PRI CENTER FOR MEDICAL ECONOMICS AND INNOVATION

ISSUE BRIEF

A Review of the WHO Technical Report: *Pricing of cancer medicines and its impacts*

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Executive Summary

The World Health Organization (WHO) claims that every $1 of R&D expenditures into cancer medicines generates a median of $14.50 in sales income, which is presented as evidence that the global income stream from cancer drugs is excessive, and should be reduced. The results of the WHO analysis, in no way, supports such a conclusion. The study committed two foundational methodological errors that invalidate its results. These errors are:

- Inappropriately eliminating 37 percent of the study population, thereby creating a large data bias. Incorporating the eliminated data could reduce the revenue multiple to $9.20.
- Failing to account for the time value of money – a fundamental financial principle. Properly accounting for the time value of money could reduce the revenue multiple further to $3.16.

The study also committed other flaws that raise additional concerns. These include:

- Demonstrating a fundamental misunderstanding of the negotiation process that sets drug prices globally;
- Excluding key benefits created by cancer medicines such as: the benefits created by better cancer treatment and longer survival rates, the potential reduction in other health care costs, and the reduction in other social costs;
- Failing to account for pharmaceutical companies' actual cost of capital; and,
- Mis-measuring health care affordability.

Introduction

In 2018, the World Health Organization published a report titled *Pricing of cancer medicines and its impacts* (WHO report).[1] The findings of this report were also the basis for an accompanying JAMA Network Open article by Tay-Teo et al. (2019).[2] One of the highly touted findings of the WHO review concludes that pharmaceutical companies received an average return of $14.50 for every dollar invested into research and development.[3] Based on this multiple, the analysis concludes that "lowering prices of cancer drugs and facilitating greater competition are essential for improving patient access, a health system's financial sustainability, and future innovation."

There are material flaws in the WHO's methodology. The purpose of this *Issue Brief* is to highlight these errors in order to demonstrate that the pricing conclusions of the study warrant skepticism. As part of this review, this *Issue Brief* uses the data reported by the WHO to recalculate the reported revenue multiple. The purpose of these calculations is to illustrate that the methodological flaws meaningfully alter the report's conclusions.

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Before discussing the flaws, it is important to emphasize two issues. First, the calculations made in this *Issue Brief* are based on the average data that are reported in the WHO analyses. Since the data reported by the authors are "median data", and without access to the original database, the values calculated by this *Issue Brief* only provide insights regarding how much the methodological errors meaningfully change the analyses' conclusions. The calculations should not be interpreted as a more accurate revenue multiple.

Second, the WHO "extracted itemized annual sales data for each cancer drug from the year of FDA approval to 2017." Sales data is not equivalent to net income (or profits). As the WHO analysis itself documents, all of the companies' costs (not just the R&D costs) must be covered by the sales revenues. Therefore, when the authors describe their results using the nomenclature "cumulative income", "average return", and "sales income", these descriptions are vague at best. These descriptions create an impression that the returns are profits when they are not. It is more precise to refer to the WHO estimate multiple as a "total sales multiple" or a "total revenue multiple" rather than an "average return" multiple.

The WHO "$14.50 Multiple"

Quoting the methodology as reported in the JAMA article, the authors state that "for R&D costs of cancer drugs, we used the estimates presented in a 2017 study that calculated the median risk-adjusted R&D cost as $794 million (range, $219-$2,827 million). This range is comparable with estimates quoted by the pharmaceutical industry." The authors then estimated the cumulative global sales income for the drugs they examined between 1989 and 2017, which they reported as $1.217 trillion. The authors then claimed that

> Based on a risk-adjusted R&D cost of $794 million ($2,827 million-$219 million), by the end of 2017, $1 (risk-adjusted) invested for R&D of the 99 drugs had generated a median of $14.50 (range, $3.30-$55.10) in sales income for the originator companies.

This multiple is then presented as evidence that the global income stream from cancer drugs is excessive, and should be reduced. The remainder of this *Issue Brief* demonstrates why the results of the WHO analysis, in no way, supports such a conclusion.

Data Biases

There are two fundamental methodological errors evident in the WHO analyses that invalidates its conclusion, both of equal importance. The first of these flaws arises because the authors introduced an unknown, but likely meaningful, bias when they were selecting the sample of drugs to evaluate. According to the WHO report:

> To systematically assess the financial return of cancer medicines, this report undertook a study to quantify the reported global incomes from the sales of individual medicines approved by the US FDA in 1989–2017 for the treatment of haematological cancers, solid tumours and related conditions such as neutropenia and hypercalcaemia (117). Itemized product sales data were extracted from the consolidated financial reports of originator companies, supplemented and verified with publicly available sources where necessary. Sales incomes were reported net of rebates and discounts but without accounting for expenses and taxes, as per International Financial Reporting Standards.
>
> ***Of the 156 US FDA-approved cancer medicines identified, 99 had data for more than half of the years since approval and were included in the analysis***. Total sales from this set of medicines (US$ 106.9 billion) represent 80.4% of the estimated global revenue of cancer medicines in 2017 (US$ 133 billion) (18). (emphasis added)

The emphasized text demonstrates the first concern. The intention of the study was to quantify the sales data of all cancer medicines approved by the FDA between 1989 and 2017. However, the study eliminated 37 percent of the study population because these medicines had insufficient data associated with them. Why these medicines had insufficient data is unknown. A probable explanation is that many (perhaps all) of these medicines were not commercially successful. If the most commercially unsuccessful medicines were excluded from the analysis, then the remaining study population will be biased toward a higher total sales revenue multiple over R&D costs – the commercially unsuccessful medicines required the same amount of R&D expenditures, but generated much fewer revenues.

In fact, in the JAMA article, the authors listed this issue as a limitation of their study. Specifically, a "sensitivity analysis incorporated full R&D costs but 0 sales incomes for the 57 drugs excluded in the base-case". The sensitivity analysis found "that the overall income return per R&D dollar remained high ($8.80)." Whether or not the sales revenue returned per R&D dollar invested "remained high" in the judgement of the authors, the sensitivity analysis estimated a revenue multiple, which incorporates the R&D expenditures of the omitted drugs, that is 39 percent lower than the reported value. Without accounting for the other methodological flaws, a potential 39 percent variation in the central estimate of the paper raises fundamental concerns about the finding's applicability.

Due to the significant change in the revenue to R&D ratio, Table 1 provides the illustrative calculations to demonstrate how this bias is leading to the large difference cited by the authors themselves and provides a sense of how large an impact this bias has likely introduced.

The first section of Table 1 creates an estimate for total sales revenues per drug based on the assumed median R&D costs of $794 million, and the estimate average return of $14.50 in sales revenue between 1989 and 2017 for every $1.00 spent on R&D. Multiplying these estimates together equals an estimate of the total cumulative sales revenue per cancer drug between 1989 and 2017, or $11.513 billion.

Applying the $11.513 billion sales revenue estimate to the range of R&D costs the WHO considered (between $219 million and $2.8 billion), creates the range of sales revenue multiples listed in Table 1, Section 1 ($4.07 billion and $52.57 billion).

The second section of Table 1 extrapolates these per drug costs across the 99 drugs that the WHO actually evaluated. Depending upon the R&D cost scenario, the aggregate estimated R&D costs would range between $21.7 billion and $279.9 billion, with the WHO assumed value equaling $78.6 billion.

Applying the relevant sales multiple estimated in Table 1, Section 1 to the aggregate estimated R&D costs equals the total cumulative sales revenues over the 1989 through 2017 time period, or $1.139 trillion. This value is slightly lower (-6.3 percent) than the total cumulative sales revenue reported by the WHO of $1.217 trillion. For informational purposes, Table 1, Section 2 reports the revenue multiple that would be consistent with the reported cumulative revenue data points.

"The purpose of calculating the cumulative revenues was to create an estimate that is comparable to the revenue multiple that would have been reported had the WHO incorporated the additional R&D expenditures into their analysis.

The purpose of calculating the cumulative revenues was to create an estimate that is comparable to the revenue multiple that would have been reported had the WHO incorporated the additional R&D expenditures into their analysis. Table 1, Section 3 evaluates the impact on the revenue multiple assuming that all 57 of the excluded medicines generated no revenues (the same assumption used in the JAMA study sensitivity analysis).

As Table 1, Section 3 illustrates, incorporating the R&D costs of all of the potential medicines reduces the estimated revenue multiple by 37 percent, similar to the value reported in the JAMA study.

The re-creation of these calculations makes it clear why the variation in the estimated multiple is material and raises serious doubts regarding the accuracy of the WHO estimates. Effectively, incorporating the 57 excluded drugs incorporates an estimate for the cost of medicines that were commercially unsuccessful into the analysis – a consideration the WHO analyses overlook. When the cost of commercial failure is included, and using the same assumptions employed in the WHO analysis (e.g. the excluded medicines contribute no revenues), the aggregate R&D costs are 58 percent larger than the author's calculations without any subsequent increase in revenues from the medicines. Put differently, the decision to exclude 57 drugs from the analysis caused the WHO to seriously underestimate the aggregate R&D costs and, consequently, seriously overestimate the sales revenue to R&D expense multiple.

These large discrepancies demonstrate that the findings are afflicted with a large potential bias that is not trivial, and raises doubts regarding the finding's reliability.

Table 1: Illustrate Calculations Quantifying the Bias Introduced by Excluding Commercially Unsuccessful Medicines

	R&D COST SCENARIO		
	LOW	WHO ASSUMED MEDIAN COSTS	HIGH
Section 1			
Risk-adjusted R&D costs (millions)	$219	$794	$2,827
Study sales multiple to R&D costs		$14.50	
Sales Revenues (millions)	$11,513	$11,513	$11,513
Implied Sales Revenue Multiple	$52.57	$14.50	$4.07
Section 2			
Total R&D Costs in millions (over the 99 drugs evaluated)	$21,681	$78,606	$279,873
Calculated Cumulative Revenues (in millions)	$1,139,787	$1,139,787	$1,139,787
Sales Revenue Multiple	$52.57	$14.50	$4.07
Reported Cumulative Revenues (in millions)	$1,216,700	$1,216,700	$1,216,700
Sales Revenue Multiple	$56.12	$15.48	$4.35
Section 3			
	R&D Costs for All 156 Approved Medicines Assume Missing Data at 0% Revenues		
Total R&D Costs over all approved medicines	$34,164	$123,864	$441,012
Reported Cumulative Revenues (in millions)	$1,139,787	$1,139,787	$1,139,787
Revenue Multiple	$33.36	$9.20	$2.58
Reduction in Revenue Multiple	-37%	-37%	-37%

Accounting for the Time Value of Money

The second of the fundamental methodological flaws arises because the analysis did not properly adjust the sales revenues that were earned over a long time period. In describing their methodology, the WHO stated:

> In total, 99 cancer medicines generated US $1,216.7 billion in cumulative incomes between 1989 and 2017, representing an average return of US $14.50 in sales income (range: US $3.30–55.10) for every dollar invested for R&D, assuming a risk-adjusted R&D cost of US $794 million (range: US $2,827 million; US $219 million) (94).

This is an inappropriate and meaningless calculation because it does not account for the time value of money – a fundamental financial principle. As their description of their methodology confirms, instead of calculating the appropriate present value of the income stream to make the dollars earned in 2017 equivalent to dollars earned in in 1989, the WHO study simply summed the nominal revenues earned on cancer medications between 1989 and 2017. This methodological flaw fundamentally alters the conclusion.

To illustrate how much of a difference this error creates, Table 2 presents the present value of a $1.217 trillion income stream earned equally over 29 years, or an income stream of $42 billion a year. An equal distribution of the costs was used for this example because the actual annual revenue data used by the WHO was not reported.

As Table 2 demonstrates, the present value of this income stream is $417.6 billion, which is significantly smaller than the cumulative income ($1.217 trillion) the WHO reported. A key assumption for a present value calculation is the discount rate used. For the calculation in Table 2, the future incomes are discounted at the average weighted average cost of capital for the biotechnology and pharmaceutical industries (10.48%) as of 2019.[4] Based on the total median R&D costs of $78.6 billion for the 99 drugs the WHO evaluated (see Table 1, Section 2), this implies a sales revenue to R&D expenditures of $5.31. Based on the total median R&D costs of $123.9 billion for all 156 drugs that were approved by the FDA (see Table 1, Section 3), this implies a sales revenue to R&D expenditures of $3.37.

Table 2: Present Value of Sales Revenue Based on Equal Annual Distribution of WHO Estimated Cumulative Revenues

	R&D COST SCENARIO		
	LOW	MEDIAN	HIGH
Cost of capital / Discount rate	10.48%	10.48%	10.48%
Present Value of Sales Revenues	$417,579	$417,579	$417,579
Revenue Multiple (over the 99 drugs evaluated)	$19.26	$5.31	$1.49
Percentage Gap to WHO Revenue Multiple	-63.4%	-63.4%	-63.4%
Revenue Multiple (over all 156 approved drugs)	$12.22	$3.37	$0.95
Percentage Gap to WHO Revenue Multiple	-76.7%	-76.7%	-76.7%

Table 2 illustrates that the failure of t he WHO analysis to appropriately take the present value of the stream of sales revenues caused the study to significantly over-estimate the multiple of the total sales revenues-to-R&D costs. Based on the assumptions used in this *Issue Brief*, the over-estimation is 63.4 percent accounting for just the R&D costs of the 99 drugs evaluated. Including the full R&D costs, the failure to appropriately take the present value of the stream of sales revenues caused the study to over-estimate the revenues-to-R&D cost by 76.7 percent.

Again, it is important to note that these calculations would not equal the actual value that the WHO should have estimated since, presumably, the WHO would use the actual distribution of sales revenues and may have decided a different discount rate would be appropriate. However, this calculation demonstrates that the study's failure to take the present value of the income stream meaningfully over-estimates the value of the sales revenues relative to the R&D expenditures.

Other Flaws

The inaccuracies introduced by inappropriately excluding approved drugs and failing to use the present value of the sales revenue stream, by themselves, invalidates the conclusions of the WHO study. However, there are still other flaws with the analysis that are important to quickly note.

The Study Demonstrates a Fundamental Misunderstanding of Monopoly Pricing

First among these, the WHO demonstrates a clear misunderstanding about microeconomic theory and monopoly pricing. Specifically, the report states "economic theory suggests that a monopolist would ***dictate prices*** of their products as a price maker because there are no close substitutes" (emphasis added). This is not what economic theory states. Monopolists do not ***dictate*** whatever price they want; monopolists establish prices within the constraints of the demand for a product. With respect to cancer medicines, the prices are set by negotiation between the drug manufacturer and either large payers, or for many countries, the government and prices are not dictated by the manufacturer.

The assertion by the authors that manufacturers dictate prices illustrates that they fundamentally misunderstand how current prices for cancer medicines have been established, and illustrates a bias on the part of the WHO. It, consequently, raises important questions regarding whether the recommendations are based on preconceived notions that were founded on faulty economic logic.

Accounting for Value

Second, the study does not adequately incorporate the value created by cancer medicines. Specifically, the study claims that there is "a lack of data to demonstrate benefits in survival and well-being, as well as broader impacts, such as the likelihood of generating financial savings through avoidance of hospitalization." This caveat demonstrates that the WHO's analysis has not adequately incorporated these key value propositions that cancer medications create. These include the benefits that the cancer medicines provide to patients, the impact from these medicines on other costs in the health care systems, the reduction in social costs, and the benefits associated with better cancer treatment and better outcomes in terms of longevity (such as the long-term increase in the 5-year survival rate).[5]

The study's bias against accounting for the value of medicines is further revealed when it claims that "the relative value of a medicine may appear to be very high when comparing against an inefficient current practice, even though the absolute magnitude of benefits of the medicine is low (i.e. marginal benefits)." Such a claim is self-contradictory. If a medicine increases value relative to current practice, then its marginal benefit is, in fact, high.

Attempts to convolute an otherwise straightforward concept illustrates the unwillingness of the WHO analysis to incorporate any potential value improvements from cancer medicines into the analysis.

Incentivizing R&D

Third, the analysis demonstrates a clear misunderstanding of the R&D process and the incentives required to fund future research. Incenting future research requires that the innovative pharmaceutical company cover its cost of capital. The concept of recouping the costs of capital is a difficult topic that is widely misunderstood.

Clearly, past R&D costs are sunk costs – regardless of the medicine's clinical benefits or commercial success, these costs cannot be changed. Therefore, for any individual medicine, it is not possible to focus on recovering the cost of capital. However, the fact remains that any innovator manufacturing company will become an unviable entity and will cease operating if it cannot, on average, price in a manner that covers its costs of capital. The purpose of granting innovative manufacturers market exclusivity is to give them the opportunity to cover its overall costs of capital. This opportunity is the positive incentive that encourages innovative manufacturers to take the large risks associated with the drug research and development process, and create new medicines that improve overall patient welfare.

> "By failing to account for the actual cost of capital for the innovative pharmaceutical companies and then over-estimating the sales revenue generated relative to the R&D costs, the WHO analysis inappropriately concludes that "the financial returns from cancer medicines and other government incentives have at least mitigated the high failure rates for cancer medicines R&D."

If the system is working correctly, after a sufficient opportunity has been granted to recover the costs of capital, actual or potential competitors should be empowered to foster a more competitive market. These competitors are the generic or biosimilar medicines that will sell at a significant discount to the patented or originator products. Consequently, once the exclusivity period has expired, the average prices for the medicines should decline and should now reflect a competitive market. The actual decline experienced in a specific country will vary depending upon the country specific policies and the extent that the government enables a competitive market to develop in these products.

By failing to account for the actual cost of capital for the innovative pharmaceutical companies and then over-estimating the sales revenue generated relative to the R&D costs, the WHO analysis inappropriately concludes that "the financial returns from cancer medicines and other government incentives have at least mitigated the high failure rates for cancer medicines R&D." The analysis continues to claim that

> At this point in time and for cancer medicines, the concerns that lower medicine prices might impair future R&D might be misplaced because (1) prices of cancer medicines bear little or no relationship with R&D costs (i.e. no observable linkage between prices and R&D costs); (2) financial returns from cancer medicines are high; (3) potential impact on revenue due to lower prices could be offset by higher volume, especially when the marginal cost of production is low; (4) governments and the non-profit-making sector have made substantial contributions to the R&D of medicines through direct funding and other incentives such as R&D tax credits or reductions.

These conclusions reveal another misunderstanding with respect to companies' cost of capital. Companies allocate their research and development investments across a portfolio of products. Some of these efforts will succeed, others will fail. The successful products must cover the capital costs for both the successes and the failures. This is a major cost for companies, and the narrow approach employed by the WHO analysis fails to consider these costs.

Since the WHO analysis cannot credibly make these conclusions, the WHO's pricing recommendations create a risk that the ability of innovative pharmaceutical manufacturers to cover their cost of capital will be significantly impaired. Consequently, in contrast to the claims of the study, the incentive for future R&D could be jeopardized if the WHO recommendations were followed.

Pricing and Affordability

Finally, there is a common misperception regarding pricing and drug affordability that the WHO analysis perpetuates. According to the WHO:

> Applying this broad framework to the context of cancer medicines, an optimal pricing policy should facilitate the supply of cancer medicines to patients in need, in a fair and timely manner without compromising the quality and safety of medicines. It must ensure ***overall affordability to individual patients*** with cancer over the full course of treatment. A health system must also be able to maintain its financial sustainability so that spending on cancer medicines would not divert resources required for the provision of other essential health products and services. (emphasis added)

To measure affordability, the WHO uses "the number of days' wages needed to pay for the cost of treatment". Putting the costs in the context of an individual's wages does not help understand the affordability of medicines. Affordability is not based on individual ability to pay, but on basic principles of insurance. As applied to health care, (depending upon the national system) people will either purchase insurance through private arrangements or receive the treatment from government provided

care because the costs associated with experiencing the adverse event are exceptionally high. Connecting affordability to individual wages contradicts the principles of insurance that would promote greater coverage and increased medical value.

Conclusion

In its report, "Pricing of cancer medicines and its impacts", the World Health Organization (WHO) inappropriately excluded medicines that would have reduced the total sales revenues earned, failed to account for the time value of money, undervalued the innovative benefits of the cancer medicines, and failed to account for the actual costs of capital required to develop innovative medicines. Put more simply, the WHO employs a flawed methodology for measuring the value of medicines.

Due to its flawed methodology, the WHO undervalues the health benefits provided by these cancer medications and erroneously concludes that the price of cancer medicines is excessive relative to their R&D costs and the value that these medicines provide. The conclusion reinforces common misunderstandings regarding the pharmaceutical market and, without changes, the deficiencies that underlie the WHO's methodology will encourage governments to adopt even more stringent price controls on medicines. The resulting prices would be uneconomically low and, as a result, would meaningfully diminish the incentives for future medical innovations. Under such a scenario, future patients will suffer as potential life-saving improvements will be jeopardized.

Endnotes

1 (2018) "Pricing of cancer medicines and its impacts" *WHO Technical Report*.

2 Tay-Teo K, Ilbawi A, and Hill SR "Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies" *JAMA Network Open* 2019;2(1).

3 Ibid.

4 The weighted average cost of capital is the estimate provided by NYU Stern Business Professor Aswath Damodaran; http://www.stern.nyu.edu/~adamodar/New_Home_Page/data.html.

5 "Survival" *National Cancer Institute: Cancer Trends Progress Report*, Data Up to Date as of: February 2019; https://progressreport.cancer.gov/after/survival.

About the Author

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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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