

## **Value-Based Purchasing and Comparative Effectiveness Research : Why the Pharmaceutical, Biotechnology, and Medical-Surgical Device Industries Should Embrace the Coming Market Evolution**

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### **Abstract:**

For a number of years, the discipline of health economics has assisted healthcare stakeholders in making informed evaluations of treatment alternatives. More specifically, health economics research quantifies the “value” of therapeutic options through examination of both clinical benefit and costs over an appropriate episode of care, thus framing the clinical benefit in economic terms.<sup>1</sup> The related fields of value-based purchasing and comparative effectiveness evaluations are intended to achieve overall healthcare cost reduction through choosing products with the highest “value.” The methodology for measurement of “value” in both fields is still evolving; however, it is now clear that both value-based purchasing and comparative effectiveness research will significantly impact the way in which pharmaceutical, biotechnology, and medical-surgical products are marketed and sold.

This paper examines the factors leading to the market’s march toward value-based purchasing and comparative effectiveness and makes specific recommendations to pharmaceutical, biotechnology, medical device, and medical-surgical manufacturers regarding the examination of both clinical and economic consequences of their products. These clinical and economic data are becoming critical to the sale of their products to medical facility purchasers, healthcare providers, and payors.

By taking an informed, proactive approach to the evolving market trend regarding value-based purchasing and comparative effectiveness research, pharmaceutical, biotechnology, and medical-surgical manufacturers will help sustain ongoing product innovation and success in the marketplace. Manufacturers and marketing teams that fail to recognize the importance of evaluating both clinical and economic data regarding their products will find themselves at a significant competitive disadvantage.

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<sup>1</sup> Bonk RJ. *Pharmacoeconomics in Perspective*. New York: Pharmaceutical Products Press; 1999:5.

## Value-Based Purchasing (VBP) and Clinical Effectiveness Research: Definitions and Historical Review on Market Impact and Relevance

Value-based purchasing (VBP) refers to the methodology that hospitals and other medical facilities employ to manage their costs while providing high-quality care. VBP efforts offer an opportunity to counter a customer's short-term fixation on price with the long-term consideration of total costs and overall value associated with using a technology or product.<sup>2</sup>

Comparative effectiveness research (CER) refers to analyses that rely on careful selection of outcomes measures for meaningful comparison of alternative therapies.<sup>3</sup> It usually involves taking two or more therapies for the same condition or two or more manufacturers for the same product and evaluating whether, in what manner, and/or for what patient populations one is better than the other.<sup>4</sup>

The United Kingdom, Australia, New Zealand, Finland, and numerous other countries currently employ CER to evaluate pharmaceutical, biotechnology, and medical-surgical products.

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<sup>2</sup> Burns LR, Wharton School Colleagues. *The Health Care Value Chain*. San Francisco, CA: Jossey-Bass; 2002:269.

<sup>3</sup> Bonk RJ. *Pharmacoeconomics in Perspective*. New York: Pharmaceutical Products Press; 1999:36.

<sup>4</sup> Burns LR. Value-based purchasing: Impact on pharma. *American Health & Drug Benefits*. January 2009;2(suppl 1):34S.

### Comparative Effectiveness in the United States

In the United States, the Agency for Healthcare Research and Quality (AHRQ) was established in 2003 to conduct evaluations on comparative effectiveness of products and services. Last year, the U.S. Senate's Comparative Effectiveness Research Act of 2008 authorized the establishment of a nonprofit quasi-government corporation called the Patient-Centered Outcomes Research Institute (PCORI). The aim of PCORI is to conduct patient-centric CER in the field of medicine and to work with medical experts and stakeholders to prioritize interventions and services to be studied.<sup>5</sup> It is currently proposed that CER will be conducted by public and private organizations approved by the Institute. The Obama administration's recent economic stimulus package allocated \$1.1 billion to advance this initiative, aimed in part at comparing alternative treatments for the same disease. Considerable discussion has erupted around whether product costs should be included with clinical outcomes in the comparative effectiveness evaluations. This remains an ongoing debate.

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<sup>5</sup> Shah NR. Evidence standards in the era of comparative effectiveness. *American Health & Drug Benefits*. January 2009;2(suppl 1):46S.

Historically, the pharmaceutical, biotechnology, and medical-surgical device industries have relied on clinical outcomes as the primary means to advance the marketing and sales strategies of their products and brands. Furthermore, manufacturers often have been reluctant to conduct head-to-head comparative effectiveness studies of their products versus alternative treatments, especially when conducting such studies was unnecessary to gain product approval.<sup>6</sup> Today, however, VBP and CER initiatives are beginning to affect pharmaceutical, biotechnology, and medical-surgical brand teams in new and profound ways, forcing the industry to rethink its strategic approaches to product marketing.

In addition to the VBP and CER initiatives, there is also a subtle shift occurring in the marketplace as drug sales are moving away from the consumer/pharmacy market and to the institutional/facility market.<sup>7</sup> As a result, more and more marketing teams are scrambling to devise methodologies to address the increasing VBP requirements among an evolving institutional product acquisition audience. As noted by Lawton Robert Burns, PhD, MBA, Professor of Health Care Management and Chair, Health

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<sup>6</sup> Burns LR. Value-based purchasing: Impact on pharma. *American Health & Drug Benefits*. January 2009;2(suppl 1):34S.

<sup>7</sup> Burns LR. Value-based purchasing: Impact on pharma. *American Health & Drug Benefits*. January 2009;2(suppl 1):33S.

Care Management Department, Wharton Center for Health Economics:

“From 1990 to 2003, retail sales have dropped from 88% to 73% of the total market. Whether they are biologics, institutional drugs, or drugs that have to be infused, this means that more sales will be going into the institutional setting, where purchasers are trying to get hospitals and physicians to collaborate and figure out how to balance the money and technology flows.... This is the threat facing the device and pharmaceutical companies.”<sup>8</sup>

The medical-surgical industry, on the other hand, has historically relied heavily upon technological innovation and a high degree of surgeon preference to drive product uptake and sales. As a result, the prospect of the Health Care Comparative Effectiveness Research Institute has the industry back on its heels, fighting vigorously against this pending market change—especially when it comes to the inclusion of head-to-head cost and/or cost-effectiveness comparisons.

For numerous obvious business reasons, it’s easy to see why the pharmaceutical, biotechnology, and medical-surgical industries are mounting resistance to the looming mandate requiring CER evaluations for some, if not all, of their products.

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<sup>8</sup> Ibid.

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*There is...a highly significant opportunity for pharmaceutical, biotechnology, and medical-surgical manufacturers of higher-priced products who embrace the comparative effectiveness research (CER) process.*

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However, the posture by industry of resisting the evolving VBP and CER migration in the marketplace should be reconsidered by management, because there is in fact a highly significant opportunity for pharmaceutical, biotechnology, and medical-surgical manufacturers of higher-priced products who embrace the CER process. The fact is, as more product sales shift from the retail to the institutional setting, the vast majority of hospital and medical facility purchasing teams are seeking a true VBP approach to product acquisition. Manufacturers who can provide cost and/or cost-effectiveness data will give their customers the information needed to make effective purchasing decisions. Moreover, these manufacturers will “stay ahead of the

sheriff”— that is, ahead of mandated product evaluations over which they may have little or no influence if required by the Comparative Effectiveness Research Institute.

Let’s take a closer look at how and why this market shift is impacting industry.

### **Embracing Change**

Medical facilities in general are moving toward VBP because they have found that the two approaches they’ve used in the past for product acquisition—(1) high-cost product purchasing driven by physicians; and then (2) low-cost product purchasing driven by finance— have both failed as methods of improving bottom-line facility performance.

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*Higher-quality and higher-priced products may result in lower costs over time, but today much more than merely a clinical “inference” about a product’s economic value in a publication is needed to support such claims among purchasers.*

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Initially, facilities took the guidance of their doctors and surgeons, buying

whatever new and costly items physicians wanted. This purchasing approach resulted in poor bottom-line performance. In response, facilities went to the opposite extreme, purchasing the least expensive products available, with a markedly lower regard for physician preference and product innovation. Soon, however, they discovered that this approach also failed to lead to bottom-line improvements, because of the cascade of hidden costs that may be associated with the use of low-price/lower-value products. This could be looked at like a *shower effect* whereby one extreme purchasing swing (innovation only) leads to the next (low-cost only), akin to adjusting a shower from hot to cold and back again, until a balanced temperature is eventually reached. Effectively, this is what purchasing teams at medical facilities are struggling with now.

Today, in order to find the middle position—that is, the balance point of true *product value*—facilities need to determine the way costs are incurred over an entire episode of patient care and whether and how these costs can be attributed to specific products. The measurement of costs associated with a product over an *entire episode* of care is a very different and much more complete process than simply examining supply costs alone. Higher-quality and higher-priced products may result in lower costs over time, but today much more than merely a clinical “inference” about a product’s economic

value in a publication is needed to support such claims among purchasers. Facilities are not usually set up to gather the cost and outcomes data necessary to determine these value-based end points, and manufacturers up until now have either not wanted to provide such data or were unable to do so.

### The Notion of Value Differs by Audience

The definition of value is quite different among the various audiences manufacturers must interface with while selling their products. Payors, facility materials management and product acquisition teams, and healthcare providers all have differing views of value. Consequently, each stakeholder has to be considered as a separate customer group with a distinctly different economic need.

For example, payors typically define value as *cost-effectiveness*. Facilities on the other hand typically define value as *budgetary impact*, but they are also interested in *patient outcomes*. Healthcare providers are interested in budgetary impact as well, but are also interested in *revenue generation*, as are facilities. Thus, the design of highly rigorous economic models—“value analysis models” or VAMs, which allow comparative data to be reviewed by key stakeholders and customer segments—must be customized for each audience.

The coordination of product-specific economic data gathering and analysis, along with the creation of powerful VAMs, sounds daunting to some marketing teams taking their first serious look at health economics. The process, however, is straightforward and precisely aligned with the notion of segmented market messaging to distinct stakeholders, a theme basic to all

strategic marketing. Once the “value creation” process is grasped and the economic and clinical needs of each customer segment in the product acquisition value chain are embraced, comparative effectiveness, comparative cost-effectiveness, and VBP initiatives can be viewed as opportunities rather than threats.

**Table 1. Differing Views of Product “Value”: Some Key Definitions**

**Cost-Effectiveness:** Payors typically prefer measurement of cost-effectiveness; i.e., measurement of total cost (over an appropriate episode of care) required to achieve a single relevant unit of clinical effectiveness. For example, cost-effectiveness of a cancer treatment may be measured as “cost per year of survival.”

**Budgetary Impact:** Healthcare facilities are frequently interested in budgetary impact; i.e., the bottom-line financial impact, over an appropriate period of time, associated with use of a particular product. For example, hospitals may want to understand the impact on their overall expenditures—not just pharmacy-specific—if they replace one surfactant brand with another.

**Revenue Generation:** Healthcare providers and facilities are often interested in revenue generation opportunities that may be achieved through use of an innovative product. For example, if a high-volume oncology center can reduce the time it takes to treat each patient by 10% using a new medical technology, it may be able to treat two more patients each day, thus generating additional revenue for the facility.

**Health Economics Is a Strategic Discipline**

As a starting point, pharmaceutical, biotechnology, and medical-surgical marketing and brand teams want to know how best to approach creating value analyses for their products. A key

first step is to segment their “value messaging” to the various audiences and stakeholders with whom they interface.

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*Today, institutional purchasing managers need comparative cost and effectiveness data, specific to their facility or facility type, to inform product acquisition decisions.*

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### **Understanding Value Analysis Models (VAMs)**

To a certain extent, the segmentation of value messaging to different audiences can be accomplished within a single VAM; however, it must incorporate the various perspectives of its audiences. Thus, a model comparing the costs and consequences of one drug or medical-surgical device versus another can often have the same basic “structure,” but the costs and consequences it captures and analyzes within that structure will vary by audience. Those different perspectives, whether addressed in a single model or via multiple models, enable stakeholders to compare “apples to apples” outputs to determine a given product’s value. Today, institutional purchasing managers need comparative cost and effectiveness data, specific to their facility or facility type, to inform product acquisition decisions. Similarly,

payors are increasingly pressured to evaluate cost-effectiveness data before granting preferred status to new pharmaceutical products or giving favorable coverage decisions for medical devices.

VAMs should always be built using the best evidence and the most rigorous analytical methods possible. Well-constructed VAMs, however, don’t have to be complicated—and indeed shouldn’t be challenging to the user. Many VAMs can be constructed within a familiar spreadsheet format. VAMs that are necessarily more complex—for whatever reason—can always be built with a simple user interface or “dashboard.” Furthermore, no matter how complex the “engine” of the VAM, its assumptions and methods must be explained in plain language that is understandable to its presenter and its audience.

### **Where to Start?**

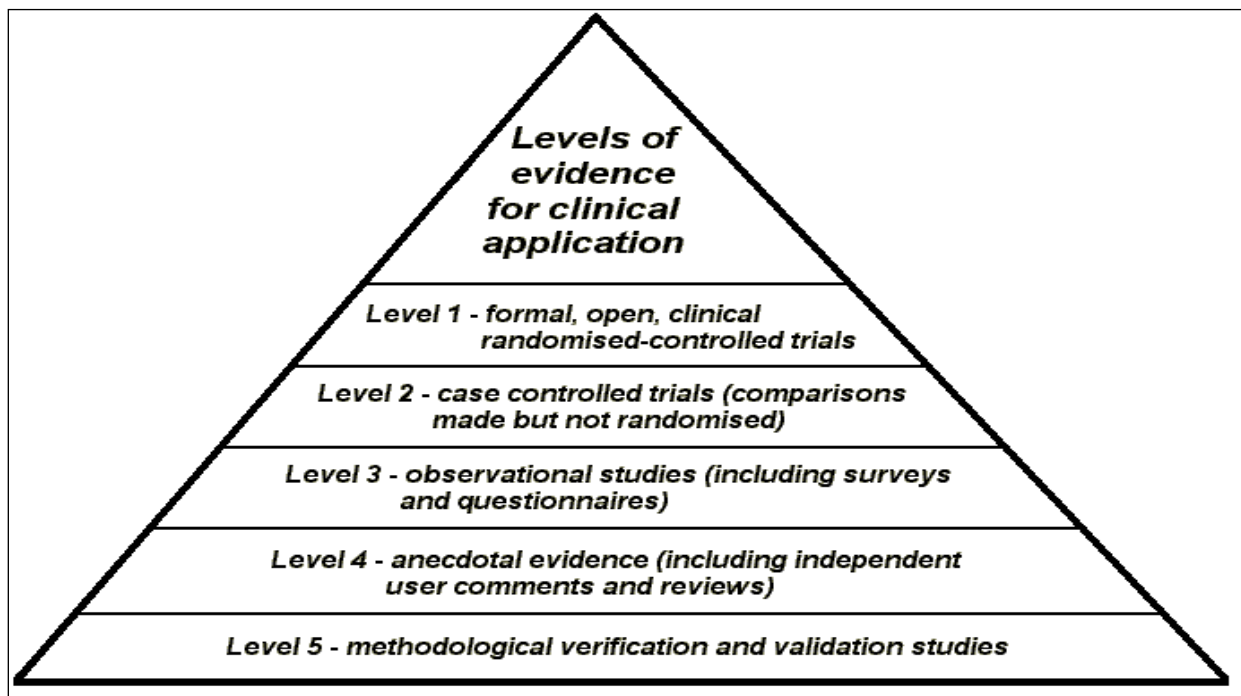
To begin, the following recommendations can help guide pharmaceutical, biotechnology, and medical-surgical marketing and brand teams in taking the initial steps to obtaining true value analyses, incorporating both costs and outcomes, for their products.

- 1. Start collecting data early:** As early as possible within the clinical development process, work with clinical colleagues to build economic end points

and/or additional health outcomes into prospective clinical trials to begin amassing the data that is key to the product's value propositions in the marketplace. This is a good beginning, as it allows preliminary VAMs to be developed based on data rather than

supposition. Ultimately, these pre-market data can and should be supplanted by post-market "actual use" data; that is, clinical and economic data collected from physicians in real-world patient environments.

**Figure 1. Levels of Evidence**



Source: <http://www.2aida.org/aida/graphics/pyramid-evidence.gif>

**2. Work with what you have as a starting point:** Even if a manufacturer has only very early data or evidence—be it a retrospective review of a payor database, a review of clinical patient charts, or a review of a hospital database—these findings can be extrapolated into a real-world model to provide meaningful product data, even if

long-term definitive comparative outcomes are not yet available. In this regard, a wide array of data, or evidence, can be leveraged in a model, each with differing levels of credibility (Figure 1).

For example, models can be designed to examine what would happen if longer-term costs increased and/or if clinical effectiveness isn't as good in actual practice as clinical efficacy in protocol-driven product trials. A well-designed VAM will allow exploration of changes in these and many other variables, pointing to a wide array of "what if" scenarios that can be useful in projecting the true value of the product in actual use.

**3. The economic modeling effort can be approached in stages:**

Retrospective data, or even early clinical data, can be used in VAMs as a credible first step to gain a foothold with payors, facilities, and physicians as additional data-gathering efforts are ongoing. Stakeholders are receptive to credible economic product findings that are "in-process," but that nevertheless clearly point to a product's value as more conclusive research continues.

**4. Conduct comparative product evaluations yourself:** As stated earlier, there is a fear among manufacturers that the Comparative Effectiveness Research Institute—in whatever form it will ultimately take—will tag their products for comparative evaluation. Rather than fearing this and waiting passively for the "bad news," industry should actively conduct rigorous comparative evaluations both before market entry and on a continuing basis.

This is a large-scale opportunity to be embraced.

**5. Engage a health economics firm:** Work with a health economics organization that can show you how comparative product data can be collected and incorporated into appropriate analyses to help drive your product or brand. Grab a leadership position that proclaims your product's value. Taking this approach will eliminate the fear that the AHRQ / Comparative Effectiveness Research Institute will conduct a study of your product over which your company has no control. Such an approach can, in fact, significantly help to advance and enforce your product's sales and position in the marketplace.

## Summary

Given the evolving shift toward comparative effectiveness research, cost-effectiveness evaluations, and value-based purchasing initiatives, pharmaceutical, biotechnology, and medical-surgical marketing and brand teams should adopt and strategically employ the use of health economics information. Despite trepidation regarding the collection and dissemination of comparative cost and effectiveness data, a proactive approach to this emerging market direction is essential. Gaining a deeper understanding of health economics, value-based purchasing, comparative effectiveness, and the current state of marketing and regulatory issues impacting the industry as a whole is of critical importance. Doing so can lead to the development of powerful, brand- and product-specific value analyses for industry to define and articulate the value proposition of its products to hospital and medical facility purchasers and acquisition teams, payors, physicians, and other stakeholders in the product-acquisition value chain.

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## About the Author



### **Josh Feldstein, Medical Editor-in-Chief and President Center for Applied Value Analysis**

Josh Feldstein leverages 25 years of pharmaceutical, medical device, and biotech experience working with U.S. and global Fortune 500 multinational, middle-market, and early-phase companies. He has designed and managed hundreds of initiatives in medical communications, medical education, health economics, and scientific publishing across 30 therapeutic categories for a wide range of clients, from Fortune 100 to early-stage companies. A published medical book author, Mr. Feldstein has written and edited textbook chapters, CME content, medical monographs, peer review journal manuscripts, slide decks, executive summaries, scientific posters, meeting reports, literature reviews, healthcare trade magazine articles, and audio and video CD/DVDs. He has coordinated qualitative and quantitative health economic research and professional education, has designed value analysis models for the medical-surgical industry, and has served as an editor for pharmaco-economic journal manuscripts for the pharmaceutical industry.