

Cost-Effectiveness As A Price Control

The benefit of more-innovative drugs for future patients comes at a (high) cost to today's patients.

by **Anupam B. Jena and Tomas Philipson**

ABSTRACT: After a technology is developed, cost-effectiveness analysis can offer an economically sound approach to adoption decisions. Little attention has been paid, however, to the incentives these criteria induce for getting technologies to market in the first place. We argue that technology adoption procedures more fully take into account the key trade-off inherent in research and development: the decreased welfare of current patients as a result of higher prices versus the increased welfare of future patients as a result of the incentives for innovation that such prices provide. Empirical evidence from a case study of HIV/AIDS provides an illustration of our conclusions. [*Health Affairs* 26, no. 3 (2007): 696–703; 10.1377/hlthaff.26.3.696]

HEALTH CARE SPENDING AS A SHARE OF national income is rising in most Westernized countries. Given the large and growing share of resources devoted to health care, many governments are grappling with how to best assess and adopt the new technologies that are critical to the observed growth in spending.¹ The major approach put forth to date in many countries has been the use of cost-effectiveness (CE) criteria to guide the adoption of new and existing technologies. As the name suggests, cost-effectiveness analysis (CEA) offers policymakers an important means of allocating often scarce health care resources based on the costs and benefits of available medical technologies.

The extensive role of such criteria is particularly stark in many non-U.S. Westernized countries—for example, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) and Australia's Pharmaceutical Benefits Advisory Committee (PBAC), both of which have been reported to follow implicit CE thresholds in technology adoption decisions. Such thresholds dictate that technologies will be adopted if their benefits, as often measured by the quality-adjusted life-years (QALYs) they provide, outweigh a given level of costs. In Australia, for example, only two of twenty-six submissions with a cost per life-year saved greater than \$57,000 were accepted for reimbursement. Similarly, only one

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of twenty-six submissions with a cost per life-year saved less than \$32,000 was rejected.² Although explicit considerations of cost-effectiveness are not used by the U.S. Centers for Medicare and Medicaid Services (CMS), it appears a reasonable prediction that technologies that cost more and have less of a health impact compared with other technologies will get greater scrutiny before adoption.

Previous literature has established the positive role that CEA can play in allocating health care resources efficiently.³ Although this literature demonstrates a solid economic foundation for using CEA to guide medical decision making after a technology has been developed, less attention has been given to the incentives these criteria induce for bringing technologies to market in the first place. Put differently, spending on highly cost-effective technologies—those for which the static benefits far outweigh the costs—is routinely considered to be an appropriate use of health care funds. If the observed cost-effectiveness of these technologies were lowered—for example, through higher prices paid to innovators—would current and future patients be worse off? The answer to this question, we argue, depends on the trade-off central to expensive, emerging technologies: the increased welfare of current patients as a result of the adoption of only cost-effective technologies versus the decreased welfare of future patients as a result of the disincentives for innovation that such price-control policies induce.

This paper aims to describe the basic ideas, for a noneconomic audience, of some of the results presented in a more technical analysis published elsewhere.⁴ Contrary to previous literature, we analyzed CEA in a dynamic context—one that considers both its appealing properties after a technology has been developed and its effect on the research and development (R&D) incentives crucial to technological change. In several respects, the CE thresholds in place in many countries resemble other mechanisms designed to control costs, such as rate-of-return regulations used in the United Kingdom (particularly price controls). In this sense, our recommendations are closely related to ongoing policy discussions of the role such cost containment procedures might play in limiting incentives to innovate. Although these procedures might increase social welfare through reduced prices once technologies are developed, their potentially negative effects on innovation are equally well understood.⁵ This is, in fact, the rationale for the patent system: to promote the inefficiency of high monopoly prices because of the innovation the system encourages. Thus, for the same reason that patents exist to promote innovation, CE criteria that implicitly limit the value of these patents should be modified to reflect the R&D incentives they induce. Technology adoption through cost-effectiveness is a price-control policy in disguise and might therefore have many of the properties of such policies.

Cost-Effectiveness And Dividing The Gains From Innovation

At its core, CEA argues for technologies for which the static benefits to patients outweigh the costs, whether they are actual costs of production or, as more commonly used, the prices paid by consumers and public payers. CEA may be conducted at several levels and from different perspectives: for example, by health plans choosing technologies to be covered for their members or by nations financing care for their citizens. Since much of the controversy over drug pricing has focused on national health systems, our analysis is most pertinent to CE assessments conducted from the perspective of national payers such as the U.K. NICE.

In theory and presumably practice, the benefits and costs used in such a CEA are incremental—for example, a given procedure improves health by one QALY at a price of \$50,000 compared with a baseline therapy. The benefit is the value of the additional QALY, which comes at an additional cost of \$50,000. The most cost-effective technologies are those for which the incremental benefits far outweigh the additional costs to the health care system.

Translating this into economic theory, we argue that technologies are most cost-effective when the associated consumer surplus—the benefits to consumers net of the price paid—is also large. Consumer surplus concerns the difference between benefits and costs, versus CE criteria, which concern the ratio.

This concept can be illustrated with a simple example of supply and demand for a given drug therapy. The demand curve for a drug reflects society's willingness to pay for a given level of provision. Its magnitude depends on several factors, one being the price (or availability) of other related technologies. For example, if the demand curve depicted the willingness to pay for loop diuretics, the demand curve's magnitude would depend on the price of substitute treatments—for example, angiotensin-converting enzyme (ACE) inhibitors. The absence of good substitutes would result in a larger willingness to pay for diuretics. One can then interpret the demand curve for loop diuretics as identifying the incremental benefit of these drugs for a given price of alternative treatments.

The area under the demand curve is the gross benefit to patients from consuming the drug. As more patients consume the drug, the gross benefit increases. The amount by which this benefit exceeds the price paid is the consumer surplus. We interpret the cost-effectiveness of this particular drug as the ratio of the gross incremental benefit to the total amount paid. The higher the gross benefit over the total amount paid, the higher its cost-effectiveness. The main implication of our analysis is that a drug's cost-effectiveness and consumer surplus are intimately related: The higher the consumer surplus, the higher the cost-effectiveness.

On the supply side, it is well known that the marginal costs of drug production are quite low, often on the order of cents per pill. If markets are competitive (price equals marginal cost), the net gains to consumers may be large. Both the consumer surplus and cost-effectiveness of the drug are high, primarily because the benefit to patients far outweighs the price they pay. Moreover, the manufacturers of the

drug make zero economic profits since the price of the drug equals its marginal cost. When markets are not competitive—as is commonly true of markets for new medical products—and producers charge prices that exceed marginal costs, the consumer surplus is lower, and producers earn profits. The extent to which these profits compare to consumer surplus defines how the gains from innovation are divided.

Cost-Effectiveness And The Incentives For Innovation

We can now return to the question we started with: If the observed cost-effectiveness of this drug were lowered—for example, through higher prices paid by consumers—would current and future patients be worse off? More generally, what are the current and future implications of policies that limit health care spending growth, through either strict price controls or CE criteria that implicitly adopt only the most cost-effective technologies?

■ **A drug's price and its marginal cost.** The answer to these questions depends on the process of drug discovery. After a drug has been discovered, economic theory tells us that society is best off if the price of the drug equals its marginal cost. The total quantity of drug supplied and consumed is at its highest, and drugs are only consumed by those whose benefit exceeds the cost of production. In this case, both consumer surplus and cost-effectiveness are high, and increases in price above marginal cost lower the welfare of current consumers.

In reality, drug discovery is an expensive ordeal, plagued by uncertainty in both the process of discovery and the ultimate effectiveness of the final product. When R&D is costly, companies require incentives to innovate, whether these incentives take the form of higher profits, subsidies for R&D, or some combination of the two. Higher profits come at a cost to current patients, health plans, and governments that pay higher prices. Higher profits, however, also stimulate innovation and are therefore beneficial to future patients.

■ **Cost-effectiveness versus “economic efficiency.”** This has the key implication that high levels of cost-effectiveness are often inconsistent with what economists commonly term “economic efficiency,” defined by the highest level of access to therapy by both current and future consumers. This can be illustrated with a simple, although extreme, example of perfect price discrimination. Suppose that a manufacturer can charge each patient his or her willingness to pay for (or benefit from) the drug—in this case, the gross benefit to patients remains the same, but the net benefit or consumer surplus becomes zero. The manufacturer sells the drug at a price that exceeds its marginal cost and earns positive profits equal to the amount previously accruing to patients in the form of consumer surplus. The transfer of net benefits from patients to the manufacturer results in an observed cost-effectiveness that is minimized: The gross benefit to patients now equals the amount paid.

■ **High prices and future innovation.** In this extreme example, economic efficiency is attained because access is maximized: Current patients consume up to the

point that the benefit equals the cost of production, and future patients are ensured that firms have the largest incentive to innovate. The benefit to future patients of more innovative drugs comes at a cost to current patients, who pay prices greater than the marginal cost of production. Importantly, this example illustrates that cost-effectiveness can be minimized when economic efficiency and access are maximized. Moreover, since all of those whose benefit exceeds the cost of production actually purchase the drug, health is maximized. More generally, if companies are able to capture the full social benefit of their innovations, the likelihood of future drug discovery is highest. And although current patients might suffer from higher prices, the future sick might benefit from the innovative products that result from such profit incentives and that would otherwise not occur. In fact, this is the justification for the patent system, which implicitly trades off the welfare of current and future consumers. Finally, while economists often make less distinction between consumers and producers than is seen in policy discussions, this distinction becomes less clear when patients themselves hold large stakes in companies and therefore benefit from increased profits, either directly as employees or indirectly through pension plans, mutual funds, and other investments in these very same companies.

The Optimal Level Of Cost-Effectiveness

Moving away from this illustrative contrast between cost-effectiveness and economic efficiency, what is the optimal level of cost-effectiveness for a technology, and what factors favor increases (that is, reductions in costs for a given benefit) or decreases in this level?

A technology might be “too cost-effective” if the benefits to patients far outweigh the amount that firms receive—an increase in profits and decrease in cost-effectiveness might be warranted to provide greater incentives for innovation. Alternatively, a technology’s cost-effectiveness might be too low if drug manufacturers are able to perfectly price-discriminate so that patients are left with no consumer surplus—if the presence of these large profits induces a “gold rush” of drug discovery efforts, profit decreases might be justified to stifle excessive investments in R&D. The optimal cost-effectiveness might also depend on how R&D into new drugs is divided between public and private efforts. In the United States, for example, health-related public R&D has roughly equaled its private counterpart for nearly fifteen years. When public R&D constitutes a significant portion of total R&D, the profits required to induce firms to innovate is presumably less, because that innovation is already subsidized by public R&D dollars. A similar result emerges when one considers the role of health insurance, which is typically thought to lead to overuse of health care services, since demand is implicitly subsidized. This overuse could lead to profits that encourage excessive levels of innovation.⁶ In both cases, there might be a scope to reduce profits and incentives for innovation, consistent with a higher level of cost-effectiveness in which consumer benefits outweigh the amount paid to producers.

Determining, then, whether producers of health care products have sufficient incentives to innovate, and therefore whether the current emphasis on cost-effectiveness is too strict or too lenient, depends on a sense of the empirical magnitudes involved. Do health care innovators, in fact, capture the full social value of their discoveries? If so, then an argument for lowering cost-effectiveness by increasing the amounts paid to firms seems unwarranted, particularly in light of the important caveats described and the fact that the lion's share of drug spending is on patented drugs. Or does the social value of research accrue primarily to patients who consume its by-products? In this case, current patent protected monopoly pricing might be insufficient, and lowering cost-effectiveness through other means might be justified if the concomitant increase in profits stimulates additional R&D. Below, we provide some preliminary empirical evidence for the latter.

Capturing The Benefits Of Research: Patients Versus Producers

The extent to which producers are actually able to capture the net social value of their innovations is important for making recommendations on whether observed levels of cost-effectiveness are too high or too low. For example, several economists have demonstrated that in the past fifty years, the social value of improvements in U.S. life expectancy alone have nearly equaled the value of gains in all other material well-being, from cellular phones to the Internet.⁷ Has this social value exceeded the costs of health care, and, if so, how much of the net social value was captured by the innovators that were partially responsible for the observed growth in health spending?

This is obviously a difficult question to answer and is certainly beyond the scope of this paper, but one can get a sense of the magnitude by considering an illustrative case study of HIV/AIDS. Since the start of the epidemic nearly twenty-five years ago, the survival prospects of people infected with HIV have improved dramatically. Within ten years of the first reported case, AZT (azidothymidine) was introduced as a first-line antiretroviral therapy. Less than a decade later, a new class of therapies was added, forming the widely acclaimed highly active antiretroviral therapy (HAART). All told, the gains in life expectancy associated with these treatments have been large.⁸ What is the net social value of these gains—that is, the gross gains to consumers net of the marginal costs of production? And how has this value been divided among patients, whose benefit in added life exceeds the price paid, and producers, whose benefit accrues in the form of profits?

In related work, we attempt to value the gains in life expectancy among all Americans with HIV/AIDS.⁹ The intuition behind our analysis is straightforward. Since the start of the epidemic, life expectancy has increased by at least five years averaged across all subsequent cohorts. With a value of \$100,000 per life-year, the gain in life has been worth more than \$500,000 per person and \$750 billion in aggregate (nearly 1.5 million Americans have been infected to date).¹⁰ Considering

people infected with HIV in the future who might also benefit from existing treatments, this value easily surpasses the trillion-dollar mark.

To determine the extent to which this gross value surpasses the costs of production and how the subsequent net social value has been divided among patients and producers, we used data on the revenues of HIV-related drugs obtained from IMS Health and reported by Frank Lichtenberg.¹¹ Assuming that marginal costs are as high as 20 percent of sales, the lifetime projected sales from HIV/AIDS drugs developed to date of roughly \$70 billion would imply lifetime profits of \$56 billion and lifetime costs of \$14 billion. Given these costs and the gross benefits calculated above, this suggests a net social value of still well over \$1 trillion. Similarly, these lifetime profits imply that of this amount, \$56 billion was captured by producers in the form of profits. Our main finding, therefore, is that a relatively small share—approximately 5 percent—of the net social value of HIV/AIDS drugs has been captured by the companies responsible for these treatments.

While HIV drugs may provide an extreme example, one can turn to published CE estimates for other new technologies for a more general analysis. In our related work, we demonstrate that with standard estimates of the value of a life-year around \$100,000, a large majority of published CEAs suggest that interventions cost only a fraction of this amount for one additional QALY. For example, among the nearly 200 CE studies contained in the Harvard Cost-Effectiveness Analysis Registry, the incremental spending on an additional QALY for the median intervention is roughly \$19,000. If the marginal costs of production are roughly 20 percent of sales and the value of an additional QALY is \$100,000, this implies a per unit profit of \$15,200 and a net social value per unit (or social surplus) of \$96,200 (or \$100,000 minus cost of production). Put together, this implies that the median producer in the Harvard registry captured nearly 16 percent of the social surplus associated with its intervention. This figure is lower if costs constitute a larger portion of sales. Although only illustrative, the case of HIV might fairly well reflect the small fraction of product value captured by innovators.

Discussion: CE Criteria And Innovation

CE criteria, by being implicit price controls, favor technologies for which the incremental static benefits exceed the associated costs. There is ample economic justification for CE desirability once technologies are developed and widely available. But less discussion has centered on the incentives such criteria provide for companies that bring technologies to market in the first place. In our view, CE criteria, if used at all, should incorporate a dynamic perspective, taking into account profits' general role in stimulating innovation. In fact, current CE thresholds, which in many ways resemble price controls, could promote innovation when such thresholds function as price floors guaranteeing innovators the social value of their discoveries. Indeed, our analysis suggests that CE thresholds should reimburse at levels consistent with current estimates of the value of a life-year—that

is, at \$100,000 per QALY versus current levels of \$50,000 or lower. Reimbursement at lesser levels might satisfy current consumers and insurers whose benefits far exceed the amount paid, but only at a cost to future patients for whom the likelihood of innovative therapies could be lower.

AT FIRST GLANCE, OUR ILLUSTRATIVE CASE of HIV/AIDS suggests that a movement toward more incentives for innovation and therefore lower levels of accepted cost-effectiveness may be warranted. Indeed, policies simultaneously arguing for a patent system and stricter CE thresholds seem somewhat schizophrenic. In some sense, patents are good because innovators exploit the market power generated by them—limiting the value of market power through cost-effectiveness, just as through other methods of controlling prices, defeats the purpose of patents.

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NOTES

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