Two-year Experience with Buprenorphine-naloxone (Suboxone) for Maintenance Treatment of Opioid Dependence Within a Private Practice Setting

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Abstract: Office-based buprenorphine-naloxone (Suboxone) treatment in the United States has significantly improved access to safe and effective opioid-dependence therapy. Little data from physicians' experiences prescribing Suboxone in private offices have been available. This retrospective chart review describes a family practitioner's first 2 years of clinical experience prescribing Suboxone for opioid dependence to 71 patients in a private office. After directly observed rapid office dose induction, Suboxone prescriptions were given monthly after evidence of continued stability. Urine was screened regularly and patients were referred for counseling and other ancillary services. Patients averaged 32 years old, 4.3 years of opioid dependence, and were primarily white (93%) and employed (70%). Fifty-two percent used heroin primarily (most by injection), and 70% had no agonist substitution therapy history. Almost half (47%) paid for their own treatment. Compliance during dose induction was excellent. Suboxone maintenance doses averaged 10 (range, 2-24) mg per day. More than 80% of urine samples were opioid-negative after Suboxone treatment began, although urinalysis did not always include a test for oxycodone. Seventy-five percent had successful outcomes by remaining in Suboxone treatment (43%), tapering successfully (21%), transferring to methadone maintenance (7%), or inpatient treatment (4%). Fifty-eight percent reported receiving counseling. Almost all (85%) paid their fees on time. There were no safety, medication abuse, or diversion issues detected. Overall, office-based Suboxone therapy was easily implemented and the physician considered the experience excellent. Suboxone maintenance was associated with good treatment retention and significantly reduced opioid use, and it is helping to reach patients, including injection drug users, without histories of agonist substitution

Key Words: buprenorphine, Suboxone, office-based addiction treatment

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Buprenorphine (Subutex) and buprenorphine-naloxone (Suboxone) are approved treatments for opioid dependence that have had a significant role in expanding access to effective opioid-dependence treatment.1-3 The sublingualtablet formulation of buprenorphine (Subutex®) is an established substitution treatment for opioid dependence. Subutex is currently available in Europe, the United States, and more than 30 countries worldwide and has made a substantive impact reducing the harm associated with opioid dependence. 1,4,5 Suboxone, a fixed-dose combination tablet containing buprenorphine and naloxone in a 4-to-1 ratio^{6,7} provides the same efficacy and safety as Subutex,8 whereas the presence of naloxone discourages its abuse or diversion in patients dependent on full mu opioid agonists. 9,10 Suboxone is presently approved for use in the United States, New Zealand, Australia, Malaysia, and the European Union. The United States has had the longest field experience with Suboxone to date, with now more than 4 years of almost exclusive use of Suboxone. Oualified physicians can now treat opioid-dependent patients in their office and prescribe Suboxone under a federal law known as the Drug Addiction Treatment Act of 2000. 11,12 No major issues with diversion or abuse of Suboxone have been reported to date.¹³ The success of the U.S. system of care with Suboxone and its safety profile in clinical use contributed to the recent amendment of DATA 2000 to lift the previous 30-patient treatment cap per physician, allowing individual physicians with the need to now treat up to 100 patients at any time.

Relatively few reports exist describing physicians' practical experiences in the United States prescribing Suboxone for opioid-dependence treatment. One report described Suboxone treatment in a family practice teaching center. Most (63%) patients treated with Suboxone remained abstinent from opioids for more than 90 days, but patients were less likely to remain in treatment if they were paying for treatment themselves, as opposed to it being paid for by insurance or a family member. This report showed the feasibility of using Suboxone in family practice settings and underscored the need for greater public funding of opioid dependence treatment.

A second report described experiences implementing the "First Step" program that used Suboxone in a therapeutic community for medical withdrawal from opioids. 15 Before implementing the First Step program, less than half of patients referred to local inpatient detoxification programs returned to begin residential treatment. In contrast, 76% of patients enrolled in the First Step program remained in the

residential treatment program at least 2 days after the buprenorphine taper, a level comparable to those of a matched cohort of nonopioid-dependent patients. The successful use of Suboxone in this program suggests that Suboxone treatment can be integrated into a wide variety of programs paralleling findings from earlier large scale trials of Suboxone for medical withdrawal. 16,17

A third report studied 99 patients being treated in a neighborhood health center or a primary care center based in a hospital. ¹⁸ At 6 months, more than half were sober and still receiving treatment, as determined by physician assessment of the patients' verbal self-report of substance use and urine drug testing. Although the urine drug testing in this study was scheduled and unwitnessed, the authors suggest that more rigorous (eg, supervised and random) testing is untenable in community settings. The authors conclude that Suboxone treatment of opioid dependence can be successful in nonspecialized, primary care settings with limited resources,

The practical experience using Suboxone for medical withdrawal also was assessed in an integrated treatment center for mental health and addiction. Suboxone treatment significantly increased treatment continuation relative to those receiving clonidine taper. The clinicians in this study used a variety of Suboxone dosing strategies, modifying them according to clinical need, without compromising the positive outcomes. The experience in this setting suggests that Suboxone treatment is flexible and robust and further supports that Suboxone treatment can be delivered successfully in diverse settings and can complement ongoing treatment programs.

The current report extends the range of reported experiences by describing the clinical experiences of a family practice physician in a private office setting who started prescribing Suboxone for opioid dependence soon after Suboxone was approved for office-based treatment in 2003. This retrospective chart review describes his first 2 years of experience with 71 opioid-dependent patients.

METHODS

Setting

The setting was the office of a solo medical practitioner located in Durham, NC. The clinical setting was in a small freestanding set of offices, consisting of a consultation room, examination room, and private bathroom. There was no other staff other than the physician. A small supply of stock Suboxone was kept available on site for inductions. This was kept in a locked cabinet, and administered doses were logged, as per Schedule III requirements. The physician (J.W.F.) began treating patients with Suboxone in his office in 2003, soon after Suboxone became available according to DATA 2000.¹¹

General Treatment Approach

All patients were seen for a comprehensive initial evaluation to determine the appropriate clinical intervention, consider treatment alternatives, and to discuss risks, side effects, and cost. If the patient was in opioid withdrawal at the time of the initial visit, he or she could be started on an

induction at that time. If not in withdrawal, a time for induction was scheduled. Patients were typically inducted onto Suboxone with daily office visits during the first 3 days of treatment. Initial doses were directly observed when possible; however, occasionally patient schedules or anticipated onset of withdrawal was incompatible with direct observation and the opportunity to start treatment that day was considered paramount. This procedure allowed for building the patient-physician relationship and observing patients' initial clinical response.

During the initial induction days, Suboxone (typically ranging from 2–4 mg) was given in divided doses to allow observation of patient reactions to the specific doses. By day 3, approximate daily dose needs often were established and the patient was provided with a prescription for Suboxone, prescribed initially for 3 to 7 days at a time, then for progressively increasing lengths. Typically, within 3 months, prescriptions for monthly supplies were written after a continued pattern of stability had been observed as evidenced by regular keeping of appointments, elimination of illicit opioid use, reduction of other illicit drug use, demonstrated psychosocial stability, and no major complaints from the patient. Evidence of recurrent instability resulted in more frequent visits and more limited prescriptions.

Urine drug screening (UDS) using on-site immunoassay test panels (Panel-Dip Device, Redwood Toxicology Laboratory, Inc., Santa Rosa, CA) was performed during regularly scheduled office visits (see below). Urine samples were always tested for appropriate temperature and for proper specific gravity and absence of adulterants if tampering was suspected. Witnessed and unscheduled UDS would probably be untenable in this community-based practice. ¹⁸ All urine samples were tested for opioids (except early tests did not include oxycodone), Δ^9 -tetrahydrocannabinol (THC), and cocaine. Urine samples were tested for methadone and/or benzodiazepines as well if use of these drugs was suspected. Point of use tests were used to provide immediate feedback and adjustment of treatment.

Patients were referred for ancillary services, such as medical and/or psychiatric treatment or more involved individual or group counseling. During regularly scheduled office visits, the physician used an informal brief office model of interaction, incorporating elements of motivational enhancement, cognitive behavioral reinforcement, and self-help group facilitation. Office visits were consistent with standard office practice, 45 to 60 minutes for initial evaluations and 15 minutes for follow-up. Regularly scheduled office visits were typically weekly for the first month, bi-weekly for the next 2 months, and monthly thereafter.

Chart Review

All data (including follow-up information) were extracted from patient records by the treating physician (J.W.F.) to preserve patient confidentiality. Patient records (n = 71) were reviewed for those whose admission dates were at least 1 year before the time of the chart review and spanned February 2003 to May 2005. Follow-up data were therefore available ranging from 12 to 24 months. De-identified data were entered by J.W.F. into a bespoke database program, which validated data for completeness and internal consis-

tency as they were being entered. The de-identified database was then shared with coauthors for data analysis. The project met federal criteria for exemption from institutional review board review.

Historical data collected included demographics (age, sex, race, marital status, employment, and how the patient was paying for services), history of opiate use (years of dependence, type of opioid used, number of previous treatment episodes, and history of opioid agonist therapy), and current medical, psychiatric, and drug dependence diagnoses, which were made or confirmed by the physician through nonstructured clinical interviews. Induction details collected included the Suboxone starting dose and the total Suboxone induction dose on the first, second, and third day of dosing. If a patient was transferred from methadone maintenance treatment or illicit methadone use, the methadone dose was noted, UDS results were evaluated before admission, twice per month during the first 3 months of treatment and monthly thereafter.

Patients were considered retained in treatment if they were still receiving care and Suboxone treatment from J.W.F. or were still receiving Suboxone treatment from another provider with whom treatment continuation could be confirmed. Retention was evaluated at the end of each week during the first month of treatment and monthly thereafter. Whether patients were currently paid up to date on their fees and the type of psychosocial supportive therapy (formal drug treatment program, individual or group counseling, psychiatric follow-up care, 12-step program) also was evaluated monthly.

Patients' disposition (ongoing maintenance, tapered successfully, transferred to another Suboxone provider, transferred to methadone, transferred to inpatient treatment, incarcerated or dropped out or lost to follow-up) was recorded.

Data Analysis

Simple descriptive statistics (counts, means, ranges, percentages) were generated by using the built-in summary functions of FileMaker Pro and Microsoft Excel software. Average maintenance doses were calculated for patients remaining in treatment after the 3-day induction phase. Drug abstinence percentages were calculated by dividing the number of substance negative samples by the number of samples actually collected (ie, missing samples were not counted as positive or negative).

RESULTS

Patient Demographics, Opiate Use, and Treatment History

Table 1 shows the means and ranges for demographic data and opiate use history. Although the range of patient ages was broad, most patients (72%) were younger than 40 years old, and the median age was the same as the mean age (32 years). Almost all (93%) were white, approximately half (52%) were never married, and most (70%) were employed. The sample was about evenly split between those who paid for their own treatment (47%) and those for whom insurance was paying for at least a portion of their treatment (53%),

although only 22% used insurance for both medication and office visits (full coverage). Patients averaged 4.3 years of opiate use and were almost evenly divided between those who used heroin and those who used prescription opioids (heroin was used by 52%, two-thirds intravenously). Most (70%) had not been treated previously with any agonist medication-assisted therapy and 5 (7%) had previously been treated with buprenorphine. Three patients transferred from methadone maintenance treatment and were receiving an average of 40 (range, 24–50) mg per day of methadone at the time of transfer. Three other patients reported illicit methadone use and self-reported average daily methadone doses of 46 (range, 20–80) mg per day.

Psychiatric and Drug Dependence Diagnoses

Table 2 lists the percentages of patients with psychiatric and drug dependence diagnoses. Most patients (62%) were

TABLE 1. Demographics and Opiate Use History ($N = 71$)		
Age (yr)	32 ± 10.7 (range, 16–62)	
Male	69	
Race		
White	93	
African American	4	
Hispanic	1.5	
Asian/Pacific Islander	1.5	
Marital Status		
Never married	52	
Married	37	
Divorced	6	
Separated	4	
Widowed	1	
Employment		
Employed (full- or part-time)	70	
Student	17	
Unemployed	13	
Form of Payments		
Self-pay	47	
Insurance (medication only)	31	
Insurance (full)	22	
Opiate dependence history		
Years of dependence	4.3 ± 3.4 (range, 1–18)	
Type of opioid		
Heroin	52 (64% IV; 36% IN)	
Oxycodone	20 (93% oral; 7% IN)	
Hydrocodone	13 (100% oral)	
Methadone	8 (100% oral)	
Oxycontin TM	7 (80% oral; 20% IN)	
Morphine	1 (100% oral)	
No. previous opiate treatment episodes	1.3	
History of agonist substitution therapy		
No history	70	
Methadone*	24	
Buprenorphine*	7	

Data are means \pm standard deviations or percentages unless otherwise indicated.* One patient had a history of both methadone and buprenorphine treatment.IV, intravenous; IN, intranasal.

TABLE 2.	Current Psychiatric and Drug Dependence
Diagnoses	

Psychiatric diagnoses	
Any psychiatric diagnosis	62
Major depression	45
Anxiety disorders	24
Attention deficit hyperactivity disorder/attention deficit disorder	11
Bipolar disorder	7
Borderline personality	1
Drug dependence diagnoses	
Opioid	100
Stimulant	28
Marijuana	23
Alcohol	13
Sedative	3

diagnosed with some psychiatric illness; major depression was the most prevalent. Approximately one-quarter of the patients were diagnosed with stimulant or marijuana dependence in addition to opioid dependence.

Induction and Maintenance Doses

The initial Suboxone dose on day 1 averaged 2.3 ± 0.9 (standard deviation (SD)) mg (n = 71; range, 2–8 mg). All patients received additional doses on the first induction day, and the total Suboxone dose given on the first day averaged 5.3 ± 0.9 (SD) mg (approximately half received 2–4 mg and approximately half received 6–10 mg) . On the second day, Suboxone doses were given to 69 of 71 patients (97%) and averaged 8.1 ± 3.8 (SD) mg (30 received 2–6 mg and 39 received 8–20 mg). On the third day, Suboxone doses were given to 67 of 71 patients (94%) and averaged 10.1 ± 5.2 (SD) mg (18 received 2–6 mg, 36 received 8–12 mg, and 13 received 16–28 mg). Suboxone maintenance doses remained mostly stable for up to 24 months, averaging 10.1 (range, 2–24) mg per day. There was a tendency for maintenance doses to remain constant or trend down slightly over time.

Patient Retention and Fee Collection

Figure 1 shows the percentage of patients retained in treatment per month. Nearly half of the patients who began treatment with Suboxone remained in treatment at the end of any given month, with J.W.F. or with another Suboxone provider. Fee collection was reliable, with at least 85% of patients compliant with fee payment at the end of each month.

Urine Drug Screening

Although all patients met criteria for opioid dependence, 22% of urine samples collected before admission tested negative for opioids, possibly because of the lack of sensitivity to oxycodone of the early tests. Use of other illicit drugs before admission was low: 85% of urine samples collected tested negative for THC, 85% tested negative for cocaine, all tested negative for amphetamine, and 91% tested negative for benzodiazepines.

Figure 2 shows the percentage of urine samples tested that were negative for opioids before admission and during

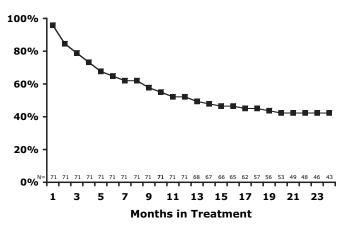


FIGURE 1. Percentage of patients retained in treatment during 24 months. The percentages include all patients who were still receiving Suboxone treatment and care from any known provider at the end of each month. The number of patients who could be evaluated declined during months 13 through 24, because charts were reviewed for patients whose admission dates were at least 1 year before the time of the chart review. Thus, some patients could not have been in treatment for more than 1 year. This figure makes the most conservative assumption, which is that patients dropped out in the month subsequent to the last month for which we have data (eg, the denominator was held constant at N=71). The small numbers above the x-axis shows the N at each month.

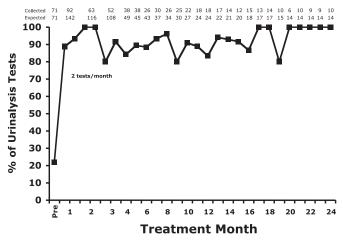


FIGURE 2. Percentage of opioid-negative urine samples during 24 months: Urinalysis did not always include oxycodone. The first row of numbers at the top of the figure shows the number of urine drug samples collected during each month. The second row of numbers shows the number of possible urine drug samples that could have been collected during each month given the number of patients still in treatment.

the course of treatment. Between 80% and 100% of samples collected from each patient were negative for opioids tested after Suboxone treatment began. Moreover, 87% of patients submitted no more than one opioid-positive urine drug sample during the course of their treatment.

Nonopioid illicit drug use remained low throughout the course of treatment: 82% of urine samples collected tested negative for THC, 90% tested negative for cocaine, 99.8% tested negative for amphetamine, and 94% tested negative for benzodiazepines.

Psychosocial Supportive Therapy

A majority (58%) of the patients received some sort of counseling. Most of the counseling received was individual or group counseling (68%) or psychiatric follow-up care (29%). A much smaller number reported involvement in a 12-step program (7%) or formal drug treatment (2%). Some patients received more than one type of counseling.

Patient Disposition

Positive treatment outcome was defined as a patient engaged in ongoing substance abuse treatment with significant reductions in opioid abuse. If the patient requested medically supervised withdrawal or tapering from agonist therapy, success was defined as no relapse to opioid use during the taper or at the time of discharge.

According to these definitions, most of the patients had positive treatment outcomes at 12 to 24 months from treatment initiation. Almost half (43%) of the patients continued in ongoing medication-assisted therapy, with JWF or after transfer to another Suboxone provider. Another 21% tapered successfully at their request and were opioid-free during and at the conclusion of the taper. Transfer to methadone maintenance (7%) or to inpatient treatment (4%), even though Suboxone treatment was discontinued, were considered positive outcomes because Suboxone served as an introduction or bridge to ongoing treatment. Only 24% were clear treatment failures in the sense that the patient dropped out or was lost to follow-up. Incarceration during the time of treatment accounted for the final 1% of patients.

DISCUSSION

This retrospective chart review adds practical field experience to the research evidence that Suboxone is a safe and effective treatment for opioid dependence in an officebased setting. Illicit opioid use was greatly reduced or eliminated in most patients, especially in those who were engaged in treatment for at least 2 months. Although testing for oxycodone was not always included in the urinalysis, use of this drug was likely reduced by Suboxone as well. Nearly half of all the patients who started Suboxone treatment were still receiving Suboxone treatment at the end of each month. This retention rate is slightly higher than the 38% reported at 1 year for new admissions to methadone maintenance therapy,²⁰ is similar to that reported for Suboxone maintenance in a family practice clinic,14 and parallels recent research findings for Suboxone in office-based treatment.²¹ Moreover, positive treatment outcomes resulted for most of the patients, with 75% continuing ongoing medication-assisted therapy with Suboxone, tapering successfully, or transferring to methadone maintenance or inpatient treatment. That 21% of patients successfully tapered from Suboxone, as defined by being opioid-free during and at the end of the dose taper, is consistent with other reports¹⁷ stands in contrast to notoriously poor outcomes with methadone tapers²² and supports a potential role for Suboxone as an alternative medication for assisting withdrawal from opioid dependence. Unfortunately, longer term follow-up was not available for these patients, therefore the number of patients who subsequently relapsed to opioid abuse is not known. Given the severe, lifelong, negative consequences of untreated opioid dependence,²³ treatments, such as Suboxone maintenance, that have the potential to draw patients into and retain them in treatment safely and effectively should be considered for adoption by the general practitioner community.

Several other findings in this report merit discussion. First, the average total day 1 induction dose of 5.3 mg per day was lower than the 8 mg typically provided on the first day in earlier reports.8,16,21 Nonetheless, day 1 doses adequately addressed patient needs, because all but 2 patients returned to receive their day 2 dose. The concerns that many new prescribers have about precipitating withdrawal with Suboxone were not borne out by this clinician's experience given that only 2 patients dropped out of treatment after day 1 and only 4 dropped out during the first 3 days of induction. In only 1 case was precipitated withdrawal a possible or likely explanation. Day 2 doses (average 8.1 mg/d) increased in accordance with published U.S. clinical guidelines for Suboxone stabilization,24 and excellent compliance was observed on day 3 as well, with all but 2 patients who received day 2 doses returning to receive their day 3 dose. These results emphasize that induction doses can remain flexible to patient needs and that patients may benefit from frequent interaction with a clinician during the induction period. Moreover, patient doses were increased rapidly according to need during dose induction. This no doubt contributed to the compliance and early treatment retention among these patients consistent with the association between direct and rapid induction with buprenorphine and better early treatment retention.²⁵ The benefit of this rapid induction also is supported by the finding that two-thirds of patients had no further evidence of opioid use after their initial admission urine drug screen, although oxycodone use was not always measured. This stands in contrast to methadone induction, in which a longer titration is common and often results in illicit supplementation.

Second, maintenance doses averaged 10.5 mg per day, which is lower than Suboxone maintenance doses used in the pivotal study⁸ and those reported in recent office-based opioid treatment research (17.5 mg/d).²¹ However, this average maintenance dose is similar to that reported in another field experience report.¹⁴ Maintenance doses used adequately addressed patient needs, because more than half of patients remained in Suboxone treatment and illicit opioid use dramatically declined. Overall, efficacy was clearly preserved, although average maintenance doses were slightly lower than current treatment recommendations of 16 to 24 mg per day.²⁴ It is not clear whether this resulted from the closely observed and titrated induction process or is related to a different patient demographic or abuse history.

Third, the patients treated in this office were fairly typical of those beginning Suboxone treatment in primary care²⁶ and family practice settings.¹⁴ Most patients were

male, white, and employed. Opioid dependence histories were relatively short, 70% had no previous history of opioid agonist therapy, and patients were a mix of intravenous heroin users and oral prescription opioid users. These characteristics provide additional support that office-based Suboxone treatment is drawing new populations of intravenous and oral opioid users into treatment.

Fourth, almost half (47%) of the patients were responsible for paying for their own treatment. Compliance with fee payments was high: 85% of patients remained current with their fees at the end of each month. Although other data suggest that paying for one's own Suboxone treatment has a strong negative influence on retention, 14 fee collection posed no problems for this office. Thus, physicians considering adopting Suboxone treatment should not be overly concerned that payment for services will be problematic.

Fifth, limited resources were needed to adequately treat patients in this office setting. A small office with no staff other than the treating physician was used, and storing medications onsite provided no logistical or security challenges. Furthermore, the treating physician encountered no behavioral problems (such as stealing or other mischief) that might disrupt a typical practice. The simplicity with which Suboxone treatment can be delivered should be encouraging to those considering adopting this therapy. The most significant issues during the treatment period were not related to the medication, fee payments, or patient behavior, but rather the 30-patient cap imposed by DATA 2000, which limited the number of patients who could be treated. Fortunately, this latter issue has been addressed with the December 2006 amendment to DATA 2000, which increased the limit to 100 patients per physician. 11

One other finding related to resource utilization merits further discussion. Most of the positive clinical outcomes noted were associated with little involvement in formal psychosocial support and with almost no involvement in formal substance abuse treatment or self-help programs, although the physician regularly recommended and encouraged patients to seek further treatment and/or support for their recovery. However, formal psychosocial supports were not mandatory for treatment and few chose to pursue them. Some of this likely reflects the demographic mix of the patients, with relatively high rates of employment (70%) and family support and relatively short periods of dependence (average 4.3 years). Moreover, the physician used the routine office visits to speak to patients and reinforce positive behavior change on a regular, recurring basis. Increasing evidence suggests that regular follow-up with a medical clinician using even brief supportive intervention can have a significant impact on maintaining abstinence,²⁷ and this has been borne out in a controlled evaluation of different levels of counseling support during office-based Suboxone treatment.21 Regardless, physicians should continue to encourage engagement in psychosocial treatment, because this is well-established to positively impact outcomes during medication-assisted treatment for opioid dependence.²⁸

Finally, there are a few limitations to this report. First, the results are based on a retrospective chart review with a relatively small sample of patients who were included based on their sequential admission to treatment. The smaller sample size was largely because of the previous 30-patient cap on office-based opioid treatment, which limited the number of patients who could be studied. Furthermore, data collection was based on clinical notations in the charts made at each clinic visit, rather than from a prospective and systematic study. Nonetheless, the data obtained provide additional evidence of the practicality and efficacy of office-based treatment using Suboxone.

CONCLUSIONS

Office-based treatment with Suboxone is an effective intervention for treating opioid dependence that is amenable for use in multiple treatment settings, including solo primary care practices. In the present report, Suboxone maintenance reduced opioid use, was not associated with any serious adverse events, was associated with high rates of treatment retention, and helped reach a broad patient population, especially those who had never before received opioid agonist medication-assisted therapy. It should not be forgotten that opioid dependence is a chronic medical disorder, and physicians with many backgrounds and in many settings can now readily qualify in the United States to treat patients with Suboxone. Hopefully, this field experience report will encourage more providers to become involved in the delivery of Suboxone treatment for opioid dependence.

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