

## **Part A: Questions and Answers Regarding the History and Evolution of Methadone Treatment of Opioid Addiction in the United States**

### **Question 1: When was opioid addiction first observed in the United States?**

**Answer:** Widespread prevalence of opioid addiction was first documented in the United States following the U.S. Civil War of 1861–1865, when narcotics administered to injured soldiers prompted observers to describe addiction as “the Army disease” (Hentoff, 1965).

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## Question 2: What is the history of opioid addiction in the United States?

**Answer:** Opioid addiction in the United States can be documented in three broad time periods:

- 1860–1910
- 1910–1950
- 1950–Present

### 1860–1910

Although opioids have been used as pain medications and anti-anxiety drugs throughout recorded history, it was not until the U.S. Civil War of 1861–1865 that widespread prevalence of opioid addiction was documented in the United States (Hentoff, 1965). The synthesis of heroin in 1874 and its commercial marketing as a “wonder drug” contributed to a pattern of iatrogenic addiction that continued into the early 1900s, with physicians, pharmacists, and patent medicine salesmen dispensing narcotics freely to patients who were primarily middle-aged, middle-class women (Courtwright, 1992; United Nations Department of Social Affairs, 1953; Acker, 2002). The Institute of Medicine estimated that by 1900, perhaps 300,000 Americans were addicted to opiates (Courtwright, 1992).

### 1910–1950

Between 1910 and 1950, opioid addiction was rarely prevalent among U.S. patients inadvertently addicted to a medical cure. The Institute of Medicine describes how successive waves of immigration and urbanization contributed to a population of opioid abusers who were in their teens or early 20s, unmarried, poor, primarily male, ethnic minorities who experimented with drugs for nonmedical purposes (Courtwright, 1992).

### 1950–Present

Intravenous use of heroin intensified in the United States after WWII, reaching epidemic proportions in urban centers during the 1950s and 1960s (Joseph, Stancliff, and Langrod, 2000). In 1967, the National Survey on Drug Use and Health (NSDUH) began collecting data on heroin use. The survey documents dramatic increases in the initiation of heroin use during the early 1970s and between 1995 and 2002 (Substance Abuse and Mental Health Services Administration, 2005), when the annual number of new heroin users ranged from 121,000 to 164,000. The National Institute on Drug Abuse (NIDA) reports that, during this period, most new users were age 18 or older (on average, 75 percent) and most were male (National Institute on Drug Abuse, 2005a). The 2003 NSDUH found that an estimated 3.7 million Americans had used heroin at some time in their lives and 314,000 in the past year. The group that represented the highest number of those users was age 26 or older (National Institute on Drug Abuse, 2005a). NIDA also reports that heroin use in 2003 was stable at low levels (National Institute on Drug Abuse, 2005b).

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Substance Abuse and Mental Health Services Administration. Table 4.4A Numbers (in Thousands) of Persons Who Initiated Heroin Use in the United States, Their Mean Age at First Use, and Rates of First Use (per 1,000 Person-Years of Exposure): 1965–2003, Based on 2002–2004 NSDUHs. *Results From the 2004 National Survey on Drug Use and Health, Detailed Tables*. Rockville, MD: SAMHSA Office of Applied Statistics, 2005. Available online at: [www.oas.samhsa.gov/nsduh/2k4nsduh/2k4tabs/Sect4peTabs1to15.pdf](http://www.oas.samhsa.gov/nsduh/2k4nsduh/2k4tabs/Sect4peTabs1to15.pdf). [Accessed March 26, 2006.]

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### Question 3: What is the history of U.S. regulation of heroin?

**Answer:** U.S. regulations governing the manufacture, distribution, or use of heroin fall into four historical time periods:

- 1860–1909: Minimal Government Involvement
- 1909–1924: Increasing Federal Government Role
- 1924–1960: Criminalization of Narcotics Use
- 1960–Present: Combined Medical-Criminal Approach

#### **1860–1909: Minimal Government Involvement**

The Institute of Medicine documents U.S. narcotics policies from the 19th century through 1992 (Courtwright, 1992). In the first years following widespread use of heroin in the United States, there were no Federal regulations about the manufacture, distribution, or use of heroin, and the few State or municipal laws that existed were enforced sporadically. Physicians, pharmacists, and opportunists were free to prescribe opioids—and treat subsequent opioid addiction—in whatever manner they chose, which contributed to widespread addiction and sometimes unscrupulous practices. Inadvertent addiction to early over-the-counter medications prompted enactment of the 1906 Pure Food and Drug Act, which first authorized Federal regulations on any medication.

#### **1909–1924: Increasing Federal Government Role**

In the United States, heroin was first placed under Federal control by the 1914 Harrison Narcotic Act, which required anyone who sold or distributed narcotics—importers, manufacturers, wholesale and retail druggists, and physicians—to register with the Federal Government and pay an excise tax. The United Nations *Bulletin on Narcotics* documents early international efforts to address opioid addiction (United Nations Department of Social Affairs, 1953). The United States was among the organizers of the 1909 International Opium Commission in Shanghai, China, and a signatory of the 1912 Hague Opium Convention, the first international treaty to make heroin a controlled substance.

#### **1924–1960: Criminalization of Narcotics Use**

Between 1924 and 1960, the United States approved a series of progressively stiffer narcotics policies, first establishing mandatory sentences for possession and sale of opioids in 1951 (Courtwright, 1992). Internationally, the United States was a signatory to two more international treaties to limit the manufacture of narcotics: the Geneva Convention of 1925 and the Limitation Convention of 1931 (United Nations Department of Social Affairs, 1953).

#### **1960–Present: Combined Medical-Criminal Approach**

Scientific advances in the 20th century revolutionized our understanding of addiction and contributed to a medical approach to drug abuse treatment coupled with criminal sanctions for drug traffickers. The 1962 White House Conference on Narcotic Drug Abuse first recommended more flexible sentencing, wider latitude in medical treatment, and more emphasis on rehabilitation and research. By 1971, the Special Action Office of Drug Abuse Prevention (SAODAP), established within the White House, was responsible for drug treatment and rehabilitation, prevention, education, training, and research.

Currently, heroin is regulated under the Controlled Substances Act. Federal policies and regulations about heroin are coordinated by the following agencies:

- The Office of National Drug Control Policy (ONDCP) operates within the White House to establish policies, priorities, and objectives for the Nation's drug control program.

- The Substance Abuse and Mental Health Services Administration (SAMHSA) operates within the U.S. Department of Health and Human Services to promote and regulate addiction treatment services.
- The Drug Enforcement Administration (DEA) operates within the Department of Justice to prevent diversion and illicit use of controlled substances and administer criminal sanctions for drug traffickers.

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## Question 4: How have U.S. regulations about treatment for heroin addiction evolved?

**Answer:** U.S. regulations about treatment for heroin addiction evolved through three time periods:

- 1914–1972
- 1972–2000
- 2000–Present

U.S. regulations about treatment for heroin addiction have evolved from strict prohibition of medical prescription of heroin to treat addiction, which began in 1914 and continued into the 1960s. Initial pilot studies testing methadone maintenance treatment for heroin addiction began in 1964, and methadone maintenance treatment was formally approved in 1972. Scientific advances prompted major reviews of Federal regulations by the Institute of Medicine in 1995 (Rettig and Yarmolinsky, 1995) and the National Institutes of Health in 1998. Both reports recommended reducing Federal regulations and improving patients' access to treatment. The Drug Addiction Treatment Act of 2000 (Substance Abuse and Mental Health Services Administration, 2000b) made significant changes in U.S. regulations about treatment for heroin addiction, reducing Federal regulations and paving the way for new pharmacotherapies to treat heroin addiction.

### 1914–1972

Although heroin became a controlled substance under the Harrison Act of 1914, the law did not expressly prohibit the medical prescription of heroin to treat addiction. The U.S. Government concluded that the Harrison Act intended to prohibit such medical uses of controlled substances, prosecuting individual doctors who prescribed the drugs. In 1919, the U.S. Supreme Court upheld the Government's position in *Webb v. United States*. In response, about 40 localities opened municipal narcotic clinics to treat addiction using a variety of methods, including medical prescription of narcotics, but by the mid-1920s, these clinics had all been closed by the Federal Government (Hentoff, 1965; Courtwright, 1992). A decade later, the U.S. Public Health Service established narcotics hospitals in Lexington, Kentucky, and Fort Worth, Texas, to treat heroin addiction. From 1935 through the 1960s, the Kentucky facility was the "single most important treatment and research facility in the country (Courtwright, 1992). In 1949, researchers at the Kentucky hospital first demonstrated that methadone could be effective in withdrawing patients from heroin, but relapse rates were as high as 90 percent in subsequent studies. A 1964 pilot study by Drs. Vincent P. Dole and Marie E. Nyswander first demonstrated that methadone maintenance could be an effective medical intervention for heroin addiction (Joseph, Stancliff, and Langrod, 2000).

### 1972–2000

Methadone maintenance treatment for heroin addiction was first approved by the U.S. Food and Drug Administration in 1972, subject to three levels of Federal regulation:

- Food and Drug Administration rules that pertained to all prescription drugs
- Drug Enforcement Administration rules that governed all controlled substances
- Unique Department of Health and Human Services rules limiting methadone maintenance treatment to strictly controlled opioid treatment programs, which also were subject to additional State or local rules

### 2000–Present

The Drug Addiction Treatment Act of 2000 (Substance Abuse and Mental Health Services Administration, 2000b) revised Federal regulations governing methadone maintenance treatment, making

them both more rigorous and more practical. While treatment providers have more latitude in planning individualized treatment regimens and prescribing methadone dosages, they also must document and analyze outcomes and correct shortcomings (Marion, 2005). The law also authorized office-based dispensing of treatment medications providing physicians met specific licensing, certification, training, and best practices requirements. Buprenorphine, a new pharmacotherapy to treat heroin addiction (Substance Abuse and Mental Health Services Administration, 2000a), was approved for office-based dispensing by the Food and Drug Administration in 2002.

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**Question 5: What is methadone?**

**Answer:** Methadone is a rigorously well-tested medication that has been safely used to treat opioid addiction in the United States for more than 40 years. Methadone

- Blocks the craving for opioids that is a major factor in relapse.
- Suppresses the symptoms of opioid withdrawal for 24 to 36 hours.
- Blocks the effects of administered heroin.
- Does not cause euphoria, intoxication, or sedation.

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**Question 6: When was methadone maintenance introduced to treat heroin addiction?**

**Answer:** For 40 years, methadone maintenance treatment has been used successfully to treat heroin addiction in the United States. From the first pilot project in 1964, when Drs. Vincent P. Dole and Marie E. Nyswander established that methadone maintenance treatment was an effective medical intervention for heroin addiction, rigorous scientific research has documented the safety and effectiveness of methadone maintenance to treat heroin addiction.

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**Question 7: How has the U.S. Government been involved in research on methadone maintenance treatment?**

**Answer:** Through the extensive research grant programs administered by the National Institutes of Health, the Federal Government funds most major medical research conducted in the United States, including research on methadone maintenance treatment. In addition, some of the research on methadone maintenance treatment has been conducted by the Federal Government itself at research facilities like the U.S. Public Health Service Hospital in Lexington, Kentucky, where methadone was first shown to be effective in treating the symptoms of heroin withdrawal.

Research on methadone maintenance treatment is the responsibility of the following Federal agencies:

- National Institute on Drug Abuse
- Substance Abuse and Mental Health Services Administration
- Centers for Disease Control and Prevention
- Food and Drug Administration

**Question 8: What is the international approach to maintenance treatment for heroin addiction?**

**Answer:** In 2004, the World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC), and the Joint United Nations Programme on HIV/AIDS (UNAIDS) adopted a joint position paper on substitution maintenance therapy for opioid dependence, calling substitution maintenance therapy one of the most effective treatment options (World Health Organization, 2004).

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