

# WANT CHEAPER DRUGS?

*More competition, not more government coercion, would greatly benefit consumers.*

◆ BY CHARLES L. HOOPER AND DAVID R. HENDERSON

**U**S. drug pricing is in the crosshairs. Martin Shkreli, formerly of Turing Pharmaceuticals and KaloBios, made headlines last fall after he hiked the price for the 1950s-era drug Daraprim (pyrimethamine) nearly 5,500 percent. Throw in some supersized price increases by Valeant Pharmaceuticals, condemnations by presidential candidates Hillary Clinton, Bernie Sanders, and Donald Trump, *Wall Street Journal* articles about high American drug prices, U.S. Senate and House committee hearings on drug pricing, and a comprehensive report on government spending on prescription drugs that is being prepared by the U.S. Department of Health and Human Services, and we have one pharmaceutical industry-sized black eye.

Every imaginable product and service has a price, and yet there is something different about pricing prescription medicines. The unique characteristics of this industry should be understood, lest politicians—eager to be seen addressing a “crisis”—severely damage an industry that has restored health and eased pain for hundreds of millions of Americans. To “fix” drug pricing, we need more competition, more cost sharing, and the liberalization of some regulations.

## ODD MARKET

Medicines prevent and cure debilitating and deadly diseases, and people place a high value on health. That’s one reason drugs are expensive. But there are more reasons. Physicians prescribe drugs, but they don’t personally pay—and often don’t know—the prices of drugs. Pharmacists know the prices, but don’t have much control over the prescribing decision. Patients are the primary beneficiaries of prescription drugs, but they pay only 22 percent

of the cost, typically through their copays. And notice our use of the word “copays.” Insured patients typically pay a fixed dollar amount—a copay—rather than a percentage of the drug’s price, so for a drug with a copay of \$20, patients do not have an incentive to care whether the drug is priced at \$100 or \$500. Third-party payers, both commercial and governmental, pay most of the cost, but they generally use a broad brush to put prescription drugs into copayment categories and apply restrictions. The result of all this is relatively muted demand-side pressure for lower drug prices.

Patients are heavily insulated from the costs of their care partly because of long-term efforts by policymakers and advocates on the political left. The Affordable Care Act was a notable exception to this trend and, according to the Kaiser Family Foundation, following the legislation’s passage, patients’ insurance deductibles have increased six times as fast as average wages. Presidential aspirant Hillary Clinton would insulate those patients more; her “solution” to the current drug price problem is to limit consumers’ monthly out-of-pocket costs for medications. This would counteract one desired effect of the Affordable Care Act—encouraging drug consumers to economize—and would ultimately lead to *higher* drug prices. Patients’ insulation from costs makes them less sensitive to all medical prices, and this lack of sensitivity encourages companies to charge higher prices. If patients paid a larger share of prices (or even knew the prices), then health care costs—including drug prices—would increase more slowly or even fall.

**FDA testing/** The U.S. Food and Drug Administration contributes to high drug prices. Its costly approval process makes it hard for new drugs to reach the market, which keeps price competition between drug makers to a minimum. Economists Joseph DiMasi, Henry Grabowski, and Ronald Hansen at the Tufts Center for the Study of Drug Development have estimated that the costs behind adding one new drug to the market total nearly

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\$2.6 billion. Why so high? Because so much of R&D is spent on drugs that fail along the way. This figure accounts for those “dry holes.” DiMasi et al. estimate these costs have increased at 7 percent per year in real terms: \$179 million in the 1970s, \$413 million in the 1980s, \$1 billion in the 1990s through early 2000s, and now \$2.6 billion. If this 7 percent annual growth rate persists, costs can be expected to double every 10 years.

This imposing cost means that far fewer drugs are discovered, developed, and marketed, which means less competition, less overall pricing pressures, and higher drug prices. This is quite apparent to drug pricers. The ninth statin drug to enter a market competes against the previous eight, perhaps with improved efficacy and a similar price, or perhaps with similar efficacy and a lower price. Competition in that market keeps prices

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down because customers have good alternatives. The first and only drug for a particular type of cancer, conversely, competes only with whatever archaic and ineffective therapies were used previously; competition is minimal and prices can be higher.

But wouldn't clinical trials still be needed absent FDA regulation, in order for the drug to earn consumer acceptance? They usually would. But even if doctors and patients would always be as cautious about new drugs as the FDA is, there would likely be more efficient ways of getting the same information about a drug's safety and efficacy. For example, the FDA required Roxo Pharma to run clinical trials for its Sprix (intranasal ketorolac tromethamine) nasal spray, a non-steroidal anti-inflammatory drug. That might have been reasonable had the active ingredient in Sprix not had two decades of real-world experience. It was clear that ketorolac worked; the only remaining questions were specific to the intranasal delivery system. What the FDA required for approval made no sense but cost millions of dollars and took two years. Moreover, doctors and patients show by their behavior with off-label uses that they are willing to consume drugs that have not been tested specifically, or approved by the FDA, for those uses.

**FOREIGN MARKETS**

It's often noted that drugs are much cheaper in other countries that have more socialized health care systems. While that is true, the disparity isn't quite as large as is claimed; for instance, U.S. consumers make much greater use of generic drugs, and generics are cheaper here than in Canada or Europe. Still, there is a significant price difference.

There are three principle reasons for this difference. First, most people around the world are poorer than Americans. Pricing based on value—economists call this “market segmentation” or “price

effect, that under normal circumstances, if they can't buy a drug cheaply, their citizens won't get it. As a result, their populations do without some breakthrough medicines.

Drug companies would likely extend price discrimination to poorer Americans if not for a perverse incentive in the nation's Medicaid program. Medicaid requires drug companies to charge it the lowest domestic price offered on every drug. That unintentionally dissuades drug companies from offering lower prices to low-income Americans who aren't enrolled in Medicaid. Those same low prices would then have to be offered to the huge Medicaid program and the smaller 340B program, lowering overall company profits. It is wrong to prevent drug companies from making mutually agreeable deals with these patients.

The third reason branded drugs are cheaper in other countries is that some governments threaten to invalidate a drug's patents if the (typically foreign) drug maker charges a price that government officials deem “too high.” Thus, so-called compulsory licensing is really just a violation of intellectual property rights. When faced with a choice between making no money or some money, most drug companies choose the latter. That outcome does not legitimize the process.

The result is that Americans subsidize global drug research and development costs because Europeans and Canadians pay so little for drugs. In essence, new drugs are developed for the U.S. market, with its large, wealthy population and generally less-regulated drug pricing. Many breakthrough drugs would never have been developed given, say, English pricing levels. Once drugs are developed for the American market, other countries effectively hitch a free—or at least cheap—ride, relying on Americans to subsidize the R&D costs. The problem is, if we Americans also try to free ride, there may not be many new rides.

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discrimination”—means setting lower prices where incomes are lower. A Wharton Business School analysis showed that price differences across countries were somewhat consistent with per-capita income differences. In some cases, people are so poor that drug companies simply provide the medicines for free.

Second, most governments negotiate drug prices. While some may cheer this, it involves the exercise of monopsony power—market power on the buyer's side. These governments are saying, in

**PUSHING PRICES DOWN**

Once a drug is approved, the \$2.6 billion development and approval cost is “sunk.” A clear-thinking company will ignore it when setting a price based on what the market will bear; the company need only recover manufacturing, marketing, and distribution costs in order to make production of the already-invented drug financially worthwhile. But at some point, all companies need to consider a price

high enough to make the whole venture profitable from the outset; the sunk costs were not always sunk and must be paid somehow. Otherwise, why would drug companies embark on a money-losing venture?

How much lower would drug prices be if not for the FDA's mandated approval costs and the subsequent damping of competition? We don't know, but some analysts have suggested a full order of magnitude less, based on observations of markets with

lots of competition and those with little. Occasionally we do get to see particular drugs that enter a market where similar drugs were marketed without FDA approval. The new drugs, which received FDA approval and marketing exclusivity, are always priced much higher. One such drug, Makena, which helps prevent premature births, was priced at 100 times the price of existing non-approved drugs for the same purpose.

The reason that drug companies even consider large price increases for their products is a perception that their drugs are currently underpriced relative to their value. In 2003, Abbott Laboratories raised the price of Norvir, an HIV drug introduced in 1996, from \$54 to \$265 a month. Abbott received widespread criticism for the decision, partly as a result of internal memos that exposed the decision as a tactic to help another Abbott HIV drug, Kaletra, which is a combination of Norvir and another drug. As offensive as the price increase was to some, Abbott believed that the price of Norvir was far below its value. The protease inhibitor had serious side effects that prevented its stand-alone use. However, Abbott had discovered that in small doses, Norvir boosted the effectiveness of other protease inhibitors; it soon enjoyed widespread use as a component in the drug cocktails taken by AIDS patients. On its own, Norvir has a low value; in combinations with other drugs, it has a high value.

With little holding them back, why don't manufacturers of drugs facing minimal competition set outlandish prices like \$1 million per dose? The simple answer is they can't; even monopolies are bounded by what consumers are willing and able to spend. Preventing pre-term births, curing hepatitis C, treating HIV, limiting the effects of Parkinson's disease, and giving cancer patients another year to live are truly valuable outcomes, but the economic value is still capped and must meet the implicit approval of health plans, physicians, and patients. After all, if any of the three balk, the sale is lost. So at least two market mechanisms limit drug prices.

Two other remedies that the federal government could use to keep pharmaceutical costs down are the approval of more over-the-counter (OTC) drugs and allowing drug reimportation.

OTC status can lead to strong price competition. For instance, OTC proton pump inhibitors and H2 antagonists are priced at about 10 percent of the prices of their prescription versions. Why would OTC drugs be so much cheaper? Patients who pay 100 percent of the cost—as they do with OTC drugs—are far more price sensitive, and companies price accordingly.

Drug reimportation—allowing patients to import drugs that have been sold in other countries—would circumvent both the FDA's high-cost approval process and Medicaid's "best price" requirement. The only requirement is that these sales should

be voluntary for all parties; U.S. drug makers should not be coerced to sell to foreign countries that then sell the drugs back into U.S. markets. Some have argued that these "re-imports" should not be allowed because the drugs are sold to wholesalers on the condition that they not be sold back to buyers in the United States. If this is the contractual arrangement with foreign

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wholesalers, then they certainly *are* breaching their contract, and that shouldn't be allowed. But enforcing contracts is not the job of U.S. Customs, the FDA, or the Department of Health and Human Services.

#### CONCLUSION

It should be noted that misbehaving drug companies like Turing and Valeant have been punished heavily for their dramatic price increases. Valeant lost 70 percent of its market share by November 2015 and Turing posted a \$15 million third-quarter loss. (And Shkreli, it should be added, was arrested for securities fraud.) A generic competitor announced that it would begin selling a version of Daraprim for 0.1 percent of Turing's price. Already facing lawsuits and government investigations, these companies have been ostracized by the rest of the pharmaceutical industry; the industry organization, BIO, even took the unusual step of expelling Turing.

Those developments underscore that the best long-term solution for keeping a lid on drug prices is good old-fashioned competition from more new drug approvals and more prescription-to-OTC approvals, combined with cost sharing and the elimination of the Medicaid "best price" regulation. Cost sharing gives patients an incentive to use medicines only when the benefits are greater than their share of the drug's price, which will put further downward pressure on prices. Not only will further competition hold down prices, but also the concomitant increased supply of good medicines will help Americans live better and longer lives.

Outrage over drug prices may someday be a historical curiosity. Until then, the industry will face periodic black eyes and politicians who, through the unintended consequences of their actions, may make matters worse. The best solution isn't one of clamping down on industry, but of relaxing some rules and unleashing a flood of new therapies. R