

We are organizations representing more than a million Americans, including public health experts and consumers committed to advancing public health and promoting access to affordable medicines.

42 U.S.C § 1498 presents a unique opportunity to significantly reduce the prices of curative hepatitis C treatments through generic competition [1]. Competition has consistently proven itself as the most effective method of ensuring drug prices continue to fall over time. In countries where generic hepatitis C treatments are available, a full course of treatment is often priced below \$1,000 [2]. Researchers have estimated that production costs of one common hepatitis C treatment to be only \$200 for a 12-week regimen [3].

Without generic competition, current policies continue to restrict access to hepatitis C treatment. Twenty-three state Medicaid programs continue to require individuals to wait until they've suffered severe liver scarring or liver failure to qualify for treatment [4]. And twenty-one states continue to impose alcohol and drug abstinence periods of greater than six months to initiate treatment [5]. Restrictions and financial barriers also continue to limit treatment in commercial insurance plans and Medicare Part D [6]. These restrictions remain contrary to current clinical guidelines, which recommend providing nearly all HCV-infected patients with treatment, and expose these individuals to a life-long elevated risk of liver cancer [7].

Unprecedented public support to lower drug prices

A clear public consensus exists to lower prescription drug prices and increase access to patients in need. Americans across the political spectrum support government action to lower drug prices. A majority of Republicans, Democrats and Independents agree that action on drug prices should be taken [8]. 92 percent of Americans agree that the government should negotiate with drug companies to get a lower price on medications for people on Medicare [9].

State and federal action on drug pricing

The U.S. Department of Health and Human Services estimated that the U.S. spent \$457 billion on prescription drugs in 2015 and projects spending more than \$500 billion this year [10]. In response to prescription drug companies charging high prices that strain budgets, multiple states have initiated legislative responses. These include transparency efforts to establish the public's right to know what drug prices are, with legislation pending in Nevada, California, and Indiana [11]. Legislatures in New York and Maryland have also recently passed laws to combat price gouging by companies [12].

Both major political parties have proposed federal legislation on drug pricing [13]. Elected officials have proposed a comprehensive reform package to lower drug prices, the *Improving Access to Affordable Prescription Drugs Act* (S.771, H.R.1776). Among the Act's eighteen provisions are requirements for increased transparency around drug prices, research & development (R&D) costs and other pertinent information; limitations on unfair price increases; and a host of other reforms [14].

Monopoly power drives high drug prices

Claims that high medicine prices in the U.S. are derived from R&D costs are not borne out by the available evidence [15]; and the American public—including Louisiana residents—often pays twice for medicines, once through funding and subsidizing pharmaceutical R&D and a second time through exorbitant prices for medicines.

Specifically, in the hepatitis C treatment space, companies have already made back their investments and generated substantial profit. In terms of hepatitis C products, Gilead Sciences has made nearly \$50 billion in sales as of March 31, 2017 [16].

The investigation into Gilead's hepatitis C treatment pricing from Sens. Ron Wyden (D-Ore.) and Charles Grassley (R-Iowa) also establishes that the company paid a fraction of those sales for research and development. Specifically, Gilead paid \$11 billion to purchase the company that held the drug's patents, Pharmasset [17]. According to its annual filings, Pharmasset spent an estimated \$62.4 million on research through Phase III clinical trials and benefitted from National Institutes of Health (NIH) grants funded by American taxpayers [18]. Gilead also stated that they spent an additional estimated \$880.3 million on total direct R&D costs [19].

Notably, most of the profit from these sales appears to have remained offshore and has not been reinvested into R&D. By placing ownership of the drug patents in an Irish subsidiary and not remitting profits back to the United States, Gilead Sciences has not paid any U.S. corporate taxes on at least \$10 billion in sales [20].

This trend in R&D costs is not isolated to a single company in the industry. A recent report found that domestic U.S. pharmaceutical companies generated sales revenue equivalent to 176 percent of their global R&D spending; revenue was calculated from the amount by which higher U.S. drug prices exceeded drug prices in other developed countries [21]. Meanwhile, prescription drug corporations spend more money on sales & marketing than on research & development [22]. Globally, the twenty largest companies earned profits of more than \$124 billion, while spending only a fraction of that on research & development costs in 2015 [23].

And it should be noted that while the prescription drug industry reaps enormous profits, it continues to engage in fraudulent and other unlawful behavior, imposing a high cost on consumers. A recent Public Citizen report, examining major financial settlements and court judgments between 1991 and 2015, found that drug companies entered into 373 settlements totaling \$35.7 billion in criminal and civil penalties [24].

Advantages of immediate state treatment of hepatitis C

There are robust legal and public health reasons to treat individuals now rather than waiting for patents to expire around 2030.

In particular, treating every person with hepatitis C now as opposed to delaying treatment until 2030 would lower medical costs [25]. Compare the costs of treatment using low-cost generics in

the paragraph below to the costs Louisiana and other states will continue to pay in lost lives, continued pain and suffering, and liver transplantation [26]. In terms of lost lives, the National Academy of Sciences estimates that the nationwide cost of not eliminating hepatitis C will exceed \$666 billion before 2030 [27].

But the costs to treat a patient with a generic drug licensed at a reasonable royalty rate rather than at current brand name prices would enable payers to significantly expand access to treatment. The estimated cost of manufacturing the latest combination regimens runs at \$96 to \$216 for twelve weeks. [28]. Currently, rather than about \$333 per pill, Indian manufactures—under a sublicense from Gilead Sciences— sell generics for a profit of \$14 per pill [29]. This translates to \$1152 for a full twelve-week course of treatment [30]. Generic treatment—including a reasonable royalty based off historical precedent at 10 percent—would save an estimated \$737.4 million in treatment costs for uninsured and Medicaid patients in Louisiana. But even a royalty of 100 percent would lower the cost of treating *every* uninsured or Medicaid-covered Louisiana resident from \$764 million to \$48.4 million [31].

These high medical costs for brand-name HCV treatments also do not include the costs of litigation. Some states, including the state Medicaid program in Washington and the prison system in Kentucky, have incurred legal costs while defending against successful lawsuits against restricted access to treatment. Ultimately, they have been required to expand treatment [32]. The Louisiana Medicaid program and Medicaid managed care programs are legally obligated to not unreasonably restrict coverage of hepatitis C drugs [33]. The Louisiana prison system is also constitutionally obligated to treat the estimated 12-35 percent of individuals with hepatitis C in the prison system [34]. Reducing treatment costs through generic competition could help Louisiana avoid such legal challenges.

Finally, at the current of rate of 324 Louisiana residents receiving treatment annually, little progress will be made towards eradicating the disease [35]; every year 250-500 people are newly infected in Louisiana [36]. It's also possible that the rate of new infections will go up with the national rate of new hepatitis C infections tripling between 2010 and 2015 [37].

High prices charged by prescription drug corporations present a public health challenge to all states. But 42 U.S.C. § 1498 presents a serious policy opportunity to increase generic competition, reduce unfair drug prices, and to expand treatment. We encourage Louisiana to explore the use of this valuable policy tool to expand access to medicines to all of its residents.

Signed:

Public Citizen
Health Global Access Project
Social Security Works
Treatment Action Group

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