

# A Way Out of the Dismal Arithmetic of Hepatitis C Treatment

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**A**lthough the medical prospects facing patients with hepatitis C virus (HCV) have never been better, the prospect of gaining access to a cure is another matter for many patients. About 2.7 million Americans suffer from chronic HCV, with 170 million worldwide.<sup>1</sup> After decades of research and billions of dollars in investment, we now have a definitive treatment—direct-acting antivirals (DAAs)—that can cure this serious illness.<sup>2</sup> Better still, the pills are relatively cheap to produce and future improvements in production technology are likely to make them even cheaper in the future.<sup>3</sup>

Despite this obviously great news for patients with HCV, there is good reason to worry about the high costs of DAA treatment: the average cost for a complete 12-week course of one such treatment is \$84,000.<sup>4</sup> At this price, many insurers are reluctant to provide full access to DAAs for all patients with HCV; Medicaid programs provide only limited access.<sup>5</sup>

### Overview

This special issue of *The American Journal of Managed Care* presents important new peer-reviewed research about the consequences of this dismal arithmetic of HCV treatment. The papers cover ground ranging from the out-of-pocket costs of a DAA treatment course to the real-world consequences—both economic and clinical—of failing to treat.

A paper by Jung et al<sup>6</sup> documents substantial out-of-pocket costs for patients with HCV on Medicare. They show that such patients face up to almost \$11,000 in out-of-pocket costs for a complete course of treatment with DAAs. Even low-income patients with HCV who qualify for low-income subsidies from the federal government can face out-of-pocket costs of up to \$1200 for a course of treatment. Another paper, by Karmarkar et al,<sup>7</sup> shows that insurance coverage greatly increases adherence to

therapy; conversely, high out-of-pocket costs greatly increase the likelihood of prematurely abandoning therapy.

Two papers document the clinical effects of DAAs on disparate populations in the real world. Younossi et al<sup>8</sup> find that the high rate of cures observed in clinical trials of patients with HCV are realized in real-world practices for treatment-naïve patients. In contrast, Lakshmi et al<sup>9</sup> find that cure rates with DAAs are lower in a population coinfecting with HIV and HCV than what would be expected based on the clinical trial data. They argue that improved adherence to therapy, including follow-up clinic visits, greatly increases the probability of a cure in this population.

Multiple papers also document the considerable direct and indirect benefits that would come from universal coverage for DAA treatment. Moreno et al<sup>10</sup> calculate savings over a longer period, and find that curing patients with HCV would save billions of healthcare dollars that would otherwise be spent on traditional therapies in the coming decades in the absence of curative treatment with DAAs. Jena et al<sup>11</sup> identify an unanticipated boon from HCV cures: treatment with DAAs benefits non-HCV patients with liver failure who are awaiting transplant by reducing wait times and mortality rates. This happens because curing patients with HCV reduces the number of those patients who will need a transplant. Finally, Linthicum et al<sup>12</sup> calculate that a strategy of widespread screening of patients for HCV, combined with treatment to cure with DAAs at an early stage of the disease, generates nearly \$1 trillion in social benefit.

Together, this collection of research makes a strong case that providing patients with HCV with access to curative treatment at an affordable price would create enormous benefits for both the patients and for society at large. Two commentaries<sup>13,14</sup> also published in this special issue argue that given these facts, insurance should cover these drugs and that patients with HCV should face little or no cost sharing to access treatment. Although this no-

tion makes sense given the benefits of DAA treatment for all patients with HCV, there is still a risk of higher insurance premiums if insurers follow this advice.

### The Price of Treatment

The central problem is that the price for a course of DAA treatment is so high. The question is, why do we tolerate such a price? The reasoning is that it may be needed to provide an incentive for research. Prior work shows that investment in research and development in the biopharmaceutical industry are responsive to profitability of new drugs.<sup>15</sup> Therefore, if we want cures for other diseases in the future, we need to make sure investing in finding cures is profitable.

However, there is a way out of this policy dilemma, and a back-of-the-envelope calculation demonstrates the possibility. At current prices, let us say the firms that produce DAAs stand to earn \$10 billion per year, to pick a round number. The drugs would generate these revenues for a few years until competition from other drugs and patent expiration eroded revenues and profits. If revenues erode at about 10% a year, and we pick an 8% discount rate to reflect the cost of capital in the pharmaceutical industry, the present value of this future revenue stream for the drug manufacturer would be about \$40 billion to \$50 billion. This number represents—roughly—the risk-free value of the intellectual property rights to the new drugs DAA.<sup>16</sup>

Thus, my proposal is the following: a benevolent buyer could purchase the intellectual property rights to these drugs and make them public. Without patent protection, the cost of the pill would likely fall precipitously toward the relatively low marginal costs of production, subsequently making universal access to treatment achievable not only in the United States, but in many other countries as well. A \$50-billion investment by an altruistic philanthropist would unleash more than \$1 trillion in value for society, and it would do so without jeopardizing incentives for finding future cures.

One practical problem with the solution, of course, is finding someone with the capacity to buy the intellectual property rights for the new hepatitis drugs. A possible option is for private charities or philanthropists to play a role; charitable giving in the United States surpassed \$350 billion in 2014 alone, so the capacity to make major investments is there. Another option is for governments or international aid organizations that already invest billions of dollars in healthcare around the world to take up the challenge.

What about the potential pitfalls? If no new resources are brought to the table, this investment in universal access for HCV might mean a diversion of resources from other worthy causes. If government borrowing finances the investment, then the costs of interest payments need to be factored

in. Another worry is that this might lead to a call for buying out patents on other new drugs with a less-clear social return on investment. The solution to this, however, is to limit such investments to cures where the wedge between societal value and firm value is so large, that even with modest overpayment, patent buy-outs are a good deal for society.

### Conclusions

We must make universal access to the cure for HCV and other diseases a top priority. There is no point in discovering medical cures if the majority of patients who would benefit cannot afford them.

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