BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Life Sciences Innovation Amid Changing Market Dynamics

Barclays Equity Analysis
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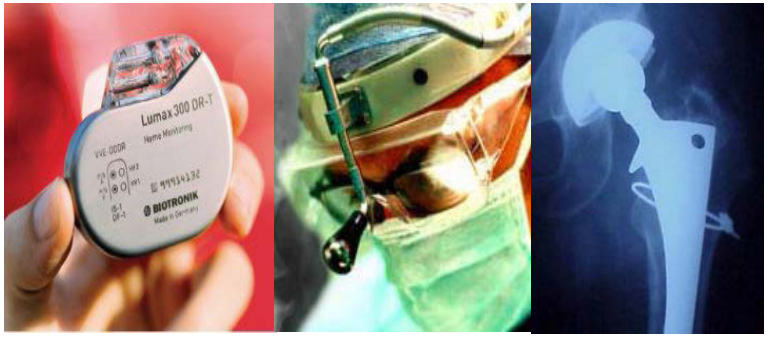
Overview



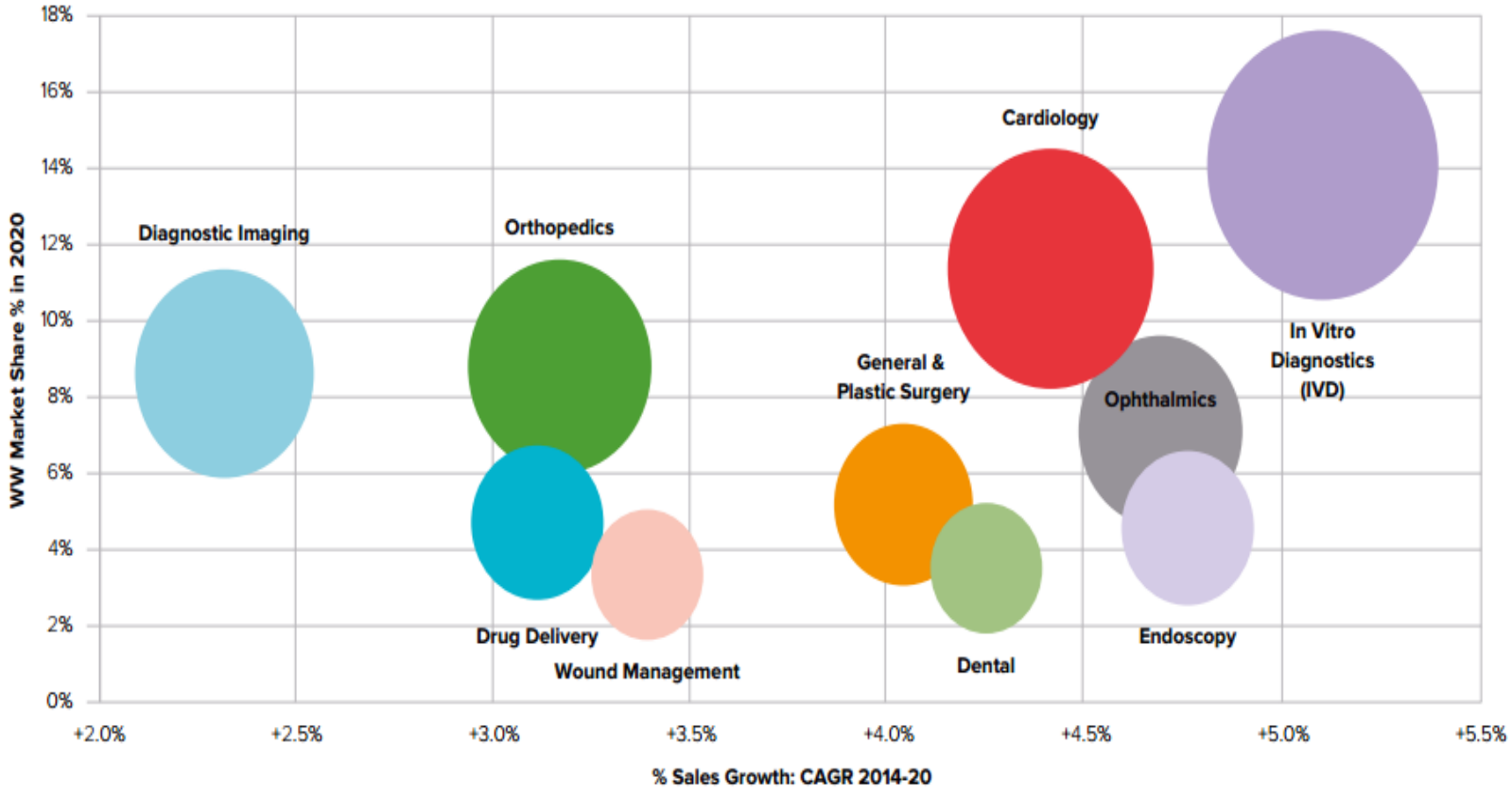
- The life sciences model under stress
- Payment incentives for providers
- Innovation in a changing environment

The MedTech Engineering Model is Working Very Well

- Incremental innovations emerge continually, improving performance through better designs, materials, scale, IT connectivity, ease of administration
- Breakthrough innovations emerge occasionally, offering radically new and better options to patients, supported by strong clinical evidence
- Medical devices, diagnostics, and imaging create knowledge-based economic growth, with high-wage jobs, taxes, and exports

Analysis on Top 10 Device Areas in 2020, Market Share & Sales Growth (2014-20)

Source: EvaluateMedTech® September 2015



Note: Size of Bubble = WW Sales in 2020

Source: EvaluateMedTech® World Preview 2015. Evaluate Ltd.

The BioPharma Science Model is Working Very Well

- Ever-stronger science leading to more effective targeting, mechanisms of action
- Incremental innovations emerge continually in oncology, orphan conditions
- Breakthrough innovations dramatically address major public health challenges (HepC, Ebola, CAD)
- Oral drugs and infused biologics create knowledge-based economic growth, with high-wage jobs, taxes, and exports

The MedTech Regulatory Model is Working Moderately Well

- FDA adjusts requirements to device type
  - Incremental innovations cleared via 510K, with minimal demands for clinical evidence
  - Breakthrough innovations authorized by PMA, with extensive demands for clinical evidence, similar to drug reviews
- Some critics say PMA and 510K are too weak, allowing unsafe devices on the market, while others say FDA regulation is too slow and costly, relative to EU
  - IOM report on 510K (2011)
  - 21st Century Cures Act (2015)

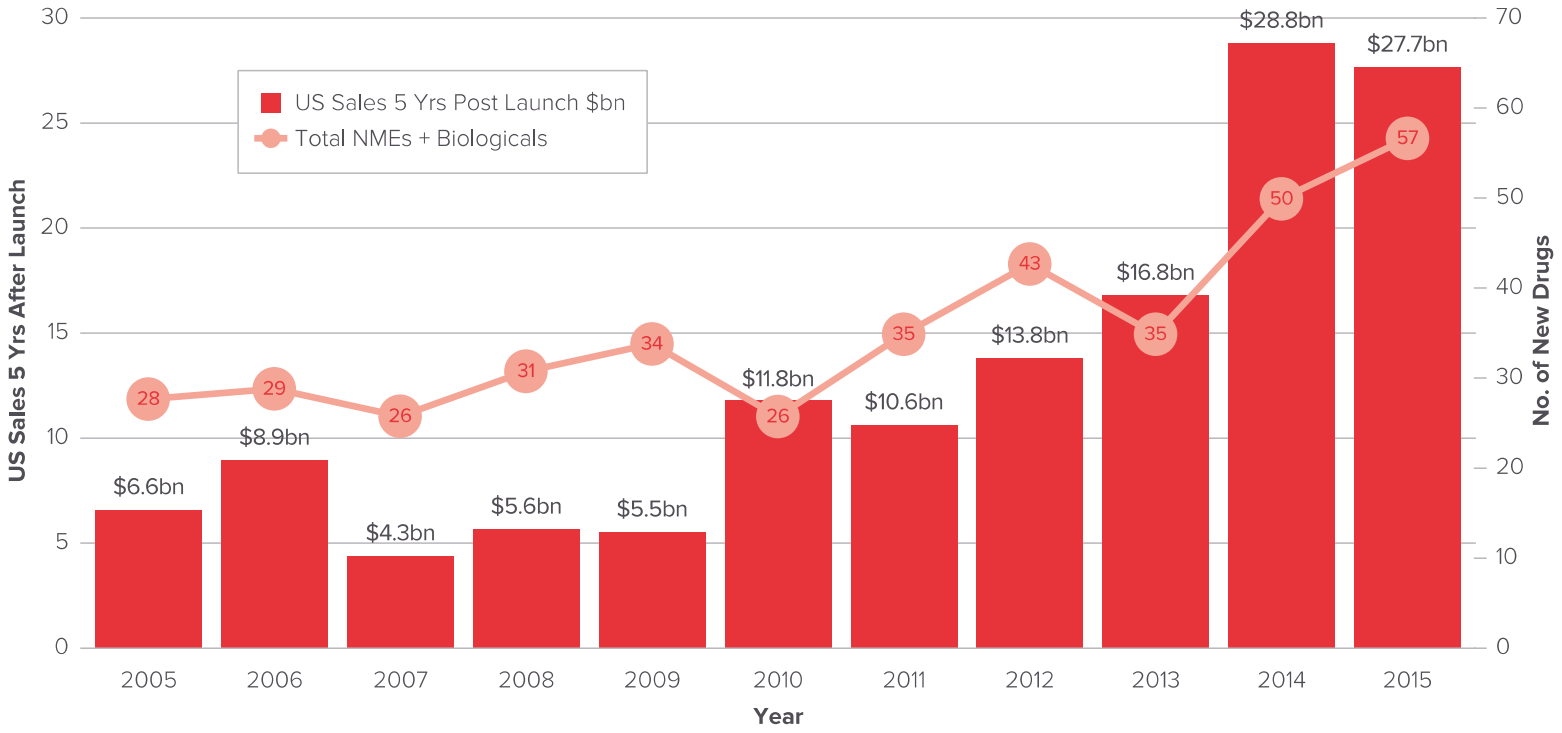
The BioPharma Regulatory Model is Working Moderately Well

- FDA has dramatically reduced review times and accelerated access to the market
  - Review times are faster than in EU, Canada
  - FDA has created four accelerated and breakthrough drug pathways, accounting for 60% of drugs approved in 2015[1]
- In 2015, FDA approved 45 NMEs, the largest number since 1996—53 NMEs

1. http://blogs.fda.gov/fdavoice/index.php/2016/01/
2. http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm

FDA Approval Count vs. Total USA Product Sales 5 Years After Launch

Source: EvaluatePharma® January 2016



2010	2011	2012	2013	2014	2015
Prevnar 13 (PFE)	Xarelto (J&J/BAY)	Eliquis (BMS/PFE)	Sovaldi (GILD)	Opdivo (BMY)	Orkambi (VRTX)
Victoza (Novo N)	Eylea (REGN/BAY)	Stribild (GILD)	Tecfidera (BIIB)	Harvoni (GILD)	Entresto (NVS)
Prolia/Xgeva (AMGN)					

The MedTech Business Model is Broken

- Breakthrough innovations are rare, and firms rely on incremental improvements with higher prices for each annual product model
- Revenue requirements lead firms to push sales beyond the limits of the evidence
- The industry has been dependent an unsophisticated purchasing environment:
  - Fragmentation of insurers, misaligned incentives between physicians and hospitals, and moral hazard by consumers
- Field of dreams: build it and they will buy it

The BioPharma Business Model is Broken

- Firms announce high launch prices, based on incomplete (Phase 2) data, and then annual price increases, with no data on performance improvements
- The industry has been dependent an unsophisticated purchasing environment:
  - Fragmentation of insurers, misaligned incentives between physicians and hospitals, and moral hazard by consumers
- BioPharma prices now are public enemy number one

Changing Payment Methods for Physicians and Hospitals

Overview of Payment Initiatives

- CMS initiatives are broad in scope, slow to be implemented, subject to lobbying, and huge in potential market impact
- Private payer initiatives are more narrow in scope, quicker to be implemented, subject to resistance from providers, and limited in impact due to insurer fragmentation
  - ACO initiatives target all specialties
  - CJR directly targets device-intensive care
  - OCM directly targets drug-intensive care
  - Anthem pathways target specialty drugs

CJR Targets Joint Replacement and, Indirectly, Imaging and Implants

- CJR builds on ACE demo, which combined hospital and MD payment (Parts A,B) for voluntarily participating hospitals, with hospitals sharing gains with physicians
- Major savings came from cheaper implants
  - FROM: (Medtech + Surgeons) v. Hospitals
  - TO: (Hospital + Surgeons) v. Medtech
- CJR is mandatory in 67 markets, combines Part A,B with incentives on readmissions
  - No sharing of savings with patients
- Could be extended to spine, PCI, other

CJR Challenges

- CJR has great strengths, compared to ACE and private payer bundled payments
  - Mandatory programs don't have to be watered down to lowest common denominator of providers
  - CMS has large market share so surgeons want and need to participate
  - Joint replacement has stable device technology, and hospitals can lower costs when aligned with MDs
- CJR model works well (from payer perspective) for procedures with incremental, not breakthrough, technologies
  - If CJR model were applied to other procedures, it would need carve-outs for breakthroughs (NTAP)

OCM Targets Oncology and, Indirectly, Drugs and Radiation

- OCM is voluntary oncology medical home program targeting 100+ large practices
- CMS pays $160/month for patients in active chemo, above the usual FFS for visits
- CMS establishes target for total spending per patient, and measures actual spending
  - Includes oncology (visits, monitoring, infused drugs, oral drugs, radiation, surgery) but also non-oncology (lab, imaging, ED, inpatient)
- Practices share ‘savings’ after CMS takes cut, if they meet quality standards

OCM Challenges

- Can oncology practices really manage the full spectrum of oncology services, much less the full spectrum on non-oncology services?
- How does CMS set the spending targets?
  - How are these adjusted for patient risk?
  - How do these adapt to new drug launches?
- Most practices cannot realistically participate
  - What about small practices? Will OCM accelerate consolidation of oncology into hospital systems?
- What will be the impact on use and price of specialty drugs (pathways and prior auth)? Why does CMS not discuss this?

Anthem Pathways Initiative Targets Oncology Drug Use

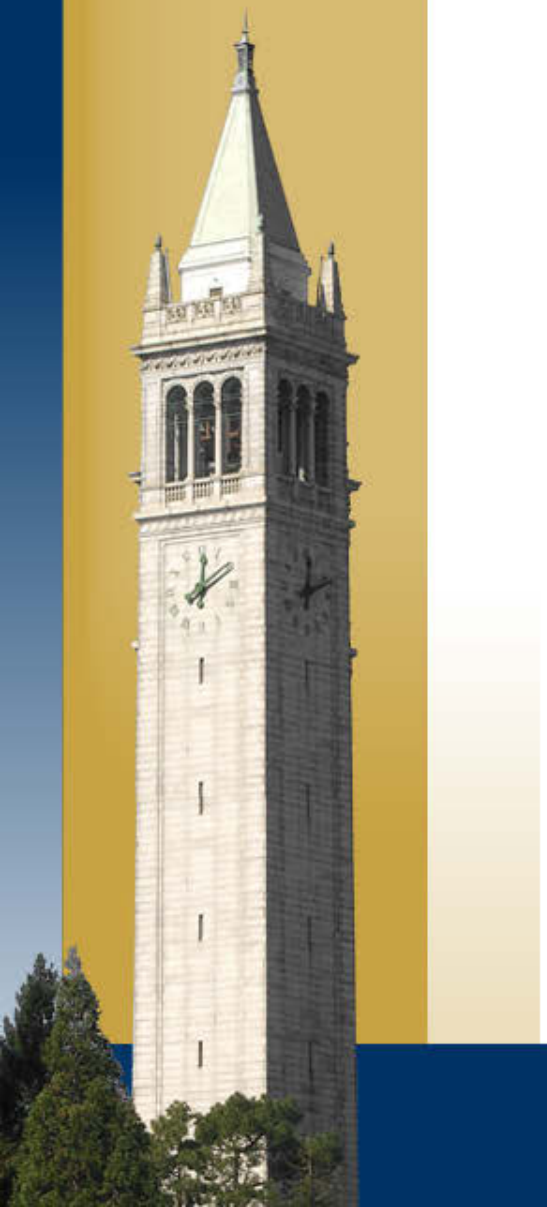
- AIM pathways program is voluntary, but has been accepted by entire oncology network
- Anthem pays $350/month for patients in active chemo, above the usual FFS for visits
- Oncologists must submit patient data (disease stage, biomarkers) and adhere to Anthem approved drug pathways
  - But practices are not responsible for non-drug oncology (radiation, surgery) or for non-oncology services to cancer patients
- Anthem does not see this as transition to bundled payment, as it does not want to put the physician at risk for cost of cancer drugs

Challenges to Anthem Pathways Initiative

- Although the largest private insurer, Anthem is only a small part of any oncologist's practice
- It will not affect practice patterns beyond drug:
  - Patient monitoring and engagement
  - Reduction in ED and hospital use
  - Radiation treatment and surgery
- Bar for participation is low and payment is high; with no risk, only limited changes?
- Hopes that, together with CMS, Aetna, United initiatives, it will influence physician behavior

"Geez Louise—I left the price tag on."

Innovation in a Changing Environment



Adapting to Change

The medtech and biopharma market (insurers, hospitals, physicians, patients) is moving from an emphasis on performance improvement, with little concern for cost, to an emphasis on cost reduction, with only a secondary concern for performance improvement.

MedTech: Raising the Bar for Breakthrough Innovation

- Breakthrough products will always gain coverage and generous pricing, but must demonstrate their value with better evidence
  - FDA may accelerate approval, but this just shifts burden of assessment to insurers, hospitals
  - Real world, comparative, clinical and cost data are the industry's friend (HTA, CEA)
- Industry must work with insurers to ensure that value-based payments and consumer cost sharing do not block adoption
  - NTAP, exemption from deductibles

MedTech: Raising the Bar on Incremental Innovation

- The medtech business model of incremental innovations sold at higher prices each year is coming to an end. This change favors:
  - No-frills product designs
  - Low manufacturing costs (global sourcing)
  - Low distribution costs
  - Products used in low-cost (ASC, office, and home) settings
  - Greater role for patient self-care
  - IT integration for continuous monitoring

BioPharma: It's Too Early to Celebrate

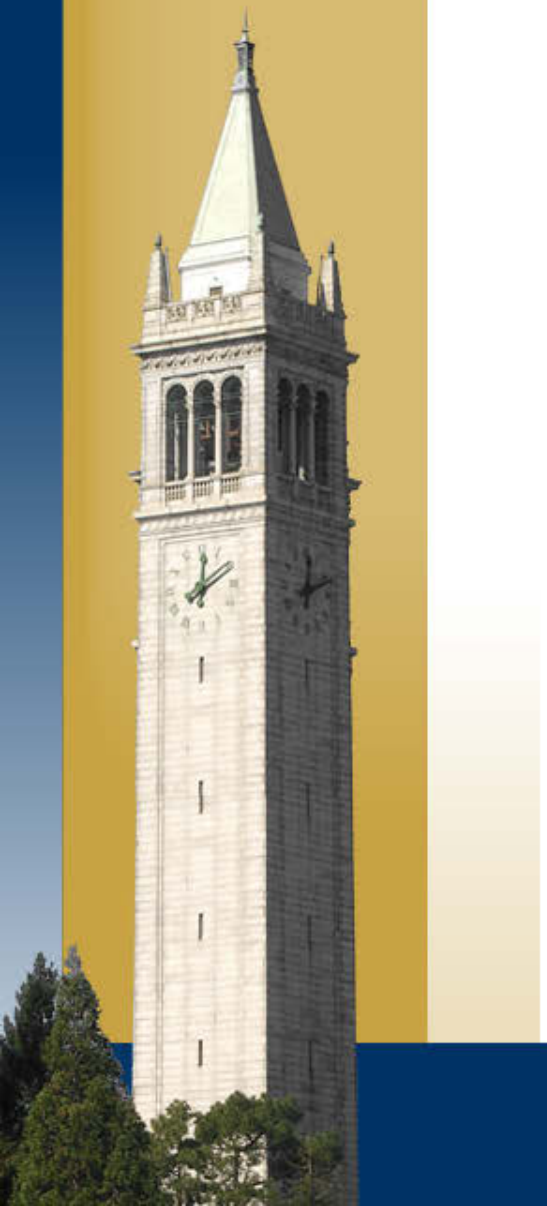
- The past decade of ever-faster FDA market access, uncontested insurance coverage, ever-higher launch prices, and annual price increases is coming to an end
- FDA responds to public and politician perspectives, and may swing back towards emphasis on safety (e.g., costs)
- Insurers and PBMs are exploiting availability of equivalent specialty drugs: limited formularies, stringent prior auth, physician incentives, consumer cost sharing

BioPharma: Demonstrating Value

- The industry must demonstrate value to the insurer (HTA, CEA, and budget impact)
- It must demonstrate value to the physician (paid via OCM, pathways adherence)
- It must demonstrate value to the IDN/ACO (paid through capitation and shared savings)
- It must demonstrate value to the consumer and patient (responsible for coinsurance)

The Future

- The tests and treatments of the future will help patients lead longer and better lives, but also will cost less to develop, less to manufacture, and less to use than the products of today
- They will generate savings inside (e.g., low-cost settings, shorter LOS) and outside the health care system (e.g., improved productivity, reduced disability
- The savings must accrue to those paying (insurers, hospitals, patients) not just to those not paying (society at large)
- This is value, as interpreted by the purchaser



PURCHASING MEDICAL INNOVATION

THE RIGHT TECHNOLOGY, FOR THE RIGHT PATIENT, AT THE RIGHT PRICE

JAMES C. ROBINSON