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Drug Pricing: With "Value" Debate In Full Swing, ICER's Influence Grows

by Melanie Senior

The Institute for Clinical and Economic Review has invited feedback on its methodology for calculating a drug's recommended price range. Industry response has been critical, but pharma can no longer afford to merely oppose value frameworks. It needs to create strategies for a world in which such frameworks are a permanent and influential part of the pricing and reimbursement landscape.

"We are not out to strangle the industry," insisted Steven Pearson, president and founder of ICER (the Institute for Clinical and Economic Review), during an interview in late 2015. "We're just out to create a framework for having a dialogue around drug price and value," he continued.

One year on, and that dialogue is certainly in full swing in the US. Industry might well be in the line of fire, but ICER's not the only one shooting. ICER reviews the cost-effectiveness and affordability of high-profile new drugs, and has indeed concluded that many of them are priced well above what might be considered value-for-money. But a series of massive drug price hikes from companies like *Turing Pharmaceuticals AG*, *Valeant Pharmaceuticals International Inc.* and *Mylan NV* has also put drug pricing front and center in an already heated US political climate. Presidential candidate Hillary Clinton is proposing a series of measures to curb excessive price increases and supports Medicare's right to negotiate prices. (Also see "*Clinton's Drug Price Plan: Threat Or Flash In The Political Pan?*" - Pink Sheet, 2 Sep, 2016.) California is balloting its citizens as to whether the state government should have the right to pay no more for drugs than the Department of Veterans Affairs, typically the lowest price watermark in the US. As *Novartis AG*'s CEO Joe Jimenez recently conceded to the UK *Financial Times*, "No matter which candidate wins, we will see a more difficult pricing environment in the US" after the election.

Organizations such as ICER, a non-profit group with no statutory authority at all, are adding fuel to the fire. Manufacturers including *Amgen Inc.*, *Bristol-Myers Squibb Co.* and *Roche* are stinging

from ICER's reports that their drugs are too pricey – even as much as 80% too pricey. Payers don't have to act on them, though some are delighted to have more justification for aggressive contracting positions and stricter coverage restrictions (that could happen with or without ICER). But there's mixed evidence, as yet, that ICER's recommended price ranges are influencing actual prices achieved. (Also see "*ICER Eyes QALY Ratios, Budget Impacts In Methods Review*" - Pink Sheet, 28 Jul, 2016.) "We're still early in the cycle of payers using this information concretely to design payment mechanisms for drugs. It's still pilots and things," admitted Pearson.

More worrisome, however, is the influence ICER reports could have on the Centers for Medicare and Medicaid Services (CMS). That agency's proposal to change the way it pays for Part B drugs (that is, drugs administered by medical providers) includes a suggestion for using value frameworks to help them determine the price paid. (Also see "*Part B Demo Could Save $2.2 Bil., CBO Says; Blocking It Would Cost Less*" - Pink Sheet, 6 Oct, 2016.) And the CMS proposal specifically mentions ICER's reports as potential models.

ICER's methodologies are still evolving. The organization recently invited feedback from all stakeholders, including pharma and patient advocacy groups, on the processes it uses to calculate a drug's recommended price range. Not many other countries' drug cost-watchdogs – many of which have been in place a lot longer – have offered industry the opportunity to influence how drugs are assessed.

ICER's Value Assessment Framework currently comprises two measures: Care Value, which is a measure of a drug's comparative clinical effectiveness and cost-effectiveness, and Health System Value, a measure of the five-year budget impact on health systems. Both together lead to a "value-based price benchmark" – the price at which patients could be treated for reasonable long-term value, without crippling the system short term.

No Shortage Of Critics

Industry responded to ICER's call with a range of criticisms. They included: too much focus on drug costs as the main determinant of health system value; the use of list prices, not actual prices paid, to determine costs; inappropriate use of the budget impact measure; inappropriate use of the quality-adjusted life year (QALY) to measure drugs' cost-effectiveness; overestimates of drug uptake rates; and (from Amgen and BMS, among others) a lack of transparency in the models.

Pharmaceutical companies aren't the only critics. A long list of big and small patient advocacy groups, including the International Myeloma Foundation, the Global Liver Institute, the National Alliance on Mental Health and CancerCare, have also attacked the ICER methodology. Like drug companies, the patient groups complained about ICER's focus on costs – particularly short-term costs – but also that its methodology doesn't reflect the concerns of patients. And while ICER

claims it does listen to – and its reports reflect – such concerns, the groups themselves argue that there's too little transparency to the process.

In part the problem is format: ICER reports are long and detailed – and the easiest point to grasp is what often ends up as the headline of articles reviewing the reports: ICER's suggested value-based price benchmarks. The report formats don't make it easy to compare, head-to-head, the various therapies on all the key efficacy, safety, convenience and economic elements. Nor does the analysis clearly show how the opinions of the groups whose expertise and points of view ICER solicits – like patient advocates – are reflected in the final analysis.

And in part the problem is that an ICER report is not a true database, one in which users can review the same set of facts and increase or decrease their relative importance to more clearly reflect the concerns of different stakeholders. Indeed, this ability to differentially "weight" the various decision-making elements is one of the key attributes of *Memorial Sloan Kettering Cancer Center*'s (MSKCC's) *DrugAbacus* system and the technology behind it. (*See sidebar, "DrugAbacus Gains Money, Sophistication."*)

Setting aside the accusation of lack of transparency (not least given the opacity surrounding how pharma sets prices to begin with), most of those points will be addressed in the revised methodology, according to Pearson. In particular, he promised "substantial changes around how we calculate [a drug's] budget impact." Budget impact attracted a wide range of opinions in the feedback. Some want it restricted to drug costs, not total health care costs; one or two want it to include shorter-term calculations; many more want it to include longer-term calculations; and several drug firms would rather scrap it all together as a component of Health System Value, since, as stated in Amgen's feedback, "It is not a measure of value."

DrugAbacus Gains Money, Sophistication

By Melanie Senior

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In February 2016, the non-profit Laura and John Arnold Foundation donated $4.7 million to Memorial Sloan Kettering Cancer Center's Evidence Driven Drug Pricing Project, home of the *DrugAbacus*.

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"We'll figure out a way to message aspects of the budget impact potential so they're not overly focused on price," said Pearson. Instead, he continued, they'll look at whether the budgetary hit will be significant enough to justify more focus on patient prioritization, for example, delaying access for some patients.

That's not likely to go down well with everyone either. Nor will Pearson's assertion that the

QALY, a controversial measure of value used most prominently at the UK's National Institute of Care and Health Excellence (NICE), will remain the "anchor" of ICER's cost-effectiveness calculation. Many drug firms, including the industry associations BIO and PhRMA, will continue to kick and scream about that.

They may be consoled, though, by ICER's proposing to move away from using list prices as the basis for calculating costs and thereby value-based benchmarks. List prices don't reflect the real prices paid for drugs, given (often significant) rebates and discounts negotiated in the marketplace – including by Medicare and Medicaid. "We will do something different ... around pricing," promised Pearson.

ICER's revised approach, due to appear in December 2016, will invite a second round of public comment.

All measures of value are complex, and involve a certain amount of judgment, as well as sophisticated health economic modeling tools. That's clear not just from the depth and breadth of discussion and commentary around ICER's work, but also from the characteristics and limitations of other value-based pricing tools that have emerged over the last year or two. (Also see "*Scoring Value: New Tools Challenge Pharma's US Pricing Bonanza*" - In Vivo, 21 Oct, 2015.) These include *DrugAbacus*, conceived by Peter Bach, MD, director of the Center for Health Policy and Outcomes at MSKCC, the *Value Framework,* established by the American Society of Clinical Oncologists (ASCO); and the National Comprehensive Cancer Network's *Evidence Blocks*, upgraded to include cost and affordability in clinical practice guidelines.

These tools aren't perfect, or comprehensive. They're all limited to cancer drugs, for starters; ASCO's framework, primarily for clinicians, only scores drugs that have been compared in head-to-head trials. But their existence, and the discussions around them, have provided a helpful level of debate – beyond catchy newspaper headlines and outraged tweets – around the factors that should influence drug pricing.

Pricing Tools Are Here To Stay

Value-based pricing tools won't go away. Existing versions are being sharpened. Several payers and a fast-increasing number of drug companies have been working with the *RxScorecard*, a web-based, interactive value-assessment tool from Real Endpoints, which provided the technological backbone and some of the research behind DrugAbacus. (Editor's note: Real Endpoints has partnered with *In Vivo*'s parent company Informa.) Based on the concept of multi-criteria decision analysis, RxScorecard establishes a flexible set of weighted value-elements for each disease category and then transparently scores each element based on publicly available data. Each element's weight can be varied based on how the user sees its relative importance – and those differential weightings will change the relative value scores (e.g., a patient group might weight a particular aspect of convenience more heavily than a payer or a physician group, which

might preferentially weight one of the efficacy elements).

And new value frameworks are in the works: consultancy Avalere Health and medical research accelerator FasterCures are developing a value tool that primarily represents the patient perspective. The *Patient Perspective Value Framework* will be published in June 2017. (Also see "*As Drug Value Frameworks Gain Traction, Patients Seek More Input*" - Pink Sheet, 28 Sep, 2016.)

Meantime, ICER's influence will continue to spread, even if the CMS proposal around Part B drugs never materializes. Clinton's proto-administration has been on the phone a few times, too, noted Pearson. Meanwhile, NICE, considered by many as a global benchmark in cost-effectiveness assessment, recently released proposals to include budget impact in its drug reviews too; something it hasn't done to date.

All of ICER's drug assessment work is funded by non-profit, objective sources, and will continue to be, insisted Pearson. ICER was turbo-charged in 2015 by funding from the Laura and John Arnold Foundation; it's currently in its second year of the two-year donation. Given the waves that ICER is making, it's unlikely to find itself short of financial contributors, though. "We still intend to grow," said Pearson.

Indeed, value frameworks are here to stay. The key for biopharmaceutical companies is to figure out how to use them. A number of drug firms have begun to employ them to vet their own pipeline agents, internally exploiting the outside assessment tools to objectively measure their relative value against marketed and competitive pipeline therapies or to uncover subpopulations in which their agent has a significant therapeutic advantage. Other companies are looking to expand the focus of value frameworks from the one-size-fits-all approach to a methodology that allows different responses based on the needs of the different customers – patients, providers, payers (and indeed the different flavors of each of those groups).

What is eminently clear, however, is that drug firms can no longer afford to merely oppose value frameworks. They have to create strategies for a world in which they are a permanent and influential part of the pricing and reimbursement landscape.