

Is health technology assessment the solution to our problem?

Published on: May 20, 2025

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Here I will summarize the themes I observed and will opine on what I think it means for the US healthcare landscape.

EYE OF THE BEHOLDER

The worlds of R&D and HEOR are beginning to talk (finally). This is long overdue, and we need a lot more of it. Despite the limited, yet growing, presence of investors and development-stage companies at the conference, there was much greater acknowledgement of the investment in R&D in the presentations and Q&A sessions.

The theme of the conference was centered around improving decision making for all and expanding HEOR horizons. More so than in prior conferences, it was clear that investors and early-stage companies were included in this. The opening plenary was titled “[Drug Price Controls—What Are the Unintended Consequences to Innovation?](#)” and included HEOR respected leaders talking about the potential consequences of government intervention in a market-based system.

The plenary speakers provided the facts:

- R&D is responsive to revenue. More revenue equals more innovation. There is uncertainty in the precise relationship between the two, [but the fact is that the relationship is positive](#). Interventions that reduce revenue will have tradeoffs in lost innovation.
- Lost innovation can be very impactful to patients. When evaluating the impact of new policies, not only should the quantity of lost innovation be assessed, but also the quality of what is lost.

Related to the [Most Favored Nation Executive Order](#), the speakers explained that:

- Companies can't simply go to other countries and tell them that there is now a higher price. There are contracts in place and limitations to “negotiating” with a government.
- An implemented Most Favored Nation policy could raise ex-US list prices while keeping the confidential net prices the same, could result in new products not being launched in some

markets, and could result in products being withdrawn from some markets.

- Outcomes of an implemented Most Favored Nation policy could include a reduction in global access to innovation, a reduction in global health, and prices in the US staying the same.
- The negative risks of these policies could be quite large, yet the positive benefits are likely limited.

So why is Most Favored Nation pricing politically appealing? The panelists said:

- The benefits of price controls are highly visible and occur in the short term (i.e., can occur before the next election cycle).
- The downsides of lost innovation take a long time to see and are often invisible to voters.

When asked what a “better” policy would be as it seems something is inevitable, panelists suggested:

- Multiple and competing [health technology assessment bodies in the United States](#) to suggest a range of potential prices.

SO WHAT

The calls for formal US health technology assessment bodies extended beyond the plenary. Despite my sincere appreciation for the goals of health technology assessment and my belief in the importance of a strong value proposition, I fear this may not solve the underlying problem driving the need for healthcare reform in the United States. Dr. Darius Lakdawalla eloquently stated during the plenary that we have a healthcare budget that is “outstripping our ability to pay for it”. Substantial costs passed on to patients and increasing health insurance premiums are related issues. Multiple and competing US health technology assessment bodies may not solve these underlying issues.

First, health technology assessment is typically focused on branded prescription drugs, not the total healthcare budget. Recent estimates suggest that spending on prescription drugs in the United States represents only around [10% of healthcare spending](#). In a [report by Sood et al.](#), it was reported that for every \$100 spent on prescription drugs through the US retail distribution system, only \$15 was kept as net profit by the manufacturer (so around 15% of the spending on prescription drugs was manufacturer net profit). If the approximate 15% manufacturer profit was cut entirely from the 10% of total healthcare spending that is on branded prescription drugs, that would not substantially reduce total healthcare spending although it could substantially reduce the incentives for biopharma innovation. [Note: These aren’t perfect numbers. Drug prices and the drug supply chain are confusing and not transparent, but I think the point I am trying to make still holds].

Second, many health technology assessment bodies use cost-effectiveness analysis to inform their decision making. Just because something is found to be “cost-effective” does not mean that it will not have a large budget impact. There are many instances in which the US market-based approach secured a lower price for a drug than conventional cost-effectiveness analysis might suggest. Check out our [CPE Exclusive on Entresto®](#) for one example of this.

Third, there were calls for multiple health technology assessment groups in the US to capture the uncertainty and variability in the approaches to health technology assessment. You might envision one health technology assessment body taking a therapeutic benefit approach, one health technology assessment body taking a conventional cost-effectiveness analysis approach, and maybe even one health technology assessment group using [generalized cost-effectiveness analysis](#) to take a broader societal perspective and capture changes in a drug’s price. In theory, these different groups would set bounds of “value” for a new drug. I appreciate this suggestion in that it would use US values and provide wide bounds of “value.” However, it would require substantial resources and infrastructure to establish multiple health technology assessment bodies, and it could have a limited impact on total healthcare spending. Based on the six CPE Exclusives we have conducted (caveat: we have only conducted 6 and this is not a fully representative sample), the US market-based price was already between a potential lower bound conventional cost-effectiveness analysis estimate and a potential upper bound generalized cost-effectiveness analysis estimate.

Fourth, although [I am a supporter of a dynamically efficient system](#) that promotes the optimal amount of innovation and uses resources efficiently, the methods are still being developed. Consensus and robust supporting evidence on the “[optimal share of the long-term value of new pharmaceutical products to offer to manufacturers](#)” does not yet exist. Similar concerns exist around a threshold (or thresholds) for cost-effectiveness analysis, especially as it relates to alternatives to the quality-adjusted life year (QALY) or the inclusion of societal impacts.

I completely agree with the need to use evidence to inform decisions and to assess the impacts of healthcare innovations, but I see this as addressing a separate issue. We must also keep sight of ways to address an increasing total healthcare budget without passing large out-of-pocket costs to people in need of health care and without reducing the incentives for innovation. I am not a policy expert, so I welcome suggestions here, but focusing only on branded drug spending to pharmaceutical manufacturers is likely not going to solve all our problems.