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A new era for drug pricing: the 'accountable choice'

By James C. Robinson

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Can we trust people to make good decisions about their own health?

As a society, we are of two minds on this matter. The fundamental institutional structures of the health care system presume that patients are uninformed and unengaged and must be protected from their own irrational decisions. Yet at the same time, and now with growing force, we are restructuring the system on the presumption that individuals can — and should — take active, informed, and cost-conscious roles as consumers.

This duality is particularly evident in our attitudes toward drugs.

Protection against bad choices. The Food and Drug Administration purportedly ensures that consumers are not able to access drugs that might be unsafe or ineffective, based on its view of the evidence. Physicians purportedly ensure that their patients do not access even an FDA-approved drug if it will not benefit them, based on physicians' views of the evidence. Insurers purportedly ensure that patients receive third-party payment only for drugs that offer economic as well as clinical value, based on insurers' views of the evidence.

Encouragement to make good choices. In addition to protecting consumers, the FDA, physicians, and insurers are now working to engage them in choosing the right medications. The FDA is making it easier for manufacturers to speed new drugs to the market, and libertarian voices on the right and left call for even quicker access under the new [“right-to-try” law](#)¹. The culture of medicine tilts ever more strongly to informed consent, shared decision-making, and the presentation of options rather than the traditional “doctor knows best” approach. Insurers are requiring that consumers pay ever-higher copayments, coinsurance, and deductibles, especially those who need high-priced specialty drugs.

Is there a middle ground between the two extremes of paternalism and libertarianism?

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[Surprise, surprise: Price hikes contributed a lot to sales growth for the biggest-selling drugs.](#)²

As an economist who recognizes the power of choice, but who also knows that people are not calculating machines, I am interested in how protection and engagement apply to consumer cost sharing.

Let’s start by admitting that the current structure of cost sharing is as inefficient, inequitable, and arcane as possible. It offers generous coverage for many patients who use ineffective or overpriced products while imposing crushing financial burdens on many patients who need lifesaving medications.

We need a makeover built on reference pricing.

Reference pricing is a structure of health insurance design based on a simple and, in my view, not unattractive principle: Society should subsidize individuals’ health care choices enough to ensure they have access to clinically appropriate and reasonably priced products for their conditions. For each medical product or service, the purchaser establishes its payment limit in reference to the available low-priced options; hence the term “reference pricing.” Individuals who want a more expensive product should pay any extra cost themselves, and not expect society (meaning their insurer) to pay for it.

We see this logic play out in other contexts. An employer, for example, pays for work-related travel up to a specified limit (per meal, per night at a hotel, and so forth). If an employee chooses to stay in a more expensive hotel, he or she pays the difference. We also see what happens when this logic does not apply, where the employer offers open-ended travel reimbursement [leading to three-martini power lunches](#)³.

Do consumers respond to incentives created by reference pricing when shopping for low-priced tests, treatments, or sites of care? Economists Timothy T. Brown, Christopher Whaley, and I [summarized the peer-reviewed literature](#)⁴ on that question in the policy journal *Health Affairs*. Every study we reviewed showed significant switching and consequent spending reductions, ranging from 10 percent to 32 percent across services as diverse as orthopedic surgery, colonoscopy, laboratory assays, and MRI tests.

Of course, not everyone switches, nor should they. There’s nothing wrong with paying more to get more — or what the individual views as more. Interestingly, the published studies we reviewed showed no quality differences between the higher-priced and the lower-priced options influenced by reference pricing.

How does reference pricing work for drugs? It begins by classifying individual products into established therapeutic classes (cardiovascular, gastrointestinal, psychiatric, and the like) and then identifying the lowest priced products within each class and subclass. The insurer or employer then sets an upper limit, equivalent to the price of the cheapest drug in the class, that it will contribute toward payment for any drug in that class. Patients who select the low-priced reference drug pay only a nominal copayment, such as \$10 for a 90-day prescription. Those who select a higher-priced drug pay the nominal copayment plus the full difference between the price of the reference drug and the price of the drug they choose — unless their physicians supply clinical reasons why their patients need higher-priced drugs. Then the additional cost sharing is waived.

In a study published last year in the [New England Journal of Medicine](#)⁷, Whaley, Brown, and I reported that many individuals whose health insurance switched from a conventional three-tier drug formulary (tier 1: generic medications; tier 2: preferred brand-name medications; tier 3: non-preferred brand-name medications) to reference pricing quickly shifted to the low-priced drugs within each therapeutic class, leading to a 14 percent reduction in spending by their employers when compared to a matched control group. Some individuals preferred to stay with the more expensive options, so overall cost sharing increased by 5 percent. The findings are summarized in an [Issue Brief](#)⁸ recently published by the Commonwealth Fund.

The NEJM report was limited to 76 therapeutic classes composed of multiple generic and me-too brands. It did not cover novel and high-priced specialty drugs (more on them in a minute). In its pure form, reference pricing assumes that the quality and effectiveness of the alternative treatments within each class are equivalent, so the consumer can focus squarely on price. Novel treatments, however, often differ in at least some dimensions of safety, effectiveness, or applicability from those already on the market.

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Are the principles of reference pricing applicable to novel therapies? They are. The differences between new and existing products need to be, and can be, compared using clinical and cost effectiveness analyses.

Although experts will always bicker over the methodological fine points, the process of determining comparative clinical and cost effectiveness is actually rather routine and is done by every pharmaceutical firm for every product. Such analyses are mandatory for coverage in Europe, though they are not required for coverage in the U.S. Health technology assessment entities such as the [National Institute for Health and Care Excellence](#)¹⁰ in the United Kingdom and the Institute for Quality and Efficiency in Health care ([IQWiG](#)¹¹) in Germany conduct analogous comparative effectiveness analyses on behalf of insurers. In the U.S., the nonprofit Institute for Clinical and Economic Review ([ICER](#)¹²) conducts its own analyses with support from philanthropic foundations.

These analyses are not rocket science.

The principles of reference pricing can and, in my opinion, should be applied to price negotiations over specialty drugs, building on methodologically sound comparative analyses. Nations such as the United

Kingdom and Germany use their analyses to limit the price to be paid for each drug. The British National Health Service, for example, will not cover drugs whose prices exceed a defined maximum relative to their incremental benefit; British citizens cannot obtain any coverage for these drugs. The U.S. could follow this path.

As an alternative, comparative effectiveness and cost analyses could be used to set an upper limit on how much the insurer will pay, rather than to set the drug's price. That gets around the fact that the manufacturer must agree on the price, while the payer has unilateral control over its payment limit. If the manufacturer wants to charge more than the agreed-upon reference payment, it would need to recover the difference from patients or third parties willing to pay more for the drug than what is charged for a therapeutically equivalent alternative. Remember that under reference pricing, the payment limit is always set high enough to cover at least one option in each therapeutic class.

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Many classes of specialty drugs now contain multiple competing FDA-approved products that offer good clinical value to patients. Insurers can base payments for each drug on the comparative effectiveness evidence, and refuse to pay more for a higher-priced drug that cannot document higher safety or effectiveness.

Of course, some therapeutic classes have only one effective drug, such as those for rare or orphan conditions. In such cases, neither reference pricing nor comparative effectiveness pricing will be directly applicable, and we can go back to debating the value of life and whether the government should impose price controls. That should be fun.

Where does this lead with respect to consumer rationality and the ability to choose medications? In a system based on reference pricing for traditional drugs and comparative-effectiveness pricing for novel drugs, the FDA and physicians would need to assess the safety, effectiveness, and appropriateness of drugs, while a [health technology assessment](#) ¹⁵ entity, like ICER or IQWiG, would be needed to assess its comparative clinical and cost effectiveness. Consumers can't perform those tasks on their own. But then consumers should be allowed — even required — to choose among the various alternatives, knowing they will pay out of their own pockets any difference between the price of the drug they choose and the reference price, and not expect their insurer to do that.

I'd like to coin a new phrase for this: accountable choice.

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