behavioral therapy for chronic pain (Thorn, 2004, 2017, 2018) and other non-drug evidence-based pain management strategies that are based on gate control theory (Melzack, 1996; Melzack & Wall, 1965; Wall, 1978).

Because addiction is a chronic, relapsing disorder (Koob, 2005; Koob & Le Moal, 2001; Koob & Volkow, 2010), it is often helpful for patients and their families to think of managing it as they would manage any chronic medical condition (e.g., bipolar disorder, diabetes, and so forth). Medication-assisted treatment (MAT) is an evidence-based means of managing opioid use disorder (Bisaga & Chernyaev (2019). MAT, also known as psychopharmacological treatments, include but are not limited to the use of (1) partial opioid agonist-antagonists such as buprenorphine (e.g., Subutex[®]), which can be used to treat withdrawal and craving, and (2) buprenorphine with naloxone added (e.g., Suboxone[®]). Pharmacological interventions can include opioid substitution such as methadone maintenance (e.g., Methadose[®], Dolophine HCL[®]), which is often a treatment of last resort for intractable heroin addiction. Finally, for emergency stabilization of overdose rather than for longer-term control of opioid dependence, opioid antagonists such as naloxone (Narcan[®]) can be used to save lives by reversing

depression of the central nervous system, respiration, and hypotension associated with opioid overdose.

Last but not least, it is important to end the stigma of addiction, which is a chronic relapsing disease that should be treated that way. The sense of isolation that individuals and families experience when struggling with addiction is unconscionable. People can change this epidemic by speaking out and ending the stigma of addiction.

What is the paradox of prevention?

The *prevention paradox* is a phenomenon described by epidemiologist Geoffrey Rose (1981), who observed that a seemingly contradictory situation in which the majority of cases of a disease occur in people who are at low or moderate risk of cardiovascular disease, whereas only a minority of cases of the same disease occur in high risk segments of a population. This phenomenon occurs because the number of people at high risk is relatively small, whereas the number of people at lower risk is much larger. In applying this concept to the field of substance use disorders, the implication is that a greater societal benefit will accrue by achieving a small reduction in substance abuse within a large group of “at-risk” users with less serious problems than by attempting to reduce substance problems among the much smaller number of substance dependent people.

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