



**Purdue Pharma Headquarters**



**Oxycontin Addict's Home**

## OxyContin: Purdue Pharma's painful medicine

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**What the strange saga of Purdue and its \$3 billion drug tells us about our national dependence on painkillers.**

By [Katherine Eban](#), contributor



FORTUNE -- We have become a nation of pill poppers. Pain tablets are the prime culprits -- more specifically, opioids. You may have never heard the word "opioid," which refers to a broad category of drugs derived from natural or synthetic forms of opium or morphine. You have, however, likely heard of many of the medications in the group, which includes everything from Percocet to Vicodin to Fentanyl. Their chemical composition is such that the U.S. is just a few carbon molecules from being a nation of heroin addicts.

Consider these statistics, all for 2010: 254 million prescriptions for opioids were filled in the U.S., according to Wall Street analysts Cowen & Co. Enough painkillers were prescribed to "medicate every American adult around the clock for a month," the federal Centers for Disease Control reported on Nov. 1. It estimated that "nonmedical use of prescription painkillers costs health insurers up to \$72.5 billion annually in direct health care costs." Opioids generated \$11 billion in revenues for pharmaceutical companies, says market research firm Frost & Sullivan.

Sellers include giants such as Abbott Labs ([ABT](#)), Novartis ([NVS](#)), Johnson & Johnson ([JNJ](#)), and (in the future) Pfizer ([PFE](#)), as well as smaller fry like Endo Pharmaceuticals ([ENDP](#)) in Newark, Del., which makes Percocet, and UCB of Belgium, which makes Lortab. Most opioids are made by big generics companies such as Watson Pharmaceuticals ([WPI](#)), with companywide sales of \$3.6 billion last year, and Covidien ([COV](#)) of Ireland, with \$10.4 billion.

Two decades ago opioid sales were a small fraction of today's figures, as such drugs were reserved for the worst cancer pain. Why? Because drugs whose chemical composition resemble heroin's are nearly as addictive as heroin itself, and doctors generally wouldn't use such powerful meds on anybody but terminal cancer patients. But that changed years ago, and ever since, addiction to painkillers has become a staple of news headlines. There are periodic lurid crimes, such as the quadruple homicide in a Long Island pharmacy this summer committed by an addict desperate for hydrocodone. More often, there are the celebrities, such as Rush Limbaugh, who admitted on his radio show years ago that he was addicted to painkillers, or actor Heath Ledger, who was found dead with oxycodone in his system, or rapper Eminem, who entered rehab to address his reliance on Vicodin and other pills.

The celebrity in rehab and the addict holding up pharmacies have both become such clichés that it's easy to view painkiller calamities as things that happen only to criminals and celebrities. But the numbers are broad and disturbing: Some 15,000 Americans died of opioid overdoses in 2008 -- triple the number for 1999, according to the new CDC findings. That's more than from heroin and cocaine combined. As Dr. Irfan Dhalla, a physician and drug-safety researcher, puts it, "That's four 9/11s a year."

The other reason it's easy to brush off opioid dependence is that unlike with heroin or cocaine, most people swallow the pills, at least initially, because their doctor tells them to. You could call it [the invisible addiction](#): countless Americans -- including all manner of businesspeople -- taking medication prescribed to them who discover, months or years later, that they can't stop. According to Physicians for Responsible Opioid Prescribing, more than 25% of opioid users meet the criteria for addiction.

### [A field guide to the 6 best-known opioids](#)

Among the sellers of opioids, none has been more successful -- or controversial -- than Purdue Pharma, maker of the No. 1 drug in the class: OxyContin, which generated \$3.1 billion in revenue in 2010. Purdue and its marketing prowess are the biggest reasons such drugs are now widely prescribed for all sorts of pain, says Dhalla: "Purdue played a very large role in making physicians feel comfortable about opioids." And as we'll see, Purdue's past and present go a long way toward explaining how so many Americans came to be in the grip of potent painkillers.

When it was introduced in the late '90s, OxyContin was touted as nearly addiction-proof -- only to leave a trail of dependence and destruction. Its marketing was misleading enough that [Purdue pleaded guilty in 2007](#) to a federal criminal count of misbranding the drug "with intent to defraud and mislead the public," paid \$635 million in penalties, and today remains on the corporate equivalent of probation.

OxyContin's bad reputation, however, has obscured a significant step. Last year Purdue began selling a reformulated version that should help reduce the worst form of abuse. The original drug had a time-release mechanism that could be defeated by crushing the pill and snorting it, smoking it, or adding water to the powder and injecting it for a heroin-like high. (Purdue's claims that the time-release process reduced the addiction risk were crucial in making doctors feel comfortable prescribing a powerful addictive drug.) By contrast, the new version breaks into chunks rather than a powder; if water is added, the result is a gelatinous goop.



So far the new OxyContin appears to be withstanding attempts to crush, snort, or inject it. The "street price" -- what addicts are willing to pay on the black market -- has dropped from \$0.73 per milligram for the old version to \$0.52 for the new, according to data from Radars (Researched Abuse, Diversion, and Addiction-Related Surveillance), a program originally designed and funded by Purdue that collects data on prescription-drug abuse. As one disgusted abuser wrote on an addiction chat site called *Bluelight* after a failed effort to mince the new version with a razorblade, "Purdue won. I knew the oxy was inside, but I could not break into the safe."

Purdue has taken a worthwhile step, but one that only highlights the paradox of opioids. There's no question that making it harder to crush OxyContin will cut down on a pernicious form of misuse (not incidentally, the one that most resembles what people think of as "drug abuse"). But at the same time, taking that step lifts a stigma from the drug and may make doctors more comfortable prescribing it, an outcome Purdue is hoping for. The result could be an even greater number of invisible addicts.

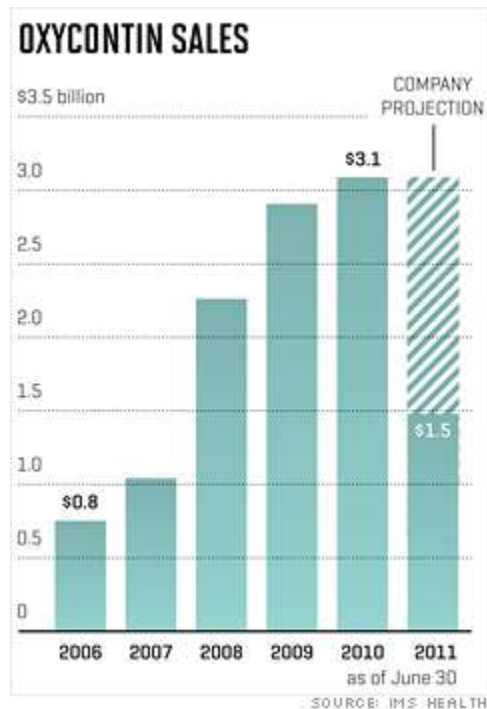
### Purdue's own drug war

Purdue is a private company in both senses of the word: It's family-owned, and it's reticent when it comes to discussing its business. But this summer, after much reluctance and multiple requests, Purdue agreed to let me visit its offices in Stamford, Conn. The mere presence of a reporter in the building seemed to disrupt Purdue's systems: An intercom started blaring, and the phones and Internet service crashed. Technicians scurried to fix the problem, and I soon found myself in a conference room, where my e-mailed query to Purdue was projected on the wall and two executives waited with stacks of documents.

Though they were wary, Alan Must, Purdue's VP for state government and public affairs, and Mark Geraci, its chief security officer, seemed eager to get a chance to speak for the company. "We are well aware of detractors," says Must. "For those individuals who think we're evil ... I don't think there's anything we can do that is going to change their opinion.

"Obviously," he says later, "the idea that our business model is based on getting patients addicted and dependent is absurd," though he acknowledges it's "not unusual for patients to become

physically dependent." In the company's view, Americans have long suffered from an epidemic of pain, and Purdue provides profound relief. Says Must: "At the end of the day, I am very proud to work for this company and proud of the things we have done."



Ironically, Purdue views itself as waging a drug war. On one side sits the company and its intended patients, who need OxyContin to alleviate real pain. On the other side are the "bad" patients who misuse painkillers to get high or cross state lines to shop for pliant doctors willing to write a prescription. Must and Geraci say Purdue has everything to gain if OxyContin is sold properly and abuse minimized. "One might argue that your sales might actually go up," Must says, "because now physicians have some confidence that when they're prescribing this product, they're not being scammed." He adds, "We are trying to be part of the solution."

Purdue is deploying large sums of money (the company won't give specifics) on programs to fight abuse and lawbreaking. The company operates Rx Patrol, a website that circulates police reports on drug crimes. Purdue offers rewards for citizens who help bring perpetrators to justice. The company distributes brochures that fit in the visors of police cars with photographs and names of frequently abused prescription drugs to make it easy to identify them. It pays for addiction hotlines, brochures that help parents figure out if their children are pilfering from the medicine cabinet, and DVDs that describe the perils of addiction. Purdue has even given thousands of height charts to pharmacies to help witnesses guess the height of robbers. (That seems an unfortunate bit of brand linkage, given that the height charts suggest -- accurately -- that dispensing OxyContin may increase the chance of [a robbery in your store.](#))

One of the company's most substantial programs consists of seminars to train police on how to recognize and respond to the abuse and [diversion of prescription drugs](#). That's why, on a September morning, I find myself in a ballroom at the Marriott Hotel in Austin. The seats are filled with wide-shouldered Texas lawmen, many in cowboy boots, most with guns holstered on hips. The teachers are two retired officers, Landon Gibbs and Ed Cartwright, now Purdue employees wearing company polo shirts. They're part of a six-person team that travels the country holding free seminars. Purdue is the only drug company to offer such a service.

Over four hours the men lead the attendees through a disturbing real-life topography of abuse and addiction: the operating-room nurse who stole anesthetic from patients before surgery,



leaving them to writhe in agony on the surgical table; the drug-addicted relatives who peel painkilling Fentanyl patches off the skin of their loved ones in nursing homes; the "pharm" parties where kids empty their parents' medicine cabinets, dump the haul into a bowl, and ingest random pills.

The presenters neither avoid nor focus on problems related to OxyContin. If they're selling anything, it's the staggering scale of the problem, with prescription-drug abuse responsible for one-third of the overdose visits to the nation's emergency rooms. "Once those pills leave those pharmacies, where are they?" Cartwright asks the group. "We don't know."

During a coffee break, I ask the participants what they think of the workshop. One attendee, an investigator with the Drug Enforcement Administration, tacitly acknowledges the tension his agency has had with the company. He tells me: "Our supervisors didn't prevent us from coming." There was a time not that long ago when they would have.

### **The brothers Sackler**

If you're an art aficionado or a denizen of the academic world, there's a good chance you recognize the name Sackler. The glorious Egyptian Temple of Dendur at New York's Metropolitan Museum of Art resides in the Sackler Wing; galleries at the Smithsonian, at Harvard, Oxford, and Peking University, as well as institutes at Clark, Tufts, and New York University, all bear the name of the family that brought the world OxyContin.

It's an impressive philanthropic legacy and all the more striking for the family's humble origins. Brothers Arthur, Mortimer, and Raymond Sackler were born in the second decade of the 20th century to Eastern European immigrants who ran a grocery store in Brooklyn. (Only Raymond, 91, is alive; he still goes to Purdue's offices.) All three brothers became psychiatrists and worked at a mental hospital in Queens in the 1940s, where their insights would later be hailed. The three "helped pioneer research of the biology of psychiatric illnesses," *BMJ* (formerly the *British Medical Journal*) wrote last year, "research that helped open the door decades later toward drug treatments."



Purdue traces its origins back to a company selling a patent medicine in Greenwich Village. Today it's headquartered in Stamford, Conn.

Leveraging their scientific prowess, the brothers branched into business. In 1952, Mortimer and Raymond bought a 60-year-old drug company called Purdue Frederick. Its principal product was a sherry-based "medicinal tonic" called Gray's Glycerine, whose earlier owner was federally

charged in 1914 for overstating the tonic's curative powers. Purdue then expanded into selling earwax removers, laxatives, and antiseptics.

Meanwhile, the brilliant eldest brother, Arthur, joined a small advertising agency that specialized in marketing pharmaceuticals. (He also funded his brothers' purchase of Purdue, according to a 2003 book by *New York Times* reporter Barry Meier called *Pain Killer: A Wonder Drug's Trail of Addiction and Death*.) Arthur was so successful that in 1997 he was one of the first people named to the Medical Advertising Hall of Fame, whose website credits him with helping "shape pharmaceutical promotion as we know it today." As early as the 1950s he was experimenting with TV marketing, and according to the entry, Arthur's scientific knowledge and ability to expand the uses for Valium helped turn it into the first \$100 million drug ever. Arthur's philosophy was to sell drugs by lavishing doctors with fancy junkets, expensive dinners, and lucrative speaking fees, an approach so effective that the entire industry adopted it.

Purdue itself remained a backwater. But the brothers had ambitions, and Arthur's research told them that pain medicine was a growth area. In 1984 Purdue took an old drug for cancer pain, morphine sulfate, added a time-release formula, and began selling it as MS Contin. Over the next decade sales exceeded \$475 million, and they spun the pain unit into its own company: Purdue Pharma. By then Arthur Sackler had died. Still, his brothers knew that if they wanted a mega-hit with a pain medication, they'd need to find a way to sell to a market much broader than dying cancer patients.

### **OxyContin's dark side**

Purdue's breakthrough would be one of marketing rather than medicine. The painkiller in OxyContin was not remotely new. Its active ingredient was oxycodone, a strong, partly modified form of an opiate alkaloid called thebaine invented in Germany in 1916. The patent had run out decades before, and the generic form was sold by a number of companies.

But with its new time-release mechanism, Purdue won FDA approval to sell OxyContin in late 1995. Purdue immediately set out to promote its new drug, following Arthur Sackler's template. The company pushed for its use in a broad range of chronic pain: everything from backaches to arthritis. Purdue knew it needed to overcome doctors' fears about addiction, so it treated the time-release formula as a magic bullet. It claimed the drug would give pain patients steadier 12-hour coverage, avoid withdrawal, and frustrate addicts seeking a euphoric rush. As one 1998 Purdue promotional video stated, the rate of addiction for opioid users treated by doctors is "much less than 1%."

The pitch worked, and sales took off: from \$45 million in 1996 to \$1.5 billion in 2002 to nearly \$3 billion by 2009. The key: Nearly half of those prescribing OxyContin were primary-care doctors rather than, say, cancer specialists, the General Accounting Office reported. Purdue had succeeded in vastly expanding the market for its drug.







But evidence quickly emerged of OxyContin's dark side. Doctors discovered that the drug lasted around eight hours rather than 12, and that patients would crash, needing more and higher doses. Patients who took moderate amounts for backaches or arthritis could find themselves hooked. Addicts saw they could easily get high by crushing the pills and then snorting, chewing, or injecting them.

In congressional testimony, Purdue's top executives would later say they first learned of problems with OxyContin in 2000, after the U.S. attorney in Maine warned of rampant abuse. But for at least three years prior, internal records show, company executives were aware of the abuse allegations. In October 1997, for example, a Purdue marketing executive e-mailed several

people, including then-COO Michael Friedman, stating that references to OxyContin abuse on addiction chat sites were "enough to keep a person busy all day." He added, "We have three people that visit the site chat rooms." (A lawyer for Friedman and two other former Purdue executives says that "substantial levels of abuse did not begin until 2000 and 2001," and cites DEA data showing the numbers of cases reported to the government first spiked in those years.)

### Opioids and the Stars

Some celebrities have been publicly linked with use of these powerful painkillers (in several cases, with more than one such medication).

Reported past users of OxyContin, generic oxycodone, or Percocet (which consists of oxycodone and acetaminophen):			Reported past users of hydrocodone, which is chemically similar to oxycodone, including Vicodin (which consists of hydrocodone and acetaminophen)		
 <b>Heath Ledger</b> (actor; oxycodone was in his blood when he died)	 <b>Rush Limbaugh</b> (radio talk show host)	 <b>Courtney Love</b> (singer)	 <b>Jamie Lee Curtis</b> (actress)	 <b>Eminem</b> (singer)	 <b>Brett Favre</b> (retired football star)
 <b>Cindy McCain</b> (businesswoman, wife of Sen. John McCain)	 <b>Winona Ryder</b> (actress)	 <b>Steven Tyler</b> (singer, American Idol judge)	 <b>Walter Payton</b> (late football legend)	 <b>Matthew Perry</b> (actor)	 <b>Nicole Richie</b> (reality TV personality)

PHOTOS: ZUMA PRESS (LEDGER, TYLER); ETHAN MILLER/GETTY (LIMBAUGH); JIM SPELLMAN/GETTY (LOVE); RONALD MARTINEZ/GETTY (FAVRE); STEVE GRANITZ/GETTY (CURTIS); JOHN BIEVER/GETTY (PAYTON); ALLEN BEREZOVSKY/GETTY (COURTIS); FRAZER HARRISON/GETTY (MCCAIN); SAM SNAP/GETTY (EHINEM)

As addiction rates began rising in the early 2000s, prosecutors and plaintiffs lawyers circled. The case grew so serious, *Fortune* has learned, that federal prosecutors formally recommended charging Purdue and its three top executives (but none of the Sacklers) with multiple felonies including conspiracy, mail and wire fraud, and money laundering, in addition to misbranding.

But Purdue dodged the worst charges. The company hired an all-star defense team, including Mary Jo White, a former U.S. attorney, and Rudolph Giuliani, then the Republican Party's presumptive presidential front-runner. The company was able to appeal above the heads of the prosecutors on the case and met with the head of the Justice Department's criminal division.

Eventually the two sides agreed that Purdue would plead guilty to a single felony count of misbranding. In May 2007 the company agreed to pay a \$600.5 million fine, and its top three executives were fined \$34.5 million (though the company picked up the tab) and subsequently left Purdue. Each of the three pleaded guilty to a misdemeanor count of misbranding. Jonathan Abram, a lawyer for the three executives -- then-CEO Michael Friedman, chief medical officer Paul Goldenheim, and general counsel Howard Udell -- asserts his clients bore no personal responsibility for wrongdoing. He says the lead prosecutor admitted that the government had found "no evidence against the three individuals to support charges based on any sort of knowing or intentional misconduct. That's why they were charged with only a strict liability misdemeanor." Abram asserts the three were "leaders" in the company's efforts to address abuse.

In its plea Purdue acknowledged that its promotional materials had contained misleading or inaccurate data and that its sales force made claims unsupported by science that falsely downplayed the addiction risks.

### **Are opioids worth it in the end?**

Long before Purdue was penalized by the government, the company sensed that the extent of OxyContin abuse and addiction threatened its franchise. By 2001 the DEA had raised the idea of imposing quotas on the drug and allowing only pain specialists to prescribe it. A Purdue medical director wrote in an e-mail that "the threat of cutting back the quotas to 1996 levels is ghastly ... [We] really are in a battle." The company's best defense became a commitment to security, which could show it was policing itself. Purdue aimed to convince key government officials, an internal strategic plan explained, that its "voluntary program to safeguard the use of OxyContin is the only effective means to proscribe it without interfering with the doctor-patient relationship."

Almost a decade later, Purdue appears to be following that approach (a contention that company spokesman James Heins disputes: "The purpose of our anti-diversion efforts has been to prevent or reduce the abuse of OxyContin and other prescription medications.") In August 2010 its new formulation debuted. Because of past marketing abuses and ongoing federal scrutiny, not to mention litigation risk and a history of bad press, Purdue has refrained from making proclamations about the new version. But Heins is adamant that the company began work on a reformulation long before its criminal case.

Eventually sales of the harder-to-abuse version of OxyContin will provide a barometer of sorts as to what portion of its business is attributable to those who snort or inject it, since they'll probably abandon the painkiller in favor of another. The new formulation seems likely to dent sales, argues Dr. Andrew Kolodny, chair of psychiatry at Maimonides Medical Center and president of Physicians for Responsible Opioid Prescribing. "Even many pain patients who are addicted and don't realize it," he says, "are actually complaining about the new formulation because it has better time release." Kolodny views Purdue as benefiting from addiction. As he puts it, "Once you've got a patient who's addicted or physically dependent, and they're going to be too sick to stop taking it, that's a very good business model."

The FDA is encouraging other painkiller manufacturers to develop tamper-resistant formulas, according to a recent report by Cowen & Co. For example, Pfizer, which is planning to get into the generic oxycodone game in coming years, is expected to use such a formula.

But the use of tamper-resistant pills is hardly going to slow the painkiller juggernaut. Analysts expect the opioid market to maintain its rapid growth. Frost & Sullivan projects an increase from today's \$11 billion to \$15.3 billion by 2016.

Meanwhile an increasing number of physicians are wondering whether opioids are worth it. "I have come to question whether the long-term treatment of nonmalignant pain is causing more harm than good," wrote a San Francisco public health internist named Mitchell Katz in a journal article last year. He subtitled it "A Believer Loses His Faith." A little less faith in painkillers right now would do the country a lot of good.

*--Reporter associate Doris Burke contributed to this article.*

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