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The Opioid Crisis: Competing Values in the Regulatory State

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Thesis. From the earliest references to the opium poppy in 3,400 B.C.E., to the Opium Wars of the mid-1800s to the present day, opium in its various forms – resin, morphine, heroin and newer synthetic forms such as fentanyl – has been used both medicinally and recreationally. Following its first opium "epidemic" during and following the Civil War, the United States made a series of decisions about opiates, as well as about the manufacture and marketing of other drug products, food and cosmetics, that put us on a course on which many values and philosophies collided: medical autonomy and privacy versus the regulatory state; the self-regulation of the medical profession versus state regulation; public health and safety versus the regulatory state; the categorization of addiction/dependence as a moral versus medical condition; the value and wisdom of rehabilitative versus criminal "solutions" to drug problems and the spending decisions that necessarily follow; and the extent of power of the regulatory state and where that power lies (in the pre-marketing approval of drugs or post-marketing, and why not both?), to name a few. The decisions that were made along the way, from the 1906 Pure Food and Drug Act to last year's SUPPORT Act, are the result of how these values and philosophies evolved based on the cultural, political, technical and public health developments of their respective times and, influenced by the vast amounts of money in the pharmaceutical industry and the strength of the medical industry, became codified into law. By examining how these policies and laws have played out in the current opioid epidemic, we can recognize the pockets of weakness in our current regulatory scheme and determine whether our current course of legislative and regulatory enactments have the chance of resolving this crisis or whether other fundamental changes are necessary to bring the United States to an acceptable level of public health.

What follows is a timeline of events and legislation, as well as statistics, that have been taken into account in developing my live presentation.

1820s: Isolation of Morphine - A German apothecary, Friedrich Serturner, isolated the active ingredient inside the opium poppy, an alkaloid, that he named morphine after the Greek god of dreams, Morpheus.[i]

1840: Opium Use in U.S. - Approximately 10,000 opium habitués in the United States.[ii]

1861-1865: Civil War Consumption of Opium **-** The Federal Army consumed approximately 10 million opium pills and over 80 tons of opium powders and tinctures (e.g., laudanum). Often the only medicine available to field surgeons, along with brandy or whiskey. The Southern Army faced constant shortages of opium. [iii]

1868: Opium Use in U.S. - Approximately 80,000 to 100,000 opium habitués in the United States.[iv]

1875: Addiction vs. Drug Tolerance - Opioid addiction first recognized by the medical community. Drug tolerance had been previously acknowledged, but not the concept of addiction. [v]

1905: Heinrich Dreser, an employee of The Bayer Company of Elberfeld, Germany, dilutes morphine with acetyls. Bayer begins production of diacetylmorphine and coins the name "heroin."

Heroin was introduced commercially in 1908 in various forms, including tinctures, pills and throat lozenges.[vi]

1906: Pure Food and Drug Act ((PL 59-384) - An act that prohibited "the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs or medicines, and liquors." [vii] The U.S. Food & Drug Administration's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, although the FDA did not go by that name until 1930.[viii]

1915: Harrison Narcotics Tax Act (Ch. 1, 38 Stat. 785) - effective date. "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." Section 2 of the act specifically permits the prescription of such substances for medical purposes, while imposing recordkeeping requirements. Criminal penalties are also provided for illegal possession and distribution.[ix]

1937: Elixir Sulfanilamide Disaster - More than 100 people died after diethylene glycol was added to sulfanilamide to make a liquid form of the drug.[x] This incident, among others, led to the passage of the 1938 Federal Food, Drug and Cosmetic Act.

1938: Federal Food, Drug and Cosmetic Act (52 Stat. 1040, codified at 21 U.S.C. Ch. 9 §§ 301 et. seq.) - "An Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes." [xi] Once effective, this act repealed the Pure Drug and Food Act, but maintained criminal and civil penalties for misbranded and adulterated food and drugs. More importantly, in Chapter V, it established a process for the pre-marketing approval of new drugs. Post-marketing authority of the FDA remained focused on adulterated and misbranded drugs and devices.

1951: The Boggs Act - This act amended the Narcotic Drugs Import and Export Act (21 U.S.C. §174), establishing minimum criminal penalties for the importation, sale, purchase or possession of narcotic drugs.[xii]

1951: The Durham-Humphrey Amendment (P.L. 82-21) - Amended the Federal Food, Drug and Cosmetic Act to specify two categories for medications: legend (prescription) and over-the-counter (OTC). It required that dangerous drugs, including those that were habit-forming, be dispensed only on the prescription of a licensed practitioner.[xiii]

1955: Introduction of the Minor Tranquilizer - The first minor tranquilizer, Miltown, was released. A year later, nearly one in twenty Americans had taken it. Psychopharmaceutical use, including the later-released Librium and Valium, reached nearly 200 million yearly prescriptions in the post war era, with Valium being the most prescribed from 1968 through 1981. [xiv]

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