Prescription Drug Price Moderation: A Voluntary Approach

Summary: The increasing cost of prescription drugs has spurred a national discussion. How do we accomplish the goals of encouraging the development of new drugs while simultaneously managing the crippling costs these marvels impose on an already-bloated healthcare system? This paper outlines an approach that builds on the success of two legislative precedents that had a significant impact on helping to control pharmaceutical prices.

Background: The Administration's American *Patients First* document outlines the problem of rising drug costs and many of the important historical factors that have led us to this point. The blueprint makes the important connection between increased regulation, periods of exclusivity, public program rebates and their impact on non-public program prices, as well as manufacturer "gaming" efforts that seek to block access to multisource versions of drugs with expired patents and exclusivity.

The Administration's proposals are a good start at getting at the problem of prescription drug cost, but there may be a better way to address the problem that creates more attractive incentives for manufacturers to modify pricing.

The Council of Economic Advisors (CEA) produced a helpful paper in February 2018 analyzing the problem of pricing behavior in the prescription drug market and offered several thoughtful proposals.

Examining the symptoms of the drug pricing problem, perhaps we can focus on a few important considerations that are the current subject of study:

Regulatory Cost of Drug Approval: The CEA document reports that the capitalized Research and Development cost for an approved drug is more than $2.5 billion. Investing this amount of money requires assurance that there is a decent chance of recovering the development cost and producing a profit over the limited period during which the drug can be marketed without a non-innovator version competitor.

International Price Controls: The American prescription drug market contributes more than 75 percent of the profits of innovator drug manufacturers. Other developed countries use price controls and monopsony power through nationalized health programs to artificially reduce the prices paid for these drugs.

Lack of Price Transparency: Discovering the price of innovator drug prices can be a daunting task. The answer to "what's the price?" depends on whether you have insurance coverage, what type of coverage, what coverage limitations may exist and whether the drug happens to be on the insurer's formulary. Lumped together, much of the lack of transparency in drug pricing can be laid at the door of intermediation. Insurers, and their PBM partners, have created a system of incentives resulting in a lack of transparency. We should note that drug prices are not the only part of the health system that remains opaque; every other sector suffers from the same problems caused by intermediation.

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Failure of Market Forces: The intermediation effect in healthcare complicates the role of competition in governing pricing. The market will provide incentives for higher value (lower cost with equivalent efficacy) when the choices are available and when value is obvious. The federal government creates the rules under which choices are made available through the FDA approval process. Intermediaries can facilitate the competitive effect when their incentives are aligned with the payer (increasingly, the consumer).

Value Determination: Because the payer and consumer are often not the same, establishing a market-based value proposition is difficult. When we make most consumer goods buying decisions the process is relatively straightforward. We determine that we need a car, judge how that car will be used, examine the options that fill the need and make a buying decision. The process is complicated when we look at all the decisions made along the way, but we make those decisions based on our perception of value.

Healthcare is different, not only because of the complicated buyer/consumer relationship, but because there is a perception that the decisions we make in healthcare are higher-stakes decisions. After all, errors in judgment in choosing treatment options could have an effect that can't be reversed.

Quantifying value in prescription drug spending is necessary and possible if the process by which the assessment is made is transparent and reasonable. By example, we can calculate the value of a novel treatment for hypertension by determining what impact on healthcare cost and quality of life the treatment represents. We cannot quantify the unquantifiable, however. The value of a lifesaving treatment can be quantified by its economic benefit, but we will probably never be able to quantify the non-economic value of a successful treatment for a deadly disease, and we should abandon attempts to do so.

Creating a System that Rewards Innovation and Affordability

The pharmaceutical industry and healthcare consumers and payers are faced with several challenges, as outlined above:

- Drug discovery is a pricey and uncertain enterprise, with relatively high risk and potentially high reward for those able to navigate the path from idea to approved product.
- Arriving at an appropriate value for prescription drugs is difficult, due to the lack of price transparency, the fact that the prescriber, the payer and the consumer are different entities, all with different incentives.
- International differences in pricing authority by central governments leave US residents to provide the lion's share of profit for the pharmaceutical industry.

Enter Hatch-Waxman and OBRA'90: The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, addressed a problem that resembles some of the issues we face today. Generic drug manufacturers were burdened by a cumbersome approval process that made drug approval long and costly. Branded manufacturers were frustrated by the time it took to get novel drugs approved for marketing (while the clock continued to tick on the patent life available to retain propriety marketing rights). The Hatch-Waxman process solved these problems by creating the Abbreviated New Drug Application, which simplified generic drug approval, and providing additional exclusivity to innovator manufacturers whose approval had been delayed by regulatory lag.

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The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) contained a provision establishing drug manufacturer rebates to the Medicaid program based on a minimum percentage of the average cost of the drug (currently 23 percent for branded drugs and 13 percent for generic drugs) and a maximum rebate equal to the difference between the average drug cost and the lowest cost available to any purchaser not exempted by the statute. The law also required state Medicaid programs to make the drugs of any manufacturer that entered into a rebate agreement with the Dept. of Health and Human Services available to Medicaid recipients.

These two laws have had a dramatic impact on the cost of prescription drugs and their accessibility to millions of Americans. Although there is an argument to be made that the OBRA '90 provisions have resulted in higher prices for non-exempt payers, the net effect has been to provide a mechanism by which a large-volume payer (Medicaid) is not disadvantaged by other payers.

Building on OBRA'90 and Hatch-Waxman: These two laws were successful because they involved tradeoffs; manufacturers traded the ability to thwart generic competition in exchange for patent extensions under Hatch-Waxman, while the taxpayer got relief from high drug prices in exchange for prohibiting states from barring coverage for covered drugs in OBRA '90.

Considering this framework in light of the issues we have identified in the modern marketplace, we might consider the following approach:

Trade Additional Exclusivity for Price Moderation: The total value of a branded drug is equivalent to *the unit price x total units sold x period of exclusivity*. Once a brand has more than a single generic competitor, additional sales become negligible, and only then when manufacturers voluntarily increase rebates to mitigate price disparity. Changing any of the three variables will have a positive or negative effect on the total profitability of the brand.

Of the three variables, the federal government can directly affect exclusivity. Total units sold is a function of the perceived value of the product and the size of its market. Unit price, while tied to a company's goals, is largely dependent on the size of the market (the number of people with the disease for which the product is indicated) and the period of exclusivity.

What if we offered manufacturers the option of providing marginal increases in brand exclusivity in exchange for price moderation based on a transparent assessment? How might this work in practice? Consider the following example:

New Drug in Existing Category: While so-called "me-too" drugs have invited criticism by many health policy observers, there are many examples of drugs that have followed a category innovator that have proven to be very helpful. In the case of a pharmaceutical company introducing a new entrant into an existing therapeutic category, there is an existing pricing structure in place that creates a pricing benchmark for the category.

If we were to create a weighted average price of existing products with existing exclusivity we can create a benchmark price for a daily or monthly cost of therapy for drugs in that category. If the manufacturer of the new drug agreed to introduce the product at a price that was sufficiently lower than the

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benchmark price, the government would grant additional exclusivity for this product for a term that reflected the amount of the discount against the benchmark.

For example, if the cost of therapy benchmark for the drug class was $100/month of therapy, and the new entrant was priced at 75 percent of the benchmark, the drug would receive an additional one year of exclusivity. Deeper discounts would earn more exclusivity up to a statutory limit.

Breakthrough Drugs Treatment: Payers point to the growth in specialty drugs as a major cost driver in healthcare costs. While many of these treatments have revolutionized positive outcomes in deadly diseases such as cancer, there are few available drug benchmarks against which to establish an economic model. In these cases, the best we may be able to do is to compute a benchmark proxy based on the potential for the drug to reduce the total cost of care for the patient.

An example might look like this. A pharmaceutical company gains approval for a novel compound shown to halt the progression of Alzheimer's disease in a plurality of patients with recent diagnosis. While not a cure, the drug holds great promise in maintaining cognitive function for extended periods. This drug is hailed as a major advance in treating a devastating disease.

A technical review by an accredited third-party organization suggests that the incremental economic impact of caring for a senior with an Alzheimer diagnosis to be approximately $100,000 over a 5-year period. Based on clinical evidence, the organization determines the financial benefit of this new drug would provide savings of $40,000 over that 5-year period, primarily by delaying the need for institutional care. This cost assessment is not inclusive of the cost of the drug.

If the cost of the drug were $40,000 or more over that 5-year period, there would be no net savings in healthcare cost because of the use of this product. If the price were higher, there would be an increase in the cost of Alzheimer's disease because of the use of this drug. Of course, if the cost of the drug were lower, there would be an economic benefit.

Armed with this assessment, the government gives the sponsoring company the option of extended market exclusivity in exchange for establishing a price that results in incremental savings. For example, if the company agreed to price the drug at a 25 percent savings in total cost of care, the company would be granted an additional year of exclusivity. If the company agreed to a 50 percent savings, the exclusivity would be extended to two years.

These percentages are for purposes of illustration, but the key is to provide some benefit to the sponsoring company in exchange for moderating the price. Additional incentives could include mandatory loosening of drug utilization management restrictions for public programs (e.g. limitations on prior authorization or quantity limits), reductions in Medicaid rebate percentages and modest reductions in responsibility for coverage gap subsidies in Medicare Part D.

Similarly, drugs priced at or above the calculated economic benefit could carry penalties, such as increased Medicaid rebate requirements, formulary restrictions in public programs and limitations on tax deductibility of marketing expenses. That may not be necessary, however, since public awareness of the calculated economic benefit would likely have a moderating effect on manufacturer pricing behavior.

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Countering International Price Disparities: The Council of Economic Advisors makes an under-appreciated point in calling out international payers and their effect on drug pricing in the United States. The US is not completely at the mercy of foreign government health policy in this area. While there are penalties for US pharmaceutical manufacturers for setting prices in the US below the minimum percentage mandated by the Medicaid rebate statute, there is no similar penalty when these firms agree to sell the same medicines in international markets for prices much lower than they can sell them in our country.

This could be addressed by amending the Medicaid rebate laws to include average prices paid in member countries of the Organization for Economic Cooperation and Development (OECD) in the calculation of "best price". These countries have well-developed economies and have been benefited from the absence of strict price regulation in the United States.

Manufacturers may make objection to this policy, but some will see the advantage in being able to tell their European customers that they are unable to offer their customary low prices because of the impact of these decisions on profitability in the world's most lucrative market. Just as manufacturers credibly rebuffed requests for deep discounts by health systems in the United States because of the potential impact on Medicaid rebate liability, the argument would be even stronger against international buyers. If manufacturers wish to continue deep discounts to OECD countries their rebate obligations will rise, and the Medicaid program will be the beneficiary.

Not Perfect, but Better: Americans have benefitted from the advances in the pharmaceutical sciences that have made our lives longer and better. The cost of these marvels has encouraged national debate on the virtue of free enterprise, unlimited pricing power and whether we can afford to be the only industrialized nation that fails to impose price controls on health care products.

We have historical evidence that incentives can have a salutary effect on pharmaceutical manufacturer behavior, even while the national temper seems to lean in favor of punishment. Most Americans would probably agree that a tradeoff between exclusivity in return for price moderation is a reasonable approach. Facing worse alternatives, the pharmaceutical industry may embrace the concept as well.

The approach outlined in this document doesn't offer a complete solution to the problem of rising prescription drug prices. This, or some iteration of this concept, may be a first step.

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