Rural Health News Service

At the tail end of last year the Food and Drug Administration approved a drug that may cure some three million Americans who have hepatitis C, a disease that interferes with liver function and can eventually lead to liver cancer. It's a serious illness; many people don't know they have it until the first symptoms show up years later, and those who do have it undergo grueling and sometimes ineffective treatments.

So when Gilead Sciences, the manufacturer of sofosbuvir, which goes by the brand name Sovaldi, announced its new drug was ready for prime time, doctors who treat patients with the disease cheered. Results of clinical trials showed side effects appeared to be mild compared to those from conventional treatment and cure rates seemed to be high. A hepatitis expert at Johns Hopkins said, "This is about as hot as I've ever seen."

Stock analysts were ecstatic. One told the New York Times global sales—about 170 million people worldwide are infected—could surpass the sales record of $13 billion set by Lipitor, the statin used to treat high cholesterol. The press touted the good news, too, as it customarily does when a new wonder drug hits the market. And as it too often does, it gave short shrift to the price.

Sovaldi has one major drawback—its budget-busting price tag. Gilead says it will cost $84,000 for the three-month treatment regime. That's $1,000 a pill.

The debut of sofosbuvir offers a clear example of how expensive technology enters the medical marketplace even before all the evidence comes in that the drug works. In Sovaldi's case not all the new drug combinations have been extensively tested. "We may be in for surprises, still," said Charles Rice, a hepatitis C expert at Rockefeller University in New York City.

It also raises important questions about who should pay for the drug. Should it be Medicare? Medicaid? Commercial insurers? Or should it be the patients whose insurance policies increasingly come with high amounts of cost-sharing in the form of deductibles and coinsurance? And what contribution does Sovaldi make to the overall high price of medical care

in the U.S., the highest in the world?

Indeed these questions can be asked about any new drug or medical device. But they aren't. Other countries have agencies that deliberate such trade-offs. We don't. To raise them conjures up unpleasant images of rationing—patients deprived of life-saving treatments. Asking them also conflicts with a deeply held American belief that the medicine man sits at the right hand of God, and we're willing to spend anything for cures and treatments even if they are extraordinarily pricey.

The entry of Sovaldi also invites serious questioning about why the price of new medical technology doesn't seem to decrease as prices for other technological advances do—computers, for example. There's no downward pressure on prices. The patent system for new drugs—protection from competition for seven to 12 years—leaves drug makers in the driver's seat. Payers pretty much have to cough up what drug makers charge. And federal rules prevent Medicare, one of the largest buyers of drugs, from negotiating with drug makers over prices. Basically, what's left is negative publicity, and the press doesn't provide much of that.

A recent NPR segment did, however, probing the high price of sofosbuvir. It questioned why the drug maker needed to make its prices so high especially given the large potential market for the drug. One hepatitis expert wanted to know why once Gilead recovered its costs it couldn't reduce the price. "I don't want to say it's unfair, but it does start feeling more exploitative," she told NPR listeners. A Gilead vice president responded "That's very unlikely that we would do that." Right now they don't have to.

Instead Gilead said it would help patients pay for the drug. You know one of those patient assistance programs that no doubt helps those who have no money for such expensive treatment. (These programs do means test; that is, help is available only for those with the lowest incomes.) But does that gesture do much to bring down the cost of the drug and thus the country's health care tab that feeds into the insurance premiums and cost of care we pay out of pocket? No, say many experts. Such programs may serve to keep drug prices high.

All this is something to ponder as we move into an election year with health care and its cost promising to dominate the campaign.