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ISSUE BRIEF

Bernie Sanders Has It All Wrong: Price Controls Will Hurt Patients, Threaten Innovation

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Introduction

Sen. Bernie Sanders envisions himself as a modern-day St. Michael slaying the dragon of high drug costs. In reality, his efforts will deny new innovative treatments to patients living in hope that, one day, they too will have access to efficacious medicines.

Sanders has found a new spear in his campaign – a recently published study in the *Journal of the American Medical Association* (JAMA) that claims innovative diabetes medicines can be profitably manufactured for around $5 a month (Barber et al 2024).[1] This publication is plagued with errors that completely invalidate its results. In addition to justifying why JAMA should retract this piece, highlighting these flaws demonstrates the real danger his policies will impose on patients.

There Are No Excesses in Profits

Before highlighting the JAMA study's flaws, it is important to debunk this notion that the manufacturers of innovative medicines earn excessive profits. The term "excessive profits" is always dubious due to its inherent vagueness. It is even less applicable to an industry whose prices are declining and profitability is lower than the market average. Both realities apply to the innovative pharmaceutical market.

Unlike most markets, where the customer can simply look at the price tag and know the cost, pharmaceutical prices are opaque. There are three important prices to follow – the gross (or list) price, the net price, and patients' out of pocket costs. From a patient perspective, it is out of pocket costs that matter; from a manufacturer perspective, it is net prices that matter. These prices are disconnected from one another due to the distortionary impact pharmacy benefit managers (PBMs) have on gross prices.

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PBMs serve large insurers, employer-sponsored health plans, and government health plans. The three largest PBMs control nearly 80 percent of the market.[2] They are also subsidiaries of large insurers – CVS Health / Caremark (33 percent of the market), Cigna / Express Scripts (24 percent), and UnitedHealth / OptumRx (22 percent).

A central function of PBMs is to negotiate discounts with drug manufacturers on behalf of insurers. PBMs have a favorable bargaining position when negotiating with manufacturers because a vibrant patient-centered healthcare system does not exist, three firms control most of the market, and PBMs essentially set the formularies (i.e., the list of drugs that patients can access).

PBMs earn more money when discounts are larger. To accommodate the need for large discounts, the list prices of drugs have been rising quickly. Although down from their double-digit annual growth rates in the early 2010s, they still grew 5.4 percent in 2023 according to the industry research source Drug Channels.[3] Net prices, the systemically relevant price that includes the large discounts PBMs *negotiate*, have been declining for the last 6 years, however. Much of the gap between ever-rising list prices but declining net prices are paid to PBMs and insurers as discounts.

The consequences of this complicated pricing structure are significant. PBM profits are high because they are extracting expensive fees and earning a percentage of the spread between gross and net prices. Insurers' costs are controlled because their costs are based on the less expensive net prices. Patient costs, on the other hand, are going up because their out-of-pocket expenditures are based on the inflated gross prices. These rising out-of-pocket costs are the prices that are so troubling to patients. However, these costs arise due to the dysfunctional pricing system not because manufacturers are raising their prices. In fact, the prices innovative manufacturers have been receiving have been declining as evidenced by the 6-year decline in net prices.

Since manufacturer profits are based on net prices, they have been consistently receiving less money for the innovative drugs the produce over the past 6 years. Not unrelated, the industry's profitability is less competitive than the total market (despite assertions to the contrary) based on the financial data maintained by NYU Professor Aswath Damodaran, last updated January 2024.[4]

As of January 2024, pharmaceutical companies' return on equity adjusted for R&D costs (a typical measure of profitability) was 12.4%; biotechnology companies had a negative return on equity (-3.9%). The return on equity for the market overall was a higher 13.8%. Financial returns vary, of course; however, over time, the pharmaceutical and biotechnology industries' returns are not exceptional compared to the market and often lag the market's overall profitability. In other words, the profits of the innovative drug manufacturers are, at best, similar to overall market profitability.

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Maintaining a competitive profitability profile is essential because the private sector plays the driving role in developing new innovative medicines. Undoubtedly, supporting basic research – the expansion of knowledge – is widely regarded as a core public good. In pursuit of this goal, NIH provided approximately $36 billion to entities including universities and medical schools in 2023.[5] While basic research is a public good, private industry expenditures are necessary to turn this research into FDA approved medicines that help people. According to the Congressional Budget Office, in 2019 "the pharmaceutical industry spent $83 billion dollars on R&D. Adjusted for inflation, that amount is about 10 times what the industry spent per year in the 1980s."[6]

Updating these expenditures to 2022, the pharmaceutical industry invested $101 billion into research and development expenditures.[7] Put differently, creating innovative medicines that treat devastating diseases requires the pharmaceutical industry to invest nearly three-times as much into drug development annually as the federal government annually spends on basic research – much of which is not even geared toward direct drug development. This huge investment discrepancy illustrates that a financially viable private sector is essential to developing efficacious medicines, which means that the profitability of these companies must be competitive in the financial marketplace.

Methodological Concerns

Barber (2024) fails to consider these essential financial realities. The authors ignore the exceptionally large research and development (R&D) expenditures required to develop innovative drugs as well as the large upfront capital costs that must be spent to manufacture many innovative drugs. The paper's premise is that the sustainable market prices for patented medicines can be determined by examining manufacturing costs alone. Disre-

garding the most expensive costs of developing innovative medicines violates a core principle of pharmaceutical economics, as well as the foundations of the broader patent system.

The study's methods are based on previously published research by some of the authors. Those studies generally evaluated prices for medicines no longer on-patent. Yet, even with respect to off-patent medicines, there are important caveats that limit the efficacy of this methodology. For instance, there is currently a concerning generic drug shortage problem that is often linked to their uneconomically low prices.[8] This growing problem of generic drug shortages raises concerns that the cost-based methodology the authors employ is inappropriate for certain off-patent drugs.

Overlooking these concerns, the study's authors apply the cost-based methodology to evaluate both on-patent innovative medicines and off-patent generic drugs and biosimilars. Evaluating on-patent and off-patent medicines with one pricing methodology is inappropriate because these are radically different markets.

Unlike the off-patent market, the cost of producing on-patent drugs includes manufacturing costs and innovation costs. Applying the cost-based methodology to on-patent medicines demonstrates that the authors assume that the prices for both innovative drugs and off-patent drugs should be based on a multiple of manufacturing costs alone. In other words, the methodology assumes that the costs of capital associated with developing innovative drugs can be ignored.

This assumption is demonstrably false.

Patents' raison d'etre is to provide innovative firms – including innovative pharmaceutical manufacturers – an opportunity to recoup the expensive cost of capital. The full cost of capital for developing innovative treatments includes the research and development expenditures (i.e. direct costs) spent, as well as compensation for the risks of failure and the lengthy amount of time the research and development process takes. Without an opportunity to fully recoup all capital costs, and it is only an opportunity not a guarantee, all innovations would cease. This constraint applies regardless of the industry – whether the innovations are for new pharmaceutical treatments or the development of artificial intelligence.

It is widely recognized that it is essential to include the capital costs when pricing innovative drugs. The United States Congressional Budget Office (CBO), for instance, acknowledges that the "expected cost to develop a new drug—***including capital costs and expenditures on drugs that fail to reach the market***—has been estimated to range from less than $1 billion to more than $2 billion.[9]" In the latest iteration of their cost of capital analyses, DiMasi et. al. estimate that the costs of developing an innovative drug, including the costs of capital and post-marketing research, are $2.9 billion.[10]

The authors of the current study completely ignore these costs in their "sustainable cost-based prices (CBP)" calculations. Instead, the only inputs included in the CBP were the costs of the active pharmaceutical ingredient (API), formulation, secondary packaging, logistical costs, profits, and an allowance for task. Further the only "profits" allowable by the authors are those that would be "reasonable" for generics or biosimilars. Therefore, the authors' estimated prices provide a grossly misleading estimate of the market prices for innovator medicines.

This deficiency alone is sufficient to invalidate the conclusions of the study. However, there are other methodological problems that undermine the study's conclusions. For example, once an innovative treatment has been approved by the FDA, producing the treatments requires significant capital expenditures to create the necessary manufacturing capacity to safely produce the drug for patients. Such expenditures are ignored by the authors.

The authors also ignore considerations regarding the value of medicines to patients and society, another cornerstone of pharmaceutical economics. Pharmaceutical prices, like all market prices, should reflect the value that they deliver to the ultimate consumer (i.e., patients). While this is a complex question, the assumption that the manufacturing costs reflect this value for innovative medicines is clearly wrong.

Another methodological flaw arises because the authors do not adequately define excessive profits despite its essential use in the study. For instance, do they consider prices that are high enough to enable innovators to recoup the cost of capital to be excessive? Based on their methodology, the answer would seem to be yes. However, as stated above, such a definition of excessive profits would severely hamper the development of innovative medicines. The failure to precisely define this concept, let alone define it accurately, undermines the validity of the authors' price estimates. The authors' suggestion that their methodology protects against excessive profits while still maintaining sustainable prices is, consequently, undermined.

As a final methodological flaw, the authors clearly misunderstand the central role that intellectual property protection and patents play in the innovative drug development process. The authors assert that patents are harmful to health and wellbeing, stating that "patents prevent competition and play a leading role in keeping prices high for a wide range of medicines."

The failure to account for the indispensable role that the patent system plays in incentivizing biopharmaceutical innovation – particularly for creating new innovative medicines to treat unmet needs – demonstrates a clear lack of knowledge that is a prerequisite for researchers before they can accurately analyze drug pricing trends. As stated above, the core purpose of patents is to provide innovators an opportunity to recoup their cost of capital and, consequently, incentivize the innovations necessary to create efficacious treatments for devastating diseases.[11]

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Only after the opportunity to recoup the cost of capital has been provided is the pricing of generics and biosimilars a consideration. It is important to note that once the exclusivity period has been provided, the sale of generics and biosimilars should be encouraged to substantially lower prices. This process of temporary patent protection followed by robust competition is essential for promoting the dual goals of innovation and affordability. And there are important successes under the current system. Approximately 90% of medicines prescribed in the U.S. are either generic or biosimilar versions of once-patented innovative medicines. This is not despite intellectual property protections; it is because of them. Failure to acknowledge the benefits from this structure threatens future biopharmaceutical innovations.

The inability or unwillingness to acknowledge these benefits demonstrates that the study's approach is inherently biased, undermining the validity of any of its conclusions.

Data Concerns

Beyond the inherently flawed methodology employed in the study, there are several data concerns that undermine the accuracy of the authors' calculations.

The analysis relies on list prices as its price measure. As described above, list prices do not reflect the exceptionally large discounts and rebates paid in the U.S. drug pricing system. These discounts and rebates include rebates and fees paid to PBMs and other intermediaries, costs associated with patient assistance programs, the 340B drug discount program, coverage gaps in Medicare Part D, and mandatory Medicaid rebates. The prices of medicines inclusive of these discounts and rebates are net prices. According to Drug Channels, "for 2022, the gross-to-net bubble [the difference between list prices and net prices] for brand-name drugs was about $300 billion. Rebates and discounts reduced the selling prices of brand-name drugs at the biggest drugmakers to ***less than half of their list prices***."[12]

Worsening this problem, the size and scale of these discounts paid in the U.S. system are unique. Thus, judging U.S. list prices to the list prices in other countries provides an inaccurate comparison of the actual market price differences. Due to the failure to account for these market realities, the study relies on erroneous price comparisons to other countries to draw its conclusions.

Compounding this error, the authors do not adjust international price comparisons for key economic differences across countries. Most obviously, comparisons across countries should account for factors such as Gross Domestic Product (GDP) per capita adjusted for purchasing power parity. Consequently, the price comparisons lack the appropriate context.

Beyond the concerns with the list price data, there are reasons to question the accuracy of the study's API data. According to the authors, the API prices were the initial input into their manufacturing cost estimates. These API prices were estimated using international API shipment data and were supplemented with direct solicitation of manufacturers, and "inference of costs based on product similarity."

Despite lengthy supplemental online content, it is not possible to determine whether these cost inferences and data sources accurately estimated actual API prices. Further, the limitations of the data were not presented, so there is little transparency on how the data were cleaned, nor was any information on the validity and reliability of the source databases provided.

Concerns with the Policy Considerations

Given the methodological flaws and data errors, the conclusions of the study are inaccurate and provide no useful information to healthcare professionals, patients, or policymakers. Compounding these inaccuracy problems, the authors fail to consider the tradeoffs that inherently arise from alternative policies.

For example, the authors offer compulsory licensing and price controls, "regardless of patents" as potential policy options. There is no consideration, however, of the impact that these policies would have on innovation. Without such an assessment, there is no way to understand the net benefit from the policy being suggested. Further, the suggestion that governments in the U.S. should use price caps does not consider the tradeoffs countries that have implemented these policies already face. In fact, the data clearly demonstrates that those countries that have implemented price controls have less access to innovative medicines – the stricter the controls, the less access patients have.

Conclusion

Due to the inherently flawed methodology and data concerns, the results from Barber et al.'s analysis do not enhance the health community's understanding of these important issues. In fact, it distracts from a more in-depth understanding and misleads policymakers such as Sen. Sanders.

He will likely continue to cite this analysis to justify his efforts to impose price controls on innovative drugs. The economic consequences from bad policies do not change, however, simply because policymakers can cite an inherently flawed study.

The bad news for patients is that the adverse consequences are clear: policies that ignore the fundamental economics of developing innovative drugs will jeopardize patient health. These lost opportunities may be more difficult for senators to measure, but they are very real for the patients living with diseases that lack efficacious treatments.

> "The economic consequences from bad policies do not change, however, simply because policymakers can cite an inherently flawed study.

Endnotes

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About the Authors

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In 2018, she received an honorary PhD from Pepperdine University's School of Public Policy for her work on health care reform.

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Dr. Winegarden's columns have been published in the *Wall Street Journal, Chicago Tribune, Investor's Business Daily,* Forbes.com, and Townhall.com. He was previously economics faculty at Marymount University, has testified before the U.S. Congress, has been interviewed and quoted in such media as CNN and Bloomberg Radio, and is asked to present his research findings at policy conferences and meetings. Previously, Dr. Winegarden worked as a business economist in Hong Kong and New York City; and a policy economist for policy and trade associations in Washington D.C. Dr. Winegarden received his Ph.D. in Economics from George Mason University.

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