

States' Perspective on Buprenorphine and Office-Based Treatment

*Prepared by The National Association of State Alcohol and Drug Abuse Directors (NASADAD)
For The Center of Substance Abuse Treatment (CSAT)
Under Cooperative Agreement No. 6 UD1 TI 01-011*

*July 2002
Washington, D.C.*

The National Association of State Alcohol and Drug Abuse Directors, Inc. (NASADAD) received a request from the Center for Substance Abuse Treatment (CSAT) to collect State input on the issues surrounding the approval of buprenorphine and its rollout in the States. A State Buprenorphine Focus Group was formed and convened on July 8th, 2002 from the membership of the NASADAD Treatment Committee and their proxies to identify those issues. This task is being completed under the CSAT Cooperative Agreement with NASADAD. A synthesis of the information in this report will be presented at CSAT's Buprenorphine Stakeholders Meeting on July 26th, 2002 sponsored by CSAT's Office of Pharmacological and Alternative Treatment (OPAT). The intent of this activity was to inform other stakeholders of the perspective of State AOD agencies and to provide guidance to CSAT as to the nature of technical assistance that may be desired by the States. Melanie Whitter, chair of NASADAD's Treatment Committee, stated that the Committee adopted buprenorphine and other treatment medications as a priority issue. The Treatment Committee is finalizing a treatment medications paper that addresses current substance abuse treatment medication practices and concerns.

The discussion began with the review and examination of issues key to the States which include:

- How the office-based dispensation of buprenorphine may impact State AOD Agencies;
- What technical assistance services may be needed to assist the States in addressing issues that may arise as office-based practice begins to be implemented; and
- What information about approved physicians and Federal activities is needed by the States.

1. Federal legislative constraints on State legislative and regulatory activities/plans to opt out within the constraint period (October 17, 2000 – October 17, 2003)/ S. 304 status

No participating State currently anticipates any "proactive" legislative action. State legislation is usually passed as a response or reaction to problems or concerns that become apparent at the State or local level. Once buprenorphine is approved, some States may react if implementation proves to be problematic. This is only a possibility but forecasting legislative behavior is difficult.

S.304 now includes provisions which would extend the existing three-year constraint period to three years from the date of the Food and Drug Administration (FDA) approval of buprenorphine. The fact of S. 304 in this Congressional session is uncertain.

2. Physician approval process

CSAT has received approximately 125 waiver requests from physicians and a significant percentage of those have already undergone review and will be recommended for approval. CSAT is using contractors to verify physician licensures and has been working with various medical associations to provide data on board certification and training that physicians have received. Currently about 2,000 to 2,500 physicians have received buprenorphine training. Those physicians were drawn from private practice and from medical staff now working in AOD treatment facilities. Additionally, there are a limited number of the American Society of Addiction Medicine (ASAM) certified physicians. Consequently, the number of physicians seeking approval will probably increase rapidly once buprenorphine is approved. These physicians are being asked for permission to place their contact information on a SAMHSA treatment provider locator web site. Currently, physicians may choose not to be listed.

Some States presently have AOD treatment provider licensure laws. Those laws require that any entity that holds itself out as offering alcohol and other drug treatment services must meet specific licensure standards established by the State. There was not unanimity among participating States that licensing laws might apply to physicians receiving approval to dispense buprenorphine or other medications available under the provisions of the Drug Abuse Treatment Act of 2000 (DATA). The majority, however, felt that the authority resident in State physician licensure is sufficiently broad to permit engagement in office-based practice of the nature envisioned by the act without additional licensure; further, it was noted that the Model Policy Guidelines of Opioid Addiction Treatment in the Medical Office drafted by the Federation of State Medical Boards of the United States, Inc., did not anticipate additional State level licensure requirements in their articulation of physician qualifications.

The focus group also briefly discussed areas of some uncertainty in the area of individual credentialing (as opposed to program or facility licensure or accreditation). The tentative consensus reached was that physician certification as an AOD counselor would not be seen as a requirement unless counseling was performed by a physician within the context of a State licensed or accredited program.

3. Approved physician State notification

CSAT estimated that about 90 percent of approved physicians will agree to be listed on the treatment facility locator web site. However, what will happen to the remaining 10 percent? Presently, without physician approval, identifying information can only be disclosed to regulatory officials. The States mentioned that it would be important to be aware of the identity of all approved physicians for a variety of reasons. It was their sense that it would be of interest to the general public, not just the State AOD treatment community. The States need access to this information to do planning and outreach activities, to ensure that physicians are kept informed, and to develop and implement best practices training for participating physicians and components of the publically supported treatment system which may be involved in the provision of services to “shared” patients.

4. Diversion/abuse potential

History provides relatively strong evidence that buprenorphine, alone or in combination, will be subject to abuse and diversion, at least to some degree. State experience with methadone, which has much more restrictive take home policies, would seem to add credence to the concern. Nevertheless, it was the consensus of the States that the potential benefits of office-based practice appear to outweigh any reservations based on diversion or abuse projections. In part that positive consensus was reached in an awareness of the fact that the National Institute on Drug Abuse (NIDA) is currently analyzing data from France suggesting dramatically lower levels of abuse than previously reported. The States requested that CSAT monitor all buprenorphine oriented research and ensure that it is made available to them on a timely basis. The States also requested that Federal authorities collaborate with State officials and individual practitioners around procedures that might minimize the current potential for multiple patient enrollment in buprenorphine assisted treatment.

5. Consumer/Public Concerns

The focus group expressed some anxiety around the lack of a clear path to be followed in instances in which a consumer might seek to resolve a complaint. In a similar vein, there is no readily visible Federally authority that might be contacted if evidence of buprenorphine abuse or diversion is found at the local level.

Historically, such matters have been brought to the State AOD Directors as the most visible individual “responsible” for drug treatment activities within a State. An analogous situation has existed for some time for methadone clinics. CSAT staff have provided extraordinary assistance to the States when methadone related problems have been identified. Focus group members recommended that CSAT establish similar assistance capabilities for office-based opiate treatment concerns that may arise.

6. Existing opioid treatment programs (OTPs)

It was the sense of the focus group that current clients of OTPs should be informed of the option of moving to a private practitioner. Some States are looking forward to the collaboration between the traditional opioid treatment provider and private practice. The more options for citizens, the better. These options should be encouraged and promoted. However, this will create practical concerns. Who, for example, would be responsible for the tapering of methadone to accommodate the transition to buprenorphine? Some States would support this as a goal. One State mentioned that they do not envision many methadone patients converting to buprenorphine. There may only be 30 patients per approved physician; this will limit the percentage of patients who might be transitioned from methadone to buprenorphine. There is also the issue of indigent clients. They will not be able to go to a private physician and there is no assurance of Medicaid coverage. The States agreed that while these issues present challenges, they also represent a new and welcome opportunity to work more closely with the medical community.

7. Access to counseling and other “traditional” AOD treatment services

A difficulty that the States will have is that physicians may be frustrated in efforts to refer because of current waiting lists. The States already have information that can be made available

to physicians about referral resources in various communities. At the current time, there is significant confusion around how ancillary services from public providers might be financed.

8. Confidentiality concerns

The States expressed concerns around physician knowledge of the requirement of 42 CFR, Part 2. They urged that physician training emphasize confidentiality compliance.

9. Technical assistance availability

Medication education and training should include counselors, physicians, and supervisors. The Addiction Technology Transfer Centers (ATTCs) should be contacted for assistance. Presently, the Central Atlantic ATTC has online programming. CSAT will have additional online training for this issue available by the end of year. Other training and technical assistance issues include the following:

- how buprenorphine should be incorporated into a comprehensive treatment program;
- training for other professions that might be called upon to provide counseling and ancillary services, e.g., psychologists and social workers in private practice;
- training for primary care physicians and medical directors of existing treatment centers;
- training conducted by the pharmaceutical companies (they are in the communities, they have representatives in every physician's office, they have great training initiatives, and this is a great opportunity for the States to work with physicians and others to forge new collaborations); and
- joint treatment planning procedures need to be addressed among program medical directors, physicians, counselors, and others.

10. Cost considerations

The States asked what Federal issues might constrain Medicaid coverage, e.g., discount negotiations. For eligible clients, many States now provide counseling services, medical evaluations, medications, and medication monitoring under Medicaid. Only medications included in the State's Medicaid formulary may be provided, however, and that does not now include buprenorphine for this use. It would probably have to be decided on a State-by-State basis whether they want to include Medicaid coverage for new treatment medications in their plans. In addition, the States need to be informed about the final pricing of buprenorphine. They will need this information to complete work around Medicaid and other planning activities.

APPENDIX A: STATE BUPRENORPHINE FOCUS GROUP CONFERENCE CALL MEETING PARTICIPANTS

July 8th, 2002

State Representatives

Ed Zborower for Christine Dye (AZ)
Megan Marx for Janet Wood (CO)
Phil Emenheiser (FL)
Melanie Whitter (IL)
John Viernes (IN)
Alex Hoehne (IN)
Kim Johnson (ME)
Flo Stein (NC)
Doug Baker (NC)
Bert Bennett (NC)
Maria Canfield (NV)
Ann Brand for Barbara Cimaglio (OR)
Hope Alcher (VA)
Ken Batton (VA)
Denise Clayborne for Robert Johnson (VA)
Kathy Fornili (VA)

Federal Representatives (CSAT)

Hal Krause
Bob Lubran
Bob Miller

NASADAD Staff

Bob Anderson
Colleen O'Donnell
Pamela Stokes

APPENDIX B: AGENDA

STATE BUPRENORPHINE FOCUS GROUP MEETING CONFERENCE CALL

July 8th, 2002 at 3:00 p.m. EST

- I. Introduction of Workgroup members
- II. Why the Focus Group was Formed
- III. Overview and Role of CSAT/SAMHSA
- IV. Description of the Workgroup meeting process

V. Discussion of buprenorphine issues

- Federal Legislative constraints on State legislative and regulatory activities/plans to opt out within the constraint period (October 17, 2000 – October 17, 2003)/ S.304 status.
- Physician approval process
- Approved physician State notification process
- Diversion/abuse potential
- Buprenorphine
- Buprenorphine in combination with naloxone
- Consumer/public complaint/concern resolution process
- Implications
- Impact on existing OTPs
- Access to counseling and other “traditional” AOD treatment services
- Confidentiality concerns
- Technical assistance availability
- Cost assumptions: Price/Medicaid/Block Grant
- Other areas suggested by CSAT/participants prior to or during the call

VI. Adjourn

APPENDIX C

Memorandum

To: NASADAD Treatment Committee Members

From: Lewis Gallant, Ph.D.

Executive Director

Date: 06/21/02

Re: Buprenorphine Issues Focus Group

CSAT has requested that NASADAD present preliminary State AOD Agency concerns/questions around the pending dispersion of buprenorphine from office-based settings at a Buprenorphine Stakeholders Meeting scheduled for July 26th, 2002. That request has been discussed with Melanie Whitter, the Chair of NASADAD's Treatment Committee, and it's felt that the Committee would be the appropriate forum to identify these concerns/questions.

NASADAD has proposed to CSAT that the issue identification process be through a Committee conference call structured for that specific purpose. That call would be held during the first two weeks in July. A draft agenda for the call is enclosed for your information along with other materials selected by staff to inform the discussion.

It is our hope that each of you will be willing to take part in this opportunity to inform other AOD treatment stakeholders of the States' perspective around Buprenorphine and office-based medically assisted treatment. Within a few days of your receipt of this memorandum you may expect a call from Pamela Stokes to inquire into your willingness to participate and dates and times that you might be available for the conference call. As is always the case, NASADAD understands that your schedules are already crowded and is appreciative of the added time and effort you contribute as a member of the Treatment Committee. Once a date and time has been agreed upon, you will be provided with conference call call-in instructions via e-mail. If you wish to contact Pam prior to her call, she may be reached at (202) 293-0090, ext. 116 or at pstokes@nasadad.org.

Thanks you for your active role in the NASADAD committee structure.

Cc: Barbara Cimaglio, President, NASADAD

Melanie Whitter, Chair, NASADAD Treatment Committee

Hal Krause, GPO, SAMHSA

Bob Anderson, Director of Research and Program Applications

File

Attachments:

1. Conference call draft agenda.
2. Title XXXV "Drug Addiction Treatment Act of 2000" legislation.
3. Federal Register Notice of Intent for Schedule III, IV, V use for maintenance and detoxification treatment of opioid addiction.
4. Buprenorphine: "Field Trials" of a New Drug from Vol. II Issue I of Qualitative Health Research, Jan. 2001 by Michael Agar

Back to Top

APPENDIX D

TITLE XXXV—WAIVER AUTHORITY FOR PHYSICIANS WHO DISPENSE OR PRESCRIBE CERTAIN NARCOTIC DRUGS FOR MAINTENANCE TREATMENT OR DETOXIFICATION TREATMENT

SEC. 3501. SHORT TITLE.

This title may be cited as the ‘Drug Addiction Treatment Act of 2000’.

SEC. 3502. AMENDMENT TO CONTROLLED SUBSTANCES ACT.

(a) IN GENERAL- Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended—

(1) in paragraph (2), by striking ‘(A) security’ and inserting ‘(i) security’, and by striking ‘(B) the maintenance’ and inserting ‘(ii) the maintenance’;

(2) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(3) by inserting ‘(1)’ after ‘(g)’;

(4) by striking ‘Practitioners who dispense’ and inserting ‘Except as provided in paragraph (2), practitioners who dispense’; and

(5) by adding at the end the following paragraph:

‘(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

‘(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

‘(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

`(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

`(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number.

`(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

`(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

`(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

`(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

`(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

`(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

`(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

`(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

`(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the

registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

`(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

`(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

`(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

`(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

`(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

`(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

`(G) For purposes of this paragraph:

`(i) The term `group practice' has the meaning given such term in section 1877(h)(4) of the Social Security Act.

`(ii) The term `qualifying physician' means a physician who is licensed under State law and who meets one or more of the following conditions:

`(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

`(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

`(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

`(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

`(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

`(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

`(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

`(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

`(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

`(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

`(ii) Not later than 120 days after the date of the enactment of the Drug Addiction Treatment Act of 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

`(I) During the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.

`(J)(i) This paragraph takes effect on the date of the enactment of the Drug Addiction Treatment Act of 2000, and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

`(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 2000, make determinations in accordance with the following:

`(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

`(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being

dispensed or possessed in violation of this Act; and may make a determination of whether such waivers have adverse consequences for the public health.

`(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.’.

(b) CONFORMING AMENDMENTS- Section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) in subsection (a), in the matter after and below paragraph (5), by striking `section 303(g)’ each place such term appears and inserting `section 303(g)(1)’; and

(2) in subsection (d), by striking `section 303(g)’ and inserting `section 303(g)(1)’.

(c) ADDITIONAL AUTHORIZATION OF APPROPRIATIONS- For the purpose of assisting the Secretary of Health and Human Services with the additional duties established for the Secretary pursuant to the amendments made by this section, there are authorized to be appropriated, in addition to other authorizations of appropriations that are available for such purpose, such sums as may be necessary for each of fiscal years 2001 through 2003.

APPENDIX E

[Federal Register: June 7, 2002 (Volume 67, Number 110)]

[Notices]

[Page 39413-39414]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr07jn02-112]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection;
Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed

collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use [[Page 39414]] of automated collection techniques

or other forms of information technology.

Proposed Project: Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) [OMB No. 0930-0234, extension]—The Drug Addiction Treatment Act of 2000 (“DATA,” Pub. L. 106-310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers.

To implement these new provisions, SAMHSA has developed a notification form (SMA 167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (i.e., independent physicians and physicians in group practices (as defined under section 1877(h)(4) of the Social Security Act) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver. However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner's registration under 21 U.S.C. 823(f).

Practitioners may use the form for two types of notification: (a) New, and (b) immediate. Under “new” notifications, practitioners may make their initial waiver requests to SAMHSA. “Immediate” notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii).

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; e-mail address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification new, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate-dependent patients; certification of capacity to refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information to the SAMHSA Substance Abuse Treatment Facility Locator.

At present, there are no narcotic drugs or combinations for use under notifications; however, SAMHSA believes that it is appropriate to develop a notification system to implement DATA in anticipation of narcotic treatment medications becoming available in the very near future. Therefore, SAMHSA recently obtained emergency OMB approval of form SMA 167 so that physicians will have it available to use if they wish to be assured that all required information is provided on their waiver submission and so that the review of submissions may be facilitated by use of a standard format for provision of the required information. Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of submission	Number of Responses per	Burden per	Total burden	response (hr.)	(hrs.)
	respondents	respondent	respondent		
Initial Application for Waiver.....	1,200	1		.083	100
Notification to Prescribe Immediately.....	33	1		.083	3
Total.....			1,200		
.....		103			

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 31, 2002.
Richard Kopanda,
Executive Officer, SAMHSA.
[FR Doc. **02-14325 Filed 6-6-02**; 8:45 am]
BILLING CODE 4162-20-P

Back to Top

APPENDIX F

Title: Buprenorphine: 'Field Trials' of a New Drug.
Subject(s): BUPRENORPHINE — Therapeutic use; DRUG abuse — Treatment — United States; NARCOTIC habit — Treatment — United States
Source: Qualitative Health Research, Jan2001, Vol. 11 Issue 1, p69, 16p
Author(s): Agar, Michael
Abstract: Focuses on a study sponsored by the National Institute on Drug Abuse to determine the effectiveness of buprenorphine, a treatment drug for narcotics addiction in the United States. Information on the results of the field trial testing to ascertain the therapeutic properties of the drug; Details on the use of clinical studies and Internet discussion lists; Results and discussion.
AN: 3903946
ISSN: 1049-7323
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BUPRENORPHINE: "FIELD TRIALS" OF A NEW DRUG

Buprenorphine is being introduced as a new treatment drug for narcotics addiction in the United States. The authors were asked by the National Institute on Drug Abuse to conduct a field trial to determine if buprenorphine might play a role in street markets. Because no street use of the drug existed in the United States, the authors used three sources of information: (a) "street readings" of clinical studies, (b) Internet discussion lists, and (c) research in other countries. By using an emergent style of analysis that relies on replication of patterns across disparate data sources, it was determined that buprenorphine has desirable characteristics from a street addict point of view. An evaluation of the field trial 5 years later evaluates its accuracy.

Buprenorphine is a new treatment drug for heroin addicts in the United States. Like methadone, it is an opioid agonist; that is, it satisfies the craving for a narcotic and prevents the withdrawal syndrome. Unlike methadone, it is also an antagonist; that is, it reacts against opiates and precipitates withdrawal. According to Navaratnam (1995), the agonist effect operates up to a certain dosage level, at which point the antagonist effect begins to operate.

We were asked by the National Institute on Drug Abuse to find out if buprenorphine currently played any role in U.S. street drug markets. From the medical and legal points of view, the question was one of what these fields call the "abuse liability" of a proposed treatment drug. Would the new treatment medication also turn into a hot street commodity, as it happened with methadone in the 1970s? Few programs used buprenorphine at the time of the study in 1996, so it played no street role in the United States, at least not among numerous different networks in

San Francisco, Baltimore, and Newark. Because few users existed in the United States, we decided to experiment with the idea of a “field trial” for the drug, as opposed to the traditional notion of a “clinical trial.” The “field” concept was borrowed from cultural anthropology with its emphasis on fieldwork, although field here is used differently from that traditional term. The logic of the field trial runs like this:

1. The field is expanded from a focus on a particular human group to any information available on the topic of interest, whether in the United States or in other countries, whether presented in media or a conversation, whether scholarly or popular in nature.
2. The field contains examples of use that vary in set and setting. The researcher’s problem is to locate and organize set/setting information that is already available along the lines of the concept of the “natural experiment.”
3. Analysis features emergent search for pattern, a style that is traditional in anthropology but also found in such areas as complexity theory (Waldorf, 1992) and marketing research (Michman, 1994). Validity derives from replication of patterns across disparate sources.
4. The analysis is anchored in a particular perspective from which the patterns are evaluated. In this case, the perspective will be that of urban American street addicts, a population with which we have decades of collective experience.

Our goal, then, is to present a field trial designed to forecast whether buprenorphine might play a role as a street narcotic in the United States and to estimate the chances that this situation might come about. To accomplish this goal, we will review a variety of different field sources and look for emergent patterns that replicate across this material from a street addict point of view. Our model of that point of view is derived from prior ethnographic work.

BUPRENORPHINE

Buprenorphine does have a history in the United States as a medication with a corresponding literature that evaluates it. This professional literature will be examined with a different filter snapped over the lens to give it a “street reading.” How would this literature make buprenorphine sound if one were an opiate addict looking to buy it in a street market? Even in the technical literature, buprenorphine clearly has some desirable characteristics from this point of view. From various online literature abstracts, we learn that buprenorphine compares favorably with morphine in the management of postoperative pain. In fact, the literature suggests longer lasting and more moderate effects.

A clinical study of 6 men with histories of opioid use also adds credibility to the hypothesis (Pickworth, Johnson, Holicky, & Cone, 1993). Those who received intravenous buprenorphine rather than a placebo reported increased positive responses to a “feel drug” question and higher scores on scales of liking, good effects, euphoria, and apathetic sedation. The authors concluded that buprenorphine has substantial abuse liability when administered intravenously.

Another study, meant to test comparative effects of sublingual versus subcutaneous use, reported varying degrees of euphoria and little dysphoria and sedation from buprenorphine, also noting that “subject liking” was reported by both subjects and observers (Jasinski, Fudala, & Johnson, 1989). And finally, in what must be one of the first clinical studies of the drug (Jasinski, Pevnick, & Griffith, 1978), buprenorphine is described as having potential as a treatment drug because it is acceptable to addicts, has prolonged action, and produces a low level of physical dependence such that addicts may easily detoxify. Such reasons are, of course, also the reasons why buprenorphine would be of interest from a street point of view as well.

Buprenorphine appears, hypothetically, as a longer, gentler “high” when compared to morphine. Returning to the abstracts, we learn that buprenorphine also has some history as an experimental drug for the treatment of opioid addiction in the United States. The effects of buprenorphine were evaluated using a rapid dose-induction procedure among 19 heroin-dependent men (Johnson, Cone, Henningfield, & Fudala, 1989). During the first 4 days of transition from heroin to buprenorphine, patients reported significantly elevated ratings of good effects, feelings of overall well-being, and decreased ratings of overall sickness. Euphoria increased and dysphoria and sedation decreased after buprenorphine administration.

A second study by the same team added that buprenorphine offered greater control of opioid withdrawal symptoms and that between-dose intervals of 48 hours could be tolerated (Fudala, Jaffe, Dax, & Johnson, 1990). In a later study (Johnson, Jaffe, & Fudala, 1992), 8 mg of buprenorphine per day compared favorably with 60 mg of methadone in treating illicit opioid use and maintaining patients in treatment. Yet another study showed that buprenorphine doses of 2 mg/day compared favorably with 30 mg/day of methadone in a heroin detoxification program (Bickel et al., 1988).

The effects of buprenorphine versus placebo on patterns of operant acquisition of heroin and money were studied in 10 male volunteers with a history of heroin addiction (Mello, Mendelson, & Kuehnle, 1982). Subjects were maintained on 8 mg/day of buprenorphine for 10 days during which they could earn money (\$1.50) or heroin (7 or 13.5 mg/injection IV) by responding on a second order schedule of reinforcement for approximately 90 minutes. Buprenorphine subjects took only between 2% and 31% of the total amount of heroin available, whereas placebo subjects took between 93% and 100%.

These studies confirm that buprenorphine might serve as a desirable substitute for heroin. But would it? This is a difficult question to answer when talking about the United States because the drug is not available. In other countries, though, buprenorphine has a different history. By scanning international studies where buprenorphine is available, we might get some clues about what could happen in the United States. What follows is a brief review of some samples of international research on buprenorphine that we found in the abstracts.

Fifty known drug addicts (median age 28.6 years) admitted to a Marseille Hospital in France between June and October 1992 were examined (Arditti et al., 1992). Buprenorphine was identified in urine in 9 (18%) of them. In another study in Scotland, the effects of prescribing restrictions on the incidence of buprenorphine hydrochloride (Temgesic) are reported (Stewart, 1991). Three months after the restrictions were imposed, the rate of abuse dropped but then rose

again over the next 8 months to nearly prerestriction values. Furthermore, as buprenorphine use declined, other opiate use doubled. The restrictions resulted in only a temporary drop in the availability of the drug.

In a second study from Scotland, researchers reported that 51% of opioid mis-users in 1988 and 70% in 1990 were receiving prescribed opioids before assessment (Griffin, Peters, & Reid, 1993.) They report that, in the prior month, injectable opioids such as Temgesic (buprenorphine) were significantly more common in 1988 than in 1990. Although there are some indications of street use of buprenorphine in England, the reports are less compelling. One article (Strang, 1991), for instance, describes a pattern of use in which sublingual tablets are crushed and the resulting powder inhaled. In another study, a description of 150 drug users in a London general practice indicates only 5 cases of reported buprenorphine use as opposed to 121 cases of reported heroin use (Cohen et al., 1992).

Another study from Finland (Hakkarainen & Hoikkala, 1992) reports on a policy debate over buprenorphine. During the 1980s, increasing Temgesic abuse was noted, and the drug was classified under the narcotics legislation. The status of that classification is under review. Barcelona also reported problem use of buprenorphine (San, Torrens, Castillo, Porta, & De La Torre, 1993). In studies carried out in 1988 and 1990, illicit use at some time was reported by 66% (1988) and 71% (1990) of patients in treatment, with respectively 5.9% and 6.1% actually testing positive for the drug. More than 70% of those with buprenorphine experience reported intravenous use. Australia also showed concerns about buprenorphine. One case study describes an intravenous buprenorphine addict with a history of injecting 4.5 mg/day for a period of 2 months (Quigley, Bredemeyer, & Seow, 1984). Other articles discuss general policy issues around the control of buprenorphine and its potential liabilities (Lebedevs, 1985; Wodak, 1984).

In a presentation at the 1995 College of Problems on Drug Dependence meeting, Kumar, Mandell, Shakuntala, and Daniels (1995) offered a poster session on buprenorphine use in Madras, India. Among 250 injecting drug users recruited in an HIV outreach, 96% had used buprenorphine—74% in the previous 30 days—and 44% were DSM III-defined buprenorphine dependent at the time of the interview.

Dr. Kumar was fortuitously encountered by the senior author at a conference. He described the history of buprenorphine use in detail. The upshot was that a dramatic increase in heroin availability created a population of addicts in the 1980s, but later political events and harsher laws resulted in a heroin shortage. Buprenorphine, manufactured locally in Tamilnadu State, provided an alternative for addicts, and its use rose dramatically. One unfortunate consequence of the shift was that buprenorphine—available in ampules—was injected, whereas heroin had been smoked. When heroin did return to the street market, addicts carried the new practice of injecting with them, with obvious increases in HIV risk.

Information on Bangladesh is contained in a report by Ahmed and Ara (1995). Their interviews with 30 addicts in treatment reveal the establishment of buprenorphine as a street drug, beginning in 1992, in response to declining quality and increasing cost in the heroin market. All 30 used buprenorphine daily and praised it for staving off withdrawal, pleasurable effects, and

ease of use—it must be injected less frequently than heroin and its availability in ampules makes for simpler preparation.

These studies do not directly answer our question of whether buprenorphine might become a commodity with competitive value in the U.S. street market. But they do show that buprenorphine has appeared as a street drug in several other countries—France, Finland, Scotland, England, Spain, Australia, India, Bangladesh—to one degree or another. The studies support the hypothesis that buprenorphine is actively sought out and that it is something that addicts in street settings are motivated to obtain. This positive view of buprenorphine's effects held by heroin addicts suggests a potentially successful street "product." Other studies—international and U.S. based—add to the possibility of success by showing how buprenorphine interacts with other street drugs in ways similar to heroin and methadone.

In Scotland, researchers reported that 727 new needle-exchange clients (93% of the total) completed an intake questionnaire in 1992 (Gruer, Cameron, & Elliott, 1993). The most common drugs injected were heroin, buprenorphine (Temgesic), and temazepam, injected by 61%, 45%, and 28%, respectively. Most clients regularly used at least two drugs, typically heroin or buprenorphine and a benzodiazepine. Another study of a 13-week detoxification program using buprenorphine and behavioral therapy reported that 89% tested positive for benzodiazepenes and 63% for cocaine at least once during the program (Bickel, Amass, Higgins, Badger, & Esch, 1997).

From a Scientific American article comes a report of buprenorphine featuring both its agonist and antagonist effects (Holloway, 1991). The article notes that Jack H. Mendelson, who had recently completed a study of 12 heroin and cocaine users taking buprenorphine, suggested that high doses of buprenorphine might enhance cocaine's effects. Mendelson's concerns are supported by a clinical study from the Connecticut Mental Health Center (Rosen, Pearsall, McDougale, Price, & Kosten, 1993). In a double-blind study of 5 cocaine- and heroin-dependent patients who had been drug free for at least 36 hours, it was found that subject ratings of cocaine's pleasurable effects as well as pulse increases resulting from cocaine use were both enhanced by buprenorphine. In his dissertation on cocaine use, Erin Brown (1993) notes that the effect of cocaine was "potentiated" by coadministration of buprenorphine and that the two drugs can act together in a synergistic manner.

These studies echo two common patterns of polydrug use among heroin addicts in the United States. According to the first one, a mix of heroin and cocaine called a "speedball" is used; in the second pattern, the effects of either heroin or methadone are boosted with benzodiazapines. The sources just cited suggest that buprenorphine fits such patterns in the same way.

The literature shows that buprenorphine's effects are desirable from a street addict's point of view, it has already appeared as a street drug in several countries, and it mixes with benzodiazapines and cocaine in ways already established in street patterns of heroin and methadone use. In addition, we asked about buprenorphine on an illicit drug listserve as another source of information for this field trial.

John French logged onto a drug discussion group on the Internet and asked about buprenorphine. The three elaborate comments he received in reply echoed the themes in the literature.

1. You can think of buprenorphine as providing opiate replacement therapy similar to methadone maintenance, but with a somewhat more interesting drug. Buprenorphine is a mixed opioid agonist/antagonist, meaning that it has some effects that are like morphine and heroin, and others that block the actions of the drug. It also seems to bind to opiate receptors in the body for a very long time, so its effects are very long lasting. Basically, buprenorphine is enough like heroin that it doesn't seem to induce a withdrawal syndrome in someone who is already addicted to morphine, methadone or heroin. Buprenorphine is also "enough" like heroin that it seems to have a mild euphoric effect, at least at low doses, so there's a bit of an incentive for former addicts to use it. Buprenorphine is not very addictive on its own (though it has seen some recreational use in areas where it's freely available). It also blocks the effects of other opiates like heroin almost completely, so someone shooting up with heroin while taking buprenorphine wouldn't achieve the high they expected.

2. In places like Scotland where the heroin supply is erratic, there is a greater reliance upon various pills. Temgesic grew in popularity because for a while, the medical profession thought that they had little potential for misuse. In fact, because they were designed to dissolve by being placed under the tongue, it was discovered that they were quite a reasonable tablet to inject as they were not laden with chalk. The strange thing about Temgesic is that they are an opiate antagonist. This means that if you've got a smack habit and you do some Temgesic, you'll end up in withdrawal. On the other hand, if you don't have a habit at all, they have an opiate-like effect. They have become popular with injectors who lack access to "real" injectable opiates in places like the Outer Hebrides.

3. There are some trials in the US at the moment I believe. I am working as a physician at a Dutch methadone programme. I started to prescribe Buprenorphine nearly a year ago in some cases: people who want to stop using opiates (it's easier to quit with buprenorphine than with methadone) and who don't want to use any other opiates (it's not working well together with other opiates). My clients (that's what patients are called) are mostly very satisfied. It is a synthetic opiate partly agonist/antagonist. It's used as a pain-killer in Holland. It must be available in the US, too.

Thus, Internet comments from those knowledgeable about buprenorphine dovetail with the reported results, suggested hypotheses, and research questions based on materials in the literature. If we summarize the different sources of information reviewed in this section, we get the following field trial results for buprenorphine:

1. Buprenorphine has characteristics that compare favorably with the desirable characteristics of morphine, methadone, and heroin. Furthermore, buprenorphine may have fewer undesirable characteristics than those drugs.

2. There are indications that buprenorphine use lends itself to polydrug use in ways similar to heroin and methadone.

3. Buprenorphine can play a role in “habit management”; that is, in situations in which a preferred narcotic is not available, buprenorphine can be used to stave off withdrawal and provide an agonist effect.
4. Buprenorphine may be the preferred narcotic in locations where heroin is not available.
5. Buprenorphine might have characteristics that lead it to become a preferred narcotic in its own right, even in a market that offers several available options.

At the end of this review, we can say that it is clear that buprenorphine has a potential role to play in the streets. We can forecast a “possible world” within which buprenorphine would find a street market in the United States. In fact, we can give an optimistic street reading on buprenorphine based on what we learned, a provisional but plausible one, given the material at hand: “Buprenorphine is a nice mellow high and it lasts a long time. It’s easy to kick, it makes a good speedball, and you can boost it with benzodiazapines.”

The results of this field trial are clear. Could buprenorphine possibly develop into a street drug in the United States? Yes, it could. We return to this question and the subjunctive verb could in the conclusion.

THE ANTAGONIST MIX

After this field trial began, we learned that a focus on buprenorphine alone would no longer answer the question about potential street use. Even as we did this study, interest in the United States was shifting from buprenorphine as a stand-alone treatment to a mix of buprenorphine and naloxone, a narcotic antagonist. Even though buprenorphine already has an antagonist effect, that effect—as we have seen—clearly does not discourage street use. Naloxone, supposedly, would beef up the antagonist and make the drug less attractive in the streets. However, such a strategy would also make it less attractive with respective implications for recruitment and retention in treatment.

Dr. John Mendelson, who was cited earlier in the literature review, showed us the results of a new study in which buprenorphine was compared with a buprenorphine/ naloxone mix during an interview with Agar and Bourgois. According to evaluations obtained from 10 subjects, buprenorphine alone was a desirable drug with a high street value. But the high user ratings of buprenorphine alone plunged when naloxone was added. The potential problem with the buprenorphine/naloxone mix lies in the classic problem with antagonists in the past. Their history shows that the few patients who succeed tend to be of higher socioeconomic status with a prior commitment to quit their narcotics addiction. It is no surprise that most addicts, when offered something that will make them sick and will never get them high, do not find the offer attractive.

Nonetheless, the focus in future U.S. clinical trials apparently will be on buprenorphine/naloxone mixes. In an interview with Agar, Dr. Richard Resnick pointed out that the addition of naloxone to buprenorphine is meant to prevent its diversion into the streets. The sublingual dose of naloxone will not affect the buprenorphine, but an individual who is addicted to heroin will feel

the effects of withdrawal. The new mixture will also offer commercial and marketing advantages from the manufacturer's point of view.

We wonder if possible strategies could be developed in the streets to manage the antagonist component of the new buprenorphine/naloxone mix. Numerous shifts in street pharmacology over the years have been observed as users have changed drugs, modes of preparation, perception of effects, and styles of use. Both Mendelson and Resnick, in interviews with us, argue that this will not occur. However, it will be an important exercise to monitor the "street trials" that will follow the clinical trials if and when buprenorphine/naloxone becomes a widely used treatment modality.

THE STREET/TREATMENT BOUNDARY

We would like to make it clear that we came to this study neither to praise nor to bury buprenorphine. Our judgment at the end of this field trial is that buprenorphine alone appears to be a worthwhile alternative treatment modality to methadone, at least worthy of further study. However, buprenorphine alone will likely lend itself to street use, as methadone did when it was introduced in the 1970s.

Mendelson, in an interview with Agar and Bourgois, pointed out possible advantages of the shift to buprenorphine: (a) Buprenorphine does not have the negative or "loser" image that methadone has acquired over the years; (b) one cannot overdose on buprenorphine, although frankly we are still wondering about agonist/antagonist interactions in the context of the normal polydrug street environment; (c) buprenorphine is not as euphoric as methadone, although again the same thing was said of methadone when it was first introduced, and the literature reviewed earlier sometimes suggests the contrary; and (d) with its longer acting effects, buprenorphine will be cheaper to administer, requiring a visit to a clinic site every few days instead of daily.

Resnick, who has experimented with buprenorphine as a treatment modality for some time, argues that the drug has other advantages as well (Resnick & Falk, 1987; Resnick et al., 1992; Resnick, Resnick, & Galanter, 1991). Stressing the diversity of the addict population, Resnick finds that buprenorphine may appeal to addicts who will not enter the health care system via methadone treatment or therapeutic communities and who are not motivated to use a narcotic antagonist. Such addicts show a higher level of psychosocial functioning when compared to nonresponders in his studies. Buprenorphine proves useful in detoxification as well, he adds.

But how do we reconcile an interest in buprenorphine as an alternative treatment for heroin addiction—something clearly supported by our two interviewees and three of the four authors of this article—with our field trial results that show buprenorphine's possible future as a street drug? Based on our collective experience with methadone maintenance over the years, we would argue that it is not a matter of reconciling a contradiction. Instead, it is a matter of accepting that you cannot have one without the other. An effective maintenance drug will always be interesting to the streets as well.

When methadone was first proposed as a maintenance drug in the 1960s, it initiated an experiment that had not been tried for decades. Since the closing of the U.S. morphine clinics in

the 1920s, if one wanted treatment, one had to eliminate physical dependence right at the beginning. Treatment started only after detoxification. Relapse rates after such treatment were uniformly high. With methadone maintenance, things changed. Now an addict could enter treatment without first kicking the habit. In fact, by some program philosophies, one would never have to kick the habit.

In other words, methadone clouded the boundary between treatment and the streets more than ever before. Now treatment included taking an opiate, rather than requiring that opiate use cease before treatment started. Methadone accommodated an addict's world and, compared to any other drug-free treatment, made it easier for him or her to experiment with a "patient" role. Treatment evaluations showed a higher retention rate for methadone compared with drug-free modalities. But then, the other side of the story is this: If a treatment modality accommodates the street world, then the street world can incorporate the treatment modality. Historically, we saw this happen with methadone, as a "medication" from the clinical point of view also became a commodity in the street markets (Agar, 1977; Agar & Stephens, 1975; Preble & Miller, 1977).

When the boundary between street and treatment turns fluid and fuzzy as it did with methadone, the treatment drug is no longer either "medication" or "dope." It is both. Buprenorphine is another chemical move in this treatment game. With its widespread use as a treatment drug in the United States, it will probably develop a street market here as well. In the next section, in which we discuss in more detail the current buprenorphine situation in France, we will see that it has, in fact, become an exceptionally popular street drug in that country and that it is injected rather than used sublingually as originally intended.

Interesting and problematic will be the development of buprenorphine/ naloxone mixes. Efforts to use naloxone to build a wall against street use may, by this logic, recruit fewer addicts and resemble the limited role that antagonists alone have always played. The paradox, again, is this: A medication with powerful and effective outreach and recruitment into treatment is also a drug with a role to play in street markets. With apologies to Gunnar Myrdal, we might call this the "American treatment dilemma" and simply close by hoping that our field trial clarifies its inevitable and enduring presence.

A YEAR-2000 UPDATE

Roughly 5 years have passed since we conducted the research on which this article is based. Since that time, needless to say, the buprenorphine story has continued. In this brief update, we first look at some of the recent literature to check whether the field trial holds up. We searched MedLine with key words buprenorphine, human, and abuse and came up with about 80 abstracts since 1995. After a brief review of this literature, we will take a look at the current situation in France, where the liberalization of prescription laws for sublingual buprenorphine in 1996 increased the street market noticeably. In fact, underground economy sales are so robust that the street price of buprenorphine is actually cheaper than the pharmacy price. Finally, we will briefly look at how buprenorphine has become more of a newsworthy topic in the United States. In general, our review of this new material will show that, with a few minor exceptions, the field trial of 5 years ago was accurate.

In recent years, the professional literature has continued to grow, with many reports evaluating buprenorphine—often by comparison with methadone—and concluding that the new drug does indeed have a role to play in the treatment of heroin addiction (see, for example, O’Connor et al., 1996, 1998; Petry, Bickel, & Badger, 1999). Some studies now discuss a lower retention rate for buprenorphine when compared to methadone (Eder et al., 1998; Fischer et al., 1999). There is more recognition of the drug’s abuse liability, although articles still neglect street views of buprenorphine, and street voices commenting on the drug are absent.

Earlier we argued that one signal of buprenorphine’s desirability from a street point of view was its ability to mix with other drugs in ways similar to heroin and methadone. By and large, this statement is still supported (see, for example, Schottenfeld, Pakes, & Kosten, 1998). However, the recent literature is more equivocal on the mix of buprenorphine and cocaine. In one comparison of methadone and buprenorphine, it is reported that the buprenorphine treatment sample produced fewer cocaine-positive urines, although the difference was not statistically significant (Eder et al., 1998). Another study concludes that buprenorphine may be more effective than methadone for controlling cocaine abuse (Foltin & Fischman, 1996). On the other hand, a third study questions the claim that buprenorphine reduces cocaine use more than methadone does (Schottenfeld, Pakes, Oliveto, Ziedonis, & Kosten, 1997).

Clearly, the jury is still out on the mix of cocaine and buprenorphine. This contrasts with our statements that cocaine mixed well with the drug. However, the ability of buprenorphine to blend in ,with benzodiazapines has held up (Eder et al., 1998). A comparison of buprenorphine and methadone patients showed no difference in use of benzodiazapines or alcohol (Schottenfeld et al., 1998). In the French case discussed below, one article actually reports several deaths caused by buprenorphine/benzodiazapine mixes (Tracqui, Kintz, & Ludes, 1998), and another suggests that the two drugs are sometimes coprescribed by physicians (Seyer, Dif, Balthazard, & Sciortino, 1998). Ethnographers and outreach workers present the mixing of buprenorphine and benzodiazepines—especially Rohypnol—as a matter of street-based common sense (Kempfer, 1998a, 1998b; A. Lovell, personal communication, May 29, 2000.).

Another part of the field trial based on the 1996 research focused on the future of buprenorphine/naloxone mixes. Several research art