Fighting For Global Access to Hepatitis C Therapies

Battle lines are drawn as the global health community prepares to face off with Big Pharma over the astronomic cost of treatment.

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With Gilead Sciences' revolutionary drug Sovaldi (sofosbuvir) finally on the market, the future of hepatitis C virus (HCV) treatment has arrived. And the coming months and years will likely only brighten, as the drug pipeline bursts with a host of highly promising combination therapies from Gilead as well as a handful of other pharmaceutical companies. But for the global health community, the fight for access to such highly effective therapy is stuck back where the similar push for thrifty production of HIV drugs was 15 years ago. In the late 1990s, the annual treatment cost for HIV was a vastly prohibitive $10,000 a year; but over time an influx of cheap Indian generic medications sent that price tag tumbling to about $100 today.

And so a similar battle begins, in which global health organizations, governments and other factions wrestle, or prepare to do so, with pharmaceutical companies over who has the right to produce direct-acting antivirals (DAAs) for hepatitis C around the globe.

The need is profound. An estimated 150 million people worldwide are living with hepatitis C, a prevalence five times that of HIV. But while HIV largely affects poorer nations, with an epidemic rooted in sub-Saharan Africa, 75 percent of the HCV burden is in middle-income countries such as China, Russia, India, Argentina, Thailand and Pakistan. Consequently, negotiating affordable prices for hep C drugs abroad may prove a comparatively thornier challenge than with HIV in Africa; pharmaceutical companies will be less than eager to cut prices too steeply in these potentially lucrative markets. A preview of coming attractions may be found in the business practices of pharmaceutical companies selling HIV drugs to the middle-income nations where that virus has spread more rapidly in recent years. The net result has often been curtailed access to life-saving medications.

"It's a pandemic, and there is an urgent need for cheap, effective, user-friendly anti-HCV oral drugs that can be given to the sickest and poorest people in the world," says Raymond F. Schinazi, PhD, a researcher at Emory University who founded Pharmasset, which developed Sovaldi before Gilead acquired the company in 2011. "We have a moral obligation to do something about it as quickly as possible."

Behind the staggering U.S. price tag of $84,000 for a 12-week course of Sovaldi lie manufacturing costs that two recent papers have estimated are actually a relative drop in the bucket.

Schinazi has guessed Sovaldi's production price tag at $1,400 or less. Meanwhile, Andrew Hill, PhD, a senior research fellow at Liverpool University, compared hepatitis C drug manufacturing costs to those of HIV drugs and has put Sovaldi's at a mere $68 to $136. With some of the other DAA's in the pipeline likely costing even less, Hill projects that a total $100 to $250 price for 12 weeks of combination hep C treatment would open the door for wide access and profits alike. Many say $500 is the threshold for affordable global access.

"I think there's huge opportunity if you look at it just in cold, financial terms," Hill says, indicating that generic companies can still make money off of drugs that have a low margin of profit when those medications are sold in high volumes.

India, with its strict pharmaceutical patent laws, is a key initial battleground where both sides of the turf are seeking to make headway. The New York City–based Initiative for Medicines, Access & Knowledge has filed an opposition to Gilead's patent of Sovaldi at the Indian Patent Office, claiming that the drug is based on existing science that predates Gilead's patent applications.

"Are we rewarding them over the top for something that's already in the science?" asks Tahir Amin, director of intellectual property at I-MAK.

Gilead, meanwhile, is already negotiating with several Indian generics to provide Sovaldi to about 60 low- and middle-income countries. Acknowledging a report in the Indian press of a possible $2,000 price tag for Sovaldi—this would be for 24 weeks of therapy for people with genotype 3—Gregg Alton, Gilead's executive vice president of corporate and medical affairs, says that nothing has been set in stone.

While Gilead's initial move toward allowing generic production may appear generous, Amin insists, "We see it as [Gilead's] way of managing competition and trying to gain favor with the Indian patent authorities [and with the] public to show that they are making the drug accessible.

"It's a kind of classic strategy," he says. "When [Gilead] feels its patents are under challenge or threat, it uses these licenses to kind of deflect, and also to get some of these generic companies that may otherwise challenge the patents into an agreement. Some of these Indian generic companies will be happy to get a license for the less-lucrative markets."
Furthermore, Amin points out, Gilead's contracts for generic production most likely will not apply to the middle-income countries where the need is the greatest. Instead, according to Alton, the company is considering selling the brand-name drug under "a system of tiered pricing" in over 125 other low-, middle- and upper-income nations, including Russia and China.

A victory for I-MAK in the Indian patent dispute would not necessarily grant generic companies the right to sell Sovaldi to the hardest-hit middle-income countries—the companies could only do so in nations where Gilead has never filed for a patent. However, Amin is hoping the case will serve as a precedent to the courts in other nations and eventually create a legal domino effect leading to wider access.

Meanwhile, the Access Campaign of Doctors Without Borders is pushing the World Health Organization to take the lead where access to hep C drugs is concerned. The campaign is hoping that WHO will include hepatitis C drugs in its program to prequalify generics drugs for low-income countries that lack the resources to approve new drugs in a timely fashion.

Rohit Malpani, the access campaign’s director of policy and analysis, insists that government must assume a major role in the fight for drug access.

“If we leave it to the pharmaceutical industry—the multinational companies that are now marketing these medicines—to decide, it would be about 15 years before you get affordable, low-cost versions, because that’s the patent barriers that exist,” Malpani says. “But it’s not really for the companies to decide, it’s actually for governments to decide whether or not multinational companies are providing these drugs at affordable prices.”

Doctors Without Borders also plans to pressure the major funders of HIV treatment—including the Global Fund to Fight AIDS, Tuberculosis and Malaria; the U.S. President’s Emergency Plan for AIDS Relief; and UNITAID—to pledge resources toward hepatitis C drugs should the prices come down. Considering the significant overlap between the HIV and HCV epidemics, such a new mission is both logical and not without precedent: UNITAID has already expanded its mandate to include fighting hep C in those who are coinfected with HIV, and the Global Fund has given grants to support HCV treatment.

It would appear that WHO is amenable to such pressure, although time will tell what kind of mettle the agency exercises in the fight for access to hep C therapy. In an emailed statement, Gottfried Hirnschall, MD, MPH, the director of the WHO’s HIV/AIDS department, indicates that the organization “is in the process of developing a global action plan to improve access to hepatitis treatment.” In March, he says, WHO will gather a “broad range of stakeholders” to discuss financial investments in greater access to treatment.

“The new hepatitis medicines are indeed very expensive,” Hirnschall writes, “and WHO is considering all possible avenues to proactively make them more affordable to all who need them, wherever they live. We have to learn from our experience with scaling up HIV treatment, where we have seen that competition is the most effective means to drive prices down and increase access in low and middle-income countries.”
