Consider Value Vs. Budget Impact In Mass. Drug Prices

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Prescription drug spending in the U.S. has received considerable public attention over the last few years, accompanied by eye-popping headlines in many media outlets. Understandably, it is an area of increasing urgency among policymakers, who are concerned about guaranteeing access to life-saving medications while trying to control the growth in healthcare spending and its effects on the budgets of both households and governments.

The issue is a prominent one is Massachusetts as well. The Massachusetts Health Policy Commission (HPC) reported that prescription drug spending in 2015 increased 10.2 percent to $8.1 billion, reflecting just over 14 percent of total healthcare expenditure in the state. These figures do not include medications dispensed in hospitals and covered under a medical benefit (such as various chemotherapy agents), which further increase the share of spending associated with prescription drugs. The HPC also reported that while prescription drug spending accounted for only about 1 in every 7 healthcare dollars spent in Massachusetts, it accounted for approximately one third of the annual growth in healthcare spending.

At the same time, the biopharmaceutical industry footprint in the state is substantial and rapidly growing, accounting for over 60,000 employees in 2015, a number which has grown 37 percent since 2006. Total industry Massachusetts-based payroll exceeded $9 billion in 2015. Therefore, the topic of prescription drug pricing and its effects on industry

profitability and investment in research and development are of great import to the local economy.

Value vs. Budget Impact

The current public discourse around prescription drug pricing often conflates distinct issues, making it more difficult to make informed policy choices. Key among these is the important distinction between value and budget impact. Value is typically measured in terms of cost-effectiveness: how much is it worth paying for a particular drug given the clinical benefits it delivers? Budget impact, however, is largely an issue of affordability: how can we pay for prescription drugs that cost a certain amount given existing budgetary constraints? These different economic dimensions often are at tension with one another. The simplest illustration of this is that living longer, all else equal, costs the healthcare system more money, as many people require medical care during their additional months and years of life. Going a step further, cynics have suggested in the past — tongue in cheek, of course — that increasing smoking rates would actually alleviate the budgetary issues of Social Security (though not those of Medicare).

At the root of many of the recent controversies over drug pricing is a focus on price alone, not the underlying value of prescription drugs. Consider, for example, a recently approved gene therapy for a form of leukemia. The one-time treatment — Kymriah — has been reported to cost $475,000, a figure that is already creating headlines. However, if the clinical benefits are substantial, it is very possible that Kymriah provides good value at that price. Moreover, existing treatments are not costless, and one has to consider cost offsets relative to the current standard of care over the entire treatment duration to properly assess the value of a prescription drug.

It is also possible for an innovative drug to confer enormous value yet impose a significant strain on budgets. In fact, that is exactly what has happened following the introduction of a new class of highly effective medications to treat hepatitis C, starting with Sovaldi (sofosbuvir) in 2013. These medications have revolutionized our ability to treat and cure patients with hepatitis C. Not only are they are highly effective, life-extending medications, their cost is lower than the typical value we ascribe to the life years gained by using them. Despite their high price, they offer an even more valuable return, making them cost-effective for most patients. The problem in this context is not one of value but rather of budget impact as the CDC estimates that there are 2.7-3.9 million people with hepatitis C in the US. In fact, the monetary impact on government and commercial health insurers associated with treating so many patients is enormous. In this particular prescription drug pricing example, it is budget impact not value that draws so much media and policy attention.

It does not follow, of course, that any price chosen by a pharmaceutical manufacturer is justifiable. There have been multiple examples of manufacturers who have seized upon regulatory loopholes, or taken advantage of settings in which they wielded market power, to set high prices, or sharply increase them over time. Examples such as Turing Pharmaceuticals, Marathon Pharmaceuticals, and Mylan's recent EpiPen woes, are just

a few of those that have received headlines in recent years. However, existing methods to evaluate value are well-suited to consider pricing in this setting as well, and price increases that are decoupled from clinical benefit will typically yield less favorable pharmacoeconomic assessments.

The same is true for evaluation of more run-of-the-mill annual price increases that are often implemented in the pharmaceutical industry. The fact that a particular drug is cost-effective at launch does not imply that it will remain so in the face of continued price increases over time. The flipside of this, of course, is that the price of newly launched drugs may overstate their long-term average costs. Over a longer horizon, future entry of generic versions that rely on the innovator drug's data will contribute to lower long-run costs.

Understanding Value

There exists a broadly accepted framework to assess value of prescription drugs through the lens of cost-effectiveness. The metric most often cited is that of an incremental cost-effectiveness ratio (ICER): calculate the incremental cost of an innovative therapy relative to the standard of care and divide it by the additional quality-adjusted life years (or, QALYs) gained from the new treatment. The result is the additional cost to attain one more QALY. If the innovative treatment is only marginally better than existing treatments but costs a whole lot more, the result is poor value — paying more than an acceptable amount for the benefit gained. If, however, the innovation is a true breakthrough delivering a substantial improvement in QALYs, even a very high price could present good value. There is active debate in the field regarding the threshold "acceptable amount" for an additional QALY, ranging from £30,000 often used by the National Institute for Health and Care Excellence (NICE) in the U.K., to over $150,000 used by some U.S. researchers. But the main takeaway is that there are well-recognized methods to evaluate the question of value. And importantly, a drug does not need to "pay for itself" in terms of offsetting reductions in medical care to offer good value. An innovative therapy can have an overall budget increasing effect and still offer great value.

Considerations for Budget Impact

The issue of budget impact raises several additional important considerations. Prominent among these is that list prices of prescription drugs are rarely paid by anyone in the industry. Rather, rebates result from a series of bilateral negotiations in which manufacturers try to secure favorable formulary placement, while payers do not want to be at a competitive disadvantage in terms of their prescription drug offerings to members. Differing degrees of bargaining power result in a range of pricing arrangements. While the lack of pricing transparency may sound ominous, the current structure often results in intense competition between manufacturers — and similarly between insurers — giving rise to substantial price discounts. In the hepatitis C market, for example, it was widely reported that a course of therapy may cost up to $100,000 per patient. At the

same time, competition among manufacturers has led to exclusivity deals with different pharmacy benefits managers with reported discounts of approximately 50 percent off the list price.

Using the appropriate pricing metric obviously has a large effect on budget impact (and is also critical to a proper assessment of value). For example, the HPC statement that prescription drugs accounted for one-third of the growth in healthcare spending in Massachusetts in 2015 was based on growth in list prices and did not factor in rebates. Once rebates are properly accounted for, growth rate in pharmaceutical spending is reduced by as much as one quarter.

Another important consideration is that of medical cost offsets. Budget impact cannot be assessed based on pharmaceutical costs alone. When innovative treatments are associated with improved clinical outcomes oftentimes that means lower use of healthcare system resources downstream (e.g., fewer emergency department visits and hospitalizations). The offsets may be more nuanced, such as in the form of substitution from inpatient- to outpatient-based care or from specialist physicians to general practitioners. Either way, changes in medical costs that result from treatment need to be considered in the budget impact calculations.

A key challenge in doing so, however, results from the fragmentation of the U.S. healthcare system. Some payers are only focused on one segment of the market, such as PBMs, and have little interest in potential medical cost offsets that do not yield direct benefits from their narrow perspective. In addition, there are temporal disconnects, as patients transition across payers and payer types; the payer who covers an initial treatment may not be the same one that realizes benefits down the road. As a result, as we have shown in a forthcoming publication, it is possible for a cost-effective treatment to be associated with "winners" and "losers" — an outcome that can create disincentives for coverage. For example, the cost of treating a 55-year hepatitis C patient may fall largely on her commercial insurer, but the benefits may largely accrue to Medicare many years later.

An additional area for consideration is out-of-pocket spending. Formularies and insurance benefit designs aim to ensure that beneficiaries and payers face similar incentives. For example, by setting copays for generic drugs at a lower cost than branded drugs, insurers provide an incentive for patients — who typically do not face the full cost of purchasing the medication — to purchase the lower cost option for the plan as well. However, if manufacturers subsidize the out-of-pocket payment, incentives can be altered, and patients may be inclined to purchase more expensive medications. While patients may be better off, payers may find their budgets adversely affected. Massachusetts bans the use of manufacturer coupons when there is a generic equivalent of the branded drug available, but there remains much variation across states in the regulation of copayment assistance programs.

Key Takeaways

Prescription drug pricing is an area of continuing public policy interest, but one in which several distinct issues are often conflated. True pharmaceutical innovation that results in improved clinical outcomes may be cost-increasing in terms of budget impact, while still providing great value in terms of cost-effectiveness. In such instances, the policy challenge should be to find ways to pay for the pharmaceutical innovation. Such policies need to go beyond simply forcing manufacturers to accept lower prices for cost-effective innovations, as such an approach may risk undermining incentives for innovation.

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