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Heroin Prescription, HIV, and Drug Policy: Emerging Regulatory Frameworks

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INTRODUCTION

Injection drug use has emerged as a critical concern of judicial and public health systems worldwide. Internationally, there are now an estimated sixteen million injection drug users (IDU) residing in every global hemisphere.¹ This population experiences a high degree of marginalization and disproportionately high levels of health and social harms compared with the general population.² Of greatest

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¹ UNITED NATIONS OFFICE ON DRUGS AND CRIME, WORLD DRUG REPORT 2011, at 30 (2011).

² See GLOBAL COMM'N ON DRUG POLICY, THE WAR ON DRUGS AND HIV/AIDS: HOW THE CRIMINALIZATION OF DRUG USE FUELS THE GLOBAL PANDEMIC 3 (June 2012) [hereinafter GLOBAL COMM'N ON DRUG POLICY, THE WAR ON DRUGS AND HIV/AIDS];

concern are heightened rates of mortality among IDU, which result primarily from epidemic levels of HIV infection and fatal overdose.

These twin epidemics of injection drug use and HIV have spurred the reevaluation of current illicit drug policies worldwide. Drug policy approaches have been remarkably consistent internationally since the latter half of the twentieth century, with almost every United Nations (UN) member state a party to the three UN Conventions related to drug use: the 1961 Single Convention, the 1972 Convention on Psychotropic Substances, and the 1988 Convention Against Illicit Trafficking.³ The result of this widespread adoption of prohibitive drug policies has been that, while the intensity of drug policies varies across countries,⁴ drug law enforcement is almost universally employed in an effort to reduce drug use and control drug-related harms.⁵

While drug law enforcement has been applied in an effort to reduce levels of drug use and the size of illicit drug markets, consensus is emerging that this approach has resulted in severe public health and social costs, including mass incarceration, the extreme social marginalization of drug users, and the rapid spread of HIV among IDU.⁶ The evidence also suggests that drug law enforcement has not achieved its primary goal: reduction of drug use or supply.⁷

Dan Werb et al., *Vienna Declaration: A Call For Evidence-Based Drug Policies*, 376 LANCET 310, 311 (2010).

³ United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, *opened for signature* Dec. 20, 1988, 1582 U.N.T.S. 164, 28 I.L.M. 493; Protocol Amending the Single Convention on Narcotic Drugs, 1961, *opened for signature* Mar. 25, 1972, 26 U.S.T. 1439, 976 U.N.T.S. 3; Convention on Psychotropic Substances, *opened for signature* Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175; Single Convention on Narcotic Drugs, *opened for signature* Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151.

⁴ Louisa Degenhardt et al., *Toward a Global View of Alcohol, Tobacco, Cannabis, and Cocaine Use: Findings From the WHO World Mental Health Surveys*, 5 PLOS MED. 1053, 1056 (2008).

⁵ INT'L NARCOTICS CONTROL BD, UNITED NATIONS, REPORT OF THE INTERNATIONAL NARCOTICS CONTROL BOARD FOR 2010, at 9–12 (2011).

⁶ See, e.g., Chris Beyrer et al., *Drug Use, Increasing Incarceration Rates, and Prison-Associated HIV Risks in Thailand*, 7 AIDS & BEHAV. 153, 159–60 (2003); Jennifer G. Clarke et al., *Active and Former Injection Drug Users Report of HIV Risk Behaviors During Periods of Incarceration*, 22 SUBSTANCE ABUSE 209, 209–10 (2001); Becky Pettit & Bruce Western, *Mass Imprisonment and the Life Course: Race and Class Inequality in U.S. Incarceration*, 69 AM. SOC. REV. 151, 164–65 (2004); Amy Rock Wohl et al., *High-Risk Behaviors During Incarceration in African-American Men Treated for HIV at Three Los Angeles Public Medical Centers*, 24 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 386, 387 (2000); Daniel Werb et al., *Effects of Police Confiscation of Illicit Drugs and Syringes Among Injection Drug Users in Vancouver*, 19 INT'L J DRUG POL'Y 332, 335–36

As such, this Article examines the scientific evidence on medical regulatory frameworks for illicit opioids and suggests an alternative drug policy that requires tolerating drug *use* to lessen the negative *results* of injection drug use, such as HIV epidemics related to the injection of illicit substances. Part I reviews the drug enforcement policies currently employed to reduce drug use and identifies some weaknesses of that approach. Part II describes an alternative drug policy through the specific example of heroin-assisted treatment for persons addicted to opioids. Part III proposes that the observed benefits of heroin-assisted treatment may translate more broadly to a new drug policy framework. By tolerating small amounts of drug use in heroin-assisted treatment and other clinically proven treatment options, policymakers can begin to combat ongoing morbidity and mortality arising from untreated drug dependence.

I

CURRENT DRUG ENFORCEMENT POLICIES

The current system of drug law enforcement aims to eliminate drug use by reducing the demand for and supply of illicit drugs. To that end, supply-side policies have become increasingly marked by drug interdiction and anti-trafficking strategies to eradicate the supply of illegal drugs in consumer markets such as North America and Europe.⁸ This has included the militarization and internationalization of counternarcotics efforts, particularly in export market zones such as Latin America, Afghanistan, and Southeast Asia.⁹

(2008); Pew Ctr. on the States, *One in 100: Behind bars in America 2008*, at 3–4 (2008), http://www.pewtrusts.org/our_work_report_detail.aspx?id=35900.

⁷ See Degenhardt, *supra* note 4, at 1061–65. See generally ARTHUR FRIES ET AL., INST. FOR DEF. ANALYSIS, IDA PAPER P-4332, THE PRICE AND PURITY OF ILLICIT DRUGS: 1981–2007 (2008).

⁸ EXEC. OFFICE OF THE PRESIDENT, BUDGET AND PERFORMANCE SUMMARY, FISCAL YEAR 2012, at 43–44 (Apr. 2011), available at http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/FY2012-Budget-and-Performance-Summary-April-2011.pdf.

⁹ See, e.g., CONNIE VEILLETTE, CONG. RESEARCH SERV., PLAN COLOMBIA: A PROGRESS REPORT 12 (2005) (Columbia); TOM KRAMER ET AL., TRANSNATIONAL INST., WITHDRAWAL SYMPTOMS IN THE GOLDEN TRIANGLE: A DRUGS MARKET IN DISARRAY 18–19 (Jan. 2009) (Southeast Asia); MINISTRY OF COUNTER NARCOTICS, NATIONAL DRUG CONTROL STRATEGY: AN UPDATED FIVE-YEAR STRATEGY FOR TACKLING THE ILLICIT DRUG PROBLEM 44 (2006) (Afg.); CORY MOLZAHN ET AL., TRANS-BORDER INST., SPECIAL REPORT, DRUG VIOLENCE IN MEXICO: DATA AND ANALYSIS THROUGH 2011, at 2 (2011) (Mexico); John Hellin, *Coca Eradication in the Andes: Lessons from Bolivia*, 12 CAPITALISM NATURE SOCIALISM 151–52 (2001) (Bolivia).

With respect to demand-side interventions, drug law enforcement is often expressed most intensely at the street level, particularly in urban centers within consumer markets.¹⁰ These interventions generally take the form of police crackdowns on open-air illicit drug markets,¹¹ with concomitant high levels of discretionary policing,¹² arrest and incarceration of drug users.¹³ Despite their aims, however, these policies have been largely unsuccessful at minimizing drug markets and drug use.¹⁴

As such, policymakers have begun to explore alternatives. In particular, the regulation of illicit drugs under a strict public health or medical system has been applied in a select number of settings, most notably in Western Europe.¹⁵ While these systems differ in application, evidence suggests that they may be effective in reducing certain-drug related harms.¹⁶

There is some evidence to suggest, however, that other—perhaps more serious—drug-related harms have emerged as a result of these policies. For example, approximately three million IDU are estimated

¹⁰ See, e.g., Ernest Drucker, *Population Impact of Mass Incarceration Under New York's Rockefeller Drug Laws: An Analysis of Life of Years Lost*, 79 J. URB. HEALTH 434, 441–43 (2002); Samuel R. Friedman et al., *Drug Arrests and Injection Drug Deterrence*, 101 AM. J. PUB. HEALTH 344, 344 (2011); Samuel R. Friedman et al., *Relationships of Deterrence and Law Enforcement to Drug-Related Harms Among Drug Injectors in US Metropolitan Areas*, 20 AIDS 93, 97 (2006).

¹¹ See, e.g., JOANNE CSETE & JONATHAN COHEN, HUMAN RIGHTS WATCH, *ABUSING THE USER: POLICE MISCONDUCT, HARM REDUCTION AND HIV/AIDS IN VANCOUVER* 10 (vol. 15, 2003); Lisa Maher & David Dixon, *The Cost of Crackdowns: Policing Cabramatta's Heroin Market*, 13 CURRENT ISSUES CRIM. JUST. 5, 5–6 (2001); Michael R. Smith, *Police-Led Crackdowns and Cleanups: An Evaluation of a Crime Control Initiative in Richmond, Virginia*, 47 CRIME & DELINQ. 60, 60–61 (2001); Evan Wood et al., *Displacement of Canada's Largest Public Illicit Drug Market in Response to a Police Crackdown*, 170 CANADIAN MED. ASS'N J. 1551, 1551 (2004); Richard S. Ehrlich, *Thailand's Drug War Leaves a Bloody Trail: Police Suspected in 'Extrajudicial Killings' of Dealers*, WASH. TIMES (Feb. 21, 2003), <http://www.washingtontimes.com/news/2003/feb/21/20030221-085615-5997r/>.

¹² Maher & Dixon, *supra* note 11, at 15–16; Werb, *supra* note 6, at 335–36.

¹³ Beyrer et al., *supra* note 6, at 158; Jonathan P. Caulkins & Sara Chandler, *Long-Run Trends in Incarceration of Drug Offenders in the United States*, 52 CRIME & DELINQ. 619, 619–20 (2006); Lisa D. Moore & Amy Elkavich, *Who's Using and Who's Doing Time: Incarceration, the War on Drugs, and Public Health*, 98 AM. J. PUB. HEALTH 782, 782 (2008).

¹⁴ See generally FRIES ET AL., *supra* note 7; Degenhardt et al., *supra* note 4, at 1054.

¹⁵ See EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION, *DRUG POLICY PROFILES: PORTUGAL* 23–24 (2011) (Port.).

¹⁶ GLENN GREENWALD, CATO INST., *DRUG DECRIMINALIZATION IN PORTUGAL: LESSONS FOR CREATING FAIR AND SUCCESSFUL DRUG POLICIES* 12–16 (2009).

to be infected with HIV globally;¹⁷ in the Russian Federation, with an estimated population of 1.8 million IDU, IDU make up 60% of all HIV cases.¹⁸ In other settings with large populations of IDU, such as China, 38.5% of all HIV-seropositive individuals are IDU, while in the United States, approximately 308 thousand of the 1.86 million American IDU are believed to be HIV-seropositive.¹⁹

Similarly, levels of fatal overdose among IDU populations are unacceptably high. The United Nations Office on Drugs and Crime estimates that globally between 99,000 and 253,000 individuals died of a drug overdose in 2010.²⁰ In the United States, overdose deaths related to heroin and cocaine use rose steadily in the 2000s, with approximately 4,500 cocaine-related and 3,000 heroin-related overdose deaths reported in 2008.²¹ Such evidence mandates that other metrics, besides supply and demand for illicit drugs, begin to guide our drug policy.

II

RESPONSES TO OPIOID DEPENDENCE

The increasing recognition of drug dependence as a chronic, treatable condition has led medical professionals to begin experimenting with medically-supervised illicit drug prescription as an alternative to prohibition-based drug policies. This Part, therefore, looks to medical regulation of opioid derivatives and physician-supervised rehabilitation programs as a model for successful drug policy.

A. Medical Regulation of Opioid Derivatives

Generally, substances are regulated for medical use if they demonstrate utility within a medical context but also exhibit potential harms. For instance, morphine is an opioid analgesic used widely in medical settings to relieve pain, and it has become an indispensable tool of medical practitioners, so much so that it has been placed on the

¹⁷ GLOBAL COMM'N ON DRUG POLICY, THE WAR ON DRUGS AND HIV/AIDS, *supra* note 2, at 4.

¹⁸ Chris Beyrer et al., *Time to Act: A Call for Comprehensive Responses to HIV in People Who Use Drugs*, 376 LANCET 551, 554, 560 (2010).

¹⁹ *Id.* at 560.

²⁰ UNITED NATIONS OFFICE ON DRUGS AND CRIME, WORLD DRUG REPORT 2012, at 17. (2012).

²¹ *Id.* at 82.

World Health Organization's List of Essential Medicines.²² However, morphine also exhibits highly addictive properties, and its use is thus highly restricted within medical contexts such as palliative care, surgical recovery, or chronic pain management.²³

Striking a balance between medical use and potential harms through regulation is replicated across the spectrum of available pharmacotherapies. As a result, the regulation of pharmacotherapies evolved considerably over the twentieth century.

Diacetylmorphine, commonly known as heroin, was originally developed in the nineteenth century and later used as a morphine substitute and cough suppressant.²⁴ Originally prescribed and distributed widely, its potent addictive properties and potential harms resulted in a rapid restriction of its application,²⁵ until it was formally prohibited in the United States in 1924.²⁶ Since that time, controlling the illicit use and supply of heroin has been a central concern of drug policies,²⁷ and the development of clinical treatment modalities for drug dependence has focused specifically on heroin dependence.

B. Current Clinical Treatments for Opioid Addiction

Currently, methadone, along with buprenorphine, represents the most widely recommended clinical therapy for opioid dependence.²⁸ Methadone is used in the context of maintenance therapy, in which individuals who are heroin-dependent transition to controlled, sustained methadone use, prescribed within a clinical context. This is done in recognition of opioid dependence as a chronic, recurring

²² WORLD HEALTH ORG., ESSENTIAL MEDICINES: WHO MODEL LIST 1-2 (13th ed. 2003).

²³ See K. Suresh Kumar et al., *Intravenous Morphine for Emergency Treatment of Cancer Pain*, 14 PALLIATIVE MED. 183, 184 (2000); Cecilia Sepúlveda et al., *Palliative Care: The World Health Organization's Global Perspective*, 24 J. PAIN & SYMPTOM MGMT 91, 91, 93 (2002).

²⁴ Walter Sneader, Dep't of Med. History, *The Discovery of Heroin*, 352 LANCET 1697, 1697-98 (1998).

²⁵ See generally Jana Sawynok, *The Therapeutic Use of Heroin: A Review of the Pharmacological Literature*, 64 CANADIAN J. PHYSIOLOGY & PHARMACOLOGY 1 (1986).

²⁶ R. Hale-White, *Ban on Heroin*, 1 BRITISH MED. J. 232, 232 (1956).

²⁷ Protocol amending the Single Convention on Narcotic Drugs, 1961, *supra* note 3; Single Convention on Narcotic Drugs, *supra* note 3.

²⁸ WHO/UNODC/UNAIDS POSITION PAPER: SUBSTITUTION MAINTENANCE THERAPY IN THE MANAGEMENT OF OPIOID DEPENDENCE AND HIV/AIDS PREVENTION 13 (2004) (Fr.).

disease.²⁹ However, methadone does not decrease an individual's physical dependence on opioids, and the goal of methadone maintenance therapy (MMT) is to stabilize an opioid user's life while reducing their potential involvement in risky drug-related behaviors.³⁰ Evidence from randomized controlled trials comparing MMT to no opioid replacement therapy suggests that use of methadone within a maintenance treatment regime significantly increases the likelihood that a heroin-dependent individual will eventually abstain from illicit heroin use.³¹ However, this approach to treating drug dependence appears limited in reducing criminality or mortality.

But the MMT approach has its limitations. In particular, use of MMT has been associated with periods (or cycles) of abstinence and relapse.³² Indeed, research suggests that those heroin users who achieve full abstinence are in the minority, despite enrollment in MMT,³³ though it has also been shown that heroin users who experience multiple, recurrent MMT treatment episodes are more likely to stay in treatment for longer episodes.³⁴ While MMT remains a first-line, clinically-proven treatment option for drug-dependent individuals, this approach has limited effectiveness at the community level. As such, complementary treatment options are needed to meaningfully reduce the incidence of drug dependence, injection drug use, and HIV transmission resulting from this behavior.

C. Heroin Prescription

The limitations of substitution maintenance therapy for opioid dependence have led to experimentation with other potential approaches to reducing ongoing illicit opioid use. In particular, it has been increasingly recognized that, while heroin is highly addictive,

²⁹ A. Thomas McLellan et al., *Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation*, 284 J. AM. MED. ASS'N 1689, 1689–90 (2000).

³⁰ RICHARD P. MATTICK ET AL., THE COCKRANE COLLABORATION, METHADONE MAINTENANCE THERAPY VERSUS NO OPIOID REPLACEMENT THERAPY FOR OPIOID DEPENDENCE 5 (2009).

³¹ *Id.* at 10.

³² Bohdan Nosyk et al., *Proportional Hazards Frailty Models for Recurrent Methadone Maintenance Treatment*, 170 AM. J. EPIDEMIOLOGY 783, 783 (2009).

³³ See Anja Dobler-Mikola et al., *Patterns of Heroin, Cocaine, and Alcohol Abuse During Long-Term Methadone Maintenance Treatment*, 29 J. SUBSTANCE ABUSE TREATMENT 259, 262 (2005).

³⁴ Nosyk et al., *supra* note 32, at 787.

many of the heroin-related harms that policymakers and clinicians have attempted to reduce—HIV transmission via the sharing of contaminated needles, fatal overdose, and involvement in acquisitive crime—are related to the context in which heroin use occurs, rather than with the use of heroin itself.³⁵ Coupled with ongoing resistance to MMT among heroin-dependent individuals and suboptimal treatment outcomes and retention in maintenance therapies, researchers and policymakers have explored the development of heroin-based treatments for opioid dependence.

1. Administration of Heroin-Assisted Treatment (HAT)

Medically-prescribed heroin-assisted treatment (HAT) is based around the provision of heroin to MMT-experienced individuals who are dependent on opioids. In randomized controlled trials (RCTs) of HAT and in settings where this therapy is prescribed, it is provided under strict medical supervision. Specifically, heroin-assisted treatment involves the prescription of a regulated dosage of heroin (e.g., diacetylmorphine) that is self-administered by those undergoing therapy under the strict supervision of medical staff in a controlled, sterile environment. In all settings in which HAT has been evaluated or implemented, the dosage of heroin is provided as an injectable substance, with one exception: clinicians in the Netherlands are given the option of prescribing diacetylmorphine base for inhalation rather than injection).

Similarly to MMT, HAT is often described as a harm reduction intervention insofar as ongoing drug use is tolerated among clients and there is generally no requirement that individuals cease using drugs. However, HAT does aim to keep opioid-dependent users in treatment, particularly those who have failed in other treatment modalities such as MMT. For this reason, HAT is a second-line treatment option available only to opiate-dependent individuals who have failed conventional substitution treatment (e.g. MMT or buprenorphine maintenance treatment).³⁶

³⁵ See DANIEL WOLFE & KASIA MALINOWSKA-SEMPRUCH, OPEN SOC'Y INST., *ILLCIT DRUG POLICIES AND THE GLOBAL HIV EPIDEMIC: EFFECTS OF UN AND NATIONAL GOVERNMENT APPROACHES 2–3* (2004); Tim Rhodes, *The 'Risk Environment': A Framework for Understanding and Reducing Drug-Related Harm*, 13 INT'L J. DRUG POL'Y 85, 88–89 (2002).

³⁶ JOHN STRANG ET AL., EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION, *NEW HEROIN-ASSISTED TREATMENT: RECENT EVIDENCE AND CURRENT PRACTICES OF SUPERVISED INJECTABLE HEROIN TREATMENT IN EUROPE AND BEYOND 11* (2012) (Lux.).

Additionally, much like other pharmacotherapies designed to treat drug dependence, HAT aims to improve health and social outcomes among drug-dependent individuals. These outcomes include a reduction in HIV risk behaviors (e.g., used syringe sharing), improved physical and mental health, reductions in or abstinence from non-prescribed drug use, reduced criminal recidivism, and improved psychosocial adjustment.³⁷ At present, HAT is provided or being evaluated in six different countries, including Switzerland,³⁸ the Netherlands,³⁹ Germany,⁴⁰ the United Kingdom,⁴¹ Spain,⁴² and Canada.⁴³ HAT is a relatively new or emerging treatment option in all of these settings, though non-supervised prescription heroin has been available to treat opioid addiction in the United Kingdom since the 1920s.⁴⁴

2. Results of HAT

A systematic review of HAT published in 2011, restricted to randomized controlled trials, identified a positive direction of effect in favor of HAT.⁴⁵ The review identified eight studies comparing participants enrolled in HAT with participants enrolled in other

³⁷ See Benedikt Fischer et al., *Heroin-Assisted Treatment (HAT) a Decade Later: A Brief Update on Science and Politics*, 84 J. URB. HEALTH 552, 554–56 (2007).

³⁸ See, e.g., Thomas V. Perneger et al., *Randomised Trial of Heroin Maintenance Programme for Addicts Who Fail in Conventional Drug Treatments*, 317 BRIT. MED. J. 13 (1998).

³⁹ See, e.g., Wim van den Brink et al., *Medical Prescription of Heroin to Treatment Resistant Heroin Addicts: Two Randomised Controlled Trials*, 327 BRIT. MED. J. 310 (2003).

⁴⁰ See, e.g., Franziska Güttinger et al., *Evaluating Long-Term Effects of Heroin-Assisted Treatment: The Results of a 6-Year Follow-Up*, 9 EUR. ADDICTION RES. 73 (2003).

⁴¹ See, e.g., 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*, 375 LANCET 1885 (2010).

⁴² See, e.g., Eugenia Oviedo-Joekes et al., *The Andalusian Trial on Heroin-Assisted Treatment: A 2 Year Follow-Up*, 29 DRUG AND ALCOHOL REVOCABLE TRUST. 75 (2010).

⁴³ See, e.g., Eugenia Oviedo-Joekes et al., *Scientific and Political Challenges in North America's First Randomized Controlled Trial of Heroin-Assisted Treatment for Severe Heroin Addiction: Rationale and Design of the NAOMI Study*, 6 CLINICAL TRIALS 261 (2009).

⁴⁴ Scientific evaluations of this approach in the United Kingdom have only recently been undertaken. Nicky Metrebian & Gerry V. Stimson, *Heroin Prescribing in the UK: Lost Opportunities for Research*, 8 ADDICTION RES. 305, 305–07 (2000).

⁴⁵ *Id.* at 308.

maintenance pharmacotherapies such as MMT and buprenorphine maintenance treatment.⁴⁶ All participants were adults who had previously failed conventional therapy.⁴⁷ Six studies found that a combination of oral methadone and HAT was more effective than oral methadone on its own in reducing illicit drug use.⁴⁸ Additionally, studies included in the review also suggested that HAT has a positive impact in reducing levels of criminality and incarceration.⁴⁹

However, the authors identified a significantly higher risk associated with adverse events related to study medication among those enrolled in HAT.⁵⁰ The authors therefore conclude that HAT is an effective pharmacotherapy for treatment-experienced drug users that should be provided under medical supervision.⁵¹

A number of observational studies of the effectiveness of HAT have also yielded important findings. A recent review undertaken by the European Monitoring Centre for Drugs and Drug Addiction noted that the majority of studies found that patients enrolled in HAT reported abstinence from illicit heroin use, though a more common outcome was a reduction in the use of illicit heroin.⁵² Additionally, the review found that while retention in treatment varied across studies in different settings, there was a marked reduction in criminal recidivism across HAT-enrolled participants, particularly when compared with participants enrolled in conventional therapy.⁵³ Longer-term studies on HAT effectiveness, some of which provide up to six years of data, have reported patient retention rates in HAT of up to 55% after two years⁵⁴ and 45.8% at six years,⁵⁵ which compare favorably to retention rates among patients enrolled in MMT.

Finally, those studies that provided cost estimates have consistently demonstrated that the direct costs of HAT exceed those of comparable pharmacotherapies such as MMT. Indeed, the cost of HAT provision in the Netherlands is estimated at €20,400, compared to a cost of

⁴⁶ MARICA FERRI ET AL., THE COCHRANE COLLABORATION, HEROIN MAINTENANCE FOR CHRONIC HEROIN-DEPENDENT INDIVIDUALS 14–15 (2012).

⁴⁷ *Id.* at 3.

⁴⁸ *Id.* at 6, 13–14.

⁴⁹ *Id.* at 13.

⁵⁰ *Id.* at 15.

⁵¹ *Id.*

⁵² See STRANG ET AL., *supra* note 36, at 12.

⁵³ *Id.* at 12.

⁵⁴ Uwe Verthein et al., *Long-Term Effects of Heroin-Assisted Treatment in Germany*, 103 ADDICTION 960, 962 (2008).

⁵⁵ Güttinger et al., *supra* note 40, at 78.

€1,600 associated with the provision of MMT.⁵⁶ Similarly, the cost of HAT in Germany was estimated at €19,000 compared to €3,500 for MMT provision.⁵⁷ These substantially higher costs are the result of greater staffing requirements related to the increased potential for adverse events associated with HAT. While such costs present a challenge, experts have noted that they are likely offset by the indirect cost savings from reduced incidence of HIV infection, arrest, and incarceration among drug users related to HAT's increased effectiveness compared with other treatment options.⁵⁸

III POLICY IMPLICATIONS

These results have wide implications for the development of comprehensive approaches to reducing drug-related harms in a variety of settings. While still a source of controversy,⁵⁹ the results of two decades of research on HAT demonstrate that it is effective as a second-line treatment option for opioid-dependent individuals for whom conventional treatment has failed.⁶⁰ Despite its higher cost relative to other standard maintenance therapies, HAT has been found to be cost-effective, primarily as a result of its increased impact on reducing recidivism.⁶¹

Policymakers have been increasingly concerned with the lack of effectiveness of drug law enforcement in reducing levels of drug use and drug-related harms.⁶² Indeed, recent research suggests that conventional drug law enforcement approaches likely exacerbate a wide range of drug-related harms, including HIV transmission, mortality, and drug market violence.⁶³ As a result, certain regions—

⁵⁶ STRANG ET AL., *supra* note 36, at 13.

⁵⁷ *Id.*

⁵⁸ *Id.* at 13–14.

⁵⁹ See Meldon Kahan et al., *Why we object to NAOMI: Heroin Maintenance in Canada*, 52 CANADIAN FAMILY PHYSICIAN 705, 705–06 (2006).

⁶⁰ FERRI ET AL., *supra* note 46, at 2–3; STRANG ET AL., *supra* note 36, at 28–29.

⁶¹ See A. UCHTENHAGEN ET AL., PRESCRIPTION OF NARCOTICS FOR HEROIN ADDICTS: MAIN RESULTS OF THE SWISS NATIONAL COHORT STUDY 63–69 (1999) (Switz).

⁶² See Degenhardt et al., *supra* note 4, at 1061–65.

⁶³ GLOBAL COMM'N ON DRUG POLICY, THE WAR ON DRUGS AND HIV/AIDS, *supra* note 2, at 2; GLOBAL COMM'N ON DRUG POLICY, WAR ON DRUGS: REPORT OF THE GLOBAL COMMISSION ON DRUG POLICY 2 (2011); Dan Werb et al., *Effect of Drug Law Enforcement on Drug Market Violence: A Systematic Review*, 22 INT'L J. DRUG POL'Y 87, 87–88 (2011).

most notably Western Europe, Latin America, and certain states in the United States—have begun to experiment with novel approaches to drug policy.⁶⁴ Within this policy framework, the focus has increasingly shifted from policies aimed at reducing drug use toward policies for managing drug-related harms, most notably the risk of HIV transmission experienced by IDU.⁶⁵ At this stage, consensus regarding the necessary steps toward evidence-based policy in this area has been reached among experts,⁶⁶ and is reflected in current guidelines from relevant UN agencies.⁶⁷ These guidelines focus on the provision of a comprehensive suite of interventions for the reduction of HIV and other drug-related harms, including the provision of opioid substitution therapy and related addiction treatment therapies. In this context, and given its proven effectiveness, HAT should be considered alongside this suite of interventions by policymakers in settings experiencing severe drug-related harms.

It is encouraging in this regard that a number of countries, including Switzerland, the Netherlands, Denmark, Germany, and the United Kingdom, provide HAT as part of a comprehensive public health-oriented drug policy approach. Unfortunately, while trials have been completed most recently in Canada and Spain,⁶⁸ the implementation of HAT within a policy framework has yet to materialize in these settings, while in Australia, political interference forced the early demise of a HAT study.⁶⁹ These experiences exemplify the opposition to HAT, and to harm reduction more broadly, that continues to exist in many settings marked by high levels of drug-related harm, most notably the United States and Russia. Policymakers in Russia have banned methadone and

⁶⁴ GREENWALD, *supra* note 16, at 1–2; *Illegal Drugs: The Great Experiment: At Last, Drug Prohibition is Being Challenged by Fresh Thinking*, ECONOMIST (Feb. 23, 2013), <http://www.economist.com/news/leaders/21572197-last-drug-prohibition-being-challenged-fresh-thinking-great-experiment>.

⁶⁵ See generally Beyrer et al., *supra* note 18, at 551–53.

⁶⁶ Wood et al., *supra* note 2, at 310–12.

⁶⁷ See generally MARTIN C. DONOGHOE ET AL., WORLD HEALTH ORG., WHO, UNODC, UNAIDS TECHNICAL GUIDE FOR COUNTRIES TO SET TARGETS FOR UNIVERSAL ACCESS TO HIV PREVENTION, TREATMENT AND CARE FOR INJECTING DRUG USERS (2009).

⁶⁸ See generally Oviedo-Joekes et al., *supra* note 42 (Spain); Oviedo-Joekes et al., *supra* note 43 (Canada).

⁶⁹ Alex D. Wodak, *Public Health and Politics: The Demise of the ACT Heroin Trial*, 167 MED. J. AUSTL. 348, 348–49 (1997).

buprenorphine, despite the fact that these are both on the World Health Organization's List of Essential Medicines.⁷⁰

While the U.S. government has supported the provision of MMT, it is unlikely, given congressional opposition to even basic harm reduction services,⁷¹ that the suite of interventions supported by the federal government will be expanded to include HAT. This is unfortunate, given the high prevalence of HIV among American IDU populations, and the failure of current policy approaches in reducing the incidence of injecting among this marginalized group.

CONCLUSION

Two decades of research demonstrates the effectiveness of HAT as a secondary treatment option for opioid-dependent individuals who have failed in conventional pharmacotherapies such as MMT. Indeed, scientific studies from a range of countries, including longitudinal studies of up to six years, have demonstrated the utility of HAT in achieving a wide range of positive outcomes among clients. Such achievements include reductions in HIV risk behaviors and illicit drug use, reduced criminal recidivism, and improved mental and physical health.⁷² The direct costs of HAT are greater than those associated with other treatment options. However, it is likely that these costs are offset by indirect savings related to reductions in HIV transmission or the arrest and incarceration of highly dependent individuals that likely stem from the provision of HAT.

As such, experts have called for the expanded provision of this clinical treatment option to support a comprehensive set of interventions, most notably MMT, to reduce drug-related harms.⁷³ Despite controversy regarding the provision of harm reduction interventions, policymakers should act urgently to provide HAT and other clinically- proven treatment options to avert ongoing morbidity and mortality arising from untreated drug dependence.⁷⁴

⁷⁰ Bertrand Audoin & Chris Beyrer, *Russia's Retrograde Stand on Drug Abuse*, N.Y. TIMES (Mar. 2, 2012), http://www.nytimes.com/2012/03/03/opinion/russias-retrograde-stand-on-drug-abuse.html?pagewanted=all&_r=1&.

⁷¹ Pete Kasperowicz, *DC Delegate: Congress has 'Killed' with Needle Exchange Prohibition*, THE HILL (Apr. 5, 2011), <http://thehill.com/blogs/floor-action/house/154047-holmes-norton-says-congress-has-killed-dc-residents-with-needle-exchange-policy>.

⁷² FERRI ET AL., *supra* note 46, at 1–2; Fischer et al., *supra* note 37, at 554–56.

⁷³ STRANG ET AL., *supra* note 36, at 162–64.

⁷⁴ Louisa Degenhardt et al., *Mortality Among Regular or Dependent Users of Heroin and Other Opioids: A Systematic Review and Meta-Analysis of Cohort Studies*, 106

ADDICTION 32, 47–48 (2011); Bradley M. Mathers et al., *Global Epidemiology of Injecting Drug Use and HIV Among People Who Inject Drugs: A Systematic Review*, 372 LANCET 1733, 1733 (2008).