The High Price of the New Hepatitis C Virus Drugs

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Although the development of effective, oral medications for chronic hepatitis C virus infection (HCV) is a scientific triumph, the high price of the newest, directly acting antiviral agents, simeprevir and sofosbuvir, has sparked a much-needed debate about the fair pricing of pharmaceuticals. In the United States, the costs for drugs alone, can range from $66 360 for simeprevir to $84 000 for sofosbuvir, or $1000 per tablet of the latter medication.1 In this issue of JAMA Internal Medicine, Ollendorf et al,1 at the Institute for Clinical and Economic Review, summarize their review of the evidence about the comparative effectiveness and economic impact of simeprevir and sofosbuvir.2 Their analysis reveals “a stark dilemma: the advent of new drugs of tremendous potential to treat millions of patients who have a serious liver infection—but at a price that the health care system in the United States may find unaffordable.”2 In the United States, an estimated 3.2 million persons have chronic HCV infection, and about 15 000 people die from the infection annually, primarily from liver failure and hepatocellular carcinoma.3 Globally, the World Health Organization (WHO) estimates that 130 to 150 million people have chronic HCV infection and that 350 000 to 500 000 people die each year from HCV-related liver diseases.4

There is no precedent for drugs with such apparent public health benefits for so many people to be priced at such high levels. As the WHO noted in April 2014, when it issued its first HCV treatment guidelines: “Although the production cost of DAAs [directly acting antiviral agents] is low, the initial prices set by companies are very high and likely to make access to these drugs difficult even in high-income countries.”4 The cost of treating chronic HCV infection is set to increase by untold billions of dollars a year. Already, sales of sofosbuvir, which is marketed by Gilead as Solvadi, were $2.3 billion in the first three months of 2014, an apparent record for sales of a drug in its first full quarter of marketing.5

In the United States, pharmaceutical companies have wide latitude to set the price of medications, which factor in the substantial costs of research and development of new agents prior to marketing approval. Nonetheless, there is a disturbing disconnection between the very high initial prices set by companies and the relatively low manufacturing costs. A recent analysis applied lessons learned from the progressive decrease in the manufacturing costs of HIV medications to estimate the minimum production costs of directly acting antiviral agents for HCV.6 The ranges of predicted manufacturing costs were $68 to $136 for a 12-week course of sofosbuvir, and $130 to $270 for a 12-week course of simeprevir. Even if the assumptions in this analysis were insufficiently conservative, the gap between the estimated manufacturing costs of these drugs and their pricing in the United States would still be striking.

At current projections, the cost of directly acting antiviral agents for HCV is likely to quickly overwhelm the budgets of any state Medicaid program or any private insurer. These high costs are of particular concern because these drugs were approved quickly based on the surrogate end point of sustained virologic response rate; they were studied in limited populations and without long-term follow-up. Under the US Food and Drug Administration’s breakthrough therapy designation, the marketing approval for sofosbuvir did not include requirements for randomized clinical trials. Company-sponsored, direct-to-consumer advertising campaigns to encourage HCV testing in healthy persons are already in full swing. A national discussion is urgently needed of the appropriate continued evidence collection and pricing for the new HCV drugs, and whether their use should be restricted to patients with advanced liver disease. The evidence report by Ollendorf et al,1 additional data from clinical trials, and forthcoming evidence reports will provide the basis for that discussion.

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