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THE BRIDGE
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Introduction: Buprenorphine and Integration

By Paul Roman, PhD, Editor

The theme of the last two issues of *The Bridge* has been the integration of the treatment of substance use disorders (SUD) into mainstream medical practice, including primary care as well as branches of specialty medicine. This is revolutionary, as it seems that the SUD treatment field has long been on the road of establishing its legitimacy as a distinctive and credible specialty of its own. This transition is however built into the Affordable Care Act, and thus change may be upon the SUD treatment field whether or not it decides to take a hand in guiding this change. Finally, the many dimensions of integration are difficult to grasp or even conceptualize all at once. There is a definite vagueness and a pervasive uncertainty.

One “solid” example of deliberate and aggressive integration was the Drug Addiction Treatment Act of 2000, legislation following the Food and Drug Administration’s approval of the use of buprenorphine for the treatment of opioid dependence. The legislation seemed very much a step ahead of the relatively small world of addiction practice in that it had a distinct mechanism for the involvement of primary care physicians, a group that seemingly contained many who shunned and ignored addiction and its treatment. DATA prescribed that those who took training and obtained a waiver were qualified to use buprenorphine while others could not. To a large degree, the legislation seemed designed to largely keep buprenorphine treatment out of the established and highly controlled system of methadone maintenance, “setting off” the innovative treatment from what had been the paradigm for several decades. Even though this major change was enacted, it has not been followed by a large body of research to establish what is and what is not happening. We are fortunate to have included in this discussion commentaries by Hannah Knudsen at the University of Kentucky and Dennis McCarty at Oregon Health Sciences University, who bring some new data to bear on the many questions surrounding buprenorphine treatment implementation.

The core of this issue is the following interview that I conducted with Dr. Jeffrey Junig, a psychiatrist in private practice in Fond du Lac, WI, who has written widely in popular media and specialized blogs about addiction medicine and the use of buprenorphine. As is seen here, he has a great deal of hands-on experience and is very articulate in considering the many issues surrounding buprenorphine. Dr. Junig holds both Master’s and PhD degrees from the University of Rochester’s Brain Research Center and his MD from the University of Rochester’s School of Medicine and Dentistry, and is a new member of the Editorial Board of *The Bridge*.

Following the interview are commentaries by nine members of *The Bridge’s* Editorial Board, including two other new members, Mr. Ron Jackson and Dr. Dennis Daley. We also welcome Dr. Ismene Petrakis of Yale University School of Medicine as a guest contributor.

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The Buprenorphine Treatment Scene: An Interview with Dr. Jeffrey Junig

Paul Roman, PhD

Question 1. The introduction to buprenorphine treatment in the U.S. has occurred through a controlled system somewhat parallel to controls on methadone. How would you envision the current buprenorphine treatment scene had these regulations never been imposed, with buprenorphine introduced into medical care with no waivers or patient limitations?

Dr. Junig: I think it would be different in good and bad ways. Without the regulations, buprenorphine would likely have become prescribed by primary care to a much greater extent, which would have saved the lives of many, many young people. There would be more buprenorphine/Suboxone in the hands of patients and non-patients. The increase in buprenorphine would likely be balanced by reductions in opioid agonists, as primary doctors would have moved chronic pain patients from agonists to buprenorphine. Any reduction in use of opioid agonists would be a good thing, whether through reducing the deaths caused by agonist diversion, or through getting people stuck on the roller-coaster of agonist dependence onto buprenorphine instead. While buprenorphine has similar discontinuation symptoms as agonists, the subjective experience of taking buprenorphine is very different from the experience with agonists—leaving people much better off after the change.

The addiction doctors who seem to see diversion-control as their primary role would see an increase in buprenorphine/Suboxone as a problem. But the dangers of buprenorphine diversion are overblown. Much 'diversion' consists of misguided self-treatment by patients who can't find a prescriber, or by former patients who were not able to maintain sobriety perfectly-enough to avoid discharge from their prescriber. Having more prescribers might have resulted in less non-prescribed use of buprenorphine.

The diversion issue is complicated, even in cases where buprenorphine is used as a bridge between agonists in addicts who do not intend to quit using. Buprenorphine has a strong protective effect against death, whether taken by prescription or through diversion. Specifically, over 35,000 US overdose deaths occur annually in the absence of buprenorphine, compared to about 40 overdose deaths each year when buprenorphine is one of the drugs in the person's system. If the people most worried about diversion are correct—i.e., if diversion consists less of 'self-treatment' than of poly-substance dependence—we would expect many more overdose victims to have buprenorphine in their bloodstream at the time of death. The bottom line: if a person takes buprenorphine for any reason—even just to avoid withdrawal until a better batch of heroin comes to town—that person is less likely to die from overdose.

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2. It is recognized that there are some geographic locations where buprenorphine access is highly limited. Aside from this troubling fact, a devil's advocate could argue that the numbers of physicians who have been waivered represents a major success. Most of the "folklore" of the field would have suggested that practically no physicians would have wanted to come forward to treat opiate addiction.
Dr. Junig: The 'folklore' is, unfortunately, largely correct. Many waivered physicians never actually prescribe buprenorphine products. Others start treating opioid dependence but then discontinued that aspect of their practice. Last weekend, headlines in Indiana described the arrest of several doctors who prescribed buprenorphine products. News stories demonized aspects of their practice styles, even though they were not at odds with DATA 2000. The articles wrote that (gasp!) they were not doing urine tests at every patient visit, they were asking for cash payments, and they didn't require counseling for every patient. The lack of ASAM support for these physicians and similar cases will have a chilling effect on physician attitudes toward treating opioid dependence.

3. Would there be any disadvantages if the current patient limit of 100 was eliminated altogether?
Dr. Junig: Many lives would be saved. Some doctors picture a sea of buprenorphine abuse, but patients who take the medication know that a 'buprenorphine habit' does not yield the experience achieved with heroin or other agonists. The ceiling effect results in constant opioid activity across the dose range, which leads to rapid tolerance—whether the buprenorphine is injected or taken sublingually. For opioid agonist addicts, the primary result from buprenorphine abuse is inadvertent treatment!

4. From your perspective, how successful have physicians been in linking buprenorphine patients with psychosocial counseling?
Dr. Junig: Successful enough. Some patients do well on buprenorphine products without counseling. While that statement is almost heresy these days, I encourage addiction doctors to do the specialty the favor of practicing evidence-based medicine, and following the data. Buprenorphine treatment is filled with a range of opinions about best practices. But where are the data?

5. Simply on the basis of their skills as physicians, and assuming they were willing to spend the time, do you think the majority of physicians could successfully deliver this psychosocial counseling?
Dr. Junig: Many different interventions fall under the label of 'counseling'. If a counselor spends each session trying to convince a patient to 'get off buprenorphine', is that effective counseling? Any physician who knows his/her patient, and cares enough to counsel, educate, and refer appropriately, should be allowed to decide what is best for the patient. Surgeons are given the responsibility to decide, all by themselves, which organ to remove—but addiction doctors aren't trusted to make decisions about counseling? No other medical specialty assumes such a high level of ignorance in their doctors!

6. From your perspective, how successful have physicians been in delivering other needed medical services (services they likely would not otherwise receive) to the patients to whom they prescribe buprenorphine?
Dr. Junig: Practices vary. I have great respect for primary care physicians who manage opioid dependence, and at the same time manage other forms of illness in the same patient. In other areas, addiction doctors have become 'super-specialists' who only provide buprenorphine treatment. I know that in my own practice, patients who initially present for buprenorphine treatment end up with much better psychiatric care than they otherwise would have received.

7. Has your buprenorphine practice added significant numbers of new primary care patients to your overall practice?
Dr. Junig: I am a psychiatrist, and buprenorphine has added new psychiatric patients. I also evaluate rashes, infections, aneurysms and pseudo-aneurysms, GI issues, and many other conditions outside of psychiatry that have some connection to the patients' buprenorphine treatment.

8. On the basis of your own experience and the experience of your colleagues, has the presence of patient addicts in your practice caused difficulties with other patients or with your colleagues/staff?
Dr. Junig: I suspect some non-addiction patients have been uncomfortable in the presence of patients with addictions who are new to treatment, who sometimes appear a bit rough. I encourage patients to talk about their concerns, and I do not believe I've lost patients over that issue.

9. What key indicators should determine when tapering off buprenorphine should begin?
Dr. Junig: Given the high rate of relapse, I believe patients have a right to ongoing buprenorphine treatment without time limitation. I advise patients about the risk of relapse. We need more data, but I suspect that age, occupational status, and personality factors play a role in risk of relapse, and should therefore be factored into decisions about discontinuation of buprenorphine

10. What are the prospects for insurance coverage for indefinite/as needed maintenance on buprenorphine?
Dr. Junig: I believe prospects will be good, IF our professional advocate agencies step up to the plate and educate insurers—and legislators. We should demand access to lifelong medication for our patients with life-long illnesses!

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11. For currently active buprenorphine-waivered physicians, what should they be considering in terms of the use of injectable naltrexone for their opiate addicted patients?

Dr. Junig: Naltrexone looks good on the surface, but too few people consider the long-term outcomes. We seem to have a fantasy that if we block a person from using for a year, counsel the heck out of the person, and then remove the block, that the patient will live happily ever after. But Australian studies show high death rates in patients who were maintained on naltrexone in the year after naltrexone was discontinued. Since we have no data showing that counseling is effective in maintaining abstinence from opioids, I am not convinced that it is a good idea to keep someone from his drug of choice with monthly injections, and then stop those injections—particularly when the injections create hypersensitivity to opioids and respiratory depression from opioids. Patients stop Vivitrol knowing that IF they relapse, they will get the biggest 'high' they've ever had… which is not a good situation for addicts! Will there be a high death rate in people who were placed on naltrexone, when the drug is discontinued? I supect the answer will be 'yes'—but in either case, I hope that physicians pay attention to that data.

12. If you found yourself appointed Czar of All Drug Treatment in the U.S., what steps would you take to improve the delivery of buprenorphine to opiate-addicted patients?

Dr. Junig: I would ask physicians to practice medicine first, and to follow the science. We have a role in preventing diversion, but that is not our primary role as physicians. Physicians should point out, and resist, any regulation or policy that increases the number of deaths from opioid dependence. Who will carry that message if not physicians?

When physicians become obsessed with out-regulating each other, the result has been policies based on opinions or business models, not on science. Some of the policies being advocated—for example quantitative testing or counseling for all patients—have large profit incentives for doctors and health systems, but stand in the way of care for uninsured or underinsured patients.

I would want to see opioid dependence treated as the disease that it is. With any new regulation, we should ask ourselves: would we do the same for asthma or hypertension? Do we require nutrition counseling, for example, in order to receive insulin? I would also assume that doctors treating addiction have the same i ntelligence, competence, and compassion to stay current with the standard of care for treating addiction, as any other physicians. We shouldn't add regulations that would not be tolerated by any other medical specialty.

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Access to Buprenorphine Treatment: Complexities Across the National Landscape

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University of Kentucky

I read with great interest the interview between Dr. Paul Roman from the University of Georgia and Dr. Jeffrey Junig. As I read the transcript, there were many points of intersection with research that our team at the University of Kentucky is conducting on the impact of the Affordable Care Act on buprenorphine treatment in the US through a grant supported by the National Institute on Drug Abuse (R33DA035641).

Our mixed methods study collected qualitative interview data in 2013 from 21 buprenorphine-prescribing physicians who have served as expert mentors to support the implementation of buprenorphine by other physicians. Currently, we are recruiting a large nationally representative sample of prescribers for a survey, and we are also examining state-level measures of treatment availability and utilization.

A striking finding of our research is how variable the availability of buprenorphine treatment is across the country. Shortages of prescribers and challenges with treatment access were noted by many of our interview participants. Several participants noted the many physicians, themselves included, are usually at the 100 patient limit. These multiple challenges were described by one participant: “You can’t get into treatment in a lot of places. That’s number one. I guess I’ll sum it up in one word; it’s access. Okay, there’s not enough Suboxone doctors to go around; if there are Suboxone doctors, they won’t accept Medicaid; they only want cash. Once you are in a Suboxone program and then the person is having trouble and you want to refer them to an IOP [intensive outpatient program], you often can’t get them into a local IOP for again, same access reasons, long waiting lists, those kind of things.” This participant notes intersecting challenges—an insufficient number of prescribers coupled with limits to treatment access that may occur when some physicians will not accept insurance for payment.

The issue of the number of waivered physicians is a key facet of our current study. We are monitoring the number of physicians who hold the X-license to prescribe buprenorphine at the state-level. One interesting finding thus far is that there has been significant growth in the number of waivered physicians since we began our study. Over a 13-month period, the total number of waivered physicians in the US has increased by more than 2,200 physicians, which represents about a 10% increase. This rate of increase outpaces the growth in the overall number of physicians in the US over the same period. At the state-level, the average number of waivered physicians has grown from about 442 to 487 physicians, which is a statistically significant increase;

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even when the numbers are adjusted for population (i.e., the number of waivered physicians per 100,000 residents in the state), the difference is still significant.

We have also begun to look at the distribution of waivered physicians across the country. At the end of 2013, the average state had 8 waivered physicians for every 100,000 residents. However, the range was quite large for this measure, with Nebraska having just 2 physicians per 100,000 residents and Vermont having almost 28 waivered physicians per 100,000 residents. Dr. Junig’s home state of Wisconsin had only 5.7 waivered physicians per 100,000 residents. A large portion of the state-level variation in the numbers of waivered physicians can be attributed to significantly greater numbers of waivered physicians in Northeastern states, relative to the rest of the country.

But the number and distribution of waivered physicians is only one aspect of the challenges of treatment access and availability. Dr. Junig notes that the 100 patient limit is a substantial barrier for patients, and that perspective was echoed by some of the participants in our qualitative interviews. As described by one qualitative participant: “The numbers of individuals that are seeking help versus the people that can provide them help—there’s a disconnect between the two…I don’t know of one of them that’s practicing …and that doesn’t have a waiting list.…I’m in the process of tapering people and some of them finally, they may, they have their last visit. But until one of those things happens, you know you can’t bring another patient in without jeopardizing the possibility of sanction from the licensure board or the Drug Enforcement Administration or other entities…I’m on about a 30-35 day wait list. I’ve got colleagues that have a 90 day wait list.”

However, other participants noted that waiting lists were not an issue in their area. One participant said, “But most providers are not overly swamped. I mean, there’s some people who are at their limits, right--you know their 100 patient limits pretty consistently--but most aren’t.” The unequal distribution of waivered physician across different parts of the country may be one influence on physicians’ perspectives about how much the 100 patient limit is a barrier to care.

It may also be useful to note that only a minority of waivered physicians actually hold a waiver to treat 100 patients. In December 2013, just 6,851 physicians were waivered for 100 patients, representing about 29% of all physicians who hold the buprenorphine waiver. This statistic does not diminish the challenges faced by physicians who are allowed to treat 100 patients and yet still have waiting lists, but does suggest that part of the conversation about increasing treatment access may need to address the limited number of physicians who seek the 100 patient waiver.

From my perspective, buprenorphine is a lifesaving medication and as such, I share Dr. Junig's concerns about patients being able to access this treatment. I hope that our research can inform some of discussion about treatment access, particularly the data regarding the unevenness of the distribution of waivered physicians across different parts of the country and the relatively few physicians who can actually treat 100 patients. The methods of payment that prescribers will accept from patients further complicates these questions about access.

The extent to which prescribers will not accept Medicaid or private insurance poses an additional barrier for patients. From a policy perspective, the prevalence of cash-only practices where insurance is not accepted may limit the extent to which health reform can actually improve patients' access to care. Our large national survey of current prescribers will help to elucidate the relationships between states' implementation of the Affordable Care Act, how physicians structure the payment aspects of buprenorphine services, and the numbers of patients receiving this lifesaving treatment. We are excited that our research can be part of this ongoing dialogue about how to increase buprenorphine treatment access and treatment quality.

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Regarding Substance Using Patients and Buprenorphine: A Primary Healthcare Challenge

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Dr. Junig presents a frank assessment of the multiple regulatory and political factors that have impeded greater utilization of buprenorphine for the treatment of opiate addiction. He suggests that by (1) eliminating the patient cap of 100 per certified physician, (2) trusting physicians to make their own counseling decisions about how they support buprenorphine treatment, (3) increasing insurance coverage for indefinite maintenance, and (4) asking physicians to follow scientific findings and fight regulations not based on them, many more physicians would treat opiate addicted patients with buprenorphine. Dr. Junig's points are well taken and underscore the complex array of provider authorities, regulatory constraints, and philosophical contentions that affect the implementation of buprenorphine treatment in the United States.

In addition to the factors discussed by Dr. Junig, we would like to highlight an additional avenue for improving buprenorphine implementation: reducing the negative regard many physicians and other healthcare providers have toward patients with substance use disorders. Gilchrist et al. (2011) found that a mixed group of health-care professionals had considerably more negative attitudes toward patients with substance use disorders compared to patients with other medical diagnoses and that their regard for these patients was poorer than that held by their colleagues in general psychiatry or in specialty addiction services. Likewise, van Boekel et al. (2014) extended these findings, demonstrating the poorer regard general medical physicians, in comparison to professionals working in psychiatry and addiction services, held toward by patients who abused alcohol or drugs.

In particular, physicians were more likely to see addiction as a consequence of the patients' weakness and to pity those they treated. In general, the stigmatization of patients with substance use disorders by healthcare providers has been a longstanding problem (Abouyanni et al., 2000; Berger, Wagner, & Baker, 2005; Chappel, Veach, & Krug, 1985; Fortney et al., 2004). Historically, this stigmatization has been greatest for patients addicted to narcotics (Campbell and Lovell, 2012). With this as a mindset, who would want to treat these patients, let alone prescribe them buprenorphine?

Healthcare providers' poor regard for patients with substance use disorders risks many negative consequences. It can lead to lower quality of healthcare, poor patient treatment adherence, and less patient utilization of substance use interventions (Bitarello et al, 2012; Fortney et al., 2004; Kahan et al., 2004). It may heighten the degree to which healthcare providers hold patients personally responsible for their addictive behaviors and limit provider willingness to offer these patients assistance (Corrigan et al., 2005). Furthermore, patients may internalize providers' negative beliefs as true about themselves (Ronzani, Higgins-Biddle, and Furtado, 2009). The under-utilization of buprenorphine may be yet another negative consequence of the ongoing poor regard many healthcare providers have for patients with substance use disorders.

In this context, efforts to implement all medication-assisted treatments for substance use disorders, including buprenorphine, have been difficult. For example, naltrexone was established as an FDA-approved pharmacotherapy for alcoholism in 1994, yet the uptake of this treatment in practice has been slow at best (Abraham, Rieckmann, McNulty, Kovas, & Roman, 2011). We are less optimistic than Dr. Junig that the number of physicians who prescribe buprenorphine would significantly increase or that this efficacious treatment would become more available to patients if regulatory constraints were lessened.

Efforts to remove misguided regulatory controls must be matched with equally strong efforts to educate and train healthcare providers to have more positive regard for patients with substance use disorders and to encourage more of them to specialize in the addiction treatment field. Fundamentally, healthcare professionals need to feel the work with this patient group is legitimate.

There is room for optimism about the possibility of reducing the negative regard some healthcare professionals have toward patients with substance use disorders. Evidence suggests that increasing exposure to buprenorphine treatment may lead to greater uptake of it. Knudsen, Abraham, Johnson, and Roman (2009) found that community treatment programs that had participated in buprenorphine treatment research studies within the NIDA Clinical Trials Network doubled in-house buprenorphine treatment over the course of two years, controlling for level of care and for-profit status. As physicians become increasingly exposed to the benefits of buprenorphine treatment and staff positively disposed toward it, they may adopt more positive attitudes toward buprenorphine and see the use of it as falling within their scope of practice. In addition, determined, well-organized educational efforts may help change providers' philosophies and practices. The NIDA and SAMHSA/CSAT Blending Initiative has provided several products designed to heighten awareness about buprenorphine treatment, dispel general myths about medication-assisted treatment, and inform providers about how to conduct short-term opioid withdrawal using buprenorphine and the benefits of using buprenorphine with young adults (Ling et al., 2010). These educational products might help promote physicians' use of buprenorphine treatment.

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Moreover, psychiatrists are getting added qualifications in addiction psychiatry, a subspecialty accredited by the Accreditation Council for Graduate Medical Education (ACGME) since 1997. At the outset, there were only 13 addiction psychiatry programs; this has grown to approximately 46 (see http://www.acgme.org/ads/Public/Reports/ReportRun?ReportId=1&CurrentYear=2013&SpecialtyId=87). Further, initiatives such as one taken by the American Academy in Addiction Psychiatry (AAAP), initiated training for prescribing buprenorphine during residency training, thereby reaching a broader group of psychiatrists, not all of whom became trained in addiction. In addition, concerted effort is being put into increasing the number of physicians, focusing primarily on primary care, who obtain a subspecialty in addiction medicine. The American Board of Addiction Medicine (ABAM) now accredits 19 fellowship programs to train physicians in addiction medicine. The programs have resulted in over 3000 physicians being certified in addiction medicine by ABAM (see http://www.abamfoundation.org/accredited-residencies-in-addiction-medicine/). We need more ABAM-supported addiction fellowship programs to build a physician workforce that has the requisite knowledge to treat patients who have substance use disorders, including using buprenorphine as part of their treatment armamentarium.

Likewise, the American Society of Addiction Medicine (ASAM) promotes physicians' education and training in the care of patients with substance use disorders. ASAM provides educational resources, online learning, and live courses to help physicians develop expertise in addiction medicine, as well as to maintain their ABAM certification. ASAM provides a professional home for like-minded physicians to share resources and expertise and to train one another in a myriad of addiction topics, such as the use of buprenorphine. Finally, the Veterans Administration (VA) recently launched the Inter-professional Addiction Treatment Advanced Fellowship Program. This fellowship provides two years of post-residency, post-doctoral research, education, and clinical training to physicians and allied healthcare professionals in advanced addiction care. Graduates are expected to become leaders in the field.

Increasing the implementation of buprenorphine treatment must occur in a healthcare context that has a more positive regard toward treating substance using patients. As more healthcare providers recognize substance use disorders as chronic health conditions that fall within their scope of practice, then they might become more open to using the array of medication-assisted therapies available to treat patient who struggle with addiction. Lessening the continued stigmatization of substance using patients through education and training of healthcare providers remains a primary healthcare challenge.

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Experience and Opinions are Valuable, But We Need Data

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I usually cringe when I hear the phrase “based on my experience” as it is likely that an opinion is forthcoming without supporting data. Still I wish to share some experiences that led me to support many of Dr. Junig’s points, “based on my mistakes” as a former administrator of a substance use treatment organization. An old adage is to never tell a story without data and never provide data without a story. I apologize for my violation of this rule.

Our original use of buprenorphine was Subutex for opiate withdrawal in a medical detoxification unit. The medication was titrated over a 5-7 day period. Several problems were encountered. The available beds were being filled with opiate patients due to the length of the detox limiting availability to people in alcohol withdrawal. There was no medical reason to keep them in the detox facility other than to continue the medication through the withdrawal period. Once the detoxification was complete, many did not link to and engage in ongoing treatment and would return to use, followed by subsequent detox episodes.

When Suboxone, a combination of buprenorphine and naloxone became available, I decided to move patients to an outpatient service that would begin with a single day of inpatient care to stabilize a patient on the medication. The medication-assisted treatment would be combined with a new evening intensive outpatient service (IOP). I decided we should use a 13-day titration schedule that had been used in a NIDA clinical trial. When I told Dennis McCarty, a fellow member of *The Bridge* editorial board of my plans, he just shook his head and said that a short detox schedule would not be successful.

Dennis was right. When we tried the 13-day titration schedule there was rebellion among the patients. They were fine with lowering the doses (which also saved them medication costs) but did not want to end use of buprenorphine. A consistent theme from the patients was “I feel fine, I am getting my life back, and I am reconnecting with my family.” Thus, we switched to a plan to provide the medication for a 2-3 month period. That also was not acceptable for some of the people served who chose to continue treatment further and go to buprenorphine certified providers in private practice, paying for monthly visits out-of-pocket.

The initial cohort of patients also complained that four nights a week of IOP was too difficult and intrusive. Some were located a distance away from the clinic and had to drive up to an hour each way. They also wanted more individual and family sessions. Having learned the principle of “listen to your customer” from our NIATx experience, the clinical staff worked with the patients to redesign the delivery system.

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The group agreed to two nights of two-hour group sessions weekly with the other evenings being available for individual or family sessions. Attendance was high. An interesting story was when a group had been scheduled for the Wednesday night before Thanksgiving, the counselor asked whether the patients wanted it cancelled. They said no and attended. They had ownership in the services.

While Medicaid covered buprenorphine in the state, no general revenue or Federal block grant funds were available to purchase the medication. Thus, we asked clients to pay for the buprenorphine, and the majority who were offered the service paid for the medication. Family members were often more than willing to assist with the funding. Of course, in choosing treatment over continuing addiction, there was a cost offset between paying for heroin or prescription opiates and the cost of the buprenorphine.

I agree with Dr. Junig that we should avoid policies, rules, and laws that restrict how buprenorphine is utilized,- such as limiting the length of time a person may be prescribed the medication or the number of patients a physician can serve. While my traditional orientation presses for me to advocate that a person receive psychosocial treatment in addition to the medication, I think this should be the choice of the patient rather than a requirement. Give them a choice of evidence-based treatments offered by the medical provider or through a referral. As computer-based treatments proliferate, this provides another option to the patient.

I also appreciate Dr. Junig’s counter to some of the media horror stories about buprenorphine such as the one he refers to from Indiana. In particular, he cites that there are only about 40 overdose deaths annually where buprenorphine is found in the person’s system. If that study based on the total of 35,000 total overdose deaths each year, it provides important data on the relative safety of the medication.

Perhaps the most important point repeatedly made by Dr. Junig is that more data are needed. There are many conflicting opinions about the use of buprenorphine, but we need sound studies to support or counter these views, and provide physicians with all the necessary components for “evidence-based practice.”

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The Necessity of Counseling in Buprenorphine Treatment

Louise Haynes, MSW
Medical University of South Carolina

I read, with interest, Dr. Junig's provocative interview. The interview points out a number of areas with potential to improve the health benefits available through enhanced utilization of buprenorphine in the treatment of addiction. I would add that since buprenorphine first became available by prescription from primary care physicians in community practice, much has been learned, and addiction services have improved. I have observed in conservative areas of the country, like South Carolina where I live, that buprenorphine has been increasingly accepted as a legitimate, life-saving treatment. The initial compromises set forth in the enabling legislation gave many communities an opportunity to gain experience with buprenorphine and to adjust their misperception and belief that medications have no role in addictions treatment. As with any innovation, the lessons learned through experience often lead to changes that can improve effectiveness and further enhance the utilization and acceptability of the new practice. Perhaps some of what we have learned about the use of buprenorphine for the treatment of opioid dependence will allow us to individualize and, when appropriate, streamline care, thus improving the availability and effectiveness of treatment.

Dr. Junig points out that requiring counseling is one of the limitations on wider use of buprenorphine, and he asks, "Where are the data?" Through the NIDA Clinical Trials Network (CTN), investigators wanted to answer the question about the added value of counseling, and Roger Weiss and colleagues examined the benefits of counseling as an adjunct to medication for the treatment of opioid dependence. Consistent with Dr. Junig's contention that some patients improve without counseling, investigators determined that overall study participants who received counseling did not have a better outcome. However, a subgroup of participants did show additional benefit from receiving counseling along with standard care. Participants with more severe addiction problems and who were adherent to the recommendation of counseling (i.e., who received sufficient counseling) did demonstrate enhanced benefit. The study was a secondary analysis designed to answer questions about the response of various subgroups to counseling.

Dr. Junig suggests that the treating physician is in the best position to determine which patients would benefit from counseling. Based on the CTN study, a critical factor in determining the treatment plan would be joint decision-making to include the client and an assessment of his or her willingness to attend counseling. In the CTN study, the mere offer of counseling was not sufficient for producing a successful outcome, regardless of the severity of the drug-related problems. No one would argue that there is no role for counseling in the treatment of opioid dependence, but requiring counseling for everyone, regardless of patient preference or need, adds barriers that inhibit best practice.

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A Business Case for Including Medication in Treatment Plans: Toward a 21st Centuryc System of Care for Alcohol and Drug Use Disorders

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Dr. Junig's interview in this issue of The Bridge examines the limits on buprenorphine prescriptions and practitioners, limited use of buprenorphine, the role of psychosocial counseling, integration with primary care, support from health plans to sustain long-term agonist therapy with buprenorphine, and ends with a plea "to follow the science." Treatment decisions should be driven by what works rather than more than a half century of orthodox thought about recovery. The interview, however, did not examine the business case for using buprenorphine. The good news is that there is a strong business case. Using medication for the treatment of alcohol and opioid use disorders is good for business and practice.

Recent studies provide good evidence that patients, practitioners, health plans and policy makers need to factor into decisions. Patients using medication for the treatment of alcohol and opioid dependence use less emergency and inpatient care and, as a result, are less costly to health plans and communities. Adding medication to treatment plans reduces the total cost of healthcare.

An analysis of the cost and utilization of health care among opioid dependent individuals enrolled in a large integrated health plan reported a mean annual cost per opioid dependent member of $11,200 (2004 dollars); the most expensive opioid dependent members were those with minimal (one visit) or no contact with addiction medicine (M = $18,604) while those who received addiction counseling services (M = $14,157) and methadone plus counseling (M = $7,163) used less inpatient and emergency care (McCarty, Perrin, Green, Polen, Leo & Lynch, 2010). The total costs of care for patients receiving methadone maintenance were 50% less than the costs for patients receiving counseling without medication and 62% lower when compared to opioid dependent patients who did not receive addiction medicine services.

An assessment of the total cost of care for opioid dependent patients prescribed buprenorphine updated the analyses with more current costs. Again, the most costly patients were members with minimal or no contact with addiction medicine services (M = $31,035; 2008 dollars); total annual healthcare costs were lower among opioid dependent members enrolled in addiction counseling (M = $17,017) and members receiving

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buprenorphine plus counseling (M = $13,578) (Lynch, McCarty, Mertens, Perrin, Green, Parthasarathy, Dickerson, Anderson & Pating, 2014). Despite the added costs of buprenorphine, opioid dependent health plan members receiving buprenorphine had the lowest total cost of care.

The benefits of including medication in treatment plans, moreover, also appeared when we examined costs of care for individuals with alcohol dependence. A meta-analysis reviewed five studies comparing costs of care for alcohol dependent patients treated with a medication approved by the Food and Drug Administration for treatment of alcohol dependence. Treatment with any medication (compared to treatment without medication) was associated with fewer days of detoxification, fewer inpatient days, and lower total costs of care (Hartung, McCarty, Fu, Wiest, Chalk & Gastfriend, 2014).

Comparative analyses among the approved medications suggest that patients receiving extended-release naltrexone tended to remain on medication for longer periods of time (relative to oral naltrexone, acamprosate, and disulfiram) and had fewer days of detoxification, fewer days of alcohol-related inpatient care, and lower total costs of care (Hartung et al., 2014). Although these studies did not randomize patients to study conditions, they used real patients treated with real clinical practices; the effects appear to be robust. The evidence is strong; the use of medication (any of the FDA approved medication) is associated with lower total costs of care for patients with alcohol use disorders.

Importantly, these cost savings reflect healthcare costs not criminal justice costs or other social costs. Health plans that offer buprenorphine and methadone for opioid dependence reduced the use of relatively expensive emergency and inpatient services and reduced total healthcare costs. Alcohol dependent patients treated with an approved medication were also associated with reductions in the use of emergency and inpatient services and lower total costs of care. Policy makers and health plans will promote the use of medication because it is good for business – lower total health care costs.

Patients, providers and payers all benefit if 21st Century addiction treatment systems promote the use of medication for treatment of alcohol and opioid use disorders. Currently, most health plans and treatment providers can improve substantially. Medicaid utilization data from Oregon (for 2012) suggested 1 in 5 smokers (22%) received a prescription to support smoking cessation, and 1 in 20 opioid dependent patients (5%) had a prescription to treat opioid dependence (additional Medicaid recipients received methadone but these data do not appear in the pharmacy database); rates were disturbingly low for alcohol dependent patients, only 1 in 50 (2%) received an approved medication to treat alcohol dependence (McCarty, Rieckmann, McConnell, Renfro & Garvey, 2014).

The National Quality Forum's consensus standards for addiction treatment recommend the use of pharmacotherapy for tobacco, alcohol, and opioid use disorders (National Quality Forum, 2007).

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The use of medication in addiction treatment should be a standard of care in the 21st Century. Health plans, providers, patients and patient families should demand that every patient be evaluated for the use of medication, educated on the value of medication, and encouraged to use and remain on medication to support their recovery. Why are we waiting?

Major health plans are not waiting; they see in their data the cost benefits of using medication in the treatment of alcohol and opioid use disorders. To promote and support the use of medication, some health plans offer preferred vendor status to addiction treatment centers that initiate the use of medication while patients are in residential and intensive outpatient settings. Other health plans offer bonuses for the use of medication or reconfigure payment rates to address added costs associated with the use of medication. Programs and payers seek better patient education, creative access to prescribers and simplified authorization for use of and access to specific medications. Rapid innovations in patient care will enhance access to medication and catalyze adoption of medication because treatment programs that offer medication now have a competitive advantage. Medication is good for business and for clinical practice.

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Some Challenges to Dr. Junig's Assertions

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First a question to the Bridge editor: Why are you interviewing a psychiatrist about the use of buprenorphine in primary care physicians? Why not interview a primary care physician about her experience with and perspectives about the issues in the use of buprenorphine in the treatment of opioid use disorder in primary care practice? I honestly don't believe that Dr. Junig has the perspective or experience to discuss this issue. So, my main recommendation is to find a primary care physician, not a psychiatrist, to answer your questions.

Second, in your first question you state that "The introduction to buprenorphine treatment in the U.S. has occurred through a controlled system somewhat parallel to controls on methadone." The buprenorphine treatment system is in no way as regulated as is methadone treatment which is constrained by federal and state rules and accreditation guidelines, none of which apply to office-based buprenorphine treatment. Now to my reactions to Dr. Junig's interview responses:

While I wholeheartedly agree with Dr. Junig on many of his points, specifically his advocacy for funding medication assisted treatment as a chronic medical disease for which time-limited treatment should not apply and that indefinite maintenance on agonist or partial agonist medication in the treatment of opioid use disorders is a perfectly acceptable treatment pathway, I do take issue with some of his other assertions.

My main point of disagreement with Dr. Junig centers on his assertion that all buprenorphine diversion occurs because those in that illicit marketplace are seeking/purchasing diverted buprenorphine for their own self-medication, either to help their own-managed withdrawal from opioids or to serve as a bridge between periods of illicit opioid use. I've heard that argument, ironically, before, early in the 1970's, about the diversion of methadone from opioid treatment programs.

It was untrue then. I've also heard this argument recently about buprenorphine to which I always reply, "Where are your data to support that contention." I think Dr. Junig is advancing a belief-based argument in order to support his expressed interest in eliminating the caseload capacity for buprenorphine-waivered physicians. I'd preferred to be informed by data about what percentage of buprenorphine diversion is attributable to the reasons Dr. Junig cites and what is attributable to individuals seeking buprenorphine in order to get high.

I'd like to have a better idea about that before making the sweeping policy change of eliminating the current 100 patient capacity limit because there are data which suggest that buprenorphine diversion increased when the 30 patient capacity limit was increased to 100 patients in 2006. Moreover, to take his assertion to its logical conclusion if, as Dr. Junig states "…if a person takes buprenorphine for any reason--- even just to avoid

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withdrawal until a better batch of heroin comes to town--- that person is less likely to die from overdose" why not at the very least make buprenorphine an unscheduled medication like naloxone or, at the extreme make, it an over-the counter medication? I can't imagine a data-based argument that would support either of those positions.

About the issue of psychosocial counseling by physicians of patient on buprenorphine, I'd like to take issue with several of Dr. Junig's assertions. First, when asked, "how successful have physicians been in linking buprenorphine patients with psychosocial counseling" he replied, "successful enough." I'm not even sure what "successful enough" means and I'd be curious to know not only how Dr. Junig defines the term he used as well as upon what data he bases this assertion. One of the shortcomings of DATA 2000 is, in my opinion, that it did not establish a mechanism for gathering data about the practices and outcomes of waivered physicians. Ideally, we'd have such data to compare and contrast who's being treated by DATA-waivered physicians and how those outcomes compare with patients being treated in Opioid Treatment Programs, for which data do exist.

The other assertion with which I'd like to take issue involves his response to the question, "Simply on the basis of their skills as physicians, and assuming they were willing to spend the time, do you think the majority of physicians could successfully deliver this psychosocial counseling?" He did not address the issue of physician time and willingness to use the precious few minutes that primary care physicians have to spend with patients. Dr, Junig is a psychiatrist and probably has a great willingness to talk with and listen to patients and will structure his patient time to accomplish those tasks. In my work with primary care physicians about their time management as it relates to assessing and intervening with substance use disorders I constantly hear those physicians concerns about time pressure. So, despite, Dr. Junig's assertion based on his practice, I think it's an open question about primary care physicians' willingness and time to deliver psychosocial counseling to their patients on buprenorphine.

And all of this goes directly to the question of an unlimited patient capacity for the treatment of patients with buprenorphine. First of all, I don't think the data exist about how many of the physicians who have the 100 patient limit are actually at that limit. Are we really ready to have physicians with 300, 500, 600 patients on buprenorphine with all of the unknown questions about treatment outcomes, e.g., how, if at all, are outcomes affected by physician caseloads, and the potential risks for diversion? With all due respect to Dr. Junig, there's no street market for albuterol or lisinopril, so his analogy to the treatment of asthma and hypertension isn't exact.

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Right on, Dr. Junig!

Holly Hagle, PhD
IRETA/National SBIRT ATTC

The theme that we are responding to for this issue of *The Bridge* is the use of buprenorphine in general medical practice: a simple request for a complex topic.

> Reacting to: "The legislation [Drug Addiction Treatment Act, DATA] was revolutionary within the relatively small world of addiction practice in that it had a distinct mechanism for the involvement of primary care physicians."

My initial reaction was total agreement. Dr. Junig captures the emotion that was swirling around the addiction field in the year 2000 when the DATA legislation was passed. It did feel revolutionary. We were thrilled to be taken seriously by the medical profession at large, especially the holy grail of medicine, primary care practitioners. It seemed so clear at the time. Yet the implementation proved difficult, as the old saying goes "the best laid plans"....

We all know there has been a varied reaction in the "real-world" to this very same DATA legislation. In fact, addiction and this very topic made it into contemporary media such as the *New York Times.*

So given all of this "hype" over pill mills and diversion, it is refreshing to have a balanced point of view from Dr. Junig as he reflects on how different the uptake of buprenorphine might have been, had it not had the DATA regulation restrictions. Dr. Junig is especially insightful when he states

> "Without the regulations, buprenorphine would likely have become prescribed by primary care to a much greater extent, which would have saved the lives of many, many young people."

As I progressed further into the interview I admired the fact that Dr. Junig took on the "overblown buprenorphine diversion issues". I can't state it as well as Dr. Junig does, when he states "Having more prescribers might have resulted in less non-prescribed use of buprenorphine." Again, another complicated "real-world" outcome from the DATA legislation.

After all as Dr. Junig states, "Buprenorphine has a strong protective effect against death, whether taken by prescription or through diversion. Specifically, over 35,000 US overdose deaths occur annually in the absence of buprenorphine, compared to about 40 overdose deaths each year when buprenorphine is one of the drugs in the person's system."

I mean, this is a serious reflection, as overdose is PREVENTABLE and life is complex, people are complex, and we live complicated lives.

Reading this interview reminded me of a conversation I had with a very esteemed and reputable New England addiction treatment center CEO at a dinner meeting recently. He was telling me about a project that he is engaged in, a partnership with a primary care practice. As this addiction treatment center is a NIATx organization they use data to make decisions and for process improvement. He shared with me one spreadsheet of about 100 (de-identified) patient data from the primary care practice. Almost all of the patients on that spreadsheet listed anxiety and depression as a co-occurring condition along with their presenting physical health condition. We don't question the PCP's authority to treat anxiety and depression, we don't question how much or little training they have to treat these mental health conditions, yet PCPs are treating these conditions and the people who have them every day.

As Dr. Junig states,

> "Surgeons are given the responsibility to decide, all by themselves, which organ to remove—but addiction doctors aren't trusted to make decisions about counseling? No other medical specialty assumes such a high level of ignorance in their doctors!"

People want help, people need help. We should not punish people for displaying symptoms of their illness. "The lack of ASAM support for these physicians and similar cases will have a chilling effect on physician attitudes toward treating opioid dependence".

The good news is that this is all fixable, as Dr. Junig states, in response to the question:

> Q: Would there be any disadvantages if the current patient limit of 100 was eliminated altogether?
> A: Many lives would be saved. For opioid agonist addicts, the primary result from buprenorphine abuse is inadvertent treatment!

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Counseling without Training?

Elizabeth Wells, PhD
University of Washington School of Social Work

Dr. Junig advocates for wider availability of buprenorphine/Suboxone for both opioid dependence treatment and reduction of harm from opioid overdose. His comments in this regard are right on, even though they most certainly will raise the hackles of those in (and outside) the recovery field who see opioid agonist or opioid agonist-antagonist treatment as unacceptable or who do not agree with harm reduction goals.

Unfortunately, the stigma associated with opioid addiction and with medication-assisted treatment keep sensible and science-based options from being followed in many cases. I also agree with Dr. Junig's position on advising patients toward long term maintenance, as the data are clear regarding relapse following stopping use of this medication or methadone. Again, this is a hard pill to swallow for many who view this type of treatment as undesirable.

My only area of disagreement with Dr. Junig relates to his answer to question number 5, "Simply on the basis of their skills as physicians, and assuming they were willing to spend the time, do you think the majority of physicians could successfully deliver this psychosocial counseling?" Having spent my career as a researcher experimentally testing psychosocial treatments in community-based addiction treatment settings, I know how difficult it is to train intelligent people to provide evidence-based psychosocial treatments. I also believe that any psychosocial intervention ought to be based on research evidence, as is the provision of buprenorphine/Suboxone. I disagree that a physician who has not received specialized training in psychosocial treatment would, by virtue of being an MD, demonstrate fidelity or competence in delivery of effective "counseling." Yes, the surgeon knows what organ to remove (Dr. Junig's example), but the surgeon is not trained to plan and deliver radiation therapy to a cancer patient or diagnose and treat a rare infectious disease. I have heard the assumption made, that MDs are intelligent and can certainly figure out how to do "counseling." The latter is not the case, and we should not be encouraging them to deliver psychosocial treatments for which they have not been specifically trained.

The best outcomes arise from a combination of science-based medications and psychosocial treatments, and both should be delivered by professionals with competence in the selected treatment.

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Some Missing Points in Dr. Junig's Interview

Dennis Daley, PhD
University of Pittsburgh

Dr. Junig's comments are well thought out and reflect someone with extensive experience with a challenging group of opioid addicted patients. In responding to his comments, I got input from several highly experienced clinicians and physicians, psychiatrists and internal medicine specialists, who have large practices involving buprenophrine.

It is important for us to recognize that the use of buprenorphine has two sides: it helps many opioid dependent individuals who may not have sought other types of treatment (especially methadone maintenance). It is safe, can be distributed in a physician's office, has few serious side effects, controls drug cravings, and helps the person feel better so he or she can benefit from other aspects of a treatment or recovery program (therapy or counseling, mutual support programs).

The negatives are that practices have little or no oversight by regulatory bodies, and there is abuse by a small group of physicians. One of the strengths (non-addiction physicians can develop practices to treat opioid addicted patients with buprenorphine) can also be a weakness since some of these clinicians do not have a solid understanding of addiction as a bio-psychosocial disease that often requires much more than a medicine to treat over the long term. These practices may have lax or minimal policies regarding other non-medicine interventions for opioid addiction. Patients diverting and selling pills is another common problem.

Dr. Juniq observes that "Many waivered physicians never actually prescribe buprenorphine products". Some have also stopped their practices treating opioid dependent patients with buprenorphine due to problems with diversion, and failure of patients to engage in psychosocial treatments that are supposed to accompany buprenorphine administration. We need data to better understand this. It is not clear why patients failed to engage in the psychosocial treatments. What were the physicians' roles in such engagement, and how strongly was such involvement recommended by the treating physicians?

There is no doubt that some physicians do not offer psychosocial treatments or offer it in a way that is not persuasive to patients. The problem is that providing only a "medical treatment" (i.e, a medication) may not promote recovery, which refers to learning to managed an "addiction" rather than just focusing on a "drug," and making changes in oneself and one's lifestyle. However, there are patients who take buprenorphine who work on personal change and growth despite not being in counseling; we just do not know how many.
Addiction specialists generally believe strongly in the role of psychosocial interventions (counseling, mutual support programs or both) with opioid addiction.

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Since opioid dependent individuals often have other problems such as clinical depression, family discord, etc, counseling can help address these. I suspect brief one-on-one counseling sessions with waivered physicians could make a difference, but in these settings it is likely that most addicted patients receive treatment in groups in which others provide support, feedback and confrontation about bad decisions. However, patients may need individual counseling as well to discuss problems or issues that they feel uncomfortable with sharing with peers in a group setting.

Dr. Junig states, "I believe patients have a right to ongoing buprenorphine treatment without time limitation." Very important issue! The initial idea of using this medicine short term (< 6 months) has proven not to be very effective at all. I believe there is a need for a much longer period of maintenance treatment. At this time, the field is not in agreement how long a person should stay on buprenorphine for maintenance treatment. Initially, the hope was that this alternative to methadone maintenance would be a much briefer treatment.

An interesting fact is that a subgroup of methadone maintenance patients remain on this medicine for de-cades. The same is true for patients in treatment with some other "chronic diseases or disorders" such as recurrent major depression. Patients with this type of depression are encouraged to remain on antidepressant medications after they are in remission as a strategy to reduce the likelihood of another recurrence; they usually also receive brief support therapy as well as medications for their recurrent depression. The field needs to understand and accept that some cases of "chronic" diseases such as opioid dependence will require long-term maintenance.

At this point, I do not believe this "maintenance phase" can be put in a time frame. But I am confident that third-party payers will eventually support maintenance on an indefinite or as needed basis As has often been said, we need to stop treating chronic conditions as acute conditions with short-term episodes of care. Would a short-term treatment approach be accepted by caregivers providing treatment to patients with diabetes, bipolar illness, schizophrenia, or some other condition?

In all due respect to Dr. Junig, his responses exclude two major issues with opioid addicted patients. First is the impact of this addiction on the family and concerned others. The emotional and financial burden created is often high as this addiction (like many others) creates havoc for many families and loved ones. He does not address how physicians should address this or if they should address it. And second, there is no discussion of the role of mutual support programs. While some NA and other 12-step sponsors and members are quite judgmental about peers in recovery taking medications such as buprenorphine, there is a movement in which some communities have specialty medication-assisted 12-step programs, thus making available a recovery program that has helped large numbers of people with all types of addiction.

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