

Sophisticated Purchasing of Pharmaceuticals Learning From Other Countries

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In 2019 and early 2020, drug pricing in the United States was a top concern of the public and therefore of politicians. President Trump, the moderate Democrats, the progressive Democrats, and some Republicans competed to denounce louder and regulate more substantially the manner by which pharmaceutical firms set their prices.¹

With the advent of the coronavirus disease 2019 (COVID-19) pandemic, all the momentum was lost, and no major legislation was passed. The attention has shifted to finding therapies and vaccines to treat and prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and the US public wants more innovation, more manufacturing capacity, and more access for all. Only the usual industry critics are publicly concerned about price.

An important question is whether the drug price reform debate was merely a tale told by novices, full of sound and fury, but signifying nothing, or whether there will be reform after COVID-19?

In an article in *JAMA Internal Medicine*, Emanuel and coauthors² remind physicians, the public, and politicians that drug prices have not decreased and that soon enough, when the pandemic begins to decline, it is likely that there will be further debate about the cost of drugs. The authors provide an answer to this concern and suggest that the United States should learn from its peers, from other developed nations that have created publicly accountable institutions for health technology assessment and drug price determination and that have reaped a return in the form of prices that are lower and better aligned with clinical value than drug prices in the United States.

The authors summarize drug assessment and pricing of 6 nations with which the United States can be compared (Australia, France, Germany, Norway, Switzerland, and the United Kingdom) and derived 2 principal lessons. The first is that successful drug purchasing is built on scientifically independent and well-resourced health technology assessment entities, either inside or closely aligned with government. The second is that unified purchasing, informed by the health technology assessment, is essential for obtaining meaningful price discounts.

Technology assessment has the potential to provide useful data to inform drug pricing. Payers in the United States (governmental programs, self-insured employers, insurers, pharmacy benefit managers) conduct their own implicit health technology assessments but usually without the transparency or evidence focus of the peer nations studied by Emanuel

et al. Most US payers do not publish the basis for their drug formulary coverage and prior authorization policies. When they do, it becomes apparent that some payers interpret the clinical literature in idiosyncratic ways. A review of coverage policies from the largest 17 private payers in the United States reported that only 15% of 4811 coverage policies had cited the same study evaluating a specific drug for a specific indication.³ US payers should be required to conduct their assessments in a transparent manner, with public proceedings and published findings, and give a clear evidence-based rationale for formulary exclusions and prior authorization requirements. Patient advocacy organizations and professional societies should have an opportunity to review and comment. Mandated transparency would push US payers toward standardizing their methods, as is occurring in Europe.

The approaches used for drug purchasing from the 6 countries studied by Emanuel et al also provide useful information regarding drug pricing. Payers in the United States negotiate discounts and rebates with drug manufacturers in ways not completely different from those used in other nations. In both contexts, payers have leverage over manufacturers to the extent payers can credibly restrict patient access to medications unless manufacturers offer a discount. This credibility varies across drugs depending on the physicians' ability to substitute therapeutically equivalent products. One role of health technology assessment in purchasing strategy is to highlight comparability across products and thereby enhance substitutability as a negotiating strategy.

Payers in the United States are using the potential of access restriction ever more successfully. The rate of growth in net prices, after accounting for rebates, is difficult to observe due to confidentiality provisions in the rebate negotiations. Estimates by price analysis organizations indicate that US prices and spending, net of negotiated rebates, have been increasing only slowly or actually have been decreasing (in 2017-2019).^{4,5}

There are 2 problems with the prevalent strategy for price negotiations in the United States. First, the interests of the payers are only imperfectly aligned with those of patients, employers, and taxpayers. Rebates are negotiated in strict confidence as are coverage and prior authorization decisions. Payers often favor high-price and high-rebate drugs over therapeutically similar low-price and low-rebate drugs because payers can retain a significant share of the rebates rather than pass them through to the patients, employers, and governmental programs.

Second, the method used by US payers to move from health technology assessment to price discounts imposes



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huge transaction costs on the system. Payers have numerous employees who create administrative restrictions on the ability of physicians to prescribe. These administrative access barriers are supplemented with onerous financial access barriers, including coinsurance and deductibles. In their turn, pharmaceutical firms have numerous employees who interact with physicians and who support patients, and thereby enhance sales revenues. Payers then further tighten administrative restrictions and increase cost sharing, leading the pharmaceutical industry to further increase its expenditures on marketing and patient support.

The convoluted approach to drug pricing in the United States creates administrative complexity for physician practices and a challenging maze for patients. One of the most admirable features of other developed nations, although not emphasized in the article by Emanuel and coauthors, is that these countries proceed from value assessment to price discount with much less bureaucratic involvement. The German system, for example, has a single national formulary that covers all drugs authorized by the European Medicines Agency, does not allow insurers to impose prior authorization on patients, and limits consumer cost sharing to a maximum of €10 per prescription (waived for children and patients with chronic illnesses).⁶

The German system of drug assessment and price determination is of particular relevance to the United States because it relies on a system of multiple competing health insurance firms rather than the single public payer found in many other nations. German insurers must cover every innovative drug as soon as authorized by the European Medicines Agency and, in the first year after launch, pay the manufacturer's full list price. During that first year, the semipublic Joint Federal Committee conducts a clinical assessment of the new drug in comparison to others that treat similar indications. This health technology assessment report is passed on to the association of insurers, which negotiates a price with the manufacturer based on the price of the comparator drug, the incremental benefit of the new drug, and the prices

charged in other European nations (although in practice many novel drugs are launched first in Germany). All insurers then pay the same price for the new drug.⁷ Manufacturers are not permitted subsequently to increase the price of their drugs without submitting new evidence of clinical benefit and going through a new set of negotiations with the insurer association. The German approach has resulted in a pattern of drug prices that are substantially lower than those paid in the United States both by private insurers and Medicare.⁸

Policy idealists see the potential for a mutually beneficial deescalation involving drug pricing, with pharmaceutical firms aligning their prices with the value-based benchmarks developed by independent health technology assessment entities such as the Institute for Clinical and Economic Review, and with payers limiting their prior authorization and cost sharing policies to levels that do not interfere with appropriate physician prescription and patient adherence.⁹

The criticisms of drug prices in the United States usually focus on the pharmaceutical industry but the problem also lies on the other side of the market. All nations buy from the same set of global pharmaceutical firms, but they differ in the manner by which they buy.

Compared with the purchasing structures in the 6 countries described by Emanuel et al, purchasing pharmaceuticals in the United States is fragmented, unsophisticated, opaque, beset with conflicts of interest, and not surprisingly, ineffective. Prices are higher in the United States than in other nations of comparable income. There is no consistent alignment between drug prices and clinical value. Insurance coverage policies are not based on scientific evidence in a consistent and transparent manner. Physicians' prescriptions are frequently rejected based on financial grounds.¹⁰ High cost sharing burdens many patients with severe illness and adds to already serious failures of prescription adherence.

It does not have to be like this. Other nations are more efficient in their purchasing processes, more effective in their outcomes, and more ethical in how they treat patients with respect to drug pricing. The United States has much to learn.

ARTICLE INFORMATION

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