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Gilead's HCV drug sofosbuvir approved by the FDA but accessible for how many?

On December 6, the U.S. Food and Drug Administration approved Gilead's sofosbuvir (Sovaldi), an oral medication for the treatment of hepatitis C virus (HCV). Sofosbuvir and other direct-acting antivirals (DAAs) coming out of the drug development pipeline are more potent, have fewer side effects, and can often be taken for a shorter duration than the current standard of care. In clinical trials, sofosbuvir demonstrated high cure rates of up to 100% when combined with other DAAs. Yet its anticipated price tag of USD $80,000 will ensure that this drug remains out of reach for the vast majority of people living with HCV.

At least 185 million people worldwide have been infected with hepatitis C virus (HCV). Each year, three to four million people are newly infected and HCV-related liver complications kill an estimated 350,000 people annually, even though HCV is treatable and curable. Currently, injectable pegylated interferon is the backbone of the standard of care and, in combination with the oral drug Ribavirin (RBV), has a cure rate of between 50 and 75% of cases, depending on the HCV genotype; however, it is associated with significant side effects. Drugs like sofosbuvir -- Gilead's "blockbuster" nucleotide polymerase inhibitor -- show much-improved cure rates (reaching up to 90-100% in clinical trials) and shorter treatment duration when combined with pegylated interferon or other DAAs. Using newer DAAs, especially if they can be used without the addition of pegylated interferon, may result in a drastically lower incidence of side effects and adverse reactions. Many more DAAs will enter the market over the next couple of years.

Ninety percent of people who have hepatitis C live in low- and middle-income countries (LMICs); most are not aware of their HCV status, nor do they have access to testing and counselling. Most people with chronic HCV do not have access to treatment, even under the current standard of care, as pegylated interferon can cost up to USD $18,000 per treatment course, or ten times their country's per capita Gross Domestic Product. Advocates are already fighting for better accessibility to treatment programs and more affordable prices of pegylated interferon. Accordingly, now is the time to ensure affordable DAAs and optimized DAA combinations that reduce treatment duration and improve both adherence and treatment outcomes for everyone who needs them.

The price of sofosbuvir in high-income countries is expected to be very high, between USD $80,000 – 90,000. Like other DAAs, sofosbuvir is used in combination with other drugs, thus the total cost of a treatment course will be even higher. In France, where sofosbuvir is approved for early access, the 12-week course of treatment costs more than USD $76,000 (USD $905 per pill). Analysts expect Gilead's drug to generate sales of USD $1.73 billion in 2014 alone.

Sofosbuvir and other DAAs coming out of late-stage development do not have to cost this much. They can be produced generically for a tiny fraction of that price, just like HIV antiretrovirals (ARVs). For example, a 12-week course of sofosbuvir, produced generically, may cost in the range of USD $68-136.[1] Ensuring universal access to affordably priced and generic DAAs could help eradicate HCV globally.

The HIV/AIDS pandemic demonstrated that corporate greed, rather than the cost of drug development and production, caused originator drug prices to be scandalously inflated. Generic competition led to radical decreases in HIV drug prices: for some molecules they dropped by 99% once generic versions became available, allowing millions more people to access life-saving ARVs. Generic production also led to the

1.Hill A, Khoo S, Ford N. What is the minimum cost per person to cure HCV? 7th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Kuala Lumpur, Malaysia, July 2013 [TULBPE16]

development of optimized fixed-dose combinations that have simplified treatment, ensured access to ideal treatment combinations, and enabled the development of pediatric versions and heat stable formulations.

We, people living with HCV, HIV/AIDS, people who use drugs, and our advocates, demand that:

- Companies, Gilead specifically, as well as generics producers must price their products close to the cost of production for all patients in all LMICs; considering the cost of production per 12-week treatment course (Ribavirin plus two DAAs) is estimated to range from USD $100 to 250[2].

- Companies should not hinder the production of generic medicines and should not interfere with the obligation of governments to guarantee the access to health for their population; including the right to grant patents for real therapeutic inventions only, the right to revoke abusive patents, and the right to issue compulsory licenses in order to protect public health interests as clearly allowed by the World Trade Organization's TRIPS agreement (Agreements on Trade related Aspects of Intellectual property rights) and reaffirmed in the Doha Declaration.

- Governments must ensure that their intellectual property (IP) laws promote, not impede, their obligation to their people's right to health. In particular, governments must use all safeguards to protect public health, and where IP laws are not written to promote public health, they should be revised accordingly.

We cannot allow more people to die from a treatable and curable disease and must learn the lessons from HIV advocacy by demanding affordable drug pricing for all, now! Failure to learn these lessons would be an unforgiveable scandal.

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2.Hill A, Khoo S, Ford N. What is the minimum cost per person to cure HCV? 7th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Kuala Lumpur, Malaysia, July 2013 [TULBPE16]