



BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Challenges and Strategies for the Medical Device Industry in the US: Potential Implications for the EU

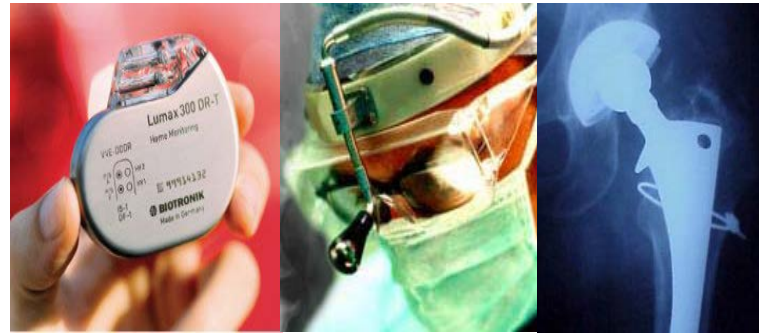
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Overview

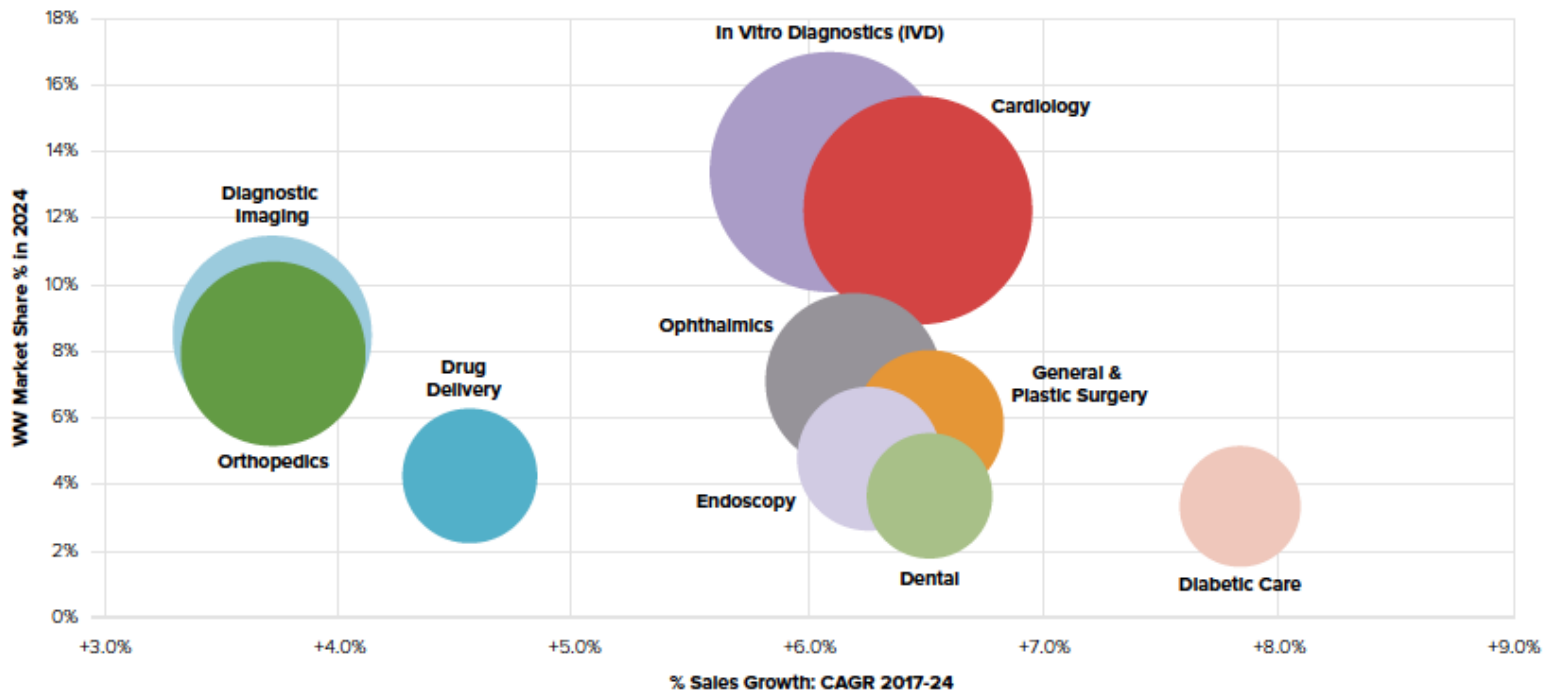


- The MedTech business model in the US
- Erosion of the traditional model
- Similarities and differences with the EU
- New opportunities for MedTech in the US
 - The rise of consumerism
 - The digital revolution
- Conclusions

Implantable Devices are Major Component of MedTech: Cardiology, Orthopedics, Endoscopy, Diabetic Care

Analysis on Top 10 Device Areas in 2024, Market Share & Sales Growth (2017-2024)

Source: Evaluate, September 2018



Note: Size of Bubble = WW Sales In 2024

Source: EvaluateMedTech® World Preview 2018; Outlook to 2024.



Traditional Medical Device Business Model

- Medical devices and equipment are purchased primarily by hospitals and clinics, not public and private insurers
- Providers traditionally faced few incentives to consider price when acquiring technology, but strong incentives to consider physician preferences
 - Competition for patients operated via non-price, technology based competition for physicians
 - Price played no role (patients were indifferent to price of hospital services, due to insurance)
 - Non-price competition led to greater diffusion and duplication of equipment and services
- Hospitals in structurally more competitive markets had higher, not lower, costs than those in structurally concentrated markets (contrary to pattern observed in markets with price competition)
- This was referred to as the “Medical Arms Race”



The Medical Arms Race

- Device firms developed strong ties to physicians and surgeons, who in turn developed strong brand affinities
 - Each doctor wanted free choice of device brand
 - These ties were supported by financial inducements
- In order to accommodate physician preferences, hospitals needed to contract with all device vendors
 - They did no formal technology assessment (HTA) before purchase, nor performance assessment later
 - No serious efforts by hospitals to limit physician financial conflicts of interest
- This undermined the ability of hospital supply management to negotiate low device prices
- Instead, high device costs were passed by hospitals on to insurers through FFS reimbursement
 - Medicare DRG payments provided a limit on device prices, but hospitals shifted costs onto private insurers

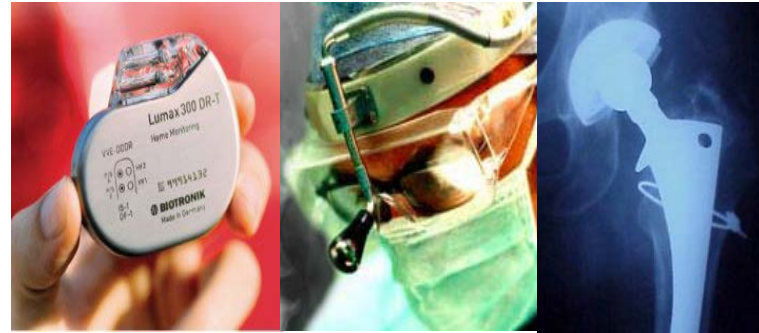


Medical Device Product and Pricing Strategy

- Medical device firms responded to the traditional market environment by developing incremental product improvements, which were sold at ever higher prices
- They developed close ties with physicians, but only limited ties with hospitals, insurers, and patients
- Some products offered breakthrough innovation, and generated large increases in sales and revenues
- However, the core business model relied on price increases from incremental changes in existing products, marketed aggressively to physicians
- This was hugely successful, but generated rising resistance from hospitals and insurers



Erosion of the Traditional Model



- The irony of success: the innovation race
- Incentives: bundled payment methods
- Capabilities: physician-hospital alignment
- New sites of clinical care

The Irony of Success

- The profitability of the traditional medtech business model attracted new entrants and competitors
 - Massive investment by venture, private equity, and public markets
 - Large number of specialized startups; small number of fully diversified global firms competing in all market segments
- Major device segments now feature multiple competitors with therapeutically similar (high-performing) products
- This creates the potential for price competition
- However, for potential competition to be translated into actual price competition, the purchasers (hospitals) need both the incentive AND the capabilities to purchase on price
- This is occurring



New Payment Methods for Hospitals

- The public Medicare insurance program pays hospitals on a prospective DRG basis, covering all services including supplies, devices, and technology
 - This gives a strong incentive for device cost management
- However, physician services are not covered by the DRG; doctors are paid FFS separately. Now, Medicare is moving from voluntary to mandatory programs to 'bundle' physician with hospital payments for device-intensive procedures (orthopedics, cardiology)
- Private insurers traditionally paid hospitals FFS, but now are following Medicare into DRGs and bundled payments, limiting hospital ability to cost shift from public to private
- They traditionally carved devices out from the DRG payment, but increasingly are exploring (ACO) payment methods that shift to hospitals and physicians full financial responsibility



New Capabilities: Alignment with Physicians

- Hospitals are consolidating into local and regional chains, and adding ambulatory and subacute care centers
- Hospitals are aligning much more closely with their physicians, in part to weaken the link between physicians and device firms
 - Employment, co-management contracts, joint ventures
 - Mandatory disclosure and limits on conflicts of interest with MedTech
- With better physician alignment, hospitals improve their ability to assess product performance and reduce prices
 - HTA: Technology assessment committees at major hospitals
 - Tendering: Narrow the range of device firms obtaining contracts
 - Gainsharing: hospitals set cost reduction targets, and share with physicians the 'savings' if targets are met. Lower device prices and spending are the major means to achieve these targets (along with shorter length of stay and fewer discharges to subacute facilities)

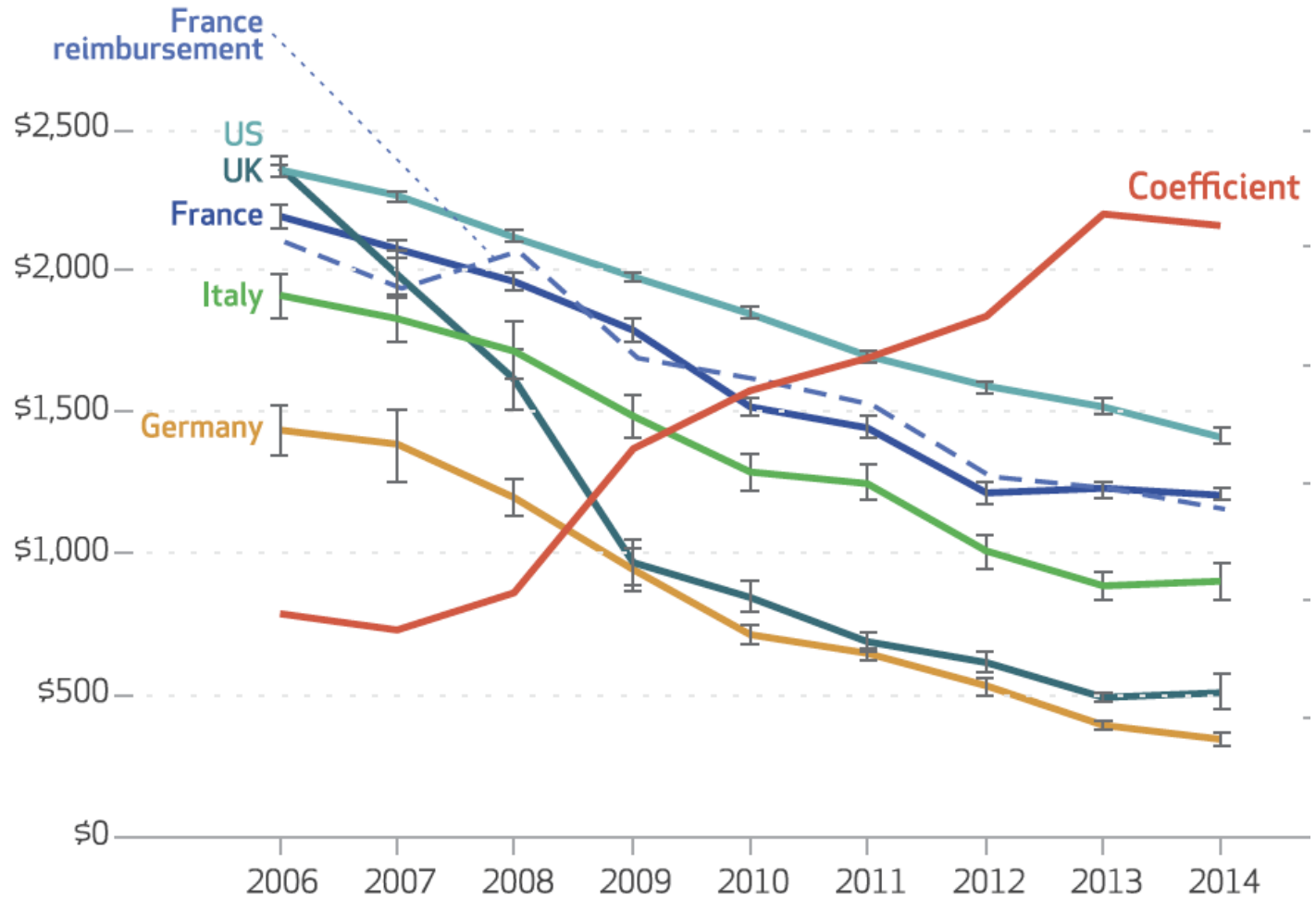


Brief Comparison to the EU



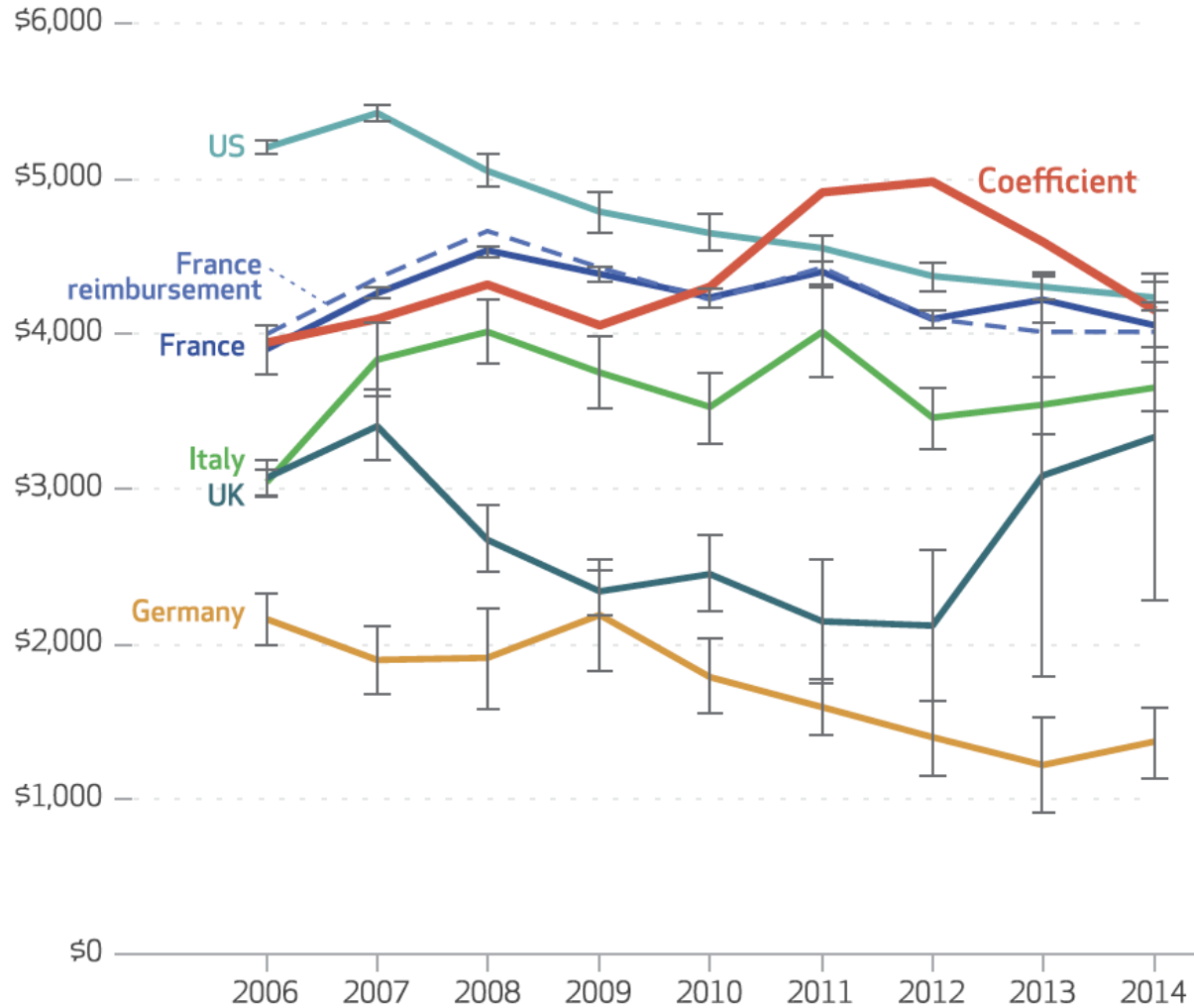
- EU nations place hospitals under greater budgetary pressures, many through DRG payments that include physician services
- Physicians are more aligned with hospital supply chain priorities, and are less insistent on unlimited choice of device
- Hospitals are able to assess performance (HTA) and use tendering to obtain better prices than US, with level of prices varying by nation

Estimated mean prices, in US dollars, of drug-eluting stents in the US and four Eu countries, 2006-14



Source: Wenzl et al. Health Affairs, October 2018.

Estimated mean prices, in US dollars, of dual-chamber pacemakers in the US and European countries, 2006-14



Source: Wenzl et al. Health Affairs, October 2018.

Emerging Opportunities: The Rise of Health Care Consumerism

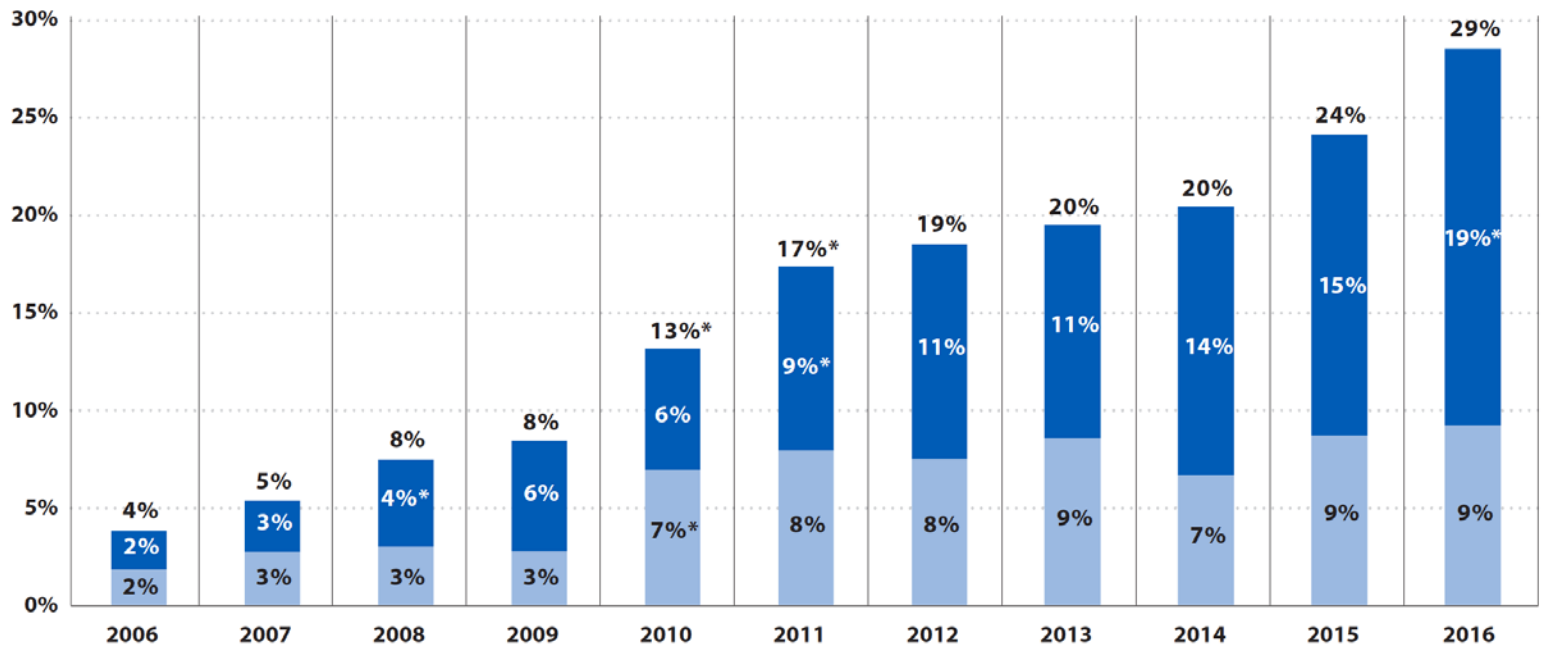


- Higher cost sharing: deductibles
- Incentives to choose low-cost clinical sites of care: reference pricing
- Culture of consumer engagement: price transparency & decision support

More Employers Require Employees to Pay High Deductibles for Health Care

EXHIBIT E

Percentage of Covered Workers Enrolled in an HDHP/HRA or HSA-Qualified HDHP, 2006-2016



*Estimate is statistically different from estimate for the previous year shown ($p < .05$).

NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more information, see the Survey Methods Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-Qualified HDHP enrollment estimates due to rounding.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

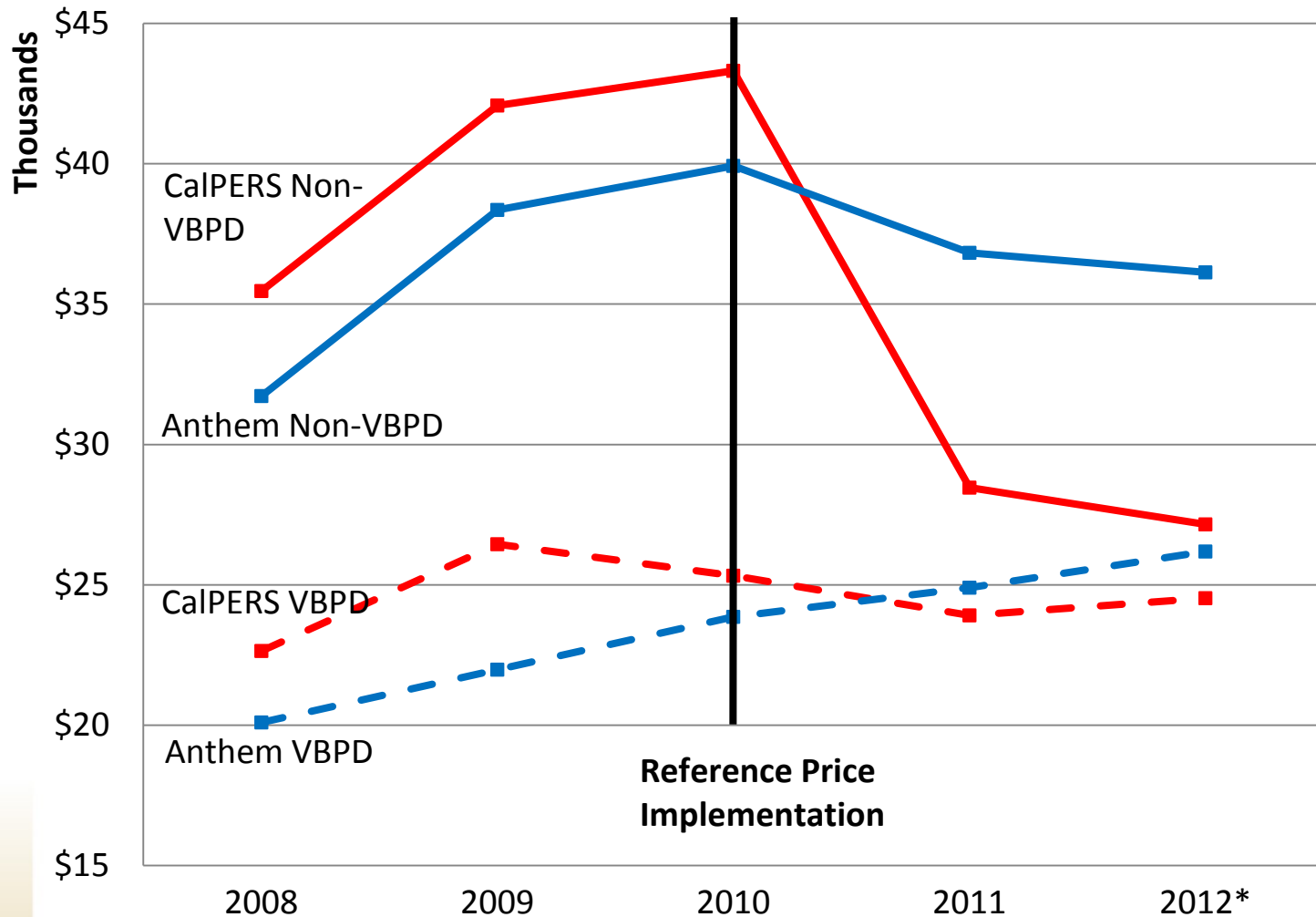
■ HSA-Qualified HDHP ■ HDHP/HRA

Some Employers Limit their Payments to Encourage Use of Low-Cost Sites of Care

- The medical arms race has resulted in high and variable prices charged by hospitals to insurers
- Payers pioneered 'reference pricing' for inpatient orthopedic surgery and expanded to ambulatory procedures to favor induce employees to use lower-cost ambulatory surgery centers over hospital outpatient departments
- Employees/patients respond by switching to lower-cost facilities

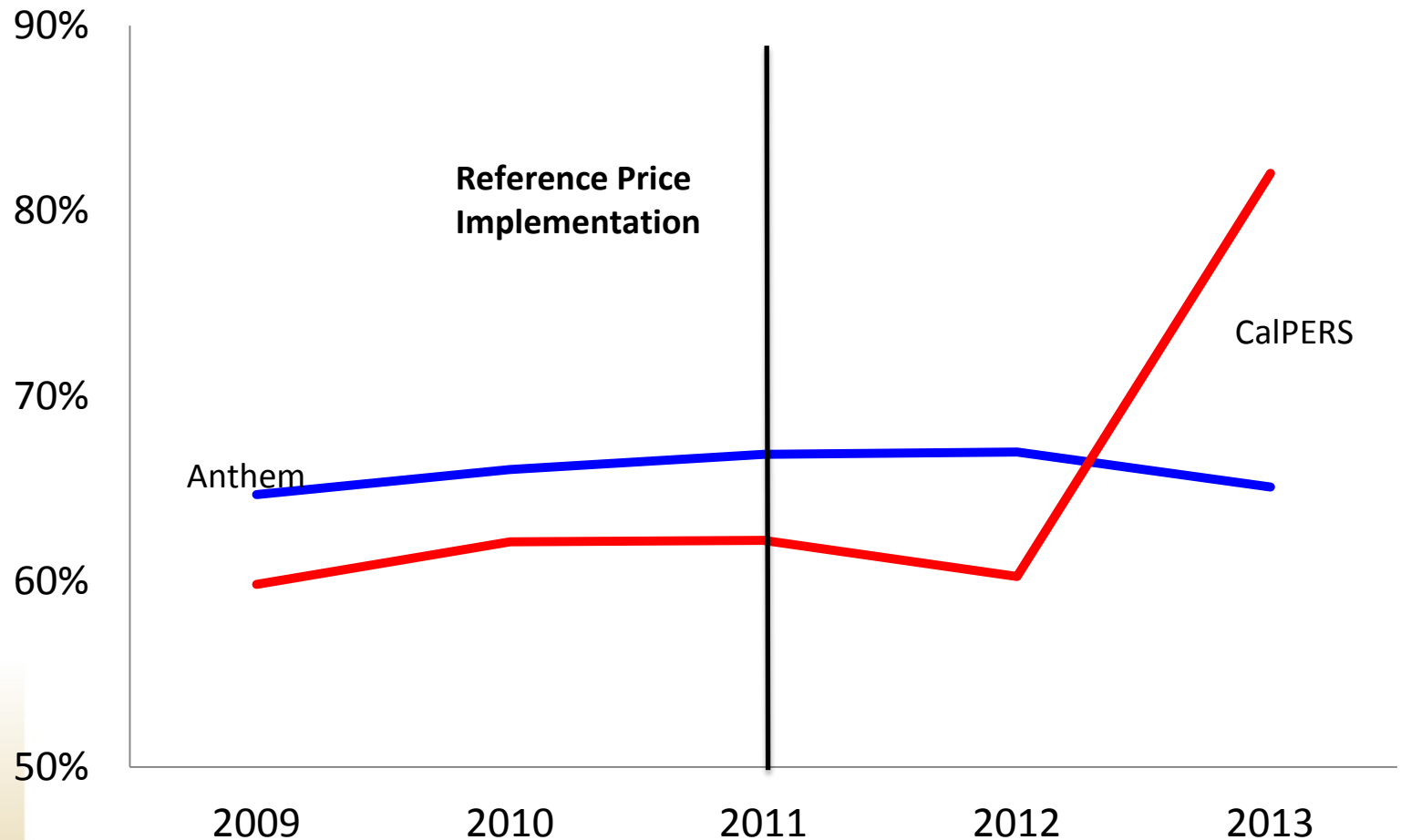


Average Price Paid for Joint Replacement by CalPERS (public employer alliance)



Source: Robinson, Brown: Health Affairs, 2013: 32(8):1392-97.

Percentage of Patients Selecting Ambulatory Center over Hospital Outpatient: Knee Arthroscopy



Source: Robinson, et al. J Bone Joint Surgery Am 2015;97:1473-81






Purchaser Initiatives to Support Consumer Choice




- Information on price & quality at competing facilities
- Active outreach to patients scheduled for procedures
- Decision support
- Developing patient-reported outcomes data



Price and Quality Transparency

Company and Product	Information Offered	Platform
<p>Castlight Health</p> 	<ul style="list-style-type: none"> • Price transparency – flagship firm • Plan benefit information for consumers • Employer analytics 	<ul style="list-style-type: none"> • Varied: web tools, delivered insights, mobile tools for employees
<p>Aetna iTriage</p> 	<ul style="list-style-type: none"> • Price comparison information from Healthcare Bluebook • Healthcare services information • Adding new services in future 	<ul style="list-style-type: none"> • Mobile integrated data platform, including an app
<p>UnitedHealthcare MyEasyBook</p> 	<ul style="list-style-type: none"> • Online health care shopping tool for consumers with high-deductible plans 	<ul style="list-style-type: none"> • Integrated in with members' claims, transparency tools, and in-network providers
<p>Guroo</p> 	<ul style="list-style-type: none"> • Cost information for over 70 common health conditions and services based on claims data from four major insurers 	<ul style="list-style-type: none"> • Consumer-facing website • Has received Medicare data as a “qualified entity”
<p>Health in Reach</p> 	<ul style="list-style-type: none"> • Comparison of licensed providers, including doctors and dentists • Discounts and deals • Online appointment system 	<ul style="list-style-type: none"> • Consumer-facing website • Providers can sign up to create a profile

Decision Support

Company	Optum (UnitedHealth Group) 	
Product	Emergency Room Decision Support	Treatment Decision Support
Goal	<ul style="list-style-type: none"> Engage health plan members after each emergency room visit to address factors that drive inappropriate ER use 	<ul style="list-style-type: none"> Connect members with the right treatment, right provider, right medication, and right lifestyle
Approach	<ul style="list-style-type: none"> Identifies and engages individuals after each emergency room visit – up to five times during the course of a year Leverages both “live” nurses and automated voice call technology to engage consumers Refers to case and disease management programs and behavioral health services Connects individuals with primary care providers (including appointment scheduling) 	<ul style="list-style-type: none"> Connects members with specially trained nurse “coaches” who address a consumer’s immediate symptom in addition to issues that impact their quality of life and care Right treatment — guidance on when and where to seek care Right provider — scheduling appointments with high-quality network providers Right medication — coaching on lower cost options, drug interactions and appropriate use Right lifestyle — referring to wellness and behavioral health services
Results	<ul style="list-style-type: none"> Individuals who were engaged by ER Decision Support had a decrease in avoidable ER visits, while individuals who did not participate had an increase in avoidable visits (2007-2008) 	<ul style="list-style-type: none"> 2-to-1 average return on investment 70 percent of callers with ER pre-intent avoid the visit after a Optum NurseLine call 8.8 hours reduced absenteeism per employee/per event

Sources: <https://www.optum.com/health-plans/clinical-management/member-support/clinical-care-management/navigate-care-options/emergency-room-decision-support.html>; <https://www.optum.com/health-plans/clinical-management/member-support/clinical-care-management/navigate-care-options/treatment-decision-support.html>

Digital Revolution



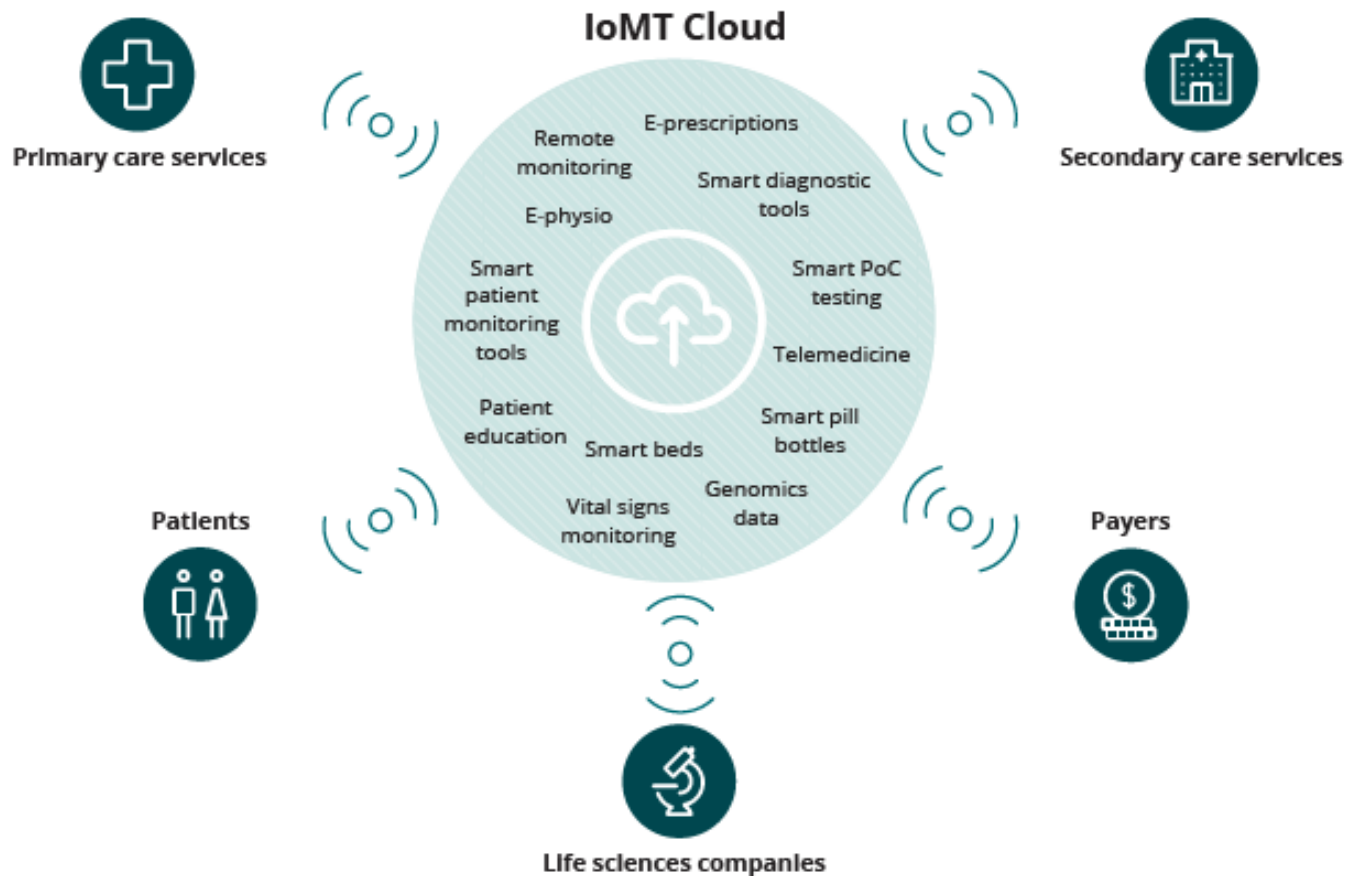
- Most consumers carry smart phones that allow continuous monitoring & support behavior change
- Medical devices increasingly contain sensors and means of transmitting data to the cloud
- MedTech firms must collaborate and compete with new entrants as their products become part of the Internet of Medical Things (IoMT)

Digital Revolution Creates Opportunities

- Smartphones allow continuous patient monitoring and support behavior change through feedback
- More and better data, once subjected to advanced analytics (AI and machine learning), can enable better physician decisions: diagnosis, interventions, adjustment of therapy
- Better data from real world contexts can support better regulation, enabling FDA to continue moving from pre-market review to lifecycle assessment of medical devices
- However, the digital revolution and IoMT require medtech firms to collaborate with software firms, connectivity providers, and other new entrants
- Some of these are becoming competitors

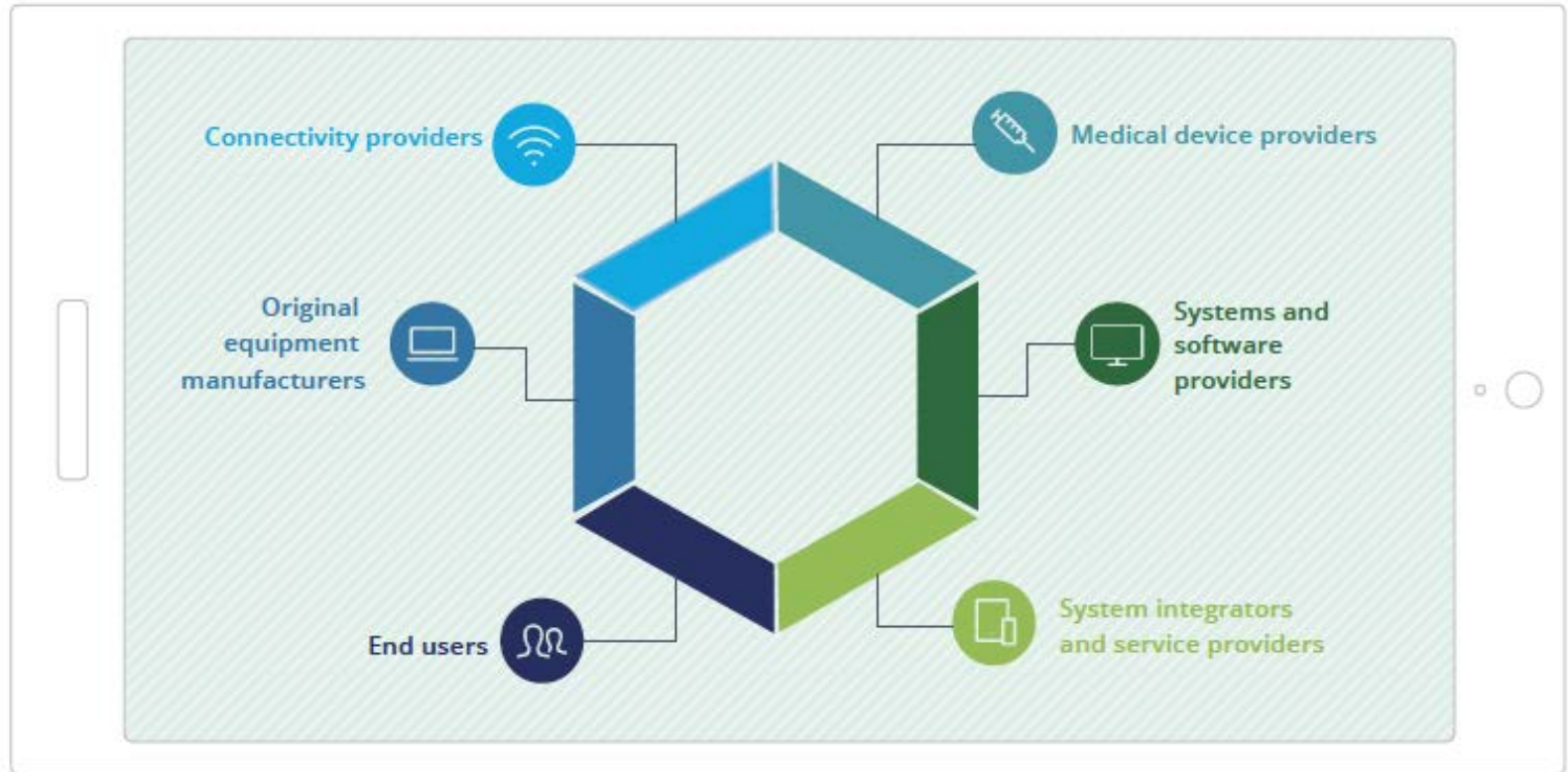


Medical Devices Increasingly Generate Data to Permit Monitoring, RWE Assessment, and Adjustment of Therapy



Source: Deloitte Center for Health Solutions. Medtech and the Internet of Medical Things. 2018.

Medical Device Firms and their Products Must Cooperate and Compete in the IoMT



Source: Deloitte Center for Health Solutions. Medtech and the Internet of Medical Things. 2018.

Growing Collaboration between Traditional MedTech and InfoTech Firms

Selected examples of digital deals, 2016-17

Partners involved	Analysis
Royal Philips and PathAI	Solution improves the precision and accuracy of routine diagnosis of breast cancer and other diseases using artificial intelligence.
Stryker and Microsoft	Augmented reality-based system integrates multiple types of data to create the operating room of the future.
Medtronic and IBM Watson Health	Next-generation predictive diabetes app that proactively alerts patients at risk of hypoglycemia of an attack hours before it actually happens.
Agfa Healthcare and IBM Watson Health	Cognitive technologies to improve the accuracy of imaging in multiple disease areas.
Johnson & Johnson (Ethicon) and Touch Surgery	Simulated surgical training program distributed via an app for doctors in remote areas of the world.
Sanofi and Verily	Launch of Onduo, a joint venture to develop a comprehensive diabetes management platform.
Johnson & Johnson and Verily	Joint venture Verb Surgical combines robotics, visualization, data analytics and connectivity to create a digital surgery prototype.

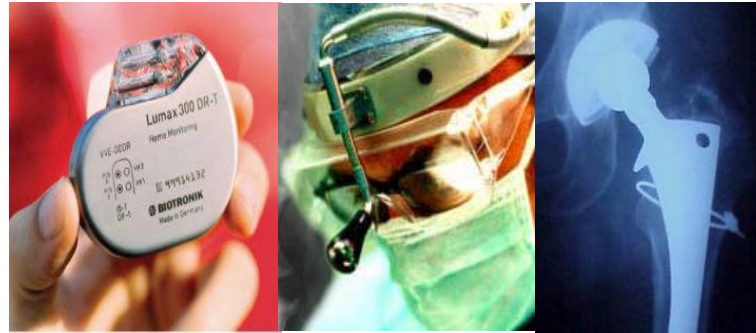
Source: EY. As Change Accelerates, How Can Medtechs Move Ahead and Stay There? Pulse of the Industry 2017

Digital Revolution and MedTech Business Model

- The sustained vitality of the device industry requires it to move 'beyond the product' to offer services and solutions. It requires developing closer and more continuous relations with patients/consumers and with insurers/hospitals
 - Increased patient engagement and 'stickiness' limits risk that insurers/hospitals will easily switch based on price
 - Manufacturers receive better info on who is using their products, how and for which purposes, problems they encounter, when they stop treatment
- Evolution of medtech relationships:
 - Yesterday: Medical arms race: personal relations with physicians
 - Today: Business-to-business (B2B) relations with hospitals
 - Tomorrow: Business-to-consumer relations with patients, within a framework of B2B relationship with providers



Conclusion



- In the US, the golden era of incremental innovation, price increases, and passive purchasers is ending
- Device firms seeking to avoid commodification (low prices, little innovation) seek to take advantage of rising consumerism and the digital revolution
- They face aroused purchasers (insurers, hospitals) and new competitors (software, connectivity firms)
- They seek to create value, demonstrate value, and appropriate value in the new environment
- Parallels in the EU?