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Fair Pricing Coalition Condemns Gilead Sciences on the High Price of New Hepatitis C Drug Sovaldi™, and Urges Rapid and Wide Dissemination of Support Program Details for Uninsured and Underinsured People Living with Hepatitis C

The Fair Pricing Coalition (FPC) today condemned Gilead Sciences for the price set for its direct acting antiviral (DAA) Sovaldi™ (sofosbuvir), a once-daily, first-in-class nucleotide polymerase inhibitor approved by the U.S. Food and Drug Administration on December 6, 2013, for the treatment of chronic hepatitis C, including those co-infected with HIV. While FPC believes that all hepatitis C virus (HCV) drugs are priced too high, the coalition of HIV and viral hepatitis treatment activists is especially dismayed by the wholesale acquisition cost (WAC) of \$84,000 for a 12-week course of Sovaldi™. For comparison purposes, the FPC notes the 12-week WAC for the recently approved NS3/4A protease inhibitor Olysio™ (simeprevir) is \$66,360.

“Sovaldi™ is a very safe and highly effective drug that will significantly shorten HCV therapy and either reduce or eliminate the need for injected pegylated interferon,” explained FPC Co-Chair Lynda Dee. “However, this does not give Gilead unconscionable pricing carte blanche, particularly when considering that Sovaldi™ still needs to be combined with ribavirin for the treatment of HCV genotype 2 for 12 weeks or genotype 3 for 24 weeks. Twelve weeks of therapy with Sovaldi™ plus both pegylated interferon and ribavirin is required for the treatment of HCV genotype 1, the most common genotype in the US, and HCV genotype 4.”

The WAC for 12 weeks of HCV treatment with pegylated interferon and ribavirin is approximately \$9,000, resulting in a combined WAC of \$93,000 for a Sovaldi™-inclusive regimen to effectively treat a single person living with HCV genotypes 1 or 4. To treat HCV genotype 3, 24 weeks of Sovaldi™ plus ribavirin is required, resulting in a Sovaldi™ WAC of \$168,000.

Price Portends an Ominous Future

“Gilead has set the bar dangerously high as other companies determine prices for similar hepatitis C drugs as they enter the market,” Dee said. The effectiveness of Sovaldi™ as a component of future pegylated interferon-free regimens for the treatment of HCV will ultimately depend on co-administration

with other DAAs currently in development, and are anticipated to come with their own high price tags.

“Sovaldi™ is expected to transform the curative landscape for hundreds of thousands of people living with hepatitis C in the U.S. who require therapy or responded poorly to previous treatment,” said Lorren Sandt, FPC Co-Chair. “Yet the high price will result in significant barriers to treatment access, particularly in limited and fixed-budget programs, such as Medicare and state Medicaid programs, AIDS Drug Assistance Programs, the Veterans Administration, and in correctional systems.”

The high price may also lead to access challenges imposed by private insurance plans and Qualified Health Plans in the new Affordable Care Act (ACA) Marketplaces, notably those with high co-payment and other out-of-pocket requirements.

“There may be reluctance to add Sovaldi™ to formularies quickly and payers may force people living with HCV to engage in step therapy in which they are first required to try less expensive options that are less effective,” Sandt added. “These options take longer to complete and are associated with serious side effects, which present a serious impediment to adherence and, ultimately, to being cured of hepatitis C.”

Concessions Where They Count

Although Gilead refused FPC’s demand for fair pricing of Sovaldi™, the company has agreed to all FPC requests for concessions regarding Sovaldi™ access programs. These include:

- The SupportPath™ (www.mysupportpath.com) patient assistance program (PAP), with a \$100,000 maximum income allowance for a household of three and 500% of the federal poverty level (FPL) eligibility criteria for larger households.
- The SupportPath™ Sovaldi™ co-pay coupon program will provide co-pay assistance for eligible patients with private insurance, including ACA Marketplace exchange patients, who need assistance paying for out-of-pocket medication costs. Most patients will pay no more than \$5 per co-pay. Co-pay assistance of up to 20% (\$16,000) of the WAC price for Sovaldi™ can also be applied toward prescription deductibles and co-insurance obligations.
- Gilead has made a contribution to the Patient Access Network (PAN) for co-pay assistance for Medicare Part D clients.

- Gilead has initiated an emergency Sovaldi™ supply program for patients that may lose their prescriptions.

Gilead has agreed to ensure access to its PAP and co-pay assistance programs for AIDS Drug Assistance Program (ADAP) patients who are co-infected with HIV, even in states with ADAP programs that will not include Sovaldi™ on their formularies.

The FPC urges Gilead to widely disseminate the details of its SupportPath™ PAP and co-pay coupon program, which must include providing written SupportPath™ information for prescribers, prominently featured SupportPath™ information in its professional and direct-to-consumer advertisements, and clear links to www.mysupportpath.com via the Gilead and Sovaldi™ websites.

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;
- Educates our communities on the impact of drug pricing on treatment access;
- Organizes grassroots-driven media campaigns to prevent or fight against unfair drug pricing practices, and
- Provides co-pay and PAP information, including contact information for approved HIV and HCV drugs at www.fairpricingcoalition.org