

BEYOND THE HYPE:

What **sofosbuvir** means—
and doesn't—for global
hepatitis C treatment



In December 2013, authorities in the U.S. and Europe approved Gilead's highly anticipated hepatitis C drug, sofosbuvir. This drug and other new treatments for hepatitis C, called direct-acting antivirals (DAAs), have created a buzz among medical and research communities, patients, and financial analysts tracking the multi-billion dollar hepatitis C treatment market. Taken in pill form rather than by injection, and with cure rates and side effect profiles better than previously seen for hepatitis C, many are hailing sofosbuvir and other new oral medicines as "miracle cures."

The new drugs, however, come with a major limitation—price. Business analysts currently estimate that Gilead could charge \$80,000 USD for a single course of treatment of sofosbuvir.^[i] With nearly 90% of the estimated 185 million people living with hepatitis C worldwide residing in low- and middle-income countries,^[ii] where government health budgets are small and where most patients have to pay for medi-

Sofosbuvir's estimated \$80,000 USD price tag for a 12-week course **makes it out of reach for nearly 90% of people living with hepatitis C** worldwide who reside in low- and middle-income countries.

cines out of pocket, this price tag means that sofosbuvir and the other new hepatitis C medicines will remain out of reach for the majority of those in need.

PEGYLATED INTERFERON

Termed the "viral time bomb" by the World Health Organization because most people living with hepatitis C are unaware of their status and can remain without symptoms for decades, hepatitis C infects three to four million new people per year.^[iii] More than 350,000 people die annually from hepatitis C-related liver diseases.^[iii] Unlike HIV,

however, hepatitis C—though also transmitted through contaminated blood—is curable.

For the past decade, the medicine pegylated interferon, or Peg-IFN, has been the backbone of hepatitis C treatment. An injectable medication, Peg-IFN is far from ideal in terms of tolerability and ease of use, but cures a significant proportion of patients who use it in combination with another medicine, ribavirin. With a price tag of up to \$20,000 USD per course, Peg-IFN has remained unaffordable, and inaccessible in most low- and middle-income countries.^[iv]

THE HEPATITIS C TREATMENT MARKET & PROJECTED REVENUES



The hepatitis C treatment market is projected to reach over \$15 billion USD through sales in rich countries that hold less than 5% of the world's hepatitis C patients.^[v]

NEW AND IMPROVED TREATMENTS—AT WHAT COST?

Clinical trial data on the new hepatitis C medicines are very promising. Oral rather than injectable, they have cured patients with some strains (genotypes) of hepatitis C more rapidly, more efficaciously, and with fewer side effects when compared to PEG-IFN. For other patients, treatment still requires Peg-IFN, and the combination of this medicine with the new oral drugs also increases treatment efficacy, and reduces treatment duration from up to 48 weeks to as little as 12. These advantages are all cause to celebrate—but only if patients can gain access to the new medicines. Sofosbuvir's estimated \$80,000 USD price tag for a 12-week course will be many times more than the current cost of Peg-IFN, and for many will be added onto the cost of that already unaffordable medicine.

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MIDDLE-INCOME COUNTRIES AND PHARMACEUTICAL PROFITS

The greatest burden of hepatitis C falls on middle-income countries, which account for nearly three-quarters of all those living with hepatitis C.^[iii] These countries are referred to as “emerging markets” by the pharmaceutical industry in anticipation of increasing numbers of citizens and governments purchasing brand name medicines over time. Current marketing approaches by the industry in these countries frequently target wealthy elites and their physicians, rather than seeking to increase sales to the population as a whole.

Profits for the manufacturers of hepatitis C drugs are expected to be enormous even if they sell no medicine in middle-income countries. The hepatitis C market is expected to reach over \$15 billion USD by 2022 from sales in Japan, five major European markets (France, Germany, Italy, Spain, UK), and the U.S. alone,^[iv] where fewer than five percent of those infected with hepatitis C reside. Sofosbuvir is expected to command the largest share of this market.^[v]

LESSONS TO BE LEARNED FROM HIV

The cost to manufacture a course of sofosbuvir is estimated to be only \$68-136 USD^[vi]—a sharp contrast to the estimated \$80,000 USD price tag—so steep price

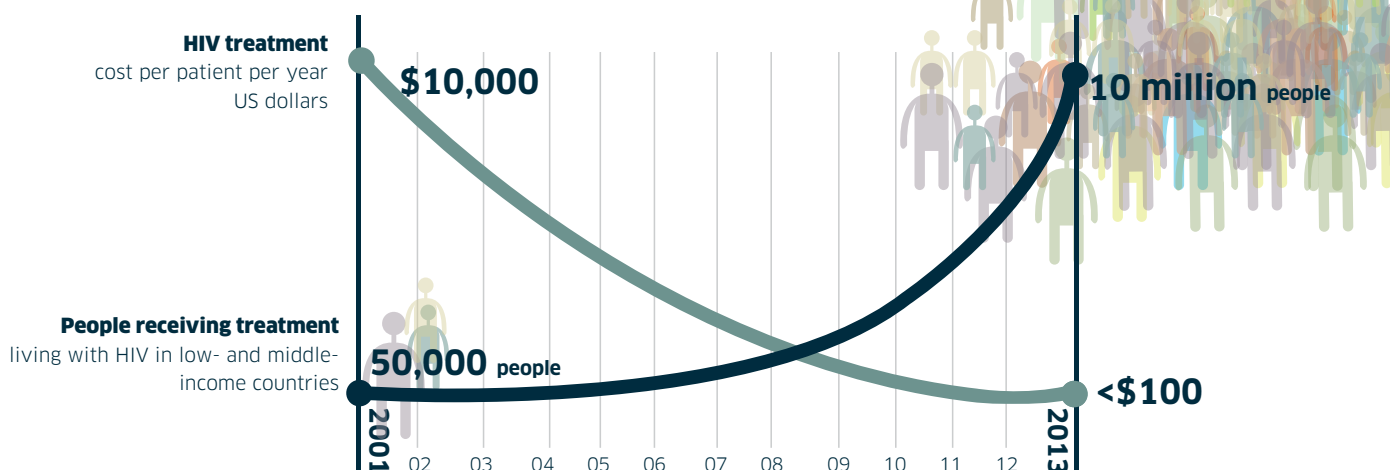
reductions are possible. The simplest solution would be for manufacturers of the new hepatitis C medicines to lower their prices to levels affordable for governments operating with limited health budgets in low-and middle-income countries. Treatment advocates worldwide, including the humanitarian aid organization, Doctors Without Borders, are already suggesting a target price of less than \$500 USD.^[vii] Unfortunately, past experience with HIV suggests that drug companies are unlikely to voluntarily extend significant discounts to middle-income countries, even if they may be open to reducing the price for the world's poorest.

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In the case of access to HIV medicines, it was the entry of generic competitors into the market that drove massive price reductions—lowering the price of antiretroviral treatment from over \$10,000 USD to under \$100 USD per patient, per year.^[viii] This competition, and the community activism that challenged a system where treatment was only for the rich, enabled the tremendous scale-up of treatment in low-and middle-income countries. Before the entry of generic medicines, only 50,000 people living with HIV in limited resource settings were receiving HIV treatment.^[ix] Today, nearly 10 million do.^[x]

The HIV example is instructive for how availability of hepatitis C medicines may also be expanded. Even where the new hepatitis C medicines are patented—granting monopolies to manufacturers and blocking the entry of generics—international law permits governments to override such patents to protect public health, for instance through compulsory licensing.^[xi] In November 2013, the public interest legal group, Initiative for Medicines, Access and Knowledge (I-MAK), challenged Gilead's sofosbuvir patent application in India, charging that the drug was not sufficiently innovative to merit patent protection, paving the way for generic manufacturing of the medicine.^[vii]

HIV TREATMENT: Reaching more by costing less



PRICE REDUCTION IS POSSIBLE

Since the new hepatitis C drugs are unlikely to be available anytime soon in low- and middle-income countries, Peg-IFN will remain critical for those who need hepatitis C treatment now. Recent experiences with this medicine underscore that change in pricing is possible. A combination of civil society advocacy and government commitment has helped to lower the price of Peg-IFN in countries as varied as the Republic of Georgia, Thailand, Ukraine, and Egypt, with brand name medicines going from \$18,000 USD for a 48-week course to as low as \$2,000 USD.^[iv]

A key question is whether citizens, government officials, and international bodies like the World Health Organization feel committed to push for truly affordable medicine pricing that prioritizes people's health over corporate profit. The new medicines may be promising from a clinical standpoint, but price reduction remains the key to ensuring scale-up, and to defusing the viral time bomb that is the hepatitis C pandemic.

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SOURCE

Cite this report as: Momenghalibaf, A (2013). "Beyond the Hype: What sofosbuvir means—and doesn't—for global hepatitis C treatment." New York, Open Society Foundations.

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