

Pharmaceutical Executive

Taking Hold of the Wheel

Healthcare decision makers do not consistently consider drugs' value. FDA needs to be pressured to change its stance on communicating economic evidence. Pharma is in the driver's seat.



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As anyone who rushed out to buy an ultra-cheap Yugo can tell you, there is a huge difference between cost and cost effectiveness. And while any smart car buyer understands this point, it is a concept that has yet to take hold at many managed care plans or public agencies charged with making drug coverage and reimbursement decisions.

In drugs, as in cars, there is often a more expensive, yet more cost effective, alternative available. For example, the cheapest drug for a particular ailment may require so many doses that it produces low compliance rates. A higher cost, once-a-day drug may appear comparable based on clinical efficacy, but be more effective in practice.

There is little doubt that patient compliance, tolerability, quality of life, work productivity, and reduced absenteeism all contribute to a drug's true effectiveness. These factors determine its overall value to patients, to their families, to payers, and ultimately, to society at large.

Despite this, FDA's cautious approach to allowing manufacturers to communicate the economic value of drugs is contributing to an already poorly informed healthcare industry, and may be curtailing consumer access to useful drugs. Even those familiar with drug regulation are probably not fully aware that FDA is completely out of step with accepted health services research and economic standards in the area of economic evaluation.

In contrast, informed healthcare observers realize that cost plays a key role in drug coverage and reimbursement decisions. When several drugs exist to treat a given ailment, it is often the product with the lowest acquisition cost that will be seen most favorably—despite other positive qualities of the more expensive product.

The reality is that healthcare decision makers do not consistently consider a drug's value. This problem does not stem from the lack of available evidence, but rather, from a sort of pincer movement—from FDA's restrictive policies on one end, and the payers' silo mentality on the other.

On FDA's end, manufacturers are effectively barred from efficiently communicating the value of their products to the

Yet, this avenue also has limitations. Many payers are either not requesting the Format, or do not have confidence in the validity of manufacturers' economic evaluations. This is unfortunate because these evaluations can help deliver good value for the considerable money payers are spending on behalf of their beneficiaries.

More realistic policies about communicating legitimate economic-evaluation evidence are in order. FDA should:

- » Educate its own staff on the value of the economic evaluation methods.
- » Provide guidance by drawing on other knowledgeable resources, such as the Agency for HealthCare Research and Quality, CDC, CMS, and the Office of the Assistant Secretary for Planning and Evaluation.
- » Craft promotion policy that allows, with disclaimers, economic evaluation.
- » Seek congressional approval if FDA has no authority to permit the promotion of the economic value of drugs.

None of this will happen without direct support and pressure from pharma. Manufacturers must be willing to stand

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market. High-quality economic evaluations are labeled "false and misleading" if a manufacturer uses them in a promotional way. FDA will only allow promotional claims that stem from randomized-controlled trials (RCTs) performed in support of approved indications.

Of course, payers can request economic evaluations from manufacturers. In this case, manufacturers are complying with an "unsolicited request," which is permitted by FDA. This is done, most effectively, via the useful "Format of Formulary Submission of Clinical and Economic Data," crafted by the Academy of Managed Care Pharmacy (AMCP).

up for the importance of communicating evidence of value to their customers.

Once FDA accepts economic evidence as legitimate, credibility among payers should be enhanced—but this alone will not suffice. The pharmaceutical industry must adhere to accepted economic evaluation guidelines, and seek partnerships with MCOs in designing and evaluating studies. Economic evaluations always require data, and often require judgment and assumptions. By partnering to use the payers' own data, agreeing on assumptions, and engaging in full transparency, manufacturers can promote decisions based on value. ■

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