Purdue Pharma and the opioid epidemic

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A pair of investigative reports by the *LA Times* has shed further light on how Purdue Pharma's marketing strategy for its painkiller OxyContin has contributed to the ongoing opioid epidemic in the United States.

Purdue Pharma launched OxyContin in 1996 based on the claim that the drug would relieve pain for 12 hours. The extended duration of the drug distinguished it from shorter-acting, but cheaper generic narcotics. Purdue marketing materials emphasized the convenience of "twice-daily dosing," which it said would provide "smooth and sustained pain control all day."

Except it did not work as marketed. For many patients the pain relief ceased before the full 12 hours. Aware of the problem, the company nonetheless continued to encourage doctors to prescribe the drug for 12-hour relief to ensure that insurance companies would cover the pricier narcotic and safeguard the billions in revenue the drug brought the company, according to an article published by the *Times* this past May.

At the same time, Purdue downplayed the risks of addiction and encouraged doctors to prescribe the drug widely for more common aches and pains.

The 12-hour interval could be "the perfect recipe for addiction," Theodore J. Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, told the *Times*. The combination of the reappearance of pain and acute withdrawal "becomes a very powerful motivator for people to take more drugs."

Now based in Stamford, Connecticut, Purdue Pharma was founded by a pair of physicians in 1892. The company was acquired in 1952 by two doctors, the brothers Raymond and Mortimer Sackler. In the 1970s and 1980s, the company focused on developing pain medicines, launching an extended release formulation of morphine, MS Contin, in 1987.

In the late 1980s, the company began developing an extended release version of the narcotic oxycodone (commonly known as Percocet). According to company executives, OxyContin would "cure the vulnerability" to generic competition.

Clinical trials of OxyContin in the early 1990s found the drug to be safe and longer acting, but for substantial numbers of patients the pain relieving effects wore off before the company's 12-hour interval goal. In one study, 95 percent of the patients resorted to a "rescue medication" at some point in the study because the effects of the painkiller had worn off prematurely.

When a doctor who was field testing the drug as part of the FDA approval process began giving it in 8 hour intervals, the company intervened, stressing that it was intended for 12 hours. This interval was emphasized not out of concern for the well-being of patients, but because it would differentiate the drug from shorter-acting, generic painkillers.

The company declined to test the drug at shorter intervals, allowing it to argue that OxyContin had only been tested for 12-hour doses.

OxyContin received FDA approval in December 1995 with a label indicating its effectiveness for 12-hour intervals. The doctor who led the FDA's medical review of the drug, Dr. Curtis Wright, left the FDA two years later to join Purdue, assisting the company with new product development.

For the launch of the new painkiller, Purdue doubled its sales force to 600 and spent $200 million on marketing, taking out ads in medical journals promoting the 12-hour dosing. "REMEMBER, EFFECTIVE RELIEF JUST TAKES TWO," reads one ad.

Drawing from evidence that emerged from court documents and a US congressional investigation, a 2011 article in the *British Medical Journal* observed that the company's marketing strategy was "particularly remarkable" given the danger of addiction and overdose posed by the drug.

"The manufacturer targeted physicians who prescribed OxyContin frequently, paid its sales representatives large bonuses as an incentive to increase OxyContin sales, and issued coupons entitling new patients to free samples at participating pharmacies," the article noted.

Company sales reps sought to convince doctors that the highly addictive narcotic should not be limited to cancer patients or the terminally ill, pitching the drug for more common conditions such as back aches and knee pain. Purdue wined and dined doctors, filled their offices with company swag, flew them out for weekend junkets at expensive resorts and encouraged them to promote the drug among their colleagues.

The marketing blitz was a success. By its fifth year on the market, OxyContin was a blockbuster drug, with $1 billion in annual revenue. By 2010, it was pulling in three times as much. Since its launch, the drug has generated an estimated $35 billion in sales. The Sackler family became fabulously wealthy, with *Forbes* magazine pegging their wealth at $14 billion.

Meanwhile, patients suffered. For many, the drug wore off before 12 hours, resulting in the return of pain, symptoms of withdrawal and intense cravings for the drug.

In response to patient complaints, doctors began prescribing the drug for shorter intervals. This posed a threat to company's bottom line as insurers were less willing to pay for the drug if it provided no added benefits above the generic alternatives.

Company officials focused on training sales reps to convince doctors to stick with the 12-hour dosing regimen. Instead of taking the drug more frequently, company sales reps encouraged doctors to prescribe the narcotic at higher doses, which often put patients into a zombie-like state, and increased the chances of addiction and overdose. This recommendation further lined the company's pockets—while a bottle of 10mg pills went for $97, a bottle of the maximum dose of 80mg sold for $630.

Purdue was not just making money off of legitimate doctor prescriptions. As the *Times* reported in a follow-up article in July, the company also failed to intervene when it became clear that certain physicians and pharmacies were funneling OxyContin pills onto a burgeoning black market.

Purdue had access to prescription data from pharmacies, which it used to target doctors writing smaller numbers of prescriptions to encourage them to write more. This data also allowed them to identify suspicious cases of physicians writing unusually large numbers of prescriptions, often at the 80mg level that was preferred in the illegal drug trade.

For example, the *Times* profiled one "clinic," Lake Medical in Los Angeles, set up in 2008, which by the end of the year had written prescriptions for more than 73,000 pills. The illegal trafficking scheme had individuals known as "cappers" pick up homeless persons from the skid row area, bring them to the clinic for a perfunctory "exam," where they would be written prescriptions, and then drive them in groups to pharmacies to fill the prescriptions. The OxyContin was then returned to the clinic to be packed for bulk sale on the black market.

Purdue placed physicians suspected of writing fraudulent prescriptions on an internal database known as "Region Zero." By 2013, the company had 1,800 physicians on the list, but reported only 8 percent of them to the authorities.

Federal law requires drugmakers to report suspicious activity to the Drug Enforcement Agency. Nonetheless, the federal government has declined to charge Purdue with any wrongdoing.

In the case of the Lake Medical clinic, the company ignored concerns raised by pharmacists at one pharmacy, who began turning away Lake Medical prescriptions on their own. Investigations by federal, state and local officials finally shut down the clinic in 2010. Not until 2013—by which point the physician had already pled guilty and a case had been built against the other drug ringleaders—did Purdue contact the US Attorney's office to offer assistance.

"It would be irresponsible to direct every single anecdotal and often unconfirmed claim of potential misprescribing to these organizations," the company's general counsel, Phil Strassburger, told the newspaper.

In 2010, the company introduced an abuse-deterrent formulation of the drug. A study published in the *New England Journal of Medicine* in 2012 found that while patient abuse of OxyContin declined, addicts typically replaced the narcotic with heroin, which poses even greater health risks.

Patients began filing court cases against the company in the early 2000s, but Purdue managed to get most of them dismissed, while other lawsuits were settled confidentially with the court records sealed. In a 2004 court case in West Virginia, the future attorney general Eric Holder helped the company reach a settlement just days before the case was set to go to trial. Purdue agreed to pay $10 million to support drug abuse prevention programs, but admitted no wrongdoing.

In 2007, the company's top three executives pled guilty to fraud for downplaying OxyContin's risk of addiction, and Purdue was ordered to pay $635 million. The fine was a small price to pay for the billions of dollars brought in by the drug.

This past May, Purdue lost its legal battle to keep court records and testimony sealed. A Kentucky judge granted a motion to unseal the records for a court case that the company had settled in December of last year by agreeing to pay $24 million while admitting no wrongdoing. The records, however, remain sealed as the company appeals the decision.

OxyContin has certainly played no small part in the current opioid epidemic and rise in drug overdoses in the United States.

A report published by the Centers for Disease Control (CDC) earlier this year documented the dramatic rise in drug overdoses in the United States. In 2014, there were 47,055 drug overdose deaths, an increase of 6.5 percent over the previous year. The CDC found that 61 percent (28,647) of these overdoses were from opioids. Between 2013 and 2014, opioid drug overdoses increased by 14 percent. The primary opioid drugs resulting in the overdoses were heroin and prescription painkillers.

"Opiod pain reliever prescribing has quadruped since 1999," states the CDC report, "and has increased in parallel with overdoses involving the most commonly used opioid pain relievers."

While Purdue's ruthless pursuit of profit has no doubt accelerated the rates of opioid addiction and drug overdoses, these alarming statistics reflect the immense social crisis faced by millions in the United States. The rising rates of drug abuse, addiction and overdoses take place in a context in which workers and youth face long-term unemployment, deteriorating working conditions, stagnant or declining wages, austerity and the dismantling of basic social services.

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