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Contact: Lynda Dee
410-332-1170
lyndamdee@aol.com

Murray Penner
240-461-0107
mpenner@nastad.org

Fair Pricing Coalition Welcomes Approval of Gilead Sciences' Combination Tablet for Hepatitis C, Urges a Uniform Price for Curative Treatment

The \$63,000 wholesale acquisition cost (WAC) for eight weeks of Harvoni™ (sofosbuvir and ledipasvir) should be extended to 12- and 24-week curative treatment durations.

The Fair Pricing Coalition (FPC) today applauded the October 10, 2014, U.S. Food and Drug Administration (FDA) approval of Harvoni, a combination tablet containing the direct acting antivirals (DAAs) sofosbuvir and ledipasvir for the curative treatment of genotype 1 hepatitis C, and called upon Gilead Sciences to establish a uniform price per cure, regardless of the length of therapy.

The FPC, a coalition of HIV and viral hepatitis treatment activists, recognizes the significant advance in treatment success and convenience of Harvoni, but is disappointed at the Wholesale Acquisition Cost (WAC) of \$1,125 per once-daily tablet, or \$63,000, \$94,500, and \$189,000 for an 8-, 12-, and 24-week course of treatment, respectively.

The FPC maintains that these costs, particularly for the 12- and 24- week courses of treatment, are exorbitant. Since they are now published, however, FPC concludes that the WAC of \$63,000 for eight weeks of Harvoni, which is projected to be the most common duration of treatment as more people living with genotype 1 hepatitis C learn of their infection

and seek care, should be made the uniform cost per cure, regardless of the length of therapy.

Harvoni's FDA approval follows that of Sovaldi® (sofosbuvir) on December 3, 2013, the price of which was denounced by FPC. The \$84,000 WAC (\$1,000 per pill) of Sovaldi has since brought rebukes from insurers, activists, government officials, health care providers, and people living with hepatitis C.

While Gilead has contended that the total price for a course of treatment with a Sovaldi-containing regimen was a modest increase compared with previous standards of care, this is an invalid argument based on the incorrect premise that these regimens were appropriately priced to begin with. So, although an eight-week course of Harvoni will result in a lower cost-per-cure than previous regimens, the \$1,125 WAC per pill means that coverage for the 50 percent or more of people living with genotype 1 hepatitis C who require 12 or 24 weeks of therapy will be unreasonably costly and therefore potentially unattainable.

"Harvoni is a remarkable breakthrough in hepatitis C treatment," explained FPC Co-Chair Lynda Dee. "It is easy to take, is associated with cure rates between 94 and 99 percent, is safe and effective in advanced liver disease, is much less toxic than older regimens, and has a manageable drug interaction profile. Yet its price sours our appreciation of these long-awaited agents, particularly now that we have examples that curative treatment is inaccessible to many because of out-of-control escalator drug pricing."

Gilead's pricing of Sovaldi, and now Harvoni, puts these medications on a par with the pricing of pharmaceuticals that are much more costly to manufacture and often for rare diseases, despite the fact that Sovaldi and Harvoni are relatively inexpensive to produce, and that at least 3.5 million people are estimated to be living with hepatitis C in the United States. These costs are putting unprecedented pressure on public and private insurers, and stripping patients and providers of the required autonomy to make treatment decisions based on need.

The FPC recognizes that Gilead Sciences is maintaining their free medications program for low-income, uninsured patients, and expanding subsidies that greatly minimize out-of-pocket expenditures, such as co-payments and co-insurance costs, associated with the placement of

Harvoni and Sovaldi in specialty drug tiers. Yet these programs are unable to address all disparities of access to treatment due to excessive pricing, resulting in a two-tiered system of care based on insurance coverage and ability to pay.

“Many resource-constrained programs, such as Medicaid, have only been covering Sovaldi-containing regimens for patients with advanced liver disease, despite the fact that people with early stages of disease can transmit the virus to others and may suffer health consequences if treatment is delayed,” said Murray Penner, FPC Co-Chair. “People living with hepatitis C who seek access to these medications are also being required to undergo degrading evaluations related to drug and alcohol use, factors which have not been scientifically substantiated as determinants of the success or failure of treatment. It remains unclear if the reduced cost associated with eight weeks of Harvoni treatment will mollify these programs and we fear these restrictions will be extended, particularly for those requiring 12 or 24 weeks of treatment.”

“A remarkably safe, effective, and easy-to-take tablet means that if it is financially accessible to the many millions of people who desperately need it, we can actually imagine eliminating this insidious disease nationally and globally,” said Dee. “Gilead has failed to comprehend that pricing its curative treatments beyond what the market can bear is a shortsighted business tactic and a failed public health opportunity, both to the detriment of people living with hepatitis C.”

The Fair Pricing Coalition (FPC) is a group of community treatment activists advocating for fair and sustainable pricing of HIV and viral hepatitis drugs in the United States. The FPC was formed in 1998, in response to the exploitative pricing of Sustiva (efavirenz).
The FPC:

- Negotiates with drug companies prior to price setting of new therapies;
- Monitors and reports on price increases;
- Collaborates with government officials and care providers on drug price reduction strategies;
- Advocates for expansion of industry sponsored drug access programs;
- Provides co-payment and patient assistant program (PAP) information for approved HIV and HCV drugs at: www.fairpricingcoalition.org;
- Educates our communities on the impact of drug pricing on treatment access; and
- Organizes grassroots-driven media campaigns to prevent or fight against unfair drug pricing practices.