

MAURA HEALEY
ATTORNEY GENERAL

THE COMMONWEALTH OF MASSACHUSETTS
OFFICE OF THE ATTORNEY GENERAL

ONE ASHBURTON PLACE
BOSTON, MASSACHUSETTS 02108

TEL: (617) 727-2200
www.mass.gov/ago

January 22, 2016

John C. Martin, Ph.D.
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, California 94404

Dear Dr. Martin:

I write to encourage you to reconsider Gilead's pricing structure for Sovaldi and Harvoni, the direct-acting antiretroviral drugs used to treat the Hepatitis C virus (HCV), so that we may actually see this infectious disease eradicated in the United States in our lifetime.

As a threshold matter, my office is considering whether Gilead's pricing strategy with respect to Sovaldi and Harvoni may constitute an unfair trade practice in violation of Massachusetts law. Because Gilead's drugs offer a cure for a serious and life-threatening infectious disease, pricing the treatment in a manner that effectively allows HCV to continue spreading through vulnerable populations, as opposed to eradicating the disease altogether, results in massive public harm. My civil enforcement attorneys will continue to examine this potential claim for unfair commercial conduct.

The purpose of this letter is to urge Gilead to adjust its pricing strategy in a way that continues to generate substantial profits for the company, while also providing a clear pathway to the eradication of this life-threatening disease in the United States.

Between 2.7 and 3.9 million people in this country are living with HCV, but fewer than 10 percent have been treated.¹ The Massachusetts Department of Public Health estimates that at least 200,000 people are infected with HCV in this state. The ongoing opiate epidemic and resultant increases in HCV infection rates further underscore the need for expanded access to treatment. According to data my office has obtained from the Department of Public Health, HCV cases among 15 to 29 year-olds jumped 138 percent between 2002 and 2014 in Massachusetts, largely due to injection drug use. Without significantly expanded access to treatment, those numbers will continue to rise.

¹ Christopher E. McGowan, MD and Dr. Michael W. Fried, MD, *Barriers to Hepatitis C Treatment*, *Liver Int.* 2012 Feb; 32(0 1): 151-156 (Feb. 2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955982>.

In Egypt, Gilead sells Sovaldi for roughly \$10 per pill,² and in India, the drug costs about \$4 per pill.³ In the United States, on the other hand, the cost is \$1,000 per pill. Gilead clearly recognizes the enormous public health benefits and profit associated with making these drugs broadly accessible in other countries. I urge you to be part of the solution here in the United States as well.

Most patients who are able to access drugs like Sovaldi and Harvoni will have a 97 percent chance of cure, and greatly reduced odds of liver cancer and early death.⁴ This is a significant achievement well worth celebrating, but as Dr. Jonathan Mermin of the Centers for Disease Control recently noted, “Patients do not benefit from a drug they cannot afford.”⁵

The National Institutes of Health recommends increasing access to treatment for all HCV-infected persons, but the prohibitive prices of Sovaldi and Harvoni, at \$84,000 and \$94,500 per course of treatment, have resulted in both public and private payers restricting access to the drugs out of budgetary necessity.⁶ Despite the introduction of similar direct-acting antiretroviral medications and the subsequent round of negotiations motivated by the advent of market competition, Gilead has not negotiated with any entity a discount large enough to allow for the type of expanded access that could lead to eradication.

Meanwhile, Gilead has enjoyed staggering profits from the sale of these drugs. In the first 21 months Sovaldi and Harvoni were on the market, Gilead sold \$20.6 billion worth of the drugs in the United States, after rebates.⁷ The U.S. Senate Committee on Finance recently published the findings of its year-long investigation of the price of Sovaldi and the resulting impact on our health care system. The report makes clear that Gilead pursued an aggressive pricing strategy aimed at maximizing revenue – not fostering access for people with HCV. Gilead implemented this strategy in spite of its own internal conclusions that more people could be treated at a lower price point and warnings from stakeholders that a high price point would result in severe access restrictions. Given the ability of these drugs to eradicate a life-threatening infectious disease, these decisions raise serious questions about ethics and fairness that go well beyond a company’s right to recoup a fair and even a substantial profit.

⁴ John W. Ward, M.D. and Jonathan H. Mermin, M.D., M.P.H., *Simple, Effective, but Out of Reach? Public Health Implications of HCV Drugs*, *The New England Journal of Medicine* (Dec. 31, 2015), available at <http://www.nejm.org/doi/full/10.1056/NEJMe1513245>.

⁵ *Id.*

⁶ *Id.*

⁷ U.S. Senate Committee on Finance, *The Price of Sovaldi and its Impact on the U.S. Health Care System*, at 2 (Dec. 1, 2015), available at <http://www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-full-report>.

As a justification for these prices, Gilead has invoked the high cost and risk associated with research and development of new drugs. Innovation is incredibly important, and companies that develop breakthrough drugs (or, as in Gilead's case, acquire such companies) should be generously rewarded. But especially in a case like this one where the breakthrough drug *cures*, a balance must be struck that allows the drug to achieve its intended purpose: the effective treatment – and achievable eradication – of a life-threatening infectious disease. Here, the Committee investigation demonstrates that Gilead was confident in its anticipated return on the \$11.2 billion investment it made in purchasing Pharmasset, the original developer of the drug that became Sovaldi. In fact, a Gilead executive remarked in an e-mail shortly after the acquisition that Gilead had received a “bargain.” This confidence was borne out in practice: Gilead sold \$12.4 billion worth of HCV medication in the first year alone, quickly recouping its outlay to acquire Pharmasset.⁸

Taxpayers across the country have been footing the bill for Gilead's record profits ever since, without the promise that would come from a plan to make Sovaldi and Harvoni accessible in a way that could eradicate HCV. In 2014, state Medicaid programs spent \$1.3 billion on Sovaldi before rebates, which allowed just 16,281 enrollees to receive the drug – fewer than 2.4 percent of Medicaid recipients believed to carry HCV.⁹ Medicare has been equally hard hit. Between January 2014 and June 2015, Medicare's spending on HCV treatments increased more than six-fold, from \$116.4 million per month to \$793.2 million per month.¹⁰

In response to the high prices of Sovaldi and Harvoni, a majority of state Medicaid programs have had to restrict access to the drugs through prior authorization criteria. If Gilead truly did not anticipate these widespread access restrictions, the company has since had ample opportunity to adjust prices or offer discounts to significantly increase access. Instead, in July 2015, Gilead severely cut back its patient assistance program, Support Path, which (by the company's own description) was designed to provide “assistance to patients who are uninsured or who need financial assistance to pay for the medicine.”¹¹ This move suggests Gilead's indifference to the burden the company's pricing strategy places on both patients and taxpayers, when the eradication or substantial diminution in new HCV cases would otherwise be within reach.

The lack of patient assistance or truly affordable rebate programs has a disproportionate impact on those who rely on public payers for their health care, including the several hundred

⁸ *Id.* at 17.

⁹ *Id.* at 82.

¹⁰ *Id.* at 92.

¹¹ Ed Silverman, *Gilead Limits Enrollment in its Hep C Patient Program to Pressure Insurers*, Wall Street Journal, July 16, 2015, available at <http://blogs.wsj.com/pharmalot/2015/07/16/gilead-limits-enrollment-in-its-hep-c-patient-program-to-pressure-insurers>.

thousand prisoners in the United States with HCV. The prevalence of HCV in prisons is 17 times the rate for the general population.¹² States have a constitutional obligation to provide medically necessary health care to people who are incarcerated, and in Massachusetts, our state Department of Correction (DOC) is currently facing a class action lawsuit calling for increased access to new HCV treatments for inmates. Unlike the federal Bureau of Prisons, however, state DOCs do not get the benefit of the discounts guaranteed to the U.S. Department of Veterans Affairs, nor are they eligible to take advantage of Medicaid or Medicare pricing. Instead, Massachusetts taxpayers bear the full burden of Gilead's exceptionally high pricing.

If our state purchased Sovaldi at its retail price of \$84,000 for all of the people who are infected with HCV in our state prisons, the cost of treating these incarcerated people would easily exceed our entire budget for prisoner health care. Nationwide, it would cost \$33 billion to treat every incarcerated person with HCV using Gilead's drugs, which is more than four times the current total health spending by state prison systems.¹³ And even if Gilead offered the largest publicly-known discount of around 40 percent¹⁴ to all departments of correction, unfettered access for incarcerated persons would still cost nearly \$20 billion. With more than 90 percent of incarcerated people released back to their communities within a few years of sentencing, incarceration offers a unique opportunity for intervention and eradication of this disease.¹⁵

Gilead's agreements with manufacturers in India and with the Egyptian government to make HCV drugs more widely available provide a model for expanding access in the United States. Gilead should offer Sovaldi and Harvoni at the same \$10-per-pill rate to public payers in the United States serving the poorest patients with the highest rates of infection. At a minimum, Gilead should consider innovative approaches to pricing and payment that would expand access to Sovaldi and Harvoni in the United States, as it has done in other countries.

Gilead has a unique opportunity to improve access, reduce morbidity and mortality associated with HCV, enhance the health and quality of life of millions of people, and reduce the continued spread of HCV – even while continuing to generate record profits for its shareholders. Gilead also has an opportunity to develop a model for pricing and compensation that will preserve financial incentives for scientists, companies and investors to develop breakthrough cures like Sovaldi without placing those cures out of the reach of the people they will help. I urge you to be a part of the solution to the HCV epidemic here in the United States, by lowering

¹² Michael Ollove, *Treating Prisoners Could Be Best Way To Eradicate Hepatitis C*, The Huffington Post, May 19, 2014, available at http://www.huffingtonpost.com/2014/05/19/hepatitis-c-prisoners_n_5352075.html.

¹³ Anna Maria Barry-Jester, *Eliminating Hepatitis C Means Treating Prisoners*, FiveThirtyEight.com, Aug. 31, 2015, available at <http://fivethirtyeight.com/features/eliminating-hepatitis-c-means-treating-prisoners>.

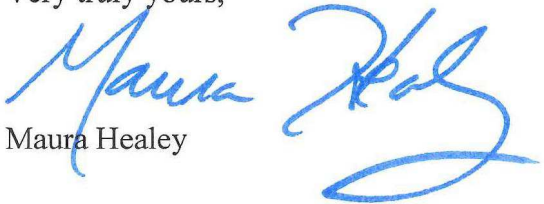
¹⁴ See, e.g., Patricia Kime, *Hepatitis C drug costing VA, DoD millions*, Military Times, Jan. 28, 2015, available at <http://www.militarytimes.com/story/military/pentagon/2015/01/07/hepatitis-c-sovaldi-cost/21334481/>.

¹⁵ Anne C. Spaulding, MD, MPH et al., *Impact of New Therapeutics for Hepatitis C Virus Infection in Incarcerated Populations*, *Top Antivir Med.* 2013 Feb-Mar; 21(1): 27–35 (2013), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3875217>.

January 22, 2016
Page 5

prices, expanding access, and ultimately bringing the goal of eradicating this infectious disease in the United States within reach in our lifetime. Please contact my Director of Policy, Joanna Lydgate, at 617-963-2955 so we can discuss this matter further. I look forward to hearing from you.

Very truly yours,


Maura Healey