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Ways To More Affordable Medicines: Elevating Value

(Credit: Shutterstock)

The U.S. needs a more constructive and inclusive approach to the challenge of affording high-quality medicines. In a column this summer, I argued for an agenda focused on reducing out-of-pocket costs to patients, elevating value as the preeminent criteria in pricing medicines, and increasing competition among medicines. I've been offering some ideas along these lines in recent columns, and here will look at the importance of recognizing and rewarding value.

It begins with acknowledging that more effective treatments are the keys not only to better health but also to financial savings—often on a very large scale. Consider that the age-adjusted U.S. death rate from heart disease has fallen by two-thirds since 1968—to about 170 people per 100,000. Translated: if the 1968 death rate had not declined, *about 1 million more Americans would have died last year from heart disease than in fact did*. So, 1 million more people each year now continue to contribute to our national economy while enriching their families and

communities in countless other ways. And in most cases, their deaths from heart disease are avoided not by costly, heroic measures such as surgery and hospitalization but by medicines such as statins and anti-clotting agents that cost pennies per day, as well as by new medical devices. It's an incredible bargain.

My take-away is simple: pricing new medicines in a way that reflects the value they are likely to deliver to the health-care system and to society is the best way to assure that breakthroughs continue. That approach will preserve the incentives for breakthrough innovation while keeping costs in line with health-care benefits and savings.

To make this work for new medicines, of course, we need to look forward rather than backward in assessing value. Fortunately, advances in information technology and health-care modeling can help us estimate the value likely to be delivered by more effective or targeted treatments. And new approaches to contracting on the part of biopharmaceutical companies and health-care payers can hold us to account for these estimates—in the real world of patient care.

To that end, my company recently has been piloting what are known as "value-based contracts" with a couple of large health insurers. In one case, for example, Lilly agreed to base a portion of our payment from the insurer on how well a particular product reduces or avoids re-hospitalization due to complications in certain heart-attack patients with a stent. More hospitalizations and increased expense to the insurer mean a lower payment to Lilly, and vice versa.

The results of our pilots have been encouraging. As a drug developer, my company gets rewarded for demonstrated value. The payer wins by protecting itself against unrealized savings. And best of all: if contracts of this sort were in widespread use, then I believe patients will benefit from being the focus of true races to the top in the quality of care. Over time, identifying and encouraging the use of high-value products should both improve patient outcomes and curb spending growth.

So why do value-based contracts remain the exception and not the norm when determining the ultimate cost of prescription drugs?

For one thing, value-based contracts wouldn't necessarily produce the best result in every situation. In disease areas where multiple drug companies offer well-established treatments or generics are prevalent—such as the markets for statins and anti-depressants—the ordinary effects of competition may be enough to produce the lowest prices. But in disease areas with limited competition and for new classes of medicines, linking a drug's reimbursement to measurable patient outcomes is a market-based, patient-centered solution that allows companies to assess value and share risk for treatment success and failure.

But here's a bigger problem: at present, some areas of federal law impede value-based contracting and need to be changed A prohibition dating from the pre-Medicare era, for example, prevents drug companies from discussing new products with insurers before they obtain regulatory approval. Such a provision is clearly outdated in this instance. Modern insurers are not babes in the woods, and keeping them in the dark about the intended patients and possible costs and benefits of new products only delays the groundwork for contract negotiations of any kind.

As an important first step towards reconsidering this prohibition, the potential benefits of allowing what is being called "preapproval information exchange" will be discussed at an FDA hearing next month. At the hearing and in a briefing before Congress, the Academy of Managed Care Pharmacy will share recommendations for improved communications on behalf of diverse stakeholders—including industry, payers, health-care providers, and patient groups—interested in recognizing and rewarding value.

A second, even more serious problem is that federal pricing regulations governing the Medicaid program and parts of Medicare create huge disincentives to value-based contracting. Under current law, for example, if Lilly or another drug manufacturer agreed to give an insurer a 50-percent reimbursement reduction under a value-based contract—for a theoretical

situation in which the product failed to deliver its promised outcome—then the company would be forced immediately to give that same "best price" to every Medicaid patient in every state, regardless of whether the product actually did what it promised or not.

The federal government's Center for Medicare & Medicaid Services has shown welcome recognition of the potential unintended consequences of "best-price" regulations—by opening a "mailbox" through which drug manufacturers can seek guidance and the agency itself can better understand value-based contracts. It should be a priority to turn the resulting lessons into reforms.

Removing these hurdles, while continuing to scale-up comprehensive health-data systems, would provide a true test of value-based contracting and bolster my larger convictions about the effectiveness of the free market in supplying affordable health-care choices.

Health insurers need leverage—to demand products that work and help to keep health-care costs at sustainable levels. Drug companies need the prospect of rewards—to drive investment in new technologies and treatments. And patients need affordable access to the best that medicine has to offer.

Government mandates cannot balance that equation. The market can.