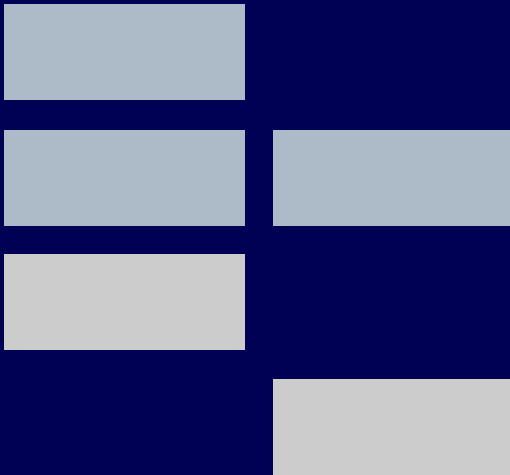




01 December 2010

# How MedTech Executives Are Responding to New Economic, Public Policy, and Cost-Containment Pressures

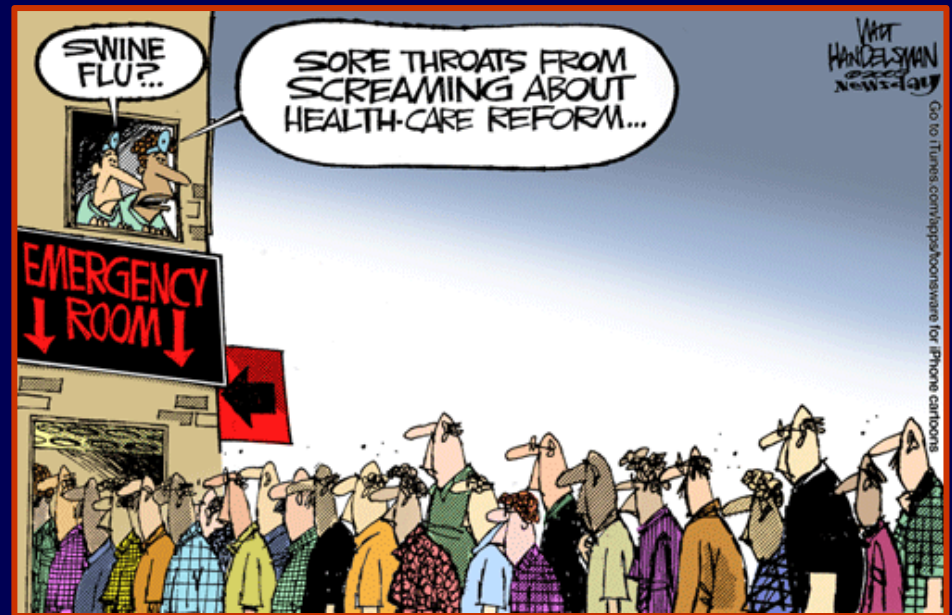
## STUDY RESULTS



# Introduction

The “MedTech” industry is facing unprecedented pressures and uncertainty due to macroeconomic, public policy, and regulatory changes

- Recession
- Healthcare cost-containment pressures
- Regulatory and enforcement efforts
- Healthcare reform



# study Overview

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**During 2010 PRTM conducted a study to capture the thinking of MedTech industry leaders on major policy, regulatory, and macroeconomic changes**

- Emphasis on understanding the implications for MedTech innovation

**The study covered the following themes:**

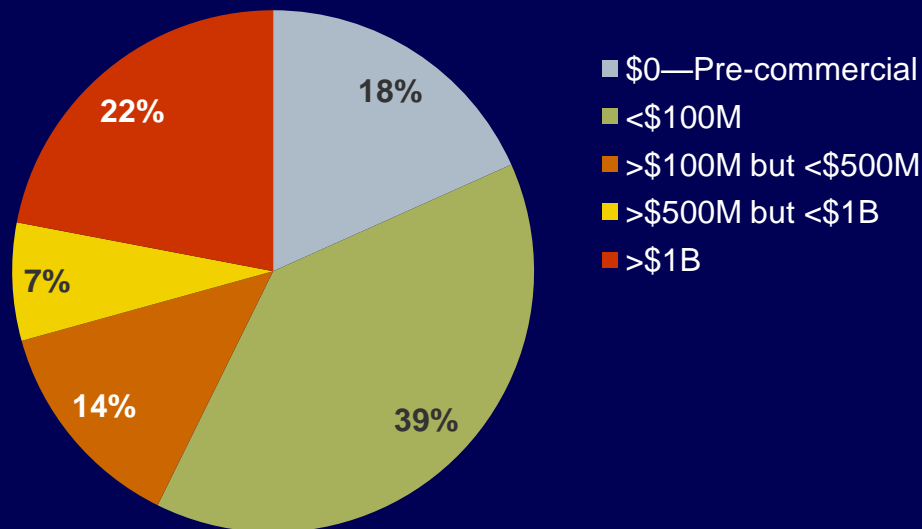
- Economic Downturn
- Public Policy Initiatives
  - Expanded Health Care Insurance Coverage
  - Device Industry Tax
  - Comparative Effectiveness Research
  - Payment Reform
- Regulatory Initiatives
  - 510(k) Reform
  - Sunshine Provision and Massachusetts Gift Ban
  - Risk Management Scrutiny
  - National Medical Device Registry
- Overall Impact

# Study Participants

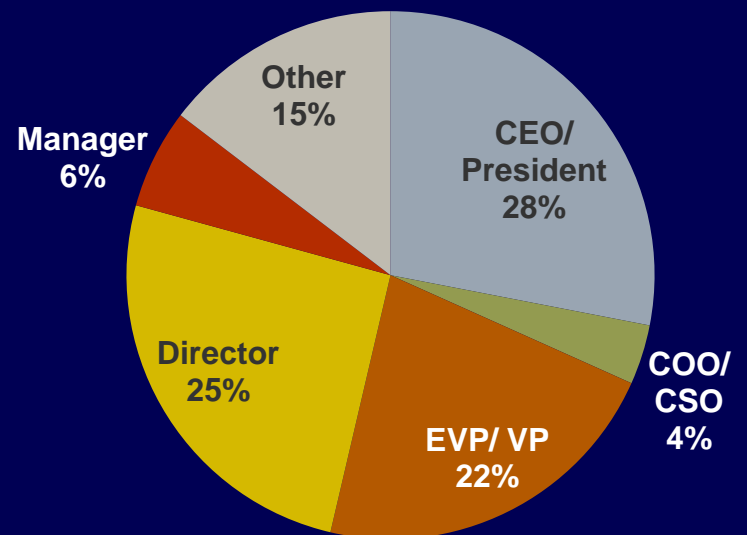
Nearly 100 MedTech industry leaders participated in the study...

- Representing a broad range of U.S. medical companies
- >50% of responses from executive management

**Company/Business Unit Size**  
(Annual Revenue)



**Respondent Positions**

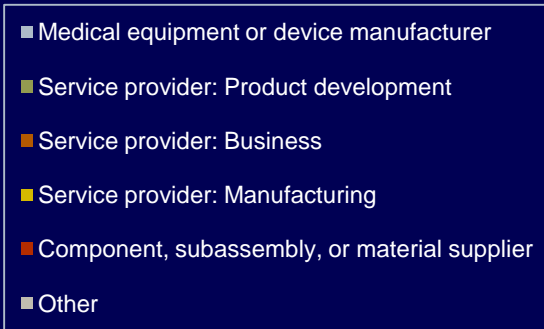
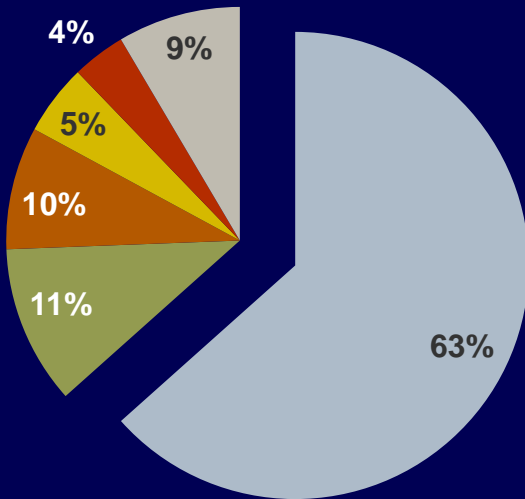


# Study Participants

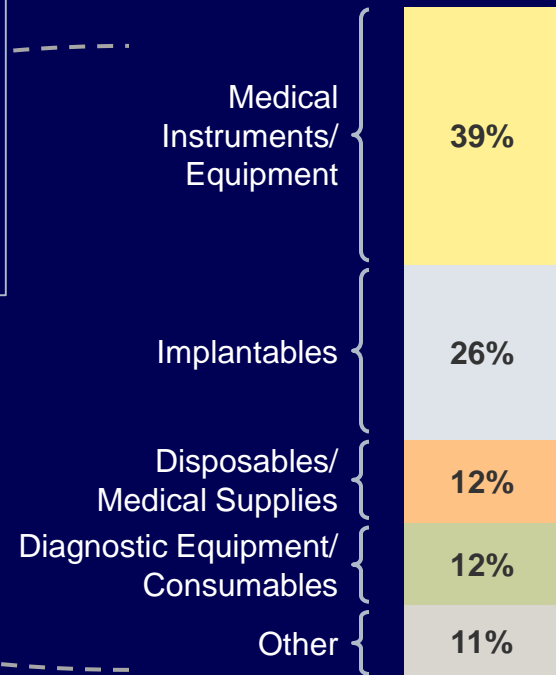
## Study participants included:

- MedTech companies (63%) and industry service providers
- Different segments of the MedTech industry

**Primary Product or Service of Respondent**



**MedTech Industry Segment**





# Study Findings and Perspectives

**MACROECONOMIC TRENDS**

PUBLIC POLICY INITIATIVES

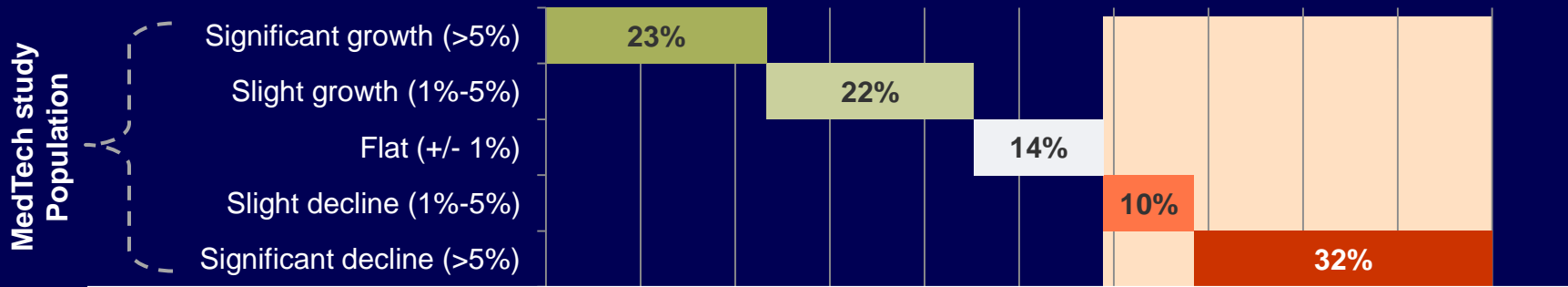
REGULATORY INITIATIVES

OVERALL IMPACT

# The MedTech Industry Is Not Immune

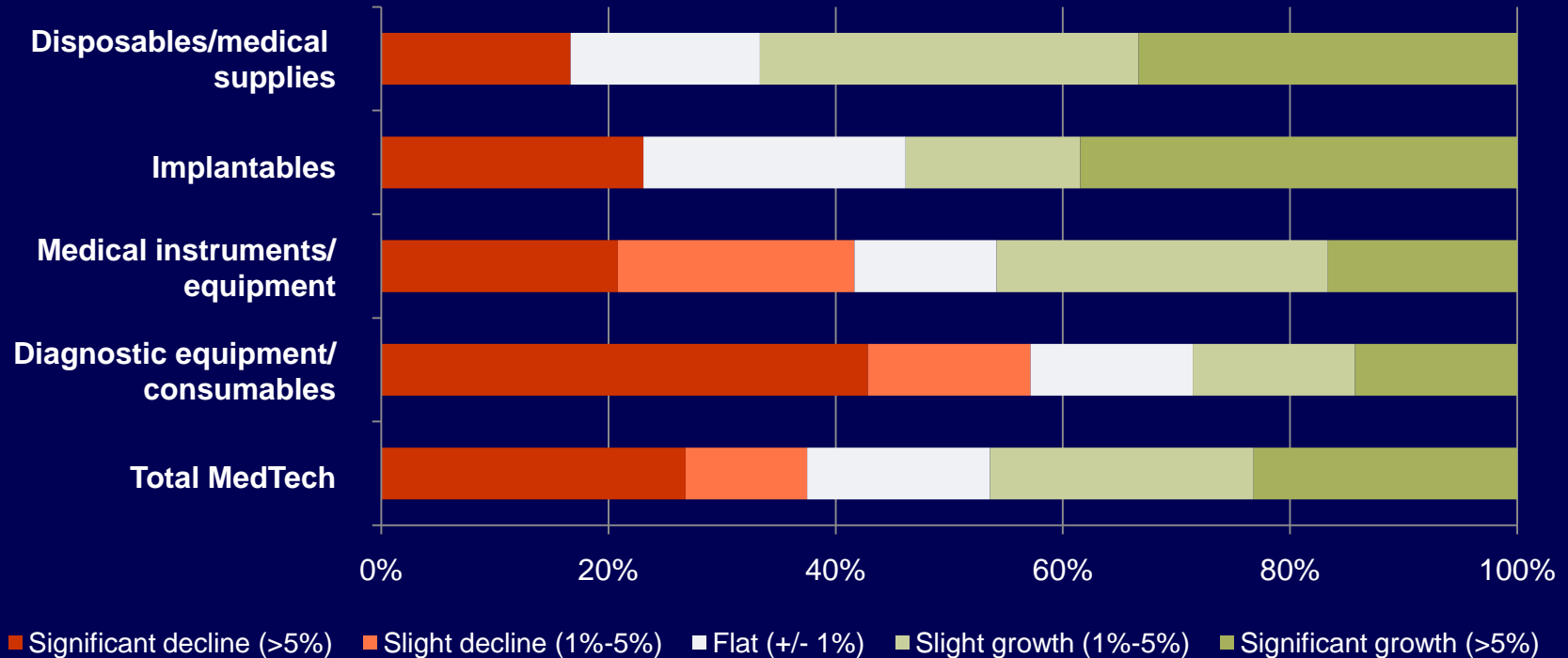
Economic downturn has affected most of the industry

How has your business performed during the current economic downturn (e.g., 2009 revenue versus 2008 revenue)?



# Capital Equipment Segments Affected Most

How has your business performed during the current economic downturn (e.g., 2009 revenue vs. 2008 revenue)?



*Medical supplies and implantable segments have been less susceptible to the downturn, while medical and diagnostic equipment have fared the worst.*



# Starts with Economic Impact on Care Providers

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## Limited care provider revenue growth and profit putting pressure on MedTech suppliers

- Reduced reimbursements
- Elective procedures delayed by consumers/patients
- Reduced endowments
- Increased MedTech supplier negotiation and competition

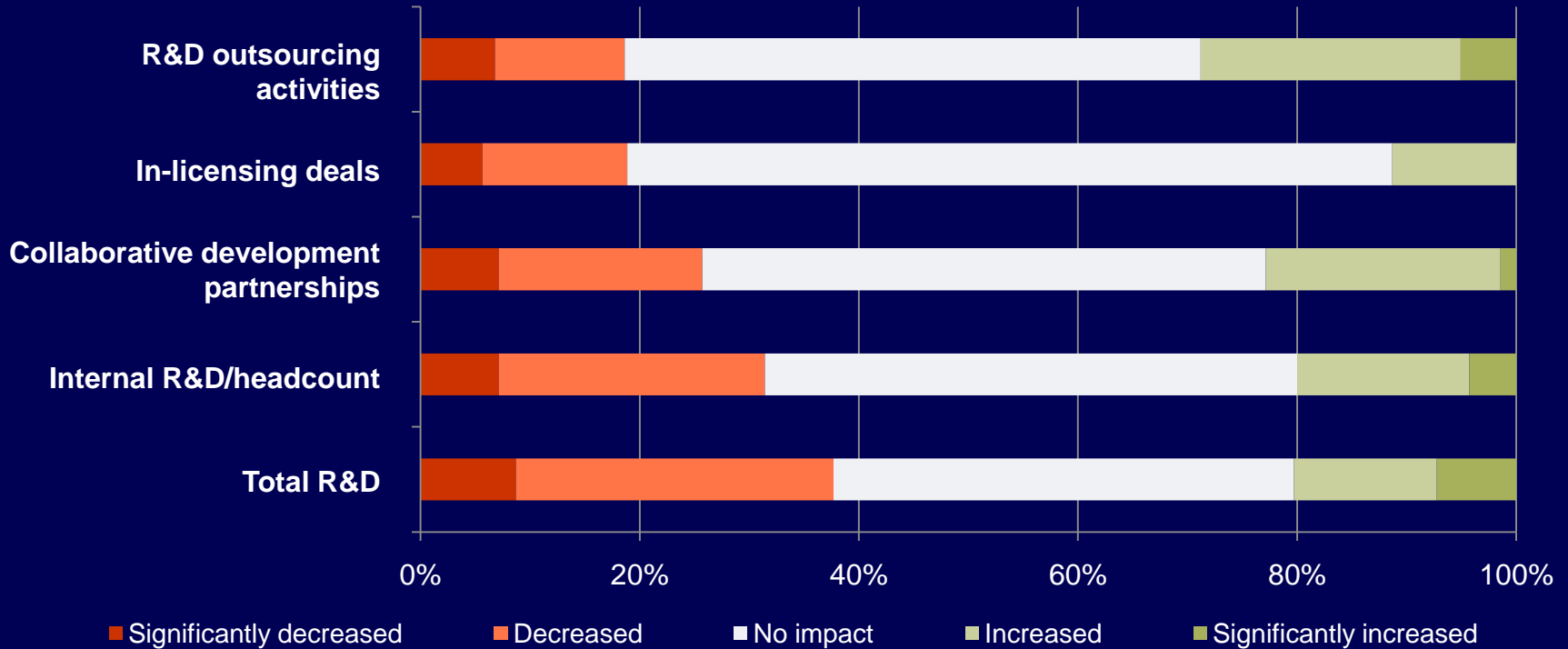
## Economic contraction and public policy uncertainty has increased the risk of care provider capital investment

- Credit/capital lending contraction
- Capacity expansion plans delayed
- Upgrades to existing equipment scrutinized

## Not just a U.S. issue

# Most MedTech are Trying to Maintain Innovation

How has the economic downturn impacted your company's investment in the following areas?



***Most companies have maintained or trimmed total and internal R&D investment, even with flat or growing revenues. There has been moderate growth in R&D outsourcing and co-development.***

# Companies Recognize Innovation Importance

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**R&D has been “on the table” for cost cutting, but often behind other operational areas such as SG&A and supply chain**

**Innovation has been responsible for sector success and will continue to be so—most believe even more so**

**Multiple structural levers are being pulled to improve productivity**

- Review priorities and focus on highest-value programs
- Realign organizational structure
- Assess lower performing employees
- Outsource/establish collaborations

**Further opportunity for transformational levers**



# Study Findings and Perspectives

MACROECONOMIC TRENDS

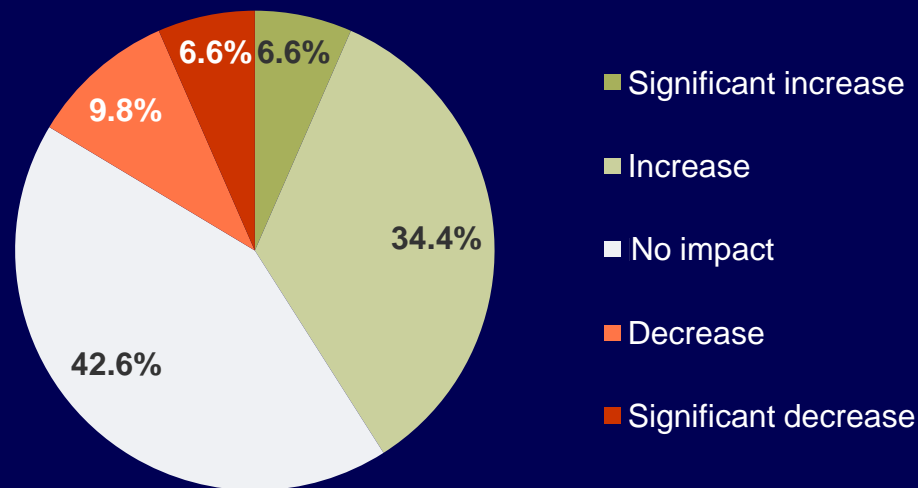
**PUBLIC POLICY INITIATIVES**

REGULATORY INITIATIVES

OVERALL IMPACT

# Expanded Health Care Insurance Coverage

What do you think will be the impact of expanded health care insurance coverage on the market size for your company's products?



*Approximately 40% of respondents believe that expanded coverage will not have any impact on their market size. The same number expect a positive impact.*

# **Some Are Skeptical of Expanded Care Benefits**

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**Most device users tend to be older and are already covered by Medicare**

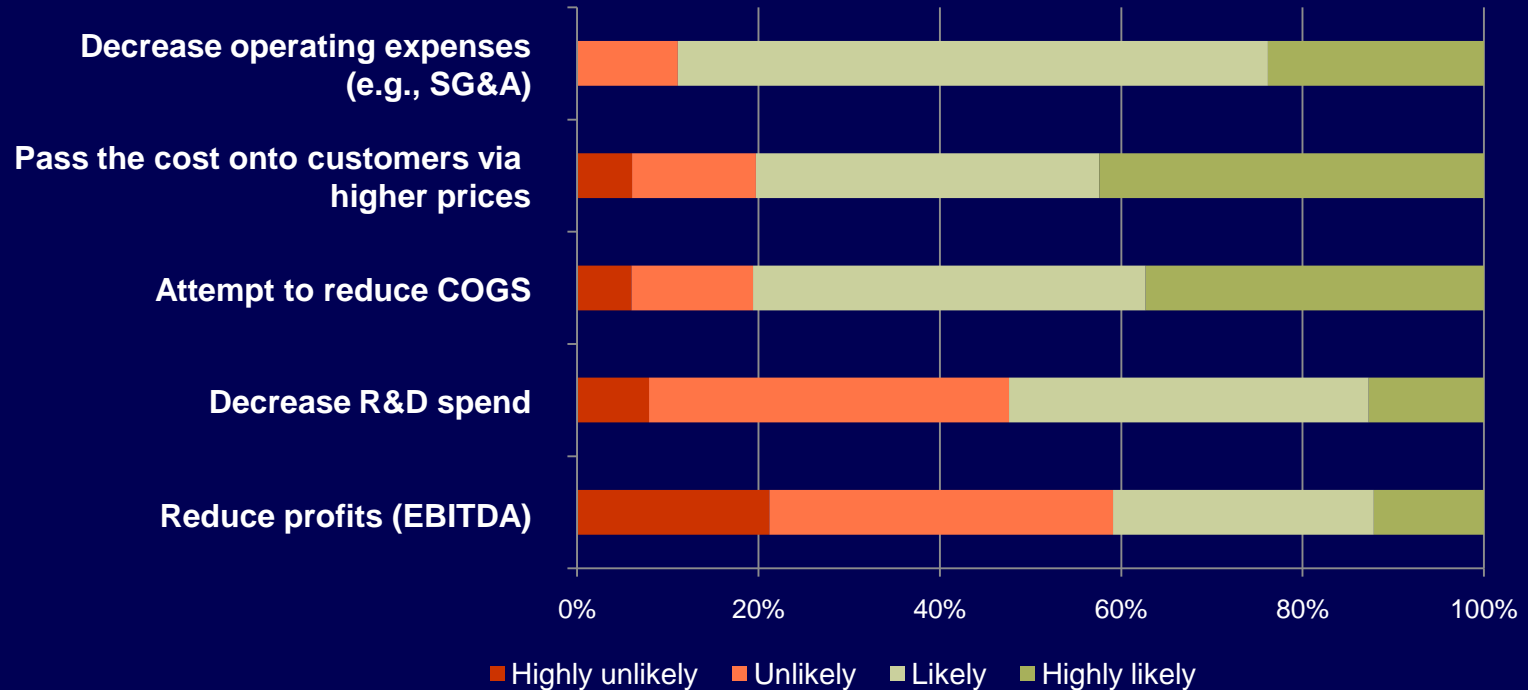
**Younger, uninsured individuals already have access to critical care needs through emergency visits**

**Newly covered individuals, will likely be younger and healthier, with fewer needs for medical devices**

**Increased population coverage will put added strain on the system and could result in rationing and even more reimbursement pressure**

# Device Excise Tax

If a device tax is implemented, how would most medical device companies likely react?



*Companies expect to absorb the device tax across all expense categories. More companies are likely to cut operating expenses or attempt to expand margins while protecting their R&D spend and profits.*

# **This Tax Will Be Countered with Cost Reductions**

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**For companies that have products that can more easily adjust prices, price increases will be attempted**

- Negotiating higher prices with payers and providers

**All will focus on cost and expense management to limit profit reduction**

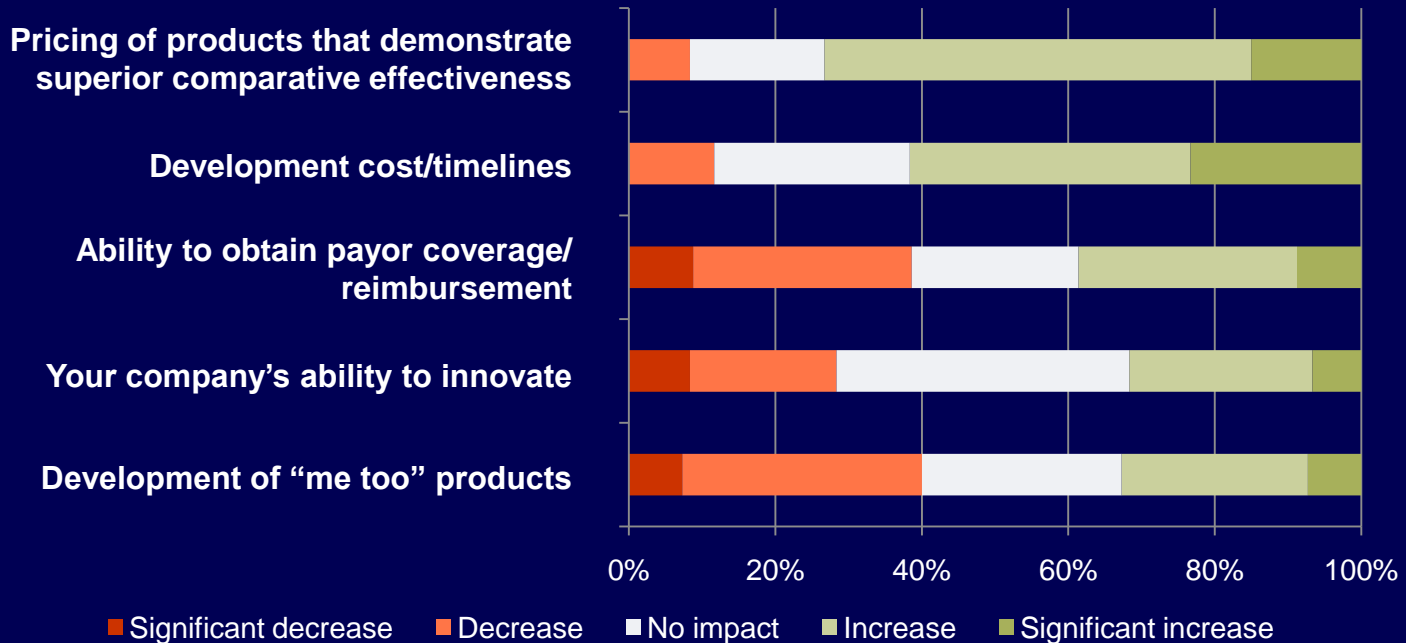
- Adjust organizations to support greater operational efficiencies
- Reduce product costs
  - Lower raw material costs through strategic sourcing and supplier management
  - Design for Cost
  - More efficient and cost-effective manufacturing processes

**Tax minimization strategies may also be employed**



# Comparative Effectiveness Research

What would be the impact of proposed comparative clinical effectiveness research activities on the following?



*Increased comparative research is expected to support price premiums, drive higher development costs/timelines, and curtail investment in "me too" products.*

# Significant Trial Investment With Implications

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## Greater R&D investment needs for each new product

- New data requirements to support efficacy comparisons and economic value
- Ability to demand price premium for superior products

## Concern that comparative research may drive product use and reimbursement decisions based on economics over health benefits

## Potential for improved innovation—improved care

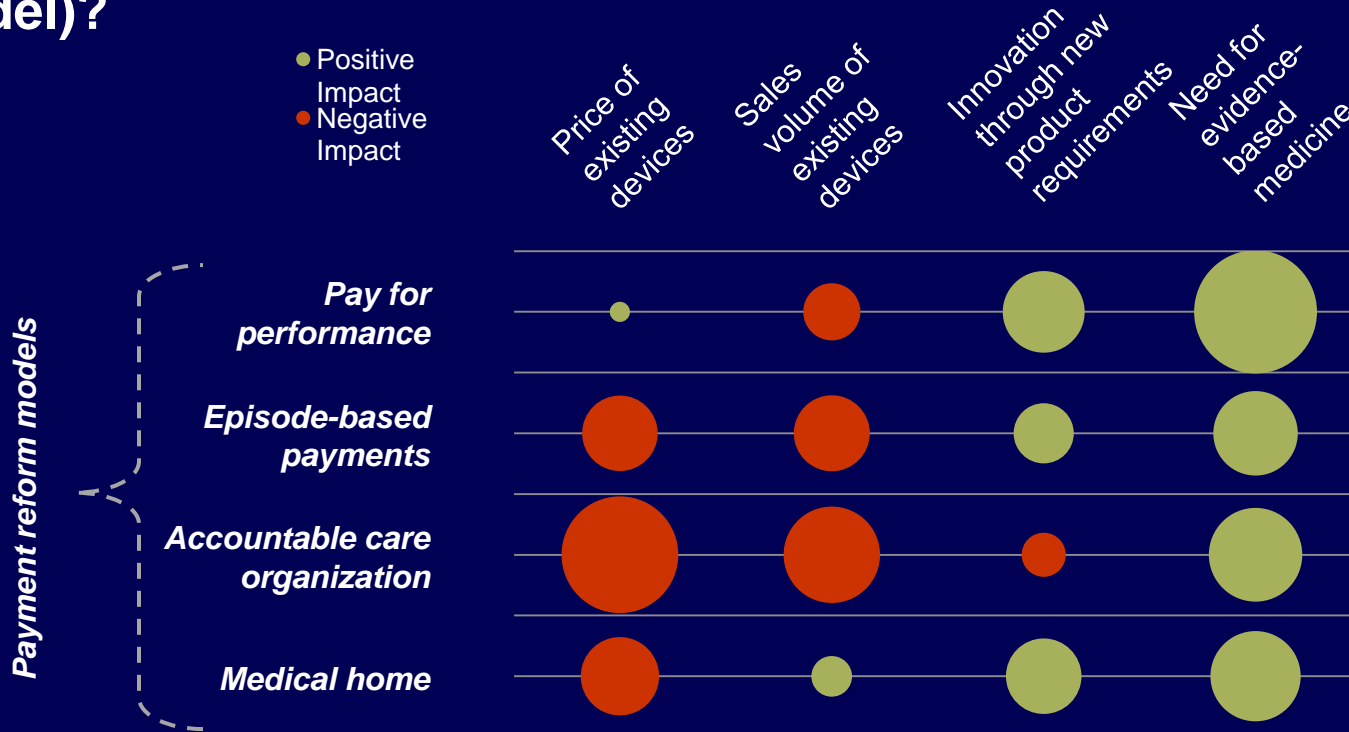
- Better understanding of current and emerging standard of care and competitive offerings
- Greater focus on differentiation and “step” improvements in benefits
- New types of innovations that address the overall care value chain rather than point-solution products

## Potential to inhibit incremental innovation

- Increased investment per offering could mean less offerings to market
- Many “big” innovations are the result of many preceding “incremental” innovations

# Payment Reforms

What would be the likely impact of different payment models on each of the following criteria (relative to the current fee-for-service model)?



*New payment models may negatively affect pricing and sales of existing medical devices, while driving innovation and evidence-based medicine.*

# Reimbursement Change Will Guide New Innovation

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## Care providers will be held more accountable and will demand solutions that help them and their patients

- Increasing pressure on the prices and sales volume of existing products
- Need to align solutions to new stakeholder motivations and behavioral changes under new payment and care delivery models

## Opportunity to develop products that are better aligned with new care models

- Greater focus on disease prevention and early detection
- Deliver better care quality, outcomes, and cost
- Improve provider productivity
- Accelerate procedure and recovery times
- Enable greater role of lower cost resources in care delivery



# Study Findings and Perspectives

MACROECONOMIC TRENDS

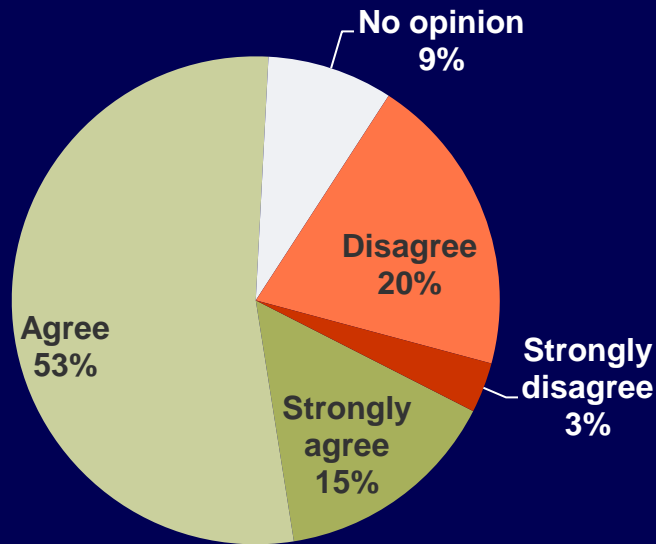
PUBLIC POLICY INITIATIVES

**REGULATORY INITIATIVES**

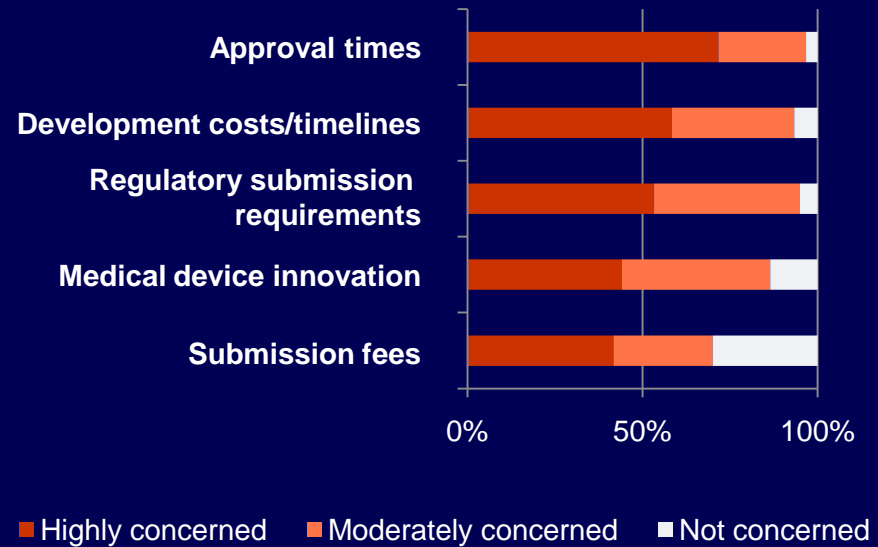
OVERALL IMPACT

# 510(k) Reform

Is the current 510(k) process adequate to support FDA's mission to protect and promote public health?



Are you concerned about the impact of 510(k) reform on the following?



*Nearly two-thirds of respondents believe the FDA's 510(k) approval process is adequate. Most are concerned about the impact on R&D cost and innovation in general*

# 510(k) Reform Could Hurt Innovation

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**The intent of 510(k) reform is to help ensure patient safety**

- Some believe that the process is a “rubber stamp” and can lead to company abuse

**Industry advocates highlight that there have been few issues with the current system**

- Current system allows the FDA to ask for more information, if concerned

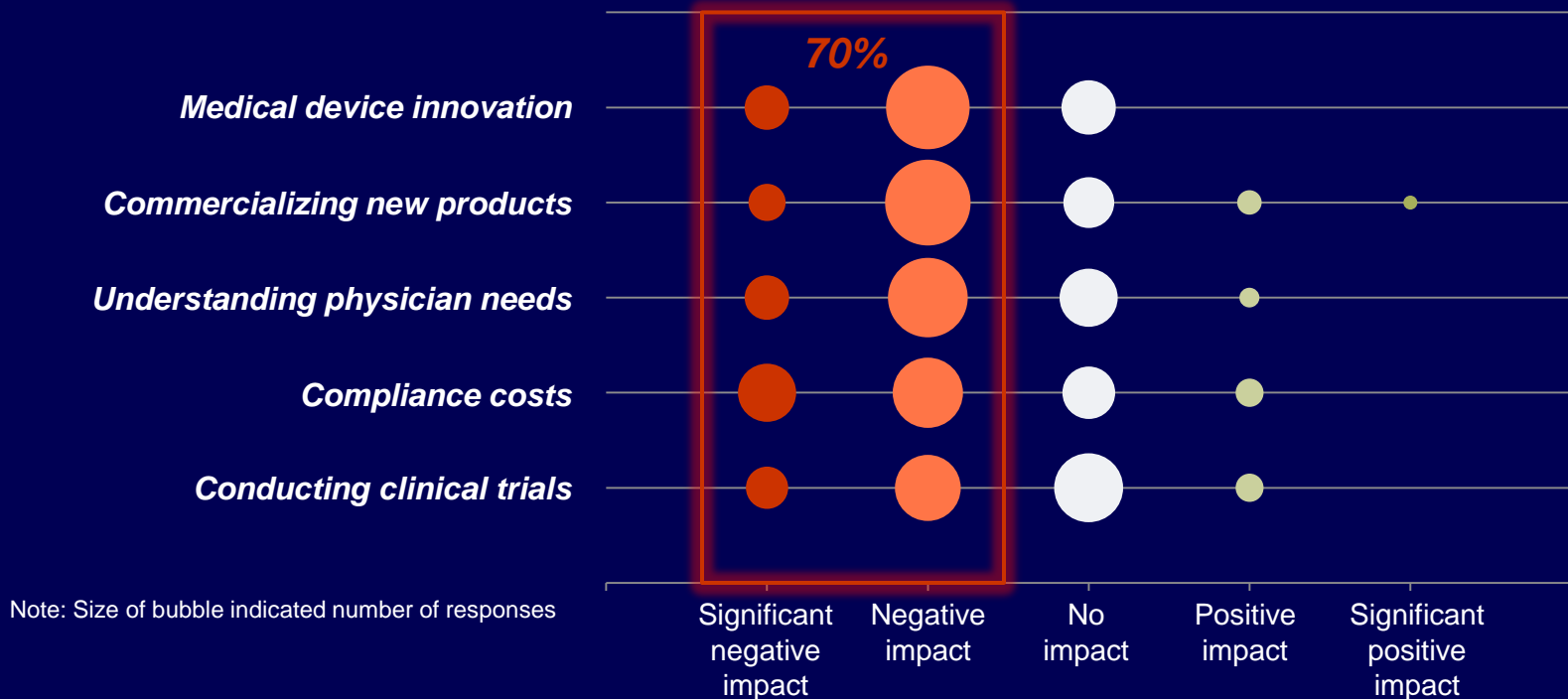
**Many believe that current 510(k) allows MedTech to quickly respond to patient needs and helps to drive innovation**

- Incremental innovations serve as basis for step-changes in innovation
- R&D / regulatory cost and time is commensurate with product type and risk

**Given that 90%+ devices go to market with 510(k) approval the potential impact is large**

# Physician Payment Sunshine Provision/Gift Ban

How would you characterize the potential impact of the Sunshine Provision and Massachusetts “Gift Ban” on the ability of medical device companies in the following areas?



*More than 70% of respondents believe these provisions will have a negative impact on innovation-related areas.*



# MedTech Companies Rely on Physician Support

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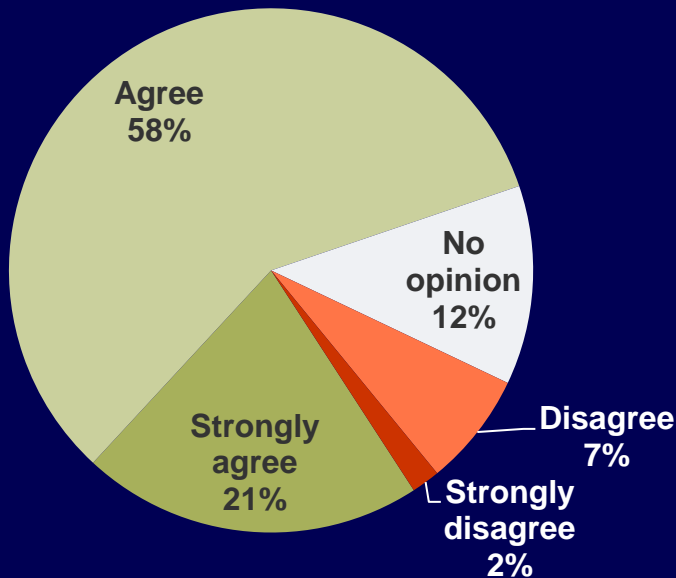
## Companies that regularly collaborate with physicians in their innovation process are most affected

- Disclosure of physician payments and associated transparency could hinder collaboration
- Orthopedics, cardiovascular, imaging, and many others regularly work closely with physicians and do not feel they can innovate without this dimension
- Critical to understanding patient and physician needs and creates incentives to improve standard of care

**Companies will need to adjust their operating mechanisms to protect themselves against potential situations and regulatory scrutiny and to comply with reporting requirements**

# Risk Management Scrutiny

Are your company's risk management practices adequate in light of FDA's increased scrutiny?



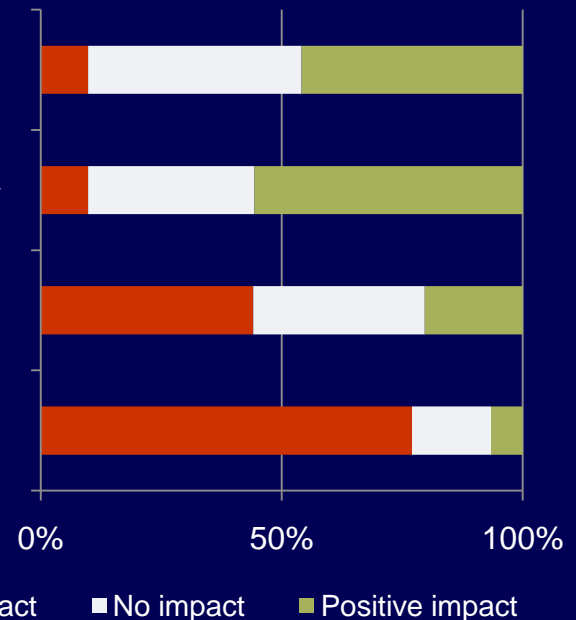
How would you describe the impact of increased scrutiny around risk management processes on the following:

Competitive advantage derived from safer and higher quality products

Product safety

Medical device innovation

Development cost/timelines



*Increased risk management scrutiny will drive product safety/quality, but may inhibit MedTech innovation and increase development costs/timelines.*

# Improved Device Safety with Increased Cost

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**Enhanced risk assessment and management practices will contribute to better definition of customer needs and context**

- Doing this work productively will be critical to controlling development costs and getting innovations to market in a timely manner

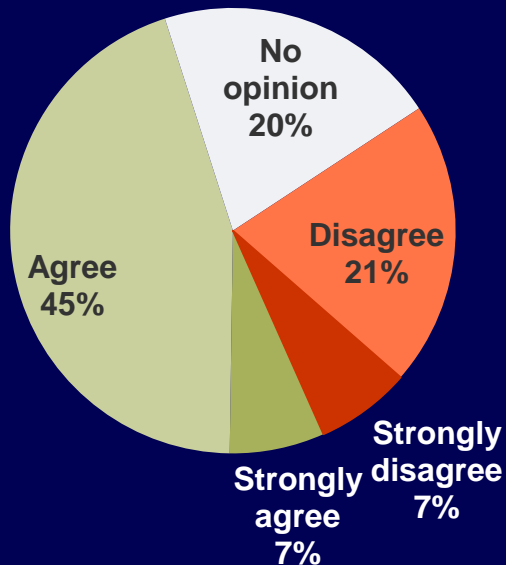
**Increased FDA scrutiny creates added compliance risk for MedTech companies**

**Many companies are currently refining their risk management practices to ensure product safety, quality and compliance**

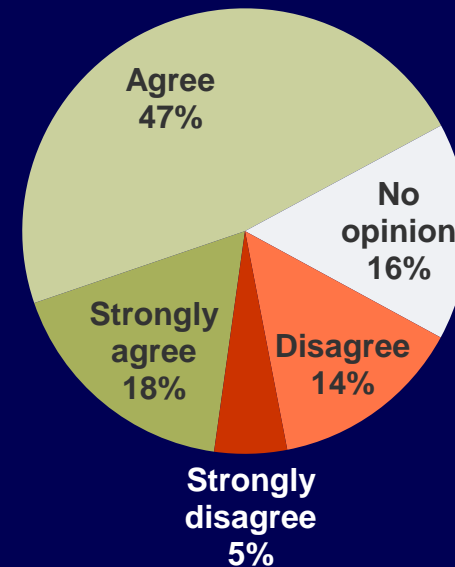
- Risk analysis, risk mitigation, risk monitoring
- Application of risk management process throughout product lifecycle

# National Medical Device Registry

Do you agree with the proposed creation of a National Medical Device Registry (NMDR)?



Do you agree that the data in the registry will be useful to your company from an R&D/innovation standpoint?



*Most respondents agree with the creation of the NMDR and expect it to provide useful data to support R&D/innovation.*

# Device Registry Implications

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**The Department of HHS will work with the FDA, CMS, Office of HIT, and Office of Veterans Affairs to define regulations for the establishment and operation of the Device registry by March 2013**

- The regulation will include devices sold after March 2010 and may include select devices sold prior to March 2010

**Device manufacturers will be required to submit information to the registry including the type, model, serial number, unique device identifier, and other TBD information for Class II and III devices**

- FDA is leading an initiative to design and implement a Unique Device Identifier system

**Device companies need to take an active role in the shaping of the Registry and its associated regulations**

**Device companies need to define strategies to make meaningful use of the new public information becoming available**



# Study Findings and Perspectives

MACROECONOMIC TRENDS

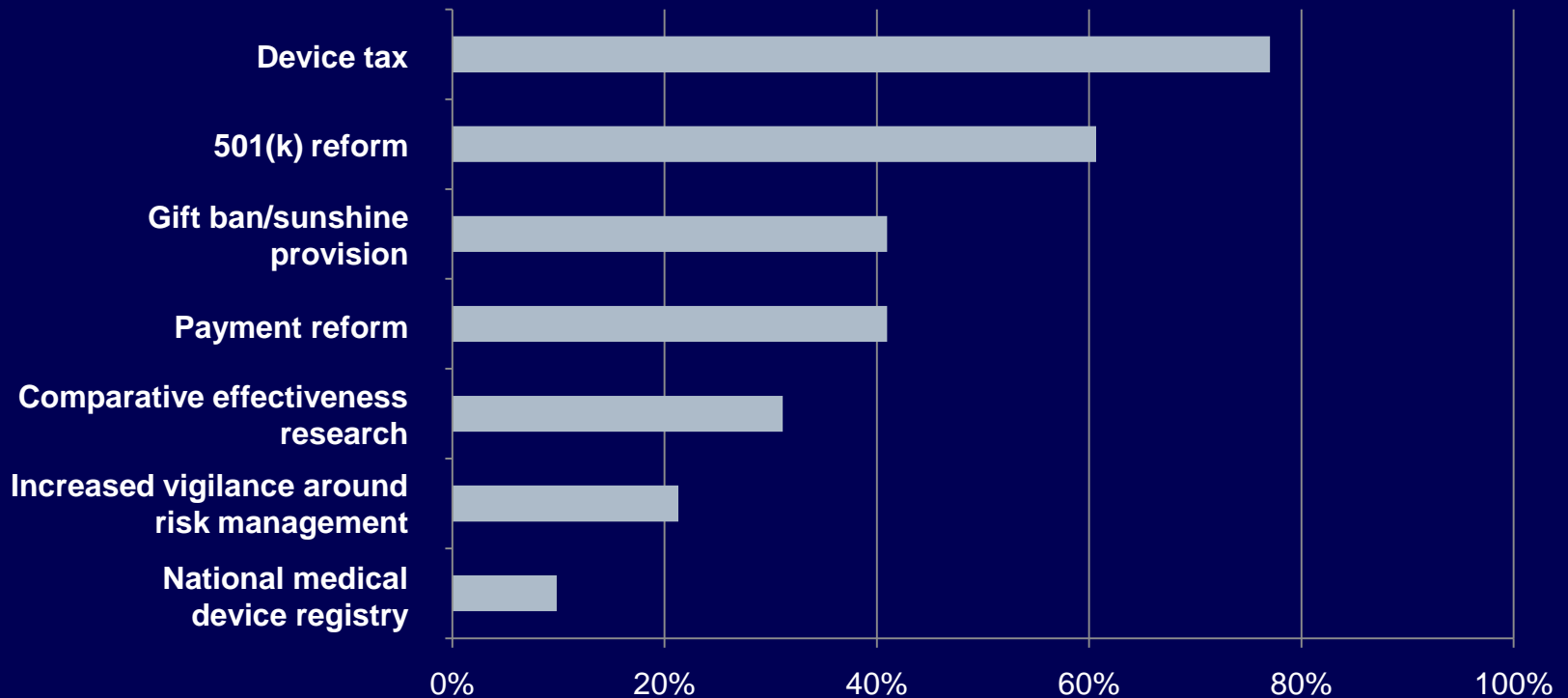
PUBLIC POLICY INITIATIVES

REGULATORY INITIATIVES

**OVERALL IMPACT**

# Priorities For MedTech Companies

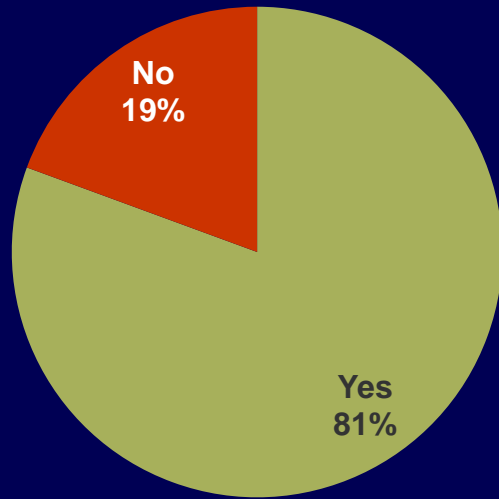
Which of the following policy and regulatory changes do you believe will have the greatest negative impact on innovation (select top three)?



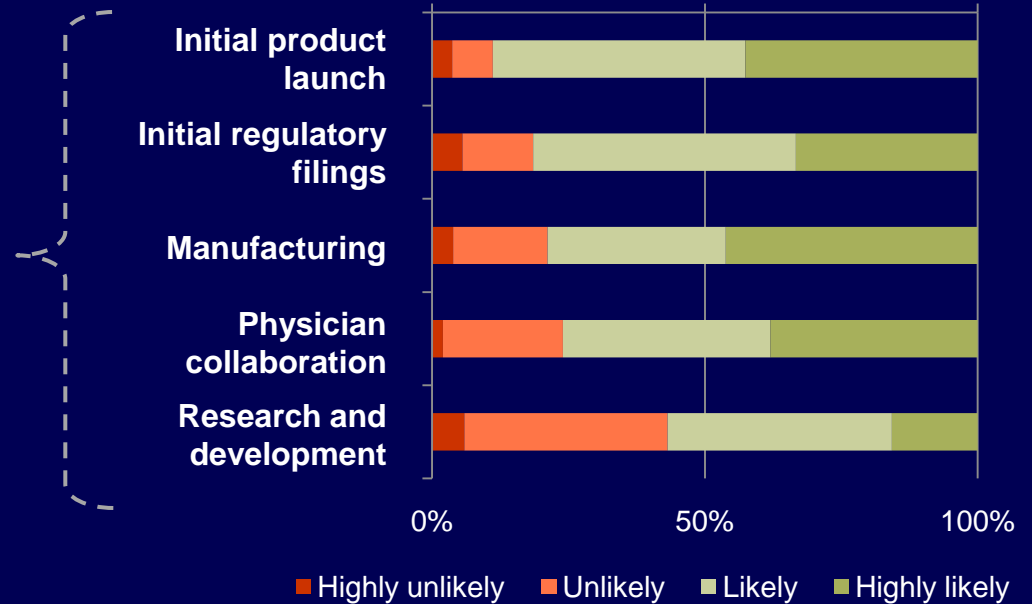
*Respondents fear that the device tax and 510(k) reform will have the greatest negative impact on MedTech innovation.*

# U.S. Changes Lead to Global Attractiveness?

Do the uncertainties resulting from economic, public policy, and regulatory changes in the U.S. make it more attractive to do business in other countries?



If so, which of the following activities are likely to move to other countries?



*The U.S. environment is making it more attractive to do business abroad—primarily new product filings and launches and manufacturing.*





# MedTech Company Response



*Management  
Consultants*

Where Innovation Operates

# Taking Advantage of Market Change...

## *Industry Dynamics*

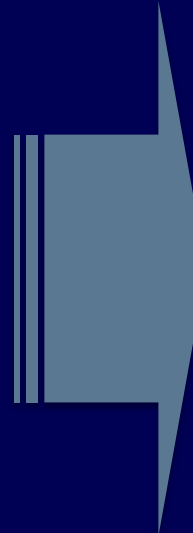
U.S. Health Care Reform

Global Recession and Credit Constraints

Increasing Regulatory Scrutiny and New Policy

Emerging Technologies

Emerging Market Opportunities and Global Competition



## *Change in Strategy*

New Solutions and Business Models

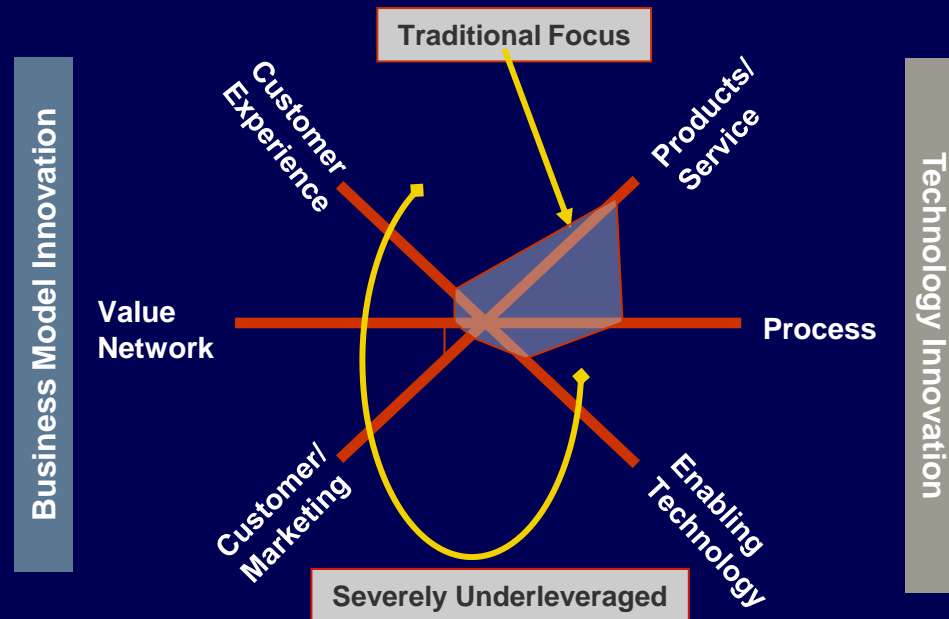
Global Target Market Emphasis and Strategies

Company Value-Chain Focus

*How will your company take advantage of this change and reposition itself for success?*

# Offering New and More Complete Solutions

New business model and product strategies to address new provider and reimbursement organization needs



Source: *Making Innovation Work*, Davila, Epstein, Shelton: Wharton School Publishing, 2006

**Consider emerging care models (i.e., home care, remote Dx, etc.)**  
**Lead in improvement of overall cost effective patient care lifecycle**  
**Change the basis of competition for your industry!**

# Globalization in Driving New Revenue Growth

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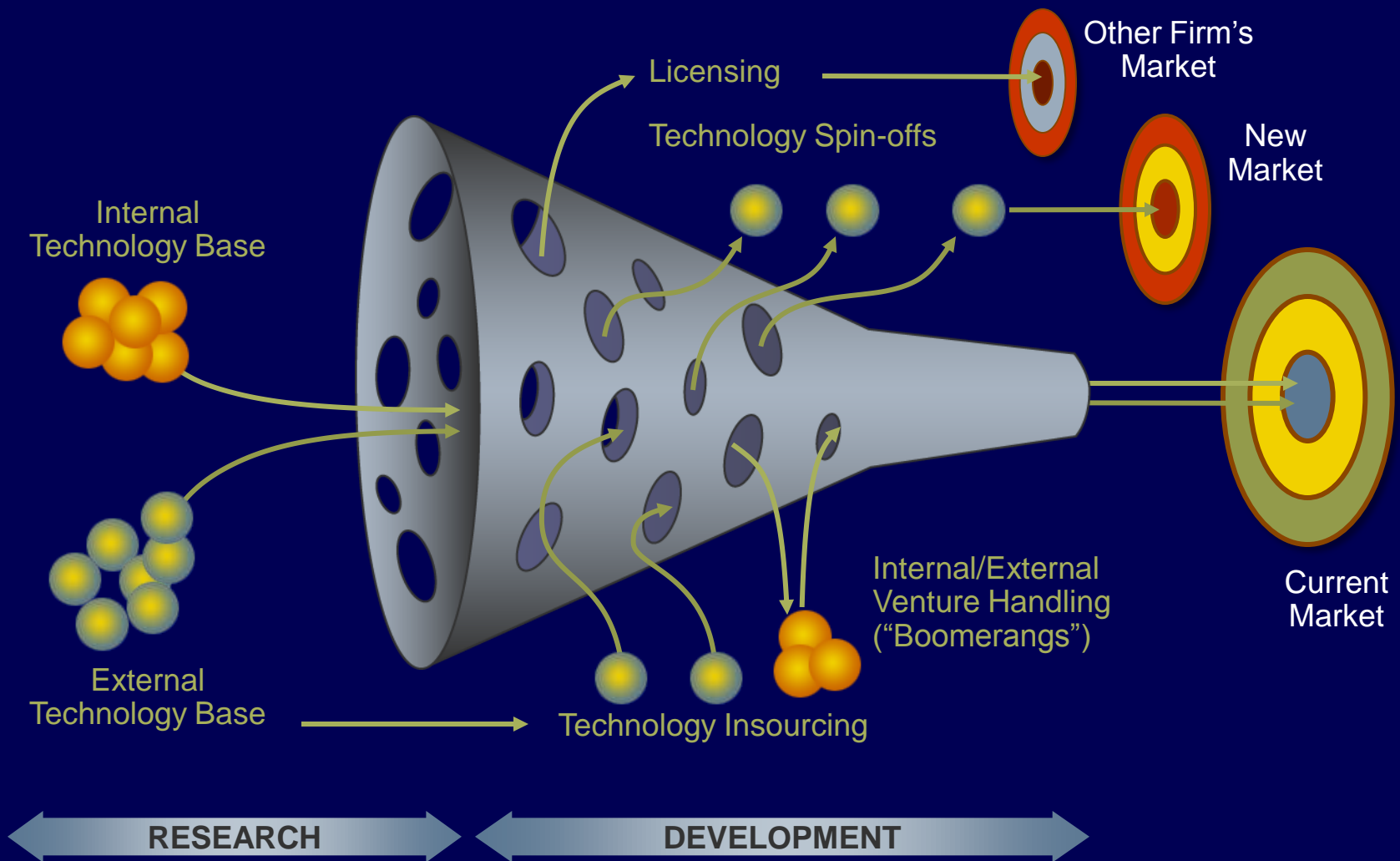
Increased emphasis on establishing global presence and driving growth in established and emerging markets

U.S. policies may increase urgency in establishing new global growth



Each market requires its own strategy aligned with the local healthcare system structure and competitive environment—“one size does not fit all”

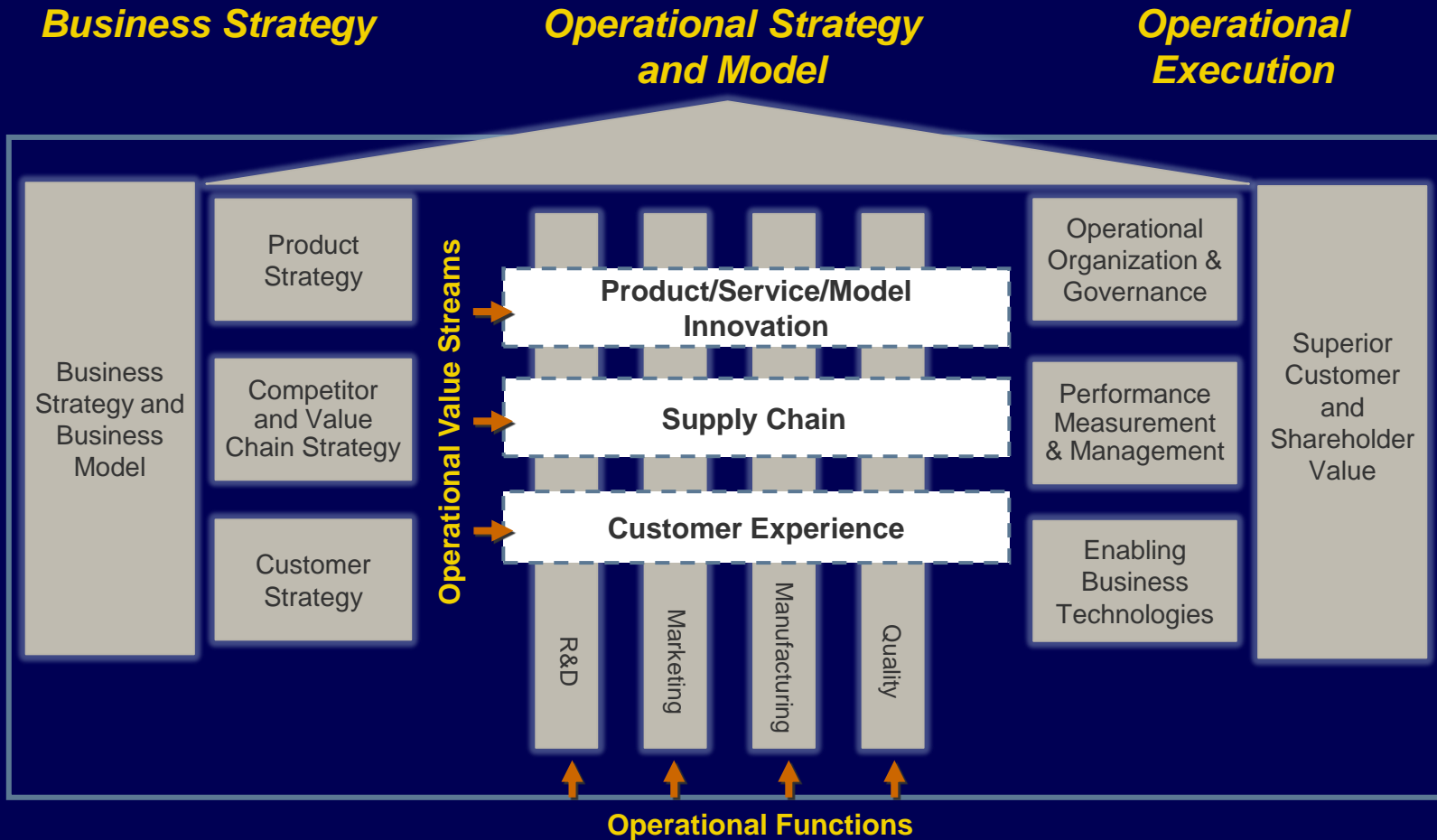
# Open Innovation to Support New Strategies



Source: Prof. Henry Chesbrough, UC Berkeley.

# To Execute Companies Need to Change Operations

All operational value chains may need to be realigned to meet new offering, market, and cost structure requirements



# Key Operational Changes to Consider

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## New innovation model

- Enhance customer needs understanding capabilities to address changing market across all stakeholders
- Enhance business and product strategy capability to move beyond the traditional recipe for success
- Practices and skills in defining more cost-effective products and services
- Business development and collaboration structure, skills, and process to support open innovation acquisitions, licensing, and collaboration
- Establishment/adjustment of global innovation/R&D footprint to take advantage of global talent and address local market needs
- Clinical, regulatory, reimbursement organization skills and practices in comparative effectiveness, global health economics
- Enhance risk management throughout product lifecycle
- Adjust practices and capacity for physician payment disclosures and monitoring

# Key Operational Changes to Consider

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## Supply chain model

- Review establishing lower-cost-country operations particularly if supports global expansion in addition to improved cost structure
- Review, consolidate, restructure supply chain asset network to improve cost structure and utilization
- Consider outsourcing for non-core operations that can be competitively sourced to improve cost, flexibility, and market expansion objectives
- Supply chain network and strategy needs to align and support changes in Innovation model, sales model, and service models

## Customer experience model

- Enhance “customer” definition to more broadly include patients, providers, payers, regulatory bodies, and other value chain participants/partners
- Enhance focus on overall customer experience in Innovation
- Align sales and service organizations and processes to support new business models and customer experience expectations