THE DOUBLE-EDGED DRUG

Addiction Treatment With a Dark Side

In Demand in Clinics and on the Street, 'Bupe' Can Be a Savior or a Menace

After two years of buprenorphine treatment, Shawn Schneider has rebounded from a self-destructive addiction to painkillers. Leslye Davis/The New York Times

By DEBORAH SONTAG NOVEMBER 16, 2013 379 COMMENTS

For Shawn Schneider, a carpenter and rock musician, the descent into addiction began one Wisconsin winter with a fall from a rooftop construction site onto the frozen ground below. As the potent pain pills prescribed for his injuries became his obsessive focus, he lost everything: his band, his job, his wife, his will to live.

Mr. Schneider was staying in his parents' basement when he washed down 40 sleeping pills with NyQuil

and beer. His father heard him gasping and intervened, a reprieve that led Mr. Schneider into rehab, not his first program, but the one where he discovered buprenorphine, a substitute opioid used to treat opioid addiction.

In the two years since, by taking his “bupe” twice daily and meeting periodically with the prescribing psychiatrist, Mr. Schneider, 38, has rebounded. He is sober, remarried, employed building houses, half of a new acoustic duo and one of the many addicts who credit buprenorphine, sold mostly in a compound called Suboxone, with saving their lives.

THE DOUBLE-EDGED DRUG
PART 2
At Clinics, Troubled Lives and Turbulent Care

Suboxone did not save Miles Malone, 20; it killed him. In 2010, a friend texted Mr. Malone an invitation to use the drug recreationally — “we can do the suboxins as soon as I give them to u, iight, dude?” — and he died that night in South Berwick, Me., of buprenorphine poisoning. The friend, Shawn Verrill, was sentenced this summer to 71 months in prison.

“I didn’t know you could overdose on Suboxone,” Mr. Verrill said in an interview at a federal prison in Otisville, N.Y. “We were just a bunch of friends getting high and hanging out, doing what 20-year-olds do. Then we went to sleep, and Miles never woke up.”

Suboxone is the blockbuster drug most people have never heard of. Surpassing well-known medications like Viagra and Adderall, it generated $1.55 billion in United States sales last year, its success fueled by an exploding opioid abuse epidemic and the embrace of federal officials who helped finance its development and promoted it as a safer, less stigmatized alternative to methadone.

But more than a decade after Suboxone went on the market, and with the Affordable Care Act poised to bring many more addicts into treatment, the high hopes have been tempered by a messy reality. Buprenorphine has become both medication and dope: a treatment with considerable successes and also failures, as well as a street and prison drug bedeviling local authorities. It has attracted unscrupulous doctors and caused more health complications and deaths than its advocates acknowledge.

It has also become a lucrative commodity, creating moneymaking opportunities — for manufacturers, doctors, drug dealers and even patients — that have undermined a public health innovation meant for social good. And the drug’s problems have emboldened some insurers to limit coverage of the medication, which cost state Medicaid agencies at least $857 million over a three-year period through 2012, a New York Times survey found.

Intended as a long-term treatment for people addicted to opioids — heroin as well as painkillers — buprenorphine, like methadone, is an opioid itself that can produce euphoria and cause dependency. Its effects are milder, however, and they plateau,

making overdoses less likely and less deadly. And unlike methadone, buprenorphine (pronounced byoo-pruh-NOR-feen) is available to addicts by prescription, though only from federally authorized doctors with restricted patient loads.

VIDEO | :42

Ken Mobley, a jailer in Whitley County, Ky., talking about the problem of Suboxone in prisons. Leslye Davis/The New York Times

Partly because of these restrictions, a volatile subculture has arisen, with cash-only buprenorphine clinics feeding a thriving underground market that caters to addicts who buy it to stave off withdrawal or treat themselves because they cannot find or afford a doctor; to recreational users who report a potent, durable buzz; and to inmates who see it as "prison heroin" and, especially in a new dissolvable filmstrip form, as ideal contraband.

"It's such a thin strip they'll put it in the Holy Bible, let it melt and eat a page right out of the good book," said Ken Mobley, a jailer in Whitley County, Ky., who randomly screened 50 inmates recently and found 21 positive for Suboxone.

Many buprenorphine doctors are addiction experts capable, they say, of treating far more than the federal limit of 100 patients. But because of that limit, an unmet demand for treatment has created a commercial opportunity for prescribers, attracting some with histories of overprescribing the very pain pills that made their patients into addicts.

A relatively high proportion of buprenorphine doctors have troubled records, a Times examination of the federal "buprenorphine physician locator" found. In West Virginia, one hub of the opioid epidemic, the doctors listed are five times as likely to have been disciplined as doctors in general; in Maine, another center, they are 14 times as likely.

Nationally, at least 1,350 of 12,780 buprenorphine doctors have been sanctioned for offenses that include excessive narcotics prescribing, insurance fraud, sexual misconduct and practicing medicine while impaired. Some have been suspended or arrested, leaving patients in the lurch.

Statistics released in the last year show sharp increases in buprenorphine seizures by law enforcement, in reports to poison centers, in emergency room visits for the nonmedical use of the drug and in pediatric hospitalizations for accidental ingestions as small as a lick.

Buprenorphine's staunchest proponents see these indicators as a byproduct of the drug's rising circulation and emphasize its safety relative to other opioids.

"The benefits are high, the risk is low and it is worth it on a population-wide basis," said Dr. Stuart Gitlow, the president of the American Society of Addiction Medicine.

But Dr. Robert Newman, a leading advocate of methadone treatment, said, "The

safety factor should not be oversold."

"It is diverted and sold on the black market," he said. "It is misused, and it does lead to medically adverse consequences, including death. It is associated with a large number of deaths."

The addiction drug was a "primary suspect" in 420 deaths in the United States reported to the Food and Drug Administration since it reached the market in 2003, according to a Times analysis of federal data.

But buprenorphine is not being monitored systematically enough to gauge the full scope of its misuse, some experts say. The Centers for Disease Control and Prevention does not track buprenorphine deaths, most medical examiners do not routinely test for it, and neither do most emergency rooms, prisons, jails and drug courts.

"I've been studying the emergence of potential drug problems in this country for over 30 years," said Eric Wish, the director of the Center for Substance Abuse Research at the University of Maryland. "This is the first drug that nobody seems to want to know about as a potential problem."

The government has a vested interest in its success.

The treatment is the fruit of an extraordinary public-private partnership between a British company and the American government, which financed clinical trials and awarded protection from competition after the drug's patent expired.

The company, now a consumer goods giant called Reckitt Benckiser, hired several federal officials who had shepherded the drug, and it has financially supported many of the scientists and doctors who are studying it and advocating its use. But over the last few years, the company's aggressive campaign to protect its lucrative franchise has alienated some of its customers and allies.

In an 11th-hour bid to thwart generic competition and dominate the market with its patent-protected Suboxone filmstrip, the company sought to convince regulators that the tablet form, which earned it billions of dollars, now presented a deadly risk to children as packaged in pill bottles.

The F.D.A. did not agree. Early this year, it approved generic tablets and asked the Federal Trade Commission to investigate potentially anticompetitive business practices by the company.

Reckitt Benckiser defended its advocacy for the Suboxone filmstrip — now its only pharmaceutical product — saying its research showed that the film was safer than the tablets, kept addicts in treatment longer and had less of a street presence. It added that it was overseeing an F.D.A.-required "risk evaluation and mitigation strategy to promote the appropriate use of buprenorphine with the goal to minimize the misuse,

abuse and multidose unintentional exposure of these products."

Dr. John Mendelson of San Francisco, a consultant for the company, said it could be proud of its management of a difficult product. "Their biggest success so far," he said, "is that the whole system has not imploded, that enough doctors have prescribed the drug appropriately that there has been no move to withdraw it from the market."

Ronni Katz, a health official in Portland, Me., is less impressed.

"I remember the early days when we met with the pharma rep in the area — I don't think he was trying to mislead us — he truly believed it was a miracle drug," she said. "But they way underestimated the potential for abuse, which means to me they really don't understand addiction."

Skeptics and Believers

Nearly a half-century ago, buprenorphine was born in the laboratory of an English company specializing in mustard and shoe polish, where chemists were competing to invent a less addictive painkiller.

"We were trying to beat morphine, not methadone," said John W. Lewis, 81, who oversaw the drug's development.

Though far more potent than morphine, buprenorphine appeared in animal tests to be unusually safe even in very high doses. In 1971, Dr. Lewis and colleagues traveled to an infirmary in Glasgow to conduct the first human tests — on themselves.

Buprenorphine made Dr. Lewis violently ill. "It quite took the edge off our stay in a splendid hotel on the banks of Loch Lomond," he said in a speech, and it exposed the painkiller's "Achilles' heel" — "the rather high incidence of nausea and vomiting."

In the mid-1970s, Dr. Lewis began shipping the drug to the United States Narcotic Farm in Lexington, Ky., to test its abuse potential on detoxified addicts. A prison that doubled as a treatment hospital, the farm was home to the government's Addiction Research Center (and at times to jazz greats like Chet Baker, Elvin Jones and Sonny Rollins).

With opposition to human research mounting, buprenorphine would be the last drug tested there; government scientists justified the research by arguing that the painkiller also had the potential to treat addiction.

"Here's the thing: The Lexingtonians were against methadone," said Nancy Campbell, a historian of drug policy. "They felt like addicts liked it too much, and it had overdose potential. They never thought abstinence and 'Just Say No' would work

with this population. So they were eager to find an alternative."

The idea of using opioid substitutes to treat opioid dependence is based on the premise that long-term drug use profoundly alters the brain, that the craving, seeking and taking of opioids is a "bio-behavioral" compulsion. While addiction is considered a chronic, relapsing disease, experts believe that replacing illegal drugs with legal ones, needles with pills or liquids and more dangerous opioids with safer ones reduces the harm to addicts and to society.

VIDEO | 1:40

Dr. Andrew Kolodny describing how buprenorphine works.
Leslye Davis/The New York Times

Like heroin, buprenorphine attaches to the brain's opioid receptors, but it does not plug in as completely. It is slower acting and longer lasting, attenuating the rush of sensation and eliminating the plummets afterward. Addicts develop a tolerance to its euphoric effects and describe themselves as normalized by it, their cravings satisfied. It also diminishes the effects of other opioids but, studies have shown, does not entirely block them, even at the highest recommended doses.

A devoted cadre of government scientists saw buprenorphine as a "holy grail" and over the next few decades "floated in between the public and private sector for most of their careers," Dr. Campbell said. The farm's pharmacist would become an executive vice president of Reckitt Benckiser Pharmaceuticals, for example, and the company would contract with the former National Institute on Drug Abuse director who originally promoted the public-private partnership.

It was a collaboration that the company, whose brand names include Lysol, resisted for a long time, said Charles O'Keeffe, a former White House drug policy official who incorporated Reckitt in the United States.

"They were grocers," he said. "Finally, I went to the board and said, 'It's for the social good.' Ultimately, they relented but said, 'Just don't spend a lot of money.' "

He did not have to. The federal drug abuse institute financed the two big clinical trials necessary to win F.D.A. approval for $28 million and later spent an additional $52.4 million for studies at its clinical research sites. At least $19 million more in studies are underway.

Further, the F.D.A. granted the company a seven-year monopoly based on its claim that it would never recoup its development costs. (Reckitt now has a market value of $56.7 billion; 21 percent of its operating profits last year came from Suboxone.)

Still, hurdles had to be cleared.

First, Mr. O'Keeffe said, "We had to change the law because it would have been illegal."

The Harrison Narcotics Act of 1914, as interpreted, prohibited doctors from prescribing narcotics to narcotics addicts “to maintain their addictions.” In the 1970s, methadone treatment was authorized but limited to clinics where the drug was dispensed, usually daily.

The original advocates of buprenorphine, though, wanted to make addiction treatment mainstream rather than segregate addicts in clinics that became lightning rods for community opposition. They wanted doctors in offices to prescribe it, just like any other take-home medication.

So Mr. O’Keeffe found “influential members of Congress interested in doing this”: Senators Carl Levin, Democrat of Michigan, and Orrin G. Hatch, Republican of Utah, with support from Senator Joseph R. Biden Jr., Democrat of Delaware. In the end, because of law enforcement concerns, the Drug Addiction Treatment Act of 2000 included unique prescribing restrictions: that doctors seek federal permission, get eight hours of training, accept a 30-patient limit and attest to their ability to make counseling referrals.

The concerns grew from other countries’ experiences with buprenorphine treatment over the previous decade; successes had been accompanied by abuses. So F.D.A. officials insisted on the addition of an “abuse deterrent” — naloxone. If addicts crushed and injected the tablets, the naloxone would precipitate excruciating withdrawal symptoms.

The Drug Enforcement Administration was skeptical, saying studies showed that naloxone did not provoke “any evidence of withdrawal” in “a substantial percentage” of opiate abusers, and that the amount in the proposed compound would produce only a half-hour of “unpleasantness” in those susceptible.

Skeptical, too, were buprenorphine’s original champions at Reckitt, who would have preferred a different additive or more naloxone. “It was not a perfect solution,” Dr. Lewis said.

Even so, Suboxone — four parts buprenorphine, one part naloxone — was created. And in late 2002, along with Subutex (plain buprenorphine), it was approved by the F.D.A. just as its target audience was about to expand unexpectedly.

An estimated 2.5 million Americans were dependent on or abused opioids last year, mostly painkillers, although heroin dependence has skyrocketed, with the number of addicts doubling over a decade to 467,000, government data indicate. In 2010, the last year studied, 19,154 people died of opioid overdoses.

“Had buprenorphine never been released and all we had was methadone, that number would be much higher,” said Dr. Andrew Kolodny, the president of Physicians for Responsible Opioid Prescribing.

Early Successes

In the early days of Suboxone, with Reckitt Benckiser barely marketing its own drug, Dr. Kolodny, then a New York City health official, crisscrossed the city with colleagues to spread the word about the new medication, entice public hospitals to try it with $10,000 rewards and urge doctors to get certified.

“We had New York City staff out there acting like drug reps,” Dr. Kolodny said.

He himself became a prescriber. “All of a sudden, I started getting calls from white kids on Long Island who were all addicted to pain pills,” he said. “It was 2003 or 2004, and my first experience of the painkiller epidemic.”

A psychiatrist accustomed to the slow, subtle effects of antidepressants and mood stabilizers, Dr. Kolodny was stunned by patients who arrived “a total mess” and in days seemed “back to normal.”

“I’m thinking, this cures all addictions,” he said.

Dr. Jeffrey T. Junig of Wisconsin experienced a similar revelation. He was concerned that buprenorphine would create “all these dry drunks, people who were no longer using but who hadn’t addressed their defects.” Instead, he witnessed something different: “The process of craving opioids itself causes people to be so one-dimensional that it is a defect itself. Freed from the obsession to use, people change.”

Buprenorphine worked so well on his first patients, middle-aged painkiller addicts, that “they would have tears rolling down their faces talking about how grateful they were,” he said.

Among them was Shawn Schneider, who had found his way to Dr. Junig after swallowing 400 milligrams of Ambien, thinking, “If I wake up, I wake up; if I die, I die.”

VIDEO | 1:10

Mr. Schneider worries that the misuse of buprenorphine could hurt those who use it legitimately. Leslye Davis/The New York Times

Like Mr. Schneider, dozens of addicts interviewed portrayed themselves as exhausted and frightened before they started on Suboxone. They acknowledged having “loved” their chosen opiate but not what turned into a miserable existence dominated by drug-seeking to avoid “dope sickness.”

Travis Norton, 33, gravitated to heroin in adolescence as a result of a misguided

infatuation with artist addicts like William S. Burroughs and Kurt Cobain, he said. For years, he cycled through costly abstinence-based programs, always returning to the needle.

“I was a chronic relapse,” said Mr. Norton, who is now an addiction counselor in a Minneapolis suburb. “I was a wreck until I started maintenance therapy in 2003. And I’ve been great since.”

Mr. Norton switched for a time to methadone when his Suboxone doctor retired. At that point, Suboxone, around $16 for an average daily dose, was considered “the rich man’s methadone.” Mr. Norton, not rich but a college-educated professional, found the methadone clinic “a ball and a chain.”

“I had to travel for my job, and there was zero flexibility,” he said. “They had thousands of clients, and I was a number.”

Dr. Edwin A. Salsitz of Beth Israel Medical Center in New York, who has been treating addiction for decades, said that in the pre-Suboxone universe, he encountered all too many middle-class addicts who refused to set foot in a clinic.

“And then sometimes, a couple of years later, they’d be H.I.V. positive, or something more catastrophic would have occurred,” he said. “There’s no way to explain what this meant to the addiction field to have another option besides the clinics.”

Reckitt Benckiser gradually built a stable of doctors paid to advocate use of the treatment, Dr. Salsitz among them.

The recruiting was tough. Those outside the addiction field were reluctant to deal with the hassles of certification, potential visits by the D.E.A. and the addicts themselves. Within the field, buprenorphine faced stiff opposition from the methadone industry as well as traditional rehabilitation programs and the Alcoholics Anonymous movement, which promotes abstinence.

Melissa Iverson, a 48-year-old former social worker living in Central Florida, said her painkiller addiction had made her go “crazy out of control” until she began taking Suboxone. Leslye Davis/The New York Times

“With Suboxone, there is a lot of misinformation out there, and the most common is you’ve replaced one drug with another,” said Melissa Iverson, a 48-year-old social worker who lives in Florida and is now on disability because of fibromyalgia.

Ms. Iverson first requested anonymity, like most other professionals interviewed, some of whom have never acknowledged their problem to their families, primary care physicians or even insurers. Eventually she decided to “come out of the closet,” saying, “The stigma needs to be tackled by real people with real names, or else it will haunt us forever.”

Relying on ever-escalating doses of painkillers to cope with her chronic pain, she had gone “crazy out of control.” Her life revolved around pills; she would pass out smoking in bed and wake up with burns on her hands or get into car accidents and nod out in the tow truck. Four years ago, she had “a psychotic break,” ended up hospitalized and “came out on Suboxone.”

In contrast to her painkiller use, she has taken Suboxone at increasingly lower doses, finding that it alleviates her pain without “those self-destructive behaviors.”

“As an addict, I was high all the time,” she said. “With Suboxone, I developed a tolerance within a week. There’s zero euphoria.”

Successes like hers multiplied until demand outstripped supply because of the limited number of doctors and the patient cap. This brought some unintended consequences.

VIDEO | 1:37

Ms. Iverson on her addiction and how Suboxone has helped her recovery. “I could think again,” she said. “I could smile again.” Leslye Davis/The New York Times

First, some prescribers pushed patients off the medication prematurely to replace them with new patients because the early treatment phase was more lucrative. Second, patients began sharing the drug, trading it and selling it. Buprenorphine trickled out onto the street.

Health officials, concerned about restricted access, lobbied alongside Reckitt Benckiser for the patient cap to be raised. “Why should we bind a healer’s hands from helping as many as he or she could?” Senator Hatch said, getting an amendment passed in 2006 that allowed doctors, on request, to go from 30 to 100 patients after a year.

The stage was set for more patients, prescriptions and problems. “It’s when the limit was raised from 30 that doctors started to get commercial about it,” said Dr. Art Van Zee, whose buprenorphine program at a federally funded community health center in rural Virginia is surrounded by for-profit clinics where doctors charge $100 for weekly visits, pulling in, he estimated, about $500,000 a year.

“They are not savvy about addiction medicine, don’t follow patients very closely, don’t do urine testing and overprescribe,” he said. “That’s how buprenorphine became a street drug in our area.”

Troubled Histories

In Fond du Lac, Wis., on the shores of Lake Winnebago, addicts come and go from a bland building housing a medical office, a cheese business and a title company. They bring their tumultuous lives into a tranquil space with hunter green walls, heathered carpet and easy-listening music, presided over by Dr. Junig’s wife, Nancy, candy jar by her side.

Fond du Lac Psychiatry is the kind of setting the original idealists envisioned. They did not foresee the buprenorphine mega-clinics that resemble and frequently double as painkiller pill mills, sometimes with armed guards to protect their cash.

They did not foresee a buprenorphine empire like the one Dr. Thomas E. Radecki, 67, built in northwestern Pennsylvania.

According to the evidence presented to a grand jury this summer, Dr. Radecki operated four clinics under the business name Doctors and Lawyers for a Drug-Free Youth, serving 1,000 people, many of whom did not need or use buprenorphine and resold it in their neighborhoods. To override the patient limit, he employed other doctors part time. He sold the drug directly to patients, which is legal, and was the country's largest individual buyer of buprenorphine in the first half of last year, according to investigators. The previous year, he netted $280,000 in profits from the tablets alone, they said.

In August, the Pennsylvania attorney general announced Dr. Radecki's arrest on charges of improper prescribing and trading addiction drugs for sex. His lawyer, John Froese, said Dr. Radecki "denies that he ever prescribed any medicine that was not helpful to his patients" or had sexual relationships with his buprenorphine patients.

Dr. Radecki lost his Illinois license for just such a relationship, and his Pennsylvania license was made probationary in 2007. Nonetheless, the federal government subsequently authorized him to prescribe buprenorphine and then expand his patient load.

"Very few if any" doctors are denied permission unless they are "under investigation or something pops up," said Rusty Payne, a D.E.A. spokesman.

The Times analyzed the disciplinary records of the doctors on the federal government's online listing of buprenorphine providers, which is not comprehensive because doctors can opt out, and calculated state-by-state disciplinary rates.

In 30 of the 31 states that provided their overall disciplinary rates for comparison, buprenorphine doctors are far more likely to have been sanctioned than doctors over all. In Florida and Kentucky, they are four times as likely to have been sanctioned. In New York, they are six times as likely; in Arizona, seven times; in Minnesota, nine times; and in Louisiana, 10 times.

Rates are even higher for the subset certified to treat the maximum patient load, The Times found in analyzing records from a sampling of states.

In Ohio, nearly 17 percent have disciplinary records, compared with 1.6 percent of all doctors. They include individuals sanctioned for: amphetamine addiction coupled with a Medicaid-fraud conviction; conducting an "excessive number of invasive procedures"; smuggling steroids from Mexico; engaging in conversations regarding a "murder for hire" and neglecting to report the rape of a pediatric patient; "digitally penetrating" patients and having sexual intercourse with them in the office.

Some were reprimanded or placed on probation before becoming Suboxone doctors; others, stripped of their licenses recently, had their offices shuttered.

This adds to the volatility of the treatment culture.

A 30-year-old Michigan woman said she was invited into treatment by a doctor who frequented the strip club where she was a bartender and who paid for her medication for several months. When he was placed on probation for "violation of duty/negligence" unrelated to her, she switched to a second doctor, who also got in trouble. After that, the woman bought her buprenorphine on the street for a year — saving $5,500 in medical and counseling fees, she noted — until she found an addiction specialist with an opening.

In some areas, like New York City, there is almost a glut of buprenorphine prescribers. In others, specialists routinely turn away addicts begging for help.

Non-specialists pick up the slack.

Reckitt Benckiser recruited "any doctor willing," said one former company drug representative who asked not to be identified to protect her career. Those in her territory ranged from "extremely passionate" to intensely commercial, she said: "One charged a $50 co-pay, and another $500 for an initial visit. I had a few physicians using the medication themselves. One guy was so enthusiastic I signed him up as a treatment advocate, but then it turned out he relapsed and lost his license."

Just because doctors have disciplinary histories does not mean that they are unscrupulous. Some of the most knowledgeable, compassionate addiction doctors are former addicts themselves, with medical board actions on their records that sometimes limit their career options.

Dr. Jeffrey T. Junig, an anesthesiologist who retrained as a psychiatrist after his own recovery from addiction, never expected to become a buprenorphine doctor. Leslye Davis/The New York Times

Dr. Junig, 53, is an anesthesiologist with a doctorate in neurochemistry who retrained as a psychiatrist after his own recovery from addiction. He did not intend to become a buprenorphine doctor.

“To be honest, I was just trying to build a practice,” he said.

Nor did he intend to become a buprenorphine blogger or the host of an online conversation about the drug through his website Suboxone Forum, which gets 30,000 visits weekly, and a LinkedIn group with nearly 800 professional members. It grew from his initial passion for the treatment — a passion that got him hired briefly as a “treatment facilitator” for Reckitt Benckiser and also got him in trouble.

In 2011, the Wisconsin medical board reprimanded him for using “tele-psychiatry” to treat five out-of-state addicts he had seen only over Skype.

Over time, Dr. Junig said, he moved “from skeptic to true believer to skeptic.” Others similarly modulated their enthusiasm as they gained a nuanced appreciation of the difficulties of managing a complex patient population and a medication that had

become a rampant street drug.

Some patients stopped and started their medication so they could still use other opiates or mixed it dangerously with drugs like Xanax. Appointments were missed, prescriptions “lost.” Patients cheated, dropped out and relapsed, sometimes fatally.

Joseph McMahon IV, a gregarious, troubled New Yorker, was prescribed a couple of thousand Suboxone pills over nearly three years. Still, he overdosed on other drugs at least five times and at 25 died of one final overdose in December 2011, turning his father, a retired New York City fire lieutenant, into a bereft chronicler of Suboxone abuse.

“My son swore Suboxone was working for him,” Joseph McMahon III said. “But if I’m an alcoholic and you switch my Budweiser for a Bud Lite, sure, I’m doing great. They call Suboxone ‘heroin in a pill.’ It makes tons of money for the pharmaceutical industry, which has us totally bamboozled, and for these doctors.”

For Dr. Junig, early positive experiences with older patients have been offset by rocky ones with a new generation of heroin and “poly-drug” abusers.

Last spring, he prepared to confront a 26-year-old patient who had landed in an emergency room with an arm infected from injecting cocaine. The man had tried to hide his cocaine use by presenting a specimen of “old urine” to Dr. Junig, who said, “I’m an inch from kicking him out, but I think he’ll die if I do.”

VIDEO | 1:29

Dr. Junig discussing the difficult choices facing doctors treating addiction patients who are not ready to get better. Leslye Davis/The New York Times

The patient, a mechanic with a young daughter, said he had “slipped up” during a period of homelessness. “It was just cocaine,” he said. “I don’t even really like cocaine. I wanted to tell you so bad, man. But if I lose the Suboxone, I’ll go back to the heroin and the pills, and then I’ll be in real trouble.”

Dr. Junig told the mechanic he would be summoned for surprise testing.

“What worries me most are the needles,” the doctor said. “But people die from cocaine, you know. What you were doing — there’s a genuine risk. If you get busted for cocaine, you could end up in a situation where social services are involved. People lose their kids.”

An Escalating Problem

In late 2009, a discovery made in a Walgreens in Michigan lit up the forums where recovering addicts chat: “Generic bupe!”

The F.D.A. had just approved generic Subutex, buprenorphine without the abuse deterrent, despite Reckitt Benckiser's effort to prevent it. It was, according to that post, about one-third the cost of brand-name Suboxone.

For the previous six years, Reckitt Benckiser, with the government's support, had successfully discouraged Subutex except in special circumstances. Doctors and insurers, told that Suboxone was safer, had favored it.

But then Suboxone itself ended up being diverted, misused and abused by injection, indicating that the safeguard was not foolproof, although Reckitt says it stands by it. So when uninsured patients clamored for the cheaper generic, some doctors, including Dr. Kolodny, started accommodating them.

"At first, I did believe the marketing that there was a booby trap in there," he said. "But my impression is that it doesn't work as well as promised as an abuse deterrent."

The most recent data signal an escalating problem with buprenorphine.

Last year, forensic laboratories identified 10,804 drug seizures as buprenorphine, up eightfold from 2006.

In 2011, emergency room visits for the nonmedical use of buprenorphine were estimated at 21,483, nearly five times what they were in 2006. Also in 2011, poison centers recorded 3,625 cases of toxic buprenorphine exposure, nearly five times as high as the previous year.

More young children were hospitalized because of accidental ingestion of buprenorphine than for any other medication in 2010 and 2011, a federal study found. Another study, financed by Reckitt, of 2,380 buprenorphine overdoses in young children found that 587 had to be hospitalized in intensive care units and that four died.

John Burke, the president of the National Association of Drug Diversion Investigators, said buprenorphine remains "down on the totem pole" of worrisome prescription drugs.

"I wouldn't say buprenorphine is not a serious problem; it's a product for addicts, so the propensity for diversion is probably much higher than with the other prescription drugs," he said. "But oxycodone, hydrocodone, Xanax — those make up the bulk of the problem."

Even so, many local authorities say buprenorphine is their nemesis.

"What we're seeing here in Delta County is really troubling," said Steven C. Parks, a prosecuting attorney in Michigan. "Arrest after arrest of people who are possessing or abusing Suboxone, who don't have a prescription for it, who are shooting it up and

who are snorting it."

"It's what has followed the oxycodone and the hydrocodone trends here," he added. "We don't have heroin yet."

Mr. Parks said a big local pharmacy had stopped stocking the medication because its employees felt "very threatened."

Pharmacy robberies for Suboxone alone are rare, but they do happen.

In June, Michelle Wilcox, 27, wearing a hooded sweatshirt and surgical gloves, handed a Maine pharmacy technician a note: "Give me all the 8 mg Subs you have. I have a weapon and I will use it." She walked out with 84 doses of Suboxone — worth about $640 — and drove off in a pickup truck, only to be arrested within hours, according to documents and interviews.

"She was just desperate," said Sheriff Scott Nichols of Franklin County, Me. "She said her own medication had been stolen."

Ms. Wilcox awaits sentencing after pleading guilty to felony robbery charges in federal court.

In Maine, Ms. Katz, the Portland health official, described a seemingly unstoppable flow of Suboxone onto the streets in recent years, with addicts injecting it. Shawn Verrill, serving time for Miles Malone's death from buprenorphine, said he used to sell the drug in York Beach to supplement his income as a lobster deliveryman.

"Every kid on the beach was looking for it," he said. "The high lasts all day."

Ms. Iverson held a handful of Suboxone tablets, sometimes called “stop signs” because of their hexagonal shape. Leslye Davis/The New York Times

Mr. Verrill said he bought cases of “stop signs” from a pharmacist and charged $10 to $12 for each orange hexagonal Suboxone tablet, earning $4,500 in a good month.

Most buprenorphine advocates interviewed said they believed that deaths were extremely rare. But Suboxone and Subutex were considered the “primary suspect” in 690 deaths — 420 in the United States — reported to the F.D.A. from spring 2003 through September.

This pales in comparison with the 2,826 deaths from methadone reported to the F.D.A. over roughly the same period, as calculated by AdverseEvents, a company that analyzes data on drug side effects. C.D.C. data, drawn from death certificates, makes it clear that number is a serious undercount. The C.D.C. does not track buprenorphine deaths, which may also be undercounted.

The F.D.A. information, which is spare, does show that more than half the American buprenorphine deaths involved other substances and that only two of 224 cases specifying “route of administration” indicated injection — the primary concern of regulators.

Fifty deaths are listed as suicides, and 69 involve unintentional overdoses, drug abuse or drug misuse. Thirty were fetal or infant deaths after exposure in the womb.

Outside the United States, 118 of the 270 deaths reported were in Sweden. Last year, Sweden's National Board of Forensic Medicine published an analysis of 100 autopsies where buprenorphine had been detected. In two-thirds, it was the direct cause of death, mostly in combination with other drugs. Swedish researchers attributed the "fatal intoxication" to low tolerance because of first-time use or a period of abstinence.

The F.D.A. cautions against assuming that a "primary suspect" drug was indeed a cause of death.

But Brian M. Overstreet, the president of AdverseEvents, said, "The reality is that hundreds of thousands of cases are reported every year by front-line health care providers who purposefully identify a drug as being the primary suspect cause of a specific adverse event.

"We believe that the link between drug and event," he continued, "is quite real."

A Death Lingers

Mr. Malone's death remains hauntingly real for his family.

In July, his mother told a federal judge: "I try very hard to forget the last time that I saw him at his wake. He wasn't smiling at me. He didn't hug me. I touched his hand, and he didn't touch me back."

Mr. Verrill pleaded guilty to the distribution of buprenorphine resulting in death. "I feel guilty," he said in the recent interview, wearing prison khaki, his arms inked with the saying, "What goes around comes around."

They were friends who had met on the beach.

On the evening of Oct. 12, 2010, Mr. Malone dropped by Mr. Verrill's garage apartment with a mutual friend. He appeared "high but not wasted," Mr. Verrill said, although a convenience store clerk had called the police saying Mr. Malone had seemed worryingly intoxicated.

All three young men did drugs. Mr. Verrill and the friend snorted Suboxone and swallowed some tranquilizers. Mr. Malone took only Suboxone, two tablets under his

tongue, Mr. Verrill said. Then they smoked marijuana, listened to country music and played video games.

Mr. Verrill said he covered Mr. Malone with a blanket when he himself went to bed, thinking he was just sleeping.

Maine's medical examiner said Mr. Malone died of buprenorphine toxicity. Traces of marijuana, but no alcohol or other drugs, were found in his system; the level of buprenorphine, though, was high for just two pills.

Before being taken into federal custody, Mr. Verrill served time at a county jail on other charges. Suboxone was everywhere, he said, with detainees paying $20 for a quarter-strip that, transformed with water into a crushable pill for snorting, was enough to "rock" two people whose systems were clean of drugs.

"People were beating each other up and taking their commissary food to sell it and buy Suboxone," he said.

Referring to the federal prison, he added: "That doesn't happen here. I'm clean now. If I hadn't been arrested for Miles's death, I'd probably be dead myself."

Competition on the Shelves

Over the years, Reckitt Benckiser started acting more like a pharmaceutical company. It built its Suboxone sales force to about 200; flew members to Italy, Mexico and Spain for motivational meetings; and paid 400 to 500 doctors as advocates, former employees said. It lobbied for influence, the only "corporate round table" member to pay at least $100,000 in dues to the American Society of Addiction Medicine.

After losing its exclusive right to sell buprenorphine in 2009, the company used the drug's problems to its advantage. Moving aggressively to protect its franchise, it fought the increased prescribing of generic buprenorphine, or Subutex, by telling doctors they would be responsible for worsening diversion and abuse.

"We had lists of the Subutex writers, and we were actively targeting them," a former employee said.

Even so, over all, Subutex prescribing increased more than tenfold the first year the generic version was sold. Since it was only a matter of time before generic Suboxone would be developed, too, the company began to argue that the black market and the pediatric poisonings demanded a new

formulation.

That formulation was the filmstrip, individually wrapped with a traceable bar code, which the company believed would be patent protected until 2023.

Its release was delayed by F.D.A. concerns that challenged the company's rationale for creating it. First, officials predicted "significant abuse and diversion," noting that 6,000 Suboxone filmstrips went missing during clinical trials.

Second, they worried that the film might be more dangerous to children because it could not be easily spit out. The individual wrappers would not help if, once opened, each dose was divided, as is common, the F.D.A. said. It demanded better labeling and a patient-counseling plan.

Once the film was approved in 2010, Reckitt Benckiser directed its sales force to discourage the use of the tablet by arguing that its packaging made it hazardous to children — "fear-based messaging," one former employee called it; "selling against our own medication," another said.

From that point, the company's representatives earned bonuses only for Suboxone film. If they did not reach a target "film market-share penetration" in their territory, they risked being dismissed, as personnel records in an employment-related lawsuit show.

The company lured patients directly by offering discounts for the film while raising the price of its tablets. It used rebates to persuade public insurers to give preference to the film. At least 15 state Medicaid agencies do; West Virginia even passed a law banning the pills and requiring the film.

In September 2012, Reckitt Benckiser, calling it "a moral obligation," announced that it would withdraw its Suboxone tablets from the market — in six months — because of "increasing concerns with pediatric exposure." It effectively asked the F.D.A. to block generic tablets for the same reason, citing a company-financed study that indicated the film was far safer.

The F.D.A. disagreed and approved generic Suboxone tablets early this year.

Since then, Reckitt's Suboxone journey has become bumpier. It is battling antitrust lawsuits by a dozen drug wholesalers and insurers who say the company "schemed" to extend its monopoly, overcharging them and, more broadly, the health care system.

In July, Reckitt Benckiser's stock suffered its biggest one-day loss in two years after

CVS Caremark announced that it would drop the film from its preferred drug list in favor of tablets. And there is a new brand on the shelves, too: Zubsolv, which its manufacturer, Orexo, says has “higher bioavailability, faster dissolve time and smaller tablet size with a new menthol taste.” Orexo’s United States medical director is Dr. Gitlow, the addiction medical society president.

In the third quarter of this year, Reckitt Benckiser’s net revenues from Suboxone declined 14 percent from the same period last year, which the company attributes to its discontinuation of the tablets. The company recently announced that it was “reviewing all options” for its pharmaceutical unit, which includes the possibility that it will sell, bringing its profitable foray into the drug business to a close.

Travis Norton, an addiction counselor, held up a dose of Suboxone in his office in Anoka, Minn. He is currently taking the drug after years of cycling through costly abstinence-based programs. Ben Garvin for The New York Times

Dr. Robert L. DuPont, the first director of the national drug abuse institute, said he marveled at the cutthroat business competition when “you couldn’t get pharma companies to even think about addiction treatment before this $1.5 billion drug got their attention.”

At a recent meeting of the addiction medicine society, “the buprenorphine sessions were all packed with doctors who wanted to get in on the gold rush,” he said. “It seems to me like they are repeating the experience of pain doctors in terms of reckless disregard of the nonmedical use of the drug.”

The system could well be at a turning point, with more drug options, lower prices and expanded insurance coverage under the new health care law and an “addiction equity” mandate. In addition, with a recent regulation change, for-profit addiction companies that run methadone clinics are expanding their buprenorphine programs, which have no patient limits, and some state governments are pressing federally funded health centers to increase nonprofit buprenorphine treatment.

For now, though, patients whose lives have been transformed by the medication say they feel stressed by the struggle to get and pay for treatment, the long waiting lists, the doctors who overcharge and the ones whose offices are shut down. The misuse and abuse of the drug make even their own relatives suspicious of them — not to mention the public and private insurers that restrict the dosage and length of treatment, despite studies showing that higher doses improve treatment retention rates and that quitting buprenorphine often leads to relapse.

Betty Jo Cumberledge, a home health aide in West Virginia, said her insurer paid “forever” for the potent narcotics she took for back pain. But it cut her off this fall after two years of Suboxone treatment for her resulting addiction. “That’s just not humanly respectful in my opinion,” she said.

She handwrote an impassioned letter, complaining that she was being “discriminated against for seeking treatment” and “saying it would be on them when I ended up relapsing and dead.” She won a six-month reprieve.

“The whole situation is a big old mess,” she said.

Rebecca R. Ruiz contributed reporting.

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379 Comments

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