

\$1,000 Sovaldi now hepatitis treatment of choice

July 29 2014, by Ricardo Alonso-Zaldivar

(AP)—A new \$1,000-per-pill drug has become the treatment of choice for Americans with hepatitis C, a liver-wasting disease that affects more than 3 million.

Even with insurers reluctant to pay, Sovaldi prescriptions have eclipsed those for all other hepatitis C pills combined in a matter of months, new data from IMS Health indicate. The promise of a real cure, with fewer nasty side effects, has prompted thousands to get treated.

But clinical and commercial successes are also triggering scrutiny for the drug's manufacturer, Gilead Sciences Inc., which just reported second-quarter profits of \$3.66 billion, or 56 percent.

Two senators have unearthed documents that suggest the initial developers of Sovaldi considered pricing it at less than half as much. The health insurance industry is publicly scolding Gilead, and state health care programs are pushing back.

The repercussions go beyond one drug and one disease. A number of promising cancer medications near approval could be drawn into the storm over costs.

"You can't put too fine a point on the sort of moral dilemma that we have here," said Michael Kleinrock, director of the IMS Institute, which studies prescription drug trends. "This is something that the research-based pharmaceutical industry reaches for all the time: a cure. But when

they achieve one, can we afford it?"

New data from IMS Health, the parent company of the institute, illustrate Sovaldi's impact since its December debut:

—The number of pharmacy prescriptions for all hepatitis C pills has soared, highlighting demand. In May, more than 48,000 prescriptions were filled for four such medications, with Sovaldi accounting for three-fourths of the total. Compare that to prescriptions for May 2013, before Sovaldi became available, which totaled about 6,200.

—In Sovaldi's first 30 weeks on the market, 62,000 new patients tried the drug, nearly three times as many as had tried an earlier medication that showed promise. That makes Sovaldi the most successful launch for any hepatitis C drug. Gilead expects to have a successor soon that will make treatment easier to tolerate, because it won't require patients to take companion medications with strong side effects.

—The weekly number of new patients going on Sovaldi has been gradually slowing, from more than 2,900 in February and March to about 1,600-1,800 in late June and early July. Kleinrock said that could indicate that pent-up initial demand is giving way to steadier levels, or it could mean that insurers are limiting access to protect their budgets.

Hepatitis C surpassed AIDS as a cause of death in the U.S. in 2007, claiming an estimated 15,000 lives that year. The illness is complex, with distinct virus types requiring different treatments. While it advances gradually, it can ultimately destroy the liver, and transplants average \$577,000.

The cost of a 12-week regimen of Sovaldi along with two companion medications that patients must also take is around \$100,000. Competing regimens with other drugs cost in the mid- to high five figures, and some

are far less effective and harder to tolerate.

Hepatitis C is a public health concern, since the disease can be transmitted by contact with infected blood, by drug users sharing needles, and sometimes through sexual activity. Many people are unaware that they carry the virus. Health officials advise all baby boomers to get tested.

At Mount Sinai Health System's liver clinic in New York City, patient advocate Angela Woody said Sovaldi has brightened the outlook for patients. But it takes effort to get insurance approval.

"We have had to jump through a great deal of hoops," Woody said. "We have two patients who applied in January and did not actually go on the medication until April."

Sovaldi's implications for Medicare and Medicaid costs have prompted rare bipartisan cooperation in Congress on a health care issue.

Sens. Ron Wyden, a Democrat, and Charles Grassley, a Republican, are asking Gilead for a detailed explanation of its pricing. Wyden chairs the Finance Committee, which oversees health insurance programs, and Grassley is a veteran of drug safety investigations.

The senators say their staffs found public documents that call into question Gilead's \$84,000 price for a full course of Sovaldi treatment, for the most common type of hepatitis C.

In 2011 filings with federal regulators, the company that originally developed Sovaldi estimated a treatment price of \$36,000. That figure was developed during Gilead's negotiations to buy the original developer, Pharmasset.

Gilead spokeswoman Amy Flood said the company has no comment.

But Gilead vice president Gregg Alton recently addressed the issue at a public forum sponsored by the American Enterprise Institute.

"To suggest that a cure for a disease like hepatitis C should be priced at \$36,000 ... would put a huge disincentive on investing in cures for our industry," he said.

Gilead took on most of the challenge—and risk—of getting government approval for Sovaldi, Alton added.

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