Changes in Regulatory and Reimbursement Environment in the US - Implications for Medical Device Companies

November 2013

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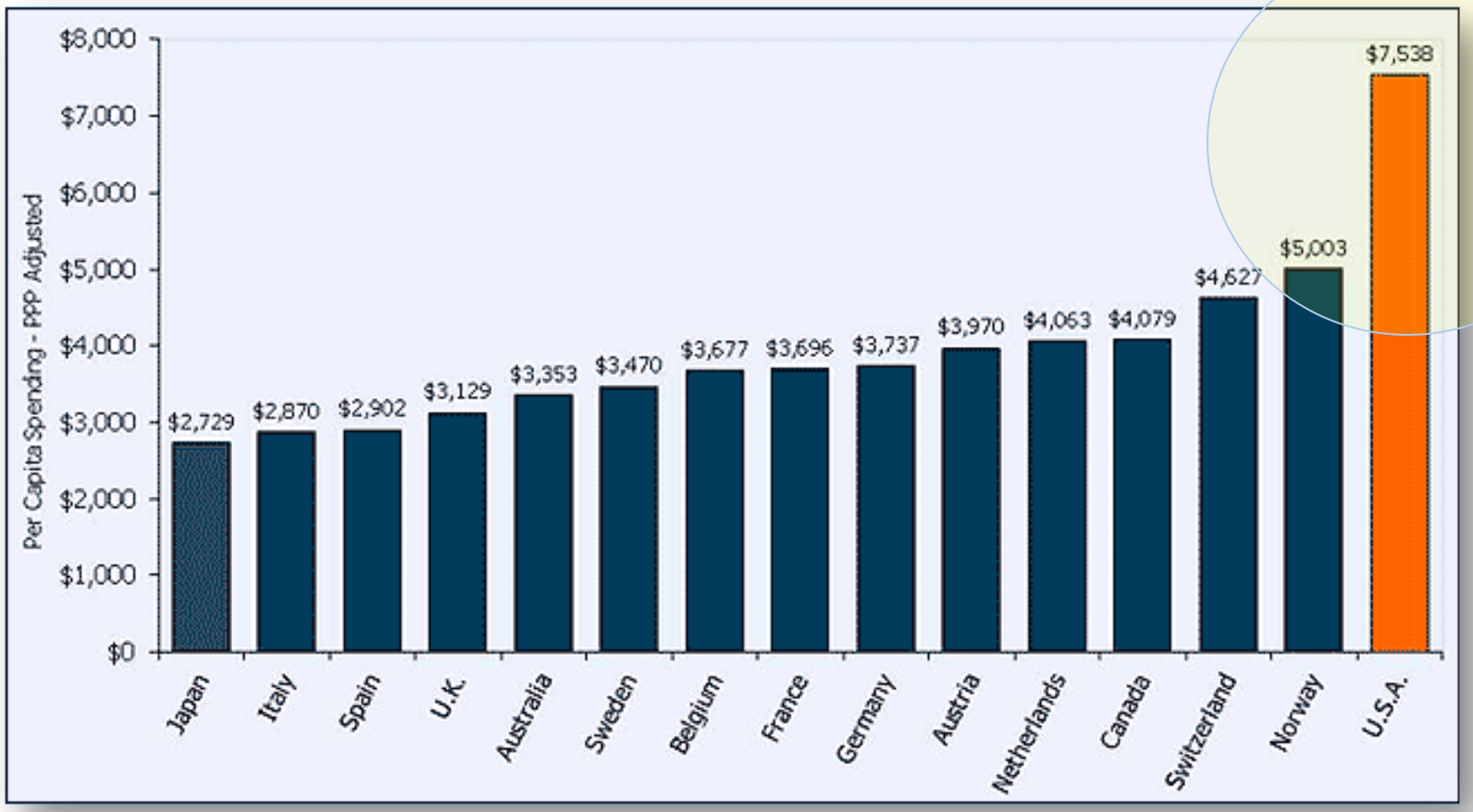
Changes in Reimbursement Environment (US) and Implications for Medical Device Companies

November 2013

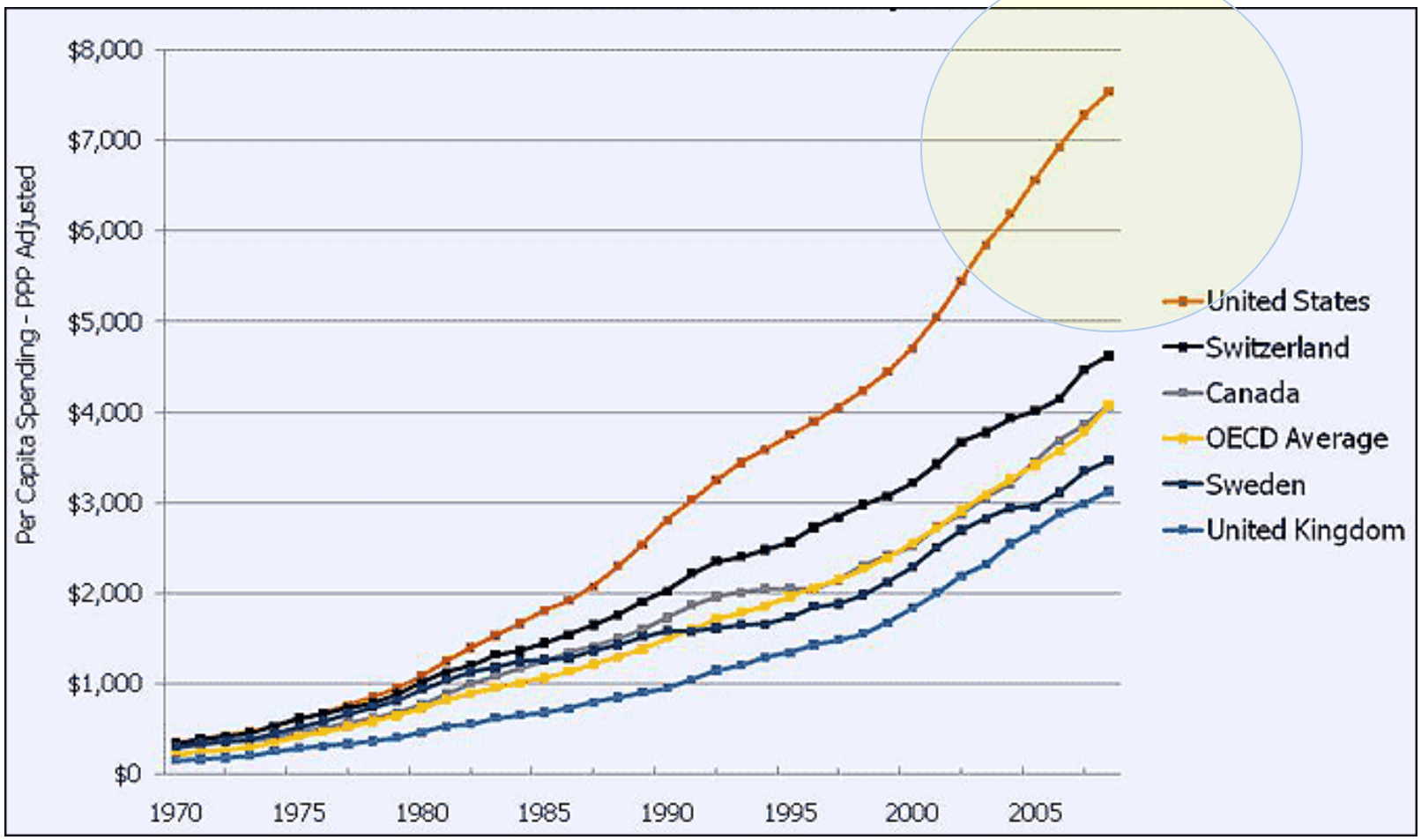
David Barone

US: Highest Health Expenditure per Capita



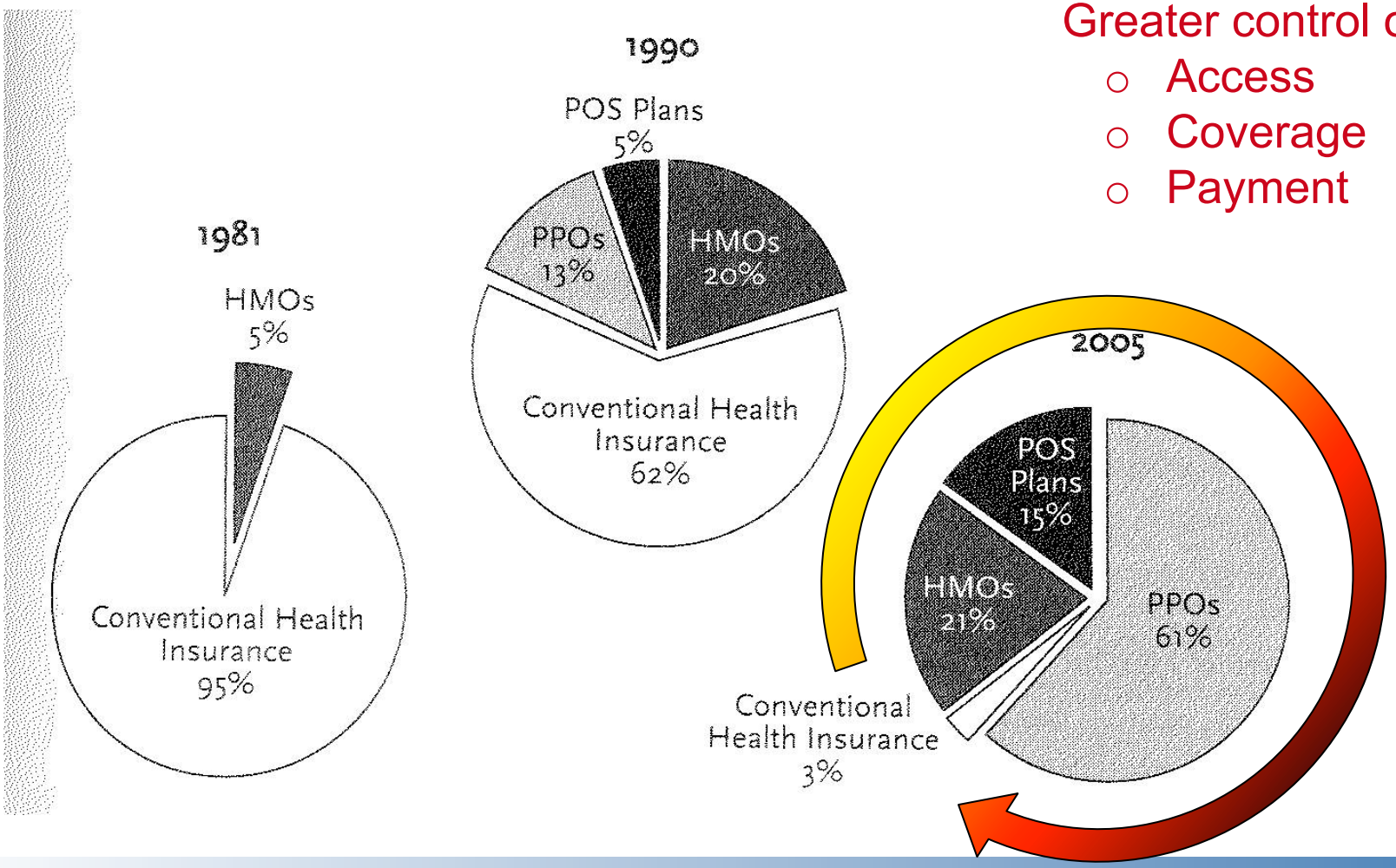
Ref: Kaiser Family Foundation, 2011

Growth in Total Health Expenditure Per Capita



Ref: Kaiser Family Foundation, 2011

The 90's Market Response → Managed Care



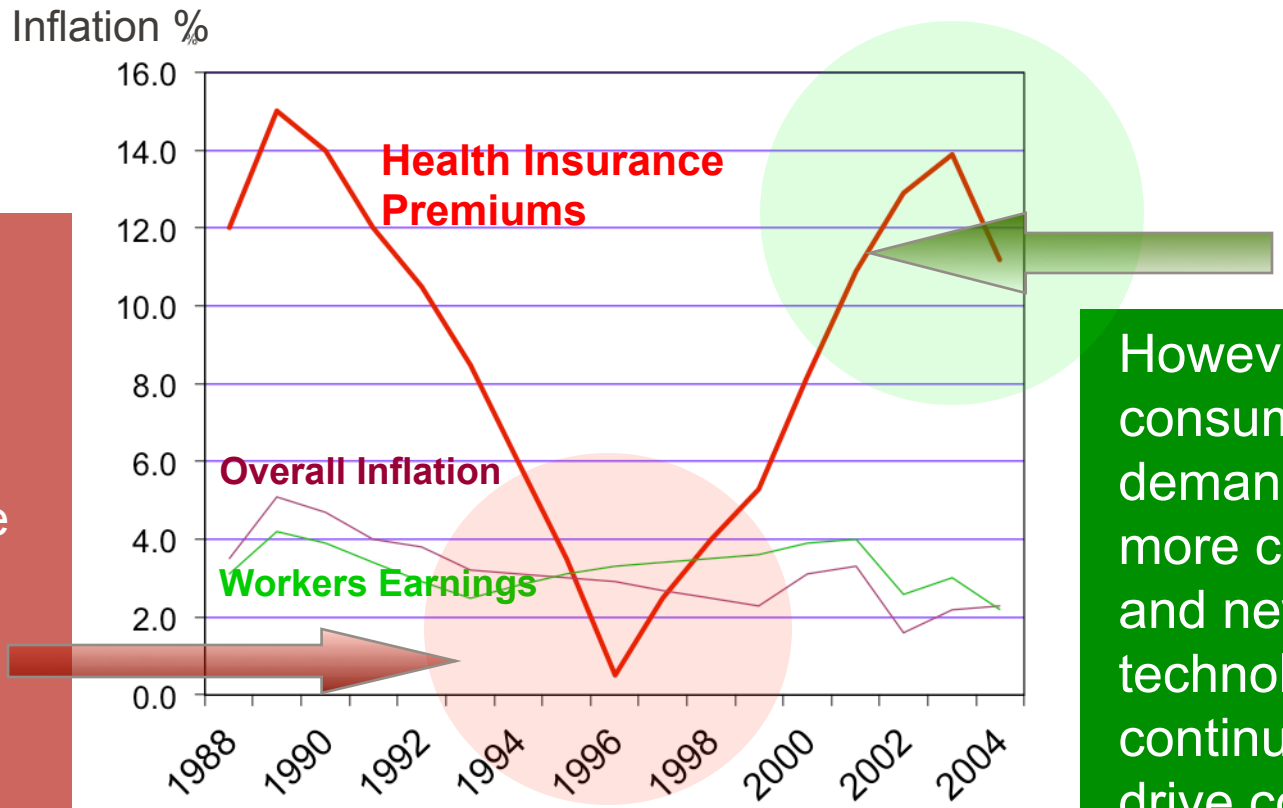
Greater control of

- Access
- Coverage
- Payment

But Medical Costs Continued to Outpace Inflation

Managed care did work for a while:

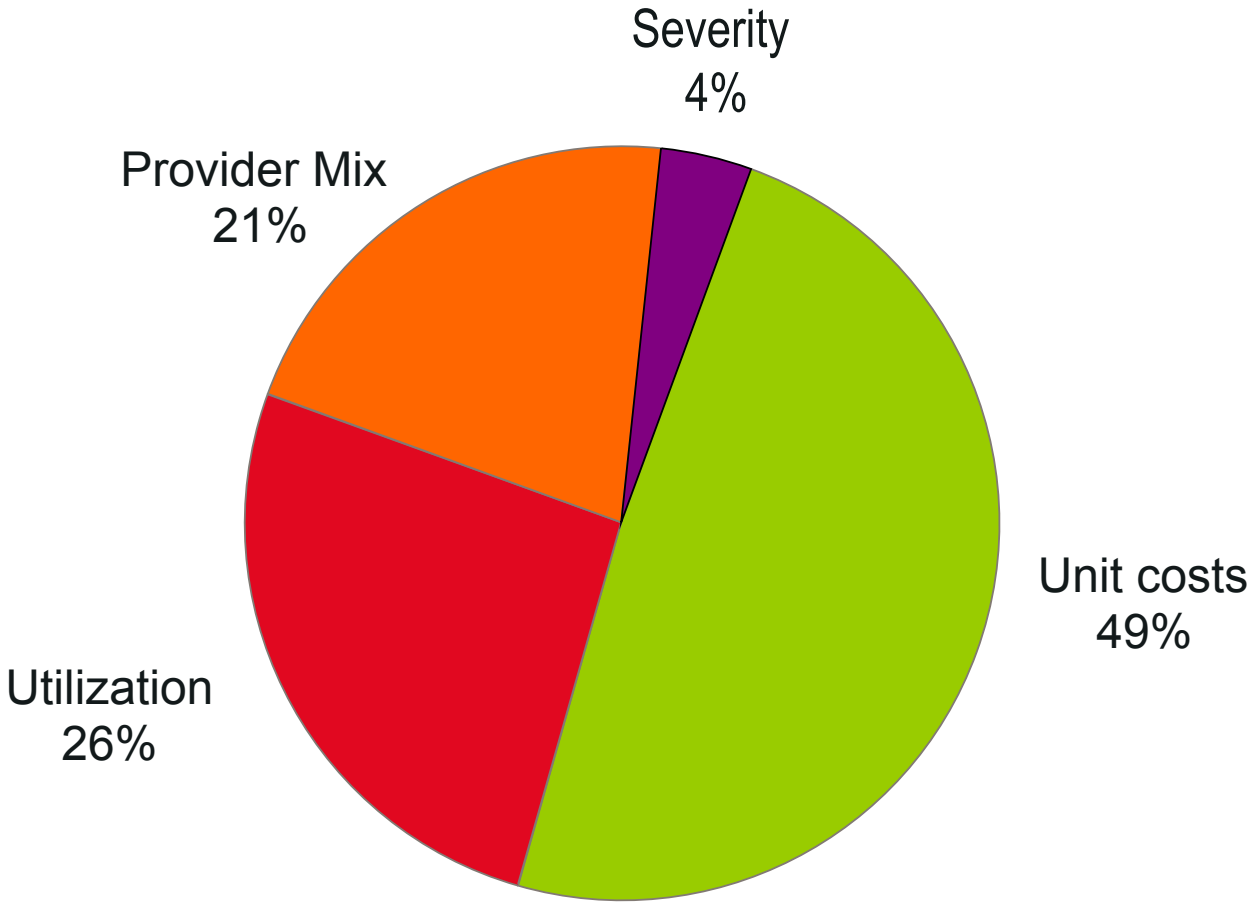
- Applying administrative restrictions to curtail utilization
- Negotiating lower fees for services



However, consumer demand for more care and new technology continued to drive costs

Source: National Coalition on Health Care, 2004

Cost Drivers



Source: BCBSMA Actuarial & Analytic Services.

The Boston Globe

Insurers may slash rates to hospitals
Some patients might have to switch MDs

By Liz Kowalczyk

Globe Staff / May 24, 2010

Insurers seeking payment changes

By Jennifer Huberdeau, North Adams Transcript

Posted: 05/26/2010 08:15:41 AM EDT

Wednesday May 26, 2010

New Bedford Standard Times

Blue Cross, Southcoast at loggerheads in contract negotiations

By Dan McDonald, dmcdonald@s-t.com
September 18, 2010

NEW BEDFORD — After seven months of talks, Southcoast Health System, the region's largest employer, and Blue Cross Blue Shield of Massachusetts, the state's largest private health insurance company, are deadlocked in negotiations over reimbursement rates for care rendered to Blue Cross policy holders at Southcoast facilities.

RUNNING A HOSPITAL

This is a blog started by a CEO of a large Boston hospital to share thoughts about hospitals, medicine, and health care issues.

Robin Hood in Reverse

Wednesday, May 12, 2010

Jim Stergios and Amy Lischko from the Pioneer Institute write a well reasoned op-ed article in today's *Boston Globe* about current events in Massachusetts, where

Pressure to Cut What Doctors Get Paid is Mounting, and There's Not Much to Stop It

By Ken Terry | June 2, 2010

Threats to doctors' incomes are multiplying — and not necessarily in a good way. While physicians are understandably focused on the latest congressional effort to head off a 21 percent cut in **Medicare** reimbursement, they should also pay attention to state regulation of insurance rates. Because if state governments decide to take a hard line on premium increases, the result will translate into lower payments to doctors and hospitals.

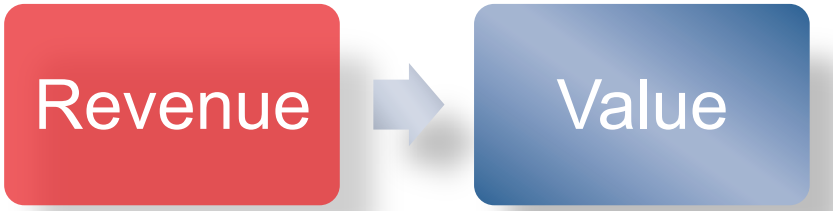
Experts Agree…

Rate reviews can help constraining the growth of costs short term, but they 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

The Big Paradigm Shift



↑ Revenue = more services x higher service fees

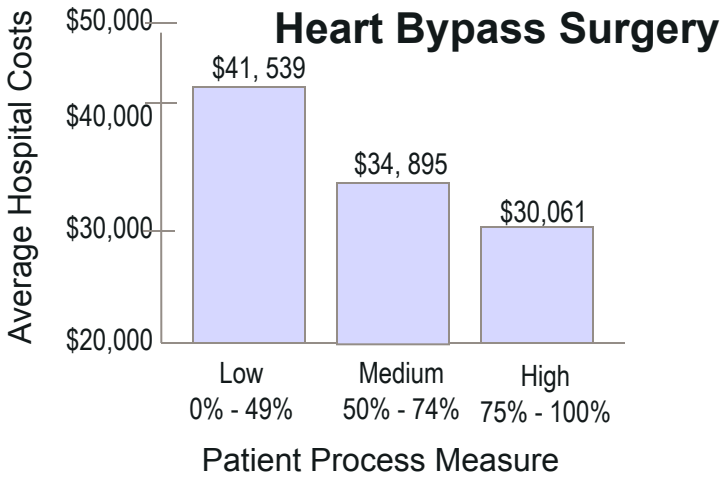
$$\uparrow \text{Value} = \frac{\text{Quality (health outcomes)}}{\text{Cost of Service}}$$

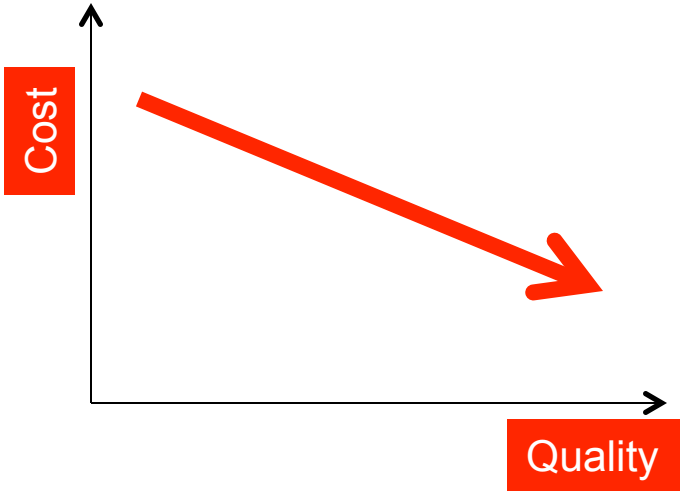
↑ Quality / ↓ Cost = ↑↑ Value

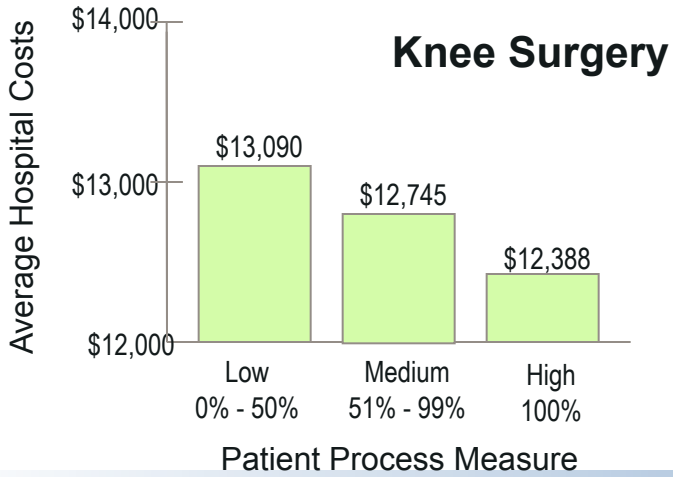
± Quality / ↓ Cost = ↑ Value

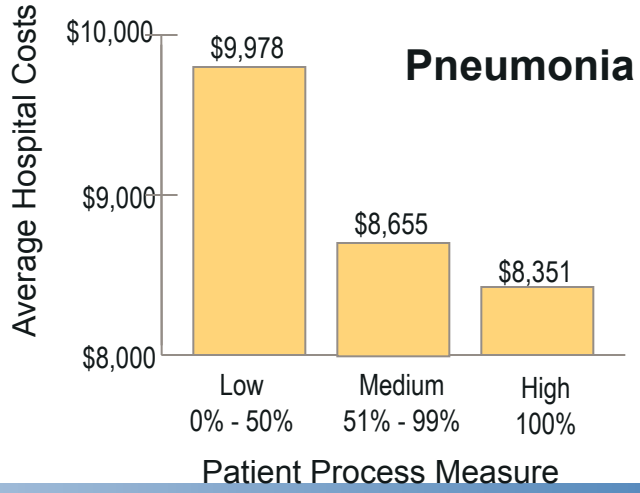
↑ Quality / ± Cost = ↑ Value

Performance Pays Off









Payment Reform: Incentivize Quality, Not Volume

Fee-for-Service

Incentives for:

- Increased volume
- Delivering more costly services

Little or no incentive for:

- Achieving positive results
- Preventive services or other services with low financial margins

Global Payment

Emphasize:

- Quality improvement
- Integration and coordination of care (within acute care episodes and chronic conditions)

Eliminate incentives for:

- Increased volume
- Providing higher-cost services over lower-cost services that are equally effective

Multiple Initiatives

Healthcare Reform Laws

- Emergency medical Treatment (1986)
- Health Insurance Portability and Accountability Act (1996)
- Medicare Prescription Drugs (2003)
- Patient Safety and Quality Improvement Act (2005)
- Health Information Technology for Economic and Clinical Health Act (2009)
- Patient Protection and Affordable Care Act (2010)

Hospitals' Value-Based Purchasing (VBP) Program

- Goal: Pay for care that rewards better value and patient outcomes, instead of just volume of services
- 2004: Requiring hospitals to report Quality Data in order to obtain 'Annual Payment Updates' [www.hospitalcompare. hhs.gov]
- 2012: Starting to pay for performance
- VBP Criteria:
  - 12 Clinical Process of Care Measures (70% weighted value)
  - 8 Patient Experience of Care Dimensions (30% weighted value)
- Future:
  - Changing criteria
  - Expanding to outpatient and ASC (2014)
  - Shifting from 'process' measures to 'outcomes'

Reduced Payments for Hospital Acquired Conditions

- Certain conditions developed while the patient is hospitalized will not justify incremental reimbursement
- Gradual implementation starting 2014
- Plans to add measures

- Foreign object retained after surgery
- Blood incompatibility
- Pressure ulcers (stage III-IV)
- Falls and trauma
- Manifestations of poor glycemic control
- Catheter-associated urinary tract infection
- Vascular catheter-associated infection
- Surgical site infection (CABG, bariatric, orthopedic)
- Deep vein thrombosis (DVT) / air embolism (total knee, hip)

Accountable Care Organizations (ACO)

- **ACO:** A local set of providers accountable for the cost and quality of care delivered to a defined population

- **Objective:** Shift from fragmented and inconsistent care to coordinated care, and from volume-based to value-based payment system

ACO's must:

- Share responsibility for coordinated care.
- Include PCP's
- Provide care across the continuum of care
- Can have flexible structures - specialists, hospitals, pharmacies, post-acute providers, etc.
- Cover min. of 5,000 beneficiaries
- Measure performance

Bundled Payments

- **Objective:** Align incentives and improve patient's care during inpatient and post-discharge recovery
- **Current system:** surgery generates claims from hospital, surgeon, anesthesiology, radiology, pathology, post-discharge providers, etc.
- **New system:** A single 'bundled' payment made to the 'team' of providers involved.

Providers can determine which services will be bundled (4 models):

- Inpatient care + 30/90 days post-discharge; single payment to all providers
- Start at discharge up to (min) 30 days after discharge (include readmission); single payment to all providers
- All services, incl. by physicians, during inpatient; paid to hospital (which pays the physicians)
- Inpatient stay at the general acute care hospital; hospitals and physicians paid separately but can share gains arising from better care coordination

Comparative Effectiveness Research (CER)

Objective: Help clinicians and patients to make care decisions by developing evidence-based information about the effectiveness of treatments relative to other options.

Coordinating Council

- 15 members council overseeing research areas
- >$1 B funding (NIH, AHRQ, HHS, other)

Traditional clinical research: examines effectiveness of one method or product at a time

Comparative effectiveness research: compares 2+ different methods

- Methods: clinical trials, analysis of claims records, computer modeling, review of existing literature, other.
- Example: randomized trial for treatment of osteoarthritis of the knee → surgery had similar outcomes to Rx + PT

Cannot recommend clinical guidelines for payments, coverage or treatment.

Implications to Medical Device Companies

FDA Approval Is Necessary But Not Enough

FDA

Does the product do what it claims - <u>Safety and efficacy</u>

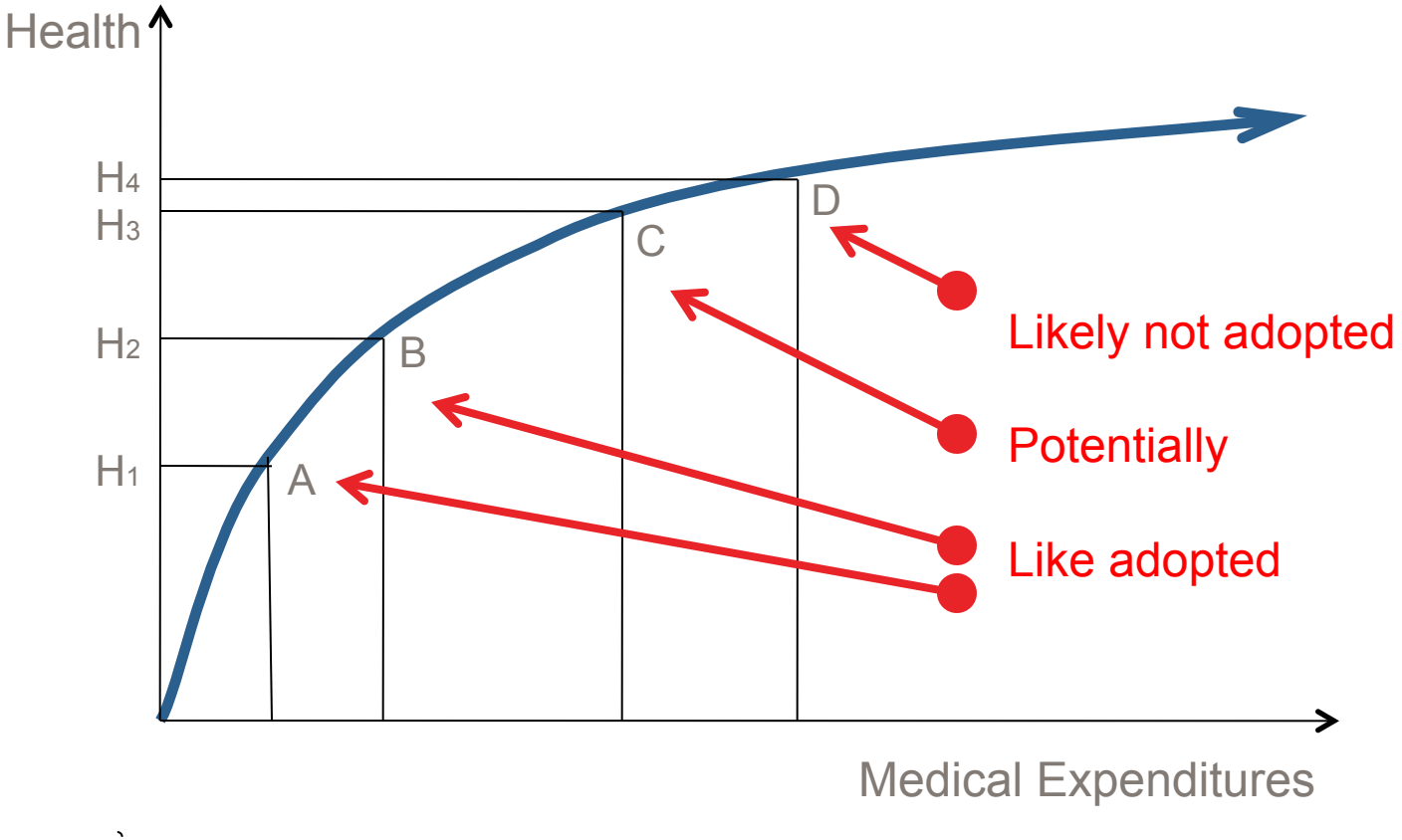
- Short-term or intermediate outcomes
- No cost considerations
- Data generated in controlled setting
- Decision made with minimally required data

Providers & Payers

Does the product / procedure improves outcomes - <u>Reasonable and necessary</u>

- Long term health outcomes
- Cost is often key consideration
- Use in “real world” - non-academic and routine conditions
- Significant evidence is required; professional societies input is important

“Value-based purchasing is on the way”



Ref.: Health Policy Issues, PJ Feldstein, 2007

Effect on Pricing

- Devices pricing will be based on ability to remove costs from the system
  - Stents versus CABG
  - Less invasive procedures, e.g. laparoscopy
  - Diagnostics screening, e.g. hospital acquired infections

- Drug prices will be based on performance and outcome
  - Cholesterol drugs – shift from surrogate endpoints, e.g. LDL, to clinical outcomes, e.g., heart attacks, mortality
  - Diabetes drugs - cardiovascular outcomes
  - Oncology drugs - show overall survival benefits

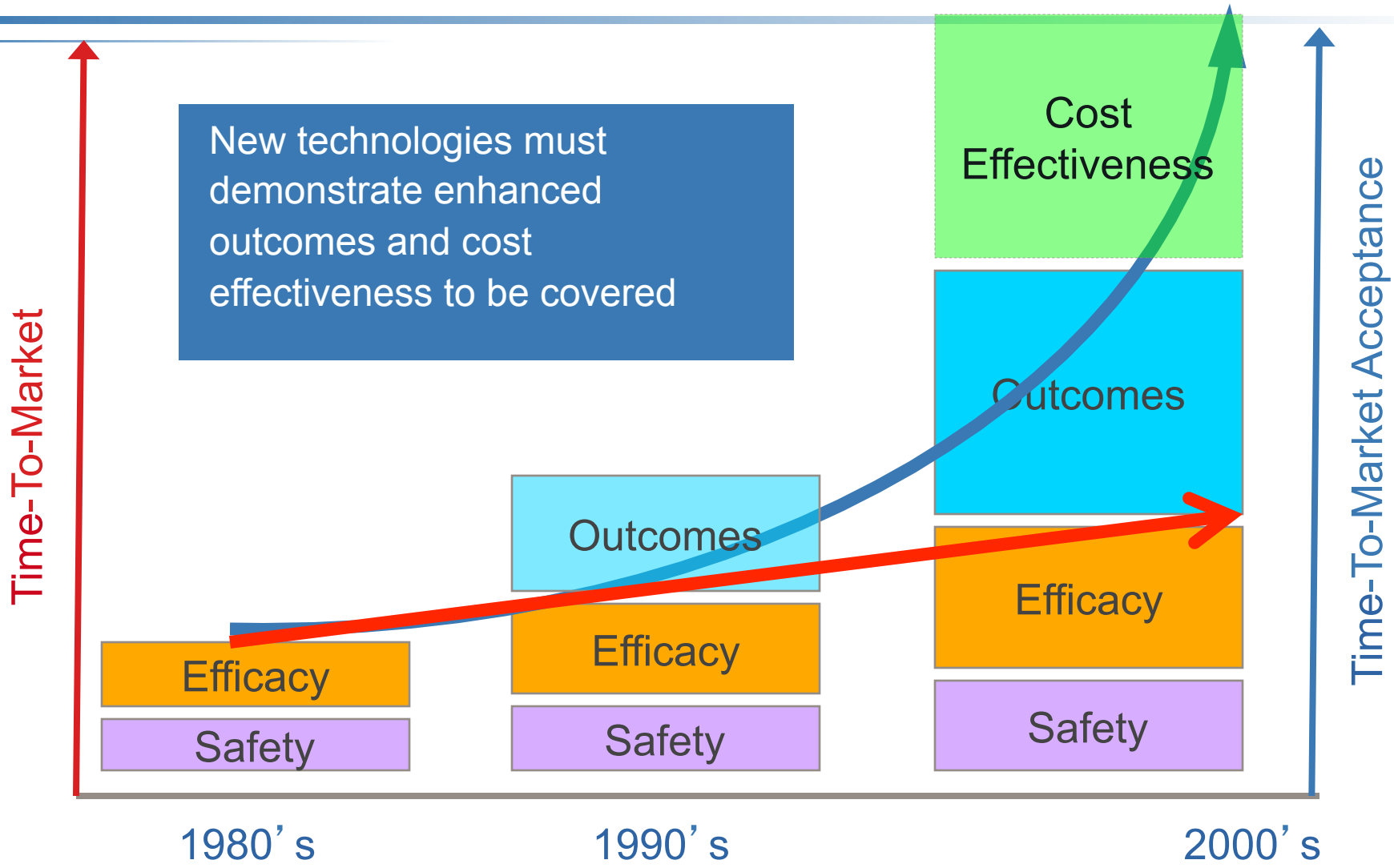
Evidence Based Medicine Is Essential

- Evidence that providers and payers are getting **quality improvements for resources used**
- Systematic and **comprehensive evaluation of the medical and economic implications** of the use of health technology
  - New technology – drugs, biologics, devices, support systems
  - New application of existing technology
- Critical evidence can often be shown only when establishing an installed base
  - May require larger populations and broader demographics
  - Longer outcomes

Not all studies are 'good evidence'

- Studies showing conflicting results
- Evidence of net benefits but the benefits are small
- Evidence that new technology is beneficial but still unclear that the 'new' is better than 'existing'.

Time To 'Market Acceptance' is Increasing

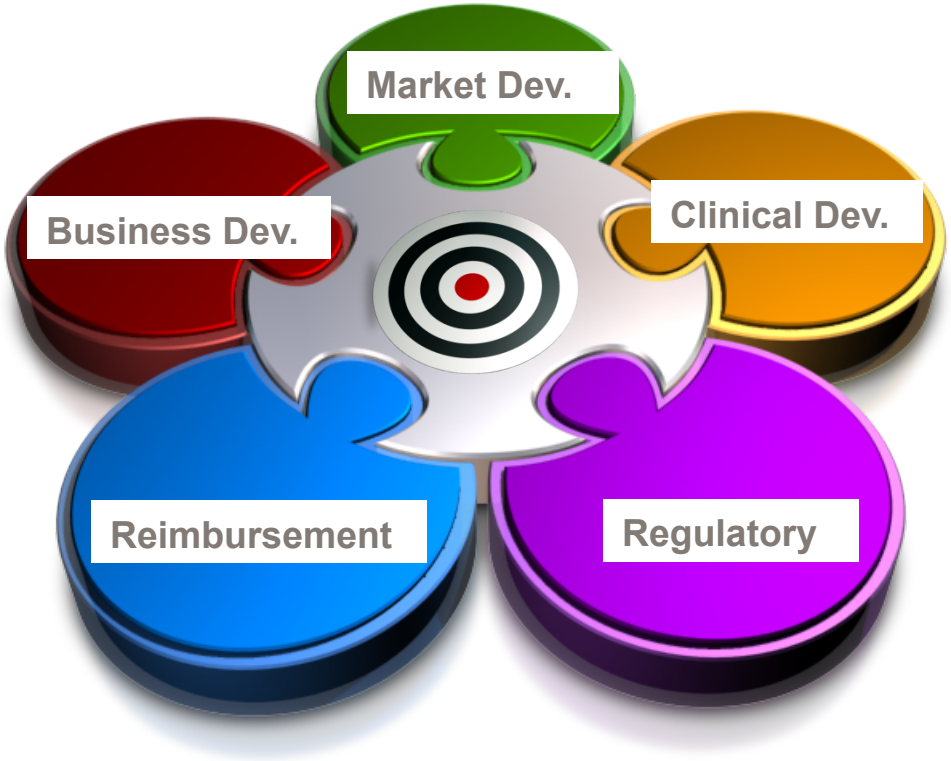


Considerable Implications to MedTech Companies

- Delayed revenue
- Need for additional funds and financing rounds
- Valuations are negatively impacted
- Business development initiatives are delayed
- Prospective distributors sit on the sidelines
- Increased risk of new competitors

So What Did We Learn at Boston MedTech Advisors?

Boston MedTech Advisors' Operations



Aesthetic Medicine

Ambulatory monitoring

Anesthesiology

Cancer Therapies

Cardiology

Critical Care

Cryosurgery

Dermatology

Emergency Medicine

General Surgery

Health IT

Hepatology

Home care

Interventional Cardiology

In-Vitro Diagnosis

Interventional Radiology

Neurology

Orthopedic

Patient Monitoring

Pulmonary

Radiology / Imaging

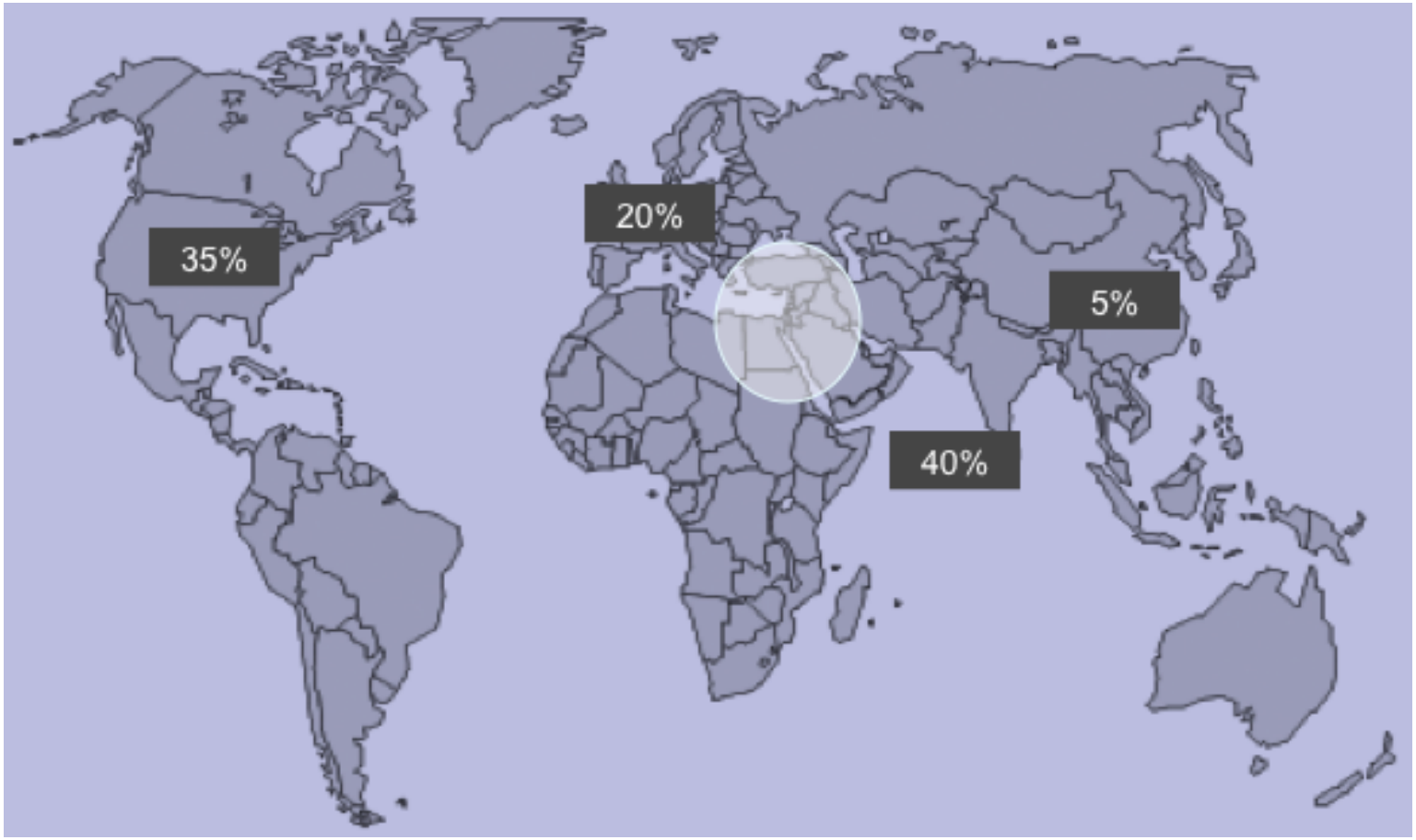
Rehabilitation Medicine

Sleep Medicine

Spine Surgery

Vascular Medicine

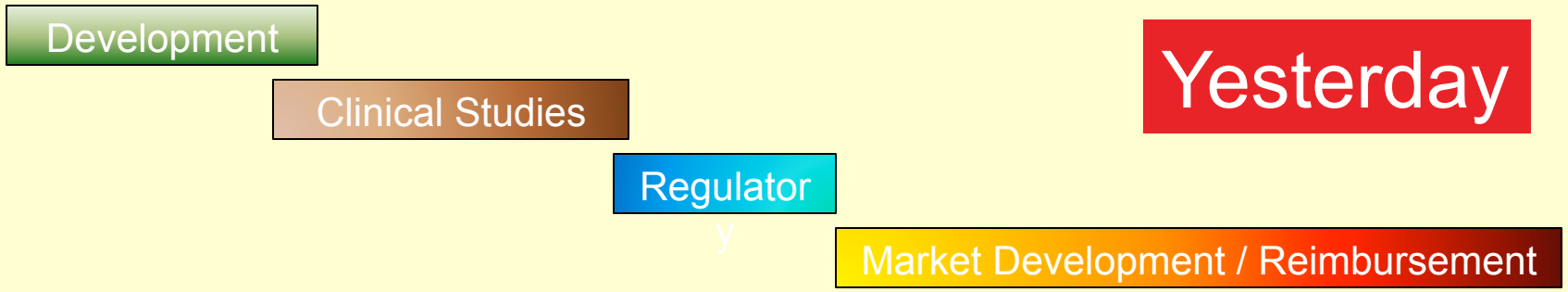
Working With Medical Technology Companies World Wide



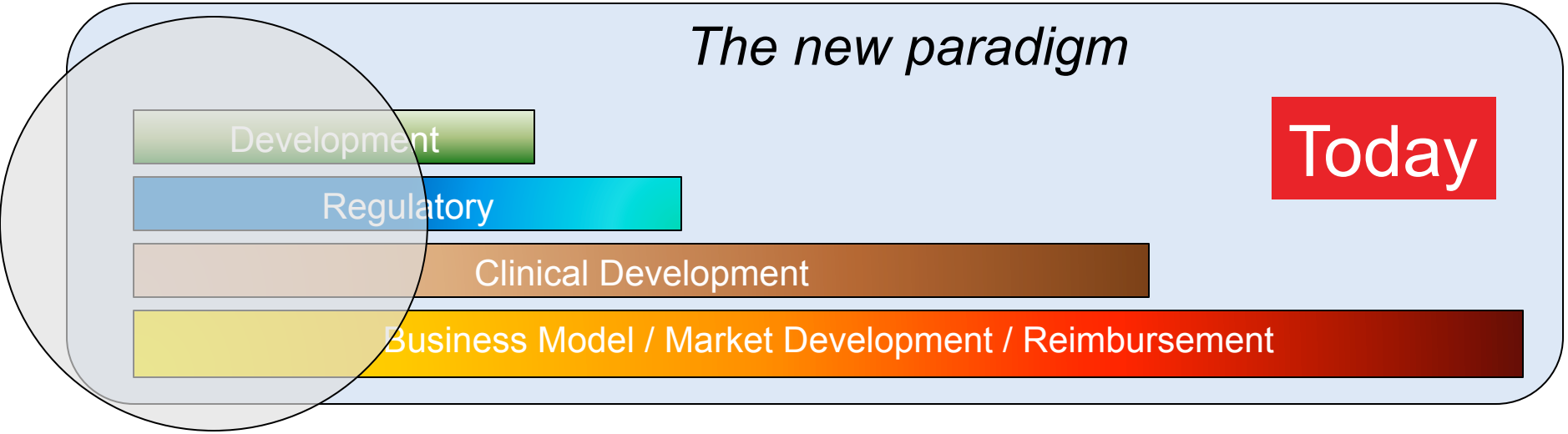
Key Lessons

- Need to understand factors leading to clinical / market adoption of the new technology and barriers to adoption
  - Not necessarily same drivers as in the past
  - More barriers than in the past
- To improve likelihood of successful business, assessment of adoption & barriers must be done at all times, starting at the early development, continuing through pre-market and post-launch phases
  - Considering new inputs (e.g., clinical data, market research), competitive developments, changes in regulations, etc.
- Appropriate R&D, regulatory, clinical, reimbursement and marketing plans cannot be developed without such knowledge
- Going to market: Instead of asking '*how quickly can we start selling?*' ask '*are we ready to start selling – and build adoption?*'
- Funding and valuations are predicated on convincing investors about the likelihood of adoption.

If you still work like this, you could run out of money and/or out of time…



The new paradigm



Changes in Regulatory Environment (US) and Implications for Early Stage Medical Device Companies

November 2013

Zvi Ladin, Ph.D.

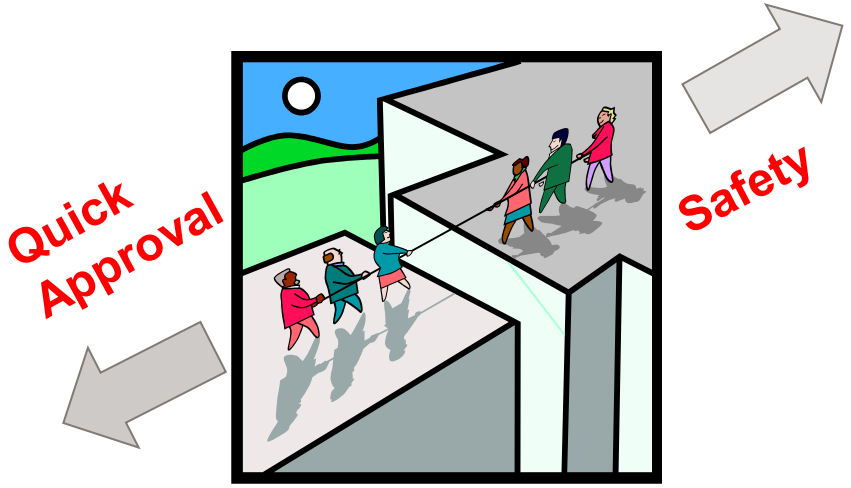
Overview

- Challenges of 510(k) program
- FDA reevaluation of 510(k) program
  - Task forces findings and recommendations
  - Institute of Medicine (IOM) review and recommendation
- Industry concerns(P T C C)
  - Predictability
  - Transparency
  - Consistency
  - Costs
- New CDRH initiatives
  - Review
  - Clinical trials
  - Homologation

The Crystal Ball

The 510(k) Process – Environment (end 2000s)

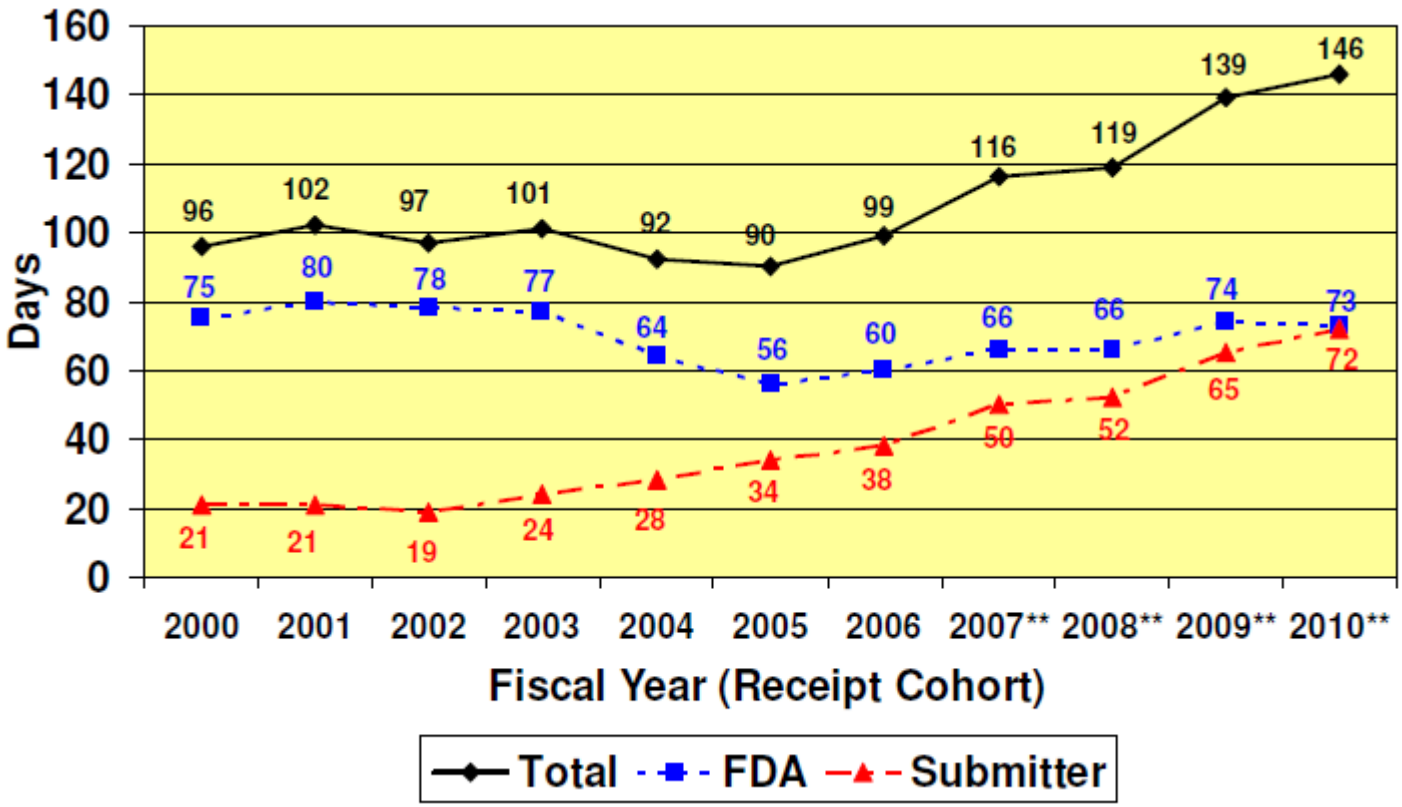
- Technological gap
  - Substantially equivalence to pre-1976 device?
- Generational change at FDA
  - ‘Baby Boomers’ retiring
  - Delays in recruitment and training of a new generation
    - Budget cuts
- Political pressures (2000s)
  - Conservative agenda
    - Abortion (RU-486 12 year review)
  - Menaflex



Cleared Medical Devices

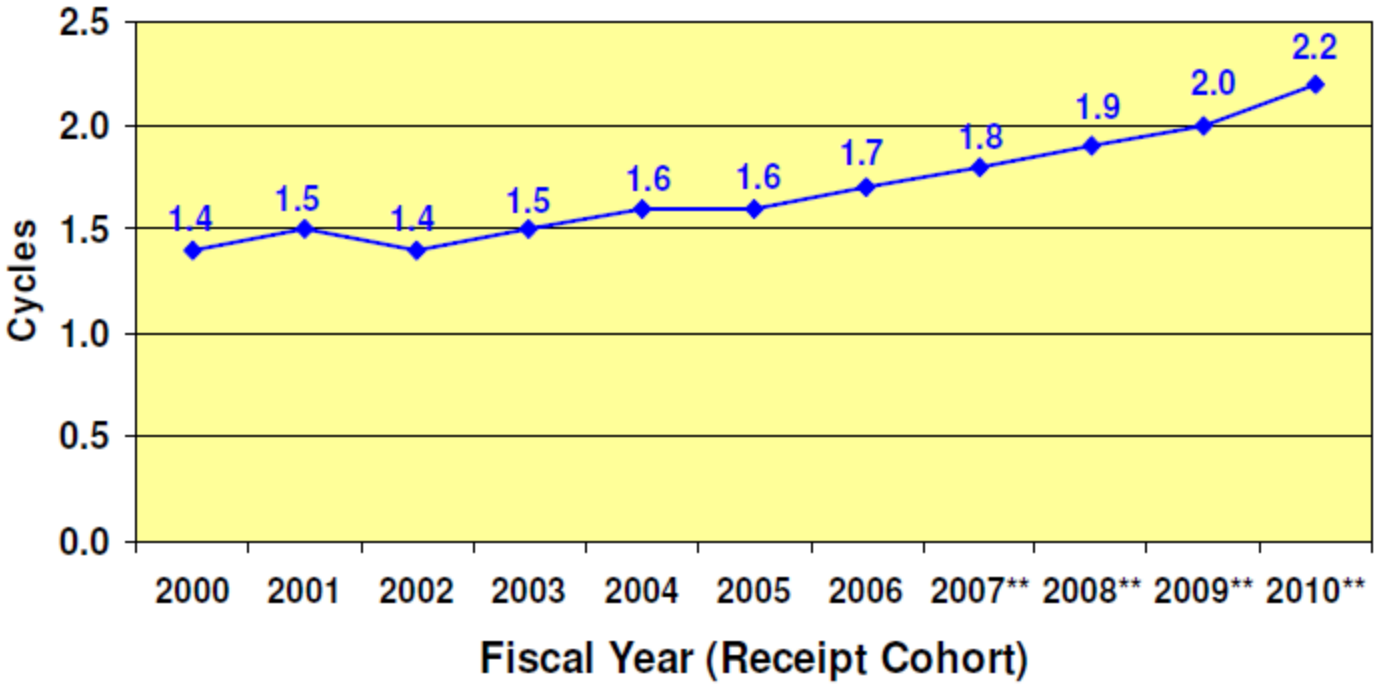
MassDevice. Eye on FDA 2009. Massachusetts Medical Devices Journal, LLC, 2009.

Average Time to 510(k) Decision *



*SE and NSE decisions only; times may not add to total due to rounding
**Cohorts still open as of September 30, 2011, data may change

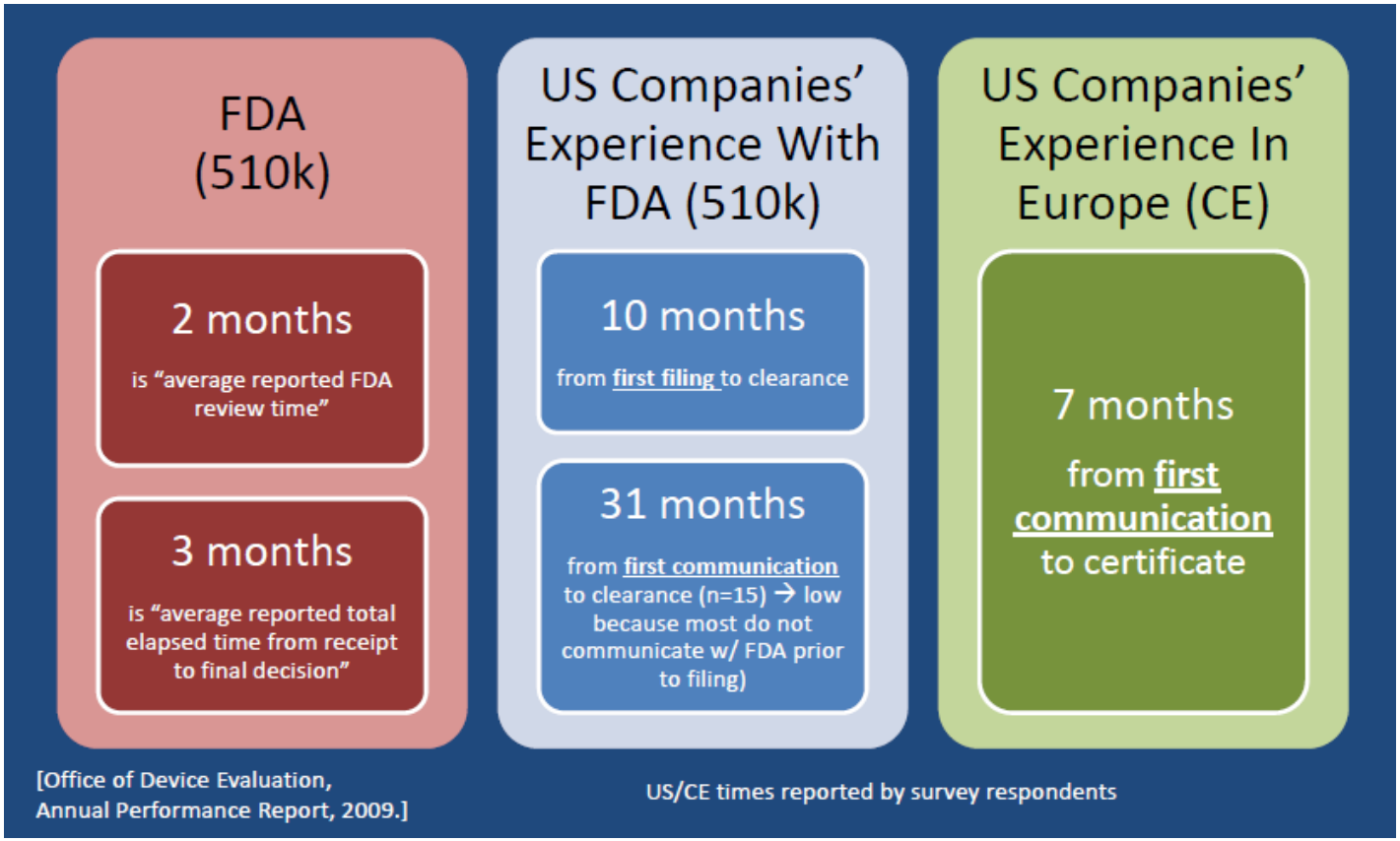
Average Number of FDA Review Cycles *



*SE and NSE decisions only; times may not add to total due to rounding
**Cohorts still open as of September 30, 2011, data may change

510(k) & CE timelines in US & Europe

Reported FDA transit times underestimate actual regulatory delay



Source: FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies, November 2010

Cost of Concept to Clearance / Industry Perspective

- Average to clear 510(k) – $31 million*
  - $24 million on FDA-dependent/related

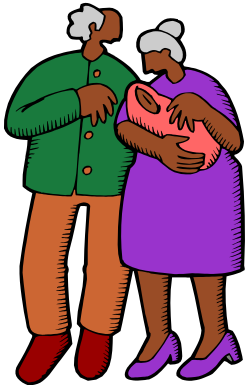
- Average to clear PMA – $94 million*
  - $75 million spent on FDA-dependent/related aspects

* Does not include reimbursement approval and sales/marketing costs.

Source: FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies, November 2010

Me Too! 510(k) Process Problems

- 510(k) approval process loophole
  - The Domino effect
- Grandfathering pre-amendment devices



- Example:
  - Boston Scientific's ProteGen Sling, vaginal mesh implants (to treat urinary incontinence) used surgical mesh implanted in the abdomen (to treat hernias) as predicate
  - Johnson & Johnson subsequently received 510(k) clearance for Gynecare TVT (vaginal surgical mesh), based on its similarity to Boston Scientific's ProteGen Sling (1998)
  - J&J wasn't required to conduct clinical testing
  - ProteGen synthetic mesh was pulled from the market in 1999

Clearance of New Technologies

Public	Industry	FDA
Safety (MoM Prosthesis)	Predictability	Scientific / Technical
Limited Testing	Transparency	Innovation / Safety
Access to Innovation	Consistency	New Information (Risks) / Effect on Clearances
Costs	Costs	Costs

510(k) Review – Promote and Protect Public Health

Sept 2009
- Two internal groups: **510(k) working group** and **Taskforce on the utilization of science in regulatory decision making**
- **Institute of Medicine** (IOM) to independently review 510(k) process

Aug 2010
- Two preliminary reports released
- 55 recommendations

Oct 2010
- Public comment period ended for preliminary reports

Jan 2011
- 36 actions to improve the 510(k) program

July 2011
- IOM report released

Quality Issues with 510(k) Submissions

- Inadequate device description
- Discrepancies throughout submission
- Problems with Indications for Use
- Failure to follow or otherwise address current guidance document(s) or recognized standards
- Performance testing required for certain device types is completely missing
- Clinical data required for certain device types is completely missing

Source: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm263385.htm

New Initiatives

- Proposed recommendations
  - Immediate implementation
  - Proposed legal / regulatory revisions
  - Complete review following IOM report
- Interagency Council on Medical Device Innovation
  - Identify unmet needs
  - Facilitate development or redesign of devices to address unmet needs
- Memorandum of Understanding (MOU) with CMS
  - Streamline review process
    - Regulatory + reimbursement

Recommendations – Innovation

- Based on 510(k) Working Group and Science Utilization Task Force

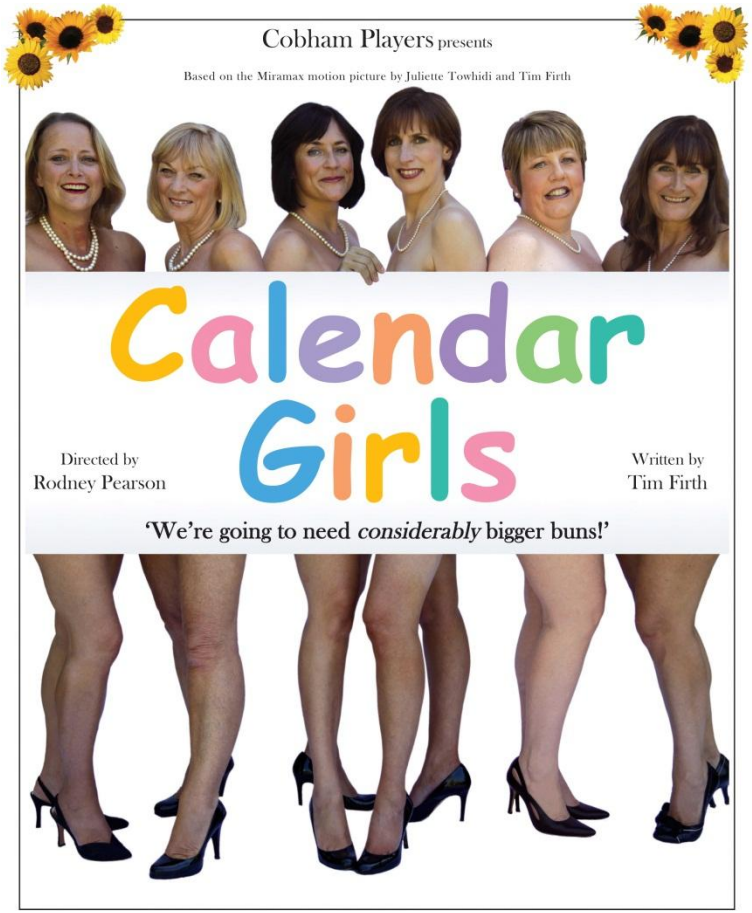
- Fostering medical device innovation
  - Streamline the premarket pathway for lower-risk novel devices (De Novo program)
  - Enhance science-based professional development for CDRH staff
  - Establish a network of **external experts** to better inform the review of cutting-edge technologies

Recommendations – Regulatory Predictability

- Establishing a new “Class IIb”
- Predictability
  - Communicate expectations
- Transparency
  - Center Science Council
- Consistency
  - Clarify “substantial equivalence’

Recommendations – Improve Patient Safety

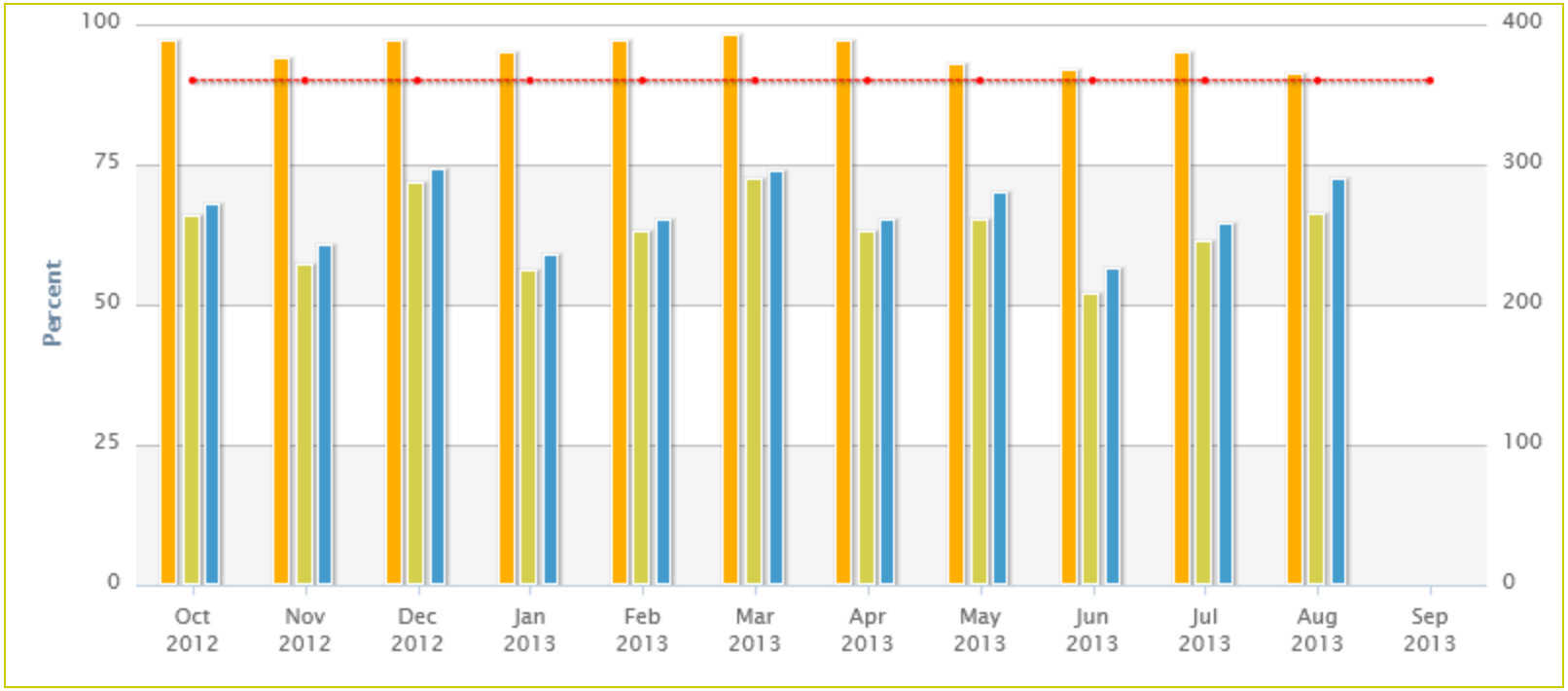
- More safety + effectiveness data
- Clarify CDRH's 510(k) rescission authority
  - Removal for safety concerns
  - Rescind clearance and ban use as predicate
- Searchable online, up-to-date, public device database
  - Photographs and design schematics
  - Summaries of FDA review decisions
  - Device labeling



CDRH Recommendations (Post 510(k) Review)

- Implement an "Assurance Case" Pilot Program
- Establish a Center Science Council
- Establish "Notice to Industry Letters" as a Standard Practice
- Clinical Trials Guidance
- Enhance Training
- Evaluation of Automatic Class III Designation (De Novo) Guidance
- Leverage External Experts
- 510(k) Paradigm Guidance
- Product Code Guidance
- Appeals Guidance
- Implement a Unique Device Identification (UDI) System
- Electronic Submissions

FDA Improved Performance – 2012/3

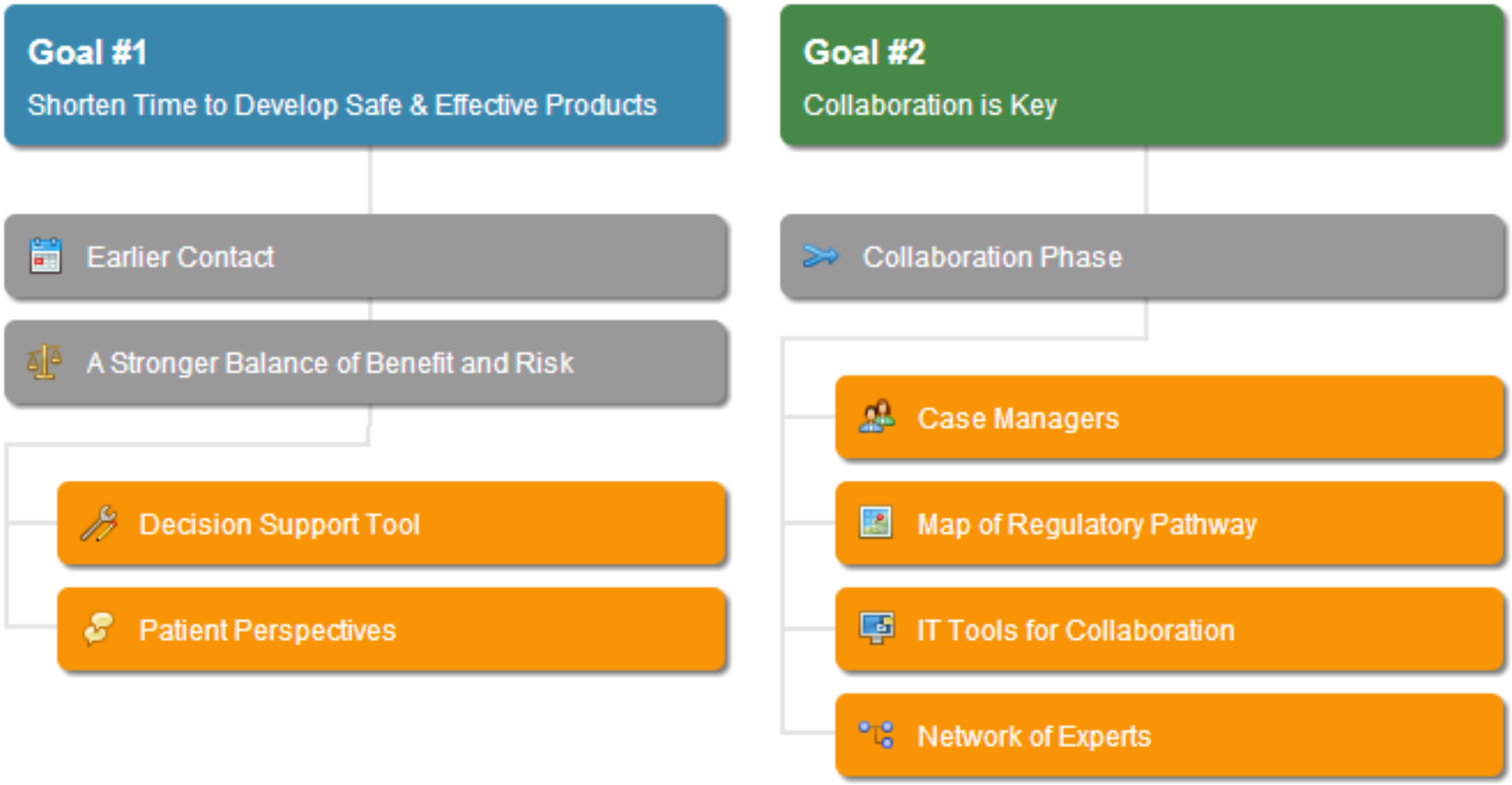


Percentage

Total number cleared within 90 days

Total number cleared

Innovation Pathway 2.0



Source: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm

Pilot Triage Program

- Create an incentive to submit good quality applications
- April 2, 2012 – October 2, 2012
- Quick Review Criteria
  - Pass quick review checklist
  - Pass a total product life cycle (Postmarket) search
  - Seek clearance for a device for which FDA has review experience and knowledge of expected performance
  - Not need for an extensive consult to complete 510(k) review
  - Contain a 510(k) Summary [and not a 510(k) Statement]
- Quick Review Tier – good quality submissions that fit quick review criteria; clear within 30 days
- Regular Review Tier - current normal 510(k) review process; clear within 90 days

Source: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm300308.htm

Facilitate US Clinical Trial

- Pre-Sub Meetings (December 2012)
  - Replaced ‘Pre-IDE’ process
  - Accommodates all submission types

- IDE Policy
  - Reject for safety only (June 2013)
  - First in human studies (September 2013)
  - Design of pivotal studies (November 2013)

Medical Device Development Tool

- New Guidance Document (November 13, 2013)
- Scientifically Validated Tool
  - Clinical outcome assessment (patient or clinician reported)
  - Test – detect or measure biomarker
  - Non-clinical assessment method or model
- CDRH Expectation
  - Within context of use – results can support regulatory decision
- Benefits
  - Broadly (industry + FDA) accepted
  - Faster decision-making

Special Reports, Workshops and Initiatives

- Patient Preference Initiative
  - Incorporating patient feedback into the regulatory process (September 2013)
- Personalized Medicine
  - *Paving the Way for Personalized Medicine* (October 2013)
- FDA / AGA (American Gastroenterological Association) Workshop
  - *Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and Metabolic Diseases* (December 2013)
- Medical Device Single Audit Program
  - Pilot program starting January 2014
  - Countries – Brazil, Canada, Australia (Japan – observer)

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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Boston MedTech Advisors

More Experience ►Better Results.

www.bmtadvisors.com
www.bmtCROgroup.com

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Our Mission, Business and Operating Principles

Mission:

Assist medical technology companies and healthcare providers to achieve their business goals by offering ethical, result-oriented, professional and cost effective advice and services.

Business:

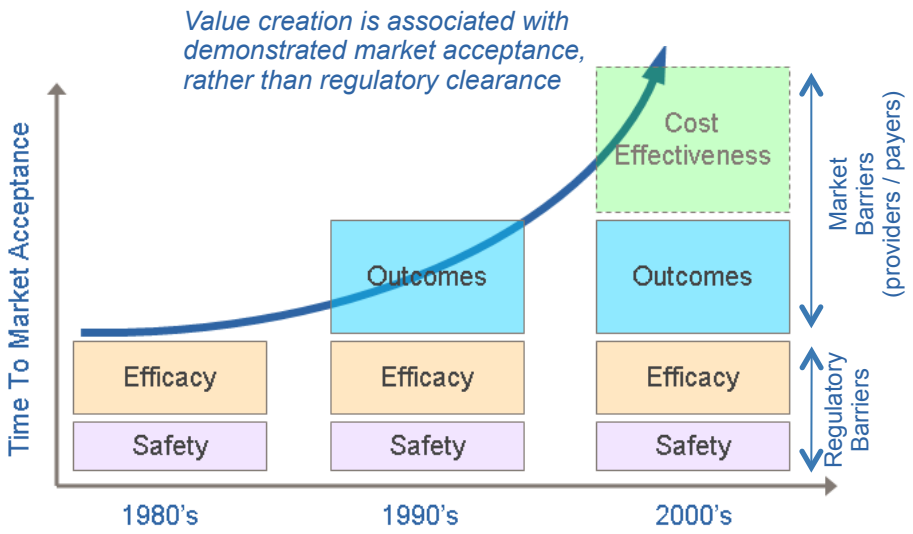
Support our clients to commercialize new products and services and to increase their market adoption, by addressing their unique and inter-dependent regulatory, clinical, reimbursement, marketing and business development requirements.

Operating Principles:

- **Provide optimal solutions** that recognize the multi-faceted aspects of today's healthcare markets and the client's unique business needs.
- **Maximize value** by delivering high quality services at a reasonable cost.
- **Leverage our own experiences**, know-how and relationships for the benefit of our clients.
- **Establish ongoing relationships** by aligning our incentives with those of our clients and partners.

Our Clients' Challenges

- **Healthcare Environment** – complex, competitive and continuously evolving
- **Regulatory Process** – intense and lengthy
- **Reimbursement** – constantly evolving rules that affect commercialization and adaptation of new technologies and procedures
- **Capital** – requires additional funding to support increased requirements for clinical evidence and marketing costs



Boston MedTech Advisors' supports companies to:

- Shorten time-to-market
- Accelerate market adoption
- Raise capital and increase enterprise value

Relevant Experiences Driving the Value to Our Clients

- Principals of Boston MedTech Advisors are entrepreneurs, founding own medtech and healthcare service companies, leveraging their extensive general management, product development, marketing, reimbursement, regulatory, clinical affairs and business development.
- We support diverse range of companies, including start-ups, pre- and post-revenue, VC-backed and public entities, enterprises based in the US, Europe, Israel and Asia, and multi-nationals.
- We provide access to an extensive network of industry, healthcare providers, academia, investors and business partners.
- We have hands-on working experience within the US and European medical technology and healthcare systems.
  - Broad industry experience, spanning over diverse and broad medical disciplines.
  - Excellent submission and communication history with the FDA and other regulatory agencies.
  - Successful record of strategizing and implementing reimbursement solutions.
  - Developing and executing marketing and business plans for new technologies and clinical services.
  - Financing of early-stage companies.

Aesthetic Medicine
Ambulatory monitoring
Anesthesiology
Cancer Therapies
Cardiology
Critical Care
Cryosurgery
Dermatology
Emergency Medicine
General Surgery
Health IT
Hepatology
Home care
Interventional Cardiology
In-Vitro Diagnosis
Interventional Radiology
Neurology
Orthopedic
Patient Monitoring
Pulmonary
Radiology / Imaging
Rehabilitation Medicine
Sleep Medicine
Spine Surgery
Vascular Medicine

Engagements *(sample)**

- Start-ups through Fortune 500 companies
  - Diagnostic, therapeutic and monitoring technologies
  - Healthcare providers - medical practices, clinics and hospitals
  - Consumer medical products and services
- Technology incubators, technology transfer and licensing offices
- Investors (private, institutional)

* Including advisors' prior relationships

When Working with Boston MedTech Advisors…

- You benefit from active involvement by an experienced US and European team, dedicated to helping your company to successfully develop and execute its plans.
- You receive comprehensive support, tailored to the specific needs of the organization, whether an early-stage or an established medical technology company.
- You can recognize significant efficiencies by working with a single entity offering vertically integrated strategy development, planning and execution services.

Expertise, practical solutions and execution in the following areas:

- Regulatory Affairs
- Clinical Trials and Evidence Development
- Technology Assessment, Market Analysis and Business Strategy
- Reimbursement and Contracting Strategy
- Business Development
- Business Plans and Financing Support

Regulatory Affairs

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Analyze the impact of FDA regulatory guidelines on product development, clinical studies and marketing plans.
- Develop rational regulatory strategies and plans, addressing short and long term corporate objectives.
- Solidify regulatory strategies by conducting pre-submission review meetings with the FDA and other regulatory agencies.
- Prepare and facilitate regulatory filings, including 510(k), PMA and IDE applications. Provide an overall management and oversight in order to reduce time-to-approval.
- Coordinate and "harmonize" FDA and CE efforts in order to increase efficiencies of regulatory activities.
- Serve as a registered ‘US Agent’ for foreign medical device manufacturers.

Clinical Trials Planning and Evidence Development

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Develop clinical study plans and protocols in support of regulatory submissions, marketing and reimbursement activities.
- Identify appropriate sites and principal investigators for clinical studies and negotiate study agreements.
- Prepare IRB, enrollment plans and pother study documentation.
- Provide technical, clinical and management oversight during clinical studies*
  - ✓ Project / trial management
  - ✓ Clinical site and patient monitoring
  - ✓ Database development, data acquisition and analysis
  - ✓ Logistical and operational support
- Prepare summaries of clinical trials for presentation to regulatory agencies, customers, business partners and investors.

* Through Boston MedTech CRO Group www.bmtCROgroup.com

Reimbursement and Contracting Strategies

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Review pertinent reimbursement codes and coverage guidelines for new products and services.
- Analyze reimbursement impact on product design, sales, marketing and business strategy.
- Develop a strategy and plans for solidifying new reimbursement codes, favorable coverage policies and adequate payments for new technologies and corresponding clinical procedures.
- Evaluate the multi-facet effects of regulatory, clinical evidence and marketing initiatives on reimbursement and identify steps to mitigate the effects of payment barriers.
- Manage the application process for new reimbursement codes and/or expansion of coverage guidelines.
- Develop reimbursement support services for end-users.
- Provide guidance for contracting with third-party payers.

Technology Assessment, Market Analysis and Business Strategy

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Assess market potential for new technologies and services.
- Conduct competitive market research and analysis.
- Analyze clinical and technical requirements, regulatory and reimbursement environments for new technologies, products and services.
- Identify new market opportunities for medical technologies and services, and identify optimal clinical applications for ‘platform’ technologies.
- Evaluate marketing strategies and develop marketing plans – pre and post launch.
- Evaluate new markets for existing products and services.

Business Development

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Identify complementary business opportunities and potential strategic partners.
- Analyze alternative sales channels.
- Initiate and facilitate business relationships, supporting product development, marketing and financing.
- Create early US or European presence, including marketing and business development arm for emerging companies.*
- Introduce larger companies seeking to augment their product or technologies portfolio to appropriate early stage players.

* In collaboration with Boston MedTech Advisors' strategic partners.

Business Plans and Financing Support

Regulatory Affairs

Clinical Trials and Evidence Development

Reimbursement and Contracting Strategy

Technology Assessment, Market Analysis and Business Strategy

Business Development

Business Plans and Financing Support

- Work with entrepreneurs and management teams to develop ‘fundable’ business plans and to optimize financing campaigns.
- Introduce entrepreneurs to VCs and private investors active in the healthcare field.
- Identify prospective strategic partners, prepare companies to appropriately explore opportunities and support all phases of the process.
- Support fundraising activities.
- Conduct due-diligence evaluations of new technologies and services.

Senior Team

David Barone, Principal

30 years experience including general, technical and operations management, strategic planning, marketing and business development. Current activities focus on advising and assisting US and off-shore medical technology organizations, ranging from start-ups to Fortune 500 companies, in areas ranging from opportunity analysis, marketing strategy and market development, reimbursement strategies, business development and financing. Prior to co-founding Boston MedTech Advisors, David held senior management positions in a number of medical device companies and has founded, financed and developed a number of healthcare companies. B.Sc., Electrical Engineering, Technion, Israel Institute of Technology, M.Sc., Bio-Medical Engineering and Master, Business Administration, both from Rensselaer Polytechnic Institute, NY.

Zvi Ladin, PhD, Principal

Over 20 years of experience in the medical industry, government and academia, focusing on developing and managing clinical, regulatory affairs and reimbursement initiatives. A co-founder of Boston MedTech Advisors, focusing on establishing regulatory strategies for therapeutic and diagnostic medical device companies, submission of regulatory applications, including 510(k) and PMAs for products in Class I-III and drug-device combination products and representing companies in negotiations with the FDA and other regulatory agencies. Dr. Ladin taught mechanical and biomedical engineering at MIT and Boston University and served as a scientific advisor to the FDA. B.Sc., Aeronautical Engineering and M.Sc., Biomedical Engineering, Technion, Israel Institute of Technology; Ph.D., Medical Engineering, MIT-Harvard Medical School Division of Health Science and Technology.

Michael Imhoff, MD, PhD, Senior Advisor

Board certified in surgery and intensive care medicine, with over 15 years of clinical experience in large medical centers and strategic consulting for leading companies in the global medical technology markets, as well as start-ups in the US and Europe. Research areas include trauma surgery, intensive care medicine, patient monitoring, clinical data management, artificial intelligence in medicine and health economics. Dr. Imhoff is an associate professor in Medical Informatics and Statistics at Ruhr-University Bochum, Germany, a reviewer for the German Research Foundation, a member of the editorial boards of and reviewer for several international biomedical journals, and author of over 300 publications and scientific presentations. Medical school: Universities of Bochum and Munster, Germany; PhD, Ruhr-University, Bochum, Germany. 1991 Recipient of the Lederle Prize for Research.

Bios *(cont.)*

Yossi Elaz, Senior Advisor

Background includes senior executive positions in large global medical device organizations, including Siemens Medical Systems, and most recently, a member of Draeger Medical's Global Management Team. Experience includes overseeing large R&D organizations, product requirements management, operations and business development activities encompassing a diverse range of medical disciplines, including platforms for patient monitoring system, therapy devices and critical care information management systems. Developed a large number of clinical partnerships with leading medical institutions and opinion leaders in US and Europe and has been involved in the evaluation of numerous medical device technologies. B.Sc., Electrical Engineering, Technion, Israel Institute of Technology.

Ninad Gujar, Senior Consultant

Background in biomedical engineering, translational research and business development. Prior experiences include neuroscience research, digital marketing, market analysis, healthcare policy, reimbursement analysis and commercial product marketing.

Andrea Nadai, Manager, BMT CRO Group

Seasoned health care professional with clinical background in physical therapy and clinical teaching. Prior experiences include the development of corporate compliance program, risk management, grant writing, searching state and federal regulations and supporting accreditations. Managed clinical support services in sponsored clinical studies, managed rehabilitation clinic operations, including physical, occupational and speech therapists, and provided direct care of patients with neurologic and orthopedic disorders in outpatient, inpatient and home-based settings. Led continuing education seminars in diverse areas, including pediatrics, gait analysis, manual therapy techniques and more. B.Sc., Physical Therapy, State University of New York, and Master, Health Professions, Northeastern University, MA.