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Want More Value From Prescription Drugs? We Need to Let Prices Rise and Fall

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Abstract
The high price of some cancer drugs has recently come under attack by the medical profession. We examine the reasons behind the pricing strategies of cancer drugs. On the one hand, prices should reflect value and research demonstrates that the health benefits from novel cancer drugs have been enormous in terms of additional years of life patients can now enjoy. This provides some justification for the high price tag of these drugs. On the other hand, drug pricing is also a product of a hidebound reimbursement system that does a poor job in letting prices adjust to new information about value. Regulators set thresholds for cost-effectiveness, which establishes not only a price ceiling but also a price floor. Manufacturers often price drugs high at launch in efforts to recoup their initial investment, but a more efficient system would allow prices to both rise and fall over time. Removing distortions in the reimbursement system is crucial to ensuring continued success in saving lives.

Keywords
health, prescription drugs, pricing, value

Disciplines
Finance and Financial Management | Health and Medical Administration | Health Services Research | Insurance | Marketing | Other Business | Other Public Health

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A group of distinguished international cancer physicians recently joined together to decry what they called the "astronomical, unsustainable, and perhaps even immoral" prices of cancer drugs.[1] In the name of saving patients, they appealed to drug manufacturers to lower their prices.

The group's remarks made for important political theater in the policy debate over healthcare costs. But they skirted the question of why the drugs' prices are high to begin with. In large part, drug manufacturers are locked into an approval and reimbursement system that distorts the underlying value of their products and makes high initial prices the best option for recouping their investment. In fact, some regulators set thresholds for cost-effectiveness, which sets not only a price ceiling but also a price floor. Introducing pricing flexibility into these systems,

1 Kantarjian et al. (2013).

which would enable drug prices to both rise and fall in response to new information about a drug's value, is crucial to ensuring that patients get the drugs they need.

The cancer physicians focused on their specialty, a relatively rare form of cancer called chronic myelogenous leukemia, or CML. Before the development of imatinib – the novel cancer drug, popularly known as Gleevec, used to treat CML – 80 percent of patients diagnosed with the disease died within 10 years. Imatinib lowered that rate to 20 percent – a reduction so dramatic that patients "now live close to normal life spans."[2]

The physicians argued that a drug's price – Gleevec costs $76,000 per year – "must reflect worth." So what is the "worth" of those extensions in lifespan that CML patients enjoy? Our research shows that imatinib, manufactured by Novartis, created more than $88 billion in social value in terms of patients' survival gains and drug-company profits over the lifetime of CML patients.[3] What is Novartis' cut? The answer is 10 percent, a fraction typical for a range of other cancer drugs: our research finds patients enjoy between 81 percent and 95 percent of the social value that drugs create, with manufacturers earning a minority of social welfare in terms of profits.[4]

The oncologists readily acknowledged that drug manufacturers deserve some positive return on their investments in order to encourage them to spend billions more on new drug research. Recouping 10 percent of the total value of cancer-drug innovations doesn't seem unreasonable, given that these drugs will eventually lose patent protection and that, over their lifetimes, they are far more cost-effective than pricing at their launch would suggest.[5]

But securing such a return on investment, short of high initial prices, is virtually impossible in our current drug approval and reimbursement system. The key problem is that information on survival benefits and the range of diseases a drug can treat often trickles out slowly over time and after a drug is on the market, but prices – which are often dictated by regulators both here and abroad – do not adjust to reflect changes to the drug's value.

Traditionally, an experimental drug's approval was predicated on demonstrating that it improved patients' survival rates vis-à-vis those under standard care. But waiting for differences in overall survival rates to show up can delay approval up to 10 years or more, blocking patients' access to potentially helpful therapies and driving up the costs of developing drugs.

2 Kantarjian et al. (2013).
3 Yin et al. (2012).
4 Lakdawalla et al. (2010).
5 Lu et al. (2012).

Recognizing these issues, regulators around the world, including the Food and Drug Administration, have started to consider "surrogate endpoints" when evaluating new drugs.[6] One such biological endpoint is tumor size, which is predictive of clinical outcomes like survival. In 2006, the FDA approved Sutent for treatment of both gastrointestinal and kidney cancers based on the drug's ability to slow tumor growth.[7] More conservative European regulators also allow surrogate endpoints, at least in conjunction with other outcome measures, when approving a drug.[8]

But approval and reimbursement are very different decisions. Progress on the approval front has collided with a hidebound reimbursement system. Even if the FDA approves a drug based on surrogate endpoints, insurers may be reluctant to reimburse for a treatment that hasn't yet demonstrated a survival benefit. This problem is exacerbated in cases where the drug is very expensive.

Consider the case of the immunotherapy drug Provenge for prostate cancer, which costs $93,000 for a course of treatment. The FDA denied approval in 2007 despite a positive recommendation from its own advisory panel, only to approve the drug 3 years later. It took another year before Medicare would pay for it. The official reason given for Medicare's holdup was to evaluate the drug's off-label uses, but doctors, including the American Society of Clinical Oncology, read the lack of immediate coverage as a consequence of the drug's high price tag.[9]

So what can be done?

Determining a drug's value at its launch is difficult. Over time, for example, we sometimes learn that a drug can help treat conditions not considered at the time of its debut, which should theoretically increase its value. In fact, the FDA approved imatinib to treat the most common form of pediatric cancer, acute lymphoblastic leukemia, in January.[10] This expanded use of imatinib may make that drug's value higher than our $88 billion estimate for CML alone.

But the current reimbursement system is simply not designed to absorb this new information and, as a result, is horribly inefficient in fairly matching a drug's value to its price. Think of a stock market insensitive to new information: On what basis would you determine the value of a company?

If regulators raised prices with evidence of added value, manufacturers would have less incentive to set high prices at a drug's launch. And regulators could argue for lower reimbursement until new clinical evidence arose to support

6 Garrido and Mangiapane (2009).
7 Food and Drug Administration (2006).
8 Garrido and Mangiapane (2009).
9 Pharmalot (2010).
10 *Wall Street Journal* (2013).

higher prices. Drug prices would thus reflect their underlying value, and products would get to market sooner.

But right now, insurers and regulators such as Medicare are trapped on the wrong path, where no one has an incentive to adjust prices. A private insurer won't offer to pay more than its competitors if a drug becomes more valuable, so prices don't rise. And Medicare follows private insurers by reimbursing based on average sales prices. In economic parlance, we are stuck at a bad equilibrium. We might look to Medicare, as the largest payer, to break out of the mold since, according to the Government Accountability Office (GAO), cancer drugs comprise over 40 percent of the most expensive medications under Medicare Part B. With Medicare taking the lead, private insurers might be forced to follow.

In many respects, we are winning the war on cancer, with patients living longer thanks largely to innovative treatments. Making cancer drug prices sensitive to new information, whether beneficial or disappointing, would help ensure continued success in saving lives.

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