



## Value-Based Payment for Medical Technologies

October 2, 2007  
Washington, DC

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### Conference Report

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### The Health Industry Forum

Stuart Altman Ph.D, Chair  
Robert Mechanic, MBA, Director  
Garen Corbett, MS, Deputy Director  
Darren Zinner, Ph.D, Senior Research Associate  
Anna Shvarts, Program Administrator

The Health Industry Forum is based at Brandeis University and chaired by Professor Stuart Altman. The Forum brings together public policy experts and senior executives from leading healthcare organizations to address challenging health policy issues. The Forum conducts independent, objective policy analysis and provides neutral venues where stakeholders work together to develop practical, actionable strategies to improve the quality and value of the US healthcare system.

Health Industry Forum ♦ Heller School for Social Policy and Management ♦ Brandeis University  
415 South Street, MS035, Waltham, MA 02454 ♦ (781) 736-8479 ♦ (781) 736-3306 (fax) ♦ [www.healthindustryforum.org](http://www.healthindustryforum.org)

## Key Themes

### Overview

- Widespread use of fee-for-service reimbursement creates economic incentives for using expensive medical services even when costs far exceed potential benefits.
- Within this system, manufacturers price their products to maximize return on investment. Pricing dynamics affect future investment, risk-taking, and resource allocation.
- Employers and insurers support a shift towards value-based payment, but need better clinical evidence to support paying more for high-value care and less for marginally useful care.
- Expanded evidence requirements are costly and can delay product sales, but purchasers can create financial incentives for evidence development.
- Third party payers have to accommodate differing patient responses to therapies, making value-based payment systems complex to administer.
- Payers are experimenting with value-based purchasing strategies including risk sharing with manufacturers and value-based benefit design.
- Value-based purchasing has both risks and benefits for manufacturers. One area for collaboration with payers is promoting appropriate use of their products.

### Context

On October 2, 2007, The Health Industry Forum hosted a conference of leading pharmaceutical and device manufacturers, health plans, government officials and health policy analysts to discuss strategies for purchasing medical technologies that would reflect clinical "value." The purpose of this meeting was to begin discussing principals and challenges for value-based payment and to articulate future needs for research and policy development.

This Overview details key themes from the Forum. Brief summaries of each session follow.

### Key Themes

- **Widespread use of fee-for-service reimbursement creates economic incentives for using expensive medical services even when costs far exceed potential benefits.**

Under fee-for-service reimbursement, providers who do more are paid more. Clinicians are eager to adopt new therapies and frequently lobby insurers to cover them quickly. Patients with health insurance generally view most medical services as valuable since they are responsible for only a fraction of the cost. Under such conditions, medical technology firms sell into markets where the end users – consumers and physicians – are price-insensitive.

- **Within this system, manufacturers price their products to maximize return on investment. Pricing dynamics affect future investment, risk-taking, and resource allocation.**

Like any rational business, pharmaceutical, biotechnology, and medical device companies price their products to maximize return on investment. While companies frequently claim that prices reflect research and development costs, prices are usually based on what manufacturers believe purchasers are willing to pay. Pricing also depends on external factors including the targeted disease, size of patient population, product performance, and availability of alternative treatments. Even when manufacturers point to clinical improvements over existing products to justify prices, comparison product prices may well have been based on "willingness to pay" rather than any objective measure of clinical value.

- **Employers and insurers support a shift towards value-based payment, but need better clinical evidence to support paying more for high-value care and less for marginally useful care.**

Employers and other purchasers want to improve clinical and economic outcomes per dollar of health care spending. Forward-thinking insurers and their customers are promoting changes in payment policy, benefit design, and provider and patient education that encourage high-value care. To do so effectively, however, purchasers need better information about the comparative effectiveness of alternative treatments. Although manufacturers are required to collect safety and efficacy evidence for FDA approval, insurers often believe these data are insufficient to justify coverage of high-cost products.

- **Expanded evidence requirements are costly and can delay product sales, but purchasers can create financial incentives for evidence development.**

The ability to assess a product's value evolves over time. Insurers frequently have to make coverage decisions for new products based on limited information. For example, evidence based on early clinical trial results may not accurately reflect long term outcomes or utilization patterns. If payers deny coverage for early stage products, they may limit diffusion of an innovation with substantial long term value. On the other hand, once technologies have diffused into widespread use, payers have great difficulty scaling back coverage even for expensive technologies that are later proven to be only marginally effective.

One approach to addressing these challenges is linking coverage to ongoing data collection, similar to Medicare's new coverage with evidence development (CED) policy. While appealing, the CED initiative has many unresolved issues including: funding for data collection; responsibility for collecting and analyzing data, whether observational data will be sufficient for refining coverage

policy, and determining how much data will ultimately be enough.

- **Third party payers have to accommodate differing patient responses to therapies, making value-based payment systems complex to administer.**

Almost every new product will likely prove cost-effective for certain classes of patients, but determining which sub-populations and indications are cost effective requires considerable data and analysis. Payers are unlikely to be able to deny treatments that are highly effective for some patients. Because determining “value” will rely heavily on patient-specific factors, payers will face an unprecedented need for medical review. Reviews that require human intervention are economically infeasible for all but the most expensive technologies. Therefore more widespread application of value-based payment principals will require very sophisticated claims and benefits systems.

- **Payers are experimenting with value-based purchasing strategies including risk sharing with manufacturers and value-based benefit design.**

Payers are exploring new ways of rewarding high value services while discouraging lower value care. One approach is explicitly linking reimbursement to patient outcomes through risk-sharing with providers or manufacturers. For example, Britain’s National Health Service has a new arrangement with Johnson and Johnson in which the company has agreed to refund the cost of its Velcade cancer treatment when the treatment is not effective. A complex issue facing the negotiators of this arrangement was defining when treatment would be considered “effective.” Payers are also considering new benefit designs that encourage patients to select high value services or providers. This approach essentially expands the “tiered” drug formulary concept to other medical services. Rather than making controversial coverage decisions, this approach shifts financial risk for treatments of variable or uncertain effectiveness to end users who are arguably the best arbiter of value.

- **Value-based purchasing has both risks and benefits for manufacturers. One area for collaboration with payers is promoting appropriate use of their products.**

In today’s healthcare market, medical products and services are both over- and under-priced. Any new health care payment structure will pose financial risk for participants. Shifting towards a value-based system will be adversarial; progress will require a framework for setting goals and evaluating the performance of new arrangements. Programs that attempt to simultaneously address both over- and under- utilization offer one area for collaboration between payers and manufacturers. In reality, evidence evaluation is imperfect. Deciding when to restrict coverage or limit reimbursement for inefficient or ineffective therapies requires strong resolve from employers, elected representatives, and society. Without this, progress is likely to be gradual.

# Framework for Considering Value in Payment and Coverage Decisions

Presenter: James Robinson, Editor in Chief, Health Affairs

## Quick Summary

- In market-based economies, prices allocate resources and reward innovation and risk taking.
- Despite claiming that their prices are driven by research and development costs, biomedical producers seek to price products based on perceived value and willingness to pay.
- Purchasers support innovation but want to leverage their purchasing power to reduce spending growth and improve value for money. Value-based purchasing strategies include demanding information about effectiveness, negotiating prices and structuring incentives to promote appropriate use of medical technologies and services.
- The role of markets in reducing medical technology prices is muted because the principal decision makers – patients and physicians – are price insensitive.
- Producers have historically had the upper hand in U.S. markets because purchasers have typically not been sophisticated nor willing to make politically unpopular decisions.
- One potential area for future collaboration between producers and purchasers is in promoting appropriate utilization of medical technologies.

## Context

Dr. Robinson outlined general principles of value-based pricing and value-based purchasing. He also described current pricing dynamics in the US marketplace.

## Key Points

- **The basic principles of market pricing hold for drugs, biotech, and devices.**

The fundamental role of prices is to allocate resources. In the biomedical arena, where the investment risks for developing new products are high, prices and profits direct investment to projects with the greatest potential economic benefits, relative to the risks. This means that prices for breakthrough therapies should be high, as the risks and benefits are high, while prices for me-too products should be low.

- **Inefficiencies in health care markets tend to favor producers of biomedical products.**

After products are introduced, economic principles suggest that the value created by innovation shifts over time from producers to consumers through competition. Insurers and hospitals play key roles in evaluating the effectiveness of new technologies, stimulating price competition, and increasing price consciousness

among patients and physicians. Historically, purchasers have been relatively passive about paying for unproven new technologies, frequently lacking information about product effectiveness and value. Limited purchaser controls combined with price-insensitive patients and physicians have allowed producers to enjoy high margins in the US. While this has supported extensive medical innovation, the relative weakness of purchasers has allowed systemic inefficiency and unjustified variation in use.

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*“Biomedical suppliers have long enjoyed unsophisticated purchasers and price-unconscious demand by patients and physicians.”*

— James Robinson

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- **Biomedical producers favor value-based pricing.**

Medical products and service prices are generally based on either cost or value.

— *Cost-Based Pricing (CBP)* is based on a product or service cost plus a small margin. Medical producers have historically claimed that their prices are driven by high R&D costs. True cost-based pricing for medical products would need to account for the cost of product failures, plus reward risk taking. However, firms have multiple products, including products in the pipeline that incur costs but never generate revenues. It would be nearly impossible to accurately allocate and measure the costs specific to any one product.

— *Value-Based Pricing (VBP)* is generally based on what someone will pay, reflecting their perceptions about product value. For example, in the software industry prices aren't set based on the costs of burning a CD, which are negligible. Prices are based on what customers are likely to be willing to pay based on the value of the product to them.

While biomedical producers frequently contend that they engage in cost-based pricing, in reality prices are based on expected willingness to pay.

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*“The [biomedical] industry is telling a cost-based story, but they really set prices based on value-based pricing. Price is based on what the market will bear.”*

— James Robinson

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Producers benefit greatly from value-based pricing because patients and physicians generally are not spending their own money and therefore value any therapy that offers any clinical benefit at all. In certain situations, producers know that insurers simply have to pay; for instance, if there are no alternative treatments. Rational producers leverage these situations to demand high prices.

▪ **In practice, value pricing is influenced by reference prices and product differentiation.**

Pricing decisions can be illustrated by the following formula:  $V$  (value) =  $R$  (reference price) +  $D$  (differentiator). The reference price reflects a similar or competing treatment. The differentiator is the producer's estimate of how patients and physicians will value the product's unique characteristics. This formula only establishes list prices. Typically, marked-up prices exceed the list price and negotiated prices fall below it.

▪ **For value-based purchasing to work, purchasers must become more sophisticated.**

Value-based purchasing occurs when sophisticated purchasers push producers to compete and innovate. Examples of value-based purchasing include:

- *Insurers.* Value-based purchasers use PBMs to negotiate drug prices, structure consumer incentives (such as tiered formularies to encourage generic use), establish payment incentives to encourage use of appropriate technologies, and require data on product effectiveness and value as they establish coverage policies.
- *Hospitals.* Value-based purchasing includes negotiating lower device prices, involving doctors and technology assessment committees in reviewing new technologies. (Forum participants described such processes as often not terribly data driven.)

▪ **When value-based pricing and purchasing meet, the outcome is a wrestling match.**

There is no socially ideal price. The reality is that producers seek to set prices to maximize returns, and purchasers do what they can to lower healthcare spending. The result is a battle that is largely low tech and fought with little data.

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*"The outcome [of value-based pricing meeting value-based purchasing] is a mud wrestling match, which is not the worst that can be imagined even if it doesn't fit a policy pundit's ideal."*

— James Robinson

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Producers and purchasers may find common ground on value-based purchasing through collaborating on encouraging more appropriate and effective use of medical technologies; possible strategies include improving compliance with prescription drugs through disease management, improving device-related outcomes through service line management, and creating incentives favoring innovation in delivery system organization through episode pricing.

# The Science and Art of Value Pricing for Medical Technologies

Presenters: **Luis Gutierrez, Jr., MBA**, President, Commercialization Services, Covance, Inc.  
**Randel Richner, BSN, MPH**, President, Neocure Bioeconomic Strategies

## Quick Summary

- The drug industry has historically relied on a “blockbuster” business model where big winners are needed to offset the R&D investments that never yield a profitable product.
- Drug manufacturers attempt to set prices that will maximize profits. They consider such factors as market size, competing products, disease severity and symptoms, and method of administration (i.e., oral versus injected).
- Device revenue is closely tied to coding, payment policy, and site of service. Devices are frequently not reimbursed directly but are paid as part of an inpatient DRG or outpatient payment rate. The current payment methods and mechanisms for building device prices into future payments influence the pricing environment.
- Device manufacturers frequently introduce products into the most complex site of service (e.g., hospital) in order to establish the highest possible cost basis for future reimbursement. The actual prices also depend on the competitive environment and negotiations with hospitals or other providers.

## Context

Mr. Gutierrez and Ms. Richner provided consultant’s perspectives on how drug and device companies set their prices.

## Key Points (Gutierrez)

### ▪ The drug industry’s R&D model appears unsustainable.

In the drug industry commercial success is rare. For every 5,000 to 10,000 drug candidates, only one is ultimately cleared for marketing. The implication of this low yield is that drug development costly. In 1975 the cost to bring a new drug to market was \$138 million; by 1987 it had grown to \$318 million; in 2000 it was \$802 million; and in 2003 the cost was estimated at \$1.7 billion.

Drug development costs are increasing because while the industry’s R&D expenditures have grown 8% annually from 1992 to 2007 (from \$31 billion to an estimated \$105 billion), the number of new molecular entities (NMEs) approved has been flat (with 26 in 1992, 27 in 2000, 22 in 2006, and just 12 so far in 2007).

*“Higher [R&D] expenditures are yielding fewer innovative products.”*

— Luis Gutierrez, Jr.

In addition, the industry is witnessing lower and slower returns for those products that do come to market. Competition from “fast followers,” product withdrawals, pricing pressures, and

patent expirations all affect pharmaceutical ROI. As a result, just 30% of the drugs that reach the market ever fully recoup their development costs.

Compounding these challenges is a shift in the industry’s business model. Pharma has relied on “blockbusters” to pay the bills and fund R&D, but science is moving toward more targeted, personalized therapies.

### ▪ Drug and biologics manufacturers consider multiple factors when setting prices.

— *Alternative therapies.* If alternatives exist, manufacturers look at “comparable” products to assess the relative cost and effectiveness of their drug. If no existing therapy exists, a producer will look at the direct and indirect costs of an illness as a measure of value for an effective therapy.

— *Market dynamics.* A product that provides evidence of improved effectiveness, better safety, reduced side effects, or cost offsets (e.g., reduced hospitalizations) relative to competing products can garner a higher price.

— *Characteristics of the drug, disease, or patients.* Manufacturers look at factors that can affect price sensitivity. Typically acute treatments command higher prices than chronic treatments; rare diseases command higher prices than common illnesses; and treatments for severe diseases or symptoms command higher prices. Other factors include the patient’s age (younger patients can mean higher prices); means of administration (injectibles are more expensive than oral treatments); and biotech products are associated with higher prices than chemically-based products.

### ▪ Pharmaceutical manufacturers price discriminate to a much lesser extent than many other industries.

Industries like airlines have pricing strategies that take advantage of differences in customers’ willingness to pay. Pharmaceutical firms only use differential pricing in limited ways:

— *Patient subsidies.* Patient assistance programs offer free drugs to qualified patients, such as those without insurance, with other programs offering co-payment assistance.

— *Volume discounts.* Manufacturers negotiate reduced prices for high volume purchasers who can influence physician and patient utilization.

— *Dose titration.* Pharmaceutical firms manage the cost per day of therapy through non-linear pricing. For example, 1 mg of a drug might be \$1.00 per day, while 3 mgs is just \$1.25/day.

— *Dosing by indication.* Manufacturers try to maximize revenue for low-dose indications while keeping prices acceptable for high-dose indications.

Price discrimination at the patient level where there is the greatest variation in the value of a treatment would be difficult given the current third party payment system for pharmaceutical products. Furthermore, the notion of individual price discrimination for medical products, which some consider more of a social than a consumer good, would not be a good public relations story for the pharmaceutical industry.

▪ **Models of paying for value have thus far been utilized infrequently in the US.**

The U.S. presently lacks a government-run body with significant resources to evaluate clinical and cost effectiveness of medical products. Instead, independent pharmacy and therapeutics committees conduct these evaluations at the local level. However, US employers and insurers have been starting to shift away from provider-centric models of paying for value and instead have placed increased costs on patients through differential cost-sharing. While patients have become more aware of costs and are becoming better informed to participate in decision-making, opportunities for improvement abound.

## Key Points (Richner)

▪ **Setting pricing for medical devices is different than for drugs.**

There are unique technology-specific confounders in attempting to evaluate the value of medical devices. These include:

- *Operator skill.* Operator skill matters in getting the best results from medical devices. Surgeons become more proficient as they gain experience using a medical device. This may not be reflected in initial clinical studies.
- *Product life cycles.* Medical device life cycles are short (often 2 years) with many incremental improvements over time. By the time outcome studies are completed the device being studied may already be outdated compared with what is currently on the market.
- *Combinatorial science.* Medical devices have a variety of issues not found in drugs involving the combination of materials—polymers, voltages, wires, and metals. The ultimate example of a combination device: drug-eluting stents.

In addition, coding, coverage, and payment are critical for assessing the economics of a potential technology.

- *Coding.* Coding is the language of providers and payers and being paid appropriately by CMS is contingent on getting the right code for a device. Coding often indicates where a procedure is performed, which affects the payment. Payment in the hospital setting is usually much higher than in a home or outpatient setting. For example, one new technology, if using an existing code, could be reimbursed in an inpatient setting at \$3,000, but if provided to patients at home would be coded as durable medical equipment and reimbursed at less than \$200. Obtaining a new code for a new technology is complex and time consuming. Many new medical devices must be fit into the existing coding structure.

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*“There are different payments in different sites for the same items or services.”*

— Randel Richner

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- *Coverage.* Medical device manufacturers may need to convince providers to purchase a new technology without a guarantee that the product will be eligible for reimbursement. CMS has 13 different payment systems and coverage decisions occur at national, regional, and local levels. Payer’s evidence thresholds for coverage are frequently different from what is required for FDA approval.

- *Payment.* Even if a novel product is covered, there is no guarantee that reimbursement will be adequate. Forecasting potential payment for a device requires assessing where it will be used, the opportunities for use in each setting, who the decision makers and gatekeepers are, and what are their incentives.

▪ **Device manufacturer pricing decisions must consider product costs and external market dynamics.**

Technology pricing entails both an internal and an external assessment of factors that could affect pricing.

- *Internal assessment.* This focuses on determining all of the costs to develop and produce a technology.
- *External assessment.* This focuses on who buys (or leases) the technology, where they will use it, the competitive environment, clinical value, and payer mix.

Medical device manufacturers must develop value stories for both insurers and providers. It is not uncommon for manufacturers to face a pricing conundrum of whether to launch a technology early (before there is extensive supporting evidence) at a low price (to be the first mover and capture market share), or whether to launch later at a higher price, with greater supporting evidence that differentiates their technology and justifies a higher price. There is significant market resistance to large price swings so initial pricing decisions often dictate future revenue streams.

## Other Important Points

- **Timing of evidence requirements.** Participants agreed on the merits of comparative effectiveness research to provide evidence on the relative clinical effectiveness and value of treatments. But manufacturers expressed concern about how and when such research would be conducted. Novel therapies often have a learning curve during which providers discover when and for whom a new product is most beneficial. If research is completed too early, it may show higher costs and lower benefits compared to a time when providers have more experience. This points to the need to view comparative effectiveness research not as a one-time snapshot but as a continuous, data-gathering process.
- **Global pricing.** In some respects, manufacturers face a no-win situation as they think about pricing globally. For example, a



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pharmaceutical company is criticized if it doesn't make its drugs available at lower prices in the developing world. Yet if it does, it

is criticized in the US with the refrain, "Why is the price so high here when they are willing to sell it for less internationally?"

## Demonstrating and Capturing the Value of Medical Technologies

Presenters: **Jacob Drapkin**, Vice President, Ethicon Endo-Surgery, Inc.  
**Scott Howell, MD, MBA**, Senior Director, Genentech

### Quick Summary

- Minimally invasive procedures (MIPs) are a technical advancement that can provide value for patients (e.g., reduced pain or shorter recuperation times), payers (shorter hospitalization and lower episode costs), and employers (quicker return to work).
- Despite this potential value, rates of adoption under the current reimbursement model may be less than optimal.
- Genentech's breast cancer drug Herceptin® (trastuzumab) illustrates how evidence of a product's potential value can evolve over time and across different indications.
- Biotechnology manufacturers set initial prices to reflect marketplace thresholds over the life cycle of the product. Administrative arrangements like Medicare's "buy and bill" reimbursement system limit the ability to increase prices to reflect new evidence of effectiveness.

### Context

Case studies from Johnson and Johnson's Ethicon Endo-surgery Unit and Genentech provide insight into how manufacturers think about pricing and positioning their products. These case studies also illustrate that there are challenges in getting new treatment methods adopted and that evidence about the value of treatments frequently evolves over time.

### Case Study: Realizing the Value of Minimally Invasive Surgery

Mr. Drapkin described key benefits of minimally invasive procedures and reviewed MIP adoption rates. The Colorado Springs School District 11, a plan with 7,000 employees, described how they modified their benefit program to take advantage of the value provided by MIPs.

- **Minimally invasive surgery is a technical development that is a win for nearly all stakeholders.**  
 Until the 1990s laparotomy ("open" surgery) was the standard of practice, but based on technical developments standards are shifting towards less invasive laparoscopy procedures. The benefits of MIPs established through an abundance of research include: reduced direct costs based on shorter hospital stays; less post-procedure pain and scarring; fewer complications; quicker recovery times and a faster return to work.

Yet despite research supporting the benefit of MIPs, adoption rates lag for many types of procedures. While 91% of cholecystectomy procedures are minimally invasive (results achieved over 17 years), just 70% of reflux surgery, 68% of gastric bypasses, 60% of breast biopsies, 41% of hysterectomies, 25% of colectomies, and 12% of hemorrhoidectomies are minimally

invasive. Some of these procedures are relatively new or lack adequate data establishing their safety. But for other procedures with proven outcomes, providers are simply slow to adopt.

One factor may be that providers make less money performing laparoscopic procedures than open ones. Minimally-invasive surgeries are more complex to conduct. In many cases these surgeries require more operating room (OR) time, but those costs are usually offset by shorter length of hospital stay. While the advantages of quicker recovery and return-to-work benefit patients and employers, there may be less of a direct financial benefit for physicians and hospitals.

- **Colorado Springs School District 11 is proactively pushing patients and providers to choose MIPs in order to improve value and reduce health care spending.**

Ken Detwiler of School District 11 defined value as "quality divided by cost." Value can be increased by improving quality or lowering cost. They see MIPs as a way to do both.

The District has implemented tiered co-payments to encourage employees to opt for MIPs versus open procedures. For inpatient care, an employee's co-payment is \$800 for a MIP and \$1,200 for an open procedure. For outpatient care the MIP co-pay is \$400 and the open co-pay is \$600.

Over the past two years about 180 MIPs have been performed on district employees. The district projects total savings from MIPs to exceed \$800,000. They view this as a win because it improves quality, lowers costs, increases value, aligns incentives, and gives patients options.

### Case Study: Cost Effectiveness, Pricing and Reimbursement for Herceptin

Dr. Howell described the biotech business model and factors that influence biotech pricing. He used Herceptin®, a treatment for breast cancer, to illustrate the challenges in determining pricing.

- **The biotech business model dictates value-based pricing, which means high prices.**

For years, conventional wisdom was that payers wouldn't pay the high cost of treatments developed for small populations, but the experience of the past decade has shown this is not the case.

A biotech business model has emerged based on willingness of payers to pay premium prices for effective treatments targeted to small populations (tens of thousands or less) who have serious conditions. Developing such treatments is high cost and high risk, but the ability to employ value-based pricing means that those who produce effective treatments can earn big rewards. This provides the incentives that biotech companies need to invest in developing such treatments.

▪ **The experience of Herceptin shows the complexities of establishing prices for drugs.**

The HER2 gene was first cloned in 1985. Herceptin was developed from 1990 to 1997 and launched in 1998. It has been approved to treat two conditions, with dramatic differences in its cost effectiveness in treating each.

- *Metastatic breast cancer.* Herceptin was originally tested and approved to treat this most difficult type of breast cancer. To target the estimated 10,000 US patients, the drug was priced at roughly \$3,200 per month. The median survival time increased 4.8 months, time to progression (TTP) decreased from 7.2 to 4.5 months in patients treated with Herceptin and chemotherapy vs, chemotherapy alone. Incremental cost effectiveness in this population was \$145,000/QALY.
- *Adjuvant treatment.* Later, Herceptin was approved for the adjuvant treatment of HER2 positive, node-positive breast cancer (annual population of about 30,000 patients). This treatment was a breakthrough. The risk of breast cancer recurrence decreased by 52% (HR=0.48, 95% CI 0.39-0.59), mortality fell by 33% (not statistically significant), and disease-free survival increased by 3 years. At roughly the same price, incremental cost effectiveness for this treatment was estimated at \$26,417/QALY.

The different level of cost effectiveness for different conditions and populations shows the risks of making coverage and reimbursement decisions based on snapshots of data. In thinking about potential pricing strategies, if Herceptin were priced to achieve a cost-effectiveness ratio of \$75,000/QALY, the monthly price for metastatic cancer would be about \$1,700 and the price for adjuvant treatment would be about \$10,400. (Herceptin's current price is around \$3,670.) Since the market for adjuvant treatment is much larger than for metastatic treatment, condition-specific pricing would benefit Genentech. But there would be significant obstacles in doing so:

- *PR issues.* How might stakeholders react to such pricing? Would there be a public relations backlash in having two prices for the same product?
- *Co-payment issues.* For patients receiving adjuvant treatment who must pay 20% of their drug costs, the burden would be \$2,000 per month.

- *Coding issues.* The J codes used for these drugs can't distinguish between conditions.
- *Reimbursement issues.* There is a six to twelve month lag time for calculating average sales price under Medicare's buy and bill system. If a company raised its prices from \$3,500 to \$10,400, physicians would stop purchasing the drug for Medicare patients because reimbursement would be substantially lower than the drug price.
- *Arbitrage and distribution issues.* The company ships vials of Herceptin to distributors who then ships the drugs to providers. The providers use the drug to treat both metastatic and adjuvant patients. Charging a different price for the same drug based on the ultimate patient's condition presents logistical challenges in the current distribution model.

Taken in concert, the magnitude of these challenges constrains Genentech's ability to alter its current pricing structure.

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## Participant Comments

- **A consequence of MIP is increased volume.** Even if the unit cost of MIPs is less than open procedures, the overall procedure volume has increased because: 1) with reduced pain and complications more patients choose surgery; and 2) as payment per procedure has gone down, some physicians have sought to make up lost revenues through volume. It was also noted that there is greater use (even overuse) of pre-screening tests.
- **Don't just look at new, look at all.** This discussion of value has focused primarily on new treatments. However, even in established areas there is wide variation in use and cost. There are opportunities to apply value-based purchasing to technologies that have been around for some time.
- **Small potatoes?** Focusing value-based purchasing on drugs and devices addresses only a small portion of overall health care spending. Some participants believed that a more pressing priority should be removing systemic inefficiencies in the delivery system. Others argued that a value-based approach for selected technologies is an important step (albeit just one of many) for improving quality and controlling costs.

# Practical Considerations for Value-Based Coverage & Payment Policy

Presenters: **Donald Moran**, President, The Moran Company  
**Joseph Dorsey, MD**, Former Corporate Medical Director, Harvard-Pilgrim  
 Respondent: **Andrew Webber**, President & CEO, National Business Coalition on Health

## Quick Summary

- As the cost of health care increases, society needs to make coverage and payment decisions based on value.
- Measuring value requires data about the effectiveness and appropriateness of treatments under a variety of clinical circumstances. Gathering this information requires an enhanced infrastructure to collect and analyze these data in an automated manner.
- The combination better information about treatments and financial incentives can change behaviors and lower costs. Tiered drug plans provide evidence of this.
- While envisioning big changes in the payment system, employers see incremental changes that can be made now.

- **Proposition 3: Implementing value-based payment will be constrained by a lack of automated administration.**

Medical review that requires human intervention will cost more than it saves for all but the most expensive services. For value-based payment to work cost effectively, medical review will have to be automated.

- **Proposition 4: Limited availability of clinical information from electronic medical records (EMRs) is the most significant constraint to value-based payment.**

Value-based payment policies will frequently require access to individual patient-level clinical information. One vision is that this information will be available through EMRs, yet this capability is lacking today. Substantial infrastructure investments are required to build the technology base needed to support value-based decision making.

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*"Our ability to do value-based purchasing will depend on exactly what evidence we find."*

— Donald Moran

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## Context

Mr. Moran and Dr. Dorsey discussed practical considerations for value-based payment. Mr. Webber provided an employer perspective.

## Key Points (Moran)

Mr. Moran organized his comments on value-based payment policies into five propositions.

- **Proposition 1: Every medical technology will be the most cost-effective treatment for someone.**

Because every treatment will have high value for some class of patients (even if that class has few people in it), it will be very difficult to eliminate coverage for those treatments. This means that value-based payment will rarely be achieved through binary (yes/no) coverage decisions. Patient-specific facts and circumstances will be critical in making "value-based" determinations.

- **Proposition 2: No technology manufacturer can recoup its costs by selling a product just to the patients for whom it is cost effective.**

This means that manufacturers will strive (within the limits of accepted rules) to expand the reach of their products into ever-wider areas. This is how the game is played today and will be played even more aggressively in the future. Therefore value-based payment is likely to be an adversarial process. It also suggests that value-based determinations will not be singular "events" but rather ongoing processes. These processes will produce volumes of comparative evidence. In contrast to today where such evidence is lacking, in the future with an abundance of evidence, the payers' challenge will be sorting the wheat from the chaff.

## Key Points (Dorsey)

Dr. Dorsey described the value of value-based payment methods and shared examples of initiatives that worked well in the past as well as others that did not.

- **Society in general, and health plans in particular, care about value-based payment.**

Society has a growing interest in value, fueled by constant cost increases and sub par quality. This focus on value is likely to grow as interest in universal coverage expands because enhanced access has the potential to "break the bank."

Health plans are in a difficult position; they are expected to control costs but are attacked for denying coverage. Employers and employees say that they want cost containment, but employers don't want confrontations with employees whose requests for care are rejected. Employers also don't want restrictions when it comes to care for themselves or their families. The concept of value-based payment offers hope for credible data that can be the basis for indicating what to cover, how much to pay, and when to say "no."

- **Some past efforts to improve value have worked while others haven't. Lessons can be learned from both.**

Examples of value-enhancing activities that Dr. Dorsey saw during his time at Harvard Pilgrim Health Care (HPHC) are:

1. *Three-tier drug benefit.* In Dr. Dorsey's opinion, the introduction of tiered drug formularies was the most

important step towards enhancing value taken during his tenure at HPHC. Prior to implementing a three-tier plan, physicians in HPHC's network were encouraged to adhere to the formulary. This put physicians in the uncomfortable role of suggesting that patients switch to another drug. When patients asked why, physicians answered, "Because that's what your insurance company wants me to do."

After moving to the three-tier benefit, patients facing higher co-payments initiated conversations with their physicians about appropriate drugs in lower-priced tiers. The patient was taking action and the physician was assisting them in this process—a different dynamic. Lower patient cost sharing also helps compliance, which improves outcomes and pharmaceutical sales. In addition, this structure motivated pharmaceutical companies to ask HPHC how much they had to lower prices to move their drugs into the lower tiers—showing the power of market forces at work.

2. *Approval of Lovenox (a patient injected form of heparin whose use does not require close monitoring of blood tests) for treatment of deep vein thrombosis (DVT) converted the standard of care for most cases of DVT from a 5-7 day hospital admission to outpatient management. Despite the high cost of Lovenox, its approval impelled a capitated group practice at one Boston hospital to be at the forefront of making Lovenox the standard of practice in the community.*
3. *Diabetes disease management.* While most who deal with diabetes management focus on glucose monitoring, HPHC conducted a careful literature review to identify the most cost-effective interventions. The most cost-effective intervention was one aspirin per day – the cost is close to zero and the clinical impact is large. The second best intervention is blood pressure control which can be achieved through effective and relatively low-cost agents. (Several other interventions were ranked as well.)

Not all efforts to enhance value at HPHC worked. Two failures were:

- *Reduced maternity LOS programs.* While HPHC had a good value-enhancing maternity program, it lacked good evidence-based data to support its program. Amidst the public outcries about "drive through deliveries" reduced maternity LOS programs were legislated out of existence.
- *Capitation.* HPHC tried to enhance value by creating financial incentives for physicians to develop creative alternatives to reduce unnecessary use for hospital emergency departments (EDs) and unnecessary admissions through efforts like extended office hours, telephonic nurse triage and hospital-based nurse case managers. These programs were successful in reducing ED utilization, but were seriously compromised by passage of 'prudent layperson' language that reduced patient

incentive to even call for advice prior to going to the ED. Although capitation can generate value, it was largely abandoned by HPHC in the face of strong resistance from physicians and hospital systems.

## Key Points (Webber)

Mr. Webber leads an organization that encompasses 65 business and health coalitions. He discussed systemic changes that employers would like to promote.

### ▪ Employers bear some responsibility for health care's woes.

Mr. Webber bluntly stated that "employers are to blame [for the problems in the health care system because] we created the incentives." Employers have paid for poor quality and have not pushed contracted health plans to differentiate payment based on performance. Employers want to help drive health care transformation, although getting CEOs to make this a priority is hard. Employers would prefer that CMS take the lead in driving change, with employers assisting in the effort.

### ▪ Employers see provider reimbursement and consumer incentives as the key areas for change.

Employers want to drive change through a series of incremental steps.

- *Payment reform.* Ultimately employers want to replace fee-for-service reimbursement with payments for episodes of care. They want some portion of physicians' compensation tied to outcomes, and want incentives to encourage primary care and reduce overuse of specialists. An immediate reform that employers can work with their health plan partners is ceasing payment for hospital-acquired infections. This would send a strong signal to providers that would improve quality and value.
- *Enhanced consumer incentives.* In an environment where transparent information is lacking, employers see high deductible health plans as a blunt instrument that will decrease demand for necessary services. Instead they favor value-based benefit design where evidence is used to structure tiered copayments based on the quality and efficiency of providers and medical interventions. Such a value-based approach will fundamentally change how consumers behave. If consumers want treatments that are not supported by evidence, they will have to pay more.

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*"We have to do value-based purchasing...there is no alternative."*

— Andrew Webber

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## Next Steps for Research and Policy Development

Presenters: **Sean Tunis, MD, MSc**, Center for Medical Technology Policy  
**Stuart Altman, Ph.D.**, Brandeis University

### Quick Summary

- Value-based purchasing in health care is an important issue that requires further development.
- For value-based approaches to work, new models are needed that allow adoption of new technologies with less-than-perfect evidence, but that also require ongoing evidence gathering and review.
- Ongoing evidence development requires an enhanced infrastructure and careful forethought about exactly what questions need to be answered and what data are needed.

### Context

Dr. Tunis and Professor Altman offered their observations on the day's discussions and potential next steps. Dr. Tunis also provided a case study of a value-based approach at CMS.

### Key Points

- While a focus on value won't solve all of the problems in health care, it will make a difference.**

Both speakers acknowledged that the health care industry faces a multitude of challenges, including inefficiency, perverse incentives, and lack of primary care providers. But in response to Forum participants who suggested that value-based purchasing shouldn't be a priority, Tunis and Altman argued that assessing the value of medical technologies is extremely important. Professor Altman commented that value-based purchasing has always been around in some form, but it has been crude. What is needed is a structured, organized approach with adequate evidence.

This Forum provided a starting point for discussing value-based pricing, purchasing, and payment. An important next step is identifying specific areas that merit a more detailed discussion. Dr. Tunis compared this to the Forum's first meeting on comparative effectiveness research which was broad in scope; it has since addressed a variety of specific issues in far greater depth.

- Payers need to find ways to cover promising new technologies with limited evidence in conjunction with a process for additional data collection.**

Going from initial testing of a new drug or device to credible comparative effectiveness studies takes an extended period of time, with multiple decision points along the way (i.e. FDA approval, insurance coverage, payment rate setting, etc.). Decision makers frequently make coverage and payment decisions with less than optimal evidence.

Dr. Tunis proposed a model that would support conditional coverage and payment with incomplete evidence conditioned on ongoing data collection which would be analyzed and reviewed. The results of this process could be used to refine the initial coverage and reimbursement policies.

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*"If we want to move to value-based coverage, reimbursement, and pricing, we have to get better at making decisions with less evidence and figuring out how to build the infrastructure and the policy to get better evidence of benefit and value going forward."*

— Sean Tunis

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### Case Study: CMS Coverage for Implantable Defibrillators

Dr. Tunis briefly described the thinking at CMS when considering coverage for implantable defibrillators for prophylactic use. CMS knew that this was potentially a \$2 to \$10 billion decision.

At the time of the decision, the best evidence indicated that patients with certain EKG abnormalities saw huge mortality benefits, while patients with normal electrocardiograms (EKGs) experienced virtually no mortality benefit.

While CMS had no broad strategy for considering value in its coverage and reimbursement decisions (and could not legally base coverage policy on explicit cost-effectiveness criteria), the ICD decision represented significant expense and uncertain evidence. CMS decided to initially cover implantable defibrillators only for those patients with EKG readings showing a "wide QRS." CMS indicated that it would be open to additional data which could convince them to modify this decision. Longer-term data showing benefit for patients who had "narrow QRS" EKG readings were subsequently produced, and CMS revised its initial coverage decision.

- A model of collecting further evidence requires a well-conceived data-gathering infrastructure.**

CMS built on this experience to develop a new model where coverage is linked to collection of further evidence. In early 2005 CMS enacted a policy labeled "coverage with evidence development", approving implantable cardiac defibrillators for a broader patient population while requiring further evidence to help clarify which patients are mostly likely to benefit from therapy.

In essence, Medicare used implicit considerations of potential value as the impetus to restrict coverage to a subgroup of patients; broader coverage would have been likely if economic factors were not an issue. Initially coverage was limited to patients with certain EKG readings, later it became contingent on

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participation in registries. In the future, payers could develop other variations of this approach to apply more nuanced coverage policies that reflect the certainty level of clinical benefit or cost-effectiveness of the proposed intervention.

Although ICD registries have been put in place, they do not contain sufficient information to answer CMS' questions. This illustrates that simply adopting a policy calling for evidence is not

sufficient. Getting the right evidence requires both data-gathering infrastructure and careful up-front evaluation of what data needs to be collected. In response to a previous presentation where Mr. Moran commented on an eventual abundance of information, Dr. Tunis suggested that it would make more sense to adopt a proactive approach of defining the wheat and the chaff up front.

## Value-Based Payment in the European Union

Presenter: **Kalipso Chalkidou, MD, Ph.D.**, Associate Director, Research and Development, National Institute for Clinical Excellence (NICE), United Kingdom

### Quick Summary

- Influential organizations in the UK have called for the National Health Service (NHS) to adopt a value-based approach in purchasing drugs.
- NICE is looking at other policies to move away from yes/no approval and coverage decisions, such as tentative approval within the context of conducting additional research. While rarely used, support for such approaches is growing.
- There is growing support for public funding to measure effectiveness and value.
- The UK is not alone. The concepts of value and effectiveness are gaining currency internationally.

### Context

Dr. Chalkidou described how the UK is approaching the value debate, as well as key developments around Europe.

### Key Points

- **There is an increasing focus on “value” in the UK.**

In February of 2007, the UK’s Office of Fair Trading (OFT), an independent non-governmental organization, recommended that the government reform its pharmaceutical price and regulation scheme—currently based on profit and price controls—with a value-based approach to pricing. The goal is for the price of drugs to reflect the value to patients and to the health system.

- **The UK has adopted other tools to help the National Health Service improve value.**

- *Comparative effectiveness information.* This involves conducting or reviewing research to understand treatments’ relative effectiveness and cost effectiveness.

- *Coverage with evidence development.* The U.K. calls this “Only in Research” (or “OIR”). OIR seeks to provide an alternative to binary approval decisions for new treatments. For promising interventions not yet supported by adequate data to justify an unqualified recommendation, the treatment is covered, but only within the context of further research. Clinicians are advised to only use the new intervention as part of a well-designed research program. Under OIR the following questions must be answered: Which patients can receive the treatment and for what indications? Who will finance the data collection? (public or private); and who gets the data that is generated?

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*“It [OIR] provides an important third option that moves us away from yes/no decisions.”*

— Kalipso Chalkidou

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OIR is rarely used at present, but there is growing interest in OIR based on desire for more flexible coverage policies

- *Risk-sharing schemes.* This approach also involves coverage for a specific set of patients who receive a treatment and participate in research. In such a scheme a treatment’s producer might share the risk by paying (perhaps through a rebate) for patients who didn’t respond to the treatment. Working through the details of risk-sharing schemes with manufacturers can be complex and adversarial.

Within the UK these alternative approaches have faced political challenges. At the heart of the debate is determining what the “default answer” should be when evidence on a product’s value is equivocal. Some parties desire a fast decision and argue that the absence of evidence to justify a “yes” decision should mean “no”. The question, however, is how the burden of proof should be split between manufacturers and public funders of research.

The public—as represented by NICE’s Citizen’s Council of 30 citizens—supports the idea of OIR. They feel that patients would be reassured to know that clinicians and the health care system dealt with uncertainty in a mature, scientific way, and avoided wasting money on unproven interventions.

- **There is growing support in the UK for funding research that is focused on value and effectiveness.**

Several reports from various organizations—including one endorsed by the then Chancellor of the Exchequer and current Prime Minister Gordon Brown—support public funding for research on the relative effectiveness of health interventions, especially new interventions. There is also a growing debate about how to use such data in compensating providers and physicians.

### Other Important Points

- **International momentum.** Activities focused on comparative effectiveness and value-based purchasing are taking place in locations such as France, Germany, Italy, the Netherlands, and Korea. Specific examples include France where drug pricing tiers are established based on clinical effectiveness; use of economic value is being considered. In Italy, a 5% tax on drug marketing is being used to fund comparative effectiveness research.