



04 May 2010

# MedTech Innovation in an Era of Change

*THE IMPACT OF ECONOMIC, PUBLIC POLICY,  
AND COST-CONTAINMENT PRESSURES*

MassMEDIC/PRTM Survey



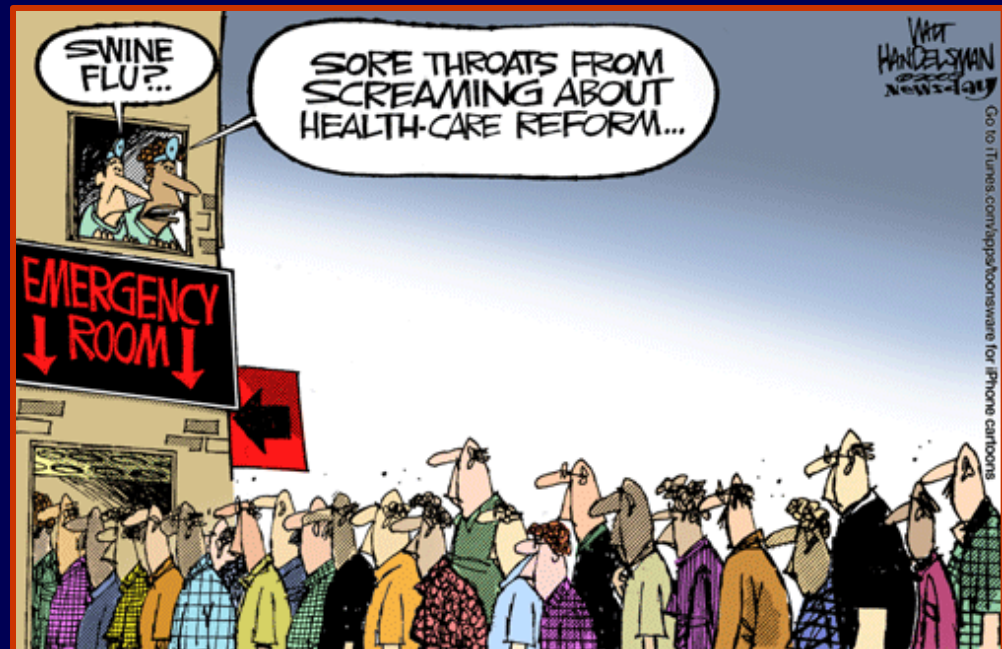
Management  
Consultants

Where Innovation Operates

# Introduction

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

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



# Survey Overview

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**Throughout March and April, MassMEDIC and PRTM conducted a survey to capture the thinking of MedTech industry leaders on major policy, regulatory, and macro-economic changes.**

- Emphasis on understanding the implications for MedTech innovation

**The online survey included 15 questions covering the following themes:**

- Economic Downturn
- Expanded Health Care Insurance Coverage and Payment Reform
- Device Industry Tax
- Comparative Effectiveness Research
- Physician Payment Sunshine Provision and Massachusetts Gift Ban
- Risk Management Scrutiny
- 510(k) Reform

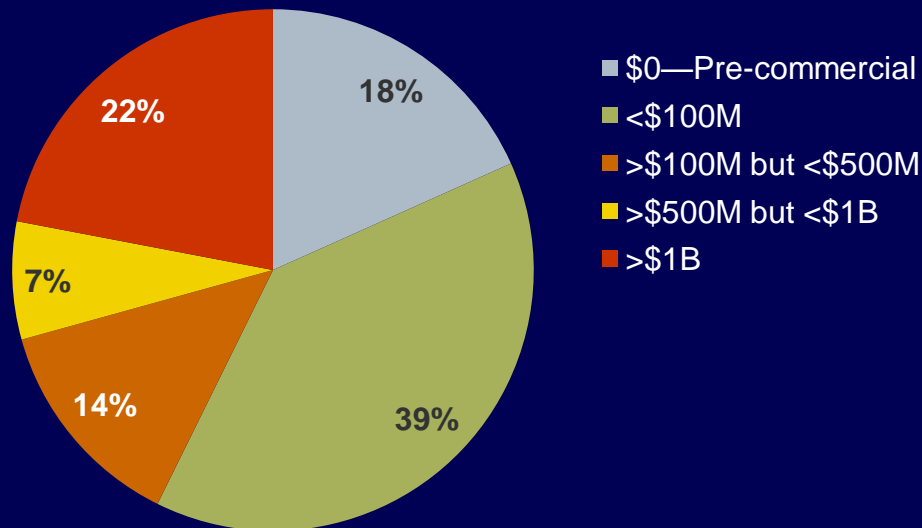
**Survey results are being presented for the first time today**

# Survey Participants

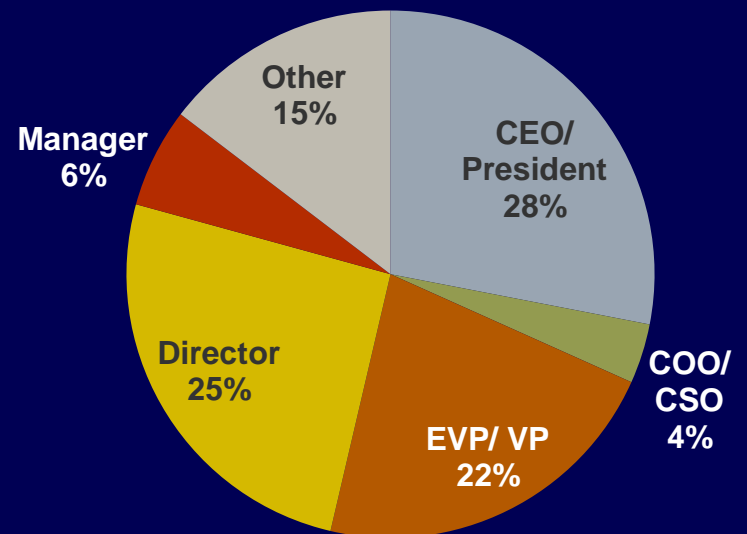
Nearly 100 MedTech industry leaders participated in the survey...

- Representing a broad range of US companies
- >50% of responses from senior management

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



**Respondent Positions**

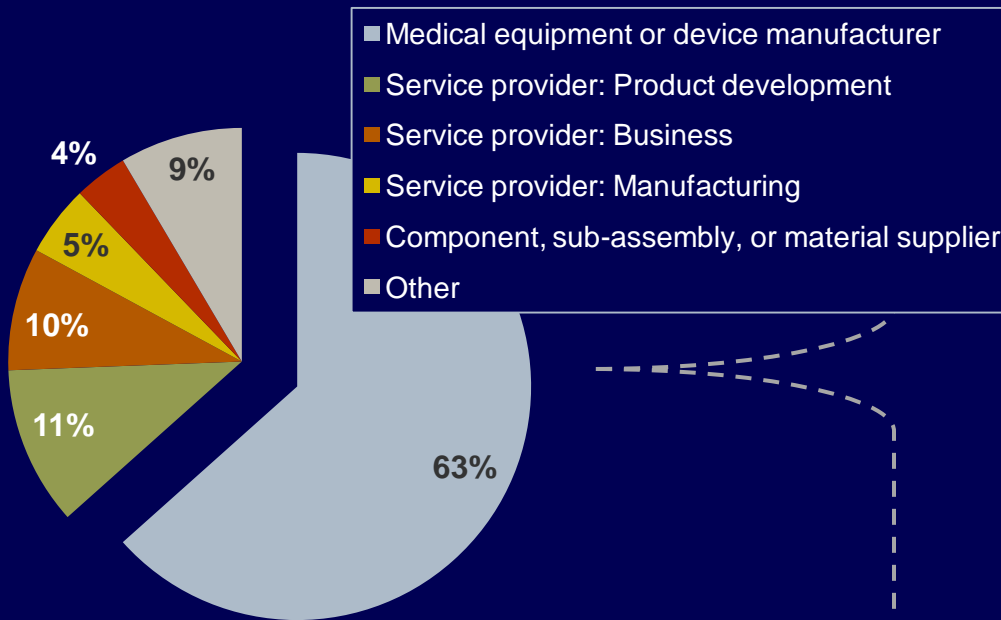


# Survey Participants

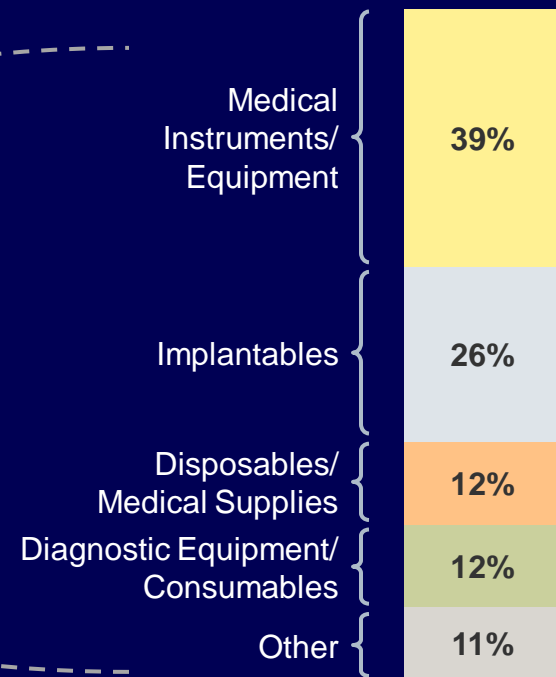
## Survey participants included:

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

### Primary Product or Service of Respondent



### MedTech Industry Segment





# Survey Findings

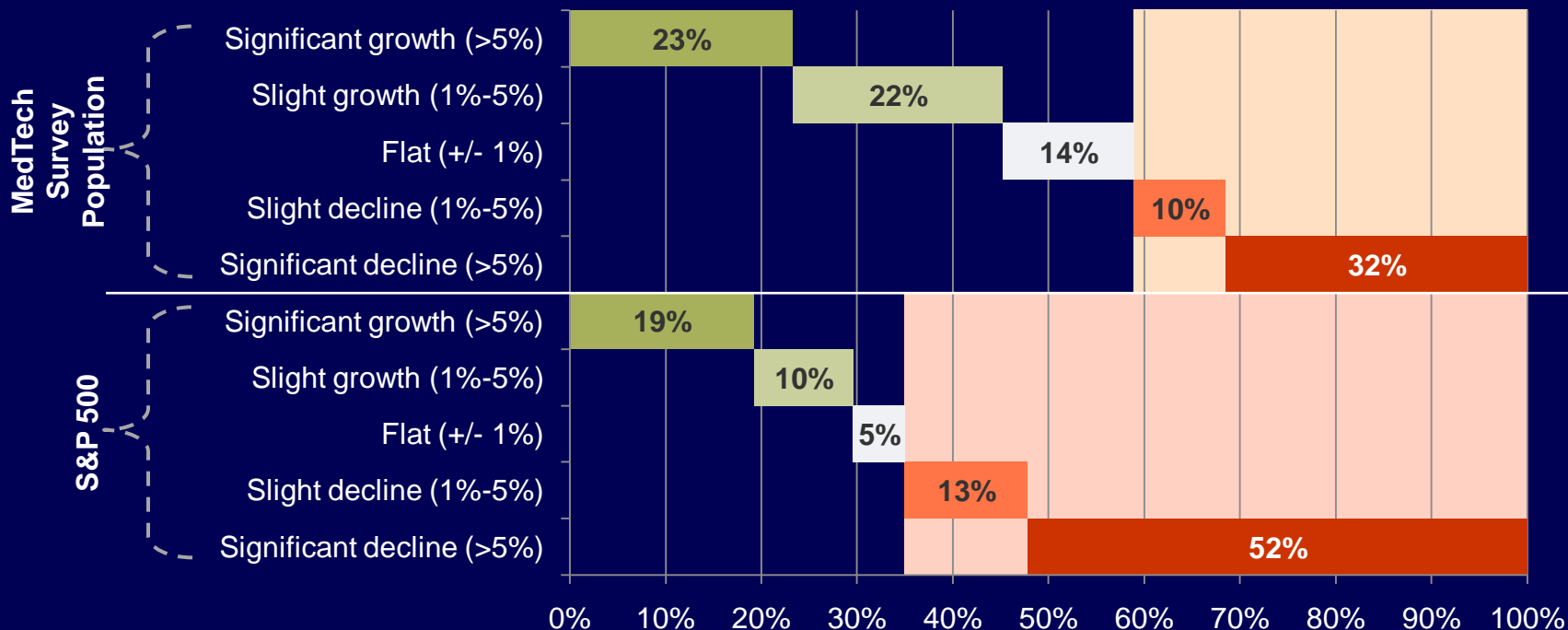
**MACROECONOMIC TRENDS**

PUBLIC POLICY AND REGULATORY  
INITIATIVES

GENERAL IMPACT

# Revenue Impact

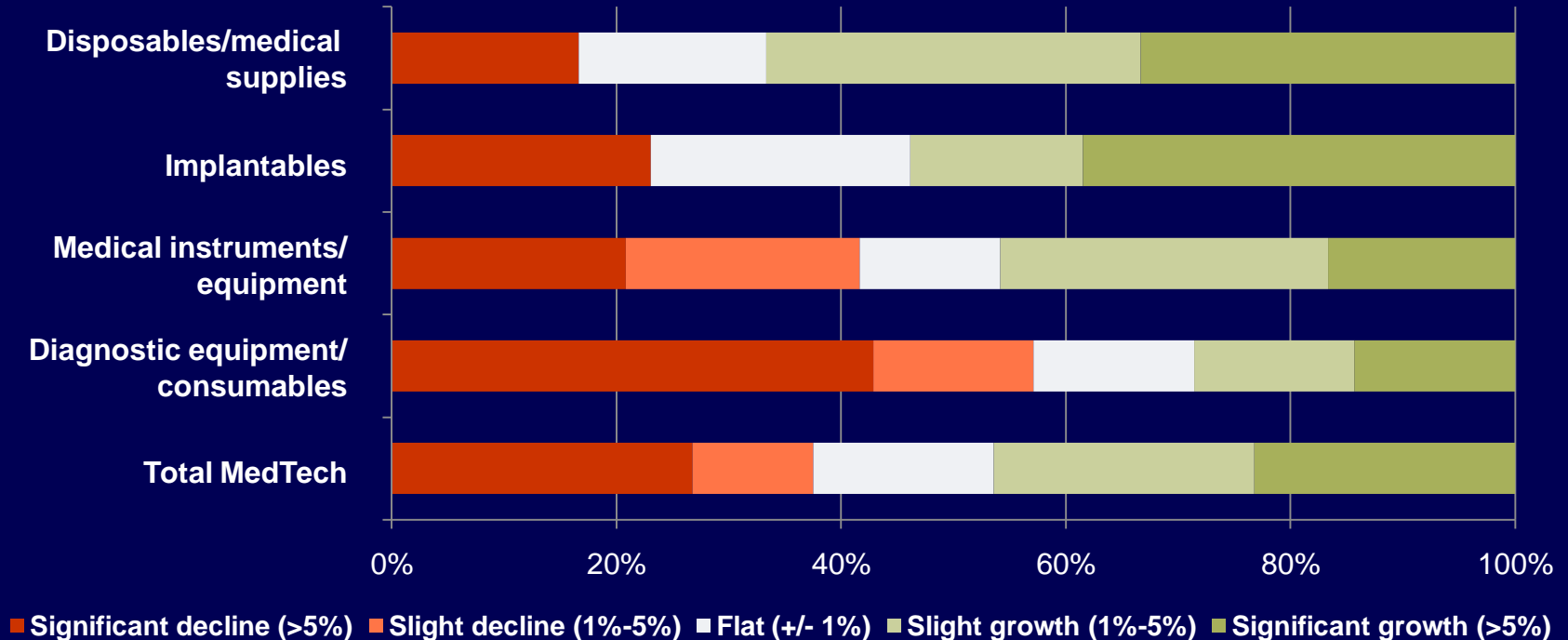
How has your business performed during the current economic downturn (e.g., 2009 revenue vs. 2008 revenue)?



*The economic downturn has had a mixed impact on the MedTech industry; in general, the MedTech industry has fared better than others.*

# Impact on Different MedTech Industry Segments

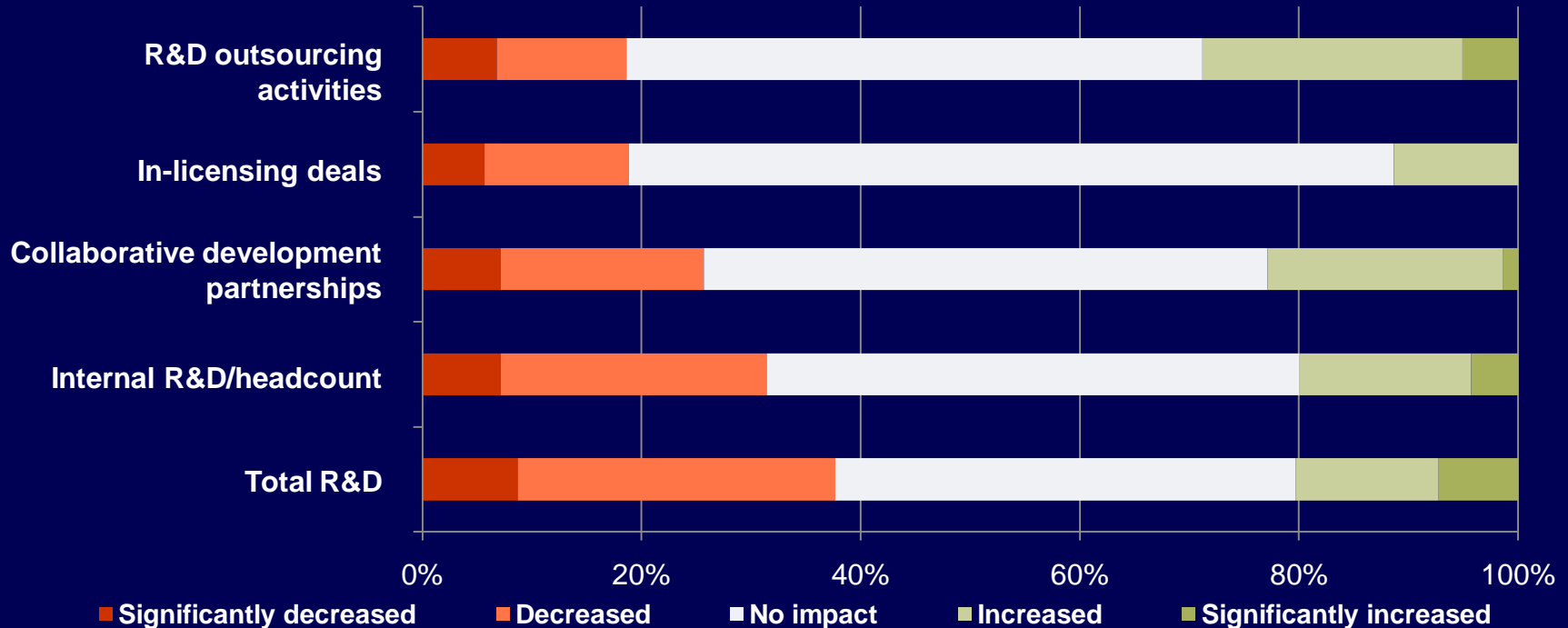
How has your business performed during the current economic downturn (e.g., 2009 revenue vs. 2008 revenue)?



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

# Impact on R&D Activities and Investment

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.*



# Survey Findings

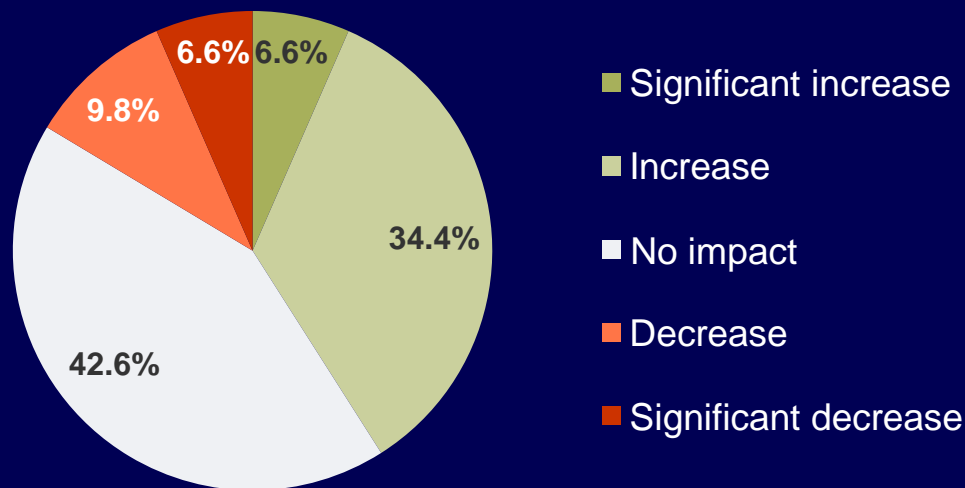
MACROECONOMIC TRENDS

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# Expanded Health Care Insurance Coverage

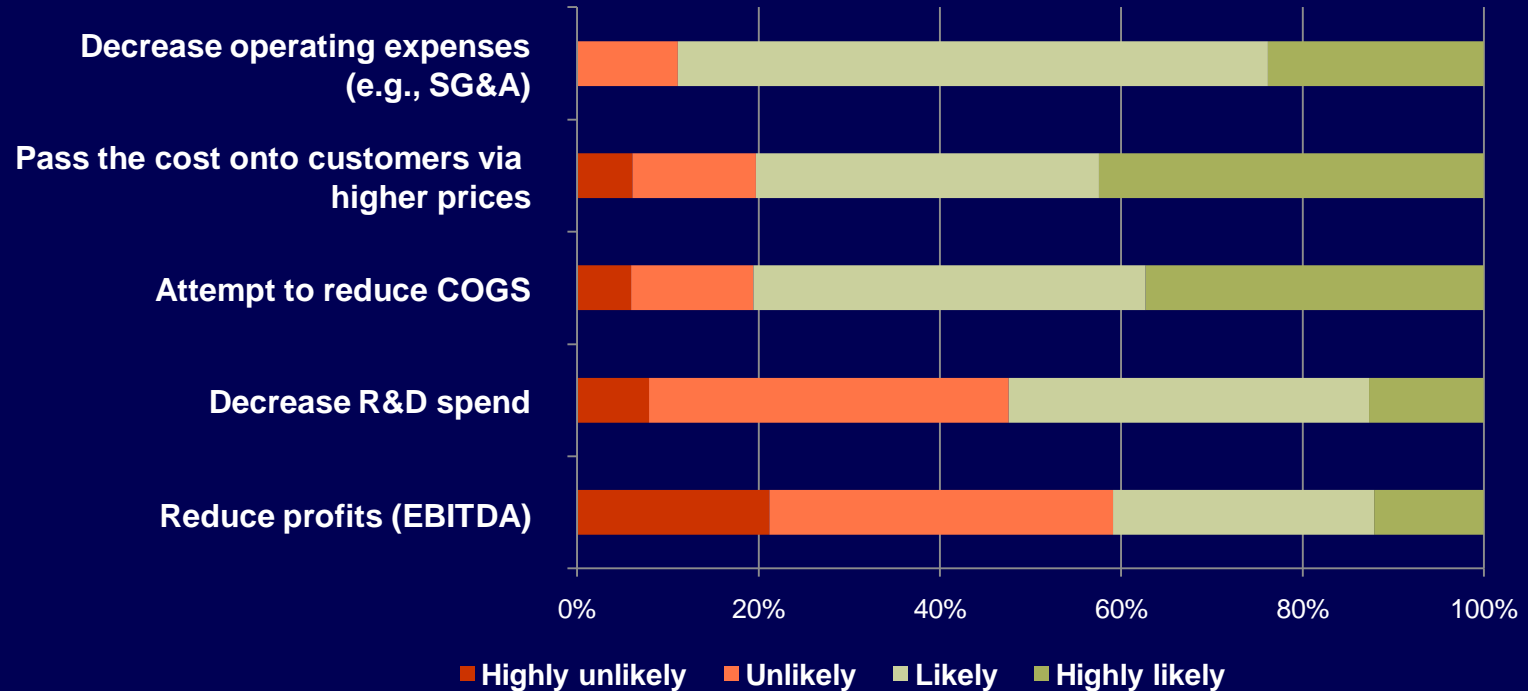
What do you think will be the impact of expanded health care insurance coverage on the market size for your company's products?



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

# Device Excise Tax

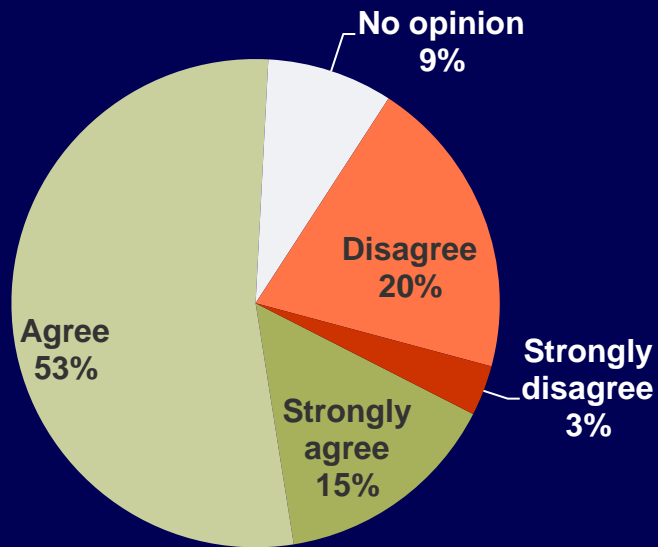
If a device tax is implemented, how would most medical device companies likely react?



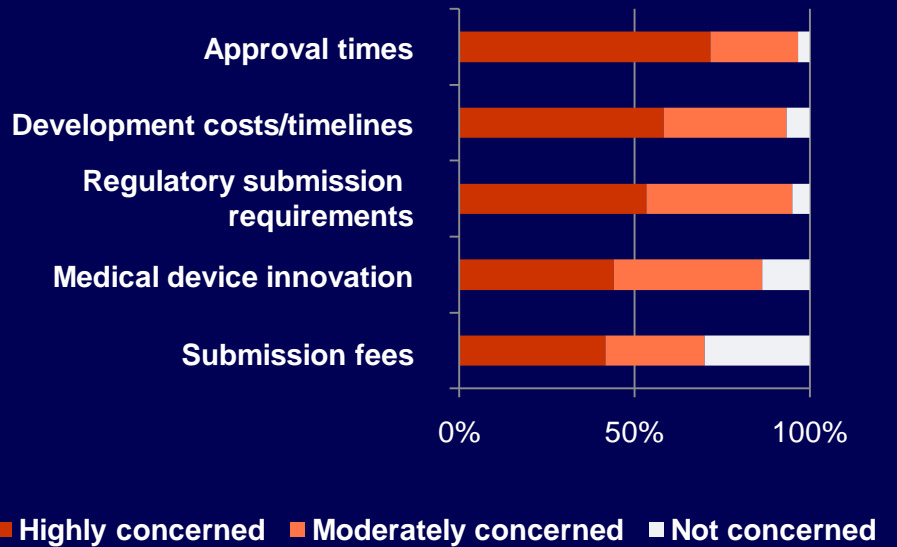
*Companies expect to absorb the device tax across all expense categories. More companies are likely to cut operating expenses or attempt to expand margins while protecting their R&D spend and profits.*

# 510(k) Reform

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



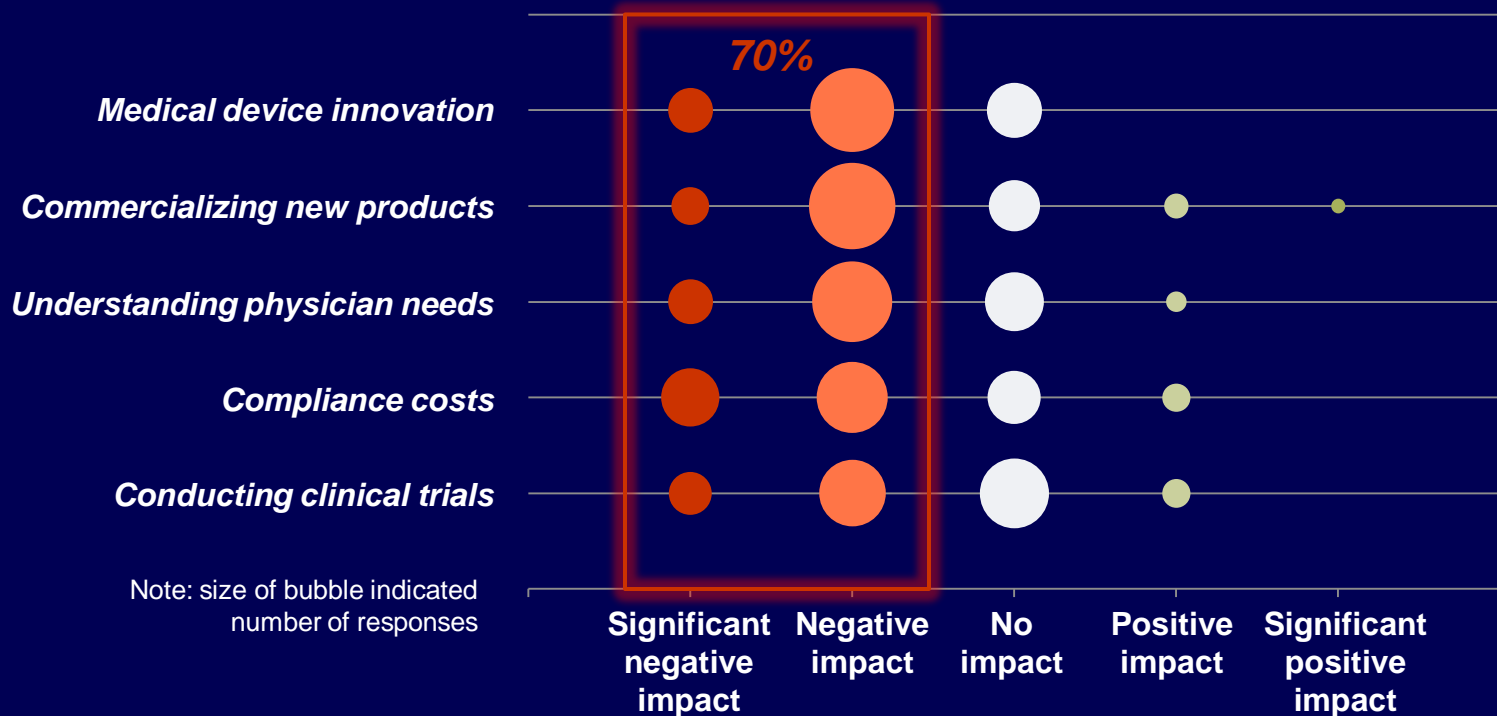
Are you concerned about the impact of 510(k) reform on the following?



*Nearly two-thirds of respondents believe the FDA's 510(k) approval process is adequate. Most are concerned about the impact of reform.*

# Physician Payment Sunshine Provision/Gift Ban

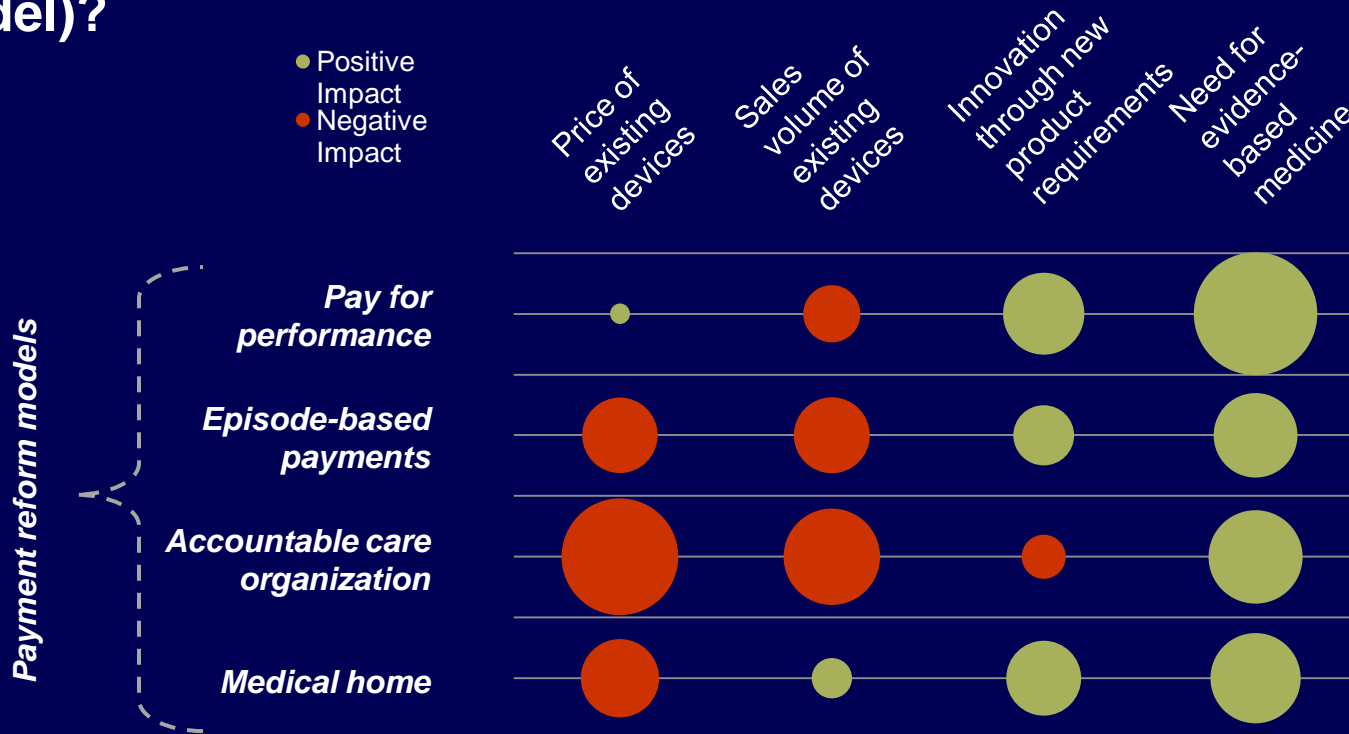
How would you characterize the potential impact of the Sunshine Provision and Massachusetts “Gift Ban” on the ability of Medical Device companies in the following areas?



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

# Payment Reform

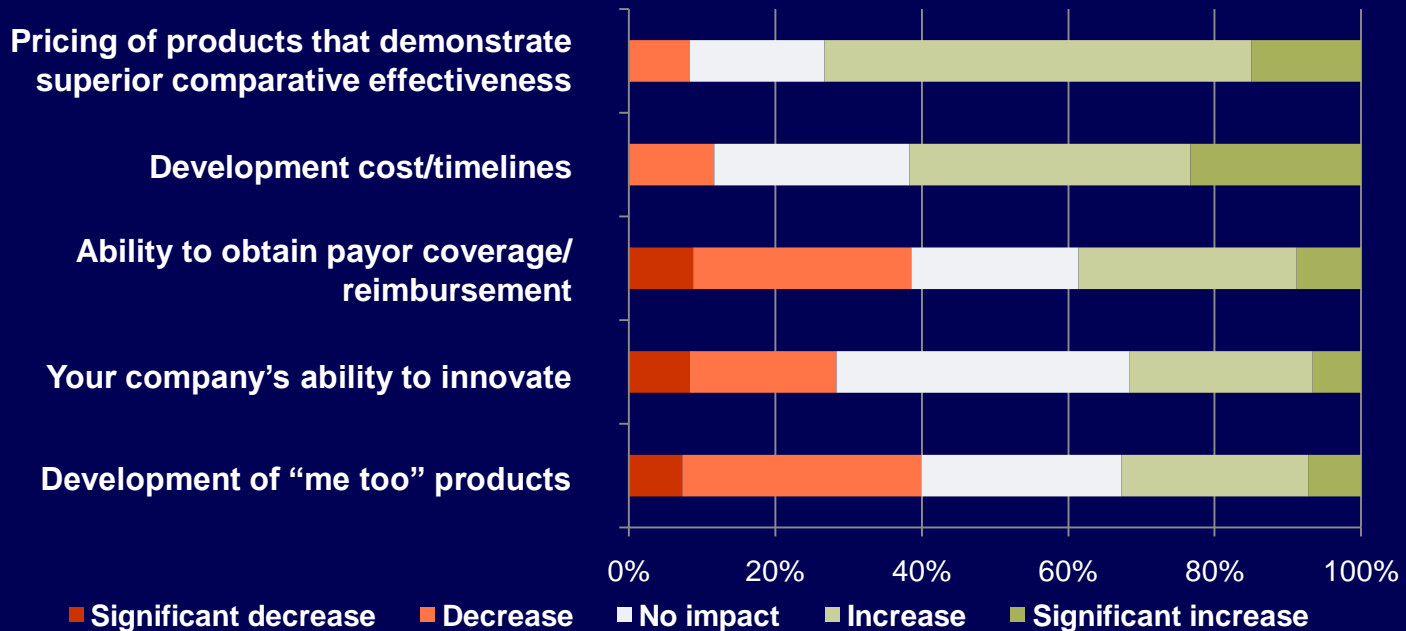
What would be the likely impact of different payment models on each of the following criteria (relative to the current fee-for-service model)?



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

# Comparative Effectiveness Research

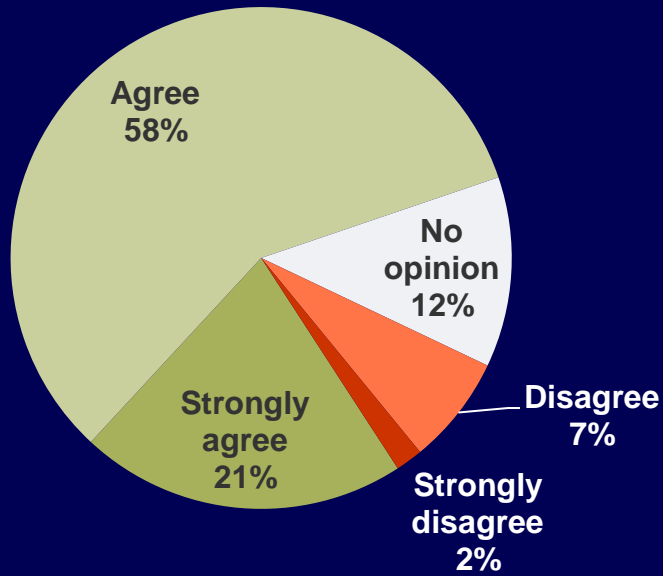
What would be the impact of proposed comparative clinical effectiveness research activities on the following?



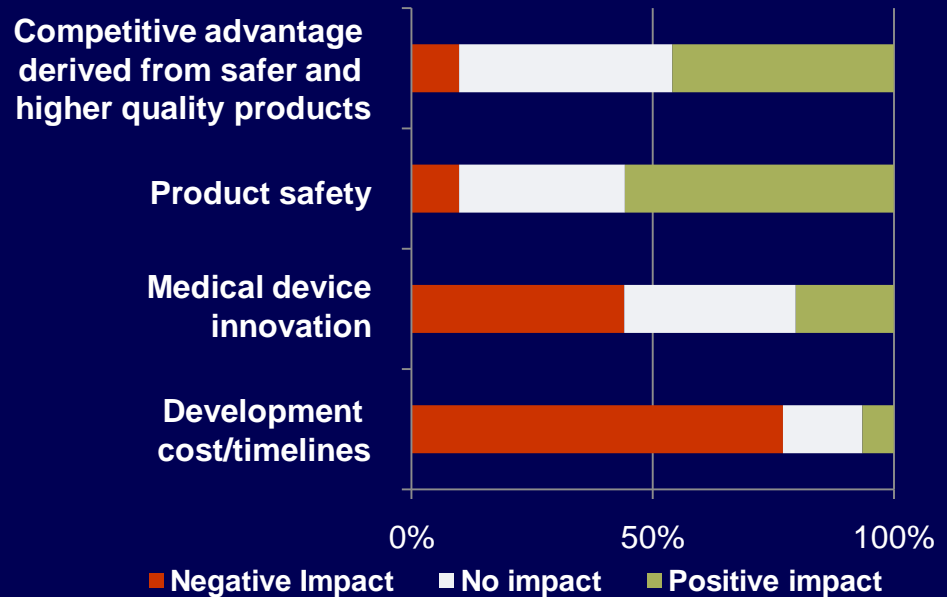
*Increased comparative research is expected to support price premiums, drive higher development costs/timelines, and curtail investment in "me too" products.*

# 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:



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



# Survey Findings

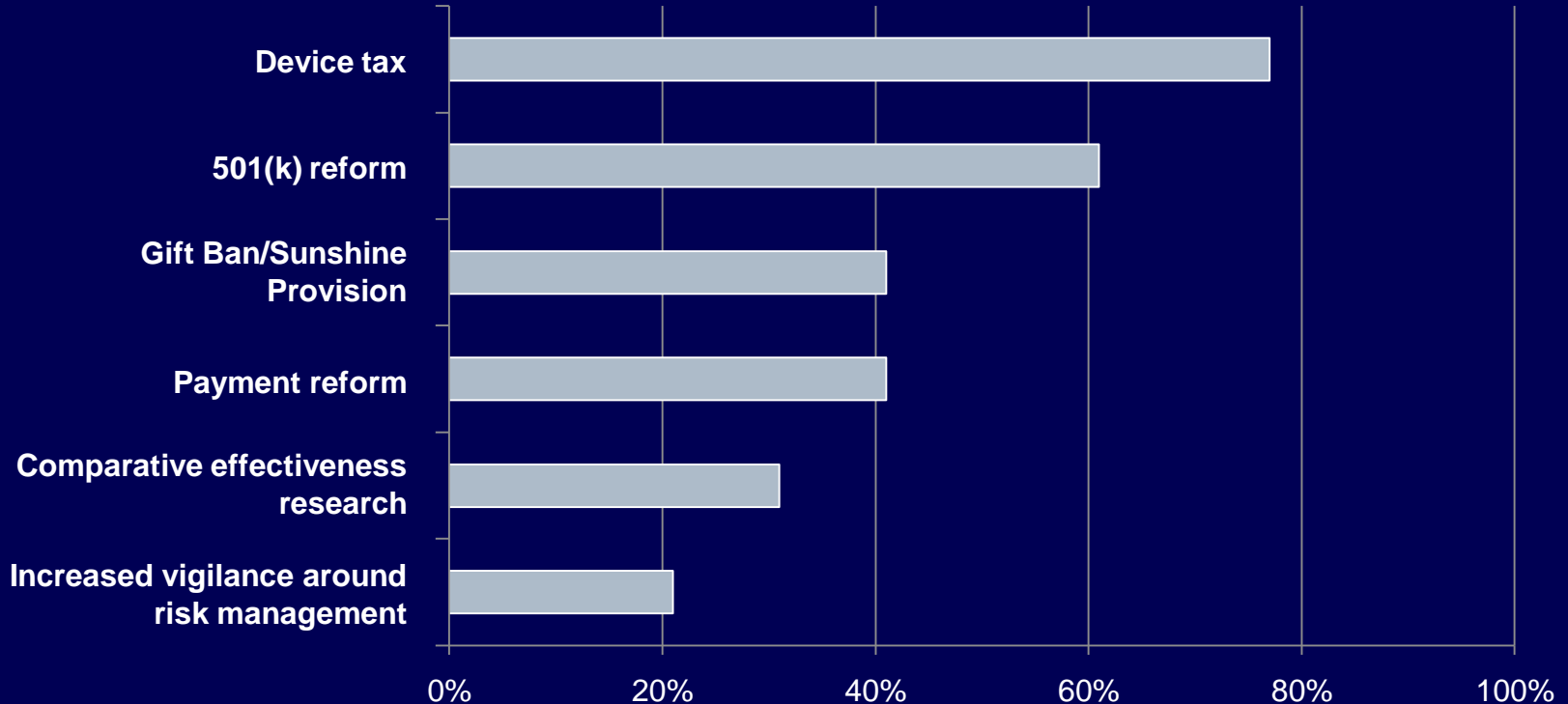
MACROECONOMIC TRENDS

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# Major Concerns

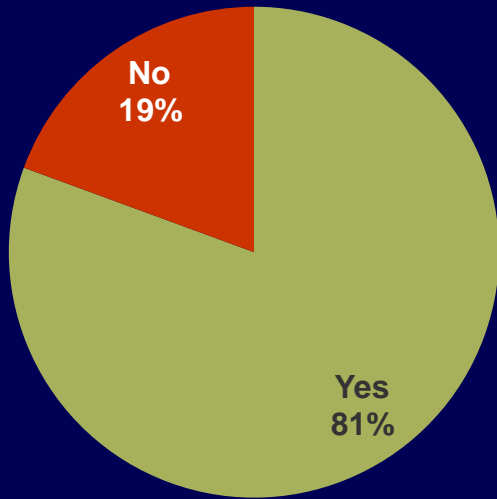
Which of the following policy and regulatory changes do you believe will have the greatest negative impact on innovation (select top three)?



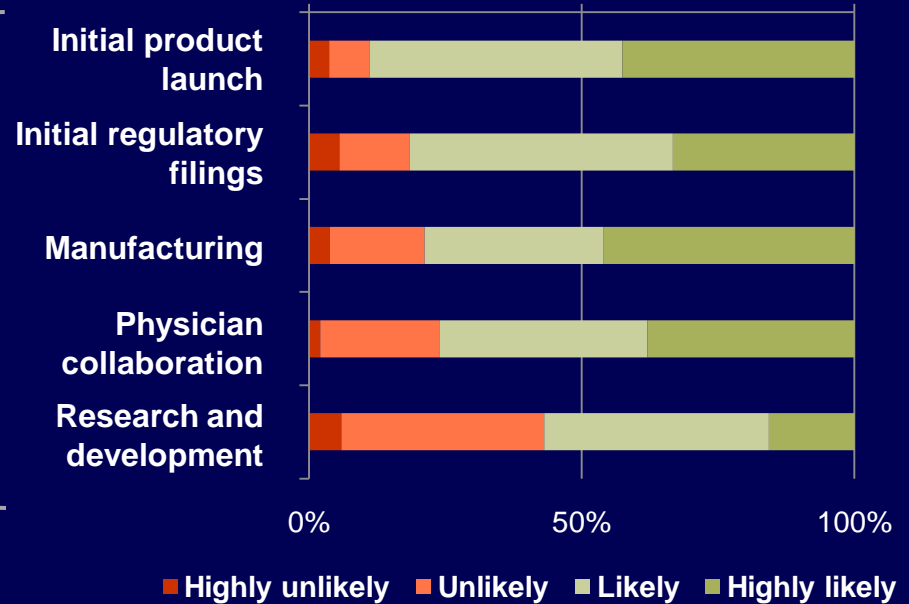
*Respondents fear that the device tax and 501(k) reform will have the greatest negative impact on MedTech innovation.*

# Is U.S. Challenging for MedTech Innovation?

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.*

# Key Takeaways

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**The economic downturn has had a mixed impact on the MedTech industry.**

**Many MedTech companies have cut back on R&D spending—some have managed to keep it flat.**

**There are mixed opinions on the impact of expanded health care coverage on MedTech market size.**

**The device tax will put even more pressure on MedTech companies to develop innovative operational strategies to cut operating expenses and expand margins in order to protect R&D spend.**

**The innovation landscape is changing—MedTech companies will need to:**

- Be creative and diligent about innovation to overcome the increasing regulatory hurdles (e.g., 510(k) reform, physician collaboration, risk management).
- Adjust their innovation strategies to take advantage of emerging opportunities (e.g., untapped market segments, new care delivery/payment models, comparative research).
- Rethink their commercialization strategies to tap into the growing potential of international markets.

# For Further Information

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**Sharad Rastogi**  
Director

**PRTM**

T +1 781.434.1273  
M +1 617.803.9373

77 Fourth Avenue  
Waltham, MA 02451  
USA

[srastogi@prtm.com](mailto:srastogi@prtm.com)

[www.prtm.com](http://www.prtm.com)