Study links abuse-deterrent OxyContin with rise in hepatitis C infections

By Brian Dixon
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According to a new study published in *Health Affairs* last week, Purdue Pharma's switch to a new abuse-deterrent formulation of OxyContin in 2010 led to a rise in hepatitis C infections as addicts switched to injecting heroin.

While prior research has established the connection between the introduction of the abuse-deterrent formulation of OxyContin and a spike in heroin overdoses, the *Health Affairs* article, written by researchers from the Rand Corporation and the Wharton School, examined the relationship between the introduction of the reformulation and hepatitis C infection rates.

The researchers noted that while opioid overdoses and addiction steadily rose in the 2000s, the rate of hepatitis C infections declined or remained stagnant—until 2010, the year that the abuse-deterrent formulation of OxyContin became available. Hepatitis C infections began to steadily increase shortly afterwards.

The study drew on data from the National Survey on Drug Use and Health, administered by the Substance Abuse and Mental Health Services Administration, to measure the nonmedical use of OxyContin in different US states, and then computed the rate of OxyContin misuse in each state before the reformulation.

The researchers then divided US states into two groups based upon whether they were above or below the median rates of Oxycontin misuse, and tested whether the growth rate of hepatitis C infections between the two groups differed, controlling for variables such as the unemployment rate and demographic composition.

Their results found that while OxyContin misuse declined after 2010, both hepatitis C infections and heroin deaths increased. Moreover, the researchers found that states with above-median misuse rates saw an increase in hepatitis C infections three times greater than those states with below-median rates (a 222 percent increase compared to a 75 percent increase).

As a falsification test, the researchers replicated their analysis looking at pain reliever misuse, but excluded OxyContin. In both groups, the hepatitis C infections grew at similar rates, demonstrating that the rise in hepatitis C rates was uniquely linked to the OxyContin reformulation.

"Thus, the rise in hepatitis C infections was primarily concentrated in states most affected by the reformulation, and this differential increase began in the year after the reformulation," the researchers wrote. "The timing of the differential increase strongly suggests that other differences across states (for example, differential changes in economic conditions due to the Great Recession or state-level opioid policy adoption) were not driving the results."

They note that this case underscores the potential "unintended consequences" of interventions addressing the abuse of prescription opioids when carried out without policies and resources necessary to address substance abuse and addiction. They warn that the transition to an abuse-deterrent formulation may lead to rising rates of other infectious diseases, such as HIV.

Purdue Pharma and the opioid epidemic

Evidence continues to build that Purdue Pharma's aggressive marketing of OxyContin—along with the criminally negligent actions of other drug manufacturers and drug distributors —was a key factor in the emergence of the opioid epidemic in the United States starting in the late 1990s.

Since 1999, overdose deaths have nearly quadrupled in the United States, rising from 6.1 per 100,000 deaths to 21.7 in 2017, according to the Centers for Disease Control and Prevention (CDC). In 2017, 47,600 people died from overdoses associated with opioids.

According to the National Safety Council, Americans are now more likely to die from an opioid overdose (1 in 96) than die in a car accident (1 in 103) or as the result of an accidental fall (1 in 114).

Following the Food and Drug Administration's (FDA) approval of Purdue Pharma's opioid painkiller OxyContin at the very end of 1995, the company immediately began a marketing blitz of the drug, claiming that it stopped pain for a full 12 hours—despite mounting evidence showing otherwise—while downplaying the drug's addictive risks.

"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," noted a 2011 article in the *British Medical Journal* .

The marketing strategy transformed OxyContin into a blockbuster drug, generating an estimated $35 billion in sales and enriching the owners of the company, the Sackler family, whose wealth is estimated at $14 billion.

The Sackler family is widely known for its philanthropic activities and has sought to distance themselves from the unethical behavior of the company they own. However, a recent court filing by the attorney general of Massachusetts cites internal company documents that highlight the Sackler's intimate and ongoing involvement in the company's efforts to market OxyContin and shift the blame of addiction onto addicts rather than the drug.

Health researchers have drawn a strong connection between the company's marketing activities and the opioid epidemic

For example, a study published last month in *JAMA Network Open*, drawing upon county-level data, found an association between doctor payments for non-research-based opioid marketing between 2013 and 2015 and an increase in mortality rates from prescription opioid overdoses in the period between 2014 and 2016.

Patients, physicians and industry critics recognized Purdue's role in the epidemic in the early 2000s, but the company was largely successful in fending off lawsuits until 2007, when a settlement was reached in which the company paid over $600 million in fines and top executives pleaded guilty to federal criminal charges.

In response to this pressure, the company introduced an abuse-deterrent formulation of OxyContin in 2010 that could no longer be crushed and snorted or dissolved and injected. OxyContin was the most widely-abused drug at the time, but no public health measures were in place to help abusers address their addiction.

As the *Health Affairs* study shows, this led opioid addicts to increasingly turn to injecting heroin, resulting in the spread of Hepatitis C infections.

The hepatitis C virus and drug prices

The hepatitis C virus (HCV) is the most common blood-borne virus in the United States. It attacks the liver and can lead to cirrhosis, liver cancer and liver failure. According to the CDC, an estimated 2.4 million individuals are living with chronic cases of HCV. In 2016, 18,153 death certificates listed HCV as a cause, although research indicates that this figure greatly underestimates the real number.

The most common mode of HCV transmission is through injectable drug use. Infection rates are particularly high among US prisoners. According to a 2014 article in *Public Health Reports*, the infection rate of HCV is 1 to 2 percent among the general population, but over 17 percent among the prison population.

While there are effective cures for HCV, efforts to address the disease have been hampered by the high prices of HCV drugs.

Since the disease was first identified in 1989, medical science has made enormous strides in the treatment of HCV. The approval by the FDA of direct-acting antiviral (DAA) drugs starting in 2011—in particular, the drugs Sovaldi (sofosbuvir) approved in 2013 and Harvoni (a combination of sofosbuvir and ledispavir) approved in 2015—represented a major advance, as these drugs significantly reduced the treatment time and side effects. In most cases, Sovaldi and Harvoni could actually cure the disease in a single course of treatment.

These medical breakthroughs, however, immediately came into conflict with the profit system under which new drugs are researched, developed and sold. When the California-based biotech company Gilead Sciences gained approval for the drugs Sovaldi and Harvoni it priced a course of treatment at $84,000 and $94,500, respectively.

Gilead Sciences acquired Sovaldi after it purchased the Georgia-based biotech company Pharmasset in 2012 for $11.2 billion. Pharmasset itself was founded in 1998 by researchers at Emory University who signed licensing agreements to acquire drug candidates discovered by university scientists.

According to a Senate report released in 2015, Pharmasset had initially planned on selling Sovaldi for $36,000 for a course of treatment. While Gilead believed that their acquisition of Pharmasset would be profitable if they priced Sovaldi at $65,000 per course of treatment, it ultimately settled on a price $20,000 higher.

As a result of the exorbitant drug prices, spending on HCV treatments has placed a significant strain on medical providers and insurers, limited patient access, and resulted in the rationing of HCV treatments, especially among vulnerable populations such as prison inmates.

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