

Opinion

Drug Value Pricing: A Way to Stop the Upward Cost Spiral?

Did you ever wonder how new drugs get to be so expensive? Clearly, pricing has no logical relationship to cost of manufacturing. Is there a pharma-approved pricing dartboard somewhere? To explore the first question, I have a personal anecdote you may find interesting. You may recall from the July 2013 Opinion that I have chronic lymphocytic leukemia (CLL). I have had 2 bouts of chemotherapy, each consisting of 6 rounds. If it sounds like a prizefight, that's because it is. But I'm not complaining; I found the alternative far less attractive. Anyway, last year the FDA approved a brand-new oral drug that was highly effective for CLL in trials: ibrutinib. The marketing geniuses named it Imbruvica (rhymes with improve). So I started on it in February. Its retail cost is \$10,000 for a 30-day supply. I blew right through the Medicare Part D donut hole in one prescription. Now that I'm on the other side of the donut, my monthly 5% copay is \$480. Dear taxpayer readers, you are paying the other 95%. Please accept my thanks, and then ask: To whom are we paying this money?

Imbruvica was developed by Pharmacyclics, which, for a song, had acquired the rights to the untested molecule in 2006. At the time, its stock price was about \$4/share. When the drug showed some success in animal testing, the Christmas tree of venture capital funding took shape, as the

share price slumped to \$2. In 2010, pharma giant Johnson & Johnson provided a huge capital infusion in return for half of the profits from Imbruvica. Finally, this spring, AbbVie bought out Pharmacyclics for \$21 billion, roughly \$250/share, to acquire its only marketable product, Imbruvica, which had achieved FDA expanded approval only months before. The point is that there are so many investors expecting a return on their risky investment that the drug has to be priced in the stratosphere. While oncology and rheumatology use the most expensive new drugs, the problem of high cost has also extended to our own sphere: age-related macular degeneration.

I believe in capitalism, investment returns, and free markets, but the trajectory of drug expense in the United States is simply unsustainable. What to do?

Price controls stifle innovation. But one approach that seems to be gaining traction is value-based pricing (sound familiar?). The Institute for Clinical and Economic Review is a private foundation-funded group that intends to produce reports on new drugs near the time of their FDA approval. These reports will include a full analysis of how well the drugs work (comparative effectiveness) and the value the treatments represent to patients (including costs of side effects and improvements in quality of life). A metric such as quality-adjusted life-years will allow

for comparisons of treatments across diseases and will include a sliding scale of suggested price points, depending on payer differences in willingness to pay. The group's independence from pharma or insurer funding is important. Full discussion among regional groups of practicing physicians, methodological experts, and leaders in patient advocacy and engagement will assist in revision of medical practice guidelines and in payer policy decisions. The first reports due this fall will evaluate cholesterol and heart failure drugs, with more to come. Is this a way out of our unacceptable upward spiral of drug cost? Only time will tell.



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