The Questionable Economic Case for Value-Based Drug Pricing in Market Health Systems

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Abstract

This article investigates the economic theory and interpretation of the concept of “value-based pricing” for new breakthrough drugs with no close substitutes in a context (such as the United States) in which a drug firm with market power sells its product to various buyers. The interpretation is different from that in a country that evaluates medicines for a single public health insurance plan or a set of heavily regulated plans. It is shown that there will not ordinarily be a single value-based price but rather a schedule of prices with different volumes of buyers at each price. Hence, it is incorrect to term a particular price the value-based price, or to argue that the profit-maximizing monopoly price is too high relative to some hypothesized

value-based price. When effectiveness of treatment or value of health is heterogeneous, the profit-maximizing price can be higher than that associated with assumed values of quality-adjusted life-years. If the firm sets a price higher than the value-based price for a set of potential buyers, the optimal strategy of the buyers is to decline to purchase that drug. The profit-maximizing price will come closer to a unique value-based price if demand is less heterogeneous.

Keywords: health care markets, insurance, pharmaceuticals, value-based pricing.

Introduction

The concept of value-based pricing was originally developed for settings in which a single health insurer or health payer (such as the UK National Health Service [NHS]) is trying to determine whether to cover a novel drug at all, and, if so, at what price [1]. Use of the concept in the United States has since taken several modified forms [2]. We first explain the NHS version, then discuss its variants, and finally use the essential concept of value-based pricing to comment on some recent uses of the term in the US setting in which there is no single insurer/payer but multiple competitive insurers proposing or willing to pay different prices for the same drug. We argue that, among several differences, a key distinguishing feature of the US setting is the need to pay attention to unobservable heterogeneity in patient values for treatments. Our attention is limited to price determinations only for new drugs with patent protection or regulatory exclusion of competition, sold to private insurance firms or individuals, and does not deal with other “value-based” frameworks.

To be clear, when we refer to value-based pricing, we are referring to the neoclassical economic concept that, at the margin, buyer valuations (willingness to pay) equal the price they do pay. We are not referring to the usage of the term that typically encompasses fairness, equity, or political considerations. Nor are we claiming that payment of the price set by a firm with market power, even though it may be value-based, is necessarily or even usually efficient.

The UK process of price setting is essentially a bargaining model. The low end of the bargaining range is the marginal cost of making copies of the drug (because of the requirement that revenue covers variable cost). The high end is the maximum benefit that NHS could achieve rather than going without (i.e., the maximum value of willingness to pay). Within that range there is no obvious way to settle on a fixed point. The NHS adopted a model in which the agreed upon price generally yields a quality-adjusted life-year (QALY) at a cost of at most £20,000 to £30,000, although prices quickly converged on the upper limit and there are now proposals to increase the amount to £50,000.

This capsule summary of bargaining in a single-payer system may be contrasted with what might be expected to happen in a system of multiple health insurers, some larger than others and some covering or attracting different populations than others, as prevails at present in the United States. There is no doubt that insurers or pharmacy benefit managers would rather pay less than pay more. But then we need to discuss a much neglected subject—how the introductory price for a breakthrough drug with no close substitutes might be set by firms that are presumably maximizing profits and that face a number of different buyers, so that the firm is not bargaining with a single entity. The fact that we focus on a novel drug with no close substitutes also rules out

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“tiered pricing.” Many critics say that US prices for new breakthrough products are set in mysterious or illogical ways. Indeed, prices do not seem to display obvious regularities such as a strong correlation with QALYs added, although there is a broad-gauge association of five- and six-figure prices with lifesaving treatments for serious illness.

In public, drug firms generally offer as a rationale for high introductory drug prices either a justification based on high research and development costs or a reference to a (usually rather vague) positive net value from the drug, sometimes backed up by citations to cost-effectiveness and cost-offset studies. They do not claim that they are charging the profit-maximizing price (even if they are). The most one learns is that the firm thinks the drug is cost-effective at the chosen price. Nothing is said about how the price happened to be chosen, nor about the fact that at a lower price it would be even more cost-effective.

The purpose of this article is not to clarify some recent easily misinterpreted uses of the concept of value-based pricing. Instead, we specify a proper interpretation of that concept on the basis of welfare economics. It is not intended to discuss the full set of concepts of value in medicine or of nondrug medical interventions.

The key omission in the conventional discussion is a mention of demand or quantity demanded, in the sense that the amount that would be sold depends on the price charged. The use of cost-effectiveness measures, which average outcomes and values, does not allow for a conventional demand curve, which is based on variation in values. Analyses often do estimate the number of people with the condition the drug could treat, multiply that by the price, and observe both how large the number is and what drug use will do to total medical care spending. But in almost all cases, no attempt is made to describe the amount of the drug that would be sold at prices other than the proposed price.

Policy remedies to this state of affairs propose to derive a value-based price from data on the outcomes, drug prices, and cost offsets associated with the product, along with assumptions about the value of outcome and the desired size or growth rate of total spending. The model for this approach has been proposed by the Institute for Clinical Effectiveness Research (ICER). The application of this model to the breakthrough drug Praluent, which treats stubborn high cholesterol, was much discussed recently [3–6], and will be used in this article. The model comments on a single posted list price and ignores the possibility of discounting or other kinds of differential pricing, and so this article too will not treat the complex topic of price discrimination.

The Economic Model of Price Setting for Patented Products or Services with Seller Market Power

This textbook model describes pricing by a firm with market power facing a heterogeneous market, setting a single monopoly price (so-called simple monopoly). The key assumption for this model is that different buyers (i.e., insurance plans) attract customers with different values of willingness to pay (partially related to income) for health outcomes. In this example, we assume (unrealistically) that there is perfect stratification across plans: all persons who select a given insurer have exactly the same value for health (say, measured in dollars per QALY). There is probably some typical or central tendency in dollars per QALY in the population of all potential insurance buyers; let us say it is $100,000. Nevertheless, there are people with higher values, although their numbers diminish as the value rises (i.e., the population demand or marginal benefit curve has a negative slope).

Imagine then that we turn these data into a demand curve for the drug, showing at each level of value/price the number of persons in insurance plans whose own value for that drug is that large or larger. There must be some very high value at which no person (or their insurers) would be willing to pay before prices fall enough so that quantity demanded is positive. The theory of simple monopoly pricing in economics tells us that we need one key set of information—not what is the average, median, modal, or acceptable value of dollars per QALY for the population, rather the demand curve: the shape of the distribution of values at different dollar amounts. Note that the revenue and profit-maximizing price (assuming near-zero marginal cost of producing the drug) is not the highest possible price that could be charged at which there would be some buyers, but instead is low enough to attract many (but by no means all) buyers.

Insurance of the conventional fee-for-service type, which pays for any approved drug (now much diminished in importance), adds complexities and distortions to the demand curve. If the insurance pays fee-for-service (with coinsurance) for the drug and the drug must be made available if physicians think it necessary (as in Medicare Part D), the demand curve becomes less elastic and the monopoly price may rise (compared with no insurance) to highly distortive levels, as supported by Garber et al. [7]. Here, we assume instead the increasingly more common and recent version of private sector insurance (and U.S. Department of Veterans Affairs [VA] policy) in which the insurer can refuse to “buy” (put on formulary) the drug at all at high prices and/or can limit its use through previous authorization rules. Then, the demand curve (across plans) is the demand schedule of firms on behalf of their insurers paying full price at the margin. This concept also has some complexities. Because of limits on the number of plans, the demand curve may not be smooth and continuous. But we will assume that there is a reasonable approximation to the private market demand curve.

We know that a profit-maximizing drug firm will choose the price on this schedule when marginal revenue equals marginal cost. Notionally, we can think of the firm beginning with some very high tentative price, and estimating how many buyers it will have at that price. The firm then asks whether the number of new buyers (plans) who might be brought in with a price cut is large enough, relative to the number of buyers at the higher price, to push total revenue. Less is collected from the former high price payers, but more is collected from the more numerous new payers. The firm compares any increase in total revenue from selling more of the product with the increase in cost on making more of the product. If the former is higher than the latter, it reduces the price and repeats this cycle until the two terms are equal. The price that prevails at that point is the profit-maximizing price.

There are two important properties of a price set in this manner:

1. It is a value-based price for those consumers/insured choosing a plan because they are willing to pay that price. The average value in this set will be higher than the price (because of the negative slope), but the price will equal the value of health added to the consumers who were just willing to be brought in by the price. Note that this proposition does not depend on the degree of market competitiveness or other aspects of how price is set. If buyers take it as given, they equate willingness to pay to it, no matter however it was set.

2. For those consumers with lower values, their plans’ optimal strategy is to walk away from the drug offered at that price. Were buyers effectively to pay the price, they would have paid more for the service than it was worth to them and thus been unable to purchase other services that were of greater value to them. Even though they would have purchased more health, they would be worse off.

An implication of this analysis is that there is no logic to the claim that the profit-maximizing drug price was set “too high”
relative to “the” value-based price—because there is no single value-based price [2,3,5]. Rather, because consumer values vary across the demand curve, there is a distribution of value-based prices. These prices vary across consumers with different values of QALYs and different medical benefits from the product. A correct statement might be that the price was set too high for consumers (at a given level of severity) with QALY values of $100,000 or some lower value, but not for others. There is no particular validity or warrant to suggest that a value of $100,000, or any single value, is somehow more valid than the higher values of those who do buy.

There is, however, one error that the seller might well have made, and one that ought to be subject to empirical investigation—although, to my knowledge, this has never been done. The price might mistakenly have been set higher than the profit-maximizing level. Excess optimism or imperfect knowledge about buyer willingness to pay could lead the firm to overestimate sales volume at a high price and underestimate the increase in volume if price were lower. Such “overpricing” behavior would harm both buyer and seller. The key empirical factor is the shape of the firm or market demand curve. If each buyer buys only a single unit of the product, it is the distribution of potential buyers with values close to the price currently being charged. If empirically there is a large number of buyers who would enter the market at a slightly lower price, the marginal revenue will be high and may well exceed marginal cost—the firm can make more money by cutting price. If there are few current nonbuyers who would pay anything slightly less than the current price, the price will not change.

The most nonsensical notion seems to be one undergirding the response of pharmacy benefit managers and some insurers to high launch prices for some breakthrough drugs, as reported in newspapers [4–6,8]. They seem to be asserting that the price proposed is higher than the drug’s value, and yet they will still be “forced” somehow to purchase the drug at that price and shift the cost to their premium payers in an unsustainable way. The whole point of the notion of value is that it reflects the maximum price above which the buyer’s optimal strategy is to walk away (or somehow curtail purchases). If a set of buyers will not walk away at a price higher than the $100,000 per QALY price, their values must be greater than $100,000 per QALY, and they are irritated but not charged more than their value.

### Estimating the Profit-Maximizing Price

What can be done empirically to determine the profit-maximizing price, see if it is less than some proposed price, and more generally characterize situations in which it will exceed social value benchmarks (such as those used in the United Kingdom)? The shape of the demand curve for a particular drug depends on two distributions: the distribution of values per QALY and the distribution of marginal clinical benefit (QALYs added) across the population treated.

Here, we provide two hypothetical examples—one using some fragmentary data on Praluent, a new high-priced drug, and the other assuming that the value of a drug is determined by income, with an income elasticity equal to 1. The income measure here is income adjusted for the percent of insurance coverage, and any income effects associated with that insurance. The main purpose is to illustrate the kind of demand data that would lead to a proper analysis of value.

We focus on the recent and much discussed case of the drug Praluent for statin-resistant high cholesterol, and the analysis of its pricing provided by the ICER, the consulting firm. We can use some of the estimates provided by the ICER to get some idea of when the list price of $14,350 would be the profit-maximizing price. The ICER estimates that, at a value per QALY of $100,000, the value-based price would be much less than the list price, at about $5,500. How many people do we think would have a value close to the higher price charged? The ICER does not address the question in this way but rather just provides some estimates of the number of people who could benefit from the drug at any price—their estimates of take-up run in the range of 500,000 to 2.7 million people.

So how many patients would have to be willing and able to pay the higher price of $14,350 to yield the same profit as would be obtained under the price cut? We can assume that the cost of manufacturing and distribution of Praluent is 25% of its selling price, or $3,588. If (say) 1 million people bought the product at that price, profits would be $1.9 billion. At a price of $14,350 and a profit margin of $10,762, there would need to be 177,552 customers to yield the same profit. Judgment is subjective, but this seems like a very optimistic estimate of buyer volume at a high price.

Are there other ways to speculate about the shape of the demand curve more generally and the relationship of the profit-maximizing price relative to near-zero marginal cost? One possibility is to assume that demand is determined by income, which predicts the value of health outcomes for people with similar clinical conditions. Here, we provide a hypothetical example of pricing for a drug, which has value proportional to income.

Table 1 presents the number of households with taxable income at various levels in 2013, as drawn from the Internal Revenue Service statistics. We assume that one unit of the drug is purchased per household, and that its value equals its annual taxable income. (Obviously, this yields very large numbers in dollars but this is just an example.) The table shows that selling the drug at $200,000 will attract about 6% of the potential market. A lower price brings in more customers, and revenue (and profit,

<table>
<thead>
<tr>
<th>Income range ($)</th>
<th>Number of returns [9] (millions)</th>
<th>Value-based price ($)</th>
<th>Number of buyers (millions)</th>
<th>Total revenue (billions $100) ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than 200,000</td>
<td>4.6</td>
<td>200,000</td>
<td>4.6</td>
<td>9.2</td>
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<tr>
<td>100,000–200,000</td>
<td>16.4</td>
<td>100,000</td>
<td>21</td>
<td>21.0</td>
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<tr>
<td>75,000–100,000</td>
<td>12.6</td>
<td>75,000</td>
<td>33.6</td>
<td>25.2</td>
</tr>
<tr>
<td>50,000–75,000</td>
<td>19.2</td>
<td>50,000</td>
<td>52.8</td>
<td>26.4</td>
</tr>
<tr>
<td>40,000–50,000</td>
<td>11.3</td>
<td>40,000</td>
<td>64.1</td>
<td>25.6</td>
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<tr>
<td>30,000–40,000</td>
<td>14.5</td>
<td>30,000</td>
<td>78.6</td>
<td>23.6</td>
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if marginal cost is low) is maximized at a price of $50,000, far from the “highest possible price.” Not only that, in this case the profit-maximizing price is lower than the ICER value-based price at $100,000 per QALY. The implication is that although the price depends on the shape of the distribution, if there are relatively many buyers with low value-based prices, the profit-maximizing price may also turn out to be relatively low.

Other Important Considerations

One important conceptual result from this analysis is that the concept of a single value-based price is likely to be more closely approximated, the less dispersed the willingness-to-pay values are in the treatable population. If health outcomes from treatment are similar and similarly valued, the demand curve will be very flat and markups very low, meaning that a price just slightly less than the typical value will bring in almost the entire market. In effect, the market in such a case would replicate the assumption of uniform social value that undergirds the UK model and a competitive market model. So not only would an ICER-type model fit, but the price that would prevail in the market would be lower, closer to its target. Conversely, if values vary across a wide range, the task of characterizing both the profit-maximizing price and (if desired) some alternative measure of social value (by using a socially assumed value for health) will be daunting—because no value is a good candidate for the social value.

What are the alternative narratives to the profit-maximizing model we have proposed, and how are they supposed to work out when the price charged is higher than the value-based price with a benchmark value such as $100,000? There are several strains of the alternative model. One version focuses on “affordability,” asserting (for example) that Praluent at its current price “is a much more significant healthcare threat to affordability than the Hepatitis C drugs are” (as stated by Marcus Thygeson, Chief Health Officer and Senior Vice President for Blue Shield of California, quoted by Pfeifer [4]). In the analysis of Praluent pricing, the ICER sets a lower bound to the price by calculating how low it needs to be so that total health care spending does not grow faster than gross domestic product + 1%, other things equal. What is never made clear is what the response to a “threat to affordability” is supposed to be. “Affordability” seems like a logically empty category and an empty threat.

Another approach is to take the lower value benchmark as given (if not made explicit) and then argue that “costs [prices] are out of alignment with the clinical benefit” (as stated by the ICER President Steven D. Pearson, quoted by Pfeifer [4]). Because the clinical benefit is not measured in monetary terms, you need a dollar per QALY conversion, and then whether or not they are out of alignment depends on what conversion factor one uses.

The real alternative, however, is a reversion to the negotiation model used to develop the value-based pricing model in the United Kingdom. These data are somehow to be used to reduce prices. But how such a finding would lead a drug firm to agree to a lower price is unclear. If an insurer is small, the drug company can just say, “Take it or leave it.” If it is larger, there might be some concessions on volume.

Practically speaking, the only US insurer with enough market share and enough political power to negotiate is Medicare. But it is at present prevented by law. Moreover, if the drug is a break-through drug with few close substitutes, short of naked political power, it is unclear what tools even Medicare would have to negotiate for lower prices. It would have to go to the UK model, brave the political firestorm, and settle for the best it can get.

Conclusions

The determination of a value-based price for assumed values of QALYs is a very useful exercise. But it is not proper to use it to evaluate the price a firm is charging and then conclude that the price is too high (or too low). Instead, it should serve as a benchmark for buyers with values close to the assumed value, informing them about the maximum price they should be willing to pay for the product before they walk away. The ICER does suggest this, but its interpreters have not been so careful. Observing that the price of a drug is higher than some value-based price in the United States does not provide a case for changing the price; rather, it provides a case for buying smaller quantities, which itself should lead to lower prices. Determining how hypothetical value-based prices compare with the profit-maximizing price would seem to be essential for policy valuation and policy development.

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