

## Foreword

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This remarkable and unusual addition to AEI's long series of economic policy volumes is quite technical in parts, excessively so for many of our readers. The authors' entirely reasonable excuse is that their arguments and conclusions rely upon rigorous theoretical reasoning that defies a fully nontechnical exposition. Accepting that excuse, I offer here a guide to what the authors are saying and why it is important. In doing so, I will try to avoid describing concepts that are well described in the book itself, but a little repetition will be unavoidable.

The entire work is motivated by a simple question: Are health care systems paying for drugs in a way that maximizes national welfare today at the cost of slowing the development of better drugs tomorrow? And in particular, are there reasons to be suspicious of the most basic and widely accepted tools employed in their pharmaceutical reimbursement policies?

In pursuit of answers, the book devotes a chapter to each of four topics, followed by a set of conclusions. Chapter 1 documents the well-known fact that health systems in the wealthier nations usually employ some form of cost-benefit analysis (what the authors call cost-effectiveness analysis) to determine how much to pay for new medical technology, including new drugs. One of the most widespread versions of this analysis involves estimating how many quality-adjusted life-years, or QALYs, are added by, for example, a drug that reduces the probability of a heart attack by 10 percent. Armed with an estimate of QALYs saved, payment authorities then look at the cost of the product. If the cost per QALY is less than some benchmark cost

(typically about \$60,000 in the United Kingdom, where this approach is more explicit than anywhere else), the product is reimbursed. The goal, in short, is to maximize cost-effectiveness when choosing among therapies, which means minimizing costs per QALY. That this is a prime goal of health care payers everywhere is hardly a matter of dispute today.

Jena and Philipson's ultimate concern, however, is not with drugs on the market today but with drugs yet to be developed. What are the implications of cost-effectiveness analyses for incentives to develop new medical technology? Their basic intuition is simple: a government payment policy that maximizes cost-effectiveness is a good way to reduce costs today, but it can bedevil the complex forces that bring better products tomorrow. Chapter 2 is devoted to explicating this point in a fairly rigorous manner, employing more calculus than most readers will feel comfortable with, with the addition of substantial dollops of subtle economic intuition in order to connect math to markets. Their starting point is a classic 1961 paper by Nobel laureate Kenneth Arrow demonstrating that if private firms do not expect to capture, through remuneration, most of the social benefits of solving a technological problem, they may have grossly inadequate incentives to address that problem. The result can be a sort of technological barrenness, or Catch-22, in which everyone would be better off if only the profits from innovation were greater.

Starting with this insight, Jena and Philipson explore the implications of standard health care reimbursement methods. Although the analysis is quite technical, in the end the approach the authors employ is a standard one in theoretical economics: they exploit a series of simplifying assumptions to derive simple but reasonable conditions that can then be tested against market data. They begin with the simple idea, familiar to students of microeconomics, that the total social gain, or surplus, from an innovative product can be broken down into producer surplus (profits) and consumer surplus (roughly speaking, the difference between what patients actually pay for the innovation and what they would be willing to pay for it). They then show how to translate very basic data into an estimate of the returns to innovation in an actual market. From this they can

derive the implications of empirical cost-effectiveness studies for the issue raised by Arrow, that is, the share of the total value of the innovation that goes to the innovators.

Chapter 3 is a fairly sophisticated empirical exercise in welfare economics. This discipline has a well-deserved reputation as a swamp of subtle, elusive, and (if one is not careful) mutually contradictory assumptions and empirical gambits that, among other things, can induce double-counting. Avoiding numerous intellectual traps, Jena and Philipson analyze the gains to society from the development of a particular class of drugs, those used to treat HIV (human immunodeficiency virus) infection and AIDS (acquired immunodeficiency syndrome, the fatal disease caused by HIV).

The development of these drugs is one of the great technological wonders of the last two decades. It has come in two waves. The first began with the approval of AZT (zidovudine, also known by its trade name Retrovir) in 1987, just three years after the discovery of HIV and its role in AIDS. The second began in 1995 when the first protease inhibitor to reach the market inaugurated the era of highly active antiretroviral therapy (HAART). Jena and Philipson's first task is to estimate the consumer surplus arising from these drugs. This is far more difficult than it sounds. Scarcity of data (on the incidence of HIV infection, for example) is only the first problem. Among others is how to take proper account of such matters as the effect of HIV drugs on the transition from HIV infection to AIDS itself, and of the economic value of longer life across diverse populations.

This part of the authors' work is a substantial contribution by itself, which was later refined in a working paper for the National Bureau of Economic Research and summarized in a recent *Health Affairs* article. Drawing on a wide range of empirical data, the authors estimate that HIV drugs have provided tremendous benefits—not from the first generation of drugs beginning with AZT, which failed to stem the course of AIDS, but from the era of HAART beginning in 1995. The data on the reduction in mortality alone are impressive (see their figure 3-2), but even more striking is the estimated total benefit. After taking account, as they must, of deaths to be prevented in the future, the authors calculate total benefits of

nearly \$1.4 trillion for the United States alone. Then a much simpler calculation yields estimated lifetime drug firm profit—producer surplus—of about \$63 billion. This producer surplus is only about 5 percent of the total surplus, leaving the other \$1.3 trillion in the hands of patients and society at large. This is a truly extraordinary benefit from drug development, all the more remarkable in view of the bizarre properties of HIV, which pose endless challenges in developing treatments.

Chapter 3 also presents several refinements to these calculations. When the lower-than-average incomes of most HIV victims are taken into account, for example, the estimated benefits from HIV drugs are substantially lower (\$800 billion), and the proportion of social value captured by manufacturer profits rises to about 8 percent. But the basic point remains: producers capture but little of the social benefits they provide.

Meanwhile, HIV drug development has not stood still. Several breakthrough drugs have just been approved or are approaching approval. But that does not necessarily mean that producers have all the R&D incentives they need. The HIV epidemic is far from stemmed, HIV cannot be eliminated in infected patients, AIDS cannot be cured, and HIV vaccine (as opposed to drug) development remains almost in limbo in the private sector.

Chapter 4 attacks the obvious question: what about drugs for other diseases? Faced with a choice between gathering truly immense amounts of data in order to deal with hundreds of drugs, or working out some new theory, Jena and Philipson opt for the latter course. They derive elegantly simple inverse relationships between cost-effectiveness and surplus appropriation by producers. Thus armed, the authors look at a convenient summary of cost-effectiveness data for some 200 drugs and derive rough estimates, not of the actual social benefits, consumer surplus, and producer surplus, but of the ratio of producer surplus to total surplus. These results are comparable to those for the HIV drug market but reveal a tendency toward a higher share of social surplus going to drug manufacturers: about 13 percent compared with 7 percent for the HIV drugs. Extending their theoretical analysis, the authors show

why it is that even a firm with a great deal of market power (high willingness to pay on the part of buyers plus an absence of competition) cannot be sure of capturing a large portion of the social benefit unless it can engage in systematic price discrimination, that is, charging very different prices to different parts of the market where demand is higher or lower than average.

The authors' conclusion pulls all these results together to suggest some lessons for public policy toward pharmaceutical prices and reimbursement. As Jena and Philipson recognize, some important points remain unresolved. For example, the role of publicly funded research is poorly understood. Also, if R&D happens to be highly productive, investment can not only approach but even exceed optimal levels, leading to inefficient "patent races," even if most of the benefits accrue to buyers rather than sellers. These problems are well known, at least in theory. But Jena and Philipson argue persuasively that there are good reasons to think that, on the whole, the current focus on cost-effectiveness leaves too little profits from innovation, thus suppressing useful research and retarding the development of life-saving new drugs. Their basic point, the one they set out to examine at the outset, is that there is a trade-off between static efficiency, in the form of relatively low prices and wider use of existing products, and dynamic efficiency, in the form of more R&D and superior products in the future. This book is the first to discuss how reimbursement policy methods affect this trade-off by placing such procedures within a standard economic framework.

This is not to say that this kind of trade-off is invariably troublesome. In many other markets, innovation reaches clearly extraordinary levels even as it seems to leave most benefits for consumers (consumer electronics, computer mass storage, and so on). That is the glory of the "creative destruction" championed by Joseph Schumpeter more than half a century ago. Competitive markets seem to do a good job at encouraging innovation while generating large amounts of consumer surplus. But in health care, governments are major payers and often the only payer. Their monopsony power stacks the deck against innovating firms, which, after all, have to compete with each other as they innovate. In other wealthy nations,

where governments are almost always the dominant payer for medical technology, the prices of drugs facing competition are much lower than in the United States (Calfée and DuPre, 2006). With a bit more theory, Jena and Philipson are able to delineate some of the strange economic properties of cost-effectiveness-based reimbursement when there is only a single buyer.

Jena and Philipson's final argument, then, is that the focus on cost-effectiveness in reimbursement policy probably sacrifices a substantial measure of pharmaceutical innovation. In the long run, society would be better off with more profits and a bit less consumer surplus, and this outcome could be achieved by jettisoning the single-minded drive for cost-effectiveness in pharmaceutical reimbursement. This would be consistent with the approach to patents, where the goal is precisely to induce R&D by providing a mechanism for firms to capture a larger portion of the benefits they provide than would otherwise occur.