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Prognosis

America's Best Weapon in the Opioid Epidemic Just Got Cheaper

By

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One of the most popular and effective treatments used to fight the U.S. opioid epidemic is about to get much cheaper.

Based in Hyderabad, a rambling boomtown in south India, [Dr. Reddy's Laboratories Ltd.](#) is a major supplier of generic drugs used by Americans for everything from infections to cardiovascular ailments. After a two-year legal battle, the company has won the right to sell a cheaper version of Suboxone Film, the [best-selling](#) opioid addiction drug in the U.S. too.

That victory will bring generic versions of the therapy to the U.S. nearly four years [sooner](#) than expected, helping cut into the bill for a drug that can cost about \$500 a month at a recommended dose.



Dr Reddy's CEO G. V. Prasad.

Photographer: Dhiraj Singh/Bloomberg

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“It’s potentially a really big deal,” said Brendan Saloner, an assistant professor at the Johns Hopkins Bloomberg School of Public Health, who has studied the opioid addiction crisis. Suboxone Film has “a really important role in the overall strategy of combating the overdose crisis,” he said, adding that placing patients on the drug cuts their risk of overdose in half.

For now, the U.S. opioid epidemic shows few signs of abating: annual opioid overdose deaths in the U.S. are expected to climb to 81,700 in 2025, a 147 percent increase from 2015, according to a study last month by the Massachusetts General Hospital Institute of Technology Assessment. The human and financial costs have led states, counties and cities to sue drugmakers and distributors, seeking billions of dollars.

Suboxone Film allows the opioid-based drug buprenorphine to be absorbed through the mouth to help control cravings and stave off withdrawal. When combined with counseling and support services, that type of medically assisted therapy is considered one of the most effective ways to treat opioid addiction.

It’s also expensive, especially for uninsured patients. Suboxone Film’s inventor, U.K.-based Indivior Plc, has raised the price of the most popular 8-milligram dose four times since 2016, a 22 percent increase, according to data from Symphony Health. Before generics entered the market, it cost \$8.56

a dose, or about \$500 a month for the twice-a-day treatment the National Institute on Drug Abuse calls most effective.

In a statement, Indivior said its price increases for Suboxone Film did not impact out of pocket costs for patients with insurance, and were intended to keep pace with inflation and fund research into new drugs. It called the market for medically assisted treatment for opioid abuse “highly competitive”.

‘At Risk’

The legal fight between Dr. Reddy’s and Indivior began in August 2016, and centers on whether Dr. Reddy’s version of Suboxone Film violates Indivior’s patent. In June last year, the U.S. Food and Drug Administration said the two drugs were medically equivalent, and Dr. Reddy’s decided to bring its version to market immediately in an “at-risk” launch.

It started sales last year, then had to halt them a month later after a federal judge issued an injunction in July. Last month, the U.S. Supreme Court ruled that Dr. Reddy’s could resume sales, agreeing with a lower court that Dr. Reddy’s was likely to win its ongoing patent case.

The legal fight isn’t over, and Dr. Reddy’s could face tens of millions of dollars in penalties if it eventually loses the patent case. But G.V. Prasad, the company’s chief executive officer, said it was a gamble worth taking, and that he thinks Indivior has fought so hard because generic competition puts their whole business at risk.

Suboxone Film accounted for nearly all of Indivior’s \$1 billion in revenue last year. Since Dr. Reddy’s version was approved by the FDA in June, Indivior’s stock has dropped by 77 percent.

Threw Everything

“I don’t think they were willing to compromise on anything,” Prasad said in an interview from his book-lined office in Hyderabad. “Sometimes companies work out a way to settle issues outside of the courts. I think this being a very large component of their business, they threw everything at it.”

Indivior referred questions about its stance on the legal case to a Feb. 20 statement announcing it was releasing its own version of generic Suboxone Film on the expectation more competition was coming.

Dr. Reddy’s 8-milligram dose began selling last month at \$6.33, according to Symphony Health. Prices should eventually drop as much as 70 percent, said Nitin Agarwal, an equity analyst who follows the generic industry for IDFC Securities in Mumbai.

“Making this accessible and affordable will impact a lot of lives,” Prasad said. “We were able to push through and bring the generic to market very early. Of course others also followed, but we were the guys who did the hard work.”

Price Drop

Prasad predicts Dr. Reddy’s will capture about a quarter of U.S. sales, splitting the rest with three other makers, including Indivior’s generic. He declined to say how far Dr. Reddy’s will eventually drop its price, though said reductions would be significant.

While Dr. Reddy’s sells opioid products as well, its version of opioid-painkiller oxycodone combined with acetaminophen accounted for only 324 prescriptions in the U.S. in February, bringing in about \$68,410 in sales, according to Symphony data.

While there have been some reports of patients abusing Suboxone’s opioid-based main ingredient, buprenorphine, addiction psychiatrists have argued these kinds of fears are overblown. The drug doesn’t cause intoxicating effects, and one study showed Suboxone, which combines buprenorphine with the opioid-reversal drug naloxone, actually had less abuse potential than buprenorphine alone.

Medicaid’s Boon

The price reductions could also be a boon for Medicaid, the U.S. health care program for the poor. Four in 10 non-elderly adults with opioid addiction are covered by Medicaid, according to the Kaiser Family Foundation. In 2018 the program spent nearly \$160 million on Suboxone Film or other branded versions of buprenorphine, a report last month from the Urban Institute showed.

“Anything that cuts costs, whether it’s to the state or federal dollars, will be critical,” Julia Zur, a senior policy analyst with the Kaiser Family Foundation, said in an interview.