

## Medical Device Innovation in the Era of the Affordable Care Act: The End of Sexy

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Ask any random passersby on the street to close their eyes and tell you what comes to mind when they think of medical innovation, and you will inevitably evoke predictable images: daring surgeons performing breakthrough procedures in glass-encased hospital towers brimming with the latest technology and miracle drugs to cure cancer. But in other industries, such as computing and the automotive industry, innovation focuses on value: better products at the same price—or even a lower one—for similar performance.

Financial markets reflect this viewpoint: Shares of Intuitive Surgical, which manufactures surgical robots and has about \$2 billion in annual revenue, are trading at a forward price-to-earnings ratio of around 25, compared with 16 for Medtronic—the world’s largest device manufacturer by market capitalization, with annual revenue of over \$20 billion—even though research has cast doubt on the superior performance of robotic over traditional surgery for prostate cancer (Hu et al., 2009). (See Figure 1.)

Few innovations in the medical device space have been adopted for their cost savings. A paper by Nelson and colleagues illustrates how foreign the concept of cost-saving innovation is to medicine (Nelson et al., 2009). They reviewed published cost-effectiveness studies from 2002 to 2007 to assess how many medical innovations led to actual savings, as opposed to having a reasonable cost per outcome. Their search yielded 2,128 cost-effectiveness ratios from 887 publications. Almost three-quarters (72 percent) of these found better outcomes at higher cost. About 16 percent described innovations that improved outcomes at lower cost, and only nine comparisons (0.4 percent of the total) analyzed innovations that lowered cost but had slightly worse outcomes. The savings of those latter innovations ranged from \$122 to \$11,672 per case against a loss in quality-adjusted life-years between 0.001 and 0.02, which corresponds to roughly nine hours to one week of a patient’s life.

In this Perspective, we explore why medical innovation has traditionally been geared so thoroughly toward improving perfor-

**Figure 1. Billboard advertising robotic surgery**



SOURCE: Kowalczyk, 2009.

mance, with little regard to cost. We focus on devices rather than pharmaceuticals, as innovation in the device space involves solving engineering problems and can thus be better planned and directed than pharmaceutical research and development, which is much more dependent on breakthrough discoveries. In addition, the more predictable clinical development pathway for devices allows manufacturers to pursue projects with incremental and lower potential upsides. As an example, a device manufacturer can invest in miniaturizing a cardiac pacemaker and will be reasonably certain that the new product will perform well enough to obtain regulatory approval based on “substantial equivalence.” In contrast, changes to a molecule to increase half-life and reduce dosing frequency may fail or could lead to other side effects with little predictability. We also focus on implantable and other single-use devices.

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*Few innovations in the medical device space have been adopted for their cost savings.*

We argue that the changing incentives in the health care sector, accelerated by the implementation of the Affordable Care Act, will force device manufacturers to redirect future investments from the spectacular toward the prudent, which we call “the end of sexy.” Lastly, we explore consequences for manufacturers, investors, and policymakers.

### **Today, Innovation in the Device Sector Focuses on the Spectacular**

For decades, medical innovation has been driven by what Burton Weisbrod termed “the health care quadrilemma” (Weisbrod, 1991). Insurance coverage of medical services implies that patients are insensitive to price, and they demand ever-greater effectiveness and convenience of care without regard to cost. Manufacturers recognize the market incentives and direct investment accordingly. Physicians are being paid per service and benefit from an ever-expanding array of treatment options. They can deploy those options without harming their patients financially and, thus, reinforce manufacturers’ capital allocation patterns. As a consequence, costs keep going up, and medical care becomes increasingly unaffordable without insurance coverage. In other words, the consequences created by the combination of comprehensive health insurance and fee-for-service payment set in motion a cycle of escalating cost with little regard for value created.

### **The Shift to Value-Based Payment Requires a New Innovation Paradigm**

Many experts have realized that the fee-for-service payment system is the glue that holds this self-reinforcing cycle together: As long as

physicians benefit from increasing the range and complexity of services, they lack an incentive to manage overall resources prudently.

Today, however, all signs point to the fee-for-service system facing the fate of the dinosaurs, a trend that started prior to but was certainly accelerated by the passage of the Affordable Care Act. UnitedHealth Group, the largest commercial insurance carrier, has stated that it is moving away from fee-for-service payment (UnitedHealthcare, 2015), and U.S. Department of Health and Human Services Secretary Sylvia Burwell announced recently that 50 percent of all Medicare payments will be tied to value generation by 2018 (Burwell, 2015).

This shift toward value-based payment will have profound effects on the health care system, as physicians and other health care providers will be held financially accountable for the overall cost of care and the health results of their patient populations. In other words, providers are now exposed to part of the financial risk and the marginal cost of care. They must now be concerned about the cost per relevant outcome achieved and cannot be advocates for better outcomes, regardless of the cost, any longer.

As an immediate effect, this sea change has triggered a wave of consolidation, as the various players have sought to acquire the capabilities, size, and financial muscle that would enable them to manage health and risk at the population level. Hospitals have merged with other hospitals and with physician groups, physician groups have merged with others, insurers have bought provider organizations, and health systems have started offering insurance. While the pre-recession years of 2005 to 2007 had an average number of 50 to 60 total mergers, 105 deals were reported in 2012 following the passage of the Affordable Care Act (Dafny, 2014). The number and percentage of physicians in independent practice also

continue to decline, with an estimated 389,008 independent physicians (57 percent) in 2000, compared with 305,575 (39 percent) in 2012 (Gamble, 2012).

One direct consequence of the corporatization of medical care is that control over business decisions increasingly shifts from physicians to managers. Purchasing of a much broader range of medical devices and supplies is now in the hands of procurement departments that work with group-purchasing organizations to negotiate volume discounts. Such centralized procurement was previously confined to commodity supplies, such as syringes and gauze pads, whereas physicians were able to order more sophisticated devices, such as cardiac catheters and artificial joints, from their preferred suppliers.

As physicians were typically isolated from the costs of the devices, they were free to base their choices on such factors as product features and opportunities to participate in sponsored research projects. In turn, manufacturers focused product development and marketing on physicians' needs, rather than on unit cost or overall cost per episode of care. Hospital executives also were not necessarily concerned about cost because they could pass it on to payers and use access to advanced technology as a differentiator in the marketplace. Thus, manufacturers competed on innovative features and spectacular attributes, rather than on price.

To illustrate, the average list price (in 2015 U.S. dollars) for a first-generation drug-eluting coronary stent in 2004, when two competing products were first on the market, was \$3,081. The average list price (in 2015 U.S. dollars) for the three competing second-generation stents, approved in 2008 based on being "non-inferior" to the previous models, was \$3,091.

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## The three forces that will drive future device innovation will be the three Ds: *deinstitutionalization*, *de-skilling*, and *defragmentation of care* in order to generate higher value.

The advent of value-based payment radically changes the incentives for providers from maximizing quality and convenience, regardless of cost, to achieving good outcomes while holding the cost per episode down. As in any industry, they will pass on cost pressure to their suppliers. Integration of hospitals and physician practices and shifting of financial risk to those health systems give greater control to managers. Elliott Krause has termed this corporatization of a profession that goes together with loss of professional autonomy and self-regulation “the death of the guilds” (Krause, 1999); we have dubbed it “the end of sexy,” as the increasing control of managers over procurement decisions will usher in a new paradigm for medical device innovation that will prioritize prudent over spectacular.

### **3-D Innovation in the “Post-Sexy” Era**

In response to the market shift to value-based payment, device manufacturers will have to pay greater attention to the implications of their innovations for the overall cost of care, offering patient-centric solutions and becoming strategic partners of health systems rather than suppliers. The three forces that will drive future device innovation will be the three Ds: *deinstitutionalization*, *de-skilling*, and *defragmentation* of care in order to generate higher value.

*Deinstitutionalization* means reducing high-cost inpatient care in hospitals and nursing homes by supporting in-home and community care and aging in place. For example, remote monitoring and telehealth approaches have the potential to enable management of patients with chronic conditions at home, thereby preventing costly exacerbations and admissions.

*De-skilling* refers to gaining efficiency by substituting capital for labor—in other words, replacing expensive and scarce medical professionals with devices that support and automate routine tasks with minimal supervision. For example, the Sedasys device allows safe delivery of intravenous propofol for sedation during routine gastroenterology procedures, thereby avoiding the need for an anesthesiologist, who charges commercial insurers \$450, on average, for those short procedures (Sedasys, 2015).

*Defragmentation* denotes a seamless flow of data and insights that follows the patient across sites of care to prevent loss of information, duplication of services, and discontinuity in decisionmaking. For example, Caregiver Homes provides a technology platform to support care for homebound elderly patients with several disabilities (Caregiver Homes, undated). Its web-based care plan can be accessed by multiple family and professional caregivers to coordinate care and share information.

## **Implications for Stakeholders**

### **Implications for Companies**

Device manufacturers who want to win in the value-based payment environment will need to accomplish three tasks: reorient research and development (R&D) investment toward frugal innovation, increase the sophistication of their clinical development programs,

and integrate their products with services into comprehensive solutions.

### Reorient R&D Investment

Comprehensive insurance coverage and fee-for-service payment mean that health care to date has been largely insulated from the threat of disruptive innovation (Christensen, 2013). This term, coined by management theorist Clayton Christensen, describes the displacement of successful companies by upstarts if they neglect perceived low-value segments of their market. New entrants can gain a foothold by serving those segments with lower-cost products and then disrupt the entire market through rapid innovation. An often-quoted example is the personal computer (PC). Initially vastly inferior to the dominant mainframe computer, the PC offered access to computing to users who could never have afforded a mainframe system. Rapid improvement in processing speed and storage capacity meant that the PC became the technology of choice for all but the most demanding users within a short period of time. In the 1980s, IBM dominated the information industry, capturing 70 percent of worldwide profits, mainly through mainframe sales. The technological shift from mainframes to PCs caught the company by surprise, contributing to a record loss of nearly \$16 billion from 1990 to 1993 (Austin and Nolan, 2000). Another example is the displacement of film by digital photography.

Because patients (and providers) have been largely unaffected by affordability concerns, health care lacks such neglected segments and the corresponding opportunity for new entrants. Even in emerging economies that tend to lack universal health insurance,

companies focused on a small and wealthy segment that could afford high-cost technologies.

But the incentives are now changing, and companies must change with them. Greater exposure of patients and providers to the cost of care through high-deductible health plans and value-based payments, respectively, implies nascent demand for lower-cost, “good enough” devices.

Thus, companies will have to reorient investment priorities toward frugal innovation. This change can take the form of simpler products with lower unit cost, a strategy that many manufacturers are now pursuing with research centers in Asia (see Box 1). Conceivably, devices that reduce quality slightly might reach the market, if cost savings justify the decrement. But frugal innovation does not preclude developing sophisticated products with high unit prices, if they can lower the overall cost of care. For example, the Mepilex Border Sacrum dressing, a foam dressing for the sacral

#### **Box 1. Device Makers’ Emerging Market Strategy and Reverse Innovation**

Several large device companies are actively pursuing frugal innovation projects to provide access to technology in emerging markets. Medtronic, for example, is developing a low-cost cardiac pacemaker that will be five to ten times cheaper than current models (Hirschler, 2012). Siemens has developed a fetal heart rate monitor that relies on simple microphones rather than expensive ultrasound technology. It can be used without specialized training and costs a fraction of the \$4,000 systems used in industrialized countries (Löscher, 2011). Crucially, such innovations, while originally conceived for developing markets, can eventually become “good enough” to displace the established and costly technologies that are in use in the developed world, a process called *reverse innovation* (DePasse and Lee, 2013).

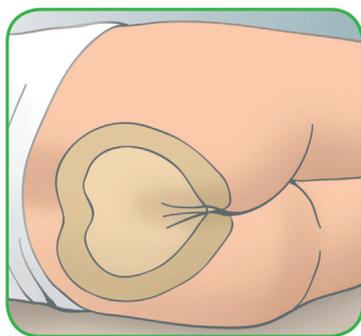
*The advent of value-based payment radically changes the incentives for providers from maximizing quality and convenience, regardless of cost, to achieving good outcomes while holding the cost per episode down.*

area (Figure 2), appears expensive, with a list price of \$96, but can prevent the occurrence of high-cost pressure ulcers (Santamaria et al., 2015).

#### Increase the Sophistication of Clinical Development Programs

Device companies have historically been able to obtain regulatory approval with a more-limited clinical development program than their counterparts in the pharmaceutical industry, as devices do not interact with the body's metabolism, which makes effects and side effects easier to predict. Simply speaking, manu-

**Figure 2. Mepilex Border Sacrum dressing**



SOURCE: Mölnlycke Health Care, undated.

facturers have to prove that their products work as intended, are substantially equivalent to existing products, and follow good manufacturing practices. Many devices can be cleared through the 510(k) or CE Mark process without the need for clinical trials, and even higher-risk implantable devices require relatively small trials. Head-to-head trials and label extension trials are also less common.

A side effect of this easier path to market is that device companies have never had to build market access and outcomes research functions that are as sophisticated as those of pharmaceutical companies. But with purchasing decisions now shifting from physicians to managers and payers, they will need to orient their clinical development programs toward the needs of multiple stakeholders. The definition of value will broaden from clinical efficacy and operator convenience to the effect on real-world clinical and patient-centric outcomes and the overall cost of care per episode.

As in the pharmaceutical industry, device companies will have to fold market access and pricing considerations into preclinical and clinical investment decisions, as opposed to regarding them as an afterthought once the product is approved. They will need to stay abreast of changes to the payment system and stakeholder demands and adjust their development programs accordingly.

Not all of the required proof points, however, will have to come from tightly regulated and expensive premarket trials. Unlike regulators, payers and other stakeholders are quite comfortable with information gleaned from post-hoc analyses, pragmatic trials, observational studies, and modeling exercises. The unloved post-market approval studies, in particular, might become a valuable data source to support such conversations, and so could registries and research consortia.

## Integrate Products with Services

The emergence of new payment models enhances the pathways through which device manufacturers can monetize the value of their innovations. Historically, the revenue model was predominately based on product sales, sometimes with arrangements to ease the burden of up-front payment for providers. The adoption of value-based payment models for providers and the associated shift of financial risk to providers means that device companies will be asked to help manage that risk and will be rewarded if they do so successfully.

Thus, companies will need to ensure that providers get the most out of their products through developing value-added services around the product and offering providers a package of integrated services that can improve quality of care and/or lower overall health care costs (Mattke, Klautzer, and Mengistu, 2012). Such integration of products and services into comprehensive solutions is common in other industries but is only just emerging in health care. An early proponent of this trend is Fresenius Medical Care, the world's largest manufacturer of dialysis equipment and operator of dialysis facilities (see Box 2).

## Implications for Payers and Regulators

Policymakers responsible for payment and device regulation need to do their part to create the right conditions for frugal innovation to thrive in the medical device sphere. Clearly, the shift toward value-based payment is an important step, but payers, especially the public ones, need to accelerate this shift and provide better visibility into its direction. In addition, regulatory policy will play an important role.

### Box 2. Fresenius Medical Care

The company that is now Fresenius Medical Care started out in a town near Frankfurt, Germany, in 1912 as a pharmaceutical manufacturer that produced cold remedies, vitamins, and, later, infusion solutions. In the 1960s, as hemodialysis was beginning to be adopted, the company saw growth opportunities for its infusion solutions, which are used in great volumes during dialysis, and additional products. Fresenius initially ventured into distribution and maintenance of dialyzers and then developed its own dialysis machines and filters. Over the next three decades, Fresenius Worldwide Dialysis became the world's largest producer of dialysis equipment (Fresenius Medical Care, 2016).

In 1996, Fresenius acquired National Medical Care, a dialysis chain with around 700 centers in the United States and other countries (Meier, 1996). The vision was that the combination of the complementary businesses of Fresenius and National Medical Care under the name Fresenius Medical Care would allow the new company to align product development with patient needs and achieve economies of scale and scope, with the explicit intention of becoming the world's largest integrated dialysis products and services company.

Several companies bid on National Medical Care, but Fresenius ultimately prevailed. And the investment paid off. According to company statements, its share price has quadrupled in the last ten years. It operates over 3,000 dialysis clinics globally, which care for over 200,000 patients—about 10 percent of the 2.2 million patients with end-stage renal disease who require dialysis treatment. Even though Fresenius Medical Care remains the largest seller of dialyzers and dialysis machines globally, about 75 percent of its 2012 revenue of 13.8 billion in U.S. dollars came from dialysis services.

## Speed Up Payment System Change and Provide a Clear Direction

The key to payment reform lies in the hands of the U.S. Centers for Medicare & Medicaid Services (CMS). Of course, its Medicare program is the largest purchaser of care in the United States and

gives direction for all payers. But, almost as importantly, it plays a crucial role in financing the development of the science behind those complex new payment models. CMS-funded research has brought the world prospective payment for hospital care based on diagnosis-related groups. Its current research program supports the design and testing of bundled payments, accountable care, and capitation models, as well as the quality measures that are an intrinsic part of those models.

This influential role carries with it a huge responsibility. CMS will need to sustain, if not accelerate, its investment into payment reform research, mirroring the efforts of its Innovation Center on the delivery side. As results come in, CMS will need to provide forward guidance on its specific direction, as different models differ substantially in how strongly they incentivize frugal innovation. Secretary Burwell’s announcement to tie 50 percent of Medicare payment to value creation by 2018 is a powerful statement, but the actual meaning of “tied to value creation” is yet to be defined. For example, the most common models of “value-based payment” today are patient-centered medical homes (PCMHs) and accountable care organizations (ACOs). Both are largely based on fee-for-service arrangements. In a PCMH, providers are paid an additional

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case management fee for chronically ill patients and may receive bonuses for meeting quality and patient experience targets. An ACO is held accountable for the overall cost of care, but, typically, only between 1 and 3 percent of its payments are at risk. In contrast, bundled payments, such as the recently announced Comprehensive Care for Joint Replacement model, and capitation put providers at risk for the full cost of care per episode and time frame, respectively.

Device companies need to make R&D investment decisions up to a decade in advance of market introduction. They will need visibility into the trajectory of payment system change, as they must adapt to future models while operating today under the incentives of fee for service.

### Create a Conducive Regulatory Environment for Cost-Saving Innovations

Regulatory policy will play an important role in determining the prospects of cost-saving innovation in the medical device industry. Nowhere is the adage “your cost is my revenue” more true than in health care with generous third-party coverage. Entrenched interests have a strong incentive to oppose innovations that threaten their revenue base and will not be shy about using political pressure to keep them from accessing the market. Here, the more-limited clinical research programs that are required for device approval turn into a double-edged sword for companies. With scarcer and less rigorous data, the U.S. Food and Drug Administration (FDA) has a greater discretion over approval and the conditions that it attaches to an approval.

Detractors can use this greater uncertainty and raise concerns about even potential or theoretical risks to patients, implying that

lower-cost devices are endangering patients. This tactic puts the FDA in a politically precarious position. On the one hand, policy-makers want it to approve cost-saving technology more quickly; on the other, Congress will be quite eager to rake FDA officials over the coals if a cost-saving technology proves to have safety problems.

Confronted with this potential controversy, the easiest position for the FDA to take, politically, may be to prevent such innovations from entering the market, leaving insurers and consumers with existing products that may be more expensive. The Sedasys system illustrates this tension (see Box 3).

The Sedasys case study illustrates the critical role that the FDA could play in enabling cost-saving innovation with an evaluation framework that minimizes risk without preventing innovation. It

### **Box 3. Sedasys**

Sedasys is a technology to sedate patients during minor surgical and interventional procedures with the drug propofol. It allows intravenous administration of the drug, combined with patient monitoring, to stop the infusion if sedation levels become too deep. Ethicon Endo-Surgery, the manufacturer of Sedasys, had executed an agreed-upon clinical trial program, and the device had met the prespecified primary endpoints. In 2008, Ethicon Endo-Surgery submitted a Premarket Approval application to the FDA and received expedited review status. In 2009, the FDA advisory panel had voted eight to two in favor of approval, but the agency overruled its own panel and asked for additional clinical trials. The American Society of Anesthesiologists and the American Association of Nurse Anesthetists had vehemently opposed the device. Ethicon Endo-Surgery refused to extend the clinical trial program and appealed the decision. After lengthy negotiations, the FDA and the manufacturer finally agreed in 2013 on approving the device without additional trials but with strict user training and post-market surveillance requirements (Frankel, 2015).

could expand its new Expedited Access for Premarket Approval program, which is currently only available to devices with a *clinically* meaningful advantage over approved products, to devices that offer significant cost reduction over existing products. It could require developers to implement risk evaluation and mitigation strategies and strengthen its adverse-event reporting systems. It could mandate post-market surveillance studies or registries to detect risks, which may not become apparent prior to approval. Admittedly, these approaches as currently implemented may not be sufficient, but they can form the basis of a future process that provides clear guidance, as well as predictable and transparent decision criteria, for evaluating cost-saving devices. Without such guidance, developers will lack the incentive to bring such technologies to market, and the upward cost spiral will continue. But at the same time, the agency operates under intense scrutiny and can only take a rational approach to risk if its paymasters in Congress permit it to do so. Unless Congress provides the necessary political cover, cost-saving innovation will remain an elusive goal.

### **Summary**

As we are witnessing a fundamental change in how we pay for medical care, the medical device industry will have to adapt to the new incentives and reorient innovation from the spectacular to the prudent—the end of sexy. Established companies that manage this reorientation successfully and new entrants that are natives of the new value-based payment world will see great rewards and will contribute to achieving the triple aim of better health, better care, and lower cost in the process. Policymakers will need to do their part and create a conducive environment for cost-saving innovation to flourish.

## References

- Austin, Robert Daniel, and Richard L. Nolan, *IBM Corporation Turnaround*, Harvard Business School Case 600-098, Boston: Harvard Business School Publishing, 2000.
- Burwell, Sylvia M., “Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care,” *New England Journal of Medicine*, Vol. 372, No. 10, January 26, 2015, pp. 897–899.
- Caregiver Homes, “Caring for Elders,” undated. As of January 21, 2016: <http://www.caregiverhomes.com/for-professionals/pro-elder>
- Christensen, Clayton, *The Innovator’s Dilemma: When New Technologies Cause Great Firms to Fail*, Boston: Harvard Business Review Press, 2013.
- Dafny, Leemore, “Hospital Industry Consolidation—Still More to Come?” *New England Journal of Medicine*, Vol. 370, No. 3, January 16, 2014, pp. 198–199.
- DePasse, Jacqueline W., and Patrick T. Lee, “A Model for ‘Reverse Innovation’ in Health Care,” *Globalization and Health*, Vol. 9, August 30, 2013, p. 40.
- Frankel, Todd C., “New Machine Could One Day Replace Anesthesiologists,” *Washington Post*, May 11, 2015. As of January 21, 2016: [https://www.washingtonpost.com/business/economy/new-machine-could-one-day-replace-anesthesiologists/2015/05/11/92e8a42c-f424-11e4-b2f3-af5479e6bbdd\\_story.html](https://www.washingtonpost.com/business/economy/new-machine-could-one-day-replace-anesthesiologists/2015/05/11/92e8a42c-f424-11e4-b2f3-af5479e6bbdd_story.html)
- Fresenius Medical Care, “History,” 2016. As of January 21, 2016: <http://www.freseniusmedicalcare.com/en/home/about-us/history/print-page-history>
- Gamble, Molly, “42 Statistics on Independent Physicians from 2000 to 2013,” *Becker’s Hospital Review*, November 19, 2012. As of January 21, 2016: <http://www.beckershospitalreview.com/hospital-physician-relationships/42-statistics-on-independent-physicians-from-2000-to-2013.html>
- Hirschler, Ben, “After \$35 Tablet Computer, Pacemakers May Be Next,” Reuters, January 25, 2012. As of January 21, 2016: <http://www.reuters.com/article/2012/01/25/us-davos-medtronic-idUSTRE800I1520120125>
- Hu, Jim C., Xiangmei Gu, Stuart R. Lipsitz, Michael J. Barry, Anthony V. D’Amico, Aaron C. Weinberg, and Nancy L. Keating, “Comparative Effectiveness of Minimally Invasive vs Open Radical Prostatectomy,” *JAMA: The Journal of the American Medical Association*, Vol. 302, No. 14, October 14, 2009, pp. 1557–1564.
- Kowalczyk, Liz, “Caution Sounded on Robot-Aided Prostate Surgery,” *Boston Globe*, October 14, 2009. As of January 21, 2016: [http://www.boston.com/news/local/massachusetts/articles/2009/10/14/study\\_scrutinizes\\_robot\\_assisted\\_prostate\\_surgery](http://www.boston.com/news/local/massachusetts/articles/2009/10/14/study_scrutinizes_robot_assisted_prostate_surgery)
- Krause, Elliott A., *Death of the Guilds: Professions, States, and the Advance of Capitalism, 1930 to the Present*, New Haven, Conn.: Yale University Press, 1999.
- Löscher, Peter, “Less Is More: In a Cost-Conscious World, Large Multinational Companies Will Have to Change Profoundly, Argues Peter Löscher, President and CEO of Siemens,” *The Economist*, November 17, 2011. As of January 21, 2016: <http://www.economist.com/node/21537984>
- Mattke, Soeren, Lisa Klautzer, and Tewodaj Mengistu, *Medicines as a Service: A New Commercial Model for Big Pharma in the Postblockbuster World*, Santa Monica, Calif.: RAND Corporation, OP-381-HLTH, 2012. As of January 21, 2016: [http://www.rand.org/pubs/occasional\\_papers/OP381.html](http://www.rand.org/pubs/occasional_papers/OP381.html)
- Meier, Barry, “German Merger for Grace’s Dialysis Unit,” *New York Times*, February 5, 1996. As of January 21, 2016: <http://www.nytimes.com/1996/02/05/business/german-merger-for-grace-s-dialysis-unit.html>
- Mölnlycke Health Care, “How to Apply Mepilex Border Sacrum,” undated. As of January 21, 2016: <http://www.molnlycke.com/patient/en/Products/Wound/Mepilex-Border-Sacrum/#How-to-apply>
- Nelson, Aaron L., Joshua T. Cohen, Dan Greenberg, and David M. Kent, “Much Cheaper, Almost as Good: Decrementally Cost-Effective Medical Innovation,” *Annals of Internal Medicine*, Vol. 151, No. 9, November 3, 2009, pp. 662–667.
- Santamaria, Nick, Marie Gerdtz, Sarah Sage, Jane McCann, Amy Freeman, Theresa Vassiliou, Stephanie De Vincentis, Ai Wei Ng, Elizabeth Manias, and Wei Liu, “A Randomised Controlled Trial of the Effectiveness of Soft Silicone Multi-Layered Foam Dressings in the Prevention of Sacral and Heel Pressure Ulcers in Trauma and Critically Ill Patients: The Border Trial,” *International Wound Journal*, Vol. 12, No. 3, June 2015, pp. 302–308.
- Sedasy, “Homepage,” 2015. As of January 21, 2016: <http://www.sedasy.com>

UnitedHealthcare, “More Than 11 Million People Can Now Receive Health Care Services from Care Providers Paid by UnitedHealthcare Based on Quality and Patient Outcomes,” Minnetonka, Minn., February 17, 2015. As of January 21, 2016:

<http://www.uhc.com/news-room/2015-news-release-archive/health-care-services-based-on-quality>

Weisbrod, Burton A., “The Health Care Quadrilemma: An Essay on Technological Change, Insurance, Quality of Care, and Cost Containment,” *Journal of Economic Literature*, Vol. 29, No. 2, June 1991, pp. 523–552.

## About This Perspective

This Perspective explores why medical innovation has traditionally been geared toward improving performance, with little regard to cost. The authors argue that the changing incentives in the health care sector, accelerated by the implementation of the Affordable Care Act, will force device manufacturers to redirect future investments from the spectacular toward the prudent and explore consequences for manufacturers, investors, and policymakers.

The authors would like to thank Richard Frank and Tom Concannon for their review and comments on an earlier version, as well as Michael Zamagias for inspiring them to write this paper.

Funding for this study was provided by philanthropic contributions from RAND supporters and income from operations.

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