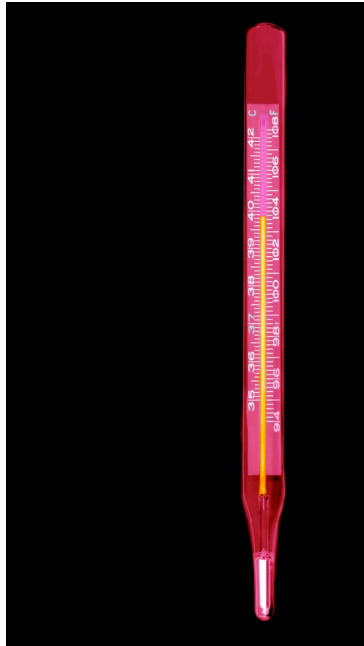


It's Easier to Measure the Cost of Health Care than Its Value

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How can there be no licensed treatment or vaccine for Ebola, a disease with a very high death rate that has caused a global public health emergency?

The answer is painful but clear: The profit potential from Ebola treatments was too small to interest large manufacturers. Ebola historically has threatened West African countries that have low standards of living. The small Canadian laboratory that produced an experimental vaccine was funded by the Canadian government, and Ebola was chosen as a research target [because it is a good model for other infectious diseases](#).

Ebola may seem remote, but the economics of innovation are the same in Africa and the United States: Innovation subsists entirely on the prospect of substantial rewards earned from the discovery of a new drug.

This brings us to hepatitis C, a chronic infectious disease affecting perhaps 3.2 million Americans. Hepatitis C virus, or HCV, infection is often asymptomatic — but its severity fluctuates, and it can progress after many years. Eventual complications include cirrhosis of the liver in 20% to 30% of patients, with grave consequences in terms of health and costs.

Until recently, standard treatment for chronic HCV was a course of combination drug therapy — with relatively poor effectiveness and serious side effects. However, several innovators have worked hard to identify breakthrough antiviral treatments. Sofosbuvir — sold under the brand name Sovaldi and taken in combination with another drug — [can eliminate the virus in more than 94% of cases](#). However, Sovaldi's manufacturer has received much criticism for the price, both in the media [and Congress](#). Many stories highlight the [\\$1,000 cost per pill](#).

While this may make for good theater, focusing solely on the cost of therapy — or, worse, the price per pill — misses four crucial points about the value of treatment, and the reward to innovation. We now discuss these four points and, subsequently, offer three solutions for the short and the long term.

1. The illusions of accounting. First, consider the case of a man who is diagnosed with diabetes at age 50. He would pay, each and every year, for oral medications and various health care services, with a lifetime cost in the hundreds of thousands of dollars. Thus, if someone came along with a diabetes cure that cost upwards of \$100,000, society should welcome it, even though the one-time price tag seems high.

Now consider hepatitis C. Treating HCV infection costs about \$85,000, but it is all paid in a matter of weeks. Using treatments available before the introduction of sofosbuvir, the present lifetime medical costs are [about \\$175,000 to \\$200,000](#). If HCV infection progresses, there is often cirrhosis of the liver and, in some cases, the need for a liver transplant. Taking into account the upfront cost of treatment — but also the lifetime benefits — researchers have found that sofosbuvir regimens [are highly cost-effective, even at current prices](#).

2. The benefits beyond the treated patient. None of these calculations takes into account additional benefits to others. The hepatitis C virus is bloodborne and can be transmitted by inadequately sterilized needles during intravenous drug use, acupuncture, tattooing, and even public shaving. Health care workers are also at risk. Therefore, each successfully treated patient functionally “cures” the disease in others (at a cost of zero for those people) — a social benefit not captured by traditional cost-effectiveness analyses.

3. The ephemeral nature of high prices. In 10 to 12 years, generics for Sovaldi will enter the market, thereby increasing competition, reducing prices, and expanding access to treatment. A similar downward trend in price occurred with highly active antiretroviral therapy (HAART) for HIV infection. Generic antiretrovirals are now a cornerstone of the emergency plan for AIDS relief, put in place by President George W. Bush, and have [done much to combat HIV in the developing world](#).

4. Long-term health improvements. HAART, introduced as HIV treatment in the 1990s, [dramatically increased survival](#) from HIV infection, although at significant financial cost. Before HAART, an HIV-positive patient could not buy a longer life at any price. HAART thus lowered the price of a longer life, even though the cost of treating HIV-infected patients appeared to rise dramatically.

With regard to Sovaldi, the [United Kingdom \(which uses a relatively stingy decision rule to cover treatments\) has agreed to cover sofosbuvir](#) for the subset of HCV-infected patients who have advanced liver disease, albeit at a lower price than the one typically cited in the United States. The lesson here: Do a “true calculation” whereby we decide, given the drug’s cost, which patients it makes sense to treat. Of course, the higher the price, the less access to new drugs for patients in need, particularly those belonging to vulnerable and disadvantaged groups. It is precisely for this reason that sofosbuvir has caused so much uproar. So what can be done?

Solutions for the Short and the Long Run

Many observers want the U.S. government to mandate lower drug prices — for example, by allowing re-importation of drugs or by having Medicare negotiate drug prices. It is tempting to believe that price reductions reduce company’s profits without affecting innovation. However, the absence of R&D into unprofitable third-world diseases, like Ebola, and the [increase in drug approvals for rare diseases under the U.S. Orphan Drug Act](#) belie this point. Indeed, economists [estimate](#) that a 10% increase in market size increases the number of new drugs by 40%. Price regulation has been shown to [delay the launch of new drugs](#), limit their availability, and [reduce the pace of innovation](#).

Furthermore, placing the vast bargaining power of the entire U.S. Medicare population in the hands of a public agency invites an overreaction. There are few tangible incentives to prevent cash-strapped public agencies (which often focus primarily on the present) from driving down pharmaceutical prices so much that future generations suffer from the depletion in innovation.

Protecting the vulnerable could take three forms:

- We could simply bite the bullet and agree to cover treatment, especially in indigent populations such as Medicaid recipients. Although it may be infeasible to provide access for all hepatitis C patients immediately, a targeted approach could maximize the reach of limited public dollars. The patients at greatest risk for developing expensive complications like end-stage liver disease — or for transmitting the disease to others — may be the best cases to start with. In time, the disease can be cured in less pressing cases, with the rate of treatment expanding, especially when a low-priced generic enters the market.
- Public payers could negotiate longer-term arrangements in which manufacturers are rewarded as the evidence of effectiveness mounts. We are starting to see such arrangements in other areas of health care under the guise of “pay for performance” — even in Medicare, where hospitals are reimbursed extra if patients avoid readmission.

- We could consider innovative, financing mechanisms (both public and private) that allow cash-strapped programs to spread out the substantial upfront cost of treatment into a more manageable stream of payments, perhaps tied to the treatment’s effectiveness. The federal government could set up an Access to Breakthroughs Fund to loan states the money to pay for highly effective treatments like sofosbuvir. To be eligible, the treatment would need to have [the FDA’s “breakthrough” designation](#). States would gradually repay the loan, perhaps through their Medicaid or corrections budgets. Companies with breakthrough therapies might also have access to capital to support trials, in return for pricing agreements with states.

These are only some of the practical ideas that are feasible. The bottom-line principle is that if we reimburse care on the basis of value — rather than price — and preserve access to that care, everyone wins in the end.

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