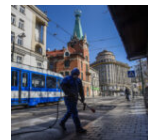


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## How much will drug price controls harm innovation? It depends

The drug industry maintains that policies like foreign reference pricing and letting Medicare negotiate prices would harm innovation. But closer examination reveals that while there is truth to that claim, it's more complex than it appears at first glance.

By ALARIC DEARMENT

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For all their differences, particularly in election season, Democrats and Republicans seem to agree on one thing: Drug prices, both list and out-of-pocket, are out of control. Both parties have backed efforts to use the power of government to bring them down. In response, the biopharma industry has said that policies forcing it to lower list prices would stifle innovation.

But on closer examination, the picture gets a little more complicated than the diametrically opposed positions of politicians and drugmakers would lead one to believe. While [studies](#) support the argument that forcing lower revenues for drug

components to keeping the drug pipeline flowing.

“It’s clear that if you basically reduce total spending on patent drugs, there will be some effect,” University of Calgary economics professor Aidan Hollis said in a phone interview. “How large the effect is is a questionable issue.”

The U.S. pays more for prescription drugs than any other country. According to the Organization for Economic Co-operation and Development, the U.S. [spent](#) \$1,220 per capita in 2018. Not surprisingly, drug companies derive the largest share of their quarterly and annual revenues from the U.S., which also tends to be their first stop when they seek regulatory approval.

Medicare accounts for much of that and, unlike health authorities in other developed countries, is statutorily prohibited from negotiating drug prices directly with manufacturers. In December, the House [passed](#) H.R. 3, a bill that would require Medicare to negotiate list prices on the drugs covered under Medicare Part D that account for most U.S. drug spending. The Trump administration has [proposed](#) international reference pricing, which would peg prices for drugs covered under Medicare Part B to average prices paid abroad. Medicare Part B covers certain outpatient drugs administered by physicians, while Part D covers prescription drugs.

These include the U.K.'s National Institute for Health and Care Excellence (NICE), Germany's Institutes for Quality and Efficiency in Health Care (IQWiG), Italy's Italian Medicines Agency (AIFA) and others that drugmakers must negotiate with after securing primary approval from regulators like the European Medicines Agency or Health Canada. NICE imposes especially strict cost-effectiveness criteria, typically requiring that the cost per quality-adjusted life year (QALY) remain below 30,000 pounds (\$39,000) as a condition for recommending a drug's use by the National Health Service in England and Wales. A QALY is a metric used to represent one year of perfect health. If the cost per QALY exceeds the 30,000-pound threshold, NICE will initially turn the drug down, followed by the manufacturer offering confidential discounts and rebates. Thus, the list prices that drugmakers take to European countries usually do not reflect the amounts that governments pay, which are trade secrets and usually unknown even to other countries. According to the OECD, drug spending in the U.K. was well below most developed countries in 2018 — \$469 per capita.

It's because of those lower prices that the Trump administration accuses other countries of getting a "free ride" on the backs of American patients, who bear the costs of innovation through higher prices. Some in the industry echo that view.

"What has happened is that the U.S. has been subsidizing innovation for the rest of the world," said Pascal Prigent, CEO of Lille, France-based drugmaker Genfit,

France spent \$653 per capita in 2018, according to the OECD.

The bigger question is how much lowering prices would affect innovation and how much spending would need to come down for there to be a significant impact.

In a review of H.R. 3, the Congressional Budget Office [estimated](#) that it would reduce federal direct spending under Medicare by \$345 billion between 2023-2029. Reduced industry revenues would, in turn, reduce R&D spending, with a \$500 billion-\$1 trillion revenue reduction yielding 8-15 fewer drugs over 10 years. The Food and Drug Administration, it noted, approves an average of about 30 drugs per year. The effect of increased use of drugs but fewer drugs entering the market on overall public health is not clear, the CBO stated.

But revenues don't just pay for the drugs of the future – they also pay for the ones that could have been.

“That price not only needs to pay for the price of development, but it also needs to pay for the price of failed development,” Prigent said.

Moreover, while the reduction of 8-15 drugs from the 300 that the FDA would approve over 10 years may not seem like much, it's impossible to know which specific drugs those could be – me-too drugs that do little to advance treatment or novel therapies that significantly change the trajectories of diseases.

What drug companies need to do is be more transparent about what they spend on research and development, said Olivier Wouters, assistant professor of health policy at the London School of Economics and Political Science.

“Companies need to be more open about the costs they incur in drug development, and then we can look more closely into these issues,” Wouters said in a phone interview.

Some of the public’s distrust of drugmakers comes from the perception that they spend more on marketing than on R&D. While some drugmakers have appeared to spend more on marketing in certain years, Regulatory Focus writer Zachary Brennan has [pointed out](#) that it is due in part to how companies define marketing and R&D, which may not be entirely clear when one looks at financial statements.

Nonetheless, it can’t be denied that drug development is a risky business. It’s heavily regulated, very expensive and fraught with the unpredictability inherent in biology. A small biotech company can spend hundreds of millions of dollars painstakingly raised from venture capital and public markets to develop its first drug, only to have everything fall apart when randomized Phase III trial data show it is too toxic, insufficiently effective or both, or it fails to secure physician uptake or payer coverage.

signs of efficacy and at least manageable toxicity. And many drugs are born in labs at universities, academic medical centers or government research institutes – often with the aid of government grants – before their inventors spin them off into startups or companies or investors swoop in to license them.

Where that early development happens is another important factor. An additional question that the debate around pricing and innovation raises is why there is often a disconnect between the size of a country's drug industry and the amount of money it pays for drugs.

Prigent said the amount of innovation that drugmakers in Europe do is thanks to the high prices they can get for drugs in the U.S. “The pharma companies in the U.K. are conducting a lot of research, and they make their profit like everyone else in the U.S.,” he said. “GlaxoSmithKline and AstraZeneca innovate, but they need the prices in the U.S. to do so – the same with Sanofi in France.”

Based on the OECD figures and their quarterly earnings, there's no question that London-based [GSK](#) and [AstraZeneca](#) and Paris-based [Sanofi](#) are not deriving the lion's share of their profit from their relatively thrifty home countries.

Other examples exist of countries with low domestic spending on drugs but lots of innovation. Switzerland has the OECD's second highest spending level, \$963 per capita, and is both highly innovative and home to two of the world's largest

less – but also have significant biopharma innovation, with Israel in particular known for its startup scene.

But there are also cases where the reverse is true. Canada spends the fourth highest amount on drugs per capita, \$832, and borders the highest-spending and most innovative country, but is “bottom of the barrel” when it comes to drug industry R&D spending, said Doug Clark, executive director of the Patented Medicine Prices Review Board, Canada’s official drug-pricing watchdog.

“So if there’s a correlation, it must be a very weak one,” Clark said in a phone interview. He added that Canada’s sparse population and lack of good health databases probably don’t increase its attractiveness for biopharma R&D despite its low corporate tax rate.

“We’ve never been a heavy hitter when it comes to pharma research and development,” Clark said.

Clark said that to the extent there is a connection between drug pricing, intellectual property protection and pharmaceutical innovation, “it’s not an organic one.” Otherwise, he said, the situation in Canada would be different.

And then there’s the odd case of Cuba, whose state-owned [Center for Molecular Immunology](#) has leveraged state support for biomedical research and the



Indeed, there are likely factors dictating the size of a country's biopharma industry that go beyond simply high drug prices, Wouters said. Drugmakers in the U.S., for example, benefit from a strong academic sector, public investment in basic research and a strong patent system.

A 2018 paper illustrates the importance of investment in basic research. Published in the journal *Proceedings of the National Academy of Sciences*, the study [showed](#) that more than \$100 billion in funding from the National Institutes of Health contributed to published research for every one of the 210 drugs that the FDA approved between 2010 and 2016, most of it associated with basic research related to biological targets for drug action. The same paper cited research showing that companies invest an average of \$1.4 billion out of pocket for each new molecular entity launched, with the total cost of capital being more than \$2.5 billion. Another study cited in the paper found that for 38% of new drugs approved by the FDA, the first synthesis or purification of the molecule came from an academic institution.

“The reason there's a lot of innovation in the U.S. is because of a big population of scientists who work on biopharmaceuticals,” Hollis said.

Hollis pointed out that while Americans spend more on drugs than anyone else, much of the development that takes place is centered on a few locations. The

rapidly as well.

“Lots of money is spent in Illinois, and probably much more than in Massachusetts, but there’s more innovation in Massachusetts,” Hollis said.

There’s no denying that sales revenues and the profits they generate are critical for maintaining a healthy product pipeline and encouraging drugmakers to take the risks involved in developing new medicines. But as with so much else in biopharma, there’s a lot more to drug development than money alone.

*Photo: Peshkova, Getty Images*



## TOPICS

2020 election, 2020 Presidential Election, Centers for Medicare and Medicaid Services, Democrats, Donald Trump, drug pricing, innovation, Medicare, R&D, Republicans



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