

A WHITE PAPER
(DRAFT)

**A NEW OPPORTUNITY TO EXPAND TREATMENT
FOR HEROIN USERS IN NEW YORK CITY:
PUBLIC POLICY CHALLENGES FOR BRINGING
BUPRENORPHINE INTO DRUG TREATMENT
PROGRAMS AND GENERAL MEDICAL PRACTICE**

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January 18, 2003

Submitted to:
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This White Paper was commissioned by New York City Department of Health and Mental Hygiene.

The authors rely heavily upon a review of the scientific literature on buprenorphine, as well as upon findings from several prior research project supported by the National Institute on Drug Abuse (NIDA) (5 T32 DA07233-19, 5R01 DA09339-03, 1R01 DA05126-08; R03 DA06413-01; 5 R01 DA09056-08; R01 DA13690-01; R01 DA10188; 5R01 DA06959; 1KD1 TI 12018; KD1 TI12049; R01 DA09920; P30 DA11041; R01 DA13551), the Arrestee Drug Abuse Monitoring program (OJP-98C-003;OJP-2001-C-003), the National Institute of Justice (95-IJ-CX0028; 99-IJ-CX0020; 98-IJ-CX-K012; 2000-7353-NY-IJ) and by National Development and Research Institutes. The opinions expressed in this report do not represent the official position of the U.S. Government, National Institute on Drug Abuse, National Institute of Justice, New York City Department of Health and Mental Hygiene, or National Development and Research Institutes, Inc. (NDRI).

The authors gratefully acknowledge the insights and contributions of reviewers of this manuscript: Herman Joseph, and W. Rees Davis.

ABSTRACT

New York City has historically had the largest number of heroin addicts in the U.S. In October 2002, the Food and Drug Administration (FDA) approved the medication buprenorphine (trade names Subutex and Suboxone) for the treatment of opiate dependence in primary care settings. Buprenorphine is a medication similar to methadone for treatment of heroin addiction and opiate prescription drug abuse. The FDA approval imposes relatively few restrictions on buprenorphine with the intent to make opiate treatment more widely available and acceptable to persons suffering from drug addiction. These buprenorphine medications are formulated, packaged, and will be prescribed so as to reduce the likelihood of abuse.

This White Paper identifies several important Policy Challenges that will be relevant to the successful integration of buprenorphine treatment for opiate dependence into general medical practice in New York City.

The history, epidemiology, and treatment for heroin dependency in the City are reviewed. The evidence suggests that about 40,000 persons are currently in heroin treatment, but an additional quarter of a million persons probably use heroin in a typical 30 day period—the vast majority sniff heroin or consume moderate amounts. Untreated heroin addiction is associated with very high rates of morbidity, mortality, polydrug use, crime, and other consequences. A proposed policy goal of having 100,000 heroin users receiving buprenorphine or methadone treatment by 2010 is achievable. Public policy should be designed to support the rapid diffusion of buprenorphine treatment by:

Training: Several thousand physicians will need to complete one-day training sessions offered by professional organizations to certify them as buprenorphine prescribers.

Financing: Medicaid and private insurance should include reimbursement rates for buprenorphine treatment following the same processes as other prescribed medications.

General Medical Practice: Health care providers and physicians in a variety of public and private settings (private practice, group practices, community health centers, hospitals, and specialty clinics [HIV/AIDS, TB, STD]) should be supported to include the assessment of opiate dependency and management (with buprenorphine) in their practice. Based on 40 years of experience with heroin addicts, the City's methadone programs and Addiction Medicine Unit at Rikers Island (city jail) should have major roles in assessment of addiction, intake, stabilization of heroin users on buprenorphine, and then refer them to other medical settings for ongoing medication management.

Integration: Since heroin users have multiple problems (crack and alcohol addictions, mental disorders, criminality, etc.), tend to initiate and then terminate treatment, and relapse to heroin use, New York City needs to maintain rapid cross referrals and information about heroin users in methadone and buprenorphine treatment. A database (with appropriate privacy safeguards) can monitor buprenorphine trends and expedite treatment admissions and referrals to other providers (e.g., psychiatrists, pain specialists) or alternative treatments (e.g., methadone maintenance).

Recruitment: Thousands of treatment-avoiding heroin users will need to be identified, attracted to or mandated by the criminal justice system to enter and remain in buprenorphine treatment.

Regulation: In order to promote the diffusion and acceptability of buprenorphine treatment, state and municipal regulations should be kept to a minimum; well-thought out federal regulations have already been established.

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EXECUTIVE SUMMARY

Following 20 years of clinical studies and extensive consultation with multiple constituencies, the Food and Drug Administration (FDA) approved in October 2002, an opiate-medication, buprenorphine, for the treatment of heroin and opiate addiction. The Drug Enforcement Administration classified buprenorphine as a Schedule III drug—meaning that it can be prescribed by general practitioners and dispensed via pharmacies like most other prescription drugs.

This White Paper is commissioned by the Division of Mental Hygiene Services of the New York City Department of Health and Mental Hygiene (DOHMH). This report primarily focuses on the five boroughs of this city. *This White Paper is primarily intended as a policy document* and addresses several policy challenges that will have to be confronted during the introduction of buprenorphine into the treatment system for heroin addiction. This White Paper does not provide treatment protocols—as they already exist—nor does it address the many issues that physicians and specialists will encounter when treating individual patients. Citations to the appropriate scientific literature are provided in the full report, but not in this Executive Summary.

This White Paper has two primary purposes: To provide key findings and information about heroin addiction, pharmacological treatments, and the planned introduction of buprenorphine in both its mono form (Subutex) and in its combined form (Suboxone; buprenorphine plus naloxone). In addition, this White Paper provides several Policy Challenges that a variety of policy makers and constituencies need to address and which will likely impact upon the long-term effectiveness of buprenorphine as an important adjunct to the treatment of heroin addiction. The following general policy goal is proposed.

POLICY GOAL: Buprenorphine therapy should be integrated into medical and clinical practice so that 100,000 or more active heroin users are routinely receiving some form of treatment in New York City by 2010 (more than double the number in treatment in 2002).

Five major Policy Challenges are briefly described; the remainder of the report elaborates on these.

Policy Challenge 1: A large number of medical doctors, pharmacists, and their support staff will need to be trained in buprenorphine treatment protocols.

Policy Challenge 2: Given the potential cost savings, buprenorphine therapy should be adequately funded by the government (mainly via Medicaid) as well as by private insurers.

Policy Challenge 3: Buprenorphine treatment should be seamlessly integrated into regular medical practice and routine operations of publicly funded clinics/programs and of private medical practitioners; strong interconnections between buprenorphine prescribers in the private and public sectors need to be developed.

Policy Challenge 4: Buprenorphine therapy should be made attractive and easily available to heroin users seeking treatment and/or referred by the criminal justice system.

Policy Challenge 5: Legislators and regulatory agencies should limit restrictions and regulations upon physician and treatment providers of buprenorphine.

SECTION I. THE HISTORICAL BACKGROUND

Brief history of heroin use/treatment in New York City. The history of heroin use and its treatment is intimately linked to this city. Among the first documented heroin users (in 1900-1910) were those in New York City. The number of heroin users in the city was so high that the New York City Department of Health Narcotics Clinic at Worth Street provided heroin and morphine doses to about 7,500 opiate addicts in 1919-20, but these clinics were closed by the U.S. government. Between 1921-1960, almost no treatment for heroin addiction was available in the City. In the 1950s and 1960s, major expansion of illicit supplies of heroin occurred; sizable proportions of young minority males in the city's growing low income neighborhoods became heroin sniffers and injectors, leading to an explosion of heroin addicts in the 1955-74 period. Most addicts primarily consumed their heroin via hypodermic needles ("mainlining" or "injecting"), often sharing their injection equipment

and heroin. This Heroin Generation continues to have the highest proportion of heroin users and injectors in the 2000s. Under Governor Nelson Rockefeller (1962-70), major expansions of drug treatment occurred. State-run facilities, residential Therapeutic Communities, and drug-free ambulatory programs were developed in the 1960s; most continue to the current time.

In the 1960s, two New York City physicians, Drs. Vincent Dole and Marie Nyswander demonstrated the efficacy of a synthetic opiate, *methadone*, for the treatment of heroin addiction; prior to that time there was no effective treatment for this disorder. When stabilized on daily maintenance doses of methadone, a very sizable proportion of heroin users began to devote their time to involvement in conventional social roles of work, family, and community. The number of methadone patients in New York City grew from about 200 in 1960 to nearly 30,000 in 1974. The City has about 38,000 methadone slots in 2002. Several subsequent evaluations have continued to demonstrate that methadone maintenance has among the best outcomes for heroin users due to higher retention rates.

Description of Buprenorphine (Subutex, Suboxone). Buprenorphine is a partial opioid agonist and has long been approved as a pain medication. It suppresses the craving and withdrawal symptoms associated with heroin use; it also blocks the euphoric effects of subsequent heroin use.

Buprenorphine is believed to have a lower probability of abuse or severity of physical dependence than most other opiate medications. More recent studies have identified optimal dosing schedules and demonstrated its efficacy and acceptability among heroin users as a treatment for their opiate dependence.

In October 2002, the U.S. Food and Drug Administration (FDA) approved two buprenorphine medications, tablets given the trade names *Subutex* and *Suboxone*, as a treatment for adults addicted to heroin and other opioid drugs such as oxycodone, morphine, and other narcotic painkillers.

Subutex is buprenorphine in its mono form. *Suboxone* tablets contain buprenorphine plus naloxone (an opiate antagonist intended to prevent injection and abuse of buprenorphine). Both forms of

buprenorphine are manufactured in tablet form so as to be taken sublingually (placed under the tongue until it dissolves) on a daily or alternate day basis. Several restrictions (participate in one-day training program, limits on number of patients, DEA registration) must be followed by physician prescribers. The physician will primarily write a prescription for Suboxone, which can be dispensed at pharmacies in a similar fashion to other prescription medications. Suboxone and Subutex have great potential as a treatment for opiate dependence because these two buprenorphine medications are not subject to the greater regulatory burden of Schedule II medications (such as methadone and LAAM) for treating heroin addiction. Numerous primary care physicians may substantially increase the screening and treatment of opiate addiction in the United States—especially in communities such as New York City where the prevalence of opiate addiction is very high. Published studies have generally shown that buprenorphine has comparable results to moderate dose methadone therapy for patients enrolling in opiate agonist therapy. The implementation of buprenorphine treatment with heroin users may provide difficult but workable problems for clinic or office-based physicians.

SECTION II. EPIDEMIOLOGY OF HEROIN USE AND HEROIN USERS

Heroin use and addiction have been defined as a major social problem in New York and American society for over 100 years.

Estimates of Heroin Users: Thousands of New Yorkers are addicted to heroin. No other city in North America (and possibly the world) has as many heroin users and injectors. Most addicts are home grown and were raised in the City's low-income neighborhoods. The best estimates project that around 200,000 persons are near daily or daily heroin users in New York City. A smaller number—probably about 50,000 persons—are likely to consume heroin on an occasional basis.

These estimates have remained relatively steady across the 1990s and into the 2000s. Yet three major and important shifts in heroin use patterns among opiate users have been documented among arrestees.

Decline in Heroin Injection: The proportion of heroin users who are injectors (use syringe and needles to inject heroin into a vein) has shown a steady decline from about two-thirds in 1990 to about a third in 2001. Among arrestees, heroin injectors consume on more days per month and use more bags per day of use compared to those who sniff, but do not inject, heroin. Across a month, heroin injectors consume about twice as much as heroin sniffers. Over 80 percent of the arrested heroin users are either sniffing heroin (regardless of regularity) or injecting it on a less than a daily basis—*so the vast majority probably have moderate heroin dependencies that can be successfully addressed via buprenorphine therapy.*

Generational Drug Preferences: Second, major generational shifts regarding heroin use and injection is evident, especially among the City's large pool of poor persons living in impoverished neighborhoods and who tend to sustain arrest. Inner-city youths born 1945-54 (who reached adulthood 1965-74 and are reaching their 50s in the 2000s) have been identified as the **Heroin Injection Generation**. Arrestees born 1955-69 (who are in their 30s and 40s in 2002), labeled the **Crack Generation**, became heavily involved with crack smoking, but smaller proportions are current heroin users and tend to avoid injection. Arrestees born 1970 and later (mainly in their teens and 20s in 2002), labeled the **Marijuana/blunt Generation**, have systematically avoided heroin use, especially via injection, and crack smoking. Their preferred drug is a **blunt** (marijuana smoked in the exterior wrap of a low cost cigar). Very few (about 5% among arrestees) young adults born after 1970 are using heroin, and even fewer are injecting it. *Ethnic Differences in Heroin Use and Injection:* Third, ethnic differences in heroin use and injection are important across generations. The avoidance of heroin use and injection is most pronounced among inner-city black and African-American youths born after 1970. Although proportionately few whites are arrested in the City, white arrestees have the highest proportion of heroin users and injectors among the three major ethnic groups. Moreover, many white heroin users reside outside of Manhattan or the five boroughs, but come to Manhattan to purchase heroin in the city's street drug markets.

Several issues will influence whether buprenorphine therapy will be relatively more successful among the subgroups of heroin users. Heroin sniffers who have recently or intermittently use heroin may be among the least likely to seek treatment, but they may be receptive to participate in buprenorphine therapy. Some ethnographers and medical personnel report having contacts with several middle and working class heroin users who have steady legal employment and private insurance. Such young adult heroin users could greatly decrease the length of their addiction careers via buprenorphine therapy. *Although criminally active heroin users are the most difficult to engage and retain in treatment, they are precisely those that the larger society and criminal justice system has the greatest interest in treating.* Former heroin users/methadone patients also relapse. Buprenorphine therapy offers these groups an important alternative to their current behavior pattern—of using heroin and avoiding treatment. Overall, virtually all heroin users should be considered for buprenorphine treatment—regardless of the route of administration (sniffed or injected), severity of use (days/month, bags per day), or criminality (none to severe).

SECTION III. TRAINING, FINANCING, AND SYSTEM INTEGRATION

To provide buprenorphine treatment to 50,000-60,000 additional heroin users, the entire health care and drug treatment professions need to collaborate to create as integrated a system of delivery as possible.

A. Training of Physicians as Buprenorphine Prescribers

New York City has very rich resources of well educated physicians, major medical centers, nationally renowned experts in every medical field, major physician training institutions, and long histories of cross-institutional collaboration. These rich resources will be able to rapidly train and certify numerous physicians in buprenorphine and addiction treatment via continuing education credits, one-day professional development seminars, and web sites. In addition, special “fact sheets” and information about buprenorphine therapy should be prepared for a variety of policy makers (political

leaders and key staff, legislators, government agency staff) in New York City and State. Similar, but more detailed materials about buprenorphine, should be prepared for the nonprescribing staff of several health care agencies (e.g. hospitals, HMOs, general clinics, specialty programs (e.g. STD, TB, HIV/AIDS, mental health). Physicians and their staff also need training in how to detect relapse to heroin use as well as manage opiate dependent patients who also have additional physical and mental health disorders and limitations in psychosocial functioning. *Pharmacists should be trained in opiate treatment and have increased responsibilities for directly observed medication, dispensing, and monitoring of patients in buprenorphine therapy.*

B. Financing Buprenorphine Treatment

How to pay for buprenorphine therapy? Few answers are available in early 2003. The retail cost of the buprenorphine medication is likely to be much higher (\$5-10/daily dose) than methadone (~\$0.70/daily dose). A careful cost analysis, however, demonstrates that buprenorphine treatment will likely be comparable to methadone treatment. As a Schedule III medication, buprenorphine has many financing options. The most important option is that a physician will typically write a prescription for Suboxone (charging only his usual office visit fee), so that the cost of purchasing the medication is shifted to patients or their insurance carrier. Buprenorphine therapy should be financed the same as, and follow the same processes, as all other prescribed medications in the pharmacoepeia. Medicaid, other government financing programs, and private insurers should negotiate fair reimbursement rates for patient office visits to physician prescribers and to pharmacists dispensing Suboxone. All third party payers should keep the societal objectives and benefits of buprenorphine treatment in mind when setting reimbursement rates. Methadone programs should have financing to support buprenorphine treatment that is independent and separate from the regulations and financing for methadone treatment—even in methadone programs. After several months of stable consumption of Suboxone treatment, many patients could become responsible for paying for their medication costs on a private basis from their employment income.

C. Integrating buprenorphine into addiction treatment and general medical practice

The advent of buprenorphine as a schedule III drug provides an opportunity to better integrate opiate addiction treatment into general medical practice. Buprenorphine is becoming widely used in Europe and Australia/New Zealand for heroin addiction. In the USA, primary reliance needs to be upon the buprenorphine/naloxone combination (Suboxone) for ongoing heroin or other opiate treatment.

1. Principles associated with expanding treatment portals in general medical practice

Avoid stigmatizing buprenorphine therapy that is likely to occur by adopting the segregated and highly regulated procedures associated with methadone programs. Provide physicians with sufficient incentives to include and treat opiate dependent patients. The amount spent and length of time an individual's treatment is supported should not be restricted given the social benefits of treatment.

2. Bring buprenorphine into several types of general medical practice

Government policy should be explicitly designed to encourage physicians to become authorized prescribers of Subutex and Suboxone to heroin users, and to provide such treatment as part of their clinical and private practice. This will include: solo physician prescribers, private clinical practices, Health Maintenance Organizations (HMOs), Community Health Clinics (CHCs), public-funded programs, and various other types of health/medical services.

3. Build upon the expertise in addiction treatment among staff in methadone programs

The expert addiction medicine staff at methadone programs needs to have a major role in introducing buprenorphine as alternative medication to heroin users and in assessing, stabilizing, and referring heroin-using patients to primary care providers and practitioners outside the programs. The availability of buprenorphine treatment could substantially expand the provision of agonist therapy for opiate addiction. Buprenorphine may also be preferred if there are fewer regulations and reporting requirements. Another advantage to involving methadone programs is that patients who cannot be stabilized with buprenorphine can be switched to methadone therapy. Experience with

buprenorphine may accelerate an expansion of methadone therapy and reduction of governmental restrictions. Methadone programs can have a critical role in an integrated system of treatment for opiate dependence using either methadone or buprenorphine.

New York City has an especially well developed network of methadone programs throughout communities most impacted by heroin addiction and can provide an excellent framework upon which to build an integrated network for bringing buprenorphine treatment into non-methadone programs and private practice. Buprenorphine Induction Centers might be established to efficiently transition heroin users into primary care settings (buprenorphine therapy) or licensed maintenance programs where methadone or methadone and buprenorphine are available. The New York City Jail System provides an excellent location for enrolling treatment-avoiding heroin users into detoxification or ongoing treatment with buprenorphine, and referring them to other treatment services after release.

4. Create an integrated and comprehensive delivery system that attracts and retains treatment-avoiding heroin users

The lifestyles of heroin users are one of high mobility and chronic instability in residence, employment, prior treatment, and criminal justice histories. In New York City, a private organization, Sociomedics, has maintained a confidential database since the 1960s of all individuals (unique persons) ever enrolled in methadone maintenance programs. In addition to preventing duplicate doses of methadone, it also confirms an individual's addiction history, expedites the exchange of medical/treatment information from a given patient's former provider to a new one, maintains data on methadone slots, and provides information on available methadone slots. Public policy should encourage the systematic development of optional databases that maintain and integrate information about buprenorphine prescribers and patients while maintaining strict patient confidentiality, privacy, and authorizing information.

SECTION IV: ENROLLING THOUSANDS OF HEROIN USERS IN TREATMENT

Thousands of treatment-avoiding heroin users will need to be attracted to a future with buprenorphine therapy. Over three-quarters of arrestees report a need for treatment and are classified as dependent on a standard scale. Moreover, 60% report having previously been in methadone or drug free treatment. Buprenorphine offers a new opportunity to the numerous current heroin users who have never entered treatment or have had prior episodes of treatment to seek buprenorphine therapy within much less restrictive environments. This large pool of *treatment avoiders* contains most of the additional treatment clients to be recruited in order to achieve the policy goal of enrolling 100,000 persons in heroin treatment in New York City by 2010.

Recruiting thousands of such avoiders will necessitate a major recruitment campaign to inform heroin users about buprenorphine, develop various incentives for entry to treatment, and otherwise try to influence the heroin subculture to view buprenorphine favorably. Buprenorphine delivered via general medical practice will provide a variety of *new portals* for entry into drug treatment for treatment-avoiding heroin users. The criminal justice system should carefully examine whether buprenorphine treatment, provided by private physicians and various public programs and programs, can be routinely used for heroin users being mandated to drug treatment.

Public policy should support a variety of financial incentives to former addicts, HIV/AIDS/STD outreach personnel, and family and friends to enroll active, treatment-avoiding heroin users into buprenorphine treatment. Such incentives could also be extended to the social networks of users/sellers of drugs, in order to facilitate the enrollment of active heroin users into treatment.

Maintaining heroin user continuity in buprenorphine treatment should remain a primary clinical goal, despite numerous difficulties with patient compliance and limited treatment progress.

Limitations associated with buprenorphine treatment. Buprenorphine may not be the most appropriate medication for opiate dependent patients with certain medical conditions. Buprenorphine patients

with severe chronic or acute pain might also need to be placed on an alternative medication such as LAAM or methadone. Polydrug use is very common among heroin users; buprenorphine will be unlikely to address crack and alcohol problems, except that buprenorphine may help retain such persons in treatment. Buprenorphine is probably not a substitute for methadone patients maintained on doses above 60 mg/day.

SECTION V. RESEARCH AND REGULATORY ISSUES

As buprenorphine is introduced into general medical practice, numerous critical research questions will arise and become important issues for expanding and improving patient care. Many of these questions can be addressed by researchers with support from NIDA, other federal funding agencies, and foundations. Several projects are needed to integrate research into practice. Community-level research is needed on heroin users' responses to buprenorphine outreach efforts and treatment.

An extensive research base, careful consultation with multiple constituencies, and review of regulations provides an excellent model for how to appropriately limit the scope and burden of regulations as they might be developed for buprenorphine. Political leaders with power to make laws and agency administrators that issue regulations in state and local governments should not develop laws/regulations about buprenorphine and treatment of heroin addiction that diminish access or reduce patient privacy; existing Federal regulations should be respected at state level. Additional laws and regulations of buprenorphine providers and patients by state or local agencies or legislatures would undermine both the federal recommendations and interfere with effective doctor/patient relationships and clinical practice.

Buprenorphine Outside New York City: In the future, physicians throughout America who become certified buprenorphine prescribers can provide opiate agonist treatment as part of their regular private or clinical practice (currently with a restriction of 30 patients). Both the buprenorphine prescriber and patients will be insulated from the stigma and disapproval of local politicians, health officials, and the community. Professional associations of physicians and the expertise in addiction

medicine developed in New York City and other large cities need to be made widely available to doctors in other locales.

CONCLUSION

The approval of buprenorphine therapy as an office-based treatment has great potential in New York City. The goal of 100,000 or more persons receiving heroin treatment by year 2010 is achievable and would more than double the number of heroin users currently in treatment. The introduction of buprenorphine into mainstream medicine portends many challenges that need to be systematically addressed by public policy makers. This effort is worthwhile, clinically, socially, and economically because buprenorphine offers many benefits for society that will accrue as heroin users are no longer active. A substantial and prudent investment in buprenorphine treatment during 2003-2010 will yield many long term benefits for individual heroin users, their families, and for all residents of New York City.

LISTING OF POLICY CHALLENGES IN WHITE PAPER

This White Paper provides 43 challenges that confront policy makers trying to make buprenorphine therapy part of regular medical practice in the future. Further elaboration of each policy challenge is provided at the page number given.

The long-range policy goal and five major policy challenges

POLICY GOAL: Buprenorphine therapy should be integrated into medical and clinical practice so that 100,000 or more active heroin users are routinely receiving some form of treatment in New York City by 2010 (8 years in the future)!	22
Policy Challenge 1: A large number of medical doctors, pharmacists, and their support staff will need to be trained in buprenorphine treatment protocols.	23
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Policy Challenge 4: Buprenorphine therapy should be made attractive and readily available to heroin users seeking treatment and/or referred by the criminal justice system.	24
Policy Challenge 5: Legislators and regulatory agencies should not create undue restrictions and regulations upon physician and treatment providers of buprenorphine.	25
In order to accomplish these challenges, many specific subchallenges will need to be addressed as intermediate issues to achieve the long-range goal.	

Physician, pharmacist and staff training in buprenorphine therapy

An important first step is to provide appropriate training and certification for physicians and their support staff in buprenorphine therapy.

Policy Challenge 6: Provide continuing education to New York City's (and the nation's) large physician community that an effective medication for opiate dependence will be available in office-based practice settings.	46
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Policy Challenge 8: Institutions having several physicians should establish incentives and provide one-day courses for their medical providers to become certified buprenorphine prescribers, obtain chemical dependence licenses, and gain skills in addiction medicine.	49
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Policy Challenge 10: Pharmacists should be trained in opiate treatment and have increased responsibilities for directly observed medication, dispensing, and monitoring of patients in buprenorphine therapy..... 50

Policy Challenge 11. Staff working with physicians and pharmacists need training in buprenorphine and addiction management, especially for signs of relapse and return to heroin use. 51

Financing buprenorphine treatment

Adequate financing of buprenorphine therapy needs to be arranged by the government and private health care payers.

Policy Challenge 12. Buprenorphine and Suboxone should be financed the same as, and follow the same processes, as all other prescribed medications in the pharmacoepeia..... 53

Policy Challenge 13. Medicaid should set appropriate payment rates to finance the medication costs of Subetex and Suboxone. 53

Policy Challenge 14: HMOs and private insurers should negotiate reimbursement rates consistent with existing physician fee schedules..... 53

Policy Challenge 15. All third party payers should keep the societal objectives of buprenorphine treatment in mind when setting reimbursement rates..... 54

Policy Challenge 16. Methadone programs should have financing to support buprenorphine treatment that is independent from the regulations and financing for methadone treatment. 54

Policy Challenge 17. Especially after several months of stable consumption of Suboxone, many clients could become responsible for paying for some of their medication costs. 55

Destigmatizing buprenorphine therapy

Policy Challenge 18: In order to avoid misperceptions (among both the public and providers) regarding the abuse potential of buprenorphine, primary reliance needs to be upon the buprenorphine/naloxone combination (Suboxone) for ongoing heroin treatment. 57

Policy Challenge 19: Special policy efforts should be made to avoid stigmatizing buprenorphine therapy by replicating the segregated and highly regulated procedures associated with methadone programs. 58

Provide ongoing support for office-based prescribing

General medical practitioners can help address many issues associated with the treatment of opiate addiction, if appropriate support is provided to these physicians and their staff.

Policy Challenge 20: Successful integration of buprenorphine treatment into office-based practice will partially be dependent on whether physicians receive sufficient incentives to accept and treat opiate dependent patients. 59

Policy Challenge 21: Effective treatment of opiate dependence with buprenorphine could last months or for an unlimited period of time for many heroin users. Government or insurance imposed time limits or financial caps should be avoided and would be counter-therapeutic. 60

Policy Challenge 22. Government policy should be explicitly designed to encourage physicians to become authorized prescribers of Subutex and Suboxone to heroin users and to help de-stigmatize the treatment of heroin addiction..... 60

Policy Challenge 23: Medical and substance abuse services that have traditionally not provided opiate agonist therapy should begin to provide buprenorphine therapy or maintain direct linkages with providers who do so. 63

Important roles for existing opiate treatment programs

Existing drug treatment programs have extensive experience and expertise in assessing and managing opiate dependent persons.

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THE WHITE PAPER

A NEW OPPORTUNITY TO EXPAND TREATMENT FOR HEROIN USERS IN NEW YORK CITY:

PUBLIC POLICY CHALLENGES FOR BRINGING BUPRENOPHINE INTO DRUG TREATMENT PROGRAMS AND GENERAL MEDICAL PRACTICE

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INTRODUCTION

Following 20 years of clinical studies and extensive consultation with multiple constituencies, the Food and Drug Administration (FDA) approved in October 2002, an opiate-medication, *buprenorphine*, for the treatment of heroin and opiate addiction. The Drug Enforcement Administration classified buprenorphine as a Schedule III drug— meaning that it can be prescribed by general practitioners and dispensed via pharmacies like most other prescription drugs. The rationale for this approval¹ is based upon the robust findings from clinical studies that have documented the safety and efficacy of buprenorphine, the recognition that opiate dependence (mainly via heroin addiction) is a chronic relapsing condition that often requires long-term use of medications such as methadone or other agonist medications such as buprenorphine to be treated effectively.

PURPOSE OF THIS WHITE PAPER

This White Paper has two primary purposes: To provide key findings and information about heroin addiction, chemotherapy treatments, and the planned introduction of buprenorphine in both its mono form (Subutex) and in its combined form (Suboxone; buprenorphine/naloxone). In addition, this White Paper provides several **Policy Challenges** that a variety of policy makers and constituencies

need to address and which will likely impact upon the long-term effectiveness of buprenorphine as an important adjunct to the treatment of heroin addiction. The two new buprenorphine medications (*Subutex* and *Suboxone*) were specifically developed to be prescribed by general practitioners, so as to make the treatment of heroin users more accessible and “friendly” to the heroin addicted consumer. (*Suboxone* is combined with an opiate antagonist medication, naloxone, which was designed to significantly reduce the likelihood of buprenorphine diversion and abuse.)

The long-range policy goal and five major policy challenges

One central overriding goal defines the long-term purpose of this newly approved medication.

POLICY GOAL: Buprenorphine therapy should be integrated into medical and clinical practice so that 100,000 or more active heroin users are routinely receiving some form of treatment in New York City by 2010 (8 years in the future)!

More detailed data (reviewed below) show that about 38,000 persons are maintained (or being detoxed) on methadone, and another 3,000-5,000 heroin users are likely enrolled in abstinence-based programs at any given time. Yet an additional 160,000-200,000 persons probably use heroin once in the past 30 days, and half of these are daily or near daily heroin users.² The availability of buprenorphine in its mono form (*Subutex*) for initiating heroin treatment and *Suboxone* for on-going therapy means that, at a minimum, an *additional* 50,000-60,000 persons could be actively treated for heroin use in a variety of settings by 2010. This goal is **achievable** if the Policy Challenges identified below can be addressed and resolved within the next three years (by 2005) and can supported by full implementation in a systematic manner in 2006-10.

Five major Policy Challenges are briefly described; the rest of this report elaborates on these.

Policy Challenge 1: A large number of medical doctors, pharmacists, and their support staff will need to be trained in buprenorphine treatment protocols.

A NYC goal of training an average of 2,000 medical doctors per year for eight years to provide buprenorphine therapy, and training double that number of their support staff (pharmacists, nurses, receptionists, clerks, counselors, etc.), is achievable. This may be the easiest challenge to overcome, since New York City has numerous experts in opiate treatment, extensive experience with methadone treatment in community programs and jails, major hospitals and medical centers engaged in physician training, and strong histories of collaboration across institutional boundaries.

Policy Challenge 2: Given the potential cost savings, buprenorphine treatment should be adequately funded by the government (mainly via Medicaid) as well as by private insurers.

A minority of current heroin users would be able to privately pay for their ongoing treatment. Yet in Dec. 2002, no clear policy to fund buprenorphine has been reached by the government or private insurers. However, since buprenorphine can be prescribed like all other Schedule III medicines—some organization or agency or individual users will need to finance much of its cost. Typically, the government-sponsored Medicaid program sets the reimbursement rate(s) for such medicines and/or patient visits to physicians. Private insurers often set similar although higher reimbursement rates, but often cap the number or frequencies of visits. An example of a fair and useful policy would have buprenorphine financed like any other newly FDA-approved medication for asthma, hypertension, or depression (like addictions, these conditions are often chronic or relapsing throughout a person's life). During the first three years, direct allocation of funds from government or foundation sources could encourage rapid and regular payments for buprenorphine treatment.

Policy Challenge 3: Buprenorphine treatment should be seamlessly integrated into regular medical practice and routine operations of publicly funded clinics/programs and private medical practitioners; strong interconnections between buprenorphine prescribers in the private and public sectors need to be developed.

While trained doctors will be able to diagnose heroin addiction, stabilize heroin users, and provide prescriptions of Suboxone to patients, the disruptive lifestyles of many heroin users will present new challenges for doctors than are typically encountered with their conventional (non-heroin-using) clientele with chronic diseases (e.g. asthma, high blood pressure, depression, obesity). Public policy should support enhanced or adjunctive services and, as needed, ensure easy transitions of heroin-abusing clientele from private practitioners to public programs and vice versa. Clinics dispensing methadone have a particularly important role in pilot testing and in advancing buprenorphine treatment (as an adjunct or alternative to methadone) for detoxification and ongoing buprenorphine therapy during the earliest years of its introduction.

Policy Challenge 4: Buprenorphine therapy should be made attractive and readily available to heroin users seeking treatment and/or referred by the criminal justice system.

The policy goal of 100,000 persons in treatment in New York City by 2010 could fail due to “customer avoidance”—consequently this needs to be carefully monitored. Failure is likely if the subcultural norms among current heroin users, especially the daily users, define buprenorphine treatment as thoroughly incompatible with their lifestyles. Addicts who might find buprenorphine treatment unacceptable are those who do not recognize they have a drug problem, who are interested in reducing their dependence but have not yet decided to stop using heroin, who still want euphoria (“get high”), or who do not want to take a long-term medication for their addiction. Well financed and integrated treatment systems can attract such heroin users who will also benefit from counseling and education, motivate them to address their drug use, and reduce concerns and misconceptions they may have about being treated with buprenorphine or other agonists.

Policy Challenge 5: Legislators and regulatory agencies should not create undue restrictions and regulations upon physician and treatment providers of buprenorphine.

The history of heroin and addiction control in the USA is replete with evidence of how key policies were passed for political reasons (e.g. be “tough on crime and addicts”), or of government agencies imposing onerous restrictions on medical personnel who engaged in treatment of heroin users.³

Ongoing and extensive consultation with medical personnel can help ensure that regulations do not undermine provider-patient relationships and/or impose major costs that are rarely funded. The FDA/SAMSHA regulations (of October 2002)⁴ regarding approval of Subutex/Suboxone as Schedule III drugs constitute recognition of the strong demand of medical professionals to have the right to prescribe opiate medications on an outpatient basis, outside of highly regulated methadone treatment programs. While some restrictions governing the use of buprenorphine for the treatment of opiate dependence in office-based settings were developed, they are substantially less than the restrictions on methadone programs. The expertise available in New York City within the medical profession and drug treatment providers will provide the kind of guidance and professional direction needed to prevent widespread misuse of buprenorphine, and to maximize its effectiveness in enrolling and treating heroin users. State and local agencies need to avoid implementing any additional regulations (such as mandatory reporting of buprenorphine patients) beyond those issued by appropriate Federal agencies.

These five Major Policy Challenges help frame the remainder of this report. Additional Policy Challenges are identified below, but often relate to one or more of the five described above.

BACKGROUND

This White Paper is commissioned by the Division of Mental Hygiene (DMH) New York City Department of Health and Mental Hygiene (DOHMH). DOHMH funds nine methadone programs in City-operated hospitals and many other programs with several heroin-using patients. As the local

government unit (LGU) charged with alcohol and substance abuse planning and funding for the City of New York, DOHMH is interested in maximizing the potential benefits of the buprenorphine treatment option. This report primarily focuses upon the five boroughs of New York City (although a small section at the end addresses buprenorphine outside the City). DMH has a special interest in how treatment for opiate dependence with buprenorphine may be implemented in methadone programs and in other public-funded clinics. This White Paper provides general information about a wide range of issues associated with the introduction of Subutex and Suboxone into general medical practice for the treatment of heroin and opiate addiction.

This White Paper is primarily intended as a policy document. It is intentionally designed around several *Policy Challenges* that will have to be confronted during the introduction of buprenorphine into the treatment system for heroin and other opiate addiction. These Policy Challenges are conceptualized as essential and crosscutting issues that necessitate decisions by key policy makers (political leaders, government regulatory and funding agencies, bureaucratic staff, clinic directors, physician associations, and many others). The manner in which these policy challenges are addressed and implemented (or not) will influence the efficiency and effectiveness of the delivery and quality of buprenorphine therapy as it is introduced during the next several years.

What it does not attempt to do: This White Paper does not provide treatment protocols. Nor will it address in any depth or detail how doctors should implement buprenorphine treatment nor attempt to address the myriad of clinical decisions that such treatment providers undertake in routine practice with such patients. Others have written such treatment protocols and there exist systematic plans to train several thousand physicians in the remainder of this decade (see Training below). Although some important references are included as endnotes, this product does not provide comprehensive references to the published articles (as would be the case in a scientific literature review). This White Paper also does not address the many benefits of buprenorphine when used as a pain medication or for other medical (not addiction) purposes. The authors have sought to write in a non-technical, but

comprehensible, manner for those readers who will know little about the medical aspects of heroin addiction and its treatment. Most policy makers will never be involved in prescribing buprenorphine nor treating heroin addicts, but they will make decisions important to the effective implementation and institutionalization of buprenorphine therapy for heroin and opiate addiction treatment and control. Medical and treatment personnel will realize that many topics about treatment implementation are ignored herein—but the authors anticipate that providers will appreciate the broader policy issues that the authors identify as critical to their long term success in delivering buprenorphine treatment to opiate users.

Overview of this White Paper

The First Section provides important information about the history of heroin addiction in New York City, the imposition of heroin prohibition, the rise of heroin treatment, methadone maintenance treatment, and the issues addressed during the approval process of buprenorphine as a treatment for opiate dependence. The Second Section delineates the lifestyles of heroin users, the diversity among heroin consumers, and identifies important subpopulations of current heroin users for whom buprenorphine treatment may be most beneficial.

The Third Section considers the critical role of physician training and financing in buprenorphine treatment and then addresses how buprenorphine and Suboxone can “open up” treatment **portals** and be integrated into general medical practice. Such efforts can improve the recruitment of and enable retention in treatment for the current heroin users who currently avoid methadone and other treatments. The Fourth Section addresses the goal of doubling the number of heroin addicts in treatment so that by 2010 there will be 100,000 heroin users in treatment for their opiate dependence.

The Fifth Section provides an overview of the need for further research to improve clinical uses of buprenorphine, documenting the responses of heroin users, addresses regulatory issues, and describes the possibilities for buprenorphine treatment outside of New York City.

SECTION I. THE HISTORICAL BACKGROUND

Brief history of heroin use in New York City.⁵

The history of heroin use and its treatment is intimately linked to this city. Among the first documented heroin users (in 1900-1910) were those in New York City. Around WWI, probably 90% of the heroin users in the USA were within 180 miles of New York City. While the Harrison Act (1915) restricted the sales of all opiate drugs to medical purposes, morphine and heroin were widely available via diversion from licit supplies. The number of heroin users in the city was so high that the New York City Department of Health Narcotics Clinic at Worth Street provided opiates to about 7,500 opiate addicts in 1919-20. Later historians indicate that this clinic was well run and moderately effective in treating addicts with maintenance doses of morphine and heroin. However, staff efforts failed in reducing opiate dosages to achieve abstinence.⁶ Nevertheless, the Prohibition Unit of the Treasury Department claimed that diversion and chaos were common and closed this narcotics clinic (and others across the nation) in 1920. Even though later Supreme Court decisions overturned the basis for closure, none of the clinics reopened. Overwhelmingly, the forces for prohibition prevailed in legislative chambers and regulatory agencies. By 1928, the Federal Government completely prohibited heroin for any purpose in the USA. Nevertheless, illegal supplies of heroin continued to enter New York in sizable quantities—and have done so for over eight decades. Between 1921-1960, almost no treatment for heroin addiction was available in the City.

In the 1950s and 1960s, major expansion of illicit supplies of heroin occurred; sizable proportions of young minority males (mainly) in the city's growing low income neighborhoods became heroin sniffers and injectors, leading to an explosion of heroin addicts in the 1955-74 period. Most addicts primarily consumed their heroin via hypodermic needles (“mainlining” or “injecting”), often sharing their injection equipment and heroin.

Development of Drug Treatment Programs: Under Governor Nelson Rockefeller (1962-70), major expansions of drug treatment occurred. State-run facilities (often converted prisons), residential Therapeutic Communities,⁷ and drug-free ambulatory programs were developed and implemented. After 1965, these abstinence-based residential and ambulatory programs became and remain an important component of heroin treatment. For over 40 years (1920-65), the only treatments available to heroin users required them to achieve and remain “abstinent” from heroin (and other drugs).

However, although these programs have proved valuable for some heroin users, one of the most consistent findings⁸ is that most heroin users who entered treatment departed from such abstinence programs within 90 days and the majority relapsed to daily heroin use. Long experience has documented that “abstinence only” programs succeed in keeping only a small minority of heroin users “off” illegal drugs completely.

Methadone plus Maintenance

In New York City, the research of Dole and Nyswander in the 1960s established the efficacy of a synthetic opiate, *methadone*, for treating heroin addiction.⁹ Methadone needs to be taken only once a day, but permits the stabilized user to feel and function normally. Methadone is longer acting than heroin. Like other opioid drugs, methadone produces dependency, but unlike heroin, which produces withdrawal symptoms within a few hours, withdrawal symptoms with methadone will typically not occur until after 24 hours. When consumed orally at appropriate dose levels, heroin users discover that they cannot get a euphoric “high” by injecting or snorting heroin. When methadone is consumed on a daily basis, a very sizable proportion of heroin users could begin to devote their time to involvement in conventional social roles of work, family, and community. During the late 1960s, methadone programs expanded greatly. The number of methadone patients in New York City grew from about 200 in 1960 to nearly 30,000 in 1974. The number of methadone clients in the City has increased to about 38,000 in 2002.¹⁰

Methadone also introduced two concepts, *maintenance* and *chemotherapy* into the framework of policy planning for drug treatment. **Maintenance** means that the heroin addict is prescribed a stable daily dose of methadone which prevents withdrawal symptoms, cravings for heroin, and does not generate a euphoric effect. Historically professional controversies have occurred about appropriate dose levels and time in treatment, often driven by ideological rather than medical criteria.¹¹

Controlled studies have generally found that heroin addicts maintained on higher doses of methadone (e.g., 80-100 mg or higher) show more substantial declines in illicit opiate use than addicts receiving low or moderate doses of methadone. Substantial evidence shows that a time limit should not be imposed on maintenance therapy. The primary criteria for success in methadone include elimination of heroin use, regular consumption of prescribed methadone dosages, no diversion, reduction in criminality, increased employment, and improved social functioning in conventional roles. The benefits of retaining heroin addicts in treatment are very substantial, even if many of these goals are not met.¹²

Several outcome evaluations have demonstrated that methadone maintenance, compared with other treatments for heroin addiction, had among the best results. A major review of drug treatment effectiveness studies by the Institute of Medicine concluded that:

Methadone maintenance has been the most rigorously studied modality and has yielded the most positive results for those who seek it.... Opiate dependent individuals have better outcomes on average in terms of illicit drug consumption and other criminal behavior when maintained on methadone than when not treated at all, when simply detoxified and released, or when methadone is tapered down, ... program expulsion, or program closure. Methadone clinics have significantly higher retention rates for opiate-dependent populations than do other treatment modalities for similar clients. Following discharge from methadone treatment, clients who stayed in treatment longer have better outcomes than clients with shorter treatment courses.¹³

Chemotherapy refers to the administration of some drug(s) that substitute for or block the action of heroin (or other drugs). During the past 25 years, the National Institute of Drug Abuse has funded many studies that seek to understand the biological mechanisms of action of opiate drugs in the brain, and to find/approve substances that meet rigorously evaluated scientific standards.¹⁴ Only a few chemotherapies (LAAM, naltrexone, naloxone, clonidine) have survived such rigorous scientific evaluations, received FDA approval as safe and effective, and been made commercially available for the treatment of opiate dependence.¹⁵

Although methadone maintenance has remained the primary chemotherapy for opiate dependence, the methadone treatment system has many drawbacks. In the 1960s, Congress imposed numerous restrictions and various other bureaucratic monitoring systems imposed regulations that were especially onerous to methadone clinic staff and to their clients. Many heroin users avoid methadone maintenance because they would not abide by these numerous restrictions. In addition, heroin addicts have created methadone folklore that keeps them away from maintenance treatment.¹⁶ Negative and ambivalent attitudes to methadone treatment are also held by the public and by treatment providers.¹⁷

Buprenorphine Development and History

Description of Buprenorphine (Subutex, Suboxone). Buprenorphine, a partial opioid agonist, has long been approved as a pain medication. It has been studied during more than 20 years of controlled-clinical studies as a treatment for opiate dependence (including heroin). Early research with buprenorphine for the treatment of opiate dependence documented the suppression of the craving and withdrawal symptoms associated with heroin; it also blocked the effects of subsequent heroin use. Unlike methadone, however, buprenorphine has a “ceiling effect.” At higher doses, its clinical effect is no longer proportional to the dose administered.¹⁸ Because buprenorphine does not have opiate-like effects at high doses there is a lower risk of overdose from buprenorphine use when

compared with heroin and methadone. Buprenorphine is believed to have a lower probability of abuse or severity of physical dependence than most other opiate medications.¹⁹ More recent studies have identified optimal dosing schedules that have demonstrated its efficacy and acceptability among heroin users as a treatment for their opiate dependence.²⁰ Doses of buprenorphine in tablet form (Suboxone or Subutex) typically range from 2mg “very low” to 24mg “high” dose.²¹

In October 2002, The U.S. Food and Drug Administration (FDA) approved two buprenorphine medications, tablets given the trade names *Subutex* and *Suboxone*, as a treatment for adults addicted to heroin and other opiate drugs such as heroin, morphine, and other prescription narcotic painkillers.²² Both forms of buprenorphine are manufactured in tablet form so as to be taken sublingually (placed under the tongue until it dissolves) on a daily or alternate day basis.

Buprenorphine is not well absorbed when taken orally (swallowed). *Subutex*, buprenorphine in its mono-form, will have euphoric effects if injected—and such injection abuse with buprenorphine has been reported. *Subutex* contains buprenorphine only, while *Suboxone* contains buprenorphine plus naloxone, a powerful opiate antagonist. As an opiate antagonist, naloxone is a medication that precipitates painful opiate withdrawal symptoms if the user injected *Suboxone* while dependent on heroin or other opiates—so most heroin users are unlikely to inject *Suboxone*.²³

The current (Oct. 2002) FDA regulations for opiate dependence treatment with buprenorphine recommend that patients first begin their treatment with *Subutex* (usually dispensed and consumed in the doctor’s office) and then, once the patient dosage has been stabilized, are switched to the buprenorphine/naloxone combination (*Suboxone*).²⁴ The physician can then write a prescription for *Suboxone*, which can be dispensed at pharmacies in a similar fashion to other prescription medications. The patient is instructed to consume the *Suboxone* tablet on a daily or every other day basis.

The FDA approval of *Suboxone* and *Subutex* may have great potential as a treatment for opiate dependence because these two buprenorphine medications are not subject to the heavy regulatory

burden of other agonist medications (methadone and LAAM) for treating heroin addiction.²⁵

Because of its low abuse liability, safety in high doses, and its recent approval in general medical practice settings, buprenorphine may be attractive and useful for a diverse number of sub-populations of opiate users. Opiate dependent patients for whom buprenorphine may be particularly appropriate include patients with less severe dependence, patients who have completed their first detoxification episode, and patients for whom methadone maintenance would cause a significant disruption in their pro-social activities such as employment, education or family commitments that require long and variable hours or over-night travel.

The approval by the FDA for physicians to prescribe buprenorphine has great potential for making a significant impact on the treatment of opiate dependence. The availability of an opiate agonist medication in office-based settings and available to the numerous primary care physicians may substantially increase the screening and treatment of opiate addiction in the United States—especially in communities such as New York City where the prevalence of opiate addiction is very high. Like methadone, buprenorphine is not recognized nor approved as a pharmacological treatment for other drugs of abuse such as cocaine, marijuana, or alcohol. However, treatment for opiate dependence—especially if it includes counseling or other psychosocial services—is likely to have secondary benefits, which could include reduction in other drug use, criminality and HIV-risk behaviors and an increase in vocational activities.²⁶

Development history, regulatory conflicts, assertion of physicians for right to prescribe. The treatment of heroin addiction with opiate agonist medications (i.e., medications that reduce or eliminate the cravings and withdrawal symptoms of addiction and block the euphoric effects of heroin) has been generally recognized as the most effective treatment for heroin/opiate dependence.²⁷ Prior to the introduction of methadone in the 1960s, there was no effective treatment for heroin addiction. Despite its efficacy, methadone was essentially removed from mainstream medicine by a combination of federal laws in the early 1970's; this removal also applied to other narcotics that were

subsequently recognized as effective in treating heroin addiction, such as LAAM.²⁸ Only specially licensed clinics (requiring state and federal approval) were permitted to prescribe and dispense methadone for the treatment of opiate dependence. Up until October 2002, with the rare exception of methadone medical maintenance (discussed in Policy Challenge 26, physicians were not permitted to prescribe these medications for opiate dependence as part of their general medical practice nor in other rehabilitation programs, unless these programs were licensed methadone maintenance treatment programs.²⁹

The approval of buprenorphine for office-based medical practice is the result of a confluence of several factors. These include: positive research findings about agonist treatment amassed over the past three decades; documentation of the great harms that untreated heroin addiction has upon individuals and upon society; the conclusion that many heroin addicts would continue and rarely recover without opiate agonist treatment; the diffusion within the research and practitioner community of the paradigm that addiction is a brain disease³⁰ and is not a moral failing nor a lack of will; and the advocacy by major professional organizations representing substance abuse treatment providers to include opiate agonist treatment within mainstream medicine.³¹

As a consequence of the closed methadone clinic system, however, most physicians have had limited experience in treating heroin addiction. Prior to the October 2002 FDA approval of buprenorphine as a Schedule III narcotic for opiate dependency treatment, buprenorphine maintenance treatment in the United States has been limited to heroin-addicted individuals enrolled in clinical trials. Several thousand patients have participated in these trials, including treatment with the buprenorphine/naloxone combination. Published studies have generally shown that buprenorphine maintenance is comparable to methadone therapy for patients enrolling in opiate agonist therapy.³² Currently several large clinical trials are testing various treatment options with buprenorphine in office-based practice settings. These on-going studies include more than a dozen community treatment programs within the Clinical Trials Network (a large multi-site study sponsored by the

National Institute on Drug Abuse). While published reports are not yet available, communication from patients and clinicians suggest that buprenorphine treatment is useful and that the treatment process is effective.³³ The wide-spread use of buprenorphine therapy across several countries, the positive findings reported in clinical trials, the emerging evidence of successful implementation with buprenorphine in community settings, and the physician-training programs (see training below) that have been set up by a number of professional societies, suggest that the implementation of buprenorphine treatment in office-based settings will not pose significant problems. The next section reviews the prevalence of heroin use, subpopulations of heroin users, and identifies several of these populations as particularly suitable for buprenorphine treatment in New York City.

SECTION II. EPIDEMIOLOGY OF HEROIN USE AND HEROIN USERS

What is the problem for which buprenorphine provides a solution? Heroin use and addiction have been defined as a major social problem in New York and American society for over 80 years. Fortunately, much has been learned about many aspects of heroin use, distribution, epidemiology, criminal justice sanctions, treatment, and various consequences of its use.

Despite harsh potential penal sanctions for heroin possession and sale, extensive data document that these policies have not deterred nor had a measurable impact upon the number of users or the intensity of heroin use/sales in New York City.³⁴ While relatively circumspect in their sales activities, many persons sell bags of heroin (usually \$10 or \$20 for a street bag) to a personally known clientele. In the 1990s, the quality of heroin in a typical street bag was substantially better (although of lesser weight) than heroin sold in the 1970s. The price per pure milligram declined in the 1990s and has not rebounded.³⁵

Estimates of Heroin Users

Indeed, research since the 1970s shows that thousands of New Yorkers remain addicted to or are daily users of heroin.³⁶ No other city in North America (and possibly the world) has as many heroin users and injectors. A disproportionately large share of the nation's heroin users reside in New York City. Most of these are home grown and were raised in the City's low-income neighborhoods.³⁷

Approximately 200,000 persons were estimated to be virtually daily heroin users in 1978, but possibly 30,000 of these have died, so the current estimates is 160,000 heroin abusers in New York City.³⁸ A smaller number—probably about 50,000 persons—are likely to consume heroin on an occasional basis.³⁹ These persons typically claim to “control” their heroin use, but continually confront ongoing risk of escalation to daily use. An additional group of about 38,000 New Yorkers are in methadone treatment and may not be using heroin.⁴⁰ Over the course of a year, heroin users

can shift their consumption between daily and more intermittent heroin use. During their career, heroin users may have episodes of methadone detoxification or maintenance, arrest and incarceration, and entry/exit into drug-free treatments.⁴¹ Overall, the pool of addicted or intermittent users of opiates is probably a quarter of a million persons in New York City. These estimates have remained relatively steady across the 1990s and into the 2000s. Yet three major and important shifts in heroin use patterns among opiate users have been documented, especially among those arrested for a variety of crimes.

Decline in Heroin Injection: First, the proportion of heroin users who are injectors (use syringe and needles to inject heroin into a vein) has shown a steady decline from about two-thirds in 1990 to about one third in 2001.⁴² The proportion of heroin users who claim to be “sniffers” (via nasal inhalation)—but claim to avoid injection—has increased by a like proportion. This means that heroin sniffers now constitute the majority of City’s heroin users, including those seeking treatment for opiate dependence. In recent years a large proportion (possibly more than half) of heroin users enrolling in methadone treatment report that they have never injected prior to 1990.⁴³

Among arrestees, heroin injectors consume on more days per month and use more bags per day of use compared to arrestees who sniff, but do not inject, heroin. In the course of a month, heroin injectors consume about twice as much as heroin sniffers.⁴⁴ The good news is that is that less than 15 percent of heroin-using arrestees are daily heroin injectors (who have the largest habits and extensive criminal histories). Over 80 percent of the arrested heroin users are either sniffing heroin (regardless of regularity) or injecting it on a less than a daily basis—*so the vast majority probably have moderate heroin dependencies that can be successfully addressed via buprenorphine therapy.*

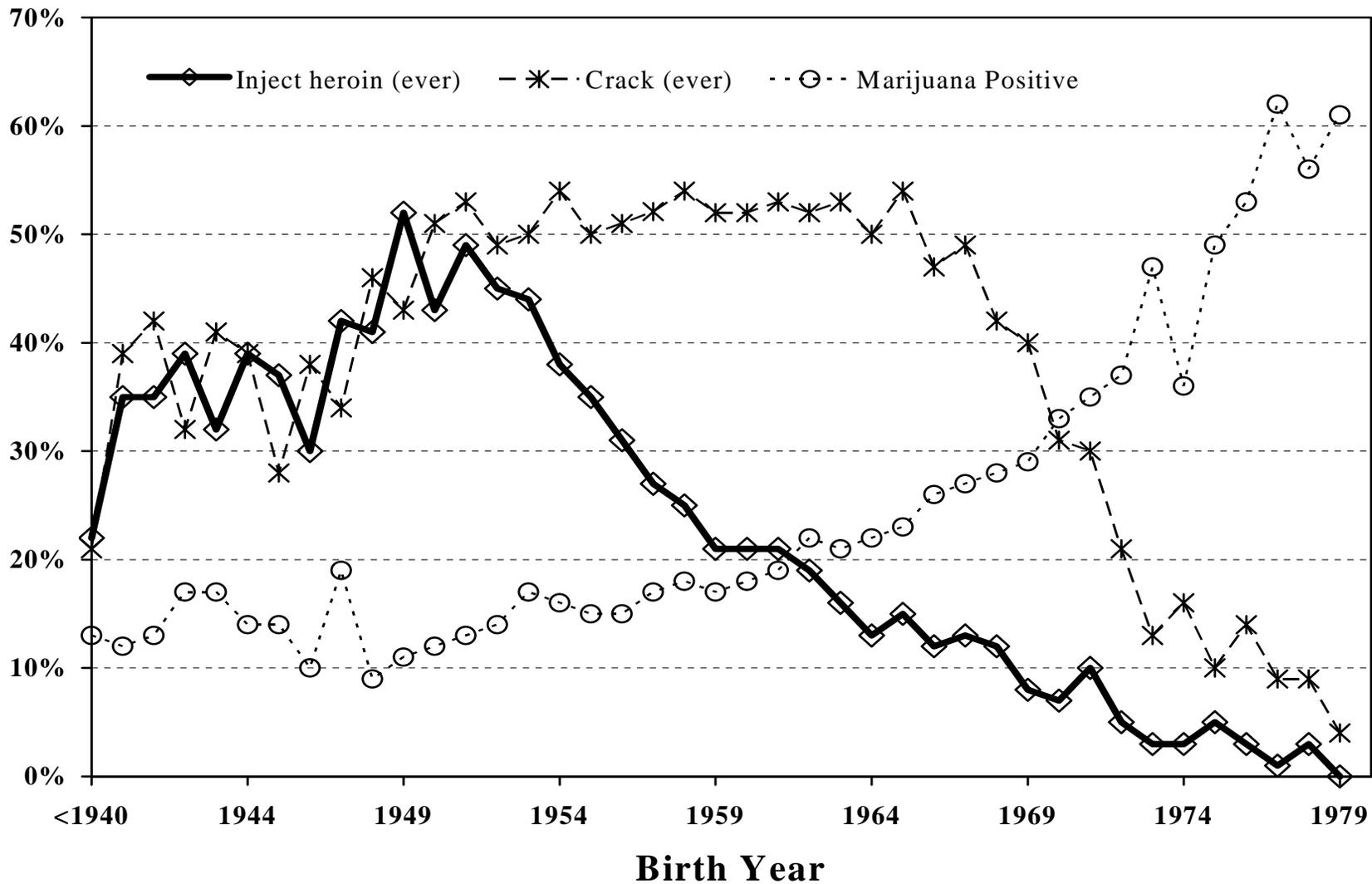


Figure 1. Key Drug Use Indicators by Birth Year (ADAM-Manhattan Arrestees Age 18+, 1987-1997) Taken from Golub, A. L., and Johnson, B. D. (1999). Cohort changes in illegal drug use among arrestees in Manhattan: From the heroin injection generation to the blunts generation. *Substance Use and Misuse*, 34(13), pp. 1733-1763

*Generational Drug Preferences:*⁴⁵ Second, major generational shifts regarding heroin use and injection are evident, especially among the City's large pool of poor persons living in impoverished neighborhoods and who tend to sustain arrest. Inner-city youths born 1945-54 (who reached adulthood 1965-74 and are reaching 50 years old in the 2000s) have been identified as the **Heroin Injection Generation**. Those being arrested or entering drug treatment from this cohort have historically had the highest proportions of heroin users and injection behaviors—regardless of ethnicity. Arrestees born 1955-69 (who are in their 30s and 40s in 2002), labeled the **Crack Generation**, became heavily involved with crack smoking, but smaller proportions used heroin and tended to avoid injection. Arrestees born 1970 and later (mainly in their teens and 20s in 2002), labeled the **Marijuana/blunt Generation**, have systematically avoided heroin use, especially via injection, and crack smoking. Their preferred drug is a **blunt** (marijuana smoked in the exterior wrap of a low cost cigar). Very few (about 5% among arrestees) young adults born after 1970 are using heroin, and even fewer are injecting it.

*Ethnic Differences in Heroin Use and Injection:*⁴⁶ Third, ethnic differences in heroin use and injection are important across generations. The avoidance of heroin use and injection is most pronounced among inner-city black and African-American youths born after 1970.⁴⁷ Among Hispanic arrestees, heroin use remains high among those in the Heroin and Crack generation, although injection use has declined; both heroin use and injection is low among Hispanics in the marijuana/blunt generation. Although proportionately few whites are arrested in the City, white arrestees have the highest proportion of heroin users and injectors among the three major ethnic groups. Moreover, many white heroin users reside outside of Manhattan or the five boroughs, but come to Manhattan to purchase heroin supplies in the city's street drug markets.⁴⁸ Should the current trends continue, the overall levels of heroin use will probably remain relatively steady, but injection practices will likely continue to diminish (possibly excepting whites). As the older generation dies

off, enters treatment, or avoids arrest, modest declines in heroin prevalence may occur during the 2000s decade. As the number of young adults from African America and Hispanic background mature (and if their avoidance of heroin continues), a further downward trend may also occur. Nevertheless, large numbers of the remaining out-of-treatment heroin users will be sufficiently addicted to take advantage of buprenorphine therapy.

Heroin Users Views of Drug Treatment. Since 1965, treatment of different types has been available to almost all heroin users in New York City—often without any direct patient payment. This has included ambulatory and residential drug free programs, methadone detoxification and methadone maintenance. Sizable subsets of heroin users have been also been confined in jail or prison for lengthy stays. An extensive set of research documents that *being in drug treatment* dramatically reduces heroin use, criminality, and illegal behaviors.⁴⁹ The research evidence also documents that most heroin users often relapse after treatment departure, but have repeated episodes of treatment during often-lengthy careers in heroin addiction.⁵⁰

Variability in Heroin Lifestyles: Research also reveals a restricted range, but with considerable heterogeneity, among heroin users.⁵¹ The large majority have not achieved many common statuses needed for conventional society (e.g., they are high school dropouts, never married/separated in adulthood, mostly unemployed/underemployed, unable to get or keep welfare, without permanent households) and have very limited economic options. Many are active in a variety of hustles to earn funds to purchase heroin or other drugs they use; shoplifting, modest thefts, prostitution, and low-level drug sales/distribution constitute their major economic activities.⁵² They are also likely to be arrested numerous times; depending upon some of their conviction offenses, several may spend years in jail or prison. A sizable number of heroin users tend to be less active in criminal offending, may maintain modest levels of employment, and keep their consumption under a semblance of control by limiting their heroin purchases, and conceal their addictions from even family and friends.⁵³

Subpopulations of heroin users appropriate for buprenorphine treatment

Virtually all heroin users will be good candidates for buprenorphine and ongoing Suboxone treatment. But several issues will influence whether buprenorphine treatment will be relatively more successful among the subgroups of heroin users discussed below. Persons seeking treatment often provide information that may be discrepant with their actual (and highly varied) heroin consumption practices; both under and over-reporting of heroin use is common.⁵⁴ Physician prescribers will be trained to administer a variety of drug tests and withdrawal symptom severity scales so that primarily those determined to be physically dependent on heroin or other opiates will actually receive buprenorphine treatment.⁵⁵

Among current (in the past 30 days) heroin-using arrestees, about half are daily (all 30 days) heroin consumers and a quarter are using heroin 3-6 days a week—all are excellent candidates for buprenorphine treatment. About a quarter of current heroin users appear to be intermittent users who claim they are “controlled users” and use it on 8 days or less a month.⁵⁶ *Such intermittent heroin users may be among the least likely to seek treatment, but may have excellent outcomes if and when participating in buprenorphine and Suboxone treatment.*

Heroin injectors (about 50%) are somewhat more likely than heroin sniffers (about 30%) to be daily heroin consumers. Also injectors typically consume about twice as much heroin per month.⁵⁷

Although the severity of heroin dependence is statistically associated with the frequency of heroin consumption, the (relatively) good news is that among arrested heroin users about two-thirds are not daily injectors.

Several subpopulations of heroin users may be especially appropriate for buprenorphine treatment. Some of these are identified below.

Middle class and stable employed. Some ethnographers and medical personnel report having contacts with several middle and working class heroin users who have steady legal employment and

private insurance.⁵⁸ While such persons are rarely encountered in arrestee populations or in public-funded drug treatment programs, they are the subpopulation for whom buprenorphine and office-based prescribing appears most promising. Middle class heroin users are especially effective at concealing their heroin consumption from almost everyone—often including their spouses, family members, and employers—because they recognize that discovery of their addiction will jeopardize their careers. If and when discovered, they may be referred by employers or pressured by family members into treatment. A closely related subgroup are physicians, nurses, and health care workers who have legal access to pharmaceutical opiates (morphine, fentanyl, Demerol, etc.) and divert some for their own use. With good incomes, private insurance or HMO coverage, such persons have good to excellent prognosis for avoiding future heroin use with buprenorphine therapy.

Heroin sniffers or smokers. In the 2000s, the vast majority (two-thirds or more) of NYC heroin users are avoiding injection, but prefer to sniff (nasal inhalation) or smoke heroin. Among such persons, over two-thirds have some days without heroin use, and relatively few sniffers consume over 5 bags of heroin a day. Most heroin sniffers choose to avoid methadone clinics. Yet such heroin sniffers constitute more than half of the City’s methadone patients.⁵⁹ If and when such heroin sniffers seek (or are referred) to treatment, they would likely choose buprenorphine treatment for several reasons. The avoidance of methadone clinic settings and ability to obtain Suboxone prescriptions from a pharmacy as a prescribed “medication” by a doctor would be attractive. Buprenorphine treatment will be highly consistent with the heroin sniffer’s subcultural belief that they can “control” their heroin use—with some help from their “medicine.” Whether sniffers continue to regularly consume Suboxone as directed, or use it intermittently so they can experience a heroin high remains an important empirical question to be documented.⁶⁰ Nevertheless, for over half of current heroin users—especially the nondaily heroin sniffers—buprenorphine has a high probability of becoming their most popular and primary form of opiate substitution treatment.

Young adults and early heroin users. In the 2000s, relatively few African-American youths (ages 16-24) are reporting any heroin use, and almost none are injecting it.⁶¹ Similar trends toward heroin avoidance are evident among Hispanic young adults. Only white youths (and a small proportion of all white youths) appear to be initiating heroin use and about half of these are becoming injectors. To the extent that those initiating heroin use during their young adult years (18-29) can be attracted to and referred to treatment, buprenorphine therapy and daily consumption of Suboxone will likely become their most attractive option (for all the reasons listed for sniffers above). Suboxone treatment will likely have the added benefit of helping younger heroin sniffers avoid progression to injection practices. The long-term policy goal, however, is to dramatically shorten young persons' careers as active heroin users—even if they continue their Suboxone medication for several years.

Criminally active heroin users. A very sizable number and proportion of all current heroin users are active in a variety of illegal hustles, mainly to raise the funds for heroin purchase (which typically run \$20-50 per day). The actual heroin consumption patterns of this subpopulation of heroin users may not be much more intense (in amounts used per day) than the above subgroups.⁶² Criminally active heroin users, however, may prove much more difficult to engage and retain in buprenorphine treatment (as is true for all other types of treatment) and prove to be the most difficult to manage in private practices.

These difficulties are most likely associated with the entire background and lifestyle of street heroin users. Most such criminally active heroin users also come from severely deprived backgrounds (in childhood, adolescence, and young adulthood), have poor education and skills for conventional roles, limited and low levels of legal employment, and have high commitments to illegal activities.⁶³ Historically, such offending heroin users have proven very difficult to treat, as they drop out rapidly, relapse after departure, and resume criminality—this is true among methadone programs as well as drug free programs.⁶⁴

Buprenorphine is unlikely to fundamentally alter the difficulties that a sociopathic clientele raises for the physicians and staff when treating such persons. Yet, *criminally active heroin users are precisely those that the larger society and criminal justice system has the greatest interest in treating*—and methadone treatment has done so for thousands. Buprenorphine treatment offers this treatment resistant clientele a new alternative to methadone and drug free programs. Office based prescribing of buprenorphine may be perceived as an attractive treatment option to such criminal heroin users—as having many fewer “hassles” than the clinics or drug free programs. Whether physician prescribers are willing to deal with such multiple problem clients is a separate question. Since many physicians often have deviant and noncompliant patients, handling the heroin user may not be so different. Physician willingness will more likely be determined by whether they can make enough money to offset their time and expenses. Buprenorphine prescribers will find that criminally active heroin users need more extensive health care, counseling, and supportive services than the typical private or clinic patient.⁶⁵

Former heroin users/methadone clients. During the past 35 years, thousands of persons have “recovered” from heroin addiction, and/or been successfully treated by methadone and other programs. Yet every year, some unknown fraction of such recovered persons may try the current high quality heroin, and be at considerable risk of relapse to daily heroin use. The advent of office-based prescription of Suboxone may offer such persons an early opportunity to return to a non-stigmatized form of treatment. Physicians will have the option of providing Suboxone to block the euphoric effects of any heroin they may try, so that they remain former heroin users.

Overall, virtually all heroin users should be considered for buprenorphine treatment—regardless of the route of administration (sniffed or injected), severity of use (days/month, bags per day), or criminality (none to severe).⁶⁶ Each heroin user needs to be individually assessed, appropriate referrals made, buprenorphine stabilization achieved, and compliance with Suboxone dosages assessed across time. If some clients drop out or become too disruptive to a provider’s private or

clinic practice, that client should be referred to an appropriate alternative program (e.g., methadone clinic, drug free). [See integration and cross referrals in Section III.]

In order to establish a comprehensive and integrated system for delivering buprenorphine treatment, thousands of physicians and pharmacists need training and certification as buprenorphine prescribers and prudent financing of buprenorphine medication and service delivery must be established.

SECTION III. TRAINING, FINANCING, AND SYSTEM INTEGRATION

In order to provide buprenorphine treatment to 50,000-60,000 additional heroin and other opiate users, a wide variety of health care and drug treatment professionals need to collaborate to create as integrated a system of delivery as possible. Several thousand⁶⁷ primary care physicians will need training about addiction and buprenorphine to become certified prescribers. Appropriate financial arrangements must be made to pay for the office visits, supportive services, and medication costs. As training and financing arrangements are worked out, public policy should be designed to open hundreds of new portals for opiate treatment around the city, as well as to develop effective systems that allow for rapid cross referrals and integration of appropriate services.

Physician, pharmacist and staff training in buprenorphine therapy

An important first step is to provide appropriate training and certification for physicians and their support staff in buprenorphine therapy.

A. Training of Physicians as Buprenorphine Prescribers

New York City has rich resources of well-educated physicians, major medical centers, nationally renowned experts in every medical field, major physician training institutions, and long histories of cross-institutional collaboration. These resources have the capacity of rapidly training and certifying numerous physicians in buprenorphine and addiction treatment.

Policy Challenge 6: Provide continuing education to New York City's (and the nation's) large physician community that an effective medication for opiate dependence will be available in office-based practice settings.

All physicians (and many related health professions) have requirements for learning about new advances in medical research and treatment. Continuing medical education (CME) credits are often acquired by attendance at professional conferences, attendance at special training courses, or web-based training offered by a variety of professional associations. The most important issues about buprenorphine treatment (an overview) could be provided as two 90-minute sessions at professional conferences or a couple of lectures at physician training institutions. Indeed, the required 8-hour

formal training session for certification as an *authorized physician prescriber* of buprenorphine could be easily delivered at the numerous annual conferences, any medical school, or appropriate city agency to its physician staff or community providers.

Policy challenge 7: Educate key policy makers, health care/substance treatment community, and general public that heroin addiction is a brain disease and that opiate agonist therapy such as buprenorphine is an effective treatment for opiate dependency.

Special “fact sheets” and information about buprenorphine therapy have been prepared (and can be improved) for a variety of policy makers (political leaders and key staff, legislators, government agency staff) in New York City and State and for the rest of America.⁶⁸ Similar, but more detailed materials about buprenorphine, should be prepared for the nonprescribing staff of several health care agencies (e.g., hospitals, HMOs, general clinics, specialty programs (e.g. STD, TB, HIV/AIDS, and mental health). Greatly simplified information sheets should be prepared for dissemination to the general public (e.g., on subways/buses and through public service announcements) and for journalists.

Physicians who wish to prescribe Subutex and Suboxone must first meet certain training requirements and complete a government form. When the training and certification are completed, the Drug Enforcement Administration (DEA) provides the physician with a practitioner number to place on all prescriptions involving Schedule III, IV, and V narcotic drugs. The DEA practitioner number goes on all prescriptions involving buprenorphine, codeine, and other prescription opiates. [If a physician already has a DEA number, they can take the 8 hours of training about buprenorphine, notify the DEA, and begin prescribing it.] There are two easy ways to obtain the required physician training: courses in classroom-like settings; and Web-based Training.

Professional Development Courses and CME Credits: The training requirements include holding certification in addiction from an approved medical board, or having completed a minimum of 8 hours of training on the treatment and management of opioid-dependent patients provided by an

authorized professional association such as the American Society of Addiction Medicine (ASAM) and four other professional associations.⁶⁹ Such training will be important since most physicians have never treated heroin addicts with opiate agonist medication. The most probable route for making such physicians eligible to prescribe buprenorphine in their office-based practice would be through an authorized training program attended at a local medical institution, public health agency, or professional association.

It is standard practice for physicians to obtain continuing medical education (CME) credits in order to maintain their skill levels and board certification. Physicians are expected to pay for CME credits as part of their continuing certification as a physician, and/or to maintain their specialization in a subfield of medicine. CME credits can now be obtained by completion of buprenorphine training courses. Such courses have been and will be offered at several national medical conferences. These one-day courses can also be delivered at a specific job site where it would be effective to train many physicians at one time (for example, training physician staff at Rikers Island Addiction Medicine Unit or from several clinics affiliated with the City's Health & Hospital Corporation).

Web site training. In addition, the required buprenorphine training can be accomplished via completing Web-based training courses currently offered by the American Psychiatric Association and American Association of Addiction Psychiatry.⁷⁰ More extensive information (e.g. 800 web pages) on buprenorphine and treatment of opiate addiction are offered by SAMHSA.⁷¹ Physicians completing the buprenorphine training can also apply directly online for a DEA number. Checking one box on this form, the practitioner will be automatically entered into the SAMHSA Treatment Facility Locator database.

Policy Challenge 8: Institutions having several physicians should establish incentives and provide one-day courses for their medical providers to become certified buprenorphine prescribers, obtain chemical dependence licenses, and gain skills in addiction medicine.

Since New York City has a relatively high prevalence of heroin addiction compared with other regions of the country, it may be desirable to bring buprenorphine training courses to where large numbers of physicians are located. Many physicians who already have a DEA number will not become buprenorphine prescribers—but having a one-day or briefer course may inform them about the details of buprenorphine and office-base addiction treatment. Such training will likely encourage them to support other medical colleagues who choose to treat heroin users with buprenorphine or methadone. The prevalence of opiate dependence in New York City is high enough that most physicians will encounter patients with this disorder during their career as medical practitioners. Ideally, by 2010 (or earlier) most NYC physicians should receive sufficient training so as to be certified to provide buprenorphine treatment if they have a chemical dependence license; this could be part of their standard medical practice. Participation in such courses may also have a secondary benefit in generating attitudinal shifts among physicians who may have negative attitudes and beliefs towards patients with addiction. Brief training courses have been found to be effective in moderating attitudes among physicians towards the treatment of addictive disorders.⁷²

Policy Challenge 9: Physicians need training in how to manage opiate dependent patients with additional physical and mental health disorders and limitations in psychosocial functioning.

Since the treatment of opiate dependence with buprenorphine has not yet been integrated into regular medical training, policy makers should give priority to training physicians who will have contact with proportionally larger numbers of opiate dependent patients. Physicians who regularly work with certain other disorders especially need training in buprenorphine. This would likely include physicians practicing in drug treatment programs, psychiatric and mental health clinics, and

infectious disease clinics such as TB, HIV and STD clinics.⁷³ Physicians working with indigent patients, especially the homeless, should also be given priority in training.

Policy Challenge 10: Pharmacists should be trained in opiate treatment and have increased responsibilities for directly observed medication, dispensing, and monitoring of patients in buprenorphine therapy.

In many European countries, community pharmacies have become a vital link in medication management. Buprenorphine therapy will increasingly rely upon a network of local pharmacies for the actual dispensing of the drug. A more active role may be needed in helping patients via medication management (e.g., directly observed consumption, obtaining urine samples, varying dose levels and pick up regularity).⁷⁴ This would become part of a trend to expand the role of community pharmacies in AIDS prevention via sales of condom and needles and syringe exchange.⁷⁵ Today, the role of community pharmacies in methadone treatment is widespread throughout Canada, Europe, and Australia. In the United Kingdom, an estimated 95% of methadone is provided through community pharmacies.⁷⁶

Methadone patients typically constitute a small percentage of a community pharmacy's clientele, with most pharmacies having fewer than ten methadone clients.⁷⁷ Most pharmacies participating in methadone treatment dispense to local patients. In some areas larger caseloads are seen in centrally located pharmacies with longer hours. Similar protocols could be established with pharmacists for dispensing buprenorphine. Pharmacists could observe the consumption of at least some of the doses – usually in a clinical consultation area set-aside for that purpose. In Europe, pharmacies involved in such treatment usually get special dispensing fees under health authority contracts or by self-paying patients.

Excellent rationales⁷⁸ exists for the clinical pharmacist's role as a buprenorphine service provider: 1) The efficacy, cost effectiveness, and patient satisfaction related to clinical pharmacy care in ambulatory environments such as anti-coagulation, anti-hypertension and diabetes clinics has been

repeatedly demonstrated. 2) Cost-savings are most likely to emerge when clinical pharmacists provide direct patient care rather than just simple chart review. 3) Under the supervision of a physician clinical pharmacists can adjust dosages for optimum patient comfort. 4) Brief counseling services could be provided. Engaging pharmacists in buprenorphine treatment will necessitate important shifts in physician-pharmacist relationships, as well as between pharmacists and patients. Pharmacists will need specialized training in appropriate drug administration, informal monitoring of adverse effects, alleviating withdrawal symptoms, minimizing diversion, and preventing relapse.⁷⁹ One model of supervised self-administration, which could include pharmacists, is the “shared care” model, which has been successfully operating in Scotland.⁸⁰ This model typically includes specialist services, general practitioners, and pharmacists. Specialist services are used to initiate methadone treatment, which is then managed routinely by a primary care physician. Within the Scottish shared care model physicians refer new patients to pharmacists and pharmacist provide the physician relevant feedback affecting patients care.⁸¹ The use of the shared care model in Scotland has substantially increased in recent years. The number of methadone clients receiving methadone through pharmacies has increased from 3,387 in 1995 to 8,792 in 2000. And the proportion of pharmacists who dispense and supervise the consumption of methadone has increased from 37% to 82%.⁸² A similar shared-care model could be developed for buprenorphine patients in New York City.

Policy Challenge 11. Staff working with physicians and pharmacists need training in buprenorphine and addiction management, especially for signs of relapse and return to heroin use.

Almost every physician who will prescribe buprenorphine to heroin users will work closely with one or more staff members (e.g., nurse, medical assistant, scheduler, bookkeeper, social worker, and pharmacist). These staff may often spend as much or more time with the patient as the physician. The expansion of opiate maintenance therapy in office-based settings will likely involve a larger number of non-physician health care providers than are currently working in methadone clinics.

These non-physician health care providers will need some training in the treatment of opioid dependence that is relevant to their profession and job function. A training curriculum would also need to be developed for providers of social services (e.g., counselors, social workers, and schedulers). Such training should include the opportunity to receive continuing education or credentialing credits that are relevant to the provider's discipline (e.g., credits needed by drug and alcohol counselors to be credentialed as substance abuse counselors or to obtain a chemical dependence license by New York State's Office of Alcoholism and Substance Abuse Services).

Financing buprenorphine treatment

Adequate financing of buprenorphine therapy needs to be arranged by the government and private health care payers.

B. Financing Buprenorphine Treatment

A critical issue involves the financing of buprenorphine treatment. Who pays? How much? And how will physician prescribers benefit? To these questions, few answers are available in 2002.

While the retail cost of the buprenorphine medication is likely to be much higher (\$5-10/daily dose) than methadone (~\$0.70/daily dose), the many costs mandated by regulations of methadone programs (e.g., counseling, urine screens, patient travel costs) more than offset the higher medication costs. A careful cost analysis demonstrates⁸³ that buprenorphine treatment will likely be comparable to methadone treatment, especially for patients with fewer comorbid problems.

While the cost of \$5-10/daily dose of Suboxone sounds high on an annual basis (\$1800 to \$3600), numerous other pharmaceutical products that alleviate a variety of chronic ailments are in this price range. The manufacturer's price is related to recouping its high investment in bringing buprenorphine to market.

As a Schedule III narcotic medication, buprenorphine has many financing options not enjoyed by methadone programs—which must employ nurses to dispense methadone as part of their service.

The most important option is that a physician will typically write a prescription for Suboxone

(charging only his usual office visit fee), so that the cost of the medication is shifted to the individual patient. Yet, relatively few heroin users getting a Suboxone prescription will go to their local pharmacy and pay full retail price from their own pocket. More commonly, a third party (Medicaid, a health maintenance organization [HMO], or other insurance carrier) will pay the majority of the retail price (with the individual possibly making a co-pay for the prescription)—as is the case with virtually all prescriptions for other medical conditions.

Policy Challenge 12. Buprenorphine and Suboxone should be financed the same as, and follow the same processes, as all other prescribed medications in the pharmacoepeia.

These medications should not be singled out for special pricing or restrictions because the usual recipient may be a heroin user. Rather, Medicaid, HMOs, and pharmacies should negotiate prices for Suboxone prescriptions (especially) that reflect the manufacturer's pricing, with volume discounts, and supply/demand factors—as with any other pharmaceutical products.⁸⁴ Different financial arrangements may be made by different parties (Medicaid, Blue Cross, HMOs).

Policy Challenge 13. Medicaid should set appropriate payment rates to finance the medication costs of Subutex and Suboxone.

The Medicaid program provides health coverage for millions of the lowest income Americans; many heroin users may be eligible for such coverage.⁸⁵ Indeed, Medicaid finances most of New York City's current methadone clinics. Medicaid also negotiates payment rates for local pharmacies that are among the lowest due to its large volume of customers. Often, Medicaid reimbursement rates are 30-60% below the manufacturer's suggested retail price—greatly reducing the medication costs to federal and state governments that share the cost of this entitlement.

Policy Challenge 14: HMOs and private insurers should negotiate reimbursement rates consistent with existing physician fee schedules.

These health care organizations and third party payers should also negotiate reimbursement rates that are satisfactory to the manufacturer and will support pharmacies to carry this medication. In addition

to the medication costs, reimbursement rates for physician services (office visits, intake/stabilization process, etc.) should be consistent with existing physician fee schedules.⁸⁶

Policy Challenge 15. All third party payers should keep the societal objectives of buprenorphine treatment in mind when setting reimbursement rates.

The potential benefits of having large numbers of heroin users receiving Suboxone treatment are very large for society. If setting the reimbursement rate(s) higher by \$1-2/daily dose will mean that almost all NYC pharmacies will dispense Suboxone, rather than only a few pharmacies, that would be a major contribution to addressing the city's heroin addiction problem. This would mean major societal benefits in terms of substantially reduced heroin abuse, property crime, and heroin sales and possible increased productivity by heroin users.⁸⁷ In the long run, this investment may bring about lower prevalence of HIV, HCV, and other infectious diseases associated with opiate use, especially intravenous drug use.⁸⁸ Restrictions on the amount spent or on length of time an individual's treatment is supported should take into account the high social value of reducing the prevalence of heroin use.

Policy Challenge 16. Methadone programs should have financing to support buprenorphine treatment that is independent from the regulations and financing for methadone treatment.

Although buprenorphine and methadone treatment are similar in many ways, methadone programs must follow many regulations (which drive up costs) and have individually negotiated Medicaid rates. If and when methadone clinics begin to use buprenorphine for heroin treatment, such services should not be included in the clinic's count of "methadone slots" (under methadone regulations). This should not be interpreted to mean that heroin users receiving buprenorphine should receive less counseling and other social services while attending methadone clinics. Rather buprenorphine services should provide extra funding to methadone clinics. For example, assume that a methadone clinic has 300 "slots" whether full or not. If that clinic adds buprenorphine treatment, the clinic should receive additional funding for its buprenorphine patients including: initial assessment of

addiction, counseling and health services, stabilization on buprenorphine doses, dispensing of Suboxone for a while, and even for referral of that patient to a private practice. Methadone patients who transfer to and receive only buprenorphine treatment should be removed from that clinic's methadone caseload (and slot count). This financing arrangement means that methadone clinics will be able to process and provide treatment to (possibly) many more patients than they are currently allowed to manage.

Policy Challenge 17. Especially after several months of stable consumption of Suboxone, many clients could become responsible for paying for some of their medication costs.

Methadone patients with stable employment and incomes are increasingly expected to pay some proportion of their treatment. Especially after heroin users have been stabilized and receive Suboxone for several months, many will be able to hold jobs and be able to afford their monthly medication costs (e.g. cover their monthly Suboxone prescriptions, which will typically be offset by private health insurance). While seeming like a high cost, the daily Suboxone cost is considerably less than the heroin they purchased. The difficulty will be to persuade the patient that paying “not to get high” is worth their financial investment. A large proportion of heroin users also spend similar amounts on a daily basis upon tobacco products. The decision to have buprenorphine patients pay for their medication should be carefully assessed as part of that patient's entire plan for rehabilitation and not as cost-cutting arrangement.

Following the above guidelines for financing buprenorphine treatment will not substantially increase the overall cost of health care in New York City or the nation.⁸⁹ Many other issues associated with the fair and equitable financing of buprenorphine treatment will continuously arise and need to be addressed by State and City policy makers, program administrators, physician associations, and other key constituencies.

C. Integrating Buprenorphine into Addiction Treatment and General Medical Practice

The advent of buprenorphine as a schedule III drug provides opportunity to better integrate opiate addiction treatment into general medical practice. The following lengthy section provides important issues and locations where such integration is most likely to occur.

1. Buprenorphine is becoming widely used in Europe and Australia/New Zealand for heroin addiction.

Several other countries introduced buprenorphine therapy earlier than the United States.

Buprenorphine was first introduced on a wide-scale basis in France and subsequently in Australia, New Zealand, the United Kingdom and several other countries in continental Europe. In many of these countries buprenorphine therapy has been and is being integrated into mainstream medicine.

a. France: The country with the most extensive experience is France. Buprenorphine as a medication for opiate treatment has been available in office-based settings in France since 1996. French policy permitted all general practitioners to prescribe buprenorphine in its mono form; the buprenorphine/naloxone combination has not been used in France.⁹⁰ The use of buprenorphine expanded rapidly in France; during the first 6 months, following its introduction, the number of patients treated with buprenorphine rose dramatically. By one account the number of patients treated with buprenorphine rose from 100 to 30,000.⁹¹ French surveys indicated that the expansion of buprenorphine availability during the late 1990s also coincided with a decline in heroin use and heroin overdose deaths during that period. However, the French experience with buprenorphine has not been without incident. Surveys of French buprenorphine maintained patients report that a significant number have injected buprenorphine.⁹² There is also a report of cross-border drug trafficking (e.g., from France to Finland) of buprenorphine.⁹³ Reports of the high-risk of intravenous abuse of buprenorphine among French heroin addicts are one of the reasons that the FDA waited until

research demonstrated the effectiveness of the buprenorphine/naloxone combination and why Subutex and Suboxone were placed in Schedule III, rather than on a less regulated drug schedule.⁹⁴

Destigmatizing buprenorphine therapy

Policy Challenge 18: In order to avoid misperceptions (among both the public and providers) regarding the abuse potential of buprenorphine, primary reliance needs to be upon the buprenorphine/naloxone combination (Suboxone) for ongoing heroin treatment.

As indicated earlier, Suboxone is not likely to be abused or injected; thus the United States should not be repeating some of the untoward consequences of the French experience. Moreover, federal guidelines for Subutex (buprenorphine only) is intended to be dispensed under the doctor's supervision, while Suboxone (the buprenorphine/naloxone combination) will generally be dispensed at pharmacies as a take-home medication. Patients receiving opiate agonist maintenance therapy with buprenorphine will primarily be prescribed Suboxone (since Subutex will typically only be prescribed during the very early period of treatment).

b. Australia and New Zealand. Buprenorphine was approved for use in Australia in 2001. In preparation for its approval the Australian government utilized the National Expert Advisory Committee on Illicit Drugs and the National Evaluation of Pharmacotherapies for Opioid Dependence to develop a set of basic policies and clinical practice guidelines for practitioners. This finally culminated in a document, "National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence" which address such issues as pharmacology, maintenance, withdrawal, adverse events and complications of buprenorphine treatment.⁹⁵ New Zealand, in response to intravenous abuse with buprenorphine in its mono form, is the only country that has marketed the buprenorphine/naloxone combination product.⁹⁶ Reports from Australia, New Zealand, and Iran regarding buprenorphine therapy indicate considerable compliance with dosing schedule, but some misuse via injection.⁹⁷

2. Principles Associated with Expanding Treatment Portals in General Medical Practice.

Expanding the traditional (methadone) clinic system has been extremely difficult because of community opposition, stigma, and regulatory climate.

Policy Challenge 19: Special policy efforts should be made to avoid stigmatizing buprenorphine therapy by replicating the segregated and highly regulated procedures associated with methadone programs.

The methadone clinic system has become stigmatized and is held in low regard by the very persons delivering and receiving its services.⁹⁸ Physicians and other health care professionals are reluctant to work in such clinics. Patients generally intend to leave treatment soon and those who are socially rehabilitated resent the continuing constraints placed on them by the clinic system. Impediments to remaining in treatment are likely to compromise effective therapy because on-going maintenance with opiate agonist medication may be most appropriate therapy for many heroin addicts. Relapse rates to chronic heroin addiction among those who leave methadone treatment are very high⁹⁹ as are overdose deaths.¹⁰⁰ These poor post-treatment outcomes even include patients who complete approved/planned methadone withdrawals.¹⁰¹ It is unknown how many heroin dependent people avoid treatment entirely because of the need to report to clinics, but researchers have documented that methadone treatment has a bad ‘rep’ on the street.¹⁰² The approval of buprenorphine for opiate treatment in office-based settings is likely to bypass many of these traditional impediments. As such, public policy has an opportunity to substantially expand the numbers of persons receiving treatment for heroin addiction. An underlying assumption of this policy paper is that the treatment of opiate dependence in an office-based setting (with buprenorphine) would, compared with such treatment in a methadone clinic setting, be more attractive to many opiate addicts because it is less stigmatizing, provides a greater degree of confidentiality, and is likely to be viewed by heroin users and the general

public as more acceptable as a medication because it is dispensed like other medications for chronic illnesses—in part because patients will not be segregated into special clinics with other addicts. The widely held assertion that opiate agonist therapy (e.g., methadone) is “a crutch” which “substitutes one addiction for another” and prevents a patient from truly recovering (becoming completely abstinent) from heroin addiction is not supported by scientific findings.¹⁰³ Publicity can be used to educate the public that heroin addiction can be effectively treated with buprenorphine medication in the privacy of a doctor’s office and that such treatment is and will be available from a large number of providers.

Provide ongoing support for office-based prescribing

General medical practitioners can help address many issues associated with the treatment of opiate addiction, if appropriate support is provided to these physicians and their staff.

Policy Challenge 20: Successful integration of buprenorphine treatment into office-based practice will partially be dependent on whether physicians receive sufficient incentives to accept and treat opiate dependent patients.

The value of insurance coverage for substance abuse has substantially declined in recent years especially when compared with the far smaller decline in general health insurance.¹⁰⁴ A decline in coverage is likely to be associated with diminished availability of proper treatment for many addicted patients. In a survey of physicians treating addiction, the majority felt that managed care had a negative impact on detoxification and rehabilitation, and upon their ethical practice of addiction medicine.¹⁰⁵ If private insurance does not provide adequate coverage for buprenorphine treatment then the opportunities for such treatment are likely to be limited among lone physician prescribers, private clinical practices, and for-profit HMOs.

Policy Challenge 21: Effective treatment of opiate dependence with buprenorphine could last months or for an unlimited period of time for many heroin users. Government or insurance imposed time limits or financial caps should be avoided and would be counter-therapeutic.

One policy which might significantly reduce the effectiveness of buprenorphine therapy would be the imposition of time-limited services. Some patients receiving this treatment may need to continue to be prescribed buprenorphine for an unlimited period of time. The need for continued, multi-year medication is similar to many other chronic conditions like hypertension, diabetes, depression, asthma.¹⁰⁶ If patients were no longer able to afford Suboxone, relapse risk would be high if they discontinued medication.¹⁰⁷

3. Bringing Buprenorphine into several types of General Medical Practice.

Physicians employed in several settings will likely have different receptivity to treating heroin users. This section briefly reviews how physicians in the different settings may decide whether to become authorized prescribers of buprenorphine.

Policy Challenge 22. Government policy should be explicitly designed to encourage physicians to become authorized prescribers of Subutex and Suboxone to heroin users and to help de-stigmatize the treatment of heroin addiction.

Closely related to physician choices will be the decisions about buprenorphine treatment made by private health insurance companies (Blue Cross/Blue Shield, Oxford, Continuum, and Cigna are among the major insurers in NYC). These private insurers have a long list of private physicians who accept their insurance reimbursements for specific services provided. Physicians in all of the following settings who become buprenorphine prescribers could greatly expand the number of portals to treatment for heroin users as well as help destigmatize such treatment and the addicts themselves.

- A. *Solo physician prescribers.* A significant number of physicians in NY engage in their own private medical practice on a full time basis. An even larger number of physicians are employed elsewhere (a hospital, HMO, clinic) but also maintain their separate private medical practices. Such private practices tend to provide health care to the more affluent, and those

patients with good health insurance. A few such physicians may choose to obtain training to become authorized prescribers of buprenorphine treatment. However, there is a possibility that a majority will not do so because of difficulties (real or perceived) associated with treating heroin-using patients and the likelihood that only a few of their patients would need these services. These difficulties include greater government oversight (e.g., DEA), lack of resources to address the various comorbidities associated with heroin addiction; and the difficulties some patients may have in paying for services due to lack of or unstable health insurance coverage.

B. *Private clinical practices.* In the era of Medicaid/Medicare, HMOs, and third party payers, most physicians in NYC have had to develop their own private medical practices in conjunction with other physicians in order to share the costs of office space, assistants, book-keeping, medical records and billing. Several collaborating physicians would be more likely to consider buprenorphine treatment than solo private practitioners since the private clinic would have additional resources to support those physicians who may wish to treat the more stable heroin-using clientele, especially those with private insurance.

Private physicians (both as solo practitioners and in private clinic settings) would be most likely to become buprenorphine prescribers for at least three reasons. First, if Medicaid and/or private insurance set attractive reimbursement rates “per visit” for heroin-using patients, some private physicians might be attracted as buprenorphine prescribers. Second, if some of their private patients (or their family members) are diagnosed as heroin users, physicians may become authorized prescribers to maintain such patients in their caseload. Third, physicians who are employed in specialized clinics (see below) with large numbers of heroin users may receive training and skill in managing such persons; such buprenorphine prescribers may refer patients to their private practices for ongoing Suboxone treatment. Outside of New York City—and especially in localities without methadone programs—

private physicians trained to prescribe buprenorphine therapy will likely become relatively more important providers of heroin treatment than in New York City. (also see end of White Paper).

- C. Health Maintenance Organizations (HMOs), Community Health Clinics (CHCs), etc. Both HMOs and CHCs provide a wide range of ambulatory health care services to their patients in a clinic setting, and have affiliation agreements with hospitals and specialists in various private settings. Patients in HMOs are at comparatively lower risk for heroin use and addiction than patients in CHC entities.

Since the 1980s, private health insurance has offered medical care by or thru HMOs (Health Insurance Plan [HIP] is one of the largest in NYC). In the 1990s many of these HMOs also began to accept relatively poor and welfare clientele (those paid by Medicaid and Medicare). In a similar fashion, a number of community health clinics were established to provide ambulatory health care for low-income populations in specific localities (such as the Upper Westside or Bushwick). The CHCs primarily rely upon Medicaid/Medicare reimbursements, but may have growing proportions of insured patients. Most patients diagnosed as heroin users are currently referred out (to methadone or drug treatment programs).

The availability of buprenorphine treatment as a Schedule III drug means that physicians in HMOs and CHCs could be encouraged to treat opiate addiction similar to the treatment of other medical conditions routinely offered patients. If they do so, such HMOs and CHCs would greatly expand access to and help eliminate the stigmatized treatment of heroin users. The availability of buprenorphine services within HMOs and CHCs may be especially valuable for heroin users whose use has recently progressed to dependence, since for many, it is within these settings that their opiate dependence would first be medically diagnosed.

Policy Challenge 23: Medical and substance abuse services that have traditionally not provided opiate agonist therapy should begin to provide buprenorphine therapy or maintain direct linkages with providers who do so.

D. *Public-funded clinic and health/medical services (non-methadone).* Many publicly funded health care clinics can serve a vital role in the introduction of buprenorphine treatment for opiate dependence. Many heroin users utilize publicly funded health services either because they have limited funds to pay for health care, lack adequate private insurance, or because they have another medical disorder that such clinics typically treat. Among health care venues that are likely to have a relatively high proportion of patients with opiate dependence are: STD, HIV/AIDS, and TB clinics, and alcohol detoxification facilities. While some of these patients may already be receiving treatment for opiate dependence (e.g., enrolled in a MMTP), others may not. Hospitals and clinics for general medical practices (e.g., HHC and maternal health) are likely to have fewer current heroin users.

Drug-free treatment programs may also include some clients who are opiate dependent, although they may also have other substance use disorders. Traditionally such programs would not permit their clients to receive methadone medication. However, within recent years some traditionally abstinence based programs (e.g., Addiction Treatment Centers; a short-term rehabilitation program operated by the New York State Office of Alcoholism and Substance Abuse Services) have begun to dispense methadone for clients who had been referred from a MMTP. Many residential drug programs also provide a variety of psychotropic drugs to address the mental health and other illnesses of their clientele. Such programs may be even more willing to dispense buprenorphine to their clientele within a supposedly “drug free” environment.¹⁰⁸

Important roles for existing opiate treatment programs

Existing drug treatment programs have extensive experience and expertise in assessing and managing opiate dependent persons.

D. Building upon the Expertise in Addiction Treatment among Staff in Methadone Programs

Methadone maintenance is the most common long-term treatment for heroin addiction in New York City and the United States. In New York City, more than 90% of patients who are being treated for opioid dependence are in methadone maintenance.¹⁰⁹

Policy Challenge 24: Methadone programs need to have a major role in introducing buprenorphine as an alternative medication for heroin users.

Methadone programs have staff who are addiction medicine experts and have special experience in assessing, diagnosing, and treating the extent of heroin dependency. Methadone clinics also have nursing staff trained to dispense agonist drugs, counseling staff, and other resources for working with some of the various medical and non-medical problems associated with heroin addiction such as HIV/AIDS, need for public assistance, and polydrug use.

The availability of buprenorphine treatment could substantially expand the provision of opiate agonist therapy for opiate addiction. Buprenorphine may become an alternative medication to methadone in traditional maintenance programs. Buprenorphine may be especially useful as a medication being offered to heroin users who seek opiate treatment for the first time or who return after relapsing. Buprenorphine may also be preferred due to fewer regulations and reporting requirements. Buprenorphine is less likely than methadone to result in adverse effects such as respiratory depression in the event of an overdose or if inadvertently taken by someone who is not opiate dependent (e.g., a child).¹¹⁰

Another advantage is that patients who cannot be stabilized with buprenorphine can be switched to methadone maintenance. Because of the ceiling effects of buprenorphine, some heroin users may not

experience sufficient alleviation of their withdrawal symptoms with buprenorphine; such patients may respond better to methadone.¹¹¹

Buprenorphine may also be a welcome alternative for current methadone patients who are stabilized on low to moderate dose methadone. Stabilized patients may have been in methadone treatment for several years and resent methadone take home dosage policies and the continuing restrictions imposed by the clinics. Such persons may readily switch to buprenorphine treatment if the clinic will provide prescriptions that can be filled at their local pharmacy or a monthly trip to the clinic. Such persons may also be referred out of a methadone clinic to a private buprenorphine prescriber. If sizable numbers of methadone patients are switched to buprenorphine treatment but remain on the clinic's rosters, they should not be counted as occupying a "methadone slot" that are subject to the numerous restrictions.¹¹² Such "triaging" of stable patients to private practices could also open up slots in MMTPs and permit staff to deliver more enhanced services to those with the greatest need. Such a change may also constitute a drawback if most of the stable methadone patients transfer to buprenorphine therapy and leave methadone clinics; this may reduce revenues and, as a consequence, increase the proportion of multiple problem patients in methadone clinics.

Policy Challenge 25: Public policy should support Buprenorphine Induction Centers to stabilize heroin users on Suboxone and then refer such patients to other clinics or buprenorphine prescribers.

Given the large number of heroin users who have multiple physical, mental, and social problems who may apply for buprenorphine therapy, existing methadone and public agencies should be encouraged to establish specialized **Buprenorphine Induction Centers (BIC)**. These BICs could be co-located near existing program intake units of a multi-clinic methadone program, a detoxification clinic, or public agency.¹¹³ The BIC could have a variety of resources (assessment and diagnosis of multiple problems, physicians with chemical dependence licenses and considerable experience in managing heroin dependent patients, social work and counseling staff) that are usually absent in most clinics

and physicians offices. BIU staff could accurately assess each heroin user's addiction severity as well as diagnose other dependencies (alcohol, cocaine/crack, marijuana, tobacco) and mental disorders. The BIC physician would provide initial dosages of Subutex (buprenorphine only) and then stabilize the patient onto Suboxone (buprenorphine plus naloxone). Most important, however, is that BIC staff would also provide a range of social services (provide showers and clothing, help apply for welfare and medical benefits), treat chronic conditions (mental health, asthma, hypertension), address co-dependencies (alcohol and crack), develop treatment plans, and locate an appropriate placement for each patient. After stabilizing the heroin user on Suboxone (usually a 1-3 month process) and partially resolving other problems, the primary goal of the BIC would be to refer and transfer each patient to a certified buprenorphine prescriber near the patient's residence and who would become that patient's primary care physician by subsequently providing ongoing buprenorphine therapy. The BIC would also identify pharmacies near the patient's residence that could dispense Suboxone. The BIC would also accept referrals from physicians who do not have appropriate assessment/diagnosis capacities, or who cannot manage multiple-problem patients, or those for whom referral to a methadone program may be most appropriate. Such BICs could most efficiently induct and stabilize large numbers of heroin users into buprenorphine therapy. The average physician prescriber would then receive a patient who was ready for ongoing buprenorphine therapy, after the most severe co-occurring problems had been addressed by the BIC.

Policy Challenge 26: Use experience with buprenorphine to foster an expansion of methadone therapy and a reduction of governmental restrictions.

For the past several years major professional organizations representing substance use treatment providers such as the American Society of Addiction Medicine (ASAM) and the American Association for the Treatment of Opioid Dependence (ATOD) have been advocating for better integration of opioid agonist treatment into mainstream medicine.¹¹⁴ This includes greater flexibility in methadone treatment and dispensing settings, particularly office-based physician prescribing and

use of community pharmacies for dispensing; an accreditation process similar to that for other medical care; and parity in third party payment schedules. Although there has been some concern that buprenorphine treatment may compete with methadone treatment¹¹⁵ a more sanguine and realistic view is that it may lead longtime providers of methadone to become more consumer-responsive.

Methadone Medical Maintenance.¹¹⁶ Certain states and localities are starting to apply for federal exemptions and approve new methadone programs in primary care settings; such programs are also known as methadone medical maintenance and Office-Based-Opioid-Therapy. Currently, very few slots are available, however there are initiatives for more slots to be created.¹¹⁷ (The largest and oldest medical maintenance program is operated by Beth Israel Medical Center in New York City.). Typically patients who enroll in medical maintenance programs are gainfully employed, have not used illicit drugs for at least three years, and have been in regular methadone treatment for an even longer period of time. The few studies that have evaluated the effectiveness of medical maintenance have indicated that it is very successful for a majority, although a minority relapse to heroin use and are referred to a methadone clinic for restabilization.¹¹⁸

Activities to promote systems integration

A variety of activities can promote integration of service delivery within and across institutional settings.

Policy Challenge 27: Buprenorphine as a treatment for opiate dependence should not be segregated from methadone maintenance. Clinics and physicians should be able to facilitate transition from one medication to the other as is medically needed and appropriate.

Some patients receiving opiate agonist therapy may respond better to methadone than to buprenorphine, and vice versa. With several years of experience in treating opiate dependence with agonist medication, methadone clinics will likely be able to prescribe and dispense both agonist medications (methadone and buprenorphine) and determine which works best for individuals and for subgroups of heroin users. Also, if the anticipated expansion of methadone medical maintenance occurs, physician providers in these

programs should include buprenorphine as an alternative medication, when medically needed and appropriate.

Policy Challenge 28. Methadone programs can have an important role in an integrated system of treatment for opiate dependence using either methadone or buprenorphine.

Methadone programs can serve several vital functions: 1) These clinics can be “intake and stabilization” centers (BICs) where heroin users can be screened for severity of dependence and placed upon and stabilized on buprenorphine dosages. 2) They can provide health assessments and psychosocial counseling (that will often be unavailable from private prescribers) and can engage resistant heroin users into a course of treatment. 3) They will provide ongoing buprenorphine treatment to many patients in parallel with methadone treatment. 4) They can refer buprenorphine-stabilized patients to private practitioners/clinics and pharmacies near the patient’s residence. 4) Clinics can accept referrals of buprenorphine clients who are too difficult and disruptive for private practitioners or nonmethadone programs to manage. 5) They can coordinate the delivery of critically important ancillary services (e.g., mental health, alcohol or cocaine treatment, HIV/AIDS services, and health care) to subgroups of heroin users with these comorbidities.¹¹⁹

Policy Challenge 29. New York City has an especially well developed network of methadone programs throughout communities most impacted by heroin addiction. This network can help provide an excellent framework upon which to build an integrated network for bringing buprenorphine treatment into non-methadone clinics and private practice.

This network of methadone programs includes those operated by the New York City Health and Hospitals Corporation (HHC) (9 clinics), Albert Einstein College of Medicine (9 clinics), Beth Israel Hospital Center (26 clinics), Addiction Research Treatment Center (7 clinics), plus several other hospitals with five or fewer clinics. An additional 10 methadone clinics are privately owned and operated; these rely upon Medicaid reimbursements and patient fees.

Detoxification clinics. In addition to the methadone clinics, New York City has 24 programs that provide short-term detoxification from heroin addiction. While each detoxification program has only a few static “slots” (5-54), individual heroin users are provided medically supervised withdrawal (detoxification) for only a few (3-21) days, so large number of individuals may be served during a year. Although detoxification is popular with heroin users because it can reduce the severity of dependence and decrease the daily cost of continuing on heroin. Detoxification is not as successful as longer term treatment (e.g., maintenance) for achieving abstinence from heroin.¹²⁰

While most of the research, development, and interest in buprenorphine have been its use as a maintenance medication (prescribed for at least 6 months), buprenorphine has also been approved for opiate detoxification. Some evidence suggests that the withdrawal experience using buprenorphine is less severe than from methadone.¹²¹ Detoxification programs, however, constitute an excellent setting for reaching treatment-avoiding heroin users who seek to lower their habit size (see below).

Integrative roles for criminal justice and data management

The City's criminal justice system and jails can assist in referring heroin users for buprenorphine therapy. Information management can maintain an appropriate flow of information while respecting patient confidentiality.

Policy Challenge 30. Use the New York City jail system as a location for enrolling treatment-avoiding heroin users into detoxification or ongoing treatment with buprenorphine, and referring them to other treatment services after release.

Rikers Island Addiction Medical Services. New York City Department of Corrections is unique in its systematic efforts to initiate and provide drug treatment among the thousands of persons arrested and held in the city's jail. Most arrested persons detained for more than 24 hours and/or sentenced to less than one year (as well as those who will be sentenced to state prison) are incarcerated in New York City's large jail facility on Rikers Island. The Addiction Medicine Unit (AMU) systematically assesses most persons entering NYC Riker's Island jail facility; inmates receive a physical examination and are assessed for heroin addiction, prior addiction history, and symptoms of opiate

withdrawal. The AMU has been and will continue to be a major contact point with treatment-avoiding heroin users with both long and short careers in addiction. The AMU provides methadone based detoxification for those assessed as needing it. For heroin users seeking entry into methadone programs, the AMU will initiate on-going methadone treatment and refer clients to community methadone programs when released from jail. A special program, Key Extended Entry Program (KEEP),¹²² has been specifically developed to help heroin users make the transition from a jail methadone program to local programs. [The KEEP program is restricted to inmates who are likely to remain at Rikers (e.g, misdemeanor offenders). Inmates who are likely to be transferred to State prison are provided short-term methadone detoxification.]

The Rikers AMU can have a major role in expanding the number of heroin users enrolled in buprenorphine treatment. The NYC correctional system has about 115,000 admissions per year and houses a little less than 15,000 inmates at any one time.¹²³ The AMU provides methadone detoxification services to about 11,000 heroin users annually.¹²⁴ The AMU could also become a BIC, conducting buprenorphine induction and initiate a course of ongoing treatment with Suboxone. Almost 11,000 treatment-avoiding heroin users would be eligible for to initiate buprenorphine therapy. In the future, the KEEP program will also be able to refer Suboxone patients to local clinics or private practitioners who are able to manage disruptive patients. Beginning buprenorphine treatment in jail settings and extending treatment to the community would also provide an alternative to methadone maintenance therapy for criminally involved heroin users.

E. Creating an Integrated and Comprehensive Delivery System that Attracts and Retains Treatment-Avoiding Heroin Users

In addition to the expertise and skill of individual physicians, clinics, and methadone programs (as reviewed above), the massive size of the New York City heroin problem and its associated drug treatment programs will necessitate a high level of case management and coordination across programs and institutional boundaries.

Policy Challenge 31: Information management about heroin users and rapid referrals to methadone programs in New York City could be replicated to support integration of buprenorphine therapy.

The lifestyle of heroin users is one of high mobility and chronic instability. During often-lengthy heroin-using careers most persons will experience many changes in their primary residence (or be homeless), change geographic locations, employment, or initiate but then dropout of various treatment programs.¹²⁵ The high legal and social stigma against heroin addiction means that heroin users routinely “slip between the cracks” of institutions designed to control their behaviors.

In New York City, a private organization, Sociomedics, has maintained a database since the 1960s of all who have been patients in methadone maintenance programs. Methadone regulations require all methadone programs to submit personal identifying information including treatment dates to Sociomedics. Their database contains over 100,000 unique individuals who have ever enrolled in methadone maintenance since the mid-1960s, each person may have several records of admission to and discharges from different methadone programs during their addiction career. The primary purpose of the Sociomedic database is to prevent a given heroin user from enrolling and receiving duplicate dosages of methadone (which it does well). But it performs many important secondary functions: a) It can quickly confirm that a potential patient has a prior history of opiate addiction (and indicate the recency), so such persons can be admitted rapidly. b) It can expedite the exchange of medical/treatment information from a given patient’s former methadone provider to a new one. c) It provides rapid information about and expedites referrals to a methadone program nearest to where the patient lives. d) It maintains information about where methadone “slots” are available, so that referrals to such slots can be made rapidly. e) It provides information to New York State about numbers of persons in methadone treatment. The Sociomedic database ensures that the numerous institutional barriers between transferring a patient from one program to another are rapidly overcome, resulting in no lapse in methadone treatment, and/or ensures rapid program entry for persons having a prior treatment episode in a methadone program.

Policy Challenge 32. Although numerous issues of confidentiality and privacy of client information need to be carefully addressed, public policy should encourage the systematic development of a database that maintains and integrates information about buprenorphine prescribers and patients.

Four possible databases can be considered:

Provider database: This database would include information on name and location of buprenorphine providers including relevant information such as the provider's sub-specialties, resources for treating comorbid disorders, type of insurance accepted, and available slots (under current regulations). Such a database could be used by BICs, providers and prospective patients (although certain sections of the data base maybe restricted to providers). Links could also be provided on treatment protocols for buprenorphine, web-based training, and a calendar of buprenorphine training courses.

Anonymous and aggregate database: This database would include relevant information regarding number of patients who are (or have been) treated for opiate dependence with buprenorphine during a given time period. This information would be in aggregate form. Important fields may include: number of patients who were admitted in buprenorphine treatment during a particular quarter-year, a categorical breakdown of time in treatment, percent of buprenorphine patients enrolled in different types of health care sites (e.g., private practice, group practice, MMTP, hospital-based, ect.). The advantage of such a database is that it could provide valuable quality control and assessment information that could significantly help assure the safe and effective expansion and delivery of buprenorphine treatment.

Anonymous individual record database. This database would include information about individual patients but which would be stripped of any identifying information such as name, social security or insurance number, birth date. The computer could generate a unique identification number for that individual. Use of individual—but anonymous—records would provide greater flexibility in addressing important buprenorphine treatment issues that would be difficult to achieve with an

aggregate database. Several important issues related to trends in enrollment, treatment outcome, safety and abuse, and cost-effectiveness could be addressed.

One of the important attractions of office-based buprenorphine therapy is that middle-class and employed persons with heroin dependencies insist on total anonymity as part of treatment. Public policy will need to be certain that the kinds of databases envisioned do not become a barrier for such persons for entering and remaining in buprenorphine treatment.

Confidential individual record database. A confidential database is distinct from an anonymous database. An anonymous record cannot be linked to the identity of a specific individual. An example would be anonymous HIV testing, in which the HIV test-result is recorded in a database but is not linked to any identifying information about the client. A confidential database is where access to an individual record is restricted to certain approved individuals. (Typically the actual record would not itself disclose an individual's identity but it would include a unique code number, which could be linked to a separate database, which would consist of identifying information, e.g., name, address, etc.) Examples would be the Sociomedics database, medical records, records of reportable diseases sent to the CDC, and records of subjects who participate in clinical trials. The advantage of a confidential database is it could give treatment providers access to relevant information about a client's prior addiction history, treatment entry/exits, and shifts from methadone to buprenorphine treatment. Clinical information from this confidential database could help buprenorphine providers develop an individualized treatment plan. Like all medical records, patient information in such a database should remain highly confidential, and made available to only limited authorized parties. Numerous details about how the information is obtained and maintained, and who has access to different parts of the database would need to be carefully negotiated.

The envisioned buprenorphine databases would have several key components that would be developed and made accessible to authorized persons only. This database would be planned to

expand and grow in terms of components (modules), linkages (to other data bases), and enrollment (of prescribers and clients). Some key modules would include: 1) Agreements and documentation of informed consent, privacy agreements, plus information release, password protections, and information security. 2) Data about each authorized buprenorphine prescriber—e.g., private physicians or at clinics/programs (names, office information, insurances accepted or not, and other specialties). 4) Pharmacies providing buprenorphine (names, locations, insurances accepted (or not), and possible pricing). Additional modules could be added at a later time, including: mapping modules to locate physicians/pharmacies near a patient's residence, referral/follow-up of patients, prescription writing/filling, client progress and/or cessation, interfaces to upload/download data to the prescriber's data management program(s) [at their office or institution], and others suggested by practitioners.

To the extent that confidentiality and information sharing with other databases can be arranged, this buprenorphine database could also arrange linkages with the Sociomedic database on methadone patients, the SAMHSA database of certified prescribers, and pharmacy prescription filling (other linkages may also be important).

Policy Challenge 33. Public policy should support interested constituencies to collaborate in the development of a buprenorphine database for the New York City metropolitan region, and possibly for the nation.

The obstacles to achieving such an integrated buprenorphine database are enormous due to the absence of agreement and probable strong disagreements from a variety of parties about whether it should exist at all, and about the content of specific modules. (However, separate database with varying degrees of privacy risk – as discussed above – may facilitate the introduction of an information system.) Noteworthy is that the hardware and programming problems are easily overcome—and that many health care organizations and providers routinely maintain more complex databases on networks and internet websites at the current time. Key policy makers will need to

strongly encourage and support representatives from many different constituencies (physicians, pharmacists, insurers, patients rights, methadone administrators, professional associations, appropriate officials from local, state, and federal agencies) to collaborate in defining what should be included and not included in development of a buprenorphine database. If and when such a buprenorphine database becomes operational, it will be highly supportive of the public policy to systematically integrate buprenorphine into general medical practice. The database proposed should not imply a mandated state registry for buprenorphine patients.

SECTION IV: ENROLLING THOUSANDS OF HEROIN USERS IN TREATMENT

Even if and when thousands of physicians are trained and certified, buprenorphine financing is arranged, numerous doctors, clinics, and programs can provide buprenorphine treatment, and cross referrals of patients can be implemented—the major challenge remains:

HOW CAN TREATMENT-AVOIDING HEROIN USERS BE RECRUITED, ENROLLED, AND RETAINED IN BUPRENORPHINE TREATMENT?

Enroll large numbers of heroin users in treatment

An anticipated major difficulty is recruiting large numbers of heroin users to enroll and remain in buprenorphine therapy.

Informing and Recruiting Heroin Users

Policy Challenge 34. Thousands of treatment-avoiding heroin users will need to be attracted to a future with buprenorphine treatment.

Almost every heroin user, especially those who use it daily or on a near daily basis, has had to think about whether or not to seek drug treatment. Indeed, research conducted among persons arrested in Manhattan on a wide range of charges shows how seriously treatment is considered among heroin users—and such criminal offenders are among the least likely to seek treatment voluntarily. Among arrested heroin users, over three-quarters report a need for treatment and are classified as dependent on a standard scale.¹²⁶ Moreover, 60% report having previously been in drug treatment. About 20% report being in current treatment—at least three-quarters of these are probably in methadone maintenance programs.¹²⁷ Even among the 40 percent who claim no prior drug treatment experience, probably most have been exposed to considerable pressures from family members, other drug users, the criminal justice system, and multiple other sources to consider entry into treatment. Because it can be prescribed in a less restricted environment than methadone, buprenorphine offers a new

opportunity to the numerous current heroin users who have never entered treatment or have had prior episodes of treatment.

At any given time, however, the vast majority of heroin users may be considered as *treatment avoiders* from the perspective of society, criminal justice, and treatment providers. That is, both irregular and daily heroin consumers claim that they enjoy the “high” from using heroin, are “in control” of their use, and perceive that they have no problems. They claim to “know about” various treatment options but have many negative opinions about such treatments.¹²⁸ While they “think about” entering treatment in the future, they are not ready to seek such help immediately.¹²⁹ They actively avoid approaching treatment programs, outreach workers, and dodge the police while supporting their heroin consumption. This large pool of *treatment avoiders* will be where most of the additional treatment clients will need to be recruited from—in order to achieve the policy goal of enrolling 100,000 persons in heroin treatment in New York City by 2010.

Recruiting thousands of such avoiders will necessitate a major recruitment campaign to inform heroin users about buprenorphine, develop various incentives for entry to treatment, and otherwise trying to influence the heroin subculture to view buprenorphine favorably. Major policy efforts should be made to prevent buprenorphine (as a medication) and the mechanisms of its delivery from being perceived as negatively within the heroin subculture as methadone currently is. But even after buprenorphine becomes regularly available as an alternative treatment, most heroin users are likely to cycle through such treatment, continue for a while, desist from, and (once no longer in treatment) probably relapse to heroin. This may occur at several times in their career.

Policy Challenge 35. Buprenorphine in general medical practice will be used to provide a variety of new portals for entry into drug treatment for treatment-avoiding heroin users.

As a Schedule III drug, buprenorphine can now be provided in numerous private medical offices and small clinics, which will become *new portals* to heroin treatment. In addition, methadone programs

and other agencies can function as Buprenorphine Induction Centers, which can stabilize and refer out patients to buprenorphine prescribers. For the first time since the 1920s, heroin users will have an opiate agonist alternative to methadone clinics, detoxification programs or to drug free programs that have been their only options for seeking drug treatment prior to 2003.

Policy Challenge 36. The criminal justice system should carefully examine whether buprenorphine therapy, provided by private physicians and various public clinics and programs, can be routinely offered to heroin users being mandated to drug treatment.

In the 1990s, the criminal justice system has become an increasingly important **portal** for entry into recovery programs by treatment-avoiding persons. Courts routinely refer heroin users to drug treatment programs as an alternative to incarceration. Moreover, court mandates for treatment are likely to expand in the decade of the 2000s.¹³⁰ But the criminal justice system refers heroin users almost exclusively to abstinence-based programs—which have modest rates of actual entry (e.g., many referred never enroll in mandated treatment) and retention (many drop out soon after entry). Although there is substantial evidence and consensus among medical professionals and evaluation studies that methadone treatment is more effective for heroin users than non-pharmacological interventions,¹³¹ relatively few courts refer mandated heroin users to methadone programs—due to the court’s concern about substituting one addiction (heroin) for another (methadone).

Buprenorphine, like methadone, is an opiate agonist medication. It has an affinity for the opiate receptor sites in the brain. These receptor sites, if occupied by buprenorphine, will no longer be sensitive to heroin or other opiates.¹³² Persons taking buprenorphine will not experience euphoria if they sniff or inject heroin, because the buprenorphine blocks the effects of heroin. Moreover, after initial stabilization, ongoing buprenorphine treatment will involve Suboxone which contains naloxone (an opiate antagonist).¹³³ This means that heroin users who obtain diverted Suboxone will likely experience unpleasant symptoms of opiate withdrawal and not get “high.”¹³⁴ If they take Suboxone regularly, the majority of opiate users would not consume heroin regularly. If Suboxone

actually stops most heroin users—especially those mandated to treatment by the courts—from using and relapsing to regular heroin use, it may prove to be a very promising therapy to achieve the criminal justice purpose—dramatically reducing heroin use as well as criminality associated with obtaining funds to purchase heroin.

Since criminally-active heroin users are likely to want to avoid withdrawal and enjoy getting high, long-term treatment with Suboxone may initially prove to be unpopular and many criminally-active heroin users may drop out of treatment. The courts and criminal justice system need to approve of and move towards acceptance of Suboxone as therapy that satisfies its treatment mandates. The backing of such legal mandates would encourage the ongoing attendance and participation in buprenorphine therapy of many reluctant heroin users—who would otherwise drop out of treatment and relapse to heroin addiction. Only court mandated treatment with Suboxone will allow the criminal justice system to effectively intervene in the heroin addiction patterns of thousands of high risk offenders who currently drop out of mandated treatment.

Policy Challenge 37. Public policy should support a variety of financial incentives to former addicts, HIV/AIDS/STD outreach personnel, and family and friends to enroll active, treatment-avoiding heroin users into buprenorphine treatment. Such incentives could also be extended to the social networks of users/sellers of drugs in order to facilitate the enrollment of active heroin users into treatment.

Despite all the “attractions” that buprenorphine and Suboxone plus a friendly and integrated treatment system may offer, many heroin users will remain uninterested. Only when the various networks of drug-using associates and family/friends begin to systematically pressure them into entry—and even bring them to several treatment portals, will enrollment and initial stabilization occur. Having funding available to pay or provide a variety of needed services to the heroin users networks will likely work better than most of the options for enlisting new pools of heroin users.¹³⁵

Other suggestions about how to recruit and help retain treatment avoiders into buprenorphine therapy may emerge in the future.

Retention of Heroin Users in Buprenorphine Treatment

Policy Challenge 38. Buprenorphine prescribers will need to stress the importance of retaining heroin users in drug treatment.

Research indicates that the longer heroin users are retained in treatment, the better their prognosis for avoiding heroin/other drugs and criminality, and for acquiring and resuming conventional social roles. Methadone treatment has been especially effective at retaining heroin users for many months and years; during such treatment episodes their heroin use is often reduced to near zero (although many other problems remain unresolved).¹³⁶ A central challenge is how to ensure that many heroin users continue to consume Suboxone on a daily basis over several months, and possibly years.

If opiate agonist therapy is prematurely terminated, the risk of relapse is very high as is the high social and legal costs (e.g., loss of job, criminal activity, incarceration) and health risks (e.g., HIV, hepatitis, death) associated with untreated heroin addiction.¹³⁷ Once a buprenorphine patient is stabilized, safeguards will need to be in place to assure continuity of treatment despite predictable setbacks. Problematic disruption in treatment could be caused by a number of events; such as: 1) loss or change in health care insurance, which could result in loss of coverage with the treating physician; 2) the patient (or physician) moving, 3) termination (without referral) by the physician which could result in a lapse of buprenorphine services; and 4) a patient terminating treatment against medical advice. The buprenorphine treatment system should include safeguards to prevent frequent disruptions in treatment and (if a disruption occurs) reduce the longevity and the severity of adverse consequences that typically follow after termination of treatment.

Two possible steps could be implemented to assure continuity of services: 1) Use of an information database (discussed above), which could facilitate referrals to and among appropriate providers; this could be similar to what is currently employed by Sociomedics for MMTPs.; and 2) supplemental emergency health insurance which could fill the gap if a patient loses his or her medical benefits.

Policy Challenge 39. Maintaining heroin user continuity in buprenorphine therapy should remain a primary clinical goal, despite numerous difficulties with patient compliance and lack of treatment progress.

Most heroin users will have one to several complications that often interfere with taking medications as directed, not complying with treatment protocols, having intermittent personal crises, and not making progress in treatment. Even among heroin users stabilized on Suboxone, some continued heroin use can be expected, possible diversion of Suboxone tablets to others may occur, involvement in heroin and other drug sales/distribution may continue, and involvement in various hustles and criminal activities may persist. In addition, heroin users are more likely to be abusing other drugs including alcohol and crack or cocaine, to have a psychiatric disorder such as major depression, and to have an infectious disease such as HIV/AIDS, hepatitis, or TB.¹³⁸ It will be important for medical practitioners to become familiar and learn how to also manage these disorders with other medications¹³⁹ because they can significantly complicate the successful treatment practice of patients.

The prevalence of psychiatric disorders may vary across persons with opioid dependence. Some studies have reported rates of over 50%; the most common disorders are depression (typically major depression), anxiety disorders, and personality disorders.¹⁴⁰ Typical complications associated with psychiatric disorders among opiate dependent persons who enroll in agonist therapy are continued illicit drug use and early termination from treatment. Medical providers who expand their practice to include opiate dependent patients will need to carefully assess patients for these disorders. These disorders can be treated with psychiatric medications (even when the patient is taking buprenorphine medication). Often psychiatric symptoms are exacerbated by substance use and some psychiatric disorders may eventually diminish with continued abstinence. However a substantial minority of patients may continue to exhibit psychiatric symptoms, even after having been stabilized on an opiate medication, such as buprenorphine.¹⁴¹ This may require on-going assessment and the availability of medication and or behavioral treatments. For more difficult cases, referrals to specialized services may be necessary.

Several co-morbid medical disorders are commonly found among persons with opioid dependence, especially those with a history of drug injection. Among the most common and serious are HIV/AIDS and hepatitis C. Similar to the health care protocols associated with the management of psychiatric disorders,¹⁴² practitioners will need to assess and treat (or refer for treatment) patients with these disorders.

Limitations of Buprenorphine Treatment

Buprenorphine may not be the most appropriate medication for opiate dependent patients with certain medical conditions. Buprenorphine patients with severe chronic or acute pain might need to be placed on an alternative maintenance medication such as LAAM or methadone.¹⁴³ Opiate agonists can be prescribed for pain or for the treatment of opiate dependence. In fact, buprenorphine has long been recognized as an effective pain medication. However, these medications, when they are used to treat opiate dependence, do not function as analgesics due to development of tolerance. Opiate patients receiving maintenance medications are just as prone to pain as is the general population and the maintenance medication that is provided is unlikely to treat current pain complaints except for the discomfort associated with drug withdrawal. Patients receiving maintenance therapy may, at times, require additional opiate medication to treat severe pain that has not responded to less aggressive approaches.¹⁴⁴ Because of buprenorphine's high affinity to the mu opiate receptor (a brain receptor implicated in both opiate dependence and pain regulation), patients treated with buprenorphine for opiate dependence will, unlike patients maintained on methadone, generally not achieve analgesic benefit if given additional opiate medication for a pain condition.¹⁴⁵ Protocols should be developed for the treatment of patients with these dual disorders and experts in both pain management and addiction should be available to physicians who prescribe Subutex and Suboxone as part of their primary care practice.

Buprenorphine is probably not appropriate for current methadone patients with dosages above 60 mg per day; methadone patients who desire less regulation will need to reduce their methadone dosage to 60 mgs or less in order to initiate buprenorphine therapy.¹⁴⁶

Limited data¹⁴⁷ suggests that buprenorphine has little effect upon the developing fetus; therefore buprenorphine may be an appropriate treatment for pregnant heroin-abusing women. (Methadone has been shown to be safe and effective for both pregnant woman and the fetus.)

Polydrug use is very common among heroin users. The greatest complications arise from co-dependence upon stimulants such as crack and cocaine and upon depressants such as alcohol and benzodiazapines.¹⁴⁸ Due to the serious comorbidities that many heroin users will present, office-based prescribers may want to follow a triage system for buprenorphine patients. For example, some providers may be best equipped to serve heroin users who are high functioning, have private insurance (or can self-pay), are not dependent on other drugs such as cocaine and alcohol, and who need few counseling services. Other buprenorphine prescribers, especially those affiliated with a clinic or larger medical practice, may be able to manage persons with multiple co-morbidities and accept Medicaid reimbursements. Abuse of benzodiazapines (a class of tranquilizing medications) raise special concerns because virtually all of the overdose deaths in Europe where buprenorphine was used (often with out-of-treatment opiate-abusers) occurred following injection with both buprenorphine and benzodiazapines.¹⁴⁹ Despite the decisions made by individual buprenorphine prescribers regarding types of patients and payments accepted, all prescribers need to recognize their responsibilities to do everything possible to ensure that each patient is treated fairly within the context of their practice. If patients seem dissatisfied and/or want to leave, or they cannot be managed with the resources available, the practitioner needs to make multiple efforts to ensure that the buprenorphine patient is referred to and actually completes the transfer to another buprenorphine prescriber who can ensure continuity of treatment.

SECTION V. RESEARCH AND REGULATORY ISSUES

As buprenorphine is introduced into general medical practice, numerous critical research questions will arise and become important issues for expanding and improving patient care. Researchers can address many of these questions with support from NIDA, other federal funding agencies, and private foundations. A few ideas are suggested below—many others will arise as experience develops.

Policy Challenge 40: An ongoing program of research is needed to demonstrate the effectiveness of buprenorphine for treatment of heroin addiction as it is integrated into office-based practices.

Need to integrate research into practice. Although several clinical efficacy studies have been conducted that have demonstrated the pharmacological benefits, safety and optimum dosing schedules of buprenorphine, long-term effectiveness studies under “real-world” conditions are needed to determine the cost-effectiveness of buprenorphine/naloxone in the USA.¹⁵⁰ Early indications are that buprenorphine treatment is effective (e.g., high retention rate, less heroin use) when provided in an office-based settings;¹⁵¹ however, more studies are needed to determine whether these benefits can be generalized to various subpopulations of heroin users. The ubiquity of user-friendly automated databases (and their increasing integration into medical practice) provides the opportunity to assess the on-going practice and effectiveness of buprenorphine treatment. Important information would include: referral source; client characteristics such as demographics, substance use history, comorbidity; and process and outcome variables such as dosing, drug use overtime, treatment retention, current status if left treatment, and patient experience of the treatment process.

Community research on heroin user’s response to buprenorphine treatment. How will active heroin users respond to buprenorphine treatment, especially those with a history of avoiding other forms of heroin treatment? Will they find it an attractive option to other forms of heroin treatment, seek out buprenorphine prescribers, and enroll in large numbers? Or will they evade and avoid heroin treatment, even if buprenorphine is viewed favorably within street culture?

Or will heroin users create folklore that is ambivalent about buprenorphine treatment? Ambivalence toward methadone treatment has been well documented among heroin users not in treatment as well as among methadone clients themselves.¹⁵² Ambivalent attitudes towards methadone include perceived side effects attributed to methadone. Some popular heroin folklore holds that methadone: “rots the bones,” that it is virtually impossible to detoxify from, has other serious side effects, and that it is ineffective.¹⁵³ Other negative perceptions of methadone hold that it promotes passivity by encouraging compliance with schedules and rules, is just another drug habit, and that it does not meet real needs such as employment and a valued social role.¹⁵⁴ Will the heroin subculture actively create folklore and beliefs about buprenorphine that are definitely unfavorable, and effectively discourage its use for treatment?

Providers and administrators as well as researchers should use the information gathered. This growing information should help providers; administrators and policy makers determine the most effective practices and, ideally, lead to more cost-effective delivery of buprenorphine treatment. During the initial years, buprenorphine prescribers could be encouraged to collaborate with professional researchers to help frame important research and policy questions, participate in research that can be funded, and make important contributions to understanding how heroin users, especially treatment avoiders, respond to buprenorphine treatment.

Limiting regulations on physicians and treatment programs

Public policy needs to limit extent of government regulation upon practitioners.

Policy Challenge 41. The extensive research base, careful consultation with multiple constituencies, and review of regulations should be used to develop a routine mechanism for how to appropriately limit the scope and burden of regulations as they might be developed for buprenorphine.

Most treatment experts agree that methadone programs have been over-regulated by many different federal, state, and local agencies.¹⁵⁵ In part, buprenorphine was approved as a Schedule III medication, to be used in office-based settings, in order to reduce the regulatory burden associated

with methadone and thereby make an effective treatment (i.e., opiate agonist therapy) more accessible and attractive to heroin users. This reflected the critical role of several professional organizations of physicians who fought to treat opiate addiction just as they treat other kinds of illness. This process should continue in the future as experience with buprenorphine treatment develops during the next few years. A federal advisory council set up to make recommendations regarding the pending approval of buprenorphine noted concern that the system established for buprenorphine treatment would be too complicated and bureaucratic;¹⁵⁶ they stated:

“[...] regulations for buprenorphine treatment should follow the usual procedures and standards used in treating any medical condition and should be kept as limited and non-restrictive as possible.” Moreover the regulatory requirements should safeguard patient confidentiality consistent with current law and standard medical practice and should not be “mandated in a way that identifies a patient as an addict to anyone who does not explicitly need that information for the care of the patient, or who does not have explicit consent for release of that information.”

The Federal Register¹⁵⁷ provides extensive documentation about comments received regarding regulations governing the prescription of buprenorphine for opiate addiction, and why decisions were made for such rescheduling. One such regulation limits the number of buprenorphine patients to 30 in a given physician or group practice; but this limit may possibly be increased by applying for a larger number from SAMHSA.¹⁵⁸ This 30-patient limit should also be reconsidered as experience with buprenorphine therapy occurs in the next few years.

Policy Challenge 42: Political leaders with power to make laws and agency administrators that issue regulations in state and local governments should not develop any laws/regulations about buprenorphine therapy that diminish access or reduce patient privacy; existing Federal regulations should be adopted at the state and local level.

As a Schedule III drug, buprenorphine can now be prescribed like any other prescription drugs (by authorized prescribers). Additional laws and regulations directed at buprenorphine providers and patients by state or local agencies or legislatures would undermine both the federal recommendations and interfere with doctor/patient relationships. Numerous additional regulations (such as those placed on methadone) will actually undermine the governmental purpose in approving buprenorphine. If widespread buprenorphine abuse and/or diversion subsequently occur, the federal government is well prepared to address the problem.

Buprenorphine Treatment Outside of New York City

This White Paper has appropriately focused upon this American city, with the absolute largest number of heroin users, and users in treatment. New York State and City government has historically been supportive of methadone maintenance treatment, and has created institutional arrangements (e.g. Sociomedics, Addiction Medical Unit at Rikers, and the KEEP program) for methadone treatment that are unique in American society. Elsewhere in the USA, heroin addiction is quite rare (with the exception of a few large cities) and local governments have generally opposed or not funded methadone treatment. Many heroin users or those dependent upon other opiates (e.g. morphine, Demerol, OxyContin, Percodan, Dilaudid) cannot not obtain any form of agonist treatment in their local community. Opposition from local politicians, health administrators, and community leaders often discourages physicians who may want to provide opiate treatment in a clinic or office setting. Indeed, such factors and a near total absence of information about whether and how many heroin/opiate users may be present in their local community means that few physicians will be interested in pursuing certification as buprenorphine prescribers.

In the future, however, physicians throughout America who become certified buprenorphine prescribers can provide opiate agonist treatment as part of their regular private or clinical practice (with a restriction on 30 buprenorphine patients). Since they will do so within the confidential and protected context of the physician-patient relationship, almost no one (other than the doctor's staff) are likely to know that a patient is a heroin user and being treated for that condition. Both the buprenorphine prescriber and patients will be insulated from the stigma and disapproval of local politicians, health officials, and the community. The primary advantage is that physicians can now begin treatment for heroin use that was not possible prior to 2003 in most communities. In many smaller communities (under 50,000 population), a couple of buprenorphine prescribers may be adequate for the entire community (depending upon the size of the heroin and opiate user network). Unlike the supportive and integrated environment for opiate treatment in New York City, certified physicians may become the only buprenorphine prescriber in a large area and have very limited or no access to appropriate counseling services, nor be able to refer highly problematic patients to other clinics or to physicians with more skills in addiction management. Indeed, physicians may need to conceal their subspeciality in addiction medicine from community leaders and other patients who might condemn his practice if it was discovered.

Policy Challenge 43: National professional associations of physicians and the expertise in addiction medicine developed in New York City and other large cities need to be made widely available to doctors in other locales.

These professional associations need to be proactively helpful in recruiting physicians, providing training and certification, fighting for funding in non-metropolitan areas, and extending buprenorphine treatment into communities where none currently exists. The decisions about financing buprenorphine and addiction treatment in large cities such as New York City, however, will likely directly benefit (and encourage) physicians in smaller communities to take the one day course and become buprenorphine prescribers and addiction medicine experts in their localities.

Evidence developing in the late 1990s and early 2000s suggests that a small proportion of white youths living in suburban and rural communities within 200 miles of New York City (and some within the City's outer boroughs) have among the higher rates of heroin use and injection and are regular participants in City's street heroin markets.¹⁵⁹ Even a single buprenorphine prescriber in a small city or rural area could have a major impact upon heroin use and addiction in that area.

Assume, for example, a county of 50,000 has 20 near daily heroin users and another 50 "weekend" users. Probably about half of the 20 near daily users are likely to "pool" their funds to buy heroin. They will have to trust 1-5 members to go into the "city" to make heroin purchases (where they must also avoid robbery and getting "beat"). The heroin purchased will be further adulterated and shared or resold so that most of the 70 heroin users in the county can purchase some for their own use.¹⁶⁰ If a local physician can identify and bring a sizable share of the 10 core heroin users into buprenorphine treatment, and if buprenorphine effectively blocks them from getting high, very few heroin users (probably none) that community would be willing to invest the time (many hours), risks (of robbery or buying "beat" heroin), and costs (transport plus drug costs) to make heroin purchases in the city. Effectively, the entire heroin supply network for that county could be put into a deep recession. Even if police arrest local heroin users for heroin selling and possession, referral to a buprenorphine prescriber will likely have a greater and a longer lasting impact on their heroin dependency than arrest and jail sentences.

CONCLUSION

The FDA approval of buprenorphine therapy as an office-based treatment has great potential in New York City. The goal of 100,000 or more persons receiving heroin treatment by year 2010 is achievable, which would more than double the number of heroin users currently in treatment. This is an important goal since prevalence studies show that up to 80% of heroin users are not currently in treatment. Beginning in 2003, however, an effective heroin treatment will be available, as well as more accessible and appealing to those who have avoided or delayed enrolling in opiate treatment. The introduction of buprenorphine into mainstream medicine portends many challenges that can be systematically addressed by public policy makers. Among the many challenges are assuring that buprenorphine treatment is affordable and competently delivered. Highly experienced addiction specialists and many related resources are available in New York City to address these challenges. Heroin users, like the general population, present diverse medical problems. Due to the comorbidities associated with the heroin-user lifestyle and the unique pharmacological properties of buprenorphine, physicians will need special training and ongoing support to address these issues. Physicians should be encouraged to participate in the training programs provided by professional organizations and be given fair reimbursement rates for their services. Policy should also assure that buprenorphine prescribers have linkages with other providers so that patients can receive specialized services (e.g., drug counseling, psychiatric assessment and treatment) or alternative medication (e.g., methadone), specialized health problems and related medication (for STD, TB, HIV/AIDS) as medically indicated.

Policy makers need to recognize that heroin addiction has a strong biological component. Many patients may require maintenance medication (Suboxone) for months or years. Because of the great harm that may occur if there were a hiatus in treatment, continuity of services and medication should be assured. Special efforts will be needed to recruit out-of-treatment heroin users and bring them to

local buprenorphine prescribers for assessment and stabilization. For patients who leave treatment and relapse to heroin use, outreach and reentry into treatment should be facilitated. Additional challenges include the establishment of a provider and patient database which does not violate confidentiality and the integration of research into practice settings. The dissemination of buprenorphine information to the public and the media will help prevent the “stigmatization” of this treatment as well as alert heroin users, their friends and family of its availability. With a public policy that is thoughtful, compassionate, ethical, and persistent, the New York treatment community can address these challenges.

Buprenorphine offers many potential benefits for society that will accrue when heroin users are no longer active. For young adults who have recently become addicted and those with less severe opiate dependence, entry into buprenorphine treatment will reduce the severity of addiction and greatly shorten their addiction careers. For the large number of current heroin sniffers, buprenorphine may be an option for detoxification (short-term or over several months) towards abstinence. Especially for the long-term, chronic heroin user who has entered and dropped out of several programs, buprenorphine will provide an ongoing therapy outside the segregated and often disliked contexts of methadone or residential programs. Especially if substantial numbers of persons selling heroin to support their addictions can be recruited and maintained, buprenorphine treatment would remove them as sellers; this would substantially lessen the availability of heroin in illicit drug markets. If 50,000-60,000 additional persons enter buprenorphine treatment, the frequency and intensity of their criminal activities will be reduced—probably leading to further decline in the City’s crime rates. Finally, buprenorphine treatment would relieve heroin users of the need to spend many hours a week raising funds and locating suppliers. Their time, labor inputs, and money could now be routinely invested in more conventional pursuits in the licit economy. *A substantial and prudent investment in buprenorphine treatment during 2003-2010 will have many long-term benefits for individual heroin users, their families, and for all residents of New York City.*

ENDNOTES

- ¹ Federal Register Oct. 7, 2002. This provides a detailed review of the scientific literature, comments from various parties about draft regulations, and the rationale for the Schedule III classification.
- ² Frank et al 1978; Frank 2001; see Section II.
- ³ Rettig and Yarmolinsky 1995; Stroller and Biglow 1999.
- ⁴ Federal Register 2002.
- ⁵ This section relies primarily upon major historical studies by: Musto 2002ab; Courtwright 2001, 2002; Courtwright, Joseph, Des Jarlais 1989; Johnson and Golub 2002. Also see Frank 2001.
- ⁶ Musto 2002a, b; Courtwright 2001, 2002.
- ⁷ DeLeon 2000.
- ⁸ Courtwright 2001, 2002. Kott et al 2001.
- ⁹ Joseph 2001; Joseph, Stancliff, Langrod 2001; Strain and Stitzer 1999.
- ¹⁰ Frank 2001; NYC DOHMH 2002; OASAS 2002.
- ¹¹ See many excellent articles in Joseph 2001; Joseph, Stancliff, Langrod 2001; NIH 1998; Novick and Joseph 1991.
- ¹² Ward et al., 1998; Magura et al., 1998.
- ¹³ Gerstein and Harwood 1990: 13-14. Also see Joseph, Appel, Schmeidler 1981.
- ¹⁴ Stimmel and Kreek 2001.
- ¹⁵ Rettig and Yarmolinsky 1995.
- ¹⁶ Goldsmith et al 1990. Hunt et al 1986; Rosenblum et al 1996.
- ¹⁷ Magura and Rosenblum 2001; Brown et al., 1974; Capelhorn et al., 1997; Capelhorn et al., 1996; Kang et al., 1997.
- ¹⁸ Walsh *et al.*, 1995; Huestis 2002; See Federal Register 2002 and SAMHSA 2002 website. For many sources of information.
- ¹⁹ McCance-Katz & Kosten, 1998.
- ²⁰ McCance-Katz, 1997; and Warner et al, 1997.
- ²¹ FDA document (<http://www.fda.gov/cder/foi/label/2002/20732lbl.pdf>).
- ²² Federal Register 2002.
- ²³ Robinson et al 1993; Tacke 2002.
- ²⁴ SAMHSA 2002 website. Physician Instructions.
- ²⁵ Federal Register 2002.
- ²⁶ Magura and Rosenblum 2001; Magura et al 1993, 1998; Wexler, Lipton, Johnson 1988; Ball & Ross, 1991.
- ²⁷ Ball & Ross, 1991
- ²⁸ See Rettig and Yarmolinsky 1995 for a history and recommended changes in methadone regulations.
- ²⁹ Stroller & Bigelow, 1999.
- ³⁰ Leshner 1999.
- ³¹ Kosten & George, 2002; Hser et al, 2001; National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, 1998; Leshner, 1999.
- ³² Barnett et al., 2001; West et al., 2000. Also see summaries in Federal Register 2002.
- ³³ Ling & Smith, 2002.
- ³⁴ Association of the Bar of the City of New York 1977. Johnson et al 1990, 2000; Johnson and Golub 2002.

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- ³⁵ Caulkins et al 1999; Johnson et al. 1985.
- ³⁶ Frank et al 1978; Frank 2001
- ³⁷ Johnson et al 1990, Johnson and Golub 2002.
- ³⁸ CEWG 2001; Frank 2001.
- ³⁹ Golub and Johnson 2003.
- ⁴⁰ New York City Department of Health and Mental Hygiene 2002 (Methadone programs in New York City).
Frank 2001.
- ⁴¹ Johnson et al 1985; Kott, Habel, Nottingham 2001.
- ⁴² Golub and Johnson 2003; Frank 2001.
- ⁴³ CEWG 2001; Frank 2001.
- ⁴⁴ Golub and Johnson 2003.
- ⁴⁵ Johnson, Thomas Golub 1998; Golub and Johnson 1999a, 2002, 2003; Johnson, Golub, Dunlap 2000.
- ⁴⁶ Golub and Johnson 2003.
- ⁴⁷ Sifaneck and Neaigus 2002; Johnson, Golub, Dunlap 2000.
- ⁴⁸ Frank 2001; Sifaneck and Neaigus 2002.
- ⁴⁹ Wexler, Lipton, Johnson 1988. Gerstein and Harwood 1990, 1992.
- ⁵⁰ Ball and Ross. 1991; Magura and Rosenblum, 2001.
- ⁵¹ Johnson et al. 1985; Frank 2001; OASAS 2002.
- ⁵² Cross et al 2001; Johnson et al 1985.
- ⁵³ Davis et al 2003.
- ⁵⁴ Golub et al 2002.
- ⁵⁵ SAMSHA web site. 2002.
- ⁵⁶ Golub and Johnson 2003.
- ⁵⁷ Golub and Johnson 2003.
- ⁵⁸ Frank 2001; Sifaneck and Neaigus 2001.
- ⁵⁹ Frank 2001; Golub and Johnson 2003.
- ⁶⁰ Comer, Collins, Fischman 2002; Robinson et al 1993.
- ⁶¹ Sifaneck and Neaigus 2002; Golub and Johnson 2003.
- ⁶² Cross et al 2001; Golub and Johnson 2003.
- ⁶³ Johnson et al 1985; Johnson and Golub 2002.
- ⁶⁴ Ball and Ross 1995; Gerstein et al 2002.
- ⁶⁵ Capelhorn 1994; Capelhorn et al 1996, 1997; Fiellin et al 2002.
- ⁶⁶ This is consistent with recommendations associated with improving methadone treatment (Rettig and Yarmolinsky 1995).
- ⁶⁷ Assuming that the primary care physician (PCP) can provide effective buprenorphine therapy to an average of 10 heroin or opiate users annually, an additional 6,000 PCPs would be need to be certified as buprenorphine prescribers.
- ⁶⁸ Extensive literature and materials have already been developed by NIDA, SAMHSA, and OASAS.
- ⁶⁹ American Academy of Addiction Psychiatry, American Medical Association, American Osteopathic Association, American Psychiatric Association. As of September 2002, at least 700 physicians nation-wide have taken the ASAM qualifying course for buprenorphine (Lloyd Sederer, Personal communication, October 15, 2002); 200 in NYS (Herman Joseph, Personal Communication, October 15, 2002).
- ⁷⁰ <http://www.aaap.org/buprenorphine/buprenorphine.html> and <http://www.psych.org/cme/apacme>

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- ⁷¹ SAMHSA 2002 website: <http://buprenorphine.samhsa.gov/Curriculum.html>
- ⁷² Karam-Hage, et al., 2001.
- ⁷³ Gilbert et al 2001; Gourevitch and Friedland 2001.
- ⁷⁴ Ward et al., 1992, 1998.
- ⁷⁵ Vlahov et al 2003; Myers et al, 1998.
- ⁷⁶ Farrell, et al., 1996.
- ⁷⁷ Sheridan, et al., 1996; Metrebian et al 2002.
- ⁷⁸ Schwatz & Tommasello 1997.
- ⁷⁹ Raisch et al, 2002.
- ⁸⁰ Weinrich & Sturt, 2000.
- ⁸¹ Matheson, Bond & Pitcarin, 2002.
- ⁸² Matheson, Bond & Pitcarin, 2002.
- ⁸³ Rosenheck and Kosten 2001
- ⁸⁴ A National Academy of Medicine report (Rettig and Yarmolinsky 1995: 31) “recommends that provisions of drug treatment benefits, including deductibles, copayments, stop-loss measures, and scheduled caps, be similar to provisions for treatment of other chronic relapsing health problems.”
- ⁸⁵ See Rettig and Yarmolinsky (1995: 266-272) about Medicaid financing of drug treatment services. New York State (especially the City) finances about a quarter of its drug treatment costs (all modalities) from third party payers (mainly Medicaid); New York State received about 42% of all third party payer funding in the nation in 1987. The figures are probably similar for 2002.
- ⁶³ Rettig and Yarmolinsky (1995: 273-297) make similar recommendations about private coverage for drug treatment.
- ⁸⁷ Johnson et al 1985; Cross et al 1985; Kott et al 2001; Preble and Casey 1969.
- ⁸⁸ Gilbert et al 2001; Hagan and Des Jarlais 2001.
- ⁸⁹ Gerstein and Harwood 1990: 200-219.
- ⁹⁰ Gonzalez, et al. 2002.
- ⁹¹ Auriancombe et al., 2001.
- ⁹² Obadia et al., 2001.
- ⁹³ Tacke, 2002.
- ⁹⁴ Federal Register, 2002..
- ⁹⁵ Biggs, et al., 2001; Lintzeris et al 2001.
- ⁹⁶ Federal Register, 2002.. Robinson et al 1993.
- ⁹⁷ Ahmadi 2002; Robinson et al 1993; Lintzeris et al 2001.
- ⁹⁸ Kang et al., 1997; Capelhorn et al., 1997; Hunt et al 1986; Goldsmith et al 1984.
- ⁹⁹ Magura and Rosenblum, 2001; Joseph, Appel, Schmeidler 1981.
- ¹⁰⁰ Zanis and Woody 1998; Joseph, Stancliff, Langrod 2001.
- ¹⁰¹ Banys, et al., 1994.
- ¹⁰² Hunt et al., 1986; Goldsmith et al, 1984; Beschner and Walters, 1985; Preble and Casey, 1969; Rosenblum et al., 1991.
- ¹⁰³ Joseph, Stancliff, Langrod 2001.
- ¹⁰⁴ Galanter et al., 2000.
- ¹⁰⁵ Ibid.
- ¹⁰⁶ McLellan et al 2000.
- ¹⁰⁷ Mark et al 2001.

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- ¹⁰⁸ No drug free program has yet indicated an interest in buprenorphine therapy.
- ¹⁰⁹ Division of Substance Abuse Services. 1989; Frank 2001.
- ¹¹⁰ Federal Register 2002.
- ¹¹¹ Schottenfeld et al 1997.
- ¹¹² See policy challenge 25.
- ¹¹³ Many drug programs have similar induction units. Large methadone programs have induction clinics, and many drug free programs require heroin users to complete a detoxification regime before entry.
- ¹¹⁴ ASAM 2002 website.
- ¹¹⁵ Curely, 2002; Federal Register, 2002..
- ¹¹⁶ Fiellin et al., 2001; Novick and Joseph, 1991; Novick et al 1994; Salsitz, Joseph, Frank 2001; Senay et. al., 1994; Schwartz and Tommasello 1997.
- ¹¹⁷ Rettig and Yarmolinsky 1995; NIH (National Institutes of Health) Consensus Conference. 1998.
- ¹¹⁸ Salitz et al 2001.
- ¹¹⁹ Gilbert et al 2001; Gourevitch and Friedland 2001; Hagan and Des Jarlais 2001.
- ¹²⁰ Mattick and Wall, 1996.
- ¹²¹ Gowing, Ali, White 2002.
- ¹²² Fallon, 2001; Magura et al, 1993; Tomasino et al., 2001.
- ¹²³ Stacey Lamon, Personal Communication, NYC Department of Health and Mental Hygiene, January 2, 2003.
- ¹²⁴ Tomasino et al., 2001
- ¹²⁵ Johnson et al. 1985; Gilbert et al 2001; Hser et al 2001.
- ¹²⁶ Johnson, Golub, Durrah. 2000.
- ¹²⁷ Frank 2001: 344 reports that 24% of NY State heroin abusers were estimated to be currently in treatment.
- ¹²⁸ DeLeon 2000; Beschner and Walters 1985; Hunt et al.1986.
- ¹²⁹ Such drug users have been described as having low readiness for treatment; Joe Simpson, Broome 1998; DeLeon 2000.
- ¹³⁰ Lamb, Greenlick, McCarty 1998; Strain and Stitzer 1999; Tomasino et al 2001; Wexler, Lipton, Johnson 1988;
- ¹³¹ Hubbard et al 1989; Gerstein et al 1990, 1992; Golub and Johnson 1999b.
- ¹³² Schottenfeld et al 1997.
- ¹³³ SAMHSA 2002 website, Physician Information on buprenorphine.
- ¹³⁴ Robinson et al 1993.
- ¹³⁵ Cross et al 2001.
- ¹³⁶ Hubbard et al 1989; Gerstein et al 1990, 1992; Joseph, Stancliff, Langrod 2001.
- ¹³⁷ Joseph and Appel 1985; Joseph, Appel, Schmeidler 1981; Hagan and Des Jarlais 2001; Kott, Habel, Nottingham 2001. Magura and Rosenblum 2001; Milby 1988; Zanis and Woody 1998.
- ¹³⁸ Strain and Stitzer 1999; Hagan and Des Jarlais 2001; Kott, Habel, Nottingham 2001; Zanis and Woody 1998.
- ¹³⁹ See interactions of agonist drugs with AIDS medications, McCance-Katz et al 1998, 2000; McCance-Katz and Kosten 1998.
- ¹⁴⁰ Fingerhood 1999.
- ¹⁴¹ Rosenblum et al., 1999.
- ¹⁴² Strain and Stitzer 1999; Warner, Kosten, O'Conner 1997.
- ¹⁴³ Stimmel and Kreek 2001.
- ¹⁴⁴ Scimeca, et al., 2000.
- ¹⁴⁵ McNicholas & Howell, 2000.

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- ¹⁴⁶ Schottenfeld et al 1997.
- ¹⁴⁷ Johnson, Jones, Fischer 2003.
- ¹⁴⁸ Gilbert et al 2001.
- ¹⁴⁹ Kintz, 2001; Kintz and Marquet 2002; Joseph 2002.
- ¹⁵⁰ Rosenheck & Kosten, 2002
- ¹⁵¹ Fiellin DA, et al, 2002.
- ¹⁵² Rosenblum et al, 1991.
- ¹⁵³ Hunt et al., 1986; Goldsmith et al, 1984.
- ¹⁵⁴ Beschner and Walters, 1985; Preble and Casey, 1969.
- ¹⁵⁵ Stroller & Bigelow, 1999; Rettig and Yarmolinsky 1995.
- ¹⁵⁶ DHHS 2002.
- ¹⁵⁷ Federal Register 2002.
- ¹⁵⁸ Federal Register 2002; SAMHSA 2002 Website. Physician Information.
- ¹⁵⁹ Golub and Johnson 2003; Frank 2001; Sifaneck and Neaigus 2001.
- ¹⁶⁰ These estimates are based on prevalence and ethnographic studies, Golub and Johnson 2003, Johnson and Golub 2002; Johnson et al 1985.

LITERATURE CITED

- Ahmadi, J. 2002. Randomized, clinical trial of buprenorphine maintenance treatment for Iranian patients with opioid dependency. Addictive Disorders and Their Treatment 1(1): 25-27.
- American Association of Addiction Psychiatry. 2002. Web-based buprenorphine training at [/www.aaap.org/buprenorphine/buprenorphine.html](http://www.aaap.org/buprenorphine/buprenorphine.html)
- American Psychiatric Association. 2002. Web-based buprenorphine training at www.psych.org/cme/apacme/
- American Society of Addiction Medicine. 2002. Website <http://www.asam.org>.
- Association of the Bar of the City of New York. 1977. The Nation's Toughest Drug Law: Evaluating the New York Experience: Final Report of the Joint Committee on New York Drug Law Evaluation. New York.
- Auriacombe M, Franques P, Tignol J. 2001. Deaths attributable to methadone vs. buprenorphine in France [letter]. Journal of American Medical Association 285, 45.
- Ball JC, Ross A. 1991. The Effectiveness Of Methadone Treatment. New York: Springer-Verlag.
- Barnett PG, Hui S. 2001. The cost-effectiveness of methadone maintenance. The Mount Sinai Journal of Medicine 67 (5&6): 365-374.
- Barnett PG, Rodgers JF, Bloch DA. 2001. A meta-analysis comparing buprenorphine to methadone for treatment of opiate dependence. Addiction 96: 683-90.
- Beschner G, Walters JM. 1985. Just another habit? The heroin user's perspective on treatment. In: Hanson, B.; Beschner, G.; Walters, J.M.; & Bovelle, E. (Eds) Life with Heroin: Voices from the Inner City. Lexington, Massachusetts: Lexington Books.
- Banys P, Tusel DJ, Sees KL, Reilly PM, Delucchi KL. 1994. Low (40 mg) versus high (80 mg) dose methadone in a 180-day heroin detoxification program. Journal of Substance Abuse Treatment 11(3):225-32.
- Biggs AL, Dorlego B, Gill T, Larkins K, Moyle K, Murray T, Perrin J, Quiqley A, Rysavy P, Sunjic S, Wilson C, Richards I. 2001. National Buprenorphine Policy. Canberra, AU: Commonwealth of Australia.
- Brown BS, Jansen DR, Bass UF. 1974. Staff attitudes and conflict regarding the use of methadone in the treatment of heroin addiction. American Journal of Psychiatry 131(2):215 – 218.
- Capelhorn JRM. 1994. A comparison of abstinence-oriented and indefinite methadone maintenance treatment. International Journal of Addictions 29(11):1361 – 1375.
- Capelhorn JRM, Hartel DM, Irwig L. 1997. Measuring and comparing the attitudes and beliefs of staff working in New York methadone maintenance clinics. Substance Use and Misuse 32(4):399 – 413.
- Capelhorn JRM, Irwig L, Saunders JB. 1996. Attitudes and beliefs of staff working in methadone maintenance clinics. Substance Use and Misuse 31(4):437 – 452.
- Caulkins JP, Satel S. 1999. Methadone patients should not be allowed to persist in cocaine use. Drug Policy Analysis Bulletin 6:1–6.

-
- Caulkins JP, Johnson BD, Taylor A, Taylor L. 1999. What drug dealers tell us about their costs of doing business. Journal of Drug Issues 29(2): 323-340.
- Comer SD, Collins ED, Fischman MW. 2002. Intravenous Buprenorphine Self-Administration by Detoxified Heroin Abusers. JPET. 301:1-11.
- Community Epidemiology Working Group (CEWG). 2001. Epidemiologic Trends in drug Abuse: Advance Report. Washington, DC: National Institute on Drug Abuse. (June).
- Courtwright DT. 2002. The Road to H: The emergence of the American Heroin Complex, 1898-1956. Pp. 4-19 in: Musto D. (Ed). 2002. One Hundred Years of Heroin. Westport, CT: Auburn House.
- Courtwright DT. 2001. Dark Paradise: A History of Opiate Addiction in America. Cambridge, MA: Harvard University Press.
- Courtwright DT, Joseph H, Des Jarlais DD. 1989. Addicts Who Survived: An Oral History of Narcotic Use in America, 1923-1965. Knoxville, TN: University of Tennessee Press.
- Cross J, Johnson BD, Davis, WR, Liberty H. 2001. Supporting the habit: Income generation activities of frequent crack users compared with frequent users of other hard drugs. Drug and Alcohol Dependence 64 (2): 191-201.
- Comer SD, Collins ED, Fischman MW. 2002. Intravenous buprenorphine self-administration by detoxified heroin abusers. Journal of Pharmacology and Experimental Therapeutics 301:1-11.
- Curley, B. FDA Approves Two Forms of Buprenorphine for Opiate Treatment. October 9, 2002. <http://www.jointogether.org/sa/news/features/reader/0%2C1854%2C554695%2C00.html>.
- Davis, W.R., Johnson, B.D., Liberty, H. & Randolph, D. 2002. Characteristics of very hidden hard drug users and sellers in Central Harlem. [in review].
- DeLeon, G. 2000. The Therapeutic Community: Theory, Model, Method. New York: Springer.
- DHHS Division of Health and Human Services 2002. Using Buprenorphine for Office-Based Treatment of Opiate Addiction. http://www.samhsa.gov/centers/csat/content/dpt/using_buprenorphine.htm;
- Division of Substance Abuse Services (DSAS). 1989. Program statistics. Albany, New York: Office of Alcoholism and Substance Abuse Services (OASAS).
- Fallon BM. 2001. The Key Extended Entry Program (KEEP): From the community side of the bridge. The Mount Sinai Journal of Medicine 68(1): 21-27.
- Farrell M., Neeleman J, Gossop M., Griffiths P., Buning E., Finch E., Strang J. 1996. The legislation, organisation and delivery of methadone in 12 EU member states. Brussels European Commission.
- Federal Register. Oct. 7, 2002. CFR part 1308 [DEA 225-F]. Rescheduling of Buprenorphine from Schedule V to Schedule III. 67(194): 62354-70.
- FDA document (<http://www.fda.gov/cder/foi/label/2002/20732lbl.pdf>).
- Fiellin, DA, O'Connor, PG, Chawarski, M, Pakes, JP, Pantalon, MV, Schottenfeld, RS. 2001. Methadone Maintenance in Primary Care: A Randomized Controlled Trial. Journal of American Medical Association. 286:1724-1731.
- Fiellin DA, Pantalon MV, Pakes JP, O'Connor PG, Chawarski M, Schottenfeld RS. 2002. Treatment of heroin dependence with buprenorphine in primary care. American Journal of Drug and Alcohol

-
- Abuse 28(2):231-41.
- Fingerhood MI. 1999. Comorbid medical disorders. Pp 118-140 in: Strain EC, Stitzer ML (Eds). Methadone Treatment for Opioid Dependence. Baltimore: The Johns Hopkins University Press.
- Frank B. 2001. An overview of heroin trends in New York City. The Mount Sinai Journal of Medicine 67 (5&6): 340-346.
- Frank B, Schmeidler J, Johnson BD, Lipton DS. 1978. Seeking truth in heroin indicators: The case of New York City. Drug and Alcohol Dependence 3(5): 345-358.
- Galanter M, Keller DS, Dermatis H, Egelko S. 2000. The impact of managed care on substance abuse treatment: A report of the American Society of Addiction Medicine. Journal of Addictive Diseases 19(3):13-34.
- Gerstein DR, Harwood HJ. (Eds). 1990. Treating Drug Problems: A Study of the Evolution, Effectiveness, and Financing of Public and Private Drug Treatment Systems. Vol. I. Washington, DC: National Academy Press.
- Gerstein DR, Harwood HJ.(Eds). 1992. Treating Drug Problems: Commissioned Papers on Historical, Institutional, and Economic Contexts of Drug Treatment. Vol. II. Washington, DC: National Academy Press.
- Gilbert L, El-Bassel N, Rajah V, et al. 2001. The converging epidemics of mood-altering drug use, HIV, HCV, and Partner Violence: A conundrum for methadone maintenance treatment. Mount Sinai Journal of Medicine 67:(5&6):452 – 463.
- Goldsmith DS, Hunt DE, Lipton DS, Strug DL. 1984. Methadone folklore: Beliefs about side effects and their impact on treatment. Human Organization (43):330 – 340.
- Golub A, Johnson BD. 1999a. Coerced treatment for drug abusing offenders: A referral device for use in New York City. International Journal of Public Administration 22(2): 187-215.
- Golub A, Johnson BD. 1999b. Cohort changes in illegal drug use among arrestees in Manhattan: From the heroin injection generation to the blunted generation. Substance Use and Misuse 34(13): 1733-1763.
- Golub A, Johnson BD. 2002. Substance use progression and hard drug abuse in inner-city New York. Pp. 90-112 in Kandel, Denise. B. (ed.) Stages and Pathways of Involvement in Drug Use: Examining the Gateway Hypothesis. New York: Cambridge University Press.
- Golub A, Johnson BD. 2003. The new heroin users among Manhattan Arrestees: Variations by race/ethnicity and mode of consumption. [in review].
- Golub A, Johnson BD, Taylor A, Liberty H. 2002. The validity of arrestee self-reports: Variations across questions and persons. Criminal Justice 19(3): 477-502.
- Gonzalez G, Oliveto A, Kosten TR. 2002. Treatment of heroin (diamorphine) addiction: Current approaches and future prospects. Drugs 62(9):1331-43.
- Gourevitch MN, Friedland, GH. 2001. Interactions between methadone and medications used to treat HIV infection. Mount Sinai Journal of Medicine 67:(5&6):429 – 436.
- Gowing L, Ali R, White J. 2002. Buprenorphine for the management of opioids withdrawal. Cochrane Database Systems Review (2)

-
- Hagan H, Des Jarlais DD. 2001. HIV and HCV infection among injecting drug users. Mount Sinai Journal of Medicine 67:(5&6):423 – 428.
- Hser YI, Hoffman V, Grella CE, Anglin MD. 2001. A 33-year follow-up of narcotics addicts. Archives of General Psychiatry 58(5):503-8.
- Huestis MA. 2002. Controlled drug administration studies of high dose buprenorphine in humans. Pp. 13-27 in Kintz P, Marquet P. Buprenorphine Therapy of Opiate Addiction. Totowa, NJ: Humana Press.
- Hubbard RL, Marsden ME, Rachal JV, et al. 1989. Drug Abuse Treatment: A National Study of Effectiveness. Chapel Hill (NC):University of North Carolina Press.
- Hunt DE, Lipton DL, Goldsmith DS, Strug DL, Spunt B. 1986. It takes your heart: The image of methadone maintenance in the addict world and its effect on recruitment into treatment. International Journal of the Addictions 20(11 & 12): 1751-1771.
- Joe GW, Simpson DD, Broome KM. 1998. Effects of readiness for drug abuse treatment on client retention and assessment of process. Addiction 93(8):1177 – 1190.
- Johnson BD, Goldstein PJ, Preble E, Schmeidler J, Lipton DS, Spunt B, Miller T. 1985. Taking Care of Business: The Economics of Crime by Heroin Abusers. Lexington, MA: Lexington Books.
- Johnson BD, Golub AL. 2002. Generational trends in heroin use and injection in New York City. Pp 90-128 in: Musto D. (Ed). One Hundred Years of Heroin. Westport, CT: Auburn House.
- Johnson BD, Golub A, Dunlap E. 2000. The rise and decline of drugs, drug markets, and violence in New York City. Pp. 164-206 in: Blumstein A, Wallman J (Eds) The Crime Drop in America, New York: Cambridge University Press.
- Johnson BD, Golub A, Durrah T. 2000. (manuscript). Heroin use, methadone, and heroin treatment among ADAM-Manhattan Arrestees. Occasional Report #1 ADAM-NYC Program. New York: National Development and Research Institutes, Inc.
- Johnson BD, Thomas G, Golub AL. 1998. Trends in heroin use among Manhattan arrestees from the heroin and crack eras. Pp. 109-130 in: JA Inciardi, LD Harrison (Eds) Heroin in the Age of Crack Cocaine, Thousand Oaks, CA: Sage.
- Johnson B, Williams T, Dei K, Sanabria H. 1990. Drug abuse and the inner city: Impact on hard drug users and the community. Pp. 9-67 in M Tonry and JQ Wilson (Eds.) Drugs and Crime. Chicago: University of Chicago Press. Crime and Justice Series, V. 13.
- Johnson RE, Jones HE, Fischer G. 2003. Use of buprenorphine in pregnancy: Patient management and effects on the neonate. Drug and Alcohol Dependence [in press].
- Johnson RE, Strain EC. 1999. Other medications for opioid dependence Pp. 281-321 in: Strain EC, Stitzer ML (Eds) Methadone Treatment for Opioid Dependence Baltimore: The Johns Hopkins University Press.
- Joseph H. (Ed). 2001. Methadone Maintenance. The Mount Sinai Journal of Medicine 67 (5&6) entire journal.
- Joseph H, Stancliff S, Langrod J. 2001. Methadone maintenance treatment (MMT): A review of historical and clinical issues. The Mount Sinai Journal of Medicine 67 (5&6): 347-364.

-
- Joseph H, Appel P. 1985. Alcoholism and methadone treatment: Consequences for the patient and program. American Journal of Drug and Alcohol Abuse 11(1&2):37 – 53.
- Joseph H, Appel P, Schmeidler J. 1981. Deaths during and after discharge from methadone maintenance treatment. Albany (NY): New York State Office of Alcoholism and Substance Abuse Services. Outcome Study Report #18.
- Kang SY, Magura S, Nwakeze P, Demsky S. 1997. Counselor attitudes in methadone maintenance. Journal on Maintenance Addiction 1(2):41 – 58.
- Karam-Hage M, Nerenberg L, Brower KJ. 2001. Modifying residents' professional attitudes about substance abuse treatment and training. American Journal on Addiction 10(1):40-7.
- Kintz P. 2001. Deaths involving buprenorphine: a compendium of French cases. Forensic Science International 121(1-2):65-69.
- Kintz P, Marquet P. 2002. Buprenorphine Therapy of Opiate Addiction. Totowa, NJ: Humana Press.
- Kosten TR, George TP. 2002. The neurobiology of opioid dependence: Implications for treatment. Science and Practice Perspectives 1(1):13-20. National Institute on Drug Abuse.
- Kott A, Habel E, Nottingham W. 2001. Analysis of behavioral patterns in five cohorts of patients retained in methadone maintenance programs. Mount Sinai Journal of Medicine 68(1):46 – 54.
- Lamb S, Greenlick MR, McCarty D. (Eds). 1998. Bridging the Gap between Practice and Research: Forging Partnerships with Community-Based Drug and Alcohol Treatment. Washington, DC: National Academy Press.
- Leshner A. 1999. Science-based views of drug addiction and its treatment. Journal of American Medical Association 282, 1314-1316.
- Ling W, Smith D. 2002. Buprenorphine: blending practice and research. Journal of Substance Abuse Treatment 23: 87-92.
- Lintzeris N, Clark N, Muhleisen P, Ritter A et al 2001. National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence. Sydney: Australia.
- Magura S, Rosenblum A. 2001. Leaving methadone treatment: Lessons learned, lessons forgotten, lessons ignored. The Mount Sinai Journal of Medicine 68(1): 62-74.
- Magura S, Kang SY, Nwakeze P, Demsky S. 1998. Temporal patterns of heroin and cocaine use among methadone patients. Substance Use and Misuse 33(12): 2441 – 2467.
- Magura S, Rosenblum A, Lewis C, Joseph H. 1993. The effectiveness of in-jail methadone maintenance. Journal of Drug Issues 23,75-99.
- Mark, TL, Woody, GE, Juday, T, Kleber, HD. 2001. The economic costs of heroin addiction in the United States. Drug and Alcohol Dependence 61:1-10.
- Matheson C, Bond CM, Pitcairn J. 2002. Community pharmacy services for drug misusers in Scotland: What difference does 5 years make? Addiction. 97(11):1405-11
- Mattick RP and Wall W. Are detoxification programmes effective? Lancet 1996, 347, 97-100.

-
- McCance EF. 1997. Overview of potential treatment medications for cocaine dependence. Pp.175: 36-72 in: Tai, B., Chiang, N., & Bridge, P. Medication Development for the Treatment of Cocaine Dependence: Issues in Clinical Efficacy Trial. Washington, DC: NIDA Research Monograph Series.
- McCance-Katz EF, Kosten TR. 1998. Psychopharmacological treatments. Pp. 596-624 in: R.J. Frances & S.I. Miller (Eds) Clinical Textbook of Addictive Disorders, 2nd Edition, Guilford Publications: New York.
- McCance-Katz EF, Farber S, et al. 2000. Decrease in methadone levels with nelfinavir mesylate. American Journal of Psychiatry 157(3): 481.
- McCance-Katz EF, Rainey PM, et al. 1998. Methadone effects on zidovudine disposition (AIDS Clinical Trials Group 262). Journal of Acquired Immune Deficiency Syndrome Human Retrovirology 18(5): 435-43.
- McLellan AT, Lewis DC, O'Brien CP, Kleber HD. 2000. Drug Dependence, a Chronic Medical Illness. Journal of American Medical Association. 284:1689-1695.
- McNicholas NL, Howell EF. 2000. Buprenorphine Clinical Practice Guidelines: Field Review Draft; Submitted to CSAT.
- Metrebian N, Carnworth T, Stimson GV, Storz T. 2002. Survey of doctors prescribing diamorphine (heroin) to opiate-dependent drug users in the United Kingdom. Addiction 97: 1155-1161.
- Milby JB. 1988. Methadone maintenance to abstinence. How many make it? Journal of Nervous Mental Disorders 176(7):409 – 422.
- Musto D. (Ed). 2002a. One Hundred Years of Heroin. Westport, CT: Auburn House.
- Musto D. 2002b. The American Disease: Origins of Narcotic Control. New York: Oxford University Press. (3rd Edition).
- Myers T, Cockerill R, Worthington C, Millson M, Rankin J. 1998. Community pharmacist perspectives on HIV/AIDS and interventions for injection drug users in Canada. AIDS Care. 10 (6):689-700.
- National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction. 1998. Effective Medical Treatment of Opiate Addiction. Journal of American Medical Association 280: 1936-43.
- New York City Department of Health and Mental Hygiene. 2002. (List of Methadone programs in New York City).
- Novick DM, Joseph H. 1991. Medical maintenance: The treatment of chronic opiate dependence in general medical practice. Journal of Substance Abuse Treatment 8(4):233.
- Novick, DM, Joseph, H, Salsitz, EA, et. al. 1994. Outcomes of treatment of socially rehabilitated methadone maintained patients in physicians' offices: Follow up at 3½ to 9¼ years. Journal General Internal Medicine 9:127-130.
- Office of Alcoholism and Substance Abuse Services (OASAS). 2002. Methadone treatment system in New York State. New York (Single State Agency) [presentation].
- Obadia Y, Perrin V, Feroni I, Vlahov D, Moatti JP. 2001. Injecting misuse of buprenorphine among French drug users. Addiction 96: 267-272.

-
- Preble E, Casey J. 1969. Taking care of business: The heroin user's life on the street. International Journal of Addiction 4:1-24.
- Raisch DW, Fye CL, Boardman KD, Sather MR. 2002. Opioid dependence treatment, including buprenorphine/naloxone. Annals of Pharmacotherapy 36(2):312-21.
- Rettig RA, Yarmolinsky A. (Eds.) 1995. Federal Regulation of Methadone Treatment. Washington, DC: National Academy Press.
- Robinson GM, Dukes PD, Robinson BJ, Cooke RR, Mahoney GN. 1993. The misuse of buprenorphine and a buprenorphine-naloxone combination in Wellington, New Zealand. Drug and Alcohol Dependence 33: 81-86.
- Rosenblum A, Foote J, Magura S, Sturiano V, Xu N, Stimmel B. 1996. Follow-up of inpatient cocaine withdrawal for cocaine-using methadone patients. Journal of Substance Abuse Treatment 13(6): 467-470.
- Rosenblum A, Fallon B, Magura S, Handelsman L, Foote J, Bernstein D. 1999. The autonomy of mood disorders among cocaine-using methadone patients. The American Journal of Drug and Alcohol Abuse 25 (1), 67-80.
- Rosenblum A, Magura S, Joseph H. 1991. Ambivalence toward methadone treatment among Intravenous Drug Users. Journal of Psychoactive Drugs 23 (1):21-27.
- Rosenheck R, Kosten T. 2001. Buprenorphine for opiate addiction: Potential economic impact. Drug and Alcohol Dependence 63, 253-262.
- Salsitz EA, Joseph H, Frank B, et al. 2000. Methadone medical maintenance (MMM): Treating chronic opioid dependence in private medical practice — a summary report. The Mount Sinai Journal of Medicine 67, 388-397.
- SAMHSA websites 2002. www.buprenorphine.samhsa.gov or to the FDA website Also [For patient handouts and physician information on prescribing buprenorphine products.] For extensive information about buprenorphine .
- Schottenfeld, RS, Pakes, JR, Oliveto, A, Ziedonis, D, Kosten, TR. 1997. Buprenorphine vs. methadone maintenance treatment of concurrent opioid dependence and cocaine abuse. Archives of General Psychiatry 54:713-720.
- Schwartz RP, Tommasello AC. 1997. A medical maintenance in methadone care: A clinical pharmacy practice opportunity. Journal of Pharmacy Practice (X) 5: 346-351.
- Scimeca MM, Savage SR, Portenoy R, Lowinson J. 2000. Treatment of pain in methadone-maintained patients. Mount Sinai Journal of Medicine 67:(5&6):412 – 422.
- Senay E, Barthwell A, Marks R, Bokos PJ. 1994. Medical maintenance: An interim report. Pp. 65-69 in: Magura S, Rosenblum A (Eds). Experimental Therapeutics in Addiction Medicine, New York: Haworth.
- Sifaneck SJ, Neaigus A. 2001. Accessing, sampling, and screening hidden populations: heroin sniffers in New York City. Addiction Research and Theory 9(6):519-543.
- Sheridan J, Strang J, Barber N, and Glanz A. 1996. Role of community pharmacies in relation to HIV prevention and drug misuse: findings from the 1995 national survey in England and Wales. British Medical Journal 313 (7052), 272-4.

-
- Stimmel B, Kreek MJ. 2001. Neurobiology of addictive behaviors and its relationship to methadone maintenance. The Mount Sinai Journal of Medicine 67, 375-380.
- Stoller KB, Bigelow GE. 1999. Regulatory, cost, and policy issues. Pp 15-37 in: Strain EC, Stitzer ML (Eds) Methadone Treatment for Opioid Dependence. Baltimore: The Johns Hopkins University Press.
- Strain EC, Stitzer ML (Eds) 1999. Methadone Treatment for Opioid Dependence. Baltimore: The Johns Hopkins University Press.
- Tacke U. 2002. Abuse of buprenorphine by intravenous injection – The French connection [Letter] Addiction 97: 135A5.
- Tomasino V, Swanson AJ, Nolan J, Shuman HI. 2001 The Key Extended Entry Program: A methadone treatment program for opiate-dependent inmates. The Mount Sinai Journal of Medicine 68(1):14-20.
- Vlahov David et al. 2003. Evaluation of the Expanded Syringe Access Program in New York. Report to the New York State Legislature. New York: New York Academy of Medicine.
- Walsh SL, June HL, Schuh KJ, Preston KL, Bigelow GE, Stitzer ML. 1995. Effects of buprenorphine and methadone in methadone-maintained subjects. Psychopharmacology. 119(3):268-76.
- Ward J, Mattick RP, Hall W. 1998. Methadone Maintenance Treatment and Other Opioid Replacement Therapies. The Netherlands: Harwood.
- Ward J, Mattick R, Hall W. 1992. Methadone Maintenance Treatment, National Drug and Alcohol Research Center. Kensington, Australia: New South Wales University Press.
- Warner EA, Kosten TR, O'Conner PG. 1997. Pharmacotherapy for opioid and cocaine abuse. Alcohol and Other Substance Abuse 81(4): 909-925.
- Weinrich M, Stuart M. 2000. Provision of methadone treatment in primary care medical practices: Review of the Scottish experience and implications for US policy. Journal of American Medical Association. 283(10):1343-8.
- West SL, O'Neal KK, Graham CW. (2000). A meta-analysis comparing the effectiveness of buprenorphine and methadone. J Subst Abuse. 12(4):405-14.
- Wexler HK, Lipton DS, Johnson BD. 1988. A Criminal Justice Strategy for Treating Cocaine-Heroin Abusing Offenders in Custody. Issues and Practices. Washington, D.C.: National Institute of Justice.
- Zanis DA, Woody GE. 1998. One-year mortality rates following methadone treatment discharge. Drug and Alcohol Dependence 52, 257 – 260.