

By James C. Robinson

ANALYSIS & COMMENTARY

Providers' Payment And Delivery System Reforms Hold Both Threats And Opportunities For The Drug And Device Industries

DOI: 10.1377/hlthaff.2012.0401
HEALTH AFFAIRS 31,
NO. 9 (2012): 2059–2067
©2012 Project HOPE—
The People-to-People Health
Foundation, Inc.

ABSTRACT For decades, medical device and specialty drug makers have produced a steady stream of breakthroughs and incremental improvements, from cancer therapies to orthopedic joint replacements, drug-eluting stents, and cardiac pacemakers. The advances were financed by a fragmented health care system that paid for whichever clinical technologies were favored by physicians without strong concern for cost. But now hospitals, health systems, insurers, and policy makers are embracing payment reforms that seek to control costs and foster uniformity in the adoption of new drugs and devices. This article explores payment reforms that will have an impact on the medical technology industry and describes opportunities for the industry to flourish in this new, more financially constrained landscape.

James C. Robinson
(james.robinson@berkeley.edu)
is the Leonard D. Schaeffer
Professor of Health
Economics and director of the
Berkeley Center for Health
Technology at the University
of California, Berkeley.

For the medical technology sector, these are the best and worst of times. Fragmented organization and fee-for-service payment for physicians and hospitals, decried by health plans and policy analysts, inadvertently have benefited the drug and device industries by permitting generous reimbursement and the rapid diffusion of products throughout the health care landscape. The resulting cycle of high revenues and margins, continued investments in research, and further product development has benefited patients with serious medical conditions and has established the United States as the global leader in biomedical innovation.

But ever-rising expenditures on new technologies and the procedures that incorporate them have created a highly visible target for payers eager to bend the health care cost curve. The medical technology sector faces the risk that contemporary policy and market interest in bundled payment, shared savings, risk-adjusted capitation, and other payment initiatives will discour-

age the adoption of new products that increase costs and will squeeze the flow of revenues vital to innovation.

At the same time, this changed landscape offers opportunities for the health care technology sector. It now has the chance to reformulate its product development, pricing, and sales processes in the context of two forces: an increasingly integrated and sophisticated provider sector looking to restrain cost growth and improve population health, and payers prepared to hold providers accountable for achieving these goals.

This article analyzes how reform of physician and hospital payment affects the medical technology industry, with an emphasis on implantable medical devices and specialty pharmaceuticals. It briefly describes traditional relationships between the providers—hospitals and physicians—and the producers—drug and device makers. The article then analyzes how providers are changing their relationships with producers in today's more constrained payment environment and the challenges and opportunities these

changes pose for technology firms.

The article draws on more than 200 interviews conducted over the past three years with executives, managers, and physician-leaders in health plans, hospital systems, drug and device firms, and consulting firms working with those entities. Where possible, it builds on published peer-reviewed and journalistic accounts of payment innovations. However, many of the changes in the contemporary market are occurring rapidly, have not been the subject of published analysis, and can be studied only through case-study methods.

Implantable Medical Devices

Implantable products from the medical device industry include orthopedic joint replacements, spine fusion implants, drug-eluting stents, cardiac pacemakers and defibrillators, and numerous other devices designed to remove disability and restore function. But the complex organizational and payment structures linking insurers, hospitals, physicians, and device manufacturers have forestalled close attention to cost, resulting in a portfolio of high-performance but also high-price products.¹

Traditionally, attending surgeons have selected implantable devices on behalf of patients. The hospital that will pay for the device and the insurer that will reimburse the hospital generally have had little involvement in the decision.²⁻⁴

Physicians have made choices based on their perceptions of quality and on their often close personal relationships with the device distributors. Many physicians have received substantial income from device firms in return for help in product development and promotion. Hospital executives and physician critics of the status quo often argue that these industry payments also are made, implicitly, in exchange for brand loyalty and for adopting each new generation of a product.⁵

Members of hospital medical staffs often have failed to agree among themselves on clinical pathways—systematic approaches to care to achieve intended outcomes—and preferred device vendors. And to some extent, hospital executives have been reluctant to force physicians to follow implantable device guidelines because they feared that to do so would prompt some surgeons to abandon the hospital in favor of competing facilities with more accommodating policies toward the selection of implantable devices.

Without aligning physicians' interests with those of the hospital, the hospital or ambulatory surgery center may pay higher device prices than would be obtained by a more integrated delivery

system. Such a system can obtain price discounts from device makers and ensure that employed surgeons use only those devices.

For example, analyses by the Integrated Healthcare Association found a severalfold range in prices paid for orthopedic, spine, and cardiac devices among California hospitals and hospital systems.⁶⁻⁸ There were greater variations and higher average prices across hospital systems with only loose physician alignment. Alignment can be obtained through physician employment, joint ventures, and partnerships with large physician organizations. Industry observers routinely assert that Kaiser Permanente, a fully integrated delivery system with employed surgeons, obtains devices at prices 10–40 percent below those available to any competitors in the private sector.

High device prices are a challenge to hospital budgets but often can be passed on to insurers with little resistance. Commercial insurers pay hospitals for each admission or inpatient day but then often reimburse the facility separately for the cost of implantable devices—a process known as “carving out.” This practice inoculates the hospital from the financial risk of new product introduction. However, it also weakens incentives to standardize vendor relationships, limit physician consulting, and develop effective supply-chain management.⁹

The practice of carving devices out of the base hospital payment is inadvertently advantageous to device companies and, in some cases, has been encouraged by them. For example, Boston Scientific developed a guidebook for hospitals on the logic and techniques of device carve-outs.¹⁰

In contrast, Medicare's diagnosis-related group payment system does create an incentive for price vigilance, because it bundles the cost of the medical device into the single prospective payment rate per admission. However, hospitals have been able to make up for Medicare payment limits by raising rates to private insurers, especially in consolidated local markets.¹¹ Insurers then include the cost of the devices in the premiums charged to employers, which in turn pass them along to employees in the form of forgone wages and to patients in the form of higher out-of-pocket cost sharing.

Specialty Pharmaceuticals

Specialty drugs include biopharmaceuticals and other products that require complex methods of distribution, administration, and monitoring. In contrast to common oral drugs, which typically are prescribed by the physician but self-administered by the patient, specialty drugs often are purchased by the physician practice and admin-

Payment methods for physician practices using specialty drugs have undermined incentives for efficient and evidence-based care.

istered to the patient in the office or infusion center.

For example, three-fourths of cancer drugs are administered in the physician office and reimbursed by the patient's medical benefit, in contrast to the pharmacy benefit that reimburses traditional oral drugs.¹² Specialty drugs thus resemble implantable devices in terms of the payment flows, financial incentives, and resulting patterns of use. Some cancer and immunology drugs can be taken orally or self-injected, but the patient needs close monitoring and dosage adjustments because of toxicity, and the pattern of use often resembles that of infused chemotherapies.¹³

The pharmaceutical and biotechnology industries are focusing on the development of specialty drugs, which are less likely than conventional oral drugs to face competition from generics and me-too products—defined as those that are structurally very similar to other drugs, with only slight differences.^{14,15} New specialty drugs typically are approved by the Food and Drug Administration (FDA) for narrow clinical indications and priced by manufacturers at premium levels. However, they are often used for off-label purposes and are prescribed in a great variety of doses and combinations and administered for a wide range of indications and disease severity levels.^{16–18}

There has been only limited adoption of evidence-based clinical pathways that standardize drug mix, sequence, dose, and monitoring for each indication and stage of disease.^{19,20} The American Society of Clinical Oncology has published estimates that approximately half of anti-cancer drugs consumed are for off-label uses, and the 2011 Genentech survey of oncologists estimates that 30 percent are used off-label. However, it has been difficult to obtain detailed data on such practices.^{12,17(p3206–07)}

Payment methods for oncology, immunology, and other physician practices using specialty drugs have undermined incentives for efficient and evidence-based care. Patients suffering from these conditions often have side effects from the treatment itself as well as exacerbations of the underlying disease, and many need continual monitoring. However, most insurers reimburse practices on a fee-for-service basis and have sought to restrain cost growth by reducing visit fees. The fee schedules do not reimburse adequately for the assessment of new cases or for the ongoing management of illnesses outside of individual patient visits.

Physician practices subsidize care management services using the payments they receive for office visits. However, as visit fees have been squeezed, physicians increasingly have relied on margins from the sale of specialty drugs to make up for payment shortfalls. This “buy and bill” method of drug distribution converts the business of oncology from one of being reimbursed for clinical evaluation and management to one of buying drugs from distributors and selling them to insurers.²¹

Many specialty practices with infusion capabilities receive a large fraction of their net revenues from drug markups rather than from the professional fees paid for their clinical activities. Such practices wrestle with financial incentives to use the drug regimens with the largest spread between the prices paid by the physician to the manufacturer and the rates reimbursed by the insurer to the physician.²² This purchasing and distribution framework discourages the adoption of evidence-based pathways and leads to unjustified variability in the patterns of drug administration across practices for patients with similar conditions.

Insurers have pushed back against the cost-increasing effects of buy-and-bill payment by shifting the standard for reimbursement from the manufacturer's list price to the average sales price at which drugs actually are sold in the market.²³ Average sales price payment can reduce drug markups but does nothing to encourage the use of clinical pathways and lower-cost drugs. That is because the markup percentage on average sales price still translates into large markups for expensive specialty drugs and small markups for inexpensive generic chemotherapies.

Average sales price payment also provides no financial reimbursement for care management activities that educate patients, monitor them for adverse side effects, avoid acute flare-ups, or reduce visits to a hospital emergency department. More generally, reimbursing the average sales price does not link drug payment to the achieve-

ment of desired patient outcomes.

Some insurers have sought to take the physician altogether out of the business of buying and selling drugs. Plans with such a goal in mind contract with specialty pharmacies to distribute drugs to physician practices, as needed, or to have the patient obtain the drug and bring it to the physician's office for administration—a practice called “white-bagging.”^{24,25} Unless accompanied by offsetting increases in professional fees, however, white-bagging induces physicians to refer patients to costly hospital-based infusion clinics.

The decline in drug markup revenues and the growing role of oral anticancer agents, for which the practice receives no drug markup, have been cited as the most difficult challenges that community-based oncology practices now face, and as the principal reasons why such practices agree to be acquired by hospitals.¹² Studies by consulting firms have documented higher provider prices for drugs and greater volumes of drugs per patient in hospital-based specialty practices as compared to community-based specialty practices.^{26,27} This highlights the tendency of some insurer efforts to save money in the short run while raising costs in the long run.

At the extreme, misdirected insurer cost control efforts that reduce visit fees and drug markups without replacing them with payment for care management encourage specialist physicians to sell their practices to hospitals and convert to an employment relationship. Hospitals can obtain high margins on specialty drugs both by using their bargaining power to wring high reimbursement rates from insurers and—for facilities benefiting from designation as special-needs hospitals—by extracting statutorily mandated discounts from pharmaceutical manufacturers.²⁸

Some insurers, such as Anthem Blue Cross in California, are pioneering new physician and drug reimbursement policies explicitly to sustain the viability of community-based practice and slow the pace of consolidation of these practices into hospital systems.

Impact Of Payment Change On The Technology Sector

IMPLANTABLE MEDICAL DEVICES Hospitals have been hampered in applying value-based purchasing principles to implantable devices because of a lack of coordination with the surgeons who select products on behalf of their patients. However, market and regulatory pressures increasingly are inducing physicians in device-intensive service lines to see their interests as aligned with those of the hospital and to give up some of their

autonomy to use whichever implantable device they prefer in favor of cooperation with the facility's supply-chain strategies, which center on standardization of implant choices for each type of procedure.²⁹

In terms of the incentives for undertaking such changes, the strongest form of aligning physician and hospital interests is joint ownership by the physicians and the hospital of ambulatory surgery and specialty inpatient facilities, because the physicians reap a considerable share of all savings. Employment of physicians by the hospital is a weaker form of aligning physician and hospital interests, because in such arrangements, physicians' personal earnings are not directly linked to hospital cost reductions.

Other strategies to align physician and hospital interests include formal gain sharing and informal department reinvestment initiatives. Under gain sharing, the hospital gives a financial bonus to physicians based on hospital device cost savings that result from physician changes in device selection. Under informal department reinvestment strategies, the device cost savings are reinvested by the hospital in the relevant service line, indirectly benefiting physicians by permitting more efficient processes. These strategies create a revenue potential for physicians who help the hospital reduce its device and service-line costs, but they typically account for only a small portion of physicians' overall earnings.^{30,31}

Another way in which hospitals can attempt to have greater control over implantable device selection and costs is through technology assessment committees. Some leading hospitals currently maintain such committees, which require physicians seeking to use a new device to present evidence to a committee of their peers about its cost and quality. Such “value assessment committees” take on some of the functions of pharmacy and therapeutics committees historically operated by health insurers.³²

Some facilities are recognizing the important differences between incremental improvements to existing devices and devices that represent breakthrough technologies. These differences can be reflected in a division of labor between a committee focused on familiar products such as orthopedic joints and cardiac pacemakers, where price looms large in the assessment of value, and a committee focused on potentially breakthrough products such as minimally invasive heart valves and artificial spine disks, where clinical performance rather than price is of primary concern.⁹

Many hospitals seek to move device selection from a series of autonomous choices made by individual physicians to a more conventional

Clinical pathways seek to limit the variability of care and achieve predictable levels of quality and costs.

supply-chain management process in which the hospital obtains better prices in exchange for guaranteed volume. This latter approach begins with a request for proposals or other systematic assessment of products among competing device firms, with the intent of awarding semi-exclusive contracts to a subset of firms that will offer good prices and service guarantees.²

Negotiation tactics include assigning individual devices to distinct classes and either setting a maximum acceptable price for each class or soliciting bid prices by class. Other options include offering volume in exchange for a sizable discount off list prices for the device firm's entire product portfolio. Some hospitals establish a maximum price as a defined percentage of the reimbursement received for a procedure from Medicare or a private insurer.⁹

SPECIALTY PHARMACEUTICALS Health plans are experimenting with new payment methods to motivate physicians to adopt evidence-based clinical pathways that favor low-cost drugs unless higher-price alternatives offer superior performance; to monitor patients for toxicity and exacerbations; and, where possible, to support the continued viability of community-based practice as an alternative to hospital-based consolidation.^{12,33,34}

Clinical pathways seek to limit the variability of care and achieve predictable levels of quality and costs. They specify a selection, dosing, and ordering of drugs for each condition; the timing of tests and monitoring for disease progression and adverse drug reaction; the use of supportive therapies and shared decision making; and transition to palliative and hospice care if necessary. In an ideal world, clinical pathways would specify a preferred course of treatment for each stage of disease based on a review of the evidence on clinical efficacy, toxicity, and cost.³⁵

For specialty physician practices, adoption of pathway-based care can be promoted through any of several payment changes. The simplest is to combine increases in the professional fee schedule with reductions in the drug markup, to

focus financial incentives on professional services and away from drug sales. Some health plans are experimenting with adding new categories of reimbursable services, including care planning and management, which offset revenue losses from forgone drug markups without encouraging unnecessary routine physician visits.³⁶

For example, Anthem Blue Cross is participating in a pilot program with US Oncology to test new payment codes for cancer care planning and patient management. The goal is to reimburse the practices for activities that promote patient monitoring and education and thereby reduce adverse side effects and hospitalizations from toxic chemotherapy. These higher payments are made under the agreement that the oncology practices will use evidence-based pathways and limit buy-and-bill drug markups.

In addition to changes in the fees paid for evaluation and management, health plans can vary the drug markup above the average sales price level based on whether the physician practice is conforming to an evidence-based pathway. The percentage markup can be higher for low-cost than for high-cost drugs, in order to equalize the dollar markup. The markup for expensive biologics could be 10 percent above average sales price, for example, while the markup for inexpensive generic chemotherapies could be 150 percent.

Such approaches contrast with Medicare's administered pricing system, which pays 6 percent above average sales price for all specialty drugs—a policy that discourages the use of low-cost products.

Episode-of-care payment can be adapted to oncology once rates have been fine-tuned to account for the site and severity of disease.³⁷ Some episode payment methods exclude pharmaceuticals, reimbursing specialty drugs separately on an invoice cost basis without markup. Such methods protect the physician practice from the financial risk of new drugs being introduced into the market or the risk of attracting sick patients who require the most expensive drugs.

UnitedHealthcare developed such an approach with large oncology practices in the Midwest in a manner that continued past levels of total reimbursement but disconnected them from drug markups. The intent was to reduce future cost trends that normally would have resulted from percentage markups' being applied to newly introduced and premium-price biopharmaceuticals.²¹

The cost of cancer drugs can be included in the episode payment, which then must be adjusted by the patient's cancer indication and stage of disease. For example, the Hill Physicians Medi-

cal Group pays contracted oncology practices on an episode basis for lung, breast, and colon cancer, with the payment depending on indication and on where the patient is in the course of treatment.

Drug costs typically are high immediately after chemotherapy begins and then decline after the course of care is completed several months later. Cost patterns then may remain low if the patient is in remission or may rise again if a new course of care is initiated. These episode payments are supplemented by stop-loss limits, which offer the physician practices additional reimbursement for the care of patients whose costs have exceeded a threshold defined in the episode protocol.³⁸

Opportunities For The Medical Technology Industry

As new drugs and devices are released, their makers must overcome three major hurdles before the products reach patients: documenting safety and efficacy to the FDA's satisfaction; convincing insurers that the product should be covered under the definition of *medical necessity*; and motivating physicians to prescribe their use. Historically, technology firms have focused on the FDA and insurers as the most difficult hurdles, relying on the fee-for-service payment methods to ease discussions with physicians over prescription and with hospitals over acquisition. This era is now drawing to a close.

Although market access and insurance coverage remain important priorities, the most significant new challenge to the medical technology industry is the shift in payment methods for physicians and hospitals. Newer methods give providers increasingly strong incentives to care about the cost of the products they use.

Changes in provider payment are both cause and consequence of changes in provider organization, including increased scale and scope, improved alignment of financial interests, and enhanced capabilities for assessing technology. These developments challenge conventional methods of designing, pricing, distributing, and selling drugs and devices. As always, challenges to the sector bring opportunities for those firms that can make changes faster and better than their competitors.

The core logic of contemporary changes in provider payment is to shift from the insurer to the provider the financial responsibility for cost-conscious choice. The core logic of technology firms' response thus needs to be a reduction in the cost of both their products and the services within which those products are embedded.

REDUCING THE COST OF TECHNOLOGY PROD-

Changes in provider payment are both cause and consequence of changes in provider organization.

UCTS Among medical technologies, innovations that increase value generally fall into one of two categories: breakthroughs and incremental improvements. Technology firms will need to be able to foster both types and then price the resulting products and aim them at different patients.

True breakthroughs in clinical performance deserve to be—and will be—rewarded with high prices. Neither physicians nor hospitals will be willing to deny patients access to new products for which substantial effectiveness has been documented in the laboratory and in real-world settings. Faced with bundled or prospective payment methods for such products, providers will push back on insurers and obtain price updates, severity adjustments, or other modifications.

Overall, providers and insurers will focus on appropriate use, seeking to limit the use of expensive innovations to those patients for whom the innovation's clinical effectiveness has been documented. This will lead to greater constraints on off-label prescription and other uses that are not supported by strong clinical literature. Technology producers will no longer have the luxury of developing products for a narrow indication but then having them prescribed and implanted for larger patient populations for whom evidence of performance is lacking.

Products that offer only incremental improvements in clinical performance represent increased value when they are priced at levels below those of existing products. Generic chemotherapies, follow-on drugs, and biosimilars can contribute to the health care system primarily by freeing up resources that can be redeployed elsewhere.

One way to address the cost of new medical technology is to focus on the engineering side of the product development cycle. Some implantable devices are overengineered, in the sense of offering functionalities that are of little value to the physician or patient but that add meaning-

fully to cost. For example, many diagnostic imaging machines contain capabilities for multiple types of images; these variants can add substantially to the cost and make them unaffordable in low-income nations and expensive in high-income ones. Such devices should be redesigned with simpler configurations, smaller components, cheaper materials, and more limited capabilities to fit constrained budgets.

The majority of patients will be well served by standardized products priced at modest levels, with only a minority needing targeted and customized products. This process of “design to value” deconstructs each functionality and characteristic of a planned device in terms of its clinical value and cost, and it uses only those that offer higher value than cost. *Value* is defined in terms of the perspective of the patients and purchasers, not that of the product designers and engineers.³⁹

For device firms, much of product development occurs in the clinical setting, in a process of experimentation, learning by doing, and incremental improvement.⁴⁰ In the future, the medical technology industry will have the opportunity to work with provider organizations that have large patient populations, the ability to develop and assess clinical pathways, and the desire to distinguish themselves as centers for research as well as for patient care. This new opportunity derives from the consolidation of provider organizations and their increased capabilities for product assessment and value purchasing. Close cooperation between medical technology producers and users of that technology is especially important for the device sector in the context of increased FDA concern for safety, because patient outcomes often depend on the skill, experience, and setting in which the device is used as well as on the physical characteristics of the device itself.⁴¹

For pharmaceutical firms, product development takes place primarily in the laboratory. However, the clinical setting is important for subsequent improvements in dosage, mode of administration, and toxicity monitoring.

The market potential of new pharmaceuticals depends on how they are inserted into the course of care and how they will be reimbursed, with resulting demands on support staff, patient education, and the fine-tuning of the care pathway. Manufacturers can partner with health care delivery systems and integrated organizations to gain insights into the product characteristics that influence adoption at the provider level as well as compliance at the patient level.

REDUCING THE COST OF TECHNOLOGY-BASED SERVICES Changes in provider payment and organization will demand not only changes in

the products developed by technology firms but also changes in the manner in which those products are used. Drug and device firms will enjoy new opportunities to cooperate with provider organizations to reduce the cost of tests, staffing, facilities, and other components of care. The most obvious examples include data exchange, distribution methods, changes in the site of care, patient education and compliance, and redesign of the process of care.

Increasingly cost-conscious provider organizations need more prompt, accurate, and complete information about the performance of the products they use currently and will use in the near future. Hospitals need help in planning for clinical technologies that are in the development pipeline, including their likely launch date; volumes and prices; implications for staffing and capacity; and whether they will cause shifts in the site of care, such as from inpatient to outpatient settings.

In the past, sales and distribution of drugs and devices have been costly and contentious, with frequent accusations of inappropriate financial incentives to physicians and excessive fees to technology representatives for “up-selling” variants that offer little incremental benefit. More stable organizational relationships between providers and producers are likely to shrink the functions of (and payments to) wholesalers, distributors, specialty pharmacies, device benefit managers, and other entities that stand between the hospital that purchases a drug or device and the manufacturer that sells it.

Hospitals and device firms can also find common ground by cooperating to streamline the actual process of care. That cooperation could include reductions in turnaround times and increases in caseloads for the operating room; application of Lean manufacturing principles to the flow of staffing, supplies, and tests; protocols for pain medication, physical therapy, and monitoring; and early planning for discharge to reduce lengths-of-stay and avoid readmissions.

Medical devices that make it possible to shift care from inpatient to less intense ambulatory and home settings will be valued highly by provider organizations once those savings accrue to them instead of flowing to the health insurers. Prospectively paid provider organizations also will capture the benefits of cost reductions for specialty pharmaceuticals and, hence, will be interested in programs that offer better patient compliance, reduce toxicity and adverse reactions, require fewer tests and less monitoring, and result in less frequent emergency department visits.

Conclusion

For the medical technology sector, these are the worst of times. Contemporary changes in provider payment, organization, and incentives will limit the industry's ability to obtain the prices and revenues that financed innovation in years past.

But for the medical technology sector, these also are the best of times. Distribution will evolve toward account management and partnership relationships with hospitals and large physician practices. Widespread provider use of technology assessment and clinical pathways will reward technology companies that are able to develop

truly innovative products; manufacture them in the most efficient manner; and document their clinical and economic value to ever more integrated, sophisticated, and cost-conscious providers.

The US health care system has suffered from the paradox of effective products' being used in ineffective processes, with fragmented organization and misaligned payment incentives for physicians and hospitals. Its future will feature increasingly integrated organizations, aligned incentives, and evidence-based clinical processes. ■

Funding for this research was provided by the Institute for Health Technology Studies (InHealth) Foundation; California Healthcare Foundation; and the Agency for Healthcare Research and Quality.

NOTES

- 1 Meier B. Costs surge for medical devices, but benefits are opaque. *New York Times*. 2009 Nov 5.
- 2 Schneller E, Montgomery K. Hospital's strategies for orchestrating selection of physician preference items. *Milbank Q*. 2007;85(2):307–35.
- 3 Robinson JC. Value-based purchasing of medical devices. *Health Aff (Millwood)*. 2008;27(6):1523–31.
- 4 Weaver C. Study: hospitals overpay for devices. *Wall Street Journal*. 2012 Feb 3.
- 5 Steinbrook R, Ross J. "Transparency reports" on industry payments to physicians and teaching hospitals. *JAMA*. 2012;307(10):1029–30.
- 6 Robinson JC, Pozen A, Tseng S, Bozic KJ. Variability in costs associated with total hip and knee replacement implants. *J Bone Jt Surg*. Forthcoming 2012.
- 7 Dolan EL, Robinson JC. Coronary angioplasty with drug eluting stents: device costs, hospital costs, and insurance payments. Berkeley (CA): University of California, Berkeley, Center for Health Technology; 2010 Sep. (Issue Brief).
- 8 Dolan EL, Robinson JC. Volumes, costs, and reimbursement for cervical fusion surgery in California hospitals, 2008. Berkeley (CA): University of California, Berkeley, Center for Health Technology; 2010 Jul. (Issue Brief).
- 9 Greenberg B, Wynn P. Navigating the new era of technology assessment. Washington (DC): Advisory Board Company; 2010 Apr 6.
- 10 Boston Scientific Neurovascular Group. Device carve-out guide: insurer contracting for neuroendovascular implantables. Minneapolis (MN): Boston Scientific Corporation; 2005.
- 11 Robinson J. Hospitals respond to Medicare payment shortfalls by both shifting costs and cutting them, based on market concentration. *Health Aff (Millwood)*. 2011;30(7):803–12.
- 12 Genentech. The 2012 Genentech oncology trend report. 4th ed. South San Francisco (CA): Genentech; 2011.
- 13 Stefanacci RG. "B" isn't always for biologics. *Manag Care*. 2012;21(2):50–4.
- 14 Express Scripts. 2011 drug trend report [Internet]. St. Louis (MO): Express Scripts; c2012 [cited 2012 Aug 1]. Available from: <http://digital.turn-page.com/i/70797>
- 15 Pollack A. For profit, industry seeks cancer drugs. *New York Times*. 2009 Sep 2.
- 16 Silverman E. Setting the bar higher for off-label use of biologics. *Biotechnol Healthc*. 2011;8(3):14–8.
- 17 American Society of Clinical Oncology. Reimbursement for cancer treatment: coverage of off-label drug indications. *J Clin Oncol*. 2006;24(19):3206–8.
- 18 Casali PG. The off-label use of drugs in oncology: a position paper by the European Society for Medical Oncology. *Ann Oncol*. 2007;18:1923–5.
- 19 National Comprehensive Cancer Network. Managed care and medical oncology: cancer is now on the table. Fort Washington (PA): NCCN; 2009. (Oncology Insights Report No. 1).
- 20 Butcher L. Will clinical pathways work? *Biotechnol Healthc*. 2010;7(3):16–20.
- 21 Newcomer LN. Changing physician incentives for cancer care to reward better patient outcomes instead of use of more costly drugs. *Health Aff (Millwood)*. 2012;31(4):780–5.
- 22 Jacobson M, Earle CC, Price M, Newhouse JP. How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment. *Health Aff (Millwood)*. 2010;29(7):1391–9.
- 23 Academy of Managed Care Pharmacy Task Force on Drug Payment Methodologies. AMCP guide to pharmaceutical payment methods, comprehensive edition, version 1.0 [Internet]. Alexandria (VA): AMCP; 2007 Oct [cited 2012 Aug 1]. Available from: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9856>
- 24 Edelman B. Specialty pharmacy booms, but for how long? *Biotechnol Healthc*. 2004;1(1):32–7.
- 25 McKain J. Connecting patients with specialty products: distribution models for biologics and other specialty pharmaceutical products. *Biotechnol Healthc*. 2012;9(2):8–13.
- 26 Fitch K, Pyensen B. Site of service cost differences for Medicare patients receiving chemotherapy. *New York (NY): Milliman*; 2011 Oct 19.
- 27 Avalere Health. Total cost of cancer care by site of service: physician office vs outpatient hospital. Washington (DC): Avalere Health; 2012 Mar.
- 28 Keough CL, Webster SA. 340B program presents opportunities—and challenges. *Healthc Financ Manag J*. 2009;63(11):42–8.
- 29 Ranawat AS, Koenig JH, Thomas AJ, Drna CD, Shapiro LA. Aligning physician and hospital incentives: the approach at hospital for special surgery. *Clin Orthop Relat Res*.

- 2009;467(10):2535–41.
- 30 Wilensky GR, Wolter N, Fischer MM. Gain sharing: a good concept getting a bad name? *Health Aff (Millwood)*. 2007;26(1):w58–67. DOI: 10.1377/hlthaff.26.1.w58.
 - 31 Ketcham JD, Furukawa MF. Hospital-physician gain sharing in cardiology. *Health Aff (Millwood)*. 2008;27(3):803–12.
 - 32 Gutowski C, Ma J, Hoo KS, Bozic KJ. Health technology assessment at the University of California-San Francisco. *J Healthc Manag*. 2011;56(1):15–29.
 - 33 Butcher L. Employers struggle to cope with the rising use of biologics. *Biotechnol Healthc*. 2011;8(4):21–4.
 - 34 Tu H, Samuel DR. Limited options to manage specialty drug spending. Washington (DC): Center for Studying Health System Change; 2012 Apr. (Research Brief No. 22).
 - 35 Holcombe D. What payers and physicians need to look for in clinical pathways. *Lyceum Newsletter Perspectives* [serial on the Internet]. 2010 Aug 2 [cited 2012 Aug 1]. Available from: <http://www.lyceumassociates.com/Newsletter/SampleArticles/tabid/867/smId/2530/ArticleID/659/refTab/777/t/What-Payers-and-Physicians-Need-to-Look-for-in-Clinical-Pathways/Default.aspx>
 - 36 Smith TJ, Hilner BE. Bending the cost curve in cancer care. *N Engl J Med*. 2011;364:2060–5.
 - 37 Bach PB, Mirkin JN, Luke JJ. Episode-based payment for cancer care: a proposed pilot for Medicare. *Health Aff (Millwood)*. 2011;30(3):500–9.
 - 38 Ayala D, Woo A. Oncology case rate: overview [Internet]. San Ramon (CA): Hill Physicians Medical Group; [cited 2012 Aug 2]. Available from: http://www.chcca.com/presentations/pfsummit7/2.7_2.pdf
 - 39 Chilukuri S, Gordon M, Musso C, Ramaswamy S. Design to value in medical devices [Internet]. Florham Park (NJ): McKinsey and Company; 2010 [cited 2012 Aug 2]. Available from: http://www.mckinsey.com/~media/mckinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/774172_Design_to_value_in_medical_devices1.ashx
 - 40 Nelson RR, Buterbaugh K, Perl M, Gelijns A. How medical know-how progresses. *Research Pol*. 2011;40(10):1339–44.
 - 41 Challoner DR, Vodra W. Medical devices and health—creating a new regulatory framework for moderate-risk devices. *N Engl J Med*. 2011;365(11):977–9.

ABOUT THE AUTHOR: JAMES C. ROBINSON



James C. Robinson is the Leonard D. Schaeffer Professor of Health Economics at the University of California, Berkeley.

In this month's *Health Affairs*, James Robinson describes a new era in which medical device and specialty drug makers will face pressures from hospitals, health systems, insurers, and policy makers seeking to control costs and foster more uniformity in the development and adoption of new technologies. However, the article also heralds opportunities for these industries to flourish, as they partner with provider

organizations to reduce costs and still develop innovative products that make the best use of personnel and other resources.

An economist, Robinson is the Leonard D. Schaeffer Professor of Health Economics and director of the Berkeley Center for Health Technology, University of California, Berkeley. He launched the center in 2008 to focus on how insurance and payment influence the development and use of innovative but high-cost drugs, biologics, and medical devices. Robinson is also on the board of directors of the Integrated Healthcare Association, a nonprofit association of large health plans, physician organizations, and hospitals that has developed the pay-for-performance and episode-of-care payment systems for

private-sector plans and providers in California.

Robinson was the editor-in-chief of *Health Affairs* during 2007–08 and now serves as a contributing editor of the journal. He has published more than 100 peer-reviewed articles in health policy, economics, and clinical journals, including the *New England Journal of Medicine* and the *Journal of the American Medical Association*. His research and professional activities have centered on the role of insurance coverage and payment methods in influencing the use, pricing, appropriateness, and cost of health care and health care technology. Robinson received a doctorate in economics from the University of California, Berkeley.