The Brave New World of Medical Devices

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It Is All About The Adoption…
More Than a Mantra

David Barone

December 17, 2014
Medical Device Industry Health Report 2014

- Projected CAGR ~5% through next 10 years
- Top 15 companies control >80% market share
- Leaving >$60B to all other companies; >$85B by 2020
- US is and will remain the most important market
  - Size, innovation, leadership / impact, pricing
  - 12 out of top 20 companies are US; 7 - EU based; 1 – Japan
- Innovation is still strong; 3,000+ 510(k) / year
- M&A: Stronger than ever
  - Deals value are up, but
  - Deals volume are down
  - Large exits: 50% w/ FDA approval; 25% CE; 25% development
Time-To-Market Is Increasing....
...But The Big Story...
The Increase In Time-To-Market Acceptance
Longer Time-To-Adoption Has Considerable Implications

- Delayed revenue
- Need for additional funds and financing rounds
- Valuations are negatively impacted
- Business development initiatives are delayed
- Increased risk of new competitors
What Changed During the Last 20 Years?

- **Resistance to change**
- **Providers are vested in current technologies and practices**
- **Greater competition**
- **Multiple decision makers with conflicting interests**
- **Changing economic incentives**
- **Evidence-based medicine… looking for more evidence**
- **Slow acceptance by payers**
- **Incremental features and benefits do not justify change**
- **Politics**
While Healthcare Markets Continue to Grow…

- More barriers
- Takes longer
- Fewer make it

Time to Market Acceptance

- Cost Effectiveness
  - Comparative Assessment
  - Outcomes
  - Efficacy
  - Safety

1980’s 1990’s 2000’s
More Changes In Store…
Health Spending Per-Capita & GDP Per-Capita (2001-10)
Do Outcomes Justify the Cost?
Payers Required a Change to Managed Care

Greater control of
- Access
- Coverage
- Payment

1981
- HMOs 5%
- Conventional Health Insurance 95%

1990
- POS Plans 5%
- PPOs 13%
- HMOs 26%
- Conventional Health Insurance 62%

2005
- POS Plans 15%
- HMOs 21%
- PPOs 61%
- Conventional Health Insurance 3%
But Healthcare Spending Continue to Exceed GDP
Cost Drivers

- Unit Costs: 49%
- Provider Mix: 21%
- Utilization: 26%
- Severity: 4%

Source: BCBSMA Actuarial & Analytic Services.
Annual Per Capita Healthcare Costs by Age

- US
- Germany
- UK
- Sweden
- Spain

$0
$5,000
$10,000
$15,000
$20,000
$25,000
$30,000
$35,000
$40,000
$45,000

10 20 30 40 50 60 70 80 90
Performance Pays Off

**Heart Bypass Surgery**

- **Low (0% - 49%)**
  - Average Hospital Costs: $41,539
- **Medium (50% - 74%)**
  - Average Hospital Costs: $34,895
- **High (75% - 100%)**
  - Average Hospital Costs: $30,061

**Pneumonia**

- **Low (0% - 50%)**
  - Average Hospital Costs: $9,978
- **Medium (51% - 99%)**
  - Average Hospital Costs: $8,655
- **High (100%)**
  - Average Hospital Costs: $8,351
Experts Agree…

Rate reviews cannot fundamentally address the growth of health care costs…

…costs must be addressed through payment reform, delivery system changes, an emphasis on prevention and consumer engagement.

National Association of Insurance Commissioners letter to Congress February 23, 2010
Patient Protection and Affordable Care Act (2010)
10,000+

Number of pages of Obamacare regulations (eight times longer than the Bible).

SOURCE: Competitive Enterprise Institute
Many Reforms and New Initiatives

- **Value-Based Purchasing (VBP) Program** - reward value and patient outcomes, instead of just volume of services

- **Reduced Payments for Hospital Acquired Conditions** - Stop paying for certain conditions developed while the patient is hospitalized

- **Accountable Care Organizations (ACO)** - shift from fragmented and inconsistent care to coordinated care and measured performance

- **Payment Reforms** - incentivize Quality, not Volume
Value-based purchasing

Devices pricing will be based on ability to remove costs from the system
Implications to Medical Device Companies
Time To ‘Market Acceptance’ is Increasing
IT'S THE ECONOMY STUPID!

ADDITION
We Have a New Landscape

- Volume based incentives  $\rightarrow$  Value based / outcomes
- Individual providers  $\rightarrow$  Providers consolidation
- Fee-for-service  $\rightarrow$  Bundled care
- Payers assume financial risk  $\rightarrow$  Payers & providers
- Site of service hospital  $\rightarrow$  Least expensive
- Documenting care  $\rightarrow$  Coordination of care
- Brand defines quality  $\rightarrow$  Quality defines brand
- Device selected by physician  $\rightarrow$  System decisions
What Do We Need To Learn Early On?

Who is the first market?
• Who will be our initial target?
• Check with all the right people, not only MD’s

Benefits
• Improved patient care and/or delivery of care
• How does our solution compare with the current standard-of-care?

Standard of care
• Guidelines
• What actually happens in the field, why?

Regulatory
• Need to understand the strategy at the very outset of product development

Reimbursement
• Cost and effectiveness of existing alternatives
• Availability and level of payments for similar devices
• Codes and payments for professional and institutional services

Clinical studies
• Roadmap beyond regulatory approval
How To Spend Early Funds?

Common mistakes:

• No clear understanding / rationale of first target market, or picking the wrong market

• Using funds to refine prototype designs (beyond proof of concept)

• Under investing in IP

• Staffing up prematurely instead of relying on external experts (typ. Offering broader experience at lower cost than internal hires)

• Rushing to market before addressing market risks

• Find out the barriers

• Develop a roadmap

• Reduce the primary risks
Transitioning To Sales

- The old good days - (1) develop, (2) sell – are over
- Make sure you have a scalable model before hiring sales force, signing national distributors or booking the 30’x30’ booth
- Without the proper evidence your ability to sell and scale are slim
- First 2 years:
  - Understand your clinical and economic value
  - Is the product ready for prime time
  - What support services are needed?
- Track meaningful metrics - #1: Repeat purchases
- Don’t jump to the water naked (w/o the skills and funds)
A Few Myths

• A great product will sell itself… *sorry, it will not*…

• We are not good at marketing, so once we get the 510k we will sign the right distributor… *and you really expect them to do your* work?…

• We don’t have money, we need to be *creative*… *cutting corners and still expect to make it*?…
More Myths…

- We will do the studies needed to get FDA / CE approvals and the early customers will do the rest… we can certainly hope this will be the case, but ‘hope’ is generally not a good plan…

- We do not need Business Plan… we really do not know what is our plan…

- Once we get money we will do the right stuff… unfortunately investors want you to do the right stuff before they give you the money …
Thank you
Clinical Evidence – 510(k) and Beyond

Zvi Ladin, PhD

December 17, 2014
FDA Vision

- **Public Health Focus**: Activities and outcomes that protect and promote public health.
- **Our People**: most critical resource; individual excellence, teamwork, and personal and professional diversity.
- **Science-Based Decisions**: decisions based on sound science using the best available data, methods, information, and tools. We value and take into account differing internal and external perspectives.
- **Innovation**: Challenge status quo and ourselves to foster positive change. Harness the creativity of our staff and stakeholders. Rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.
- **Transparency**: Foster public trust and predictability by providing meaningful and timely information about products we regulate and the decisions we make.
- **Honesty and Integrity**: Maintain public trust by acting with integrity and honesty. Our actions adhere to the highest ethical standards and the law.
- **Accountability**: Hold ourselves accountable for actions we do and do not take. Acknowledge our errors and learn from them.
CDRH 2014 – 2015 Strategic Priorities

- #1 – Strengthen the Clinical Trial Enterprise
- #2 – Right Balance Between Pre/Post market Data Collection
- #3 – Provide Excellent Customer Service
  - Measurable Outcomes
Strengthen Clinical Trial Enterprise

- October 1, 2013 – Guidance Document: IDEs for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies
  - Risk mitigating strategies to protect human subjects
  - Pilot Program
  - Approval with Conditions
  - Staged Approval
  - Communication of issues related to study design and future considerations
  - Limiting disapproval authority
Early Results Program Goals

• IDE Applications cleared within two review cycles:
  • FY 2011 – 46%
  • FY 2013 – 77%

• Median Time to full study approval:
  • FY 2011 – 435 days
  • FY 2013 – 174 days

• Goals:
  • By 9/30/2014 reduce % of IDEs with > 2 cycles by 25% (compared to FY 2013)
  • By 9/30/2014 offer sponsors of disapproved IDEs teleconference or meeting within 10 days of IDE decision
  • By 6/30/2015 reduce overall median time to full IDE approval to 30 days.
Early Feasibility (EF)/FIH IDE Studies

• By 6/30/2015 increase number of EF/FIH studies to each Division compared to FY 2013 performance

• Implementation:
  • Establish premarket clinical trials program in ODE
  • Incorporate benefit-risk framework
  • Establish process to resolve application-specific issues
  • Education and training for CDRH review staff
  • Develop real-time metrics to track CDRH and Industry clinical trial performance
Pre-/Post- Market Data Collection

- Life-cycle approach to understanding benefit-risk profile of medical devices
    - Patient early access benefits vs. risks of use
    - Assessment of alternatives to proposed treatment
  - Least Burdensome provisions of the federal law
- National Medical Device Postmarket Surveillance System
- Case for Quality Initiative
  - Help manufacturers identify and deploy quality-related design and production practices
- International Harmonization
  - International Medical Device Regulators Forum
  - Single audit program
Pre/Post Marketing Balance – Goals

• By 12/31/2014 – review of 50% of device types subject to PMA and determine
  • Balance of Pre/Post marketing data
  • Down-classification
• By 6/30/2015 – review 75% of device types (as above)
• By 12/31/2015 – review 100% of device types (as Above)
• FDA Actions:
  • Collect public comments
  • Perform review as above
  • Implement a mechanism for creating Pre/Post marketing balance
  • Incorporate features of the Innovation Pathway
Excellent Customer Service

- Understanding and addressing stakeholders’ and colleagues’ needs through
  - Active listening
  - Problem solving
  - Seeking out ideas
  - Explaining rationale for decisions and requests for information
  - Learning from mistakes
  - ‘Doing our best’
- Goal – to encourage device makers to choose US first when bringing their products to market
- Allow US providers gain access to innovative technologies
Customer Satisfaction Goals

- By 12/31/2014: ≥ 70% satisfaction
- By 6/30/2015: ≥ 80% satisfaction
- By 12/31/2015: ≥ 90% satisfaction

Implementation:
- Customer Service Standards
- Use standardized surveys
- Establish program to monitor and address feedback, including CAPA processes
2014 Milestones in FDA Regulation of Clinical Trials

- February – Requests for Feedback: Pre-Sub Program and Meetings with FDA
- March – Information Sheet Guidance – Clinical Investigator Administrative Actions – Disqualification
- May – Transferring Clinical Investigation Oversight to Another IRB
- July – Informed Consent Information Sheet
FDA Update – The Big Picture (12/11/2014)

• Bill Maisel, Deputy Director of Science at CDRH
  • 75% reduction in IDE processing time:
    • In 2011 – average > 400 days
    • In 2014 – average = 101 days
  • Consider ‘Down Classification’ of Class III Devices
    • 50% of products reviewed
    • Results will be published beginning of 2015
  • ‘Expedited Access PMA (aka ‘Fast Track’):
    • High risk devices
    • Areas of high need
    • Analogous to accelerated approval process for new drugs
  • User Satisfaction
    • Goal – 70% satisfaction
    • Survey – 84% satisfied
New Guidance Document (8/2014)

- Intended to allow trial launch even when there are outstanding issues*
  - Approval with Conditions
  - Staged Approval
  - Study Design Considerations
  - Future Considerations
- FDA cannot disapprove a study because:
  - Investigation may not support SE or *de novo* or approval
  - Investigation may not meet requirement relating to approval, or
  - Additional/different investigation needed for clearance

* – Under certain circumstances
HHS Notice of Proposed Rulemaking (Nov. 19, 2014)

- Implementation reporting requirement for clinical trials included in FDA Amendments Act of 2007 (FDAAA)
- Developed in collaboration between FDA and NIH
- Generally not applicable to Phase I trials of “drugs and biological products and small feasibility studies of devices”
- www.Clinicaltrials.gov
  - Clinical Researchers – Clarifications of registration requirement
  - Major expansion – trials of unapproved, unlicensed and uncleared products
  - Submission of summary trial results
- Rationale
  - Prevent repeated trials of unsafe/ineffective devices
  - Maximize use/information dissemination from participation of patients
- Specifies how
  - Data needs to be submitted
- Does not affect
  - Study design
  - Data to be collected (what, how)

178,000 studies on clinicaltrials.gov
15,000 studies posted summaries
Notable Changes from Current Requirements

• A streamlined approach for determining:
  • Trials subject to proposed regulations and
  • Individual responsible for submitting required information

• Expansion of trials subject to summary results reporting to unapproved products.

• Additional registration requirements and results submission

• Procedures for delaying results submission when studying an unapproved, unlicensed, or uncleared product or a new use of a previously approved, licensed, or cleared product and

• More rapid updating of several data

• Procedures for timely corrections to any errors
FDASIA Report to Congress – 510(k)

• FDASIA – FDA Safety and Innovation Act (July 9, 2012)
• Requirement – within 18 months submit report to Congress:
  • Requirements for regulatory submission for modified device cleared under 510(k)
    • Pressures on FDA
      • Patient groups:
        • Greater regulatory control
        • FDA should require periodic reports
      • Manufacturers
        • Keep current policy (1997)
FDA Plans for 1997 Policy

• Leave 1997 policy intact
• Targeted revisions
  • Use of quality system processes in deciding submission/note to file
• Updated:
  • Flowchart
  • Examples
  • Proper documentation of rationale and decision-making process
• Device-specific Guidance Documents
  • Address specific changes
• Specific guidance on 510(k) submissions for changes to device software
Next Steps

- Implementation of ongoing initiatives to improve the unpredictable, inefficient, and expensive regulatory processes
- Independent assessment of FDA device review process management
  - Phase 1: March 31, 2013 – September 30, 2014
  - Phase 2: October 1, 2014 – February 29, 2016
- Electronic submissions
  - January 28, 2015 – new standard for clinical trial data format
- International collaboration
  - Inspections
  - Clearances
- 510(k) – Closer to the end?
Thank You!

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