Heroin-Assisted Treatment in the United States: An Opportunity

28 October 2016

We are the Drug Policy Alliance.

Existing Federal Law

Requirements for Narcotic Maintenance Therapies Generally: A practitioner "may administer or dispense directly…a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment" subject to certain conditions; the practitioner must be registered separately with the DEA as a narcotic treatment program and in compliance with DEA regulations. *See* CFR Section 1306.04(c).

Additional Requirements for Heroin-Assisted Treatment: For heroin to be prescribed or administered, a specific exemption for medical research would have to be granted by the Attorney General. *See* 21 U.S.C. § 872(e). Any proposed increase in availability of heroin under the research exemption would have to be submitted by the DEA to the International Narcotics Control Board (INCB), which would then need to approve the import or manufacture of the drug.

State Strategy

Question of Politics, Not Law: There are few if any federal legal and logistical barriers to implementing HAT in the U.S.; in fact a number of heroin research trials are currently underway in the U.S., and the DEA consistently requests and receives permission from INCB to import the necessary amount of the drug for this research to proceed.

State Police Power: States have the duty to protect and preserve the welfare of their citizens. The legal authority to fulfill this duty, called the "police power," has been recognized as a basic attribute of the state since the founding of the nation. Given the evidence in support of HAT, a state could view HAT as a reasonable public health measure with the potential to address the host of problems associated with heroin dependence. Permitting HAT would therefore be a logical and prudent exercise of the police power.

State Strategy—Cont.

State Legislation Permitting HAT: There is no question that state legislatures have the power to modify state law to remove any legal impediments to HAT operation. Nevada and Maryland have introduced legislation that would both remove barriers and affirmatively establish a HAT pilot program (in coordination with the federal government).

States Lead Drug Policy Reform: Absent state pressure, the federal government does not act to address the harms of drug use and drug prohibition. State pressure is necessary to move HAT forward in the U.S. Moreover, state-level authorization can be tailored to the unique needs of New Mexico as opposed to a one-size-fits-all federal approach.

New Mexico Has Always Pushed Boundaries: New Mexico was the first state to license the production and distribution of medical marijuana. New Mexico was the first state to pass Good Samaritan legislation. It has a rich tradition of putting the health needs of its residents first, as is required to move HAT forward in the United States.

HEROIN OVERDOSE IN NM: A LOOK AT DEATH AND ED VISITS

By: Shelly Moeller, MPH, MCRP

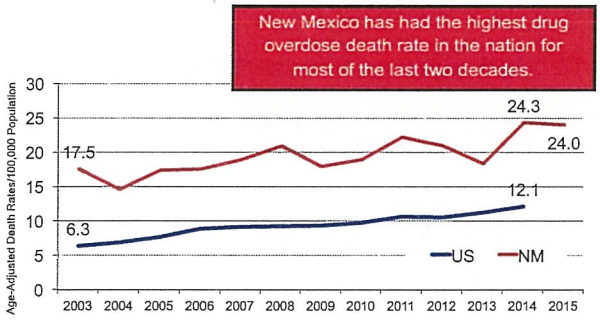
Drug Poisoning was the leading cause of death for New Mexicans aged 25-54 yrs.

Age Group	Leading Cause of Death, 2014
<1	Congenital Anomalies – 37 deaths
1-9	MV Crash – 14 deaths
10-14	Suicide by Firearm -
15-24	MV Crash Death – 86 deaths
25-54	**Poisoning – 381 deaths**
55-64	Malignant Neoplasms – 662 deaths
65+	Heart Disease – 2,748 Deaths

From 2011-2015, there were 1,969 drug poisoning deaths among 25-54 yr. olds, of which 509, **25%, were heroin related.**

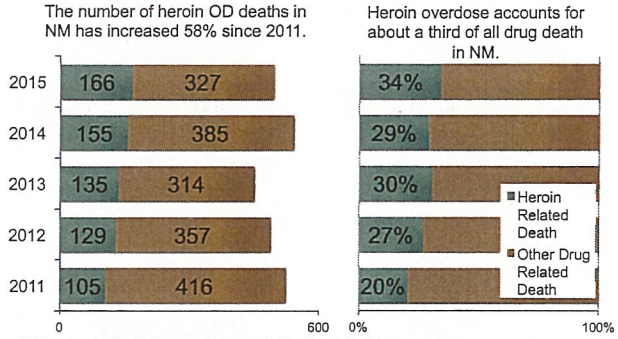
Source: CDC Web Based Statistics Query and Reporting System; NM Department of Health Emergency Response Division Drug Epidemiology

A Look at the Trends in Drug Overdose Death Rates in the US and NM



Source: NM Department of Health Emergency Response Division Drug Epidemiology

Burden of Heroin Related Drug Overdose Death in NM, 2011-2015



Source: NM Department of Health Emergency Response Division Drug Epidemiology

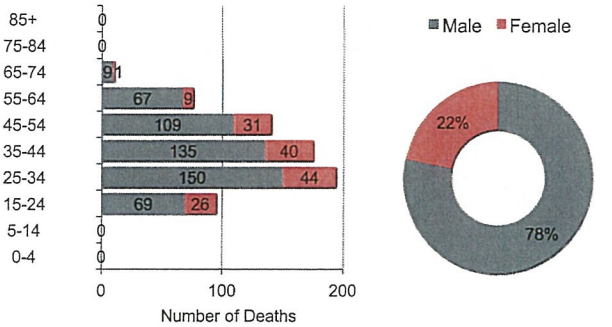
From 2011-2015, in NM.....

1 out of 3 drug overdose deaths in NM was heroin related.

The number of heroin overdose death increased 58%.

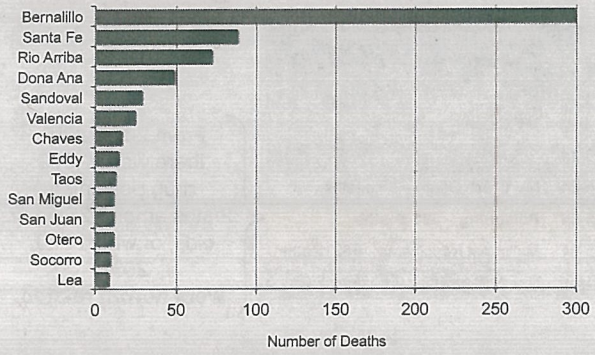
Source: NM Department of Health Emergency Response Division Drug Epidemiology

Heroin Related Death By Age and Gender, 2011-2015



Source: NM Department of Health Emergency Response Division Drug Epidemiology

Bernalillo County carries the heaviest burden of heroin death in NM.

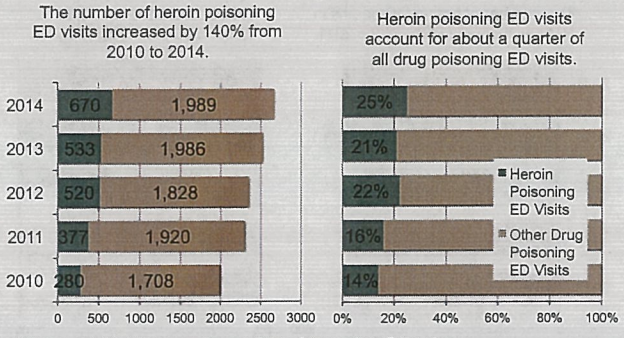


Source: NM Department of Health Emergency Response Division Drug Epidemiology

In NM.....

- More men than women die of a heroin drug overdose. 3:1 ratio – men to women.
- Bernalillo county carries the heaviest burden of heroin related death in NM.
- 75% of the people who died of a heroin overdose in 2011-2015 were 25-54 years old.

Heroin Poisoning ED Visits in NM, Years 2010-2014



Source: NM Department of Health Emergency Response Division Substance Abuse Epidemiology

Drug Replacement and Maintenance Therapy in NM: Buprenorphine and Methadone Use in NM, 2016

- 14 Methadone Clinics statewide with ~ 5,090 patients as of October 2016 (Source: NM Human Services Department.)
- ~4,200 Suboxone patients as of 2016 Q2 (Source: NM DOH ERD)

Heroin-Assisted Treatment (HAT)

February 2016

We are the Drug Policy Alliance.

Drug replacement and maintenance therapies have a long history of providing individuals struggling with problematic drug use with legal access to drugs that would otherwise be obtained through illegal means. More than a half dozen countries in Europe and Canada have implemented heroin-assisted treatment (HAT) programs. Under HAT, pharmacological heroin is administered under strict controls in a clinical setting to those who have failed in other treatments like methadone. Every published evaluation of HAT has shown extremely positive outcomes: major reductions in illicit drug use, crime, disease and overdose; and improvements in health, wellbeing, social reintegration and treatment retention. The U.S. should implement this innovative health-centered model.

HAT: A Successful Second-Line Treatment

Several countries have gone beyond methadone and adopted heroin-assisted treatment (HAT) programs, which have proven enormously successful and now operate in Switzerland,[1] Netherlands,[2] United Kingdom,[3] Germany,[4] Spain,[5] Denmark,[6] Belgium,[7] Canada,[8] and Luxembourg.[9] Also known as heroin maintenance, HAT allows for the provision of pharmacological grade heroin[10] (diacetylmorphine) to select heroin-dependent people who have not previously responded to other forms of treatment. Typically, patients receive injectable or inhalable heroin 2-3 times per day from a doctor in a clinic setting under strict controls.

HAT Improves Health, Social Functioning and Quality of Life

Peer-reviewed studies around the world have found that HAT is associated with decreased illicit drug use, crime, overdose fatalities, and risky injecting, as well as improvements in physical and mental health, employment and social relations.[11] In contrast, few reports have appeared in the scientific literature demonstrating any harmful consequences of HAT.

HAT Significantly Reduces Illicit Heroin Use

E*very HAT trial* has shown a marked decrease in illicit 'street' heroin use. A 2015 systematic review and meta-analysis published in the *British Journal of Psychiatry* reviewed six randomized controlled trials of HAT and found that, across all trials, there was a greater reduction in the use of illicit heroin among HAT patients compared to the control groups (who generally only received methadone). The authors concluded that "heroin-prescribing, as a part of highly regulated regimen, is a feasible and effective treatment for a particularly difficult-to-treat group of heroin-dependent patients."[12]

Similarly, a 2011 *Cochrane* systematic review concluded, "Each study found a superior reduction in illicit drug use in the heroin arm rather than in the methadone arm…the measures of effect obtained are consistently statistically significant."[13]

The first Canadian HAT trial reported a two-thirds (67 percent) reduction in illicit drug use or other illegal activity among HAT participants.[14] Similar reductions in illicit heroin use were reported from HAT trials in the UK (72 percent)[15] and Germany (69 percent).[16] HAT patients experience less (and less severe) cravings, helping to explain their decreased use.[17] HAT has also demonstrated an added benefit of reducing participants' use of alcohol and other drugs.[18]

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HAT is Cost-Effective
HAT is not just more effective at reducing street drug use than methadone,[19] but it has also proven to be more cost-effective.[20] While HAT does cost more than methadone initially, cost-benefit studies demonstrate that these higher costs are more than offset by savings in criminal justice and health care.[21]

HAT has been restricted to those who have not responded to other forms of treatment; although evidence now shows HAT is effective even for people with no previous methadone experience or those who switch from methadone to HAT – suggesting that it could easily be scaled up.[22]

HAT Improves Treatment Retention
Once someone begins a HAT program, they are likely to stick around. Retention rates in HAT programs dwarf those of convention treatments.[23] A 2016 systematic review of the past five years of research, for example, found that "heroin-assisted treatment was associated with better retention than methadone among treatment-refractory patients" at 12 month follow-up.[24]

Patients express a strong preference for HAT over methadone or other standard treatments.[25] Moreover, those who end up dropping out of HAT usually do not relapse, but rather tend to freely choose to switch to another form of treatment (like methadone) or to abstinence;[26] while others continue to receive HAT on a long-term basis, with lasting positive results.[27]

HAT Decreases Crime
HAT participants are also much less likely to commit acquisitive crimes and other non-drug offenses. As a result, HAT programs have been shown to decrease crime in areas where they are situated – leading to additional cost savings of the HAT model.[28]

HAT Reduces Demand and Shrinks Drug Markets
Substitution therapies like HAT represent the most effective approaches to demand reduction because they acknowledge that many dependent or serious drug consumers simply cannot or will not cease using their preferred substance of choice (or a close substitute) – regardless of its legal status or the impact their consumption might have on other countries. HAT programs have been so successful precisely because they focus on reducing *illicit* demand – not demand per se – and channeling this demand towards a *licit*, regulated supply.[29]

HAT programs currently serve a subsection of the using population that is small, but which consumes a disproportionate amount of heroin.

Available evidence indicates that HAT programs can help destabilize local heroin markets. One published article concluded that HAT participants "accounted for a substantial proportion of consumption of illicit heroin, and that removing them from the illicit market has damaged the market's viability." It further states that "by removing retail workers [who] no longer sold drugs to existing users, and...no longer recruited new users into the market...the heroin prescription market may thus have had a significant impact on heroin markets in Switzerland."[30]

HAT in the United States?
An exploratory analysis of the benefits of implementing HAT in Baltimore concluded, "Enough evidence has emerged in the last 10 years to merit reconsideration of its potential for Baltimore, and the U.S. more generally."[31]

Researchers, harm reduction advocates and health officials have expressed interest in studying and implementing HAT in the U.S., but zero tolerance policies and federal law have stood in the way of this evidence-based method of treatment.

Congress should amend federal law to make clear that cities that want to conduct trial HAT programs can do so without federal interference. Congress should also fund domestic pilot projects to study this life-saving and successful health-centered intervention.

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[1] A. Uchtenhagen, "Heroin-assisted treatment in Switzerland: a case study in policy change," *Addiction* 105, no. 1 (2010); A. A. Uchtenhagen, "Heroin maintenance treatment: From idea to research to practice," *Drug and Alcohol Review* 30, no. 2 (2011).
[2] Peter Blanken et al., "Heroin-assisted treatment in the Netherlands: History, findings, and international context," *European Neuropsychopharmacology* 20(2010).
[3] John Strang et al., "Supervised injectable heroin or injectable methadone versus optimised oral methadone as treatment for chronic heroin addicts in England after persistent failure in orthodox treatment (RIOTT): a randomised trial," *The Lancet* 375, no. 9729 (2010).
[4] U. Verthein et al., "Long-term effects of heroin-assisted treatment in Germany," *Addiction* 103, no. 6 (2008); U. Verthein, C. Haasen, and J. Reimer, "Switching from methadone to diamorphine: 2-year results of the german heroin-assisted treatment trial," *Subst Use Misuse* 46, no. 8 (2011); C. Haasen et al., "Heroin-assisted treatment for opioid dependence: randomised controlled trial," *Br J Psychiatry* 191(2007).
[5] E. Oviedo-Joekes et al., "The Andalusian trial on heroin-assisted treatment: a 2 year follow-up," *Drug Alcohol Rev* 29, no. 1 (2010); E. Perea-Milla et al., "Efficacy of prescribed injectable diacetylmorphine in the Andalusian trial: Bayesian analysis of responders and non-responders according to a multi domain outcome index," *Trials* 10(2009).

[6] Convinced by the impressive results from other countries, Denmark moved ahead with implementing HAT programs without conducting its own randomized controlled trial. *See* Uchtenhagen, "Heroin maintenance treatment: From idea to research to practice."
[7] I. Demaret et al., "Efficacy of heroin-assisted treatment in belgium: a randomised controlled trial," *Eur Addict Res* 21, no. 4 (2015).
[8] Eugenia Oviedo-Joekes et al., "Diacetylmorphine versus methadone for the treatment of opioid addiction," *N Engl J Med* 361, no. 8 (2009).
[9] European Monitoring Centre on Drugs and Drugs Addiction, "Country overview: Luxembourg," http://www.emcdda.europa.eu/countries/luxembourg.
[10] The Canadian trial involved an arm of the study that received another opioid agonist, hydromorphone, instead of heroin; these subjects showed similarly impressive results. A second randomized trial in Canada currently underway is administering heroin as well as hydromorphone. *See* E. Oviedo-Joekes et al., "Double-blind injectable hydromorphone versus diacetylmorphine for the treatment of opioid dependence: a pilot study," *J Subst Abuse Treat* 38, no. 4 (2010); Providence Health Care, "The Study to Assess Longer-term Opioid Medication Effectiveness (SALOME)," http://www.providencehealthcare.org/salome/index.html.
[11] Marica Ferri, M. Davoli, and C. A. Perucci, "Heroin maintenance for chronic heroin-dependent individuals," *Cochrane Database Syst Rev*, no. 12 (2011); Verthein, Haasen, and Reimer, "Switching from methadone to diamorphine: 2-year results of the german heroin-assisted treatment trial; P. Blanken et al., "Outcome of long-term heroin-assisted treatment offered to chronic, treatment-resistant heroin addicts in the Netherlands," *Addiction* 105, no. 2 (2010); A. Karow et al., "Quality of life under maintenance treatment with heroin versus methadone in patients with opioid dependence," *Drug Alcohol Depend* 112, no. 3 (2010); Uchtenhagen, "Heroin-assisted treatment in Switzerland: a case study in policy change; Oviedo-Joekes et al., "Diacetylmorphine versus methadone for the treatment of opioid addiction; Haasen et al., "Heroin-assisted treatment for opioid dependence: randomised controlled trial; Benedikt Fischer et al., "Heroin-assisted Treatment (HAT) a Decade Later: A Brief Update on Science and Politics," *Journal of Urban Health* 84, no. 4 (2007); M. P. Garcia-Portilla et al., "Long term outcomes of pharmacological treatments for opioid dependence: does methadone still lead the pack?," *Br J Clin Pharmacol* 77, no. 2 (2014); John Strang, Teodora Groshkova, and Nicola Metrebian, *New Heroin-Assisted Treatment: Recent Evidence and Current Practices of Supervised Injectable Heroin Treatment in Europe and Beyond* (Lisbon: European Monitoring Centre for Drugs and Drug Addiction, 2012); M. T. Schechter and P. Kendall, "Is there a need for heroin substitution treatment in Vancouver's Downtown Eastside? Yes there is, and in many other places too," *Can J Public Health* 102, no. 2 (2011); Karow et al., "Quality of life under maintenance treatment with heroin versus methadone in patients with opioid dependence; J. Rehm et al., "Mortality in heroin-assisted treatment in Switzerland 1994-2000," *Drug Alcohol Depend* 79, no. 2 (2005); Robert P Schwartz et al., "Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009," *American journal of public health* 103, no. 5 (2013); U Verthein, I Schäfer, and P Degkwitz, "[Social Integration after 4 Years of Heroin-Assisted Treatment.]," *Die Rehabilitation* 52, no. 4 (2012); Carlos Nordt and Rudolf Stohler, "Combined effects of law enforcement and substitution treatment on heroin mortality," *Drug and Alcohol Review* 29, no. 5 (2010); B. Nosyk et al., "Health related quality of life trajectories of patients in opioid substitution treatment," *Drug Alcohol Depend* 118, no. 2-3 (2011).
[12] J. Strang et al., "Heroin on trial: systematic review and meta-analysis of randomised trials of diamorphine-prescribing as treatment for refractory heroin addictiondagger," *Br J Psychiatry* 207, no. 1 (2015): 11.
[13] Ferri, Davoli, and Perucci, "Heroin maintenance for chronic heroin-dependent individuals," 10.
[14] Oviedo-Joekes et al., "Diacetylmorphine versus methadone for the treatment of opioid addiction."
[15] Strang et al., "Supervised injectable heroin or injectable methadone versus optimised oral methadone as treatment for chronic heroin addicts in England after persistent failure in orthodox treatment (RIOTT): a randomised trial."
[16] Haasen et al., "Heroin-assisted treatment for opioid dependence: randomised controlled trial."
[17] P. Blanken et al., "Craving and illicit heroin use among patients in heroin-assisted treatment," *Drug Alcohol Depend* 120, no. 1-3 (2012).
[18] Blanken et al., "Outcome of long-term heroin-assisted treatment offered to chronic, treatment-resistant heroin addicts in the Netherlands; F. J. Eiroa-Orosa et al., "Benzodiazepine use among patients in heroin-assisted vs. methadone maintenance treatment: findings of the German randomized controlled trial," *Drug Alcohol Depend* 112, no. 3 (2010); C. Haasen et al., "Effects of heroin-assisted treatment on alcohol consumption: findings of the German randomized controlled trial," *Alcohol* 43, no. 4 (2009).
[19] Verthein, Haasen, and Reimer, "Switching from methadone to diamorphine: 2-year results of the german heroin-assisted treatment trial."
[20] B. Nosyk et al., "Cost-effectiveness of diacetylmorphine versus methadone for chronic opioid dependence refractory to treatment," *CMAJ* 184, no. 6 (2012); Sarah Byford et al., "Cost-effectiveness of injectable opioid treatment v. oral methadone for chronic heroin addiction," *The British Journal of Psychiatry* (2013).
[21] Marcel G.W. Dijkgraaf et al., "Cost Utility Analysis of Co-Prescribed Heroin Compared With Methadone Maintenance Treatment in Heroin Addicts in Two Randomised Trials," *BMJ* 330, no. 1297 (2005).
[22] C. Haasen et al., "Is heroin-assisted treatment effective for patients with no previous maintenance treatment? Results from a German randomised controlled trial," *Eur Addict Res* 16, no. 3 (2010).
[23] Ferri, Davoli, and Perucci, "Heroin maintenance for chronic heroin-dependent individuals; Blanken et al., "Outcome of long-term heroin-assisted treatment offered to chronic, treatment-resistant heroin addicts in the Netherlands; B. Nosyk et al., "The effect of motivational status on treatment outcome in the North American Opiate Medication Initiative (NAOMI) study," *Drug Alcohol Depend* 111, no. 1-2 (2010); Oviedo-Joekes et al., "Diacetylmorphine versus methadone for the treatment of opioid addiction; Haasen et al., "Heroin-assisted treatment for opioid dependence: randomised controlled trial."
[24] C. Timko et al., "Retention in medication-assisted treatment for opiate dependence: A systematic review," *J Addict Dis* 35, no. 1 (2016): 22.
[25] L. K. Bald et al., "Heroin or Conventional Opioid Maintenance? The Patients' Perspective," *J Addict Med* (2013); K. I. Marchand et al., "Client satisfaction among participants in a randomized trial comparing oral methadone and injectable diacetylmorphine for long-term opioid-dependency," *BMC Health Serv Res* 11(2011).
[26] Jürgen Rehm et al., "Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study," *The Lancet* 358, no. 9291 (2001); Peter Reuter, *Can Heroin Maintenance Help Baltimore?: What Baltimore Can Learn from the Experience of Other Countries* (Abell Foundation, 2009).
[27] Blanken et al., "Outcome of long-term heroin-assisted treatment offered to chronic, treatment-resistant heroin addicts in the Netherlands," 300; Verthein et al., "Long-term effects of heroin-assisted treatment in Germany," 960; Oviedo-Joekes et al., "The Andalusian trial on heroin-assisted treatment: a 2 year follow-up; Garcia-Portilla et al., "Long term outcomes of pharmacological treatments for opioid dependence: does methadone still lead the pack?; U. Frick et al., "Long-Term Follow-Up of Orally Administered Diacetylmorphine Substitution Treatment," *European Addiction Research* 16, no. 3 (2010); F. Güttinger et al., "Evaluating Long-Term Effects of Heroin-Assisted Treatment: The Results of a 6-Year Follow-Up," *European Addiction Research* 9, no. 2 (2003).
[28] B. P. van der Zanden et al., "Patterns of acquisitive crime during methadone maintenance treatment among patients eligible for heroin assisted treatment," *Drug Alcohol Depend* 86, no. 1 (2007); Martin Killias et al., "Effects of Drug Substitution Programs on Offending Among Drug-Addicts: A Systematic Review," (2009); R. Lobmann and U. Verthein, "Explaining the effectiveness of heroin-assisted treatment on crime reductions," *Law Hum Behav* 33, no. 1 (2009); Garcia-Portilla et al., "Long term outcomes of pharmacological treatments for opioid dependence: does methadone still lead the pack?; Frick et al., "Long-Term Follow-Up of Orally Administered Diacetylmorphine Substitution Treatment; I Demaret et al., "Reduction in Acquisitive Crime During a Heroin-Assisted Treatment: a Post-Hoc Study," *J Addict Res Ther* 6, no. 208 (2015).
[29] Daniel Robelo, "Demand Reduction or Redirection? Channeling Illicit Drug Demand towards a Regulated Supply to Diminish Violence in Latin America," *Or. L. Rev.* 91(2013).
[30] Martin Killias, Marcelo Fernando Aebi, and Kriminologe Jurist, "The impact of heroin prescription on heroin markets in Switzerland," *Crime Prevention Studies* 11(2000).
[31] P. Reuter, "Can Heroin Maintenance Help Baltimore," *Baltimore, MD: Abell Foundation* (2009): 32.

HOUSE BILL 1267

J1 6lr1312

By: **Delegate Morhaim**
Introduced and read first time: February 12, 2016
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Poly–Morphone–Assisted Treatment Pilot Program – Harm Reduction Act of 2016

FOR the purpose of establishing the Poly–Morphone–Assisted Treatment Pilot Program; requiring the Program to begin on or before a certain date and to continue for a certain number of years; providing for the purpose of the Program; establishing the Poly–Morphone–Assisted Treatment Pilot Program Advisory Board; providing for the purpose and membership of the Advisory Board; providing for the terms of the members of the Advisory Board; requiring the Secretary of Health and Mental Hygiene to designate the chair of the Advisory Board; providing that a member of the Advisory Board may not receive certain compensation, but is entitled to certain reimbursement; requiring the Department of Health and Mental Hygiene to provide staff support for the Advisory Board; requiring a certain health care facility to submit a certain proposal to participate in the Program; requiring the Advisory Board to review certain proposals; requiring the Advisory Board, within a certain time period after receiving a certain proposal, to approve a health care facility for participation in the Program under certain circumstances or to deny the request to participate in the Program in a certain manner; requiring a health care facility that participates in the Program to conduct certain research, adopt certain guidelines and protocols, and take certain measures to develop and implement the Program; authorizing certain persons to provide and receive certain treatment, notwithstanding certain provisions of law; prohibiting the provision or receipt of certain treatment from being a basis for a certain seizure or forfeiture, notwithstanding certain provisions of law; prohibiting the imposition of certain penalties on certain persons based solely on the provision or receipt of certain treatment, notwithstanding certain provisions of law; authorizing certain providers to collect or attempt to collect certain fees and certain reimbursement, notwithstanding certain provisions of law; authorizing recipients of services under the Program to remit payment for certain fees, notwithstanding certain provisions of law; authorizing certain health insurance carriers to reimburse certain providers for certain fees, notwithstanding certain provisions of law; providing that certain health care practitioners may not be subject to certain

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.

disciplinary action under certain circumstances; exempting certain providers from certain requirements under the Prescription Drug Monitoring Program under certain circumstances; authorizing certain providers to fund the costs of providing certain treatment under the Program with certain appropriations, certain revenue, certain grants and assistance, and certain money; requiring certain health care facilities to submit certain reports to the Department and Advisory Board on or before certain dates; requiring the Department to submit certain compilations of certain reports to the Governor and to the General Assembly on or before certain dates; defining certain terms; providing for the termination of this Act; and generally relating to the Poly–Morphone–Assisted Treatment Pilot Program.

BY adding to
Article – Health – General
Section 8–1101 through 8–1108 to be under the new subtitle "Subtitle 11. Poly–Morphone–Assisted Treatment Pilot Program"
Annotated Code of Maryland
(2015 Replacement Volume)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 11. POLY–MORPHONE–ASSISTED TREATMENT PILOT PROGRAM.

8–1101.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "ADVISORY BOARD" MEANS THE POLY–MORPHONE–ASSISTED TREATMENT PILOT PROGRAM ADVISORY BOARD ESTABLISHED UNDER THIS SUBTITLE.

(C) "HEALTH CARE FACILITY" MEANS A FACILITY OR OFFICE WHERE HEALTH OR MEDICAL CARE IS PROVIDED TO PATIENTS BY A HEALTH CARE PRACTITIONER.

(D) "HEALTH CARE PRACTITIONER" MEANS A PERSON WHO IS:

(1) LICENSED, CERTIFIED, OR OTHERWISE AUTHORIZED UNDER THE HEALTH OCCUPATIONS ARTICLE TO PROVIDE HEALTH CARE SERVICES IN THE ORDINARY COURSE OF BUSINESS OR PRACTICE OF A PROFESSION; AND

(2) AUTHORIZED TO PRESCRIBE DRUGS UNDER THE HEALTH OCCUPATIONS ARTICLE.

(E) "OPIOID–DEPENDENT INDIVIDUAL" MEANS AN INDIVIDUAL WHO HAS AN OPIOID DEPENDENCE.

(F) (1) "OPIOID DEPENDENCE" HAS THE MEANING STATED IN THE DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, 4TH EDITION, PUBLISHED BY THE AMERICAN PSYCHIATRIC ASSOCIATION.

(2) "OPIOID DEPENDENCE" INCLUDES:

(I) A MALADAPTIVE PATTERN OF SUBSTANCE USE LEADING TO CLINICALLY SIGNIFICANT IMPAIRMENT OR DISTRESS; AND

(II) A COMBINATION OF SEVERAL OF THE FOLLOWING SIGNS AND SYMPTOMS:

1. INCREASING DRUG TOLERANCE;

2. WITHDRAWAL SIGNS AND SYMPTOMS;

3. A DESIRE OR UNSUCCESSFUL EFFORTS TO CUT DOWN OR CONTROL SUBSTANCE USE;

4. LOSS OF SOCIAL, OCCUPATIONAL, OR RECREATIONAL ACTIVITIES BECAUSE OF SUBSTANCE USE; AND

5. CONTINUING SUBSTANCE USE DESPITE CONSEQUENCES.

(G) "PHARMACEUTICAL–GRADE HEROIN" MEANS DIACETYLMORPHINE OR ITS EQUIVALENT.

(H) "POLY–MORPHONE–ASSISTED TREATMENT" MEANS THE ADMINISTERING OR DISPENSING OF PHARMACEUTICAL–GRADE HEROIN, HYDROMORPHONE, OR OTHER OPIATES BY A HEALTH CARE PRACTITIONER IN A HEALTH CARE FACILITY TO SELECT OPIOID–DEPENDENT INDIVIDUALS.

(I) "PROGRAM" MEANS THE POLY–MORPHONE–ASSISTED TREATMENT PILOT PROGRAM ESTABLISHED UNDER THIS SUBTITLE.

(J) "PROGRAM PROVIDER" MEANS A HEALTH CARE FACILITY OR HEALTH CARE PRACTITIONER THAT HAS RECEIVED APPROVAL FROM THE ADVISORY BOARD TO PROVIDE POLY–MORPHONE–ASSISTED TREATMENT.

(K) "PROGRAM RECIPIENT" MEANS AN INDIVIDUAL SELECTED TO RECEIVE POLY–MORPHONE–ASSISTED TREATMENT PROVIDED UNDER THE PROGRAM.

8–1102.

(A) THERE IS A POLY–MORPHONE–ASSISTED TREATMENT PILOT PROGRAM.

(B) THE PROGRAM SHALL BEGIN ON OR BEFORE JANUARY 1, 2018, AND CONTINUE FOR A PERIOD OF 4 YEARS.

(C) THE PURPOSE OF THE PROGRAM IS TO:

(1) PROVIDE POLY–MORPHONE–ASSISTED TREATMENT AT PARTICIPATING HEALTH CARE FACILITIES TO OPIOID–DEPENDENT INDIVIDUALS WHO DO NOT BENEFIT FROM OR CANNOT TOLERATE TREATMENT WITH DRUGS USED IN OPIOID REPLACEMENT THERAPY, INCLUDING METHADONE AND BUPRENORPHINE; AND

(2) EVALUATE THE EFFECTIVENESS OF POLY–MORPHONE–ASSISTED TREATMENT WHEN COMPARED TO CONVENTIONAL TREATMENT METHODS AND INTERVENTIONS, INCLUDING OPIOID REPLACEMENT THERAPY.

8–1103.

(A) THERE IS A POLY–MORPHONE–ASSISTED TREATMENT PILOT PROGRAM ADVISORY BOARD.

(B) THE ADVISORY BOARD CONSISTS OF:

(1) THE SECRETARY, OR THE SECRETARY'S DESIGNEE; AND

(2) THE FOLLOWING MEMBERS, APPOINTED BY THE SECRETARY:

(I) ONE PHYSICIAN WITH EXPERTISE IN ADDICTION MEDICINE;

(II) ONE NURSE WITH EXPERTISE IN ADDICTION TREATMENT;

(III) ONE SOCIAL WORKER;

(IV) ONE ADDICTION COUNSELOR;

(V) ONE REPRESENTATIVE OF LAW ENFORCEMENT; AND

(VI) ONE REPRESENTATIVE FROM A SCHOOL OF PUBLIC HEALTH WITH EXPERTISE IN ADDICTION TREATMENT.

(C) (1) (I) THE TERM OF AN APPOINTED MEMBER IS 3 YEARS.

(II) THE TERMS OF THE APPOINTED MEMBERS ARE STAGGERED AS REQUIRED BY THE TERMS PROVIDED ON OCTOBER 1, 2016.

(III) AT THE END OF A TERM, AN APPOINTED MEMBER CONTINUES TO SERVE UNTIL A SUCCESSOR IS APPOINTED AND QUALIFIES.

(IV) AN APPOINTED MEMBER MAY NOT SERVE MORE THAN TWO CONSECUTIVE FULL TERMS.

(V) AN APPOINTED MEMBER WHO IS APPOINTED AFTER A TERM HAS BEGUN SERVES ONLY FOR THE REST OF THE TERM AND UNTIL A SUCCESSOR IS APPOINTED AND QUALIFIES.

(2) THE SECRETARY SHALL DESIGNATE THE CHAIR FROM AMONG THE MEMBERS OF THE ADVISORY BOARD.

(3) A MAJORITY OF THE MEMBERS PRESENT AT A MEETING IS A QUORUM.

(4) A MEMBER OF THE ADVISORY BOARD:

(I) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE ADVISORY BOARD; BUT

(II) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.

(5) THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE SHALL PROVIDE STAFF SUPPORT FOR THE ADVISORY BOARD.

(D) THE PURPOSE OF THE ADVISORY BOARD IS TO:

(1) REVIEW PROPOSALS SUBMITTED BY HEALTH CARE FACILITIES REQUESTING PARTICIPATION IN THE PROGRAM; AND

(2) APPROVE HEALTH CARE FACILITIES THAT DEMONSTRATE AN ABILITY TO CARRY OUT THE REQUIREMENTS FOR PROGRAM PROVIDERS ESTABLISHED UNDER § 8–1105 OF THIS SUBTITLE AND HEALTH CARE PRACTITIONERS FOR PARTICIPATION IN THE PROGRAM.

8–1104.

(A) TO PARTICIPATE IN THE PROGRAM, A HEALTH CARE FACILITY SHALL SUBMIT A PROPOSAL TO THE DEPARTMENT REQUESTING APPROVAL TO PARTICIPATE IN THE PROGRAM.

(B) THE ADVISORY BOARD SHALL REVIEW EACH PROPOSAL SUBMITTED UNDER SUBSECTION (A) OF THIS SECTION.

(C) WITHIN 30 DAYS AFTER RECEIVING A PROPOSAL SUBMITTED UNDER SUBSECTION (A) OF THIS SECTION, THE ADVISORY BOARD SHALL:

(1) APPROVE A HEALTH CARE FACILITY FOR PARTICIPATION IN THE PROGRAM IF THE FACILITY DEMONSTRATES IN ITS PROPOSAL ITS ABILITY TO CARRY OUT THE REQUIREMENTS FOR PROGRAM PROVIDERS UNDER § 8–1105 OF THIS SUBTITLE; OR

(2) DENY THE REQUEST TO PARTICIPATE IN THE PROGRAM, STATING:

(I) THE ADVISORY BOARD'S REASONS FOR THE DENIAL; AND

(II) MODIFICATIONS THAT MAY BE MADE TO THE PROPOSAL SUBMITTED TO OBTAIN APPROVAL FROM THE ADVISORY BOARD TO PARTICIPATE IN THE PROGRAM.

8–1105.

A HEALTH CARE FACILITY THAT PARTICIPATES IN THE PROGRAM SHALL CONDUCT RESEARCH, ADOPT GUIDELINES AND PROTOCOLS, AND TAKE MEASURES NECESSARY TO DEVELOP AND IMPLEMENT THE PROGRAM, INCLUDING:

(1) ASCERTAINING NUMBERS, TRENDS, PATTERNS, RISK FACTORS, AND DEMOGRAPHIC DATA RELATED TO OPIOID DEPENDENCE IN THE STATE;

(2) REVIEWING THE HEROIN–ASSISTED TREATMENT STUDIES AND PROGRAMS IMPLEMENTED IN OTHER COUNTRIES AND DETERMINING BEST PRACTICES;

(3) DEVELOPING CRITERIA FOR SELECTING THE HEALTH CARE FACILITIES AND HEALTH CARE PRACTITIONERS WHO WILL PARTICIPATE IN THE PROGRAM;

(4) ESTABLISHING SCREENING AND ELIGIBILITY CRITERIA FOR INDIVIDUALS WHO WILL RECEIVE TREATMENT PROVIDED UNDER THE PROGRAM;

(5) DEVELOPING AN EFFECTIVE RECRUITMENT STRATEGY FOR INDIVIDUALS WHO WILL RECEIVE TREATMENT IN THE PROGRAM;

(6) ESTABLISHING ASSESSMENT AND TREATMENT PROTOCOLS;

(7) ESTABLISHING BEST CLINICAL PRACTICES FOR CONTINUITY OF CARE AND ACUTE CARE FOR UNMET OR URGENT MEDICAL AND PSYCHIATRIC NEEDS OF PROGRAM RECIPIENTS;

(8) (I) COORDINATING WITH THE FEDERAL GOVERNMENT TO OBTAIN PHARMACEUTICAL–GRADE HEROIN AND OTHER OPIATES REQUIRED FOR USE IN THE PROGRAM; OR

(II) IF UNABLE TO OBTAIN PHARMACEUTICAL–GRADE HEROIN AND OTHER OPIATES IN COORDINATION WITH THE FEDERAL GOVERNMENT, CONDUCTING AN INVENTORY OF AVAILABLE SOURCES OF PHARMACEUTICAL–GRADE HEROIN AND OTHER OPIATES AND CONTRACTING WITH THE BEST AVAILABLE SOURCE FOR THE RECEIPT OF THESE DRUGS REQUIRED FOR USE IN THE PROGRAM;

(9) DEVELOPING A BROAD–BASED EVALUATION OF THE PROGRAM THAT:

(I) MEASURES OUTCOMES FOR PROGRAM RECIPIENTS, INCLUDING:

1. RETENTION IN TREATMENT;

2. MORBIDITY AND MORTALITY;

3. CONTINUING OR NEW ILLICIT DRUG USE;

4. THE COST OF TREATMENT; AND

5. THE COMMISSION OF CRIMES AND OTHER SOCIETAL OUTCOMES;

(II) INCLUDES A COMPARISON TO OTHER TREATMENT METHODS AND INTERVENTIONS; AND

(III) ESTABLISHES PROCEDURES FOR DATA COLLECTION; AND

(10) ESTABLISHING A PLAN FOR THE STORAGE AND ADMINISTRATION OF PHARMACEUTICAL–GRADE HEROIN, HYDROMORPHONE, AND OTHER OPIATES PROVIDED UNDER THE PROGRAM.

8–1106.

(A) NOTWITHSTANDING ANY OTHER PROVISION OF STATE OR LOCAL LAW:

(1) A PROGRAM PROVIDER MAY PROVIDE POLY–MORPHONE–ASSISTED TREATMENT TO PROGRAM RECIPIENTS;

(2) A PROGRAM RECIPIENT MAY RECEIVE POLY–MORPHONE–ASSISTED TREATMENT FROM A PROGRAM PROVIDER;

(3) THE PROVISION OR RECEIPT OF POLY–MORPHONE–ASSISTED TREATMENT AUTHORIZED UNDER THE PROGRAM MAY NOT BE A BASIS FOR THE SEIZURE OR FORFEITURE OF ANY PRODUCTS, MATERIALS, EQUIPMENT, PROPERTY, OR ASSETS;

(4) A STATE OR LOCAL CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTY MAY NOT BE IMPOSED ON ANY PERSON PARTICIPATING IN THE PROGRAM BASED SOLELY ON THE PROVISION OR RECEIPT OF POLY–MORPHONE–ASSISTED TREATMENT PROVIDED UNDER THE PROGRAM;

(5) A PROGRAM PROVIDER MAY:

(I) COLLECT OR ATTEMPT TO COLLECT FEES FROM A PROGRAM RECIPIENT FOR POLY–MORPHONE–ASSISTED TREATMENT AND OTHER HEALTH CARE SERVICES; AND

(II) OBTAIN OR ATTEMPT TO OBTAIN REIMBURSEMENT FOR POLY–MORPHONE–ASSISTED TREATMENT AND OTHER HEALTH CARE SERVICES

PROVIDED TO A PROGRAM RECIPIENT FROM A HEALTH INSURANCE CARRIER THAT PROVIDES COVERAGE FOR SERVICES PROVIDED TO THE PROGRAM RECIPIENT;

(6) A PROGRAM RECIPIENT MAY REMIT PAYMENT FOR FEES CHARGED BY A PROGRAM PROVIDER FOR POLY–MORPHONE–ASSISTED TREATMENT AND OTHER HEALTH CARE SERVICES PROVIDED TO THE PROGRAM RECIPIENT; AND

(7) A HEALTH INSURANCE CARRIER THAT PROVIDES COVERAGE FOR SERVICES PROVIDED TO A PROGRAM RECIPIENT MAY REIMBURSE A PROGRAM PROVIDER FOR FEES CHARGED BY THE PROGRAM PROVIDER FOR POLY–MORPHONE–ASSISTED TREATMENT AND OTHER HEALTH CARE SERVICES PROVIDED TO THE PROGRAM RECIPIENT.

(B) A HEALTH CARE PRACTITIONER WHO PARTICIPATES IN THE PROGRAM MAY NOT BE SUBJECT TO ANY DISCIPLINARY ACTION UNDER THE HEALTH OCCUPATIONS ARTICLE SOLELY FOR THE ACT OF PROVIDING POLY–MORPHONE–ASSISTED TREATMENT THAT IS IN ACCORDANCE WITH PROTOCOLS AND GUIDELINES APPROVED BY THE ADVISORY BOARD UNDER § 8–1104 OF THIS SUBTITLE.

(C) A PROGRAM PROVIDER IS EXEMPT FROM ANY REQUIREMENTS ESTABLISHED UNDER TITLE 21, SUBTITLE 2A OF THIS ARTICLE WHEN PROVIDING POLY–MORPHONE–ASSISTED TREATMENT TO RECIPIENTS IN THE PROGRAM.

8–1107.

A PROGRAM PROVIDER MAY FUND THE COSTS OF PROVIDING POLY–MORPHONE–ASSISTED TREATMENT UNDER THE PROGRAM WITH:

(1) APPROPRIATIONS PROVIDED IN THE STATE BUDGET;

(2) REVENUE FROM FEES CHARGED FOR POLY–MORPHONE–ASSISTED TREATMENT AND OTHER HEALTH CARE SERVICES PROVIDED TO PROGRAM RECIPIENTS;

(3) GRANTS OR OTHER ASSISTANCE FROM FEDERAL, STATE, OR LOCAL GOVERNMENT; AND

(4) ANY OTHER MONEY MADE AVAILABLE TO THE PROGRAM PROVIDER FROM ANY PUBLIC OR PRIVATE SOURCE.

8–1108.

(A) (1) ON OR BEFORE NOVEMBER 30, 2018, AND ON OR BEFORE NOVEMBER 1 OF EACH SUBSEQUENT YEAR, A HEALTH CARE FACILITY THAT PARTICIPATES IN THE PROGRAM SHALL SUBMIT A REPORT ON THE STATUS OF IMPLEMENTING THE PROGRAM TO THE DEPARTMENT AND THE ADVISORY BOARD.

(2) THE REPORT REQUIRED ON OR BEFORE NOVEMBER 1, 2021, SHALL INCLUDE:

(I) AN ANALYSIS OF THE PROGRAM EVALUATION DATA;

(II) A DETERMINATION OF WHETHER THE PROGRAM DIRECTLY RESULTS IN:

1. HEALTH RISKS THAT OUTWEIGH THE BENEFITS TO PROGRAM RECIPIENTS; AND

2. SIGNIFICANT SAFETY CONSEQUENCES TO THE PUBLIC;

(III) AN ASSESSMENT OF THE NEED FOR POLY–MORPHONE–ASSISTED TREATMENT;

(IV) ANY RECOMMENDATIONS AND CONCLUSIONS CONCERNING THE DESIRABILITY OF TRANSITIONING THE PROGRAM INTO A PERMANENT POLY–MORPHONE–ASSISTED TREATMENT PROGRAM;

(V) AN EVALUATION OF THE NEED TO EXPAND THE PROGRAM TO INCLUDE ADDITIONAL LOCATIONS AND PARTICIPANTS;

(VI) A DETERMINATION OF WHETHER ANY MODIFICATIONS OR ADDITIONS TO THE GUIDELINES OR PROTOCOLS GOVERNING THE PROGRAM ARE NECESSARY TO TRANSITION THE PROGRAM TO A PERMANENT POLY–MORPHONE–ASSISTED TREATMENT PROGRAM; AND

(VII) A RECOMMENDATION AS TO WHETHER PROGRAM RECIPIENTS WHO HAVE BENEFITED FROM PARTICIPATION IN THE PROGRAM, AS MEDICALLY DETERMINED BY A PHYSICIAN, SHOULD HAVE COMPASSIONATE ACCESS TO POLY–MORPHONE–ASSISTED TREATMENT FOLLOWING THE CONCLUSION OF THE PROGRAM.

(B) ON OR BEFORE DECEMBER 30, 2018, AND ON OR BEFORE DECEMBER 1 OF EACH SUBSEQUENT YEAR, THE DEPARTMENT SHALL SUBMIT A COMPILATION OF THE REPORTS REQUIRED UNDER SUBSECTION (A)(1) OF THIS SECTION TO THE

GOVERNOR AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2016. It shall remain effective for a period of 5 years and 9 months and, at the end of June 30, 2022, with no further action required by the General Assembly, this Act shall be abrogated and of no further force and effect.