

The Hepatitis C Battle

Who's winning, who's losing, and what can be done to end it?

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Introduction

Hepatitis C is an infection of the liver caused by the hepatitis C virus, or HCV. The CDC estimates that 3.5 million Americans have chronic HCV infection.¹ There is no vaccine for HCV, as there are for the A and B strains, and if untreated, HCV damages the liver and is potentially fatal.

This complex medical issue is made even more complicated by a tangled web of healthcare legislation and cost containment initiatives, both past and present. These include the Medicare Modernization Act, The Health Information Technology for Economic and Clinical Health (HITECH) Act, and the Affordable Care Act. In addition, the vast majority of those with HCV were born between 1945 and 1965, which means that the number of HCV-infected Americans who are eligible for Medicare is on the rise,² heaping greater burden on an already over-burdened system.

Modern medications, which are proven to have a 90% cure rate or better,³ offer hope for HCV patients but at a very high price—nearly \$95,000 for a 12-week treatment of one of the latest and most effective drugs on the market. Naturally, payers are balking at footing the bill for treatment.

HEPATITIS C FACTS



29,718

Estimated number of cases of acute HCV infections in the U.S. in 2013



3.5 million

Number of Americans estimated to have chronic HCV infection



75%

Portion of HCV-infected patients that fall into the baby-boom generation



30%-40%

Percentage of liver transplants estimated to be due to chronic HCV



\$575,000

Average cost for a liver transplant and first-year expenses



\$9.1 billion

Projected economic impact of chronic HCV by 2024

Sources: Centers for Disease Control and Prevention (CDC); the National Foundation for Transplants (NFT)

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Meanwhile, many ailing patients, whose insurance providers have denied treatments because their illnesses haven't yet advanced to critical status, wait to become sicker in the hopes that the medications will eventually be covered. Lawmakers are struggling to find solutions, but most currently proposed plans are failing to gain traction.

Pricing for huge profits

For many years, those afflicted with hepatitis C had few treatment options, none of which were considered curative. But from 2011 to 2014, the FDA approved several new medications.

Sovaldi, approved by the FDA in December 2013, was the first drug that was considered both safe and effective without the need for co-administration of interferon. In addition, Sovaldi was proven to clear the virus from the body. When this happens—referred to as a sustained virologic response (SVR)—patients can be pronounced cured and are likely to remain HCV-free thereafter.

As a result, Sovaldi must have seemed like a miracle drug to both prescribers and HCV patients. The

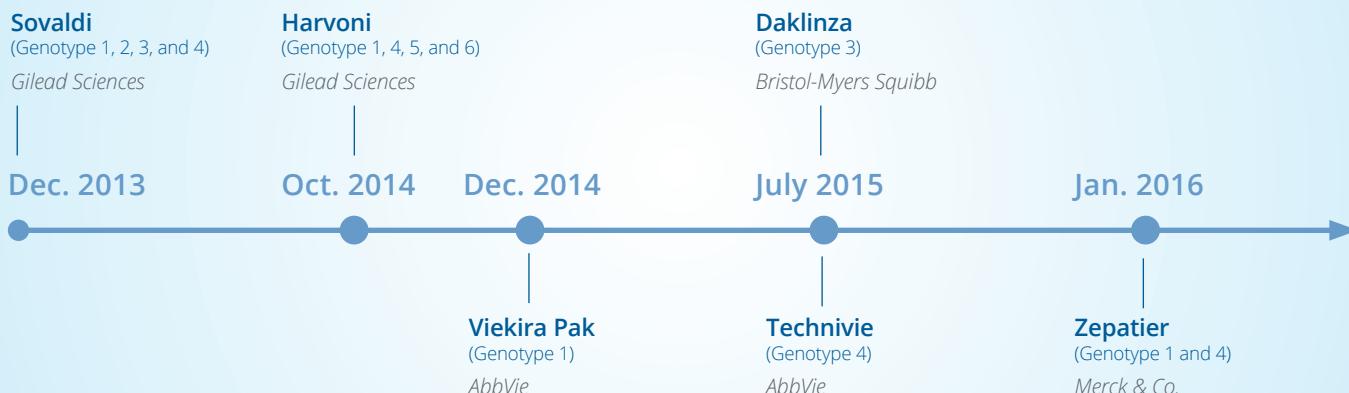
drug's manufacturer, Gilead Sciences, Inc., priced it accordingly—at \$1,000 per pill. That made the total cost for a 12-week treatment a whopping \$84,000. Interestingly, Pharmasset, the original developer of Sovaldi, said it would charge half that. But Gilead bought Pharmasset in 2011, and the rest is history.⁴

Gilead's second and more effective product combined Sovaldi's ingredient, sofosbuvir, with a new drug, ledipasvir. Gilead sells the new combination medication under the brand name Harvoni for an even higher price—\$1,125 per pill or \$94,500 for a 12-week regimen.

If the CDC's estimate of 3.5 million chronic HCV cases in the U.S. is accurate, this means that treating all of them with Harvoni would cost payers, in total, nearly \$331 billion. That's more than was spent in total on all medications combined (\$329.2 billion) in the U.S. in 2013⁵ according to the IMS Institute for Healthcare Informatics.

IMS data for 2014 shows a marked increase in total U.S. medication spending to \$373.9 billion, owing in large part to money spent on new hepatitis C

FDA APPROVAL TIME LINE



Source: U.S. Food and Drug Administration

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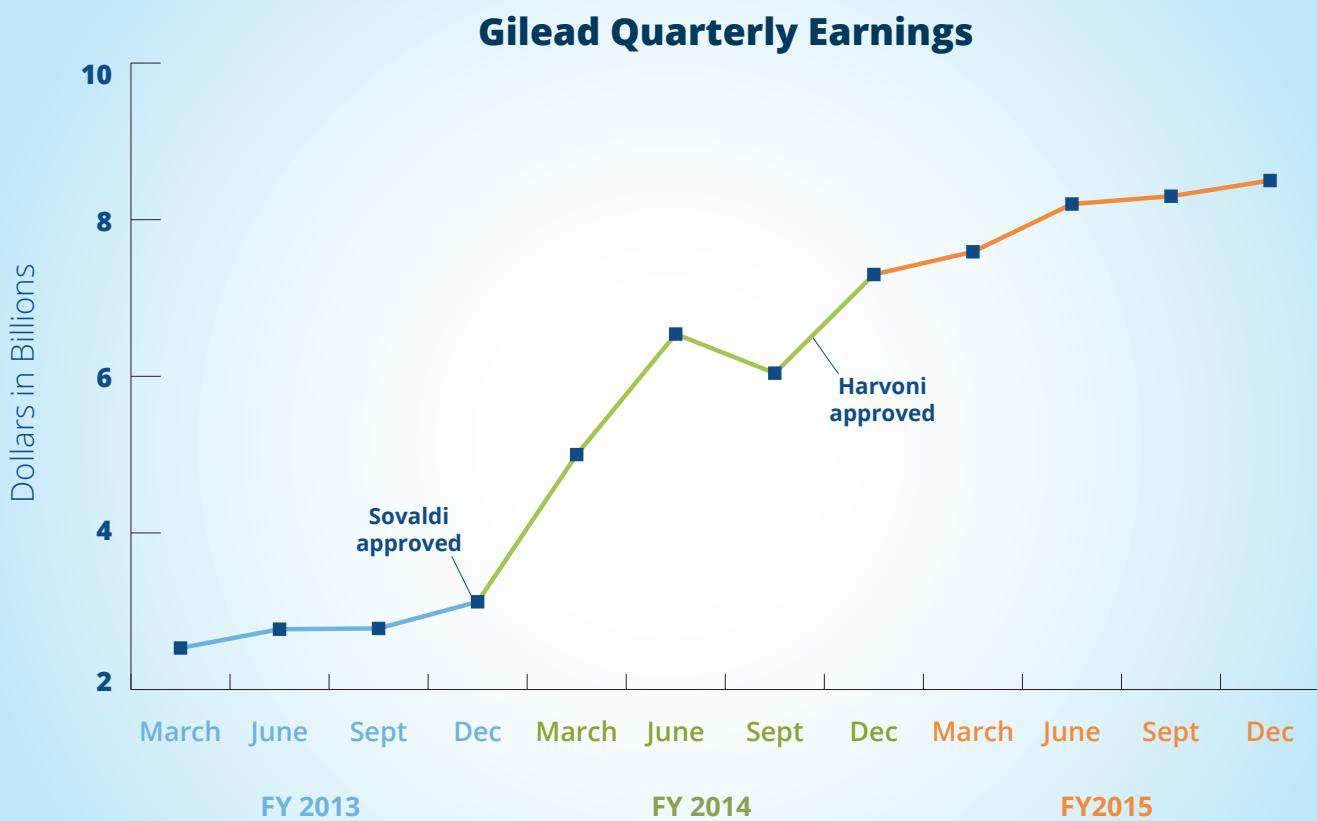
drugs.⁶ Other high-cost specialty drugs contributed to America's increased medication expenditures, but, while pricey, many of these serve fairly small populations. In contrast, demand for hepatitis C medications is much more broad, and in 2014, Sovaldi and Harvoni themselves were said to be responsible for adding "half a percentage point to the 2014 health spending inflation rate."⁷

While patients and payers are at odds, Gilead Sciences is padding its pockets. In its year-end 2014 earnings report, Gilead announced total revenue of \$24.9 billion (compared to \$11.2 billion for 2013, before these drugs were available). The vast majority—\$22.8 billion—was generated by antiviral products. Sales were primarily Sovaldi and Harvoni, the latter having been approved by the FDA in October 2014.⁸

What's worse is that Gilead seems to be quite willing to slash its prices outside the U.S., where it's charging significantly less for Sovaldi (\$55,000 in Canada and the U.K. and just \$900 in Egypt⁹). This dramatic difference has led some, including U.S. lawmakers, to accuse Gilead of price gouging.

Current payer strategies

Paying for these costly yet effective treatments varies by insurance provider, and Medicaid coverage varies from state to state. According to data released by Sens. Charles Grassley, R-Iowa, and Ron Wyden, D-Ore., who participated in a Senate Finance Committee investigation into Sovaldi pricing, some states covered as many as 9.1% of their HCV-infected Medicaid enrollees while others cov-



ered less than 1%.¹⁰ Clearly, a patient's chance for help may depend on where he or she lives.

Of course, Medicaid's inability to cover all enrollees is understandable, especially when you consider that money allocated to one Harvoni treatment equates to healthcare for approximately 29 Medicaid enrollees based on average cost per enrollee.¹¹ Therefore, states have had to control HCV treatment costs with prior authorizations and preferred drug lists.

Private insurers share the same concerns and, like Medicaid, have established criteria for eligibility. Generally, insurers seem more willing to approve therapy for those with some liver damage and for those who have tried other less expensive options without success.

There is one bit of good news for veterans, however. Although the Department of Veterans Affairs (VA) had been approving or denying treatment based on the state of the beneficiary's liver disease, it announced recently that it would cover HCV medications for all of its afflicted veterans. The VA reported that increased funding from Congress and a lower-priced drug now available made expanded treatment possible.¹²

Lowering drug costs and increasing coverage

For millions of Americans, there is only one objective—affordable access to effective treatments. For those who have been denied coverage, this goal may seem unrealistic, but there may be a glimmer of hope on the horizon.

Legislative

In a presidential election year, candidates are focusing significant attention on rising drug prices. Some of the measures proposed include:

- Allowing Medicare to negotiate prices for high-cost drugs (this was specifically banned in 2003 when the Part D drug benefit was added)¹³
- Capping patients' out-of-pocket drug expenses
- Allowing the importation of drugs from Canada and other industrialized countries
- Limiting drug manufacturers' spending on patient marketing

Competitive

Although some have accused Gilead of price gouging, others might say that it's just shrewd business. After all, ours is a free market economy based on supply and demand. However, sick people need to get better, so they don't really have a choice, or they didn't, until recently.

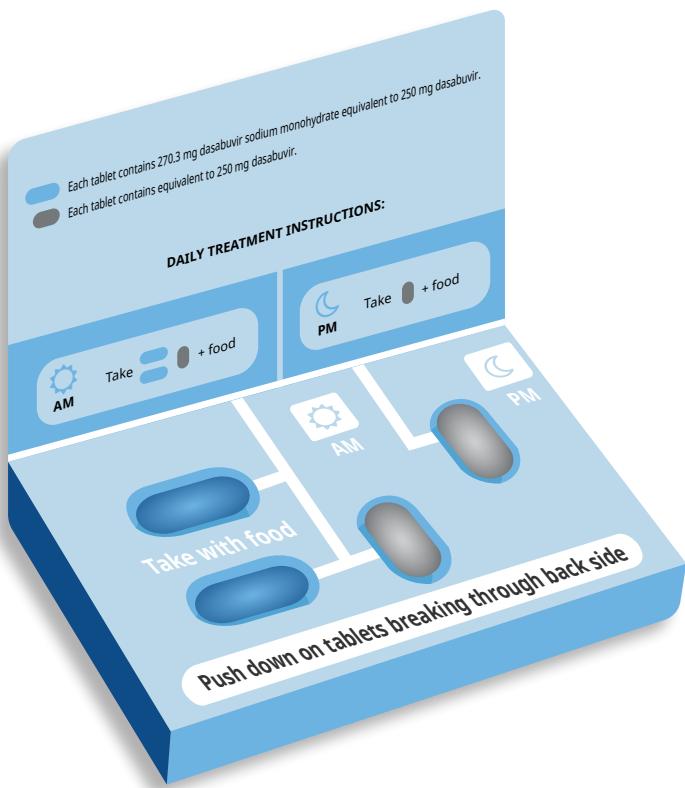
On December 19, 2014, the FDA approved Viekira Pak from AbbVie Inc.¹⁴ The data indicated that cure rates of this 6-pill-per-day regimen very nearly mirrored that of Harvoni, with a sustained virologic response of 91-100 percent.¹⁵



Three days after FDA approval, Express Scripts announced that Viekira Pak would be its preferred treatment for Hepatitis C genotype 1 (the most common type). Express Scripts also said it would no longer cover Sovaldi and Harvoni for genotype 1 patients.

The impact was swift. Gilead's stock price plunged nearly 20% in less than a week. In response just a few months later, Gilead announced discounted rates for Harvoni with Aetna, Anthem, CVS, Cigna, Humana, and UnitedHealth Group.¹⁶

Most recently, the VA—described by the news source *Military Times* to be the “largest single provider of hepatitis C care in the U.S.”—reportedly entered into an agreement with Merck for its newly approved hepatitis C drug Zepatier. The FDA approved Zepatier in January 2016 for the treatment of chronic hepatitis C virus genotypes 1 and 4 infections in adult patients.



According to the FDA's news release, Zepatier had an overall SVR (which suggested that the participants' infections had been cured) in “94-97 percent of genotype 1-infected subjects and [in] 97-100 percent in genotype 4-infected subjects.”¹⁷

What was most notable about Zepatier's release, however, was its price—\$54,600 for a 12-week regimen. The pricing strategy, according to a Merck spokesperson, was inspired by the company's interest in helping to “broaden and accelerate patient access to treatment and move us closer to our shared goal of reducing the burden of chronic HCV in the U.S.”¹⁸

There is at least one other medication in the pipeline that could also lead to lower pricing. It was developed by Achillion Pharmaceuticals and licensed to Johnson & Johnson. The companies haven't yet sought FDA approval, but tests indicate that the drug, odalasvir, achieves 100% cure rates in as little as six weeks when paired with Sovaldi. Now, Johnson & Johnson is conducting additional studies pairing odalasvir with its own medications in an attempt to shorten the therapy to just four weeks.¹⁹ Shorter treatment times could mean a less costly cure in the long run.

Where does that leave us?

There's no question that these HCV medications can be life-changing for those with chronic infection, and the drugs' availability is positive for Americans and for the 150 million people around the world who need treatment.²⁰ In fact, the sickest HCV patients would probably say that no price is too high to pay for a cure.

Unfortunately, payers seem to be saying that they can't afford to see it that way. Yet allowing patients to become sicker before finally covering treatment

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is likely to lead to additional cost because patients with chronic HCV are more likely to:

- Contract liver cancer
- Develop type 2 diabetes
- Experience plaque build-up in the arteries
- Be at higher risk for stroke

These comorbidities could end up costing payers more in the long run.

In Gilead's defense, despite the Senate investigation and harsh criticisms, some see the pricing as Gilead's golden opportunity to cash in before competing products hit the market. And it's possible that rivals might have opted to do the same if their drugs had been the first available.

Now, with several viable options on the market, the cost of a cure is likely to be reined in, making the drugs more accessible for all. In the meantime, specialty pharmacies can use their expertise to help patients find assistance programs and adhere to their therapies to ensure results.

References

1. Viral Hepatitis - Hepatitis C Information; Centers for Disease Control and Prevention; <http://www.cdc.gov/hepatitis/hcv/cfaq.htm#overview>
2. Hepatitis C: Why Baby Boomers Should Get Tested; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; <http://www.cdc.gov/knowmorehepatitis/Media/PDFs/FactSheet-Boomers.pdf>
3. Hepatitis C treatment cures over 90 percent of patients who also have cirrhosis; ScienceDaily; <https://www.sciencedaily.com/releases/2014/04/140412093400.htm>
4. Pharma Execs Don't Know Why Anyone is Upset by a \$94,500 Miracle Cure; Paul Barrett and Robert Langreth; <http://www.bloomberg.com/news/articles/2015-06-03/specialty-drug-costs-gilead-s-hepatitis-c-cures-spur-backlash>
5. IMS Health Study: Spending Growth Returns for U.S. Medicines; IMS Institute for Healthcare Informatics; <http://www.imshealth.com/en/about-us/news/ims-health-study:-spending-growth-returns-for-u.s.-medicines>
6. Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014; IMS Institute for Healthcare Informatics; <http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-in-the-us-2014>
7. Candidates' Drug-Price Plans may Miss the Mark; Julie Rovner; Kaiser Health News; <http://khn.org/news/candidates-drug-price-plans-may-miss-the-mark/>
8. Gilead Sciences Announces Fourth Quarter and Full Year 2014 Financial Results; <https://www.gilead.com/news/press-releases/2015/2/gilead-sciences-announces-fourth-quarter-and-full-year-2014-financial-results>
9. The Sovaldi Tax: Gilead Can't Justify The Price It's Asking For Hepatitis C Therapy; Steve Miller; Forbes; <http://www.forbes.com/sites/theapotheccary/2014/06/17/the-sovaldi-tax-gilead-can't-justify-the-price-its-asking-americans-to-pay/#60c62e65e14a>

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10. Medicaid expenditures on Sovaldi and patients treated (2014); <https://www.arcgis.com/home/item.html?id=390dcc12b37248d9b6f3b5418c31820e>
11. Medicaid Spending per Enrollee; <http://kff.org/medicaid/state-indicator/medicaid-spending-per-enrollee/>
12. VA Expands Hepatitis C Drug Treatment; <http://www.va.gov/opa/pressrel/pressrelease.cfm?id=2762>
13. Sanders to introduce bill targeting high drug prices; Peter Sullivan; <http://thehill.com/policy/healthcare/252473-sanders-to-introduce-bill-targeting-high-drug-prices>
14. FDA approves Viekira Pak to treat hepatitis C; <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm>
15. FDA approves Viekira Pak to treat hepatitis C; <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm>
16. Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind \$84,000 Hepatitis Drug; <http://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug>
17. FDA approves Zepatier for treatment of chronic hepatitis C genotypes 1 and 4; <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm483828.htm>
18. Merck Receives FDA Approval of Zepatier; <http://www.mercknewsroom.com/news-release/prescription-medicine-news/merck-receives-fda-approval-zepatier-elbasvir-and-grazoprevi>
19. Why Achillion Pharmaceuticals Shares Crashed 37% in January; <http://www.fool.com/investing/general/2016/02/04/why-achillion-pharmaceuticals-shares-crashed-37-in.aspx>
20. Hepatitis C Fact sheet N°164; World Health Organization; <http://www.who.int/mediacentre/factsheets/fs164/en/>

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Our thanks to Ron Lanton III, president of True North Political Solutions in Washington, D.C., for his help developing this white paper. Ron, who holds a juris doctor degree from The Ohio State University Moritz College of Law and a bachelor of arts degree from Miami University of Ohio, has more than 20 years of combined government affairs and legal experience. Most recently, he created and oversaw the government affairs department for a pharmaceutical wholesaler, served as the company's exclusive lobbyist, and advocated for its healthcare customers. For more information about True North Political Solutions, go to www.truenorthps.com.