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Jessica G. Katz

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HEROIN MAINTENANCE TREATMENT: ITS EFFECTIVENESS AND THE LEGISLATIVE CHANGES NECESSARY TO IMPLEMENT IT IN THE U.S.

Jessica G. Katz

I. INTRODUCTION

Heroin is the most rapidly acting and widely abused opiate. According to the 2008 National Survey on Drug Use and Health, approximately 3.8 million Americans over the age of twelve have tried heroin at least once in their lives. This number has increased by 643,000 Americans since 2004. In 2008, 282,000 Americans over the age of twelve were dependent on heroin. An estimated 5,000 to 10,000 intravenous drug users die of overdoses every year.

* J.D. candidate, The Catholic University of America, Columbus School of Law, May 2011; B.S., Grand Valley State University, 2007. The author would like to thank the staff and editors of The Journal of Contemporary Health Law and Policy Vol. XXVI for their hard work, and patience, during the editing process. She would also like to thank Professor Megan LaBelle for her guidance in drafting this Note. Finally, the author would like to thank her family for their unwavering love and support, particularly Charlie for bringing this topic to her attention and for being patient, helpful, and encouraging throughout the writing process.


2. See OFFICE OF APPLIED STUDIES, 2008 NATIONAL SURVEY ON DRUG USE AND HEALTH: NATIONAL FINDINGS Table G.1, Appendix G (HHS 2009) [hereinafter 2008 NATIONAL SURVEY ON DRUG USE AND HEALTH: NATIONAL FINDINGS], available at http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm.

3. Id.

4. See generally id. The number of individuals who received treatment for heroin addiction increased from 235,143 in 1997 to 246,871 just ten years later. Heroin Facts & Figures, supra note 1.
Since the 1970s, the U.S. has directed its efforts toward establishing a drug-free nation. Unfortunately, the War on Drugs has demonized drugs and those who abuse them, focusing on incarceration as the main deterrent. Treatment methods that do not conform to this policy face extreme opposition. For example, methadone maintenance treatment (MMT) is


7. In 1971, President Nixon named drug abuse as “public enemy number one in the United States” and announced the creation of the Special Action Office for Drug Abuse Prevention (SAODAP), to be headed by Dr. Jerome Jaffe, a leading methadone treatment specialist. See Frontline, Thirty Years of America’s Drug War: A Chronology, Public Broadcasting Company, http://www.pbs.org/wgbh/pages/frontline/shows/drugs/cron/ (last visited Mar. 18, 2010). The term “drug” is statutorily defined as:

(A) articles recognized in the official United States Pharmacopœia, official Homeopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause A, B, or C.


See also Drug Prevention & Control, 21 U.S.C. § 802(12) (2009) (providing “[t]he term “drug” has the meaning given that term by section 321(g)(1) of this title”). A controlled substance is “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.” 21 U.S.C. § 802(6). This Note will refer to drugs as defined by 21 U.S.C. § 802(6), and will focus on opiates specifically.


currently the nationally recognized treatment for heroin addiction; however, it was ardently contested when it was introduced.  

European nations facing similar problems with heroin addiction have conducted a series of studies evaluating the effectiveness of heroin maintenance treatment (HMT). This type of treatment is a variant of MMT that provides heroin addicts with controlled doses of pure heroin, instead of, or in conjunction with, methadone, in a sterile and supervised setting. The success of these studies generated interest in conducting a similar study in North America. This led to the North American Opiate Medication Initiative (NAOMI), a Canadian study modeled after the European studies. NAOMI’s successful results were published in the New England Journal of Medicine in August, 2009.

When conceptualizing a North American HMT study, researchers were discouraged by the stringent anti-drug laws of the United States because, in their current form, they prohibit such a study. However, five studies have

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12. Perneger et al., supra note 11, at 13-14; van den Brink et al., supra note 11, at 311; Haasen et al., supra note 11, at 56; March et al, supra note 11, at 204-05.


14. Id. at 778.

15. Id.

16. Id.
been successfully conducted in other countries, which confirm the effectiveness of HMT in treating heroin addiction.\(^\text{17}\) Thus, it is time for the U.S. to explore the value of using HMT in rehabilitating the American heroin-addicted population. The U.S. needs to encourage state legislation that will promote an American study on the effectiveness of HMT. While similar legislation has already been passed in several states,\(^\text{18}\) the Supreme Court’s broad ruling in \textit{Gonzales v. Raich}\(^\text{19}\) has discouraged any action under the state laws.

This Note will argue that U.S. drug policy, particularly post-\textit{Raich}, must be revised to encourage state legislation that would allow an HMT study to be conducted in the U.S. The first section will provide background information on the severity of the heroin problem in the U.S. and relevant statistics based on the current MMT procedure. Next, this Note will describe the European and Canadian studies on HMT and their results. The next section will discuss current U.S. drug laws and policies, how they stand as a barrier to HMT, and will compare these policies to the harm-reduction policies of Europe and Canada. Finally, this Note will discuss possible adjustments to the current U.S. drug policy that would allow an HMT study to be administered in this country. It will also address arguments that would likely be raised in opposition to studying the effectiveness of HMT, as well as recent developments under the Obama Administration that may lead to further reform and support for an HMT study in America.

\(^{17}\) Perneger et al., \textit{supra} note 11, at 13-14; van den Brink et al., \textit{supra} note 11, at 311; Haasen et al., \textit{supra} note 11, at 56 ; March et al, \textit{supra} note 11, at 204-05.


\(^{19}\) See generally \textit{Gonzales v. Raich}, 545 U.S. 1 (2005).

II. BACKGROUND

A. Heroin Statistics

Users seek out heroin for the immediate feeling of euphoria, which, for intravenous users, takes seven to eight seconds to experience.\(^{21}\) Other short-term effects include a warm flushing of the skin, dry mouth, heavy extremities, depression of the central nervous system that clouds mental functioning, and slowed breathing, sometimes to the point of respiratory failure.\(^{22}\) The long-term effects that users can experience include collapsed veins, infection of the heart lining and valves, abscesses, liver disease, pulmonary complications (including various types of pneumonia), and, most insidious, increased tolerance that requires progressively larger doses to regain the initial euphoric feeling.\(^{23}\)

Heroin users are at a particularly high risk for contracting Human Immunodeficiency Virus (HIV),\(^{24}\) hepatitis C,\(^{25}\) and other infectious diseases because they often share needles.\(^{26}\) Additionally, they rarely know the strength of the doses they self-administer, making overdoses more likely.\(^{27}\)

\(^{21}\) Heroin Facts & Figures, supra note 1.

\(^{22}\) Id.

\(^{23}\) Id.

\(^{24}\) Human immunodeficiency virus (HIV) damages the immune system, interfering with the body's ability to fight off disease and making the body more susceptible to certain cancers and to infections that the body normally resists, such as pneumonia and meningitis. There is no cure for HIV, and without treatment to control the virus, HIV can progress to Acquired immunodeficiency syndrome (AIDS). Mayo Clinic Staff, Definition: HIV/AIDS, Mayo Clinic, http://www.mayoclinic.com/health/hiv-aids/DS00005 (last visited Mar. 18, 2010).

\(^{25}\) Hepatitis C is a viral infection passed through contact with contaminated blood. It is "one of several hepatitis viruses and is generally considered to be among the most serious of these viruses." Hepatitis C attacks the liver and generally does not exhibit symptoms in the early stages, but is detected decades after contraction when liver damage is found in routine testing. Mayo Clinic Staff, Definition: Hepatitis C, Mayo Clinic, http://www.mayoclinic.com/health/hepatitis-c/DS00097 (last visited Mar. 18, 2010).

\(^{26}\) Heroin Facts & Figures, supra note 1.

\(^{27}\) Id.
The most common form of heroin available on the street is low-purity. This form of heroin is dangerous because it is usually mixed with a variety of substances, including sugar, starch, quinine, strychnine, and other poisons that can be injurious if injected into the body. In 2006, emergency departments around the country reported 113 million visits, 189,780 of which were related to heroin use.

In a 2008 survey, 13.3 percent of eighth graders, 17.2 percent of tenth graders, and 25.4 percent of twelfth graders in the U.S. reported that heroin was "fairly easy" or "very easy" to obtain. Though abuse of other substances is more prevalent, the highly addictive nature and destructive features of heroin addiction make it a serious problem in the U.S.

B. Methadone Treatment

The leading treatment for heroin addiction is MMT. Established in the 1970s, MMT has been celebrated as the most effective tool against heroin addiction. Methadone occupies the opioid receptors in the addict's brain.

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28. Id.

29. Id.

30. Id.

31. Id.

32. In 2008, 4,199 Americans age twelve or older reported marijuana abuse, 1,716 reported abuse of pain relievers, 1,411 reported abuse of cocaine, and 282 reported abuse of heroin. See 2008 NATIONAL SURVEY ON DRUG USE AND HEALTH: NATIONAL FINDINGS, supra note 2, at 75 Figure 7.2. The number of heroin addicts increased from 2007 to 2008 by sixty-nine. See THE WHITE HOUSE, THE PRESIDENT'S NATIONAL DRUG CONTROL STRATEGY ANNUAL REPORT 15 Figure 7 (2009) [hereinafter THE PRESIDENT'S NATIONAL DRUG CONTROL STRATEGY ANNUAL REPORT], available at http://www.whitehousedrugpolicy.gov/publications/policy/ndcs09/2009ndcs.pdf.

33. METHADONE MAINTENANCE TREATMENT, supra note 5, at 1.


35. Id. See also METHADONE MAINTENANCE TREATMENT, supra note 5, at 1.
and releases slowly enough that it need be taken only once a day. However, methadone does not produce the euphoric sensation that the user experiences with heroin. Under MMT, the patient is still "physically dependent on the opioid, but is freed from the uncontrolled, compulsive, and disruptive behavior seen in heroin addicts."

MMT is effective in treating heroin addiction. The National Institute on Drug Abuse (NIDA) reports that outpatients receiving MMT decreased their weekly heroin use by sixty-nine percent, their criminal activity by fifty-two percent, and increased their full-time employment by twenty-four percent. Additionally, heroin addicts who are redirected from street use of intravenous heroin to oral methadone are diverted from sharing needles and engaging in illicit activities, such as robbery and prostitution. This contributes to a decline in the spread of HIV and AIDS, hepatitis B and C, and other sexually transmitted diseases.

However, there are serious limits to MMT. Even though the success rates for MMT are impressive, only twenty percent of the estimated 810,000 heroin addicts in the U.S. were able to access this form of treatment in the year 2000. MMT clinics tend to administer low doses of methadone to their patients (approximately thirty milligrams per day) despite compelling research finding that dosages should be determined on an individual basis, and that most heroin addicts benefit from dosages between sixty to 120

36. Methadone, supra note 34.
37. Id.
38. Id.
40. Methadone, supra note 34.
41. Id.
42. Id.
milligrams of methadone or more.\textsuperscript{44} Research has shown that MMT requires a minimum of twelve months to be effective, "and some opiate-addicted individuals will continue to benefit from methadone maintenance treatment over a period of years."\textsuperscript{45} Nevertheless, most MMT patients drop out of their program well short of the necessary twelve-month period.\textsuperscript{46} This often occurs because patients are expelled for failing to observe clinic regulations or are persuaded to leave early by medical staff.\textsuperscript{47} Additional barriers to MMT, such as inconvenient clinic locations, fees, forms to fill out, referral requirements, waiting lists, lack of providers, and negative stereotypes that affect the treatment environment, create discouraging problems that impede addicts who are seeking treatment.\textsuperscript{48}

Until recently, the Food and Drug Administration (FDA) regulated methadone clinics, which had to obtain a license to operate.\textsuperscript{49} States often imposed stricter regulations than the FDA, and individual clinics frequently instituted even more stringent protocols than required by the states for fear of violating state or federal regulation.\textsuperscript{50} In 2001, the MMT regulations were reformed: methadone administration became regulated by the Center for Substance Abuse Treatment (CSAT), an agency of the Substance Abuse and Mental Health Services Administration (SAMHSA) under the U.S. Department of Health and Human Services.\textsuperscript{51} Additionally, clinics are no

\textsuperscript{44} \textit{Methadone Maintenance Treatment}, supra note 5, at 2.

\textsuperscript{45} \textit{Id.}

\textsuperscript{46} \textit{Id.}

\textsuperscript{47} \textit{Id.}


\textsuperscript{50} \textit{Id.}

\textsuperscript{51} \textit{Id.}; \textit{See generally Substance Abuse Treatment for Injection Drug Users: A Strategy with Many Benefits}, supra note 43.
longer required to be licensed. Instead, an accreditation program is used that is expected to "improve the quality of care through a greater emphasis on individualized treatment planning, increased medical supervision, and assessment of patient outcomes." The effects of the new regulation system have not been reported yet; however, U.S. drug policy still needs to address the untreated eighty percent of the heroin-addicted community.

III. EMPIRICAL RESEARCH ON HEROIN MAINTENANCE TREATMENT

A. The Swiss Study

Recent interest in HMT can be traced to a Swiss study conducted between 1995 and 1996. The study was open to individuals who had been residents of Geneva since 1994, were twenty years of age or older; had been addicted to intravenous heroin for more than two years; consumed opiates on a daily basis; suffered social problems, poor health or both due to drug use; and had undergone two or more previously unsuccessful attempts at drug treatment. The study divided its eighty participants into two groups: one group would be admitted to the HMT program immediately, and one group would be placed on a waiting list and given priority to enter the HMT program in six months.

Patients came to the Geneva clinic three times a day for their treatment. While in these facilities, medical professionals gave patients information on safe intravenous injection practices. The study participants were then

52. NATIONAL ALLIANCE OF METHADONE ADVOCATES, supra note 49; See generally SUBSTANCE ABUSE TREATMENT FOR INJECTION DRUG USERS: A STRATEGY WITH MANY BENEFITS, supra note 43.

53. NATIONAL ALLIANCE OF METHADONE ADVOCATES, supra note 49; see generally SUBSTANCE ABUSE TREATMENT FOR INJECTION DRUG USERS: A STRATEGY WITH MANY BENEFITS, supra note 43.

54. See generally Perneger et al., supra note 11.

55. Id. at 13.

56. Id. at 13-14. Participants on the waiting list were encouraged to seek alternate treatment options in the meantime, and were considered the study's control group. Id. at 14.

57. Id.

58. Id.
allowed to inject heroin themselves.\textsuperscript{59} They were monitored for thirty minutes following injection before they were allowed to leave the clinic.\textsuperscript{60} Furthermore, "all patients received psychological counselling, HIV prevention counseling, social and legal support services, and somatic primary care."\textsuperscript{61}

Six months after completion of the study, ten of the twenty-four subjects in the control group were still using street heroin daily.\textsuperscript{62} However, in the experimental group, twenty-one of the twenty-seven participants reported that they had not used any street heroin in the previous month.\textsuperscript{63} The HMT group also experienced social and societal benefits: mental health improved in the experimental group, with severe depression decreasing in both groups, "but severe anxiety decreasing only in the experimental group."\textsuperscript{64} Difficulty controlling anger and the number of suicide attempts also decreased at a higher rate in the experimental group.\textsuperscript{65} Furthermore, experimental participants saw a sharp decrease in their reliance on "street life," with a decrease in drug offenses, property damage, and illegal income generators (such as drug dealing, commercial sex, and theft).\textsuperscript{66} Even "existence of the programme in an urban neighbourhood" did not cause any measurable problems in the surrounding society.\textsuperscript{67}

\begin{itemize}
\item 59. \textit{Id.}
\item 60. Perneger et al., \textit{supra} note 11, at 14.
\item 61. \textit{Id.}
\item 62. \textit{See id.} at 15, Table 2. Data was collected from fifty-one patients total: twenty-seven in the experimental group, and twenty-four in the "waiting list" control group. Nineteen participants in the control group entered methadone maintenance while on the waiting list, which provided researchers a comparison between HMT and MMT. \textit{Id.} at 14.
\item 63. \textit{See id.} at 15, Table 2.
\item 64. \textit{Id.} at 15.
\item 65. \textit{Id.}
\item 66. Perneger et al., \textit{supra} note 11, at 15.
\item 67. \textit{Id.} at 17.
\end{itemize}
B. Subsequent European Studies

The success of the HMT study in Switzerland inspired a series of studies in the Netherlands, Germany, and Spain that sought to verify and replicate the findings of the Swiss study. The Dutch and German studies were much larger than the Swiss study, with 549 and 1,032 participants respectively. The Spanish study, with a smaller participant group of sixty-two, was aimed at testing the success of the earlier studies in the unique Spanish population. All three were modeled closely after the Swiss study, with some variations.

The subsequent European studies of HMT as heroin addiction treatment confirmed Switzerland’s findings; HMT “was significantly more effective” than methadone treatment alone in terms of improving health and social functioning and decreasing illicit drug use. These studies confirmed the earlier findings that long-term treatment is necessary for increased improvement. While researchers were not prepared to recommend HMT as a “first-line” therapy, the European researchers were confident that HMT was a “viable alternative treatment that should be made available to patients

68. Id. at 13-14; van den Brink et al., supra note 11, at 311; Haasen et al., supra note 11, at 56; March et al., supra note 11, at 204-05.

69. See van den Brink et al., supra note 11, at 310; Haasen et al., supra note 11, at 56.

70. March et al., supra note 11, at 204-05. “Despite the evidence for the feasibility and effectiveness of DAM [diacetylmorphine] prescription, the implementation of this treatment within different cultural contexts faces political barriers that make it necessary to validate those results on the local target population.” Id. at 204.

71. See id.

72. van den Brink et al., supra note 11, at 311. See also Haasen et al., supra note 11, at 59-60 (stating that “heroin-assisted treatment of people with severe opioid dependence and treatment resistance more effectively improved health and reduced illicit drug use than methadone maintenance treatment”).

73. March et al., supra note 11, at 209 (finding “greater improvement in terms of physical health, risk behavior for HIV infection, [and] street heroin use” in the experimental group); Haasen et al., supra note 11, at 59 (finding decreased street use of heroin in both groups, with a “more pronounced reduction in the heroin group”).

74. Haasen et al., supra note 11, at 60.
who, throughout their addiction, have not improved with other approaches.  

A synthesis of the European studies on HMT supports the adoption of HMT programs in Europe. Americans, claiming cultural and other fundamental differences, would need evidence pertaining to their own unique drug culture. Due to financial and logistical barriers that prevented the implementation of an HMT program in the U.S., a study of the efficacy of HMT in North America was conducted in Canada.

C. The Canadian Study – NAOMI

Eligibility factors for inclusion in the Canadian NAOMI program were similar to those for the European studies. Participants were randomly

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75. March et al., supra note 11, at 210. See also van den Brink et al., supra note 11, at 312 (noting that the “study provides strong evidence of the efficacy of prescribed heroin for addicts who are resistant to other forms of treatment”); Haasen et al., supra note 11, at 61 (recognizing “strong further evidence of the efficacy of prescribed heroin in the treatment of people with opioid dependence who have not profited from other forms of treatment”).


77. Oviedo-Joekes et al., supra note 13, at 777 (stating that “[b]ecause of financial and logistical barriers in the United States, the trial could be conducted only in Canada”).

78. Eligible participants were those whose opioid dependence met three or more of the seven criteria listed in the DSM-IV, who were twenty-five years of age or older, had used opiates for at least five years, injected opiates daily, had not changed their city of residence for at least one year, had attempted a minimum of two previous treatments for opioid dependence (“including at least one attempt at methadone maintenance treatment in which they received 60 mg or more of methadone daily for at least 30 days during a 40-day period”), and had not been part of a methadone maintenance treatment for at least six months prior to being part of this study. Id. at 778. The DSM-IV defines substance dependence as:

   a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring any time in the same 12-month period:

   1. Tolerance, as defined by either of the following:
      (a) A need for markedly increased amounts of the substance to achieve intoxication or the desired effect or
      (b) Markedly diminished effect with continued use of the same amount of the substance.

   2. Withdrawal, as manifested by either of the following:
assigned to three groups: 115 participants would receive diacetylmorphine (heroin), 111 would receive methadone, and twenty-five would receive hydromorphone. The experimental group received a maximum daily dose of 1,000 milligrams intravenously heroin, which was "self-administered under supervision in the treatment clinics up to three times daily." Experimental subjects were monitored for fifteen minutes before and thirty minutes after injection, and could change their treatment plans to partial or total use of oral methadone at any time.

The results of the Canadian study were evaluated for two primary outcome measures: "retention in addiction treatment at 12 months" and

(a) The characteristic withdrawal syndrome for the substance or
(b) The same (or closely related) substance is taken to relieve or avoid withdrawal symptoms.

3. The substance is often taken in larger amounts or over a longer period than intended.
4. There is a persistent desire or unsuccessful efforts to cut down or control substance use.
5. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.
6. Important social, occupational, or recreational activities are given up or reduced because of substance use.
7. The substance use is continued despite knowledge of having a persistent physical or psychological problem that is likely to have been caused or exacerbated by the substance (for example, current cocaine use despite recognition of cocaine-induced depression or continued drinking despite recognition that an ulcer was made worse by alcohol consumption).

AMERICAN PSYCHIATRIC ASSOCIATION, SUBSTANCE RELATED DISORDERS IN DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 191, 197-98 (2009).


80. Oviedo-Joekes et al., supra note 13, at 778.

81. Id. at 778-79.

82. Id. at 779 (defining outcome as “receipt of the study medication on at least 10 of the 14 days before the 12-month assessment, or confirmation of retention in any other treatment program or abstinence from opioids during this interval.”).
"reduction in illicit-drug use or other illegal activities." Researchers have determined that "[t]he rate of retention in treatment for addiction was 87.8%" percent for the heroin group and 54.1 percent for the methadone group. In the heroin group, sixty-seven percent of participants confirmed decreased illicit-drug use or illegal activity, compared to 47.7 percent in the methadone group. The average number of days that participants used street heroin in the prior month decreased “from 26.6 to 5.3 in the diacetylmorphine [heroin] group and from 27.4 to 12 in the methadone group.”

The Canadian study comports with the European studies, implying that the findings in favor of HMT in Europe may be translated to North American populations. The Canadian researchers, like their European colleagues, concluded that “[t]he diacetylmorphine [heroin] group had greater improvements with respect to medical and psychiatric status, economic status, employment situation, and family and social relations . . . suggest[ing] a positive treatment effect beyond a reduction in illicit-drug use or other illegal activities." Although replication and cost-utility studies would provide more solid support, the Canadian study provides a strong argument for reforming drug policy in North America.

D. The Aftermath of the European Studies

Switzerland has continued operating HMT centers since the initial study in 1995. Today, there are twenty-three centers throughout Switzerland that administer prescription heroin to nearly 1,300 addicts under strict supervision. As in the initial study, these centers supplement heroin addiction treatments with psychiatric and social counseling. The centers

83. Id.
84. Id. at 780.
85. Id.
86. Oviedo-Joekes et al., supra note 13, at 781.
87. Id. at 784.
89. Id.
90. Id.
operate under special authorization from the Swiss Federal Office of Public Health.  

The Swiss officials in charge of the national HMT program are required to submit an annual report that provides the most recent statistics of the program. The reports define elements that will be considered in determining whether the program has been successful, including: sustained commitment to treatment, improvement in physical and mental health, progress in social integration, and permanent abstinence from opiate consumption. The 2007 report found that more than seventy percent of all HMT patients (who are considered to be treatment-resistant) stayed in the program for one year and almost sixty percent stayed for two or more years. Indeed, the average retention rate for participants in the HMT programs in Switzerland is approximately three years. Evidence implied that mental stress in HMT patients decreases during treatment.

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92. FEDERAL DEP’T OF HOME AFFAIRS ET AL., HEROIN-ASSISTED TREATMENT/TREATMENT WITH DIACETYLMOORPHINE (HAT) IN 2007, 1 n. 1 (2008) [hereinafter HEROIN-ASSISTED TREATMENT/TREATMENT WITH DIACETYLMOORPHINE (HAT) IN 2007]. “This report is written every year and submitted to the Federal Council pursuant to Article 16, Paragraph 1(g) of the Ordinance concerning the Medical Prescription of Heroin of 8th March 1999.” Id.


94. HEROIN-ASSISTED TREATMENT/TREATMENT WITH DIACETYLMOORPHINE (HAT) IN 2007, supra note 92, at 12.

95. Id.

96. Id. at 13.
statistics also show significant improvement in social integration for HMT patients who are in treatment for at least one year.\textsuperscript{97}

In 2003, a study reported the results of a survey of sixty-four percent of the 175 patients enrolled in an HMT program between January, 1994 and March, 1995 and had left their programs.\textsuperscript{98} Of these, 111 patients reported having completed either a methadone treatment or an abstinence-oriented therapy, and sixteen percent of those 111 patients reported that they had been abstinent from opiate use in the six months prior to the survey.\textsuperscript{99}

The 2007 report found that new enrollment in Swiss HMT programs has been decreasing steadily since 2002, from 300 enrollments that year to 130 in 2007.\textsuperscript{100} Furthermore, the median age of newly enrolled HMT patients has increased from 30.8 in 1994 to thirty-eight in 2007.\textsuperscript{101} Officials inferred from these statistics that "fewer persons in general and above all only a few very young persons are today seriously heroin dependent."\textsuperscript{102} This inference is supported by a 2006 study that found that heroin consumption in Zurich had risen "from 80 persons in 1975 to 850 persons in 1990 and dropped back to 150 in 2002," a decrease of four percent per year.\textsuperscript{103} Swiss health surveys also indicate "a decrease in experience of heroin consumption among 15 to 39 year olds from 1.3% in 1992 to 0.9% in 2002."\textsuperscript{104} In late 2008, in light of such promising statistics, sixty-eight percent of voters supported a plan to incorporate the prescription heroin program into the national health policy permanently.\textsuperscript{105}

\begin{footnotes}
\item[97] Id. at 17. "Patients who have been in treatment for at least one year are more likely to have stable living arrangements (96%) and to live alone (58%) than new enrollments (73% and 46% respectively)." Id. at 17.
\item[98] Id.
\item[99] Id. The survey also showed a significant decrease in patients' concomitant use of other substances. \textit{Heroin-assisted Treatment/Treatment with diacetylmorphine (HAT) in 2007}, supra note 92, at 18.
\item[100] Id. at 7.
\item[101] Id.
\item[102] Id.
\item[103] Id. at 11.
\item[104] Id.
\end{footnotes}
In mid-2009, the German Parliament followed suit, passing a law allowing the prescription of heroin to “long-term users who fail to respond to other treatments . . . [who are] aged 23 or over . . . have been addicted for at least five years and have undergone two unsuccessful rehabilitation programmes. . . .”106 Unlike the Swiss scheme, the German law will allow qualifying addicts to receive their prescriptions over the counter rather than in a clinic.107

The Netherlands, like Switzerland, has continued operating its fifteen HMT clinics since 2006, serving nearly 600 patients.108 New studies have been initiated in Britain and Belgium.109 In February, 2008, the Danish Parliament approved a two-year pilot scheme for prescription heroin programs.110 The Danish program will administer heroin and methadone in combination to approximately 500 “of the worst affected and most marginalized addicts in the country.”111

Nations throughout Europe have not only recognized the validity of HMT, but have enacted legislation to make HMT available to its heroin-addicted populations. In the U.S., the Controlled Substances Act (CSA) and court rulings seem to stand as obstacles to similar legislation that might benefit

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107. Id. See also van den Brink et al., supra note 11, at 310 (reporting that in Danish study, modeled after Swiss study, “[p]articipants . . . were not allowed to take any [heroin] home”).


109. Id.


111. AFP, supra note 110.
American heroin addicts. However, minor changes in the federal drug control legislation and greater federal trust in the actions of state governments could pave the way for HMT in the U.S.

IV. U.S. Drug Policy: A Barrier or a Smoke-Screen?

The U.S. declared war on illicit drugs in the 1980s, vowing to eradicate drug use inside its borders within ten years. Almost thirty years later, the U.S. drug problem is still a stark and destructive reality. Recently, the U.S. government found seven million Americans who meet the established standards for illicit drug abuse or dependence.

Thanks to its policies and programs, the President’s National Drug Control Strategy (NDCS) boasts significant decreases in youth drug use for a number of illegal drugs during the period between 2001 to 2008; though, notably, the only drug whose use did not decrease was heroin. The NDCS is concerned with alcohol use and a wide range of illegal drug use. However, it is mainly focused on marijuana, which it has identified as not only an important gateway drug to more serious substance abuse, but also a risk in and of itself due to a recently researched link between marijuana use and mental illness. This broad focus results in minimized attention for heroin abuse and treatment.

112. See infra Sec. IV.


114. THE PRESIDENT’S NATIONAL DRUG CONTROL STRATEGY ANNUAL REPORT, supra note 32, at 1.

115. Id. at 2, Fig. 2.

116. Id. at 2.

117. Id. See Figure 2 (describing change in “youth drug use” from 2001 to 2008, including alcohol, cigarettes, and illegal substances). Id. at 2.

118. See generally id. (emphasizing marijuana and other illicit drugs).
A. The War on Drugs in Action: Criminalization and the Controlled
Substances Act

The U.S. drug policy is known for its emphasis on criminalization. In
2007, approximately 1,841,200 Americans were arrested for drug-related
offenses at the state or local level; 82.5 percent of these were for
possession. In 1995, only twenty-three percent of adult probationers were
released on the condition of seeking substance abuse treatment. In 2002,
fifty-three percent of inmates were dependent on or had abused drugs.
However, only 16.9 percent of these individuals received treatment while
incarcerated. In 2009, the U.S. National Drug Control Budget spent 3.65
billion dollars on domestic law enforcement and 3.84 billion on interdiction,
compared to 3.42 billion dollars on treatment and 1.79 billion on
prevention. In 2010, the budget will increase by 251 billion dollars for
domestic law enforcement and interdiction, and will decrease by thirty-nine
billion dollars for treatment and prevention.

The main legislation through which the War on Drugs is waged is the
CSA. Enacted in 1970, the CSA recognizes that drug abuse has “a
substantial and detrimental effect on the health and general welfare of the

119. Mamber, supra note 8, at 620-22.

/content/dcf/contents.cfm (last visited Mar. 18, 2010).

121. THOMAS P. BONCZAR CHARACTERISTICS OF ADULTS ON PROBATION, 1995 7 (DOJ

122. JENNIFER C. KARBERG & DORIS J. JAMES SUBSTANCE DEPENDENCE, ABUSE, AND
TREATMENT OF JAIL INMATES, 2002 3, 8 (DOJ 2005), http://bjs.ojp.usdoj.gov/content
/pub/pdf/sdatji02.pdf.

123. Id.

124. OFFICE OF NATIONAL DRUG CONTROL POLICY NATIONAL DRUG CONTROL
BUDGET: FY 2010 BUDGET HIGHLIGHTS 2, Fig. 1 (2009), http://www.wilsoncenter.

125. Id. The 2010 budget allots 3.737 billion dollars for domestic law enforcement
and approximately four billion dollars for interdiction, an increase of eighty-three million
dollars and 168 million dollars, respectively. Id.

American people,” and, therefore, legitimizes federal control of drug manufacture and distribution under Article I, Section 8, Clause 3 of the U.S. Constitution—the Commerce Clause.\textsuperscript{127}

The CSA established five schedules of controlled substances.\textsuperscript{128} These schedules graduate in gravity from Schedule V, drugs that have low potential for abuse and have currently accepted medical use in treatment in the United States,\textsuperscript{129} to Schedule I, drugs that have a high potential for abuse and have “no currently accepted medical use in treatment in the United States.”\textsuperscript{130} Heroin is currently listed as a Schedule I substance.\textsuperscript{131} Methadone, a synthetic form of heroin and the foundation of MMT, is categorized as a Schedule II substance,\textsuperscript{132} indicating a high potential for abuse and “a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.”\textsuperscript{133}

\section*{B. International Issues: Treaty Obligations and International Drug Policies}

The U.S. also justifies the enactment of the CSA by relying on its obligations as a party to the Single Convention on Narcotic Drugs (Convention).\textsuperscript{134} The Convention requires that member states “adopt such measures as will ensure that [drug abuse and trafficking] . . . shall be punishable offences when committed intentionally, and that serious offences shall be liable to adequate punishment particularly by imprisonment or other penalties of deprivation of liberty.”\textsuperscript{135}

\begin{footnotesize}
\begin{enumerate}
\item \textit{Id.} at §§ 801(1)-(6) (2009). \textit{See also} U.S. CONST. art. 1, § 8, cl. 3.
\item 21 U.S.C. § 812.
\item \textit{Id.} at §§ 812(b)(5)(A)-(B).
\item \textit{Id.} at § 812(b)(1)(B).
\item \textit{Id.} at § 812(c) Schedule I (b)(10).
\item \textit{Id.} at § 812(c) Schedule II (b)(11). “Methadone is a synthetic agent that works by ‘occupying’ the brain receptor sites affected by heroin and other opiates.” \textit{METHADONE MAINTENANCE TREATMENT, supra} note 5, at 1.
\end{enumerate}
\end{footnotesize}
The Convention utilizes a schedule organization of drugs similar to that found in the CSA.\footnote{Id.} Under the Convention's organization, both heroin and methadone are listed under Schedule I.\footnote{Id. at Schedules.} Notably, the Convention obliges signatories to "take such legislative and administrative measures as may be necessary . . . subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs."\footnote{Id. at Art. 4(c) (emphasis added).} Additionally, the Convention requires that drugs under Schedule I be manufactured only by those granted a license to do so, except if carried out by a state enterprise.\footnote{Id. at Art. 29 (1).} The Convention's limitations on Schedule I drugs reflect recognition that even these dangerous substances could have medical and scientific value, and should be available for use accordingly. The U.S., however, has precluded that possibility for drugs categorized under Schedule I of the CSA.\footnote{Drug Abuse Prevention & Control, 21 U.S.C. § 812(b)(1)(B-C) (2009). See also Single Convention on Narcotic Drugs, supra note 119, at Art. 39 (permitting states to adopt "measures of control more strict or severe than those provided by this Convention").}

Also party to the Convention are Switzerland, the Netherlands, Germany, Spain, and Canada—the sites of successful HMT studies throughout the past fifteen years.\footnote{Single Convention on Narcotic Drugs, supra note 135, at Final Act of the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs, para. 3.} This would imply that signatories' obligations under the Convention do not preclude them from conducting a study of a serious drug's medical value. Since these nations and the U.S. share the same obligations under the Convention, it is puzzling that U.S. drug laws are so much more stringent than Canadian and European drug laws to the point of barrning an HMT study within its own borders.

The difference between U.S. and European drug laws is best explained by the diversity in policies. European nations, with cooperation in European
Union (E.U.) legislation, support a harm-reduction model of drug control.\textsuperscript{142} This policy focuses on drug addiction and abuse as a public health concern, rather than a criminal issue.\textsuperscript{143} The Maastricht Treaty, the first major E.U. treaty to refer specifically to the drug phenomenon, stipulates in Article 129 that "community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education."\textsuperscript{144} Though specific health initiatives and activities are left to the individual European nations to direct, the adopted view of the E.U. generally emphasizes education and public health.\textsuperscript{145}

Although Canada’s drug policy once mirrored the criminalization model of the U.S., it is now moving toward the European approach of harm-reduction.\textsuperscript{146} A prime example of this change is the 1.5 million dollars the Canadian government is providing to support scientific evaluation of a safe-

\begin{itemize}
  \item \textsuperscript{142} See generally International Harm Reduction Network Global State of Harm Reduction: Western Europe, http://www.ihra.net/WesternEurope#HarmReductionPolicies (last visited Mar. 18, 2010).
  \item \textsuperscript{143} Drug Policy Alliance Network, Reducing Harm: Treatment and Beyond http://www.drugpolicy.org/reducingharm/ (last visited Mar. 18, 2010) [hereinafter Reducing Harm: Treatment and Beyond].
  \item \textsuperscript{145} European Legal Database on Drugs Country Profiles, supra note 144.
  \item \textsuperscript{146} Drug Policy Alliance Network Drug Policy Around the World: Canada, http://www.drugpolicy.org/global/drugpolicyby/northamerica/canada/ (last visited Mar. 18, 2010). As enacted, Canadian drug laws recognize the possibility of medicinal or scientific value of even Schedule I substances. For instance:

    The Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons or any controlled substance or precursor or any class thereof from the application of all or any of the provisions of this Act or the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

    Controlled Drugs & Substances Act, 1996 S.C., Part VI, Para.56 (Can.).
\end{itemize}
injection drug site in Vancouver over a three-year period. The U.S. aversion to a harm-reduction approach to drug control was very clear in the Bush Administration's drug czar, John Walters', response to Canada's support of safe-injection drug sites, suggesting that such sites would amount to "state-sponsored personal suicide."148

V. LEGISLATIVE SOLUTIONS AND POLITICAL OBSTACLES

The European and Canadian studies on HMT bring to light important and relevant insight for the U.S.'s heroin-addicted population. While MMT continues to be successful for some heroin addicts, a significant number of addicts never receive MMT.149 Even with the use of MMT, changes in the number of individuals who are addicted to heroin addiction are minimal at best.150 American heroin addicts could benefit greatly from HMT. However, significant barriers exist in the form of strict anti-drug legislation and extremely prejudicial attitudes towards illicit drug use in the U.S.151 An HMT study must be conducted in the U.S. to validate the international results and utilize them in U.S. drug policy. To do so, the U.S. must adjust its drug laws and overcome significant moral, political, and normative opposition from its citizens.

147. Reducing Harm: Treatment and Beyond, supra note 143.


149. METHADONE, supra note 34; THE PRESIDENT'S NATIONAL DRUG CONTROL STRATEGY ANNUAL REPORT, supra note 32, at 2, Fig. 2.

150. METHADONE, supra note 34; THE PRESIDENT'S NATIONAL DRUG CONTROL STRATEGY ANNUAL REPORT, supra note 32, at 2, Fig. 2 (indicating no change in youth heroin use between 2001 and 2008).

151. See discussion infra Part V.A.
A. Federal Legislation: Amending the Scheduling of Heroin in the CSA

Currently, the CSA does not recognize any medical value in heroin. In fact, the CSA does not even recognize that heroin can be safely used under medical supervision, as it would be in HMT. As the law currently stands, it is a significant obstacle, if not a complete bar, to an HMT study. However, if heroin's categorization under the CSA were amended from Schedule I to Schedule II, where its medical value could be recognized, an HMT study could be conducted legally in the U.S.

The CSA is updated and republished annually and provides explicit procedures for amending the placement of a drug within a given schedule. The Attorney General may hold a hearing to amend the scheduling of a drug “(1) on his own motion, [(2)] at the request of the Secretary [of Health and Human Services], or [(3)] on the petition of any interested party.” Before conducting such proceedings, the Attorney General must ask for a scientific and medical evaluation and seek a recommendation from the Secretary. The Secretary’s evaluation and recommendation will consider any scientific evidence available regarding the drug’s pharmacological effect, the “state of current scientific knowledge regarding the drug . . .,” any risk to public health, the drug’s “psychic or physiological dependence liability,” and “whether the substance is an immediate precursor of a substance already controlled.” Additionally, the Secretary will consider the scientific and medical considerations related to the drug’s “actual or relative potential for abuse;” its history and “current pattern of abuse;” and “[t]he scope, duration,


153. Id. at § 812(b)(1)(C).

154. See id. at § 812(b)(2).

155. Id. at § 812(a).


157. Id. at § 811(a).

158. Id. at § 811(b).

159. Id. at §§ 811(b)-(c).
and significance of abuse." The Secretary's scientific and medical findings are binding on the Attorney General.

Considering these factors, the Secretary could conceivably recommend that heroin be reclassified from a Schedule I to a Schedule II narcotic. Although heroin poses a high risk of dependence and abuse, methadone does as well. Methadone is categorized in Schedule II because it is recognized as having an "accepted medical use ... with severe restrictions," despite the fact that abuse of methadone "may lead to severe psychological or physical dependence." The gravity and dangers of heroin use and methadone use are so similar that it appears arbitrary to place one in a more restrictive schedule than the other.

According to the CSA, placement of a drug within any given schedule is prohibited "unless the findings required for such schedule are made with respect to such drug or other substance." Substantial evidence exists in support of removing heroin from Schedule I and adding it to Schedule II. European and Canadian studies on HMT have provided scientific proof that heroin, in the restricted scope of maintenance treatment, has a positive pharmacological effect in addiction treatment.

1. Benefits – "Legalization" of HMT and the 2001 MMT Regulation Reforms

By moving heroin from Schedule I to Schedule II of the CSA, the U.S. government would establish that heroin could be used medicinally in HMT administration. Substances in Schedule II have a "currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," despite a "high potential for abuse" and a

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160. Id. at § 811(b).

161. Id.

162. See supra discussion at Sec. II.


165. Id. at § 812(b).

166. See generally Haasen et al., supra note 11; van den Brink et al., supra note 11; Perneger et al., supra note 11.
finding that "[a]buse of the drug or other substances may lead to severe psychological or physical dependence."167 Under that definition, the government would have broad discretion to regulate medically administered heroin. For example, the FDA has not approved methadone for use in pain management, and "[a]s of January 1, 2008, manufacturers of 40 milligram methadone hydrochloride dispersible tablets have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals."168 As such, medicinal use of methadone is restricted almost exclusively to addiction treatment. Use of medicinal heroin could be similarly restricted to HMT clinics.

The 2001 reform of the methadone regulations provides an optimal model for regulation of heroin for HMT purposes.169 The Center for Substance Abuse Treatment (CSAT) is currently overseeing the accreditation system for MMT clinics and the use of methadone in those clinics.170 The CSAT could regulate HMT clinics the same way it regulates MMT clinics. Although the effects of the 2001 regulation reform are not yet known, the existence of an established program that could be used as a model in implementing HMT regulation is promising.

2. Obstacles – Historically Negative Treatment of Heroin

Legislative changes do not occur in a vacuum. Any amendments to the CSA would need to overcome substantial moral, political, and normative opposition.171 The legislative debate over heroin control is not new. In 1924, Congress held impassioned hearings to discuss amendments to the 1914 Harrison Narcotics Act,172 which had banned recreational use of


169. NATIONAL ALLIANCE OF METHADONE ADVOCATES, supra note 49.

170. Id.

171. See March et al., supra note 11, at 204 (stating that “[d]espite the evidence for the feasibility and effectiveness of DAM [diacetilmorphine] prescription, the implementation of this treatment within different cultural contexts faces political barriers that make it necessary to validate those results on the local target population.”).

172. 1914 Harrison Narcotics Act, 63 P.L. 223; 63 Cong. Ch. 1; 38 Stat. 785 (1914).
narcotics. The proposed amendments, which would have restricted the use of heroin exclusively for medicinal purposes, were thwarted by moral arguments and sensational claims that tended to misconstrue, or even ignore, relevant facts that would undermine the amendments. The Harrison Act was replaced by the Comprehensive Drug Abuse Prevention and Control Act in 1970, which established the Controlled Substance Act and its schedules of controlled substances. As soon as 1980, challenges to the CSA’s rigid controls emerged. Congressman Stephen Neal (D-NC), in a discussion with a panel of cancer researchers regarding the medicinal value of marijuana and heroin in pain management, posited that:

we need more study, but to get the study, we need a substance available to you to study, but as long as it’s under Schedule I, it will not be available, because the assumption will be that there is no medical use. It’s a Catch-22 situation, it seems to me.

Despite evidence of heroin’s medical value, and an apparent willingness by the public to accept at least controlled medicinal uses for


176. Stoll, supra note 174, at 177.


178. Id. at 32.

179. Perneger et al., supra note 11, at 13-14; van den Brink et al., supra note 11, at 311; Haasen et al., supra note 11, at 56; March et al, supra note 11, at 204-05; Oviedo-Joekes et al., supra note 13, at 777.
heroin,180 Congress continues to perpetuate “a model of drug control more suited to law enforcement than to medical concerns.”181

In the early 1970s, when heroin addiction was reaching its peak, New York City briefly considered instituting an HMT program.182 The initial plans for treatment were far below the standards modern research has established,183 but the public opposition focused on far more dramatic points. Harlem’s Congressman Charles Rangel (D-NY) urged the American people to “open up their eyes and recognize heroin for what it is – a killer, not a drug on which a human being should be maintained.”184 The head of the Bureau of Narcotics and Dangerous Drugs (predecessor to the Drug Enforcement Administration) considered the idea of HMT to be a “medical surrender on the treatment of addiction” that would have the effect of “consigning hundreds of thousands of our citizens to the slavery of heroin addiction forever.”185

More recently, Congress convened hearings in response to the Swiss heroin maintenance trials.186 The hearings called two Swiss doctors as witnesses, both of whom were strong opponents of both needle exchange programs and HMT.187 The doctors and two U.S. witnesses condemned


181. Stoll, supra note 174, at 179.


184. Id. at 15.

185. Id.


heroin maintenance as "a fast track to moral corruption and the first step towards genuine disintegration of public security."  

Despite heroin's losing record in Congress, the U.S. experience with methadone suggests that even the most zealous opposition can be overcome with enough evidence and support. Although it is now regarded as the most successful treatment of opioid addiction, the introduction of methadone as a viable treatment option was initially met with fervent resistance. In 1973, Congressman Rangel deplored the administration's perceived lack of effort in combating the American drug addiction problem, and disparaged the relatively new MMT initiative as a government action "to permanently narcotize a significant portion of the young and poor." In 1998, after two decades of MMT in the U.S., Senators John McCain (R-AZ), Dan Coats (R-IN), and Paul Coverdell (R-GA) submitted a resolution criticizing the use of methadone to treat heroin, raising concerns that methadone did nothing more than transfer dependence from one highly addictive drug to another. Despite lingering concerns over methadone's addictive qualities, methadone remains the most effective treatment for heroin addiction in the U.S.  

Aeschbach, Swiss physician and member of board, "Youth Without Drugs" & Erne Matthias, expert on Swiss drug policy).


189. See METHADONE supra note 34; METHADONE MAINTENANCE TREATMENT, supra note 5, at 1.


191. Id.


194. See METHADONE, supra note 34; METHADONE MAINTENANCE TREATMENT, supra note 5, at 1.
After years of condemning heroin as a plague and an enemy, it would be difficult to garner support for prescribing it to heroin addicts in the name of addiction treatment. Specifically, it is difficult to imagine either the Attorney General or the Secretary of Health and Human Services proactively initiating hearings to amend heroin’s placement in the CSA Schedules. However, similar arguments against methadone eventually ebbed in the face of compelling evidence of the drug’s utility. The success of the European and Canadian trials may provide enough evidence to overcome the fierce opposition that HMT is sure to face.

B. State Legislation: Encouraging States to Experiment with HMT

Although the American journey to HMT begins with federal action, it cannot be limited to federal direction. An HMT program instituted at the national level would likely be too uniform to account for community differences, and would impose upon unwilling Americans an addiction treatment program they may not support or understand. A federally-constructed HMT program would be an enormous undertaking. Without the participation of at least a majority of states, it would likely fail in a notorious and very public way. A program as controversial as HMT should be instituted by individual, interested populations—such as individual states—that are willing to support and investigate a program that may be unpopular with the national majority.

Progressive state legislation in the area of drug control is not a novel concept. In 1996, Arizona voters passed Proposition 200, also known as the Drug Medicalization, Prevention and Control Act of 1996 (DMPCA). The proposed legislative amendment would permit CSA Schedule I drugs to be used for medical purposes. The proposal was an effort to recognize

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196. See id. See also METHADONE, supra note 34; METHADONE MAINTENANCE TREATMENT, supra note 5, at 1-2 (stating that MMT is “the most effective treatment for opiate addiction,” despite controversy and criticism “in the U.S. and other countries”).


drug abuse as a public health problem that should be addressed medically rather than criminally.\footnote{199} After several years of legislative modification, the DMPCA was eventually enacted under Arizona’s criminal code, limiting medical prescription of Schedule I substances “to treat a disease, or to relieve the pain and suffering of a seriously ill patient or terminally ill patient.”\footnote{200} While fourteen states have enacted legislation legalizing medicinal use of marijuana,\footnote{201} Arizona is the only state to legalize prescription of all Schedule I substances.

1. Benefits – “States as Laboratories”

Allowing individual states to experiment with HMT programs in their own communities, without interference from federal drug control officials, would provide the rest of the country with concrete evidence to support establishment of more HMT clinics nationwide. Although the European and Canadian studies provide substantial evidence, additional support from successful U.S. HMT programs or studies would afford American people with evidence that HMT works within the context of the U.S. heroin abuse problem.

The argument for “states as laboratories” is an established one. In 1932, Justice Brandeis celebrated the American federal system for the possibility “that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”\footnote{202} Nearly seventy-five years later, Justice O’Connor reiterated that point in support of the Compassionate Use Act, a state law enacted in 1996 that legalized medical use of marijuana in California.\footnote{203}

In a country with a population of over 300 million people, the idea of governing everyone with one policy is short-sighted. Indeed, one of James

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\footnote{199}{The Drug Medicalization, Prevention, and Control Act of 1996, § 2(1), Ariz. Prop. 200.}


\footnote{201}{See Active State Medical Marijuana Programs, supra note 18.}

\footnote{202}{New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis J., dissenting).}

\footnote{203}{Gonzales v. Raich, 545 U.S. 1, 42 (2005) (O’Connor J., dissenting).}
Madison's arguments in support of the Constitution was that a large, unified polity would be made up of so many differing politics and opinions that no one "faction" (the antithesis to democracy, in Madison's view) could seize control of the entire nation and enforce a tyranny of the majority.\textsuperscript{204} This system best supports the ideals of democracy, and satisfies more citizens than would an all-encompassing unitary power.\textsuperscript{205} Under federalism, a voter who is in the political minority of his community has a choice. The voter can stay and live under a policy with which he does not agree, or "vote with [his] feet" and move to a community that comports more with his political views.\textsuperscript{206} The "states as laboratories" system supported by federalism is particularly conducive to the issue of HMT in the U.S. By allowing the individual states to experiment with HMT, the federal government avoids the risk of large-scale (and public) failure and simultaneously allows for the accumulation of U.S. evidence of HMT efficacy.

2. Obstacles – Gonzales v. Raich and its Effect on "States as Laboratories"

The CSA, particularly after Gonzales v. Raich, which effectively outlaws \textit{inter alia} the use of Schedule I substances, preempts any state legislation legalizing medicinal use of Schedule I substances.\textsuperscript{207} In Raich, the Supreme Court upheld the jurisdiction of the CSA over the sale, manufacture, and possession of all drugs in the U.S., whether in intrastate or interstate commerce.\textsuperscript{208} The federally-enacted CSA, and the federal agents acting under its authority, rely upon Article I, Section 8, Clause 3 of the U.S. Constitution, the Commerce Clause, for their federal power.\textsuperscript{209} Under U.S. law, there are three categories of activities that Congress may regulate under

\begin{itemize}
  \item \textsuperscript{204} \textit{The Federalist Papers} No. 10 (James Madison).
  
  \item \textsuperscript{205} See Ilya Somin, Gonzales v. Raich: \textit{Federalism as a Casualty of the War on Drugs}, 15 \textit{Cornell J. L. & Pub. Pol'y} 507, 540 (2006).
  
  \item \textsuperscript{206} \textit{Id.} at 541.
  
  \item \textsuperscript{207} See U.S. Const., art. VI, cl. 2. "The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail." \textit{Raich}, 545 U.S. at 29.
  
  \item \textsuperscript{208} \textit{Raich}, 545 U.S. at 22.
  
  \item \textsuperscript{209} Drug Abuse Prevention & Control, 21 U.S.C. § 801(3) (2009). "A major portion of the traffic in controlled substances flows through \textit{interstate} and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow . . . nonetheless have a \textit{substantial and direct effect} upon interstate commerce." \textit{Id.}\
\end{itemize}
its Commerce Clause powers: "channels of interstate commerce . . ., instrumentalities of interstate commerce, and persons or things in interstate commerce [even though the threat may come only from intrastate activities], and activities that substantially affect interstate commerce."210

The Raich Court reasoned that Congress could have a rational belief that a producer of medicinal marijuana whose supply is in excess of his legitimate customer demands might sell the excess marijuana to someone out of state.211 While one instance of such behavior is not significant enough to affect interstate commerce, an aggregation of many similar instances could have a significant effect on interstate commerce and the interstate drug market.212 Therefore, Congressional supervision under the CSA is permissible pursuant to the Commerce Clause.213 Additionally, the Court recognized that the California Health and Safety Code, which permits doctors to prescribe marijuana for a patient afflicted with "any other illness for which marijuana provides relief" is open-ended and "broad enough to allow even the most scrupulous doctor to conclude that some recreational uses would be therapeutic."214 In contrast, the use of most prescribed legal drugs is constrained by "the dosage and duration of the usage."215 The Court reasoned that the liberal discretion provided to doctors in prescribing marijuana "provides them with an economic incentive to grant their patients permission to use the drug."216 The Court determined that the combination of the economic incentive and the aggregation theory have a substantial relation to or effect on interstate commerce and justify Congress's regulation of noncommercial drug-related activities.217


211. Raich, 545 U.S. at 30-32.

212. Id. at 32.

213. Id. at 32-33.

214. Id. at 31.

215. Id. at 30.

216. Id.

217. Raich, 545 U.S. at 30-33.
Raich was decided after *U.S. v. Lopez*\(^{218}\) in 1995 and *U.S. v. Morrison*\(^{219}\) in 2000, and was a surprising departure from the Commerce Clause interpretation in those cases. Both cases involved challenges to federal legislation that would have authorized strict regulations, based upon Congress' Commerce Clause powers.\(^{220}\) Neither case found the regulated activity—gun-possession in *Lopez*, and violent crime in *Morrison*—to be permissibly regulated under the Commerce Clause.\(^{221}\) The Court expressed concern in both cases that by allowing Congress to regulate the activity at issue, it would give Congress limitless control over areas of individual action that were traditionally left to the states to regulate.\(^{222}\)

The rationale behind the *Raich* decision is strikingly similar to the government's arguments in *Lopez* and *Morrison*—relation to interstate

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220. In *Lopez*, the Court ruled that the Gun-Free School Zones Act of 1990, which prohibited possession of a firearm in a school zone exceeded Congress' authority to regulate under the Commerce Clause. See generally *Lopez*, 514 U. S. at 549. In *Morrison*, the Court ruled that the Violence Against Women Act, providing a federal civil remedy for victims of gender-motivated crimes, was a similarly unconstitutional extension of Congress' Commerce Clause powers. See generally *Morrison*, 529 U. S. at 598.

221. *Morrison*, 529 U. S. at 615-16; *Lopez*, 529 U. S. at 564.

222. The Court noted:

If accepted, petitioners' reasoning would allow Congress to regulate any crime as long as the nationwide, aggregated impact of that crime has substantial effects on employment, production, transit, or consumption...[and] will not limit Congress to regulating violence but may, as we suggested in *Lopez*, be applied equally as well to family law and other areas of traditional state regulation since the aggregate effect of marriage, divorce, and childrearing on the national economy is undoubtedly significant.

*Morrison*, 529 U. S. at 615-16.

Under the theories that the Government presents in support of § 922(q), it is difficult to perceive any limitation on federal power, even in areas such as criminal law enforcement or education where States historically have been sovereign. Thus, if we were to accept the Government's arguments, we are hard pressed to posit any activity by an individual that Congress is without power to regulate.

commerce and aggregation of activities—and yet, the Court came to the opposite conclusion in *Raich*. The *Raich* Court distinguished the case from *Lopez* and *Morrison* by drawing a distinction between the respondents' arguments in both cases. According to the Court, the respondents in *Raich* challenged the constitutionality of "individual applications of a concededly valid statutory scheme [the CSA]" whereas *Lopez* and *Morrison* challenged the constitutionality of the statutory schemes themselves. Whether or not such a distinction is valid, the result has been the vast expansion of federal control over individual actions and severe encroachment upon traditional areas of state sovereignty—the very concerns behind the decisions of *Lopez* and *Morrison*.

Chief Justice Rehnquist and Justices O'Connor and Thomas dissented, rejecting the Court's acceptance of a tenuous connection between intrastate marijuana production and consumption and interstate commerce. Justice O'Connor expounded on Justice Brandeis' 1932 concept of states as laboratories for democracy, describing the extensive jurisdiction of the CSA as "stif[ing] an express choice by some States, concerned for the lives and liberties of their people, to regulate [drugs] differently." She insisted that federal law must protect the space states have to experiment. The views of these credible and distinguished jurists could someday be the basis for revisiting the *Raich* decision and its expansion of the CSA.

Since *Raich*, the CSA enjoys nearly unbridled jurisdiction over drug offenses anywhere in the U.S. This renders progressive legislation, like Arizona's DMPCA, impotent. With federal law occupying the traditional state fields of criminal law and public health, states are unwilling or unable to experiment with innovative and modern solutions for old problems.

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223. Gonzales v. Raich, 545 U.S. 1, 33 (2005).

224. See discussion at Sec. IV; *Raich*, 545 U.S. at 23.

225. *Raich*, 545 U.S. at 23.

226. Id. at 42 (O'Connor J., dissenting).

227. Id. at 57 (O'Connor J., dissenting).

228. Id.

229. See Kiefer, supra note 20; Stern & DiFonzo, supra note 20, at 720 n. 340; Boyd, supra note 20, at 1260.

230. See Kiefer, supra note 20.
The stifling effects of *Raich* on state autonomy and federalism can be compared to the similar effects that resulted from Prohibition Era legislation. Like the CSA, the Eighteenth Amendment and subsequent Prohibition legislation grossly increased the federal government’s oversight of criminal law. This resulted in an increase in the federal prison population by more than fifty percent. Similarly, post-CSA America saw an increase in incarcerated drug offenders from 16.3 percent of the incarcerated population in 1970 to 61.3 percent in 1994. After *Raich*, that percentage decreased to fifty-three percent by 2006, still more than three times the proportion in 1970.

The Eighteenth Amendment and its progeny also served to severely thwart U.S. federalism and the opportunity for U.S. citizens to seek out communities with political opinions similar to their own. Instead, residents of “Wet” states were forced to conform to a national standard that they did not support. Under the CSA, modern citizens are likewise deprived of the opportunity to participate effectively in their own governance.

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231. It is particularly notable that Prohibition Era legislation began with the Eighteenth Amendment, a constitutional amendment that implies that the broad congressional powers over alcohol control could not have been supported by the Commerce Clause, as Congress and the Court reasoned with the CSA. See Somin, *supra* note 205, at 547-50.

232. *Id.* at 548.


235. William J. Sobel et al., *Prisoners in 2006* Table 12 (2006), http://proxy.baremetal.com/cspd.org/research/p06.pdf (indicating that 93,751 of the total federal prison population of 176,268 inmates were drug offenders).

236. See discussion at Sec. IV, Somin, *supra* note 205, at 547.


238. Fourteen U.S. states have enacted legislation legalizing medical use of marijuana. See Active State Medical Marijuana Programs, *supra* note 18.
legislation, Congress should not be allowed or even inclined to marginalize a vast proportion of the population by usurping state autonomy.

State legislation establishing an HMT program could easily address the problems posed by the Raich Court. The Court's concern with a patient's sale of any excess of his prescription heroin is negated by the design of the HMT procedure because, in the majority of HMT programs, patients receive their heroin doses in a clinic and are not permitted to remove any heroin from the premises. Rather, patients self-administer their heroin dosage in the clinic, and are subsequently monitored for a period of time (usually thirty minutes). The post-administration supervision not only protects against complications and overdoses, but also ensures that patients do not sneak extra heroin out with them when they leave the clinic.

The one caveat that HMT clinics may face is that they must obtain a stock of heroin from somewhere. If a clinic's supply came from out-of-state, the transaction would undeniably put HMT clinics within the jurisdiction of the CSA. However, if the federal government amends the CSA to re-categorize heroin from Schedule I to Schedule II and establishes regulations for HMT clinics generally, then the CSA would no longer pose a threat to HMT programs or the state communities that would launch them. Thus, HMT depends not only upon the re-categorization of heroin as a dangerous, yet medically-valuable, substance, but also upon federal restraint under the CSA.

C. The Obama Administration and Hope for Change in Drug Control

The tide of U.S. drug policy may be shifting in favor of state autonomy under the Obama Administration. In October 2009, the U.S. Department of Justice issued a memorandum discouraging federal prosecutors from


240. Perneger et al., supra note 11, at 14; Haasen et al., supra note 11, at 56.

241. Perneger et al., supra note 11, at 14; van den Brink et al., supra note 11, at 310.
targeting medicinal marijuana users and their suppliers.242 The memorandum advised that it is not a good use of resources to prosecute “individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.”243 The Obama Administration’s recognition of the states’ autonomy in passing—and now enforcing—legislation legalizing medicinal marijuana use signals a significant move away from the more stringent drug policies of past administrations.244 If this recognition of states’ rights extends to Arizona’s DMPCA, then Arizona’s implementation of an HMT study could be facilitated.245

Scientific research on Schedule I substances has progressed under the radar of the legislative struggle. In September 2008, the FDA approved research on the effect of lysergic acid diethylamide, or LSD, on “end-of-life anxiety in terminally ill patients.”246 Though the study was conducted in Switzerland, the FDA’s approval allows data from the clinical trials to be used in the U.S.247 In 2004, a researcher in South Carolina obtained FDA approval to study the therapeutic effects of MDMA, more commonly known


243. Memorandum from Justice Dep’t, supra note 242; See also Marijuana Policy Is Shifted, supra note 242.

244. See Marijuana Policy Is Shifted, supra note 242.

245. Memorandum from Justice Dep’t, supra note 242. Since the memorandum specifies “compliance with existing state laws”, it is likely that only Arizona, protected by its DMPCA, could possibly establish an HMT program before any federal drug law changes occur. Id. (emphasis added).


247. Id.
as ecstasy, on symptoms of post-traumatic stress disorder. Since both LSD and MDMA are categorized as Schedule I substances, a compelling case can be made that these studies set a precedent for studies of the medicinal value of other Schedule I substances, such as heroin.

Opponents may point out that LSD and MDMA are hallucinogens, whereas heroin is a narcotic. The important difference between these classes of illicit drugs is that hallucinogens are generally not physically addictive, whereas heroin, a narcotic, is physically addictive. The non-addictive nature of hallucinogens like LSD and MDMA, some might argue, make them less dangerous for use in therapy. However, hallucinogens are psychologically addictive: they cause a psychological reaction—feelings of euphoria or dramatic hallucinations—that users then seek to experience repeatedly until they become psychologically dependent on the drug. This psychologically addictive potential is likely what earned LSD and MDMA their places in Schedule I, alongside the physically addictive heroin.

Even if one were to argue that the supervised administration of LSD and MDMA in these studies off-set the danger of addiction, this argument fails

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249. Approval was likely possible because of the Raich Court’s interpretation of the CSA to “prohibit entirely the possession or use of substances listed in Schedule I, except as a part of a strictly controlled research project.” Gonzales v. Raich, 545 U.S. 1, 24 (2005) (emphasis added).


252. See Drug Abuse Prevention & Control, Schedule I(a)(9), Schedule I(b)(10), & Schedule I(c)(1) (2009). Indeed, the U.S. Drug Enforcement Administration equates LSD with MDMA and heroin when describing LSD’s scheduling in the Controlled Substances Act. DEA, LSD, http://www.justice.gov/dea/concern/lsd.html#foot3 (last visited Mar. 18, 2010). “LSD is a Schedule I substance under the Controlled Substances Act. Schedule I drugs, which include heroin and MDMA, have a high potential for abuse and serve no legitimate medical purpose.” (emphasis added). Id.
Heroin Maintenance Treatment

considering that HMT features similarly supervised administration and would be designed to avoid exacerbating the addiction problem. Another likely argument is that the LSD and MDMA studies test the medicinal value of these substances in treating unrelated psychological disorders, whereas HMT is a process of treating heroin addiction with heroin. However, this argument raises the question of how logical it would be to expose participants, already suffering from psychological distress, to the potentially addictive nature of Schedule I substances. HMT has been recognized not as a cure, but as a tool in the addict’s gradual progression from addiction to recovery.

D. The Key to HMT in the United States

It would be naïve to expect the U.S. to establish HMT clinics, which would legally administer pure, intravenous heroin to heroin addicts, without extreme caution and oversight. For this reason, the steps to be taken toward U.S. HMT clinics should be small and heavily regulated. The first step would be to initiate a study of HMT effectiveness in the U.S. heroin-addicted population. To effectuate a U.S. study of HMT, legislative changes would need to take place at both the federal and state levels.

At the federal level, the Attorney General or Secretary of Health and Human Services would need to initiate hearings to re-categorize heroin as a Schedule II substance. While the Attorney General can initiate these hearings on his own, the public need not wait for him to do so: the Attorney General can also initiate hearings on the “petition of any interested party.” Moving heroin to Schedule II would illustrate that the government recognizes the medical value of heroin in an HMT setting, but still considers it to be an extremely addictive and dangerous substance that requires strict regulation. Methadone is currently recognized this way. Despite the demonization of heroin as an illegal drug, U.S. authorities can legitimately

253. Perneger et al., supra note 11, at 13-14; van den Brink et al., supra note 11, at 311; Haasen et al., supra note 11, at 56; March et al, supra note 11, at 204-05; Oviedo-Joekes et al, supra note 13, at 777.


255. Id. at § 811(a).


257. See id. at Schedule II(b)(11).

258. See supra Section IV(A)(b).
and justifiably rely on the HMT trials in Europe and Canada for evidence of the successful use of heroin in HMT. Indeed, this possibility was left open in the CSA-expanding majority decision of Raich: "[a]s the Solicitor General confirmed during oral argument, the statute authorizes procedures for the reclassification of Schedule I drugs."259

Once heroin is moved to Schedule II, the U.S. government could automatically apply the new methadone regulations to the clinical use of heroin.260 By subjecting heroin to the same stringent regulations that are currently applied to methadone, government authorities would not only be equating heroin with methadone, but would also be secure that the minor easing of prohibition on heroin would be just that—minor. Heroin would still be heavily regulated, and would be available only for HMT research and treatment.

By authorizing heroin for the same usages as methadone, individual states could start their own HMT clinics—or, more realistically, researchers in U.S. institutions could conduct U.S. studies on HMT effectiveness. Indeed, for the purposes of an HMT study, the federal government need not initiate lengthy and arduous rescheduling hearings. The Raich court interpreted the CSA to "prohibit entirely the possession or use of substances listed in Schedule I, except as a part of a strictly controlled research project."261 Once a study of HMT effectiveness has been conducted and replicated in the U.S., American legislators and the American public may become more confident in the value of and need for HMT. By the same token, HMT clinics would not be imposed upon unwilling states by a federal system. Instead, states with more aggravated heroin problems and a genuine interest in HMT could establish clinics within their states, largely on their own terms. Although evidence suggests that HMT clinics do not cause any disturbance to surrounding neighborhoods,262 citizens who oppose the introduction of HMT clinics could "vote with their feet,"263 and move to an HMT-free community.

While the decision in Raich appears problematic, it merely upheld the application of the CSA, specifically the actions of federal agents who seized

259. Gonzales v. Raich, 545 U.S. 1, 33 (2005).

260. See supra Section II.B.

261. Raich, 545 U.S. at 24 (emphasis added).

262. See Perneger et al., supra note 11, at 17.

263. Somin, supra note 205, at 541.
and destroyed a substance that is listed as a prohibited Schedule I drug. The concerns regarding federal preemption of state drug laws after Raich is only realized if federal agents act on their authority under the CSA. Under the Obama administration, federal prosecutors have been instructed to avoid prosecuting medical marijuana patients and their suppliers if those individuals' actions were in accordance with an existing state law permitting medicinal use of marijuana. If a similar direction were given for heroin obtained for HMT studies, researchers would have nothing to fear from the expanded post-Raich CSA, assuming that the researcher in possession of heroin was operating legally under applicable regulations.

Any U.S. initiative toward studying HMT will likely face significant opposition, but such resistance will probably focus on political and moral opinions. Practically, it is possible to begin an HMT study in the U.S. There is abundant scientific evidence to support such a program, and procedures are built into the CSA to facilitate a substance's scheduling to be amended, as would be required by an HMT program in the U.S. Perhaps the Obama Administration's progressive attitude toward drug control will encourage the changes and initiatives necessary to study the effectiveness of HMT in the U.S., thereby making treatment available to a previously unreachable group of heroin addiction sufferers.

264. *Raich*, 545 U.S. at 26-27. The court noted:

We have no difficulty concluding that Congress acted rationally in determining that none of the characteristics making up the purported class, whether viewed individually or in the aggregate, compelled an exemption from the CSA; rather, the subdivided class of activities defined by the Court of Appeals was an essential part of the larger regulatory scheme.

Id.

265. See Memorandum from Justice Dep't on Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana to Selected United States Attorneys, supra note 242.

266. See generally Christian Haasen et al., *supra* note 11; van den Brink et al., *supra* note 11; Perneger et al., *supra* note 11; Oviedo-Jeckes et al., *supra* note 13.


268. See *supra* Subsection D.
VI. CONCLUSION

The goal of drug control is to eradicate illegal drug use entirely. The reality, however, is that a considerable number of Americans are already addicted to dangerous illegal drugs, such as heroin. This state of affairs must be attacked with the most effective treatment available. While MMT in the U.S. is effective, it fails to reach a substantial number of suffering addicts,\textsuperscript{269} and therefore needs supplementation. The U.S. is faced with growing evidence that HMT is successful and safe.\textsuperscript{270} Yet, the current drug control laws fail to recognize these findings.\textsuperscript{271}

The CSA should be amended to re-categorize heroin as a Schedule II drug, recognizing its medical value under "severe restrictions."\textsuperscript{272} Additionally, enforcement of the CSA should be properly limited to interstate drug problems, such as trafficking, to encourage individual states to conduct their own studies, "without risk to the rest of the country."\textsuperscript{273} The Obama Administration has taken positive steps toward restraining its enforcement of federal drug laws,\textsuperscript{274} and several studies of medicinal use of Schedule I drugs have already been approved by the FDA.\textsuperscript{275} These steps may set the proper precedent for advocating a U.S. HMT study. This would ensure that thousands of heroin addicts would gain an opportunity for successful addiction treatment, and U.S. drug policy would take a positive step toward eliminating heroin addiction.

\textsuperscript{269.} METHADONE, supra note 34.

\textsuperscript{270.} See generally Haasen et al., supra note 11; van den Brink et al., supra note 11; Perneger et al., supra note 11; Oviedo-Joekes et al., supra note 13.


\textsuperscript{272.} Id. at § 812(b)(2)(B).

\textsuperscript{273.} New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis J., dissenting) (describing individual states as laboratories that may conduct "social and economic experiments").

\textsuperscript{274.} See Memorandum from Justice Dep't on Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana to Selected United States Attorneys, supra note 242.