HEALTH & MEDICINE

Why Are (Some) U.S. Drug Prices So High?

The Hatch–Waxman Act promotes both pharmaceutical innovation and price competition, confounding simple comparisons of U.S. and foreign drug prices.

BY WILLIAM S. COMANOR

Former president Donald Trump and House Speaker Nancy Pelosi have rarely agreed on policy or political issues. I can think of only one major issue where they did: the nearly universal claim that U.S. drug prices are too high. In one of the last major policy actions of his presidency, Trump issued two executive orders aimed at lowering prescription drug prices that affect Medicare beneficiaries. Pelosi championed the "Cummings Lower Drug Costs Now Act," which passed her chamber in 2019 but languished in the Senate. (In the current Congress, a new version has been introduced in the House.) On its passage, she stated that "prescription drug prices are out of control," and that the proposed law would bring them down.

More recently, President Joe Biden has joined the chorus. He is quoted as saying that "all of us ... could agree that prescription drug prices are outrageously priced in America."

This view extends beyond the Trump–Pelosi–Biden consensus. In 2017, the National Academy of Sciences published an extensive report, "Making Medicines Affordable: A National Imperative," with the underlying conclusion that Americans spend too much on prescription drugs. The report states that "annual expenditures ... now exceed a half trillion dollars and account for nearly 17 percent of the nation's personal health care bill." It notes that the United States "spends about twice as much on health care as a fraction of gross domestic product as the average of the other nine" countries used for comparison. By implication, that conclusion applies to pharmaceuticals. It has become a broadly accepted fact that U.S. drug prices are too high and we spend too much on them.

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The principal evidence for this judgment is that foreign prices for the same drugs are often much lower than what is charged in the United States. That simple observation is considered sufficient to find that U.S. pharmaceutical prices are excessive.

To be sure, complications could disrupt that conclusion. Most comparisons do not account for the fact that countries may use different quantities of the same drug. The U.S. could potentially use smaller quantities of high-priced "brand-name" drugs but larger quantities of lower priced "generic" alternatives so that simple comparisons of brand-name prices can be misleading. Indeed, noted below, that issue is relevant for U.S.–international comparisons.

Since price comparisons over a small set of drugs cannot establish overall comparative prices, the best approach is to calculate price indices limited to those drugs sold in different countries. This is the approach taken in a recent report, "International Prescription Drug Price Comparisons," produced by the RAND Corporation, a highly regarded research organization. Observed prices are weighted (multiplied) by their reported quantities in one of the two comparator countries. Since our attention is focused on U.S. prices, the RAND study appropriately employs U.S. quantity weights. Furthermore, since the pharmaceutical sector produces and sells more than a thousand medicinal molecules, the RAND authors are correct that the best approach is to calculate price indices for the existing set of overlapping products.

THE U.S. PHARMACEUTICAL SECTOR

Before reviewing the RAND report's drug price comparisons, we must consider some distinct features of the U.S. pharmaceutical supply structure, many of which are fundamentally different from those found elsewhere. As Tom Rice points out in his 2021 book

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Health Insurance Systems: An International Comparison, "nearly all of the countries [included in his discussion] either set pharmaceutical price levels or engage in explicit negotiations with manufacturers." However, "none of these activities are carried out by the U.S. federal government." Instead, "current U.S. policy ... prohibits government negotiation and relies instead on competition."

That U.S. policy of relying on competition is correct and longstanding. As far back as the passage of the Hatch–Waxman Act in 1984, this policy direction was established. Unlike other countries, U.S. policymakers emphasize the societal gains from pharmaceutical innovation, fostering a rapid pace of new product introductions as well as those from securing low, competitive prices. The Hatch–Waxman framers recognized the conflict between these two policy objectives.

With both objectives in mind, the Hatch–Waxman framers created a second distinct pharmaceutical industry that had not previously existed. Indeed, this law was the most striking exercise of industrial policy, carried out through regulatory reform, in U.S. economic history. And it happened because a conservative Republican senator from Utah, Orrin Hatch, and a liberal Democratic congressman from West Los Angeles, Henry Waxman, worked together. By changing the regulatory structure enforced by the Food and Drug Administration, the law effectively created the U.S. generic pharmaceutical industry.

Because of the legislation, the United States has two distinct pharmaceutical industries, designed to achieve very different objectives. The branded industry, comprised of the "Big Pharma" drug companies and—later—innovator startups, was tasked with promoting a rapid pace of new product introductions intended to serve the health needs of the country and the world. (See "Why Punish the Drug Industry that's Combating COVID?" p. 4.) The Hatch–Waxman framers acknowledged that high prices might be charged for new therapeutic agents, but they would be limited more effectively to the duration of the associated drug patents. As those patents expired, the law would allow and even encourage generic companies to enter the market with competing low-priced formulations of the established drug.

Under the Hatch–Waxman Act, potential entrants do not need to demonstrate anew by costly and socially wasteful duplicative testing the safety and efficacy of already existing pharmaceuti-

cals, as had previously been the case. To receive FDA marketing approval, a competitor need only demonstrate bioequivalence, meaning that its version of the drug produces a biochemical response similar to that of the patented drug. This provision sharply reduced the cost of entry. While Big Pharma firms can set high prices for new drugs during their products' patent lives, the Hatch–Waxman framers anticipated sharply lower prices once generic entrants appeared and price competition became effective.

The then-fledgling generic industry was designed to assure low prices for drugs for which patent protection had expired. This objective would be achieved not through price regulation or government intervention into the price-setting process, but through competition. Where branded prices exceeded production costs, the framers believed, a bevy of new firms would flock to the industry, attracted by the prospect of undercutting the high prices charged for therapeutically effective pharmaceuticals. If there were profits to be made, the Hatch–Waxman framers presumed that generic producers would appear.

For this scheme to work, physicians and patients would need to view generic pharmaceuticals as comparable in quality to their branded alternatives. At the time the legislation was being debated, arguments were made that "knock off" drugs would not be trusted despite FDA certification of their bioequivalence. Overall, there were serious questions as to whether the new policy of two distinct U.S. drug industries, not found anywhere else in the world, would actually work. But that was 37 years ago, and now we have the answers.

Table 1, which reports data for 2019, tells the story. When the Hatch–Waxman Act was passed in 1984, generic prescriptions accounted for merely 14% of total prescriptions. By 2019, they dominated the pharmaceutical sector and represented fully 90% of all dispensed prescriptions. Generics achieved that result by continually reducing prices such that they now represent only 29% of total spending on pharmaceuticals after accounting for discounts, rebates, and other price concessions.

Table 1

U.S. Branded and Generic Pharmaceutical Industries, 2019

	Total	Branded	Generic
Dispensed prescription (millions)	4,217.8	413.3 (9.8%)	3,804.5 (90.2%)
Total invoice spending ($billions)	$511.4	$409.1 (80.0%)	$102.3 (20.0%)
Total spending after discounts, rebates and other price concessions on brands ($billions)	$356.0	$253.7 (71.3%)	$102.3 (28.7%)
Average revenue per prescription	$84.40	$613.84	$26.89

Source: "Medicine Spending and Affordability in the United States," IQVIA Institute for Human Data Science, May 2020.

In contrast, the branded industry receives more than 70% of aggregate net revenues even while providing only 10% of dispensed prescriptions. This disconnect is striking and associated, of course, with major differences in the average price per prescription between the two industries: over $600 for branded drugs but only $26.89 for generics. Based on these data, an appropriate response to the question of whether average U.S. drug prices are high or low is *both*. By regulatory design, there are two pharmaceutical industries: one with high prices and the other with low ones. And this result is just what the Hatch–Waxman framers had in mind.

INTERNATIONAL PRICE COMPARISONS AND THE RAND REPORT

The RAND authors were tasked by the U.S. Department of Health and Human Services with "understanding the extent to which drug prices are higher in the United States than in other countries." To this end, they explain and then derive "price indices as a tool to compare drug prices between countries." However, the authors pay little attention to the presence of two distinct U.S. pharmaceutical industries. In effect, they compute a "fruit" index containing "apples" and "oranges" with little concern paid to the striking price differences between them.

In the discussion that follows, I largely ignore the authors' overall index, which mixes together the prices of branded and generic drugs. I focus, instead, on their separate price indices for branded and generic pharmaceuticals, which is where they make their most important contributions. And rather than deal with their full sample of 32 comparator countries, I consider only Japan, Germany, and the United Kingdom, which are the three largest consumers by volume of pharmaceuticals after the United States. As indicated in the first part of Table 2, U.S. sales of combined branded and generic drugs are much greater than those found in any of the next largest countries.

The data presented in the second part of Table 2 describe the different compositions of U.S. pharmaceutical sales as compared with its largest rivals. Consistent with the data presented earlier on prescriptions, the physical volume of U.S. generic sales was 84% of the country's total in 2018, although its sales revenue was only 12% of the total. The next largest countries all had smaller shares of physical units accounted for by unbranded generics but larger shares of sales revenue. These data indicate the very different pharmaceutical supply structures in the United States and elsewhere.

Table 3 reports the RAND report's major findings. Consistent with the data provided earlier, and after making the appropriate net price correction, U.S. branded drug prices are more than double their foreign counterparts in Japan and the UK and just under that level in Germany. However, these averages apply to only 16% of the pharmaceutical physical units sold in the United States.

In contrast, as also indicated in Table 3, the RAND report finds that U.S. average generic drug prices are much *lower* than those reported for the three large comparator counties: only 43% for Japan, 62% for Germany, and 68% for the UK. And these averages

Table 2

Sales and Quantities of Branded and Generic Pharmaceuticals, 2018

	United States	Japan	Germany	United Kingdom
Sales (billions of U.S. dollars)	$464.0	$73.2	$39.9	$23.7
Volume (billions of standard units)	243.4	213.7	58.4	60.5
Unbranded generic drugs: Share of sales revenues	12%	13%	16%	20%
Unbranded generic drugs: share of physical volume	84%	34%	63%	62%

Source: "International Prescription Drug Price Comparisons," by Andrew W. Mulcahy et al., RAND Research Report RR2956, 2021, Tables 3.1 and 3.2, pp. 19–20.

Table 3

U.S. Pharmaceutical Price Indices as Percentage of Other-country Price Indices, 2018

	Japan	Germany	United Kingdom
U.S. branded originator prices			
Invoice prices	307%	280%	349%
With net pricing correction	206%	187%	234%
Unbranded generic prices	43%	62%	68%

Source: "International Prescription Drug Price Comparisons," by Andrew W. Mulcahy et al., RAND Research Report RR2956, 2021, Tables 3.2, 3.13, 3.3, pp. 27, 35, 28.

apply to fully 84% of the pharmaceutical standard units sold in the United States. To a far greater extent than elsewhere, U.S. pharmaceutical prices diverge between the branded and generic markets. Competition determines price outcomes in generic markets but not so much for those supplied by branded pharmaceuticals, which remain largely the province of patent-protected product monopolies.

While the RAND report provides a useful discussion of price index economics and also valuable price indices concerning U.S. pharmaceuticals, it suffers from a lack of connection to the underlying market conditions. Its concluding statement makes that disconnect clear:

> We found that 2018 drug prices in the United States were substantially higher than those in other countries. The magnitude of this difference between prices in the United States and other countries was substantial.... Only unbranded generics had lower prices than in most comparator countries.

What is missing from the statement is that, by their own reported data, fully 84% of total pharmaceutical quantities are represented by unbranded generics. That category of pharmaceuticals hardly represents an exception to a larger conclusion put forth in the report.

POLICY CONCLUSIONS

The RAND report confirms the common notion that U.S. consumers pay high branded drug prices as compared to other developed nations. It also confirms the less recognized fact that U.S. consumers pay lower generic prices than elsewhere. This division reflects U.S. policymakers' dual goals of promoting pharmaceutical innovation while also reducing the prices of long-established drugs. To gain the benefits of therapeutically advanced new drugs, the Hatch–Waxman policymakers willingly tolerated high branded prices. Whether those prices are excessive or not turns on whether they exceed levels required to achieve the drug innovation policy objective and not on whether they are higher than elsewhere.

There is empirical evidence in a study by F.M. Scherer that drug companies' net revenues are an important predictor of pharmaceutical company ratios of research and development expenditures to sales. There is also evidence that larger therapeutic markets, which promise greater revenues, directly entice the entry of new medications and new molecular entities. The point here is that pharmaceutical innovation is an economic activity that is pursued, like other economic activities, for financial gain.

Even when new pharmaceuticals build upon basic scientific discoveries made in government and university facilities, company resources are required. On this point, an empirical study by Andrew Toole estimated that for every public dollar allocated to basic biopharmaceutical research, an additional $8.38 is spent on pharmaceutical R&D. In a recent report, the Congressional Budget Office emphasized

> the complementary relationship between public and private R&D spending [which] arises mainly because NIH funding focuses on basic research that leads to the discovery of new drugs, whereas private spending focuses on applications of such research.

A major factor in private R&D spending is the cost of the extensive clinical trials required before the Food and Drug Administration grants marketing approval. These trials can cost upward of $100 million per drug according to estimates by Joseph DiMasi and colleagues. The point here is not to diminish the importance of public research but rather to note its complementarity to industry research in circumstances where both efforts are essential.

To be sure, pharmaceutical R&D is inherently uncertain. While not all research programs lead to therapeutically important new drugs, many do. A striking example is the development of pharmaceutical treatments to combat the virulent AIDS epidemic.

An empirical study by Tomas Philipson and Anupam Jena of the comparative aggregate treatment costs and social benefits reported that the survival gains associated with the new AIDS treatments were conservatively valued at 20 times the observed treatment costs.

While the AIDS example may be atypical, Philipson and Jena also noted that for a larger sample of 200 branded pharmaceuticals, societal values exceed treatment costs by as much as 10 times. Moreover, for new drugs that are no better than existing ones, these pharmaceuticals are generally priced at about the same level as their established rivals, according to my research with John Lu. For the most part, and with some exceptions, the prices charged for branded drugs lie well below the social value of their therapeutic contributions, as explained in a forthcoming paper by Mark Pauly et al.

Because advanced new pharmaceuticals benefit all countries, each has an incentive to free ride off the high prices and resulting incentive effects of others.

Between 1990 and 2015, U.S. life expectancy increased by 3.3 years, and a recent study by Jason Buxbaum et al. apportioned that improvement among leading contributory factors. The authors emphasized that the 12 most significant factors together contributed 85% (2.9 years) of the aggregate gain. Among those factors, pharmaceuticals was the second most important, after public health measures. Drugs represented 44% of the aggregate improvement in mortality rates, although partly offset by a survival deterioration of 9% associated largely with the opioid crisis. Still, the net gain from pharmaceuticals was 35% of the total. These findings, the authors point out, "underscore the central role of medications in explaining reduced mortality."

Another report by the Congressional Budget Office examined the connection between pharmaceutical prices and innovation. When bills are offered or passed in either chamber of Congress, they are commonly "scored" by this impartial office to describe the implications of the proposed legislation. For the most part, the CBO provides budgetary implications but sometimes also offers additional non-budgetary effects. The CBO "scored" the 2019 Cummings legislation mentioned earlier.

The bill's objective was to reduce drug prices by instructing the secretary of health and human services to negotiate the prices of "selected drugs" so they do not exceed 120% of their average price charged in a specified group of countries. In such circumstances, the CBO estimated that government spending would fall by $456 billion over a 10-year period. The CBO also estimated that, because of the diminished revenue for newly patented drugs, eight fewer drugs would be introduced over the 2020–2029 period, and 30 fewer drugs over the subsequent decade. A subsequent CBO staff report reduced those figures to two fewer drugs in the current decade and 23 fewer in the next decade, but also estimated there would be 34 fewer drugs in the following decade. The report explained, "The change would be small for the first few years … [but] would increase substantially as decisions in earlier phases of development affect later phases."

The evident tradeoff between prices and innovation raises the policy question of why other developed nations have enforced far lower prices despite having similar menus of advanced pharmaceuticals. Wouldn't their lower revenues yield fewer new drugs? The answer lies in the reality that the tradeoff between branded prices and innovation does not affect other countries nearly as much as it does the United States.

As disclosed in the RAND report, the United States accounts for 58% of total pharmaceutical sales revenue among nations in the Organisation for Economic Co-Operation and Development, whereas the second and third highest counties, Japan and Germany, are 9% and 5% respectively. Moreover, because U.S. branded prices are higher than elsewhere, the United States accounts for approximately 78% of worldwide industry profits. All other countries, in aggregate, account for less than one-third of that amount. Put simply, U.S. profits incentivize global innovation.

Whether this striking imbalance resulting from high U.S. branded drug prices is "excessive" or not depends on policy objectives pertaining specifically to the branded industry. As emphasized in a 2018 report by the President's Council of Economic Advisers, "worldwide profits drive innovation incentives," which in turn depend at least partially on the prices paid by government health insurance programs. The report continues, "Providing innovative returns is a global public goods problem that leads to classic under-provision through government free-riding." Because advanced new pharmaceuticals benefit all countries, each has an incentive to free ride off the high prices and resulting incentive effects of others. While this incentive applies particularly to smaller countries that contribute little to overall innovative returns, it is least applicable to the United States, which in effect has no one to free ride on. In a sense, the United States is captive to its overwhelming position in the worldwide pharmaceutical marketplace.

Fundamentally, the reason why U.S. branded drug prices are so high is that the societal gains from therapeutically advanced new products are embodied in the prices that informed collective buyers are willing to pay. While most other countries can presume

that pharmaceutical innovation is largely unaffected by its pricing decisions, the United States cannot. There are advantages to this heady role, including that advanced new drugs are typically introduced first in the United States. But there are obvious disadvantages as well, and among them is that policymakers such as the Hatch–Waxman framers cannot avoid accounting for effects on new product introduction when setting policies affecting prices. The compromise solution contained in that striking piece of legislation will not be duplicated elsewhere. *R*

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