

SOVALDI DRUG

US patients travelling to India in search of cheaper Hepatitis C drug

High price of Sovaldi, combined with demand from US patients, is creating an extreme form of medical tourism

By SHANNON PETERPITCE & KETAKI GOKHALE
NEW YORK/MUMBAI

This is how far one Express Scripts Holding Co. executive was willing to go to secure inexpensive versions of Gilead Sciences Inc.'s hepatitis C drug Sovaldi, unavailable to US consumers under federal drug import and patent laws.

His plane docks a cruise ship flying an Indian flag off the coast of Miami. Stock the ship with versions of Sovaldi sold in India for \$83,000 less than the US retail price for 12 weeks of treatment. Ferry US patients to the boat and send them home with the potentially life-saving medicines at a huge discount.

The only wrinkle in his plan wasn't the absurdity of a pharmacy benefit manager manning and operating a cruise ship full of drugs from India. The problem, after doing some quick research into the idea, was that it would probably violate US drug reimportation laws that limit the value of drugs brought into the country to \$1,500—the price of one and a half Sovaldi tablets in the US, said Steve Miller, chief medical officer, Express Scripts, who came up with the idea.

"I was trying to be as creative as possible," Miller said in an interview. "This is what the market is demanding, this level of creativity that almost borders on the ridiculous."

Miller quickly dropped the drug boat scheme, but he says he is still searching for creative ways to save money on the \$84,000 Sovaldi, which Express Scripts stopped covering for many patients this year because of the cost. He isn't alone. A cottage industry of drug distributors, medical tourism agencies and consultants is emerging to offer patients in the US and other developed countries cheap copies of Sovaldi from countries where it is sold for 1% of the US price.

Control costs

Patients in the US and Europe have struggled to get access to the drug after insurers and governments limited its use to the sickest patients to control costs, leaving the rest waiting while the virus attacks and scars their liver.

Employers have warned that the cost of covering the drug could be a financial catastrophe. The Southeastern Pennsylvania Transportation Authority, for instance, said it spent almost \$3 million on Sovaldi last year for its employees and retirees, according to a lawsuit it filed against Gilead Sciences Inc. over the price.

Meanwhile, a group of generic drugmakers are licensed to sell copies of Sovaldi in 81 mostly low-income countries, and this year began selling it in India for about \$900 for a 12-week regimen under an agreement with Gilead intended to help patients in poorest countries get access to the medication.

While Americans have crossed the border to Canada for years to get access to low-cost drugs or travelled to the Caribbean for cheap surgeries, the high price of Sovaldi combined with the demand from patients is creating an extreme form of medical tourism.

There are 3.2 million people in the US with chronic hepatitis C.



Cheaper alternatives: A file photo of a laboratory of Gilead Sciences, which makes Sovaldi.

Sovaldi, which has been on the market in the US for less than two years, has shown to cure at least 90% of people of the liver-destroying virus.

High Interest

"I know people who have hepatitis C and the only thing they can think about is getting this drug," said Jonathan Idelheid, chief executive officer (CEO) of the Palm Beach Gardens, Florida-based Medical Tourism Association, who said that his group's members are gearing up to help patients start travelling to lower-cost countries to buy the drug. "There is definitely a high interest in going abroad."

Leena Menghani, a lawyer working with patients to gain affordable access to hepatitis drugs, said the current situation reminds her of the early days of AIDS epidemic when patients from South Africa were travelling to Thailand or India for antiviral drugs.

The demand is "coming from countries where treatment is being rationed and patients are waiting in line for treatment in the public healthcare system, or their insurance doesn't cover it, and they are desperate to get on to treatment," said Menghani.

Overseas trip

Health Flight Solutions, an Orlando, Florida-based firm that provides technology services to medical tourism agencies, is putting together a network of foreign doctors and hospitals willing to prescribe the drug to US patients, said CEO Anuja Agrawal. She said her company is working with the generic manufacturers to verify that the hospitals in her network aren't getting counterfeit drugs.

"We have already seen some movement, but I think we are going to see an explosion over the next several months," she said.

Greg Jefferys, a 61-year-old historian from Australia, is one of those who has already made the trip. Jefferys' doctor told him the government wouldn't subsidize the cost of Sovaldi for him as his disease wasn't advanced enough. He'd have to wait until the virus further scarred his liver or pay the retail price of nearly \$90,000.

It was money he didn't have and he didn't want to get any sicker so when a friend mentioned to him that the drug was being sold for much less in India, he immediately booked a trip there.

Modern facility

When Jefferys landed in May,

a mutual acquaintance in India referred him to a doctor at the Apollo Hospital in Chennai, a gleaming, modern facility that specialized in treating patients from overseas, he said.

The doctor, he saw was trained in the UK and had practised for years in London. He charged \$20 for the appointment.

"To buy the drugs, his doctor referred him to a drug distributor who works for Mylan NV, one of the licensed generic manufacturers.

The distributor, located on the top floor of a house with boxes scattered about, sold him the full course of treatment for \$1,000—the price of one pill in Australia and the US. The flight, hotel and transportation were an additional \$2,000.

Jefferys said he has no doubt he got the actual drug, not a counterfeit, and will find out for sure when he gets his viral load checked in a few days. Since writing about his experience on his blog, he said he has been getting inundated with emails from patients around the world asking how they can do the same after being denied the drug in their home country.

"What are your choices? One is to wait for the liver to get cirrhosis and get real sick or go to India and get the medication," he said. "The cost for me was \$3,000. You'd spend that on an old car—that isn't a lot of money to pay to get your health back."

Travel costs

Until recently, travelling abroad for the drugs through a medical tourism agency cost patients around \$40,000 for the drug in countries where it was already being sold for less than in the US though not nearly as low as the prices now available. Those costs included the flight, accommodations, doctor bills and testing, and travel agent fees, said Agrawal. She expects that to drop significantly to about "several thousand dollars" now that the cheap generics have come on the market.

Gilead has put some measures in place to try to prevent the drug from being sold outside the low-income countries, such as requiring the products have a unique trade name and asking the generic companies to try to

ensure patients have a valid prescription.

But Gilead does not require patients show proof of citizenship, which could make it more difficult for patients in the poorer countries to get access, and there is little it can do to stop patients from buying medicine online or travelling overseas, said Gregg Alton, Gilead's executive vice-president of corporate and medical affairs.

"We aren't surprised; we know this was going to happen. This is a reality of having these types of programmes," said Alton. "As soon as gray market develops, there isn't much we can do to control it at a pharmacy level."

Patient treatment

Instead, Gilead is trying to improve access in the US and other countries by negotiating with insurers and governments and setting up a patient assistance program for those without insurance or high co-pays.

Ikris Pharma Network, a consultancy which helps patients source drugs that are hard to find, has been getting 50-60 inquiries a day about the drug since the first generic was introduced in India in March, said Praveen Sikri, the general manager at the Delhi-based firm.

He has helped patients travel to India to purchase generic versions of Sovaldi or buy it through friends and relatives, he said. So far, most of the patients buying India-made generics of the drug are from Asian countries including China and Singapore, and Dubai, with a small number coming from Europe and the US, he said.

There are also firms online who say that they are selling the drug. A search by Bloomberg News found more than a dozen Indian drug distributors who say they are selling generic versions of Sovaldi made by Mylan, Cipla Ltd and Natco Pharma Ltd for about \$1,000 for the 12-week course of therapy.

The companies say they will ship the drug worldwide or sell directly to patients who come to India to buy it.

Verifying quality

That is concerning to US regulators who fear the quality of the medicines being sold online outside the traditional supply chain

can't be verified. The US Food and Drug Administration (FDA) has warned in the past that many drugs sold by Internet pharmacies are counterfeit and don't contain the appropriate amount of the active ingredient or, at worst, are tainted with harmful chemicals.

The FDA has not issued any specific warnings on Sovaldi.

In the past several years, the FDA has found cases of fake cancer drugs that don't contain any of the active ingredients, the antiviral Tamiflu tainted with an antibiotic that can cause severe allergic reactions, and the erectile dysfunction drug Cialis containing painkillers.

Arvind Jain, manager at Deep Lifecare, a Delhi-based pharmaceutical exporter, said the firm is selling Mylan or Natco generics of Sovaldi for about \$850 for the full 12-week course.

He said most of the business is coming from word-of-mouth and he's willing to ship the drug.

"Lots of people from around the world are making inquiries about this medicine," Jain said.

Dark web

Varun Medicals, a pharmaceutical wholesaler in Maharashtra, says it's selling a generic version of Sovaldi made by Natco for about \$950 for the full course of therapy. He said he has received requests from the US for more information, but no one has placed an order.

Both companies were found doing a search for Sovaldi on the online marketplace India Mart and advertise dozens of other generic drugs for sale on their websites.

Mylan spokeswoman Nina Devlin said in a statement that the company doesn't sell to any "e-commerce entities" when asked about companies claiming to sell the drug online.

Anant Atal, a spokesman for Cipla, didn't respond to an email and a call seeking comment.

M. Adinarayana, a spokesman for Natco, didn't respond to an email seeking comment.

The drug is also showing up for sale alongside illegal goods and narcotics on the dark web, which can only be accessed through identity-hiding software.

Cyber-security analysts at data security firm Dell Secure Works found drugs the seller claimed were Cipla generics of Sovaldi for sale for \$1,031.

The seller, who it ships worldwide, including to the US and Europe, and takes payment in Bitcoins.

There are no details on who the seller is other than a username, which is a region outside of Moscow, and a 100% positive rating from 22 users.

Other sellers weren't always what they appeared to be.

DropShipMD, a "distribution, trading and drop shipping" company, says on its website it will ship generic Sovaldi made by Mylan for \$1,300 and other generic versions for \$1,500 to customers in the US and Europe with a prescription via express mail. It also offers patients the option to pick the drug up in Mumbai with cash.

Located at the address listed for DropShipMD, a basement unit in a rundown Mumbai apartment complex with tinted windows and a vinyl door, is another drug exporter, Vivin International.

Ramesh Akhela, CEO of Vivin International, said his firm has no affiliation with DropShipMD, which he said was using his address without his permission.

Akhela said his company does sell Natco's generic Sovaldi to Singapore and Africa, though he insisted it doesn't ship to the US. All the more reason, companies like Agrawal's say, patients need them to help ensure they are getting the real drug. "When the margin is that high, there are going to be a lot of people who will try to make a quick buck on it," said Agrawal. feedback@themint.com

J S (SP) /
Director

5/16

Approved
10/16
Commitment (10/17)

Ted, NIK
10-6-15

Miscellaneous