

Pharmaceutical Research and Manufacturers of America
950 F. Street, NW, Suite 300
Washington, DC 20004

Dear PhRMA Representative:

The undersigned organizations work closely with clients at risk for and living with Hepatitis C (HCV). Our coalition is focused on legal, regulatory, and policy reforms to improve the health of individuals impacted by HCV. We are gravely concerned about the lack of access to direct-Acting Antivirals (DAAs) used to treat the disease. We write to you after many months of unsuccessful discussion with state officials regarding inadequate coverage of medically necessary HCV treatment for individuals enrolled in Medicaid in Illinois. While we have deep respect for the Illinois Department of Healthcare and Family Services (HFS) leadership and know they are sympathetic to this population of low-income, chronically ill Illinois citizens, our efforts have not yet led to to a resolution. Time is short and the crisis is real.

In Illinois, as in the rest of the country, HCV has reached epidemic proportions. Over three million people in the United States are estimated to be infected, and there are over 68,400 cases reported in Illinois alone. Many of our new cases are at least in part correlated with the growing increase in heroin and opioid-related substance use in Illinois. Without significantly expanded access to treatment, the number of infected persons and the number of persons who perish from lack of access to the cure will continue to rise in our state.

In addition, a significant number of people with HIV have HCV co-infection. The progression of HCV-related liver fibrosis is accelerated in people with untreated HIV infection. Liver disease caused by HCV is now a leading cause of death in these persons.

The development of DAA has revolutionized care for people with HCV. These drugs are potent, tolerable, have manageable interactions and are associated with high cure rates. In fact, DAAs have become the standard of care for virtually all HCV-infected persons, but the prohibitively high prices have resulted in HFS and the Illinois Department of Corrections restricting access to the drug out of budgetary necessity. Unfortunately, the astronomical cost for curative therapy has limited the state's ability to provide care to those in need and reduce the risk of transmission to

others across the state.

In addition, the burden to treat those infected with HCV disproportionately falls on state taxpayers. HCV disproportionately affects low-income populations with taxpayer funded insurance such as Medicaid. Up to half of patients with HCV eligible for these new treatments are estimated to have taxpayer funded insurance, and an estimated 20% to 30% of all patients with HCV are covered under Medicaid, thus representing a specific burden to state budgets.¹² Illinois is currently grappling with a significant budget deficit; part of the solution has been decreasing and delaying payments to Medicaid health plans. These cuts impact a large portion of the state's Medicaid population and play a role in the state limiting access to vital DAA medications.

Thus far, PhRMA members have not negotiated a large enough discount with Illinois HFS to allow for the type of expanded access that could lead to HCV eradication. Meanwhile, it is impossible to ignore that your members have enjoyed staggering profits from the sale of these drugs.³

We write to encourage you to ask your members to reconsider pricing structure for DAAs so that we may actually see this infectious disease eradicated in our lifetime. We urge your membership 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 elimination of this life-threatening disease in the United States.

In other countries, PhRMA members sell these medications for substantially less per pill than in the United States. This clear recognition of the enormous public health benefits and profit associated with making these drugs broadly accessible throughout the world indicates that manufacturers can play a larger role in the solution here at home too.

While we have heard as justification for these prices the high cost and risk associated with research and development of new drugs, in a case like this where the breakthrough drug cures, a

¹ Chhatwal, J, Kanwal F, Roberts MS, Dunn MA. Cost-Effectiveness of Budget Impact on Hepatitis C Virus Treatment with Sofosbuvir and Ledipasvir in the United States. *Ann Intern Med* 2015;162:397-406.

² Schiff L. Finding Truth in a World Full of Spin: Myth-Busting in the Case of Sovaldi. *Clinical Therapeutics* 2015;37:1092-112.

³ 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.

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. Illinois taxpayers are being asked to fund your membership's record profits, without the promise that would come from a plan to make DAAs accessible in a way that could eradicate HCV.

If our state purchased these medications at either retail price or even with only the Medicaid discount for all of the people who are infected with HCV on Medicaid and in our prisons, the cost would easily exceed our entire budget for Illinois's Department of Public Health.

We also note that some of your members have reduced their provision of patient assistance programs to help finance DAAs. 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 thousands of Medicaid recipients and incarcerated persons in Illinois.

Your members' agreements with manufacturers in countries such as India and Egypt to make HCV drugs more widely available provide a model for expanding access in Illinois. We urge your members should offer these Medications at the same \$10-per-pill rate to HFS to serve our poorest patients with the highest rates of infection. At a minimum, your members should consider innovative approaches to pricing and payment that would expand access to these drugs in Illinois, as it has done in other countries.

PhRMA members have a unique opportunity to improve access, reduce morbidity and mortality associated with HCV, enhance the health of millions of people, and reduce the continued spread of the disease while still generating record profits. Your members also have an opportunity to develop a model for pricing and compensation that will preserve financial incentives for scientists, companies and investors to develop breakthrough cures without placing those cures out of the reach. We urge you to be a part of the solution to the HCV epidemic in Illinois by negotiating with the Illinois Department of Healthcare and Family Services and the Illinois Department of Corrections to significantly lower the costs of these medications for the populations they serve.

Sincerely,

Carrie Chapman, Director of Policy Advocacy
The Legal Council for Health Justice

Ruth Edwards, Program Director, ALC
The Legal Council for Health Justice

Ramon Gardenhire, Vice President of Policy and Advocacy

AIDS Foundation of Chicago

cc: AbbVie, Bristol Meyers Squibb, Merck, Gilead