What happens when government agencies and health care providers disagree on the value of medical treatments?

The question bears growing importance in light of new federal policy that would allow Medicare to negotiate prescription drug prices. The Inflation Reduction Act of 2022, signed into law by President Joe Biden, authorizes the Centers for Medicare & Medicaid Services to negotiate prices for certain medications under Medicare Parts B and D. The Congressional Budget Office estimates that the law will reduce the federal deficit by $237 billion over 10 years.¹

But sometimes cost savings comes at the expense of health care quality.

Recent research confirms that governments define medication value differently than physicians do. The difference in perspectives and priorities could lead to unintended consequences for patients as price negotiations allow governments to override physicians’ judgement.
In 2022, to explore the gap between U.S. physicians’ definition of value and the value notions of governments that engage in price negotiations, researchers looked to Germany. The country’s Federal Joint Committee, or G-BA, makes value assessments and also serves as the centralized decision-making body in Germany’s health care system.

The study asked 350 U.S. physicians, including gastroenterologists, rheumatologists, oncologists and dermatologists, to consider the “level of benefit” of medications used to treat one of three diseases: ulcerative colitis, psoriatic arthritis or multiple myeloma. The physicians’ ratings were then compared to the government valuation of those same medications for similar patients.

Just 10% of surveyed U.S. physicians agreed with the G-BA’s negative assessments of innovative medications for these diseases. The overwhelming majority disagreed: 93% of surveyed physicians disagreed with the G-BA assessment of ulcerative colitis medications. Of those who disagreed, 90% thought the medications had additional benefits for patients.

90% of surveyed physicians disagreed with the G-BA assessment of psoriatic arthritis medications. Of those who disagreed, 88% thought the medications had additional benefits for patients.

94% of surveyed physicians disagreed with the G-BA assessment of multiple myeloma medications. Of those who disagreed, 93% thought the medications had additional benefits for patients.

94% of surveyed U.S. physicians disagreed with the G-BA’s negative assessment of innovative diabetes medications. Of those who disagreed, 97% said the medications provided additional clinical value for patients with diabetes.

These findings echo similar 2019 research, which found that:

- 89% of surveyed U.S. physicians disagreed with the G-BA’s negative assessment of innovative diabetes medications.
- Of those who disagreed, 97% said the medications provided additional clinical value for patients with diabetes.

A Fundamental Mismatch

The findings reveal a wide gap between government-level definitions of value and the real-world experiences and values of actual physicians.
How could the government-level assessment and the opinions of physicians differ so greatly?

Perhaps because they have very different priorities and perspectives.

When asked about broader value considerations, physicians identified factors such as:

- Unmet needs
- Ability to extend life long enough for the next treatment to become available
- Route of drug administration
- Frequency of drug administration
- Indirect benefits, such as the ability of the patient or caregiver to work

### Physicians Who Value Broader Medication Benefits

**By Disease State Being Treated**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Ulcerative Colitis</th>
<th>Psoriatic Arthritis</th>
<th>Multiple Myeloma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmet needs</td>
<td>95%</td>
<td>94%</td>
<td>73%</td>
</tr>
<tr>
<td>Ability to extend life long enough</td>
<td>89%</td>
<td>87%</td>
<td>71%</td>
</tr>
<tr>
<td>for the next treatment to become</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of drug administration</td>
<td>87%</td>
<td>81%</td>
<td>71%</td>
</tr>
<tr>
<td>Frequency of administration</td>
<td>82%</td>
<td>77%</td>
<td>58%</td>
</tr>
<tr>
<td>Ability of patient or caregiver to</td>
<td>85%</td>
<td>79%</td>
<td>63%</td>
</tr>
<tr>
<td>work</td>
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</table>

Factors like these impact physicians’ ability to personalize treatment based on a patient’s health history, lifestyle and personal preferences. Physicians’ responses also reflect the importance of clinical nuance. In real-world settings, physicians must consider patient allergies, drug-to-drug interactions or logistical limitations that impact how frequently a patient can visit the clinic.

By failing to incorporate these factors, Germany exemplifies how government-level value judgements may exclude the treatment benefits that matter most to practicing physicians — and their patients.
Governments and physicians don’t just prioritize different factors; they also approach the question of value from two very different perspectives.

Physicians are individual professionals who have regular interactions with and care about their patients. Their analyses are science based but patient specific, and their definitions of health care value are naturally holistic, including both quantitative and qualitative factors.

Governments and health technology assessment organizations have a different scope.

In the example of Germany, the Federal Joint Committee states its primary role as specifying “what adequate, appropriate, and cost-effective healthcare means as defined by German law.”

As with other regulatory bureaucracies, the focus is on high-level outcomes and aggregated data analysis that impact the overall health care system.³

Simply put, government value assessments are concerned with the overall system, while individual physicians are concerned with their specific patients.

Value assessment organizations tasked with assisting the government in implementing the Inflation Reduction Act’s price negotiation provisions must find ways to meaningfully incorporate the views of physicians and their patients.
Inability to access new treatment when patients need it. In the UK, for example, it takes approximately 14 years for a newly approved cancer treatment to become available to patients. In the United States, Medicare Part D plans are required to cover drugs selected for price negotiation, but there are no policies to protect access to other medications. Health plans could use formulary design or utilization management tools like prior authorization and step therapy to make other medications, including innovative drugs, harder to access.

Less personalized care as physicians feel compelled to chart treatment courses based on pricing and coverage. Physicians may feel pressured to prescribe whichever drug carries the lowest price as a result of Medicare negotiation, even if that option is not the best fit for a particular patient. Meanwhile, utilization management barriers, which already undermine patient-centered care for Medicare beneficiaries, could grow worse.

More frequent non-medical switching, where health plans drive stable patients from their prescribed medication to an alternative that’s more profitable for the health plan. Non-medical switching can lead to new side effects, re-emerging symptoms and interactions with other medications. Of surveyed patients who’d experienced non-medical switching, almost 60% experienced a complication from their new medication and one in 10 required hospitalization.

Impact on U.S. research and development and innovation. The EU’s research investment was, historically, higher than the United States’ by 24%. After the EU adopted price controls in the early 2000s, research and development in the EU fell behind that of the United States by 15%. Economists at the University of Chicago have already predicted that the Inflation Reduction Act may lead to 135 fewer new drugs being brought to market over the next 20 years. Because many medications are ultimately approved to treat multiple conditions, a reduction in new medications will have a ripple effect on patients across disease states.

The Inflation Reduction Act stands to have a multifaceted impact on how drugs are developed and which drugs are available to patients. Understanding the difference in value definitions among governments, health technology assessment organizations and physicians is critical.
As the Inflation Reduction Act takes effect, policymakers should be mindful that limited definitions of value could yield unintended consequences — reducing patient access instead of improving it.

As the research detailed above illustrates, government-led value assessments often differ from those of physicians. They regularly fail to capture the full picture of a drug’s benefits to patients. Decision makers must recognize these potential pitfalls in advance and be prepared to chart a path forward that accounts for the needs of real individual patients, not just budgets and health care systems.
References


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