

New JAMA drug pricing issue examines key evidence in pitched battle

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With battles over the future of American health care being waged in the courts and at the ballot box, *JAMA*, the *Journal of the American Medical Association*, has devoted its latest issue to better understanding what Deputy Editor Gregory Curfman called the "challenging problem" of "relentless increases" in prescription drug prices.

The new issue calls into question high R&D cost estimates often leveraged by the industry to justify high drug prices, reviews pricing trends that have significantly outpaced inflation, and highlights research revealing that pharma companies have substantially higher profit margins than comparable non-pharma companies in the S&P 500.

The pharma profits study, led by Fred Ledley, Bentley University professor of natural & applied science and management, found that the profitability of large pharmaceutical companies between 2000 and 2018 was "significantly greater" than other large, public companies. However, difference was less pronounced when taking into account company size, year and R&D expenses, the authors said.

"The public sees profits made by pharmaceutical companies as a major factor contributing to the price of prescription drugs," according to a Kaiser Family Foundation Health Tracking Poll, published March 1, which found that at least eight in 10 respondents, across party lines, said that "profits made by pharmaceutical companies are a 'major factor' in the price of prescription drugs."

Ledley told *BioWorld* the study speaks to that perception, which may be influenced by the significant amount of hyperbole in the public conversation around how profitable pharmaceutical companies are. Despite many top-line numbers cited on industry profitability, closer examination found few of them to be rigorous, he said.

"We need these companies to provide for the public," especially in important therapeutic areas such as cancer, heart disease and Alzheimer's disease, Ledley said. "In order to make effective policy that ensures that drugs are affordable, but also that they're available requires a lot of data," he said. As policy makers seek to reduce prices, it's important to understand the impacts of the mechanisms they employ on drugmakers' abilities to keep providing the products that the public needs. "Key to that, in this society, is profit," he said.

Amortizing costs?

Another article looked at the estimated investment needed to bring a new medicine to market between 2009 and 2018. A review of 63 of 355 new therapeutic drugs and biologic agents approved by the FDA during that period found the estimated median capitalized R&D cost per product was \$985 million, including expenditures on failed trials, according to the authors.

"The mean cost of developing a new drug has been the subject of debate, with recent estimates ranging from \$314 million to \$2.8 billion," wrote lead author Olivier Wouters, an assistant professor of health policy at the London School of Economics and Political Science, and his co-authors. Greater transparency around R&D costs is "essential for analysts to check the veracity of claims by companies that the steep prices of new drugs are driven by high development outlays," they said. "While these expenditures are undoubtedly high, as shown in this study, it is important for policy makers, regulators and payers to know the exact scale of these investments."

In an editorial accompanying the evaluation, Merck & Co. Inc. CEO Kenneth Frazier acknowledged that the report "contributes new perspectives on the costs associated with drug," but criticized its methods for excluding most products from larger companies that usually report research expenses in aggregate form in favor of products from smaller companies that often address orphan indications where R&D cost data was more closely tied to individual products and for which accelerated approval often reduces clinical development costs.

"Regardless of the precision of numerical estimates, one conclusion is clear: drug development is fraught with the risk of failure and ever-increasing development costs," Frazier wrote. "These factors contribute to disturbing projections of further declines in

research and development productivity across the industry and the influence that could have on the innovation ecosystem."

Rising prices

A third investigation in the issue used net pricing data on branded pharmaceutical products in the U.S. between 2007 and 2018 to determine that, during that period, list prices had increased by 159% and net prices had risen by 60%. "Although discounts partially offset list price increases of branded products from 2007 to 2018, there was still a substantial increase in net prices over this period," wrote lead author Inmaculada Hernandez, an assistant professor of pharmacy and therapeutics at the University of Pittsburgh School of Pharmacy.

"Over the 11 years from 2007 to 2018, net prices increased every year by an average of 4.5 percentage points, or 3.5 times faster than inflation," Hernandez and her colleagues found, an estimate consistent with a recent HHS Office of Inspector General report.

Though acknowledging that U.S. branded drug prices have risen over time, industry veteran and medicines pricing expert Manny Duenas said that the analysis missed a few important points. For instance, he said, analyses should focus on total drug expenditures over time, which have been stable as a percentage of overall health care spend. The *JAMA* analysis also fails to take account of the significant medical cost offsets from innovations like curative medicines for hepatitis C virus, the mandatory discounts provided to certain U.S. government payers and institutions and the substantial offsetting value of patent expiries, he said. Negative pricing pressure the drug industry faces outside the U.S., such as government-legislated price reductions and tendering, should also be considered, he added.

The latest issue of *JAMA*, published March 3, also includes articles estimating health care spending for the most common health conditions in the U.S., a study of funding for U.S. gene therapy trials by technology type and therapeutic area, and a discussion of the underlying causes of generic drug shortages in the U.S.