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Invited Commentary | Statistics and Research Methods

Quantifying Research and Development Expenditures in the Drug Industry

Olivier J. Wouters, PhD; Aaron S. Kesselheim, MD, JD, MPH

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US patients pay more than twice as much per capita for brand-name prescription drugs as patients in most other developed countries.[1] Since Joseph Biden was elected President in 2020, the federal government has undertaken a variety of initiatives to address these high costs: the Federal Trade Commission has moved to challenge improper patents listed by brand-name drug companies, the Department of Health and Human Services has proposed guidance to allow the government to relicense patented pharmaceutical products developed with federal funding that are marketed at extreme and unjustified prices, and, perhaps most notably, Congress passed the Inflation Reduction Act of 2022, which authorized Medicare for the first time to negotiate the prices of top-selling medicines and capped out-of-pocket spending for patients with Medicare Part D.[2]

Pharmaceutical industry lobbying organizations have generally opposed these initiatives, arguing that lower drug prices will make it difficult, if not impossible, for their member companies to recoup their investments in innovation and thereby disincentivize the development of new medicines. The high level of investment required to develop a new drug has long been the most prominent talking point deployed by the drug industry to oppose drug pricing reform efforts. However, surprisingly little is known about the costs of drug development, because firms rarely disclose verifiable information about the expenses related to individual drug candidates. The most widely cited studies on the topic reported that the average cost of developing a new therapeutic agent has nearly tripled since the turn of the century, from $1.3 billion in 2003 to $3.4 billion in 2013 (adjusted to 2023 US dollars).[3,4] These estimates, which accounted for both spending on failed trials and expected returns for investors (ie, the cost of capital), relied on a sample provided confidentially by large pharmaceutical firms to an industry-funded research group. Because the underlying data have never been publicly disclosed, these estimates cannot be independently validated or scrutinized for selection bias.[5] Other studies,[6-8] using publicly available sources such as audited financial information in public securities filings, have pegged the median cost at between $640 million and $1.4 billion (2023 US dollars), although those estimates have their own limitations.

Sertkaya and colleagues[9] provide new estimates of drug development costs. Using data obtained from proprietary and public sources covering 2000 to 2018, they estimated an average research and development investment of $879.3 million in 2018 US dollars (or $1.1 billion in 2023 US dollars) to bring a new drug to market.[9] Although the estimate is similar to earlier studies, the study is differentiated by a new bottom-up approach that is complementary to previous top-down approaches and that yields detailed cost breakdowns.

As with previous studies, Sertkaya and colleagues[9] adjusted for spending on failed trials and capitalized their estimates (using an 11.0% discount rate) to account for the cost of capital. Their estimates by therapeutic area ranged from $378.7 million (or $459.0 million in 2023 dollars) for anti-infective drugs to $1756.2 million (or $2.1 billion in 2023 dollars) for anesthetics and pain drugs.[9] Differences from previous studies may reflect the time periods, companies, and products analyzed, as well as discrepancies in some of the assumptions underpinning the cost calculations. Of course, there are important assumptions and caveats to the study by Sertkaya and colleagues[9]; for example, the authors were limited by lags in reporting of clinical trial costs and incomplete data on non-US clinical trial costs, and their approach to estimating preclinical costs was imprecise, also owing to lack of data.

The cost of new drug development remains of perennial interest to scholars and elected officials because of the important role it plays in informing public policy. Development costs are among the

factors the Inflation Reduction Act instructs Medicare to consider when negotiating drug prices. In some states, Prescription Drug Affordability Boards are required to consider development costs when determining whether residents are overpaying for prescription drugs. This is sensible, to a degree, as policymakers seek to signal to manufacturers their interest in the investment required to develop clinically valuable medical advances. However, it would be unfortunate to take an approach to drug pricing that rewards drugs developed through bloated and inefficient processes over drugs with the most meaningful clinical benefits.

Another way in which research regarding drug development costs is relevant to policymakers is for the design of incentive mechanisms to spur socially valuable innovation. Congress, for example, could use such data to inform approaches to public drug development (as proposed in the Affordable Drug Manufacturing Act of 2023) or to set the size of the financial rewards for developing products that address unmet health needs (as occurred during the COVID-19 pandemic). At a time of rapid technological innovation and dynamic policy debates regarding the role of government in drug pricing, Sertkaya and colleagues[9] make a welcome contribution to the existing literature.

ARTICLE INFORMATION

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Corresponding Author: Aaron S. Kesselheim, MD, JD, MPH, Department of Medicine, Brigham and Women's Hospital, 1620 Tremont St, Ste 3030, Boston, MA 02120 (akesselheim@bwh.harvard.edu).

Author Affiliations: Department of Health Policy, London School of Economics and Political Science, London, United Kingdom (Wouters); Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts (Kesselheim).

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