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MassMEDIC 19th Annual Meeting

**Vibrant and Growing –
An Updated Profile of the Medical
Device Industry in Massachusetts**

May 6, 2015

MassMEDIC
Massachusetts Medical Device Industry Council





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Massachusetts Medical Device Industry Overview



Massachusetts' Economic, Academic, and Technological Landscape Support Medical Device Innovation and Development



Massachusetts Among Top States in Federal R&D and Venture Capital Funding

- Ranked #2 in federal R&D funding received for universities and other nonprofits (CA – #1, TX – #3).
- Largest increase in federal R&D funding received of +\$800M (+26%) since 2006.
- Ranked #2 in federal grant programs received to enable small companies to conduct Phase 1 proof-of-concept research and Phase 2 prototype development.
- Ranked #2 in overall Venture Capital funding received, but #1 as percentage of GDP.
- Ranked #2 in number of angel investor groups (CA – #1, TX – #3).
- Massachusetts VC firms accounted for ~33% of all U.S. VC in 2013, tripling amount raised in 2012.



Highly Educated Work Force, Especially in STEM (Science, Technology, Engineering, and Math)

- 66% of working age adults have at least some college education; 45% have bachelor degrees.
- 25% increase in total STEM degrees including 56% increase in Biological and Biomedical Sciences degrees.

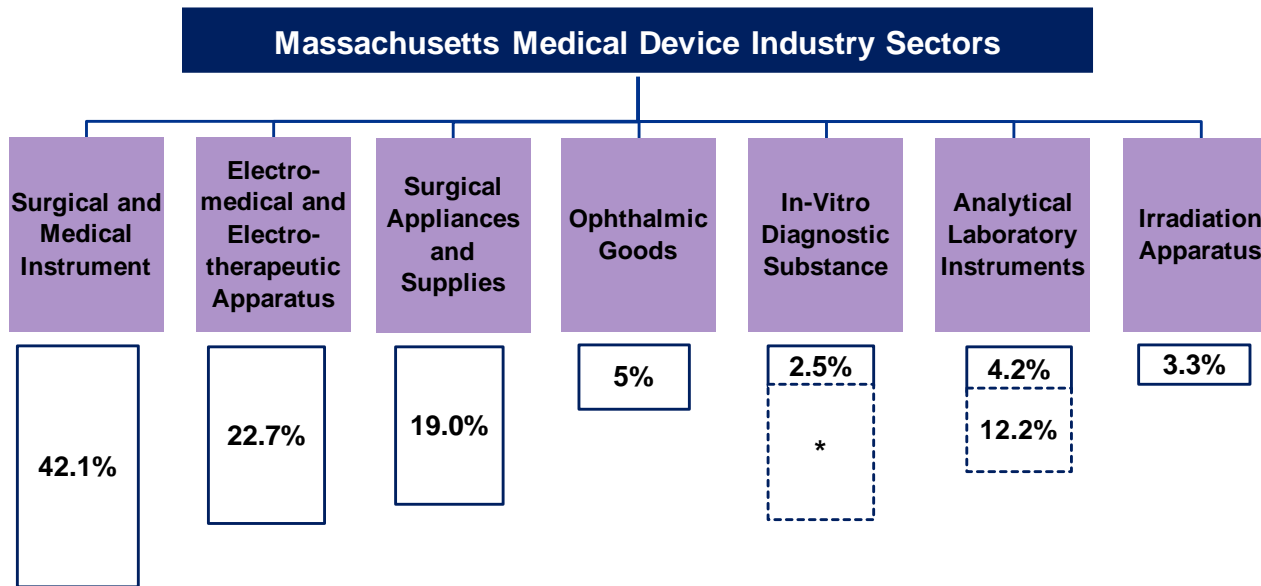


Leader in Technology IP Licenses and Patents

- Massachusetts ranked #1 in technology IP licenses held by hospitals, research institutions and universities, moving ahead of California over the last 10 years.
- Massachusetts ranked #1 in patents per capita, with Drugs & Medical making up 30%.
- Massachusetts ranked #2 in PMA approvals and 510(k) approvals.
- Massachusetts ranked #4 in drug approvals (NJ – #1; based on corporate headquarter locations).

Source: Massachusetts Technology Collaborative, The Massachusetts Innovation Economy Annual Index 2014

480 Massachusetts companies focus on Medical Devices (20% increase from 2011); with Surgical and Medical Instrument manufacturers leading the pack.



of Mass Med Device Companies by primary business
 Companies that may be relevant

**Diagnostic companies are categorized as pharma and provider*
Note: Dental Equipment and Supplies Manufacturing are excluded.

U.S. Industry Growth

- At an estimated \$125.4 billion in 2013, the U.S. Medical Device market is the world's largest.
- The market is projected to grow at a CAGR of 6.1% over the 2013-2018 period.

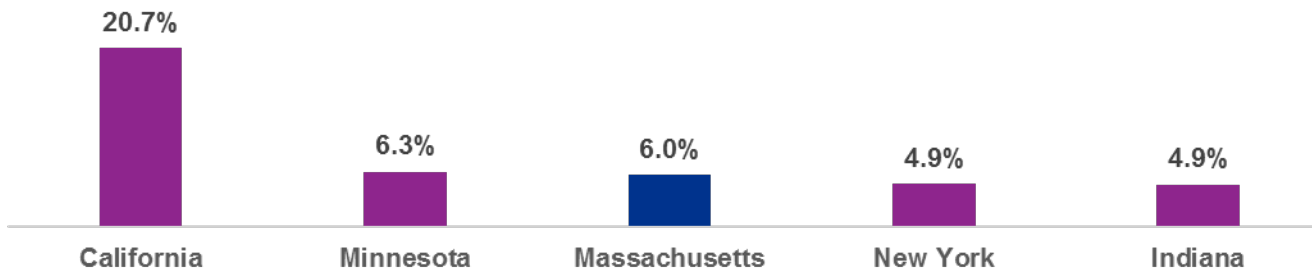
Massachusetts Industry Growth

- MassMEDIC 2015 survey results indicated that companies feel that product / technology innovations, increased share in existing markets, and geographic expansion to new markets are the key contributors to growth.

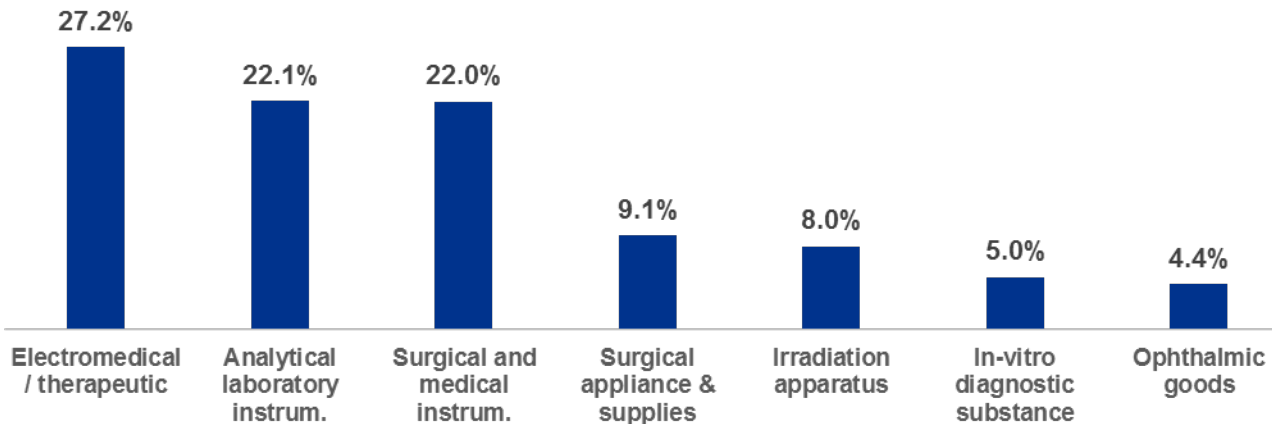
Source: Dun & Bradstreet Hoovers, March 2015
 'The Medical Device Market: USA' Espicom Report dated December 12, 2014

Massachusetts Medical Device employment has decreased in recent years, falling from #2 to #3 behind Minnesota.

U.S. Medical Device Employment – Top Five States as % of National



Massachusetts Employment by Sector



U.S. Industry Employment

- From 2008 – 2012, the overall national Medical Device industry employment decreased by 3%.
- Massachusetts’ employment has decreased by 5%, falling from #2 to #3 behind Minnesota.
- New York and Indiana replaced Pennsylvania and Florida in the top five states.

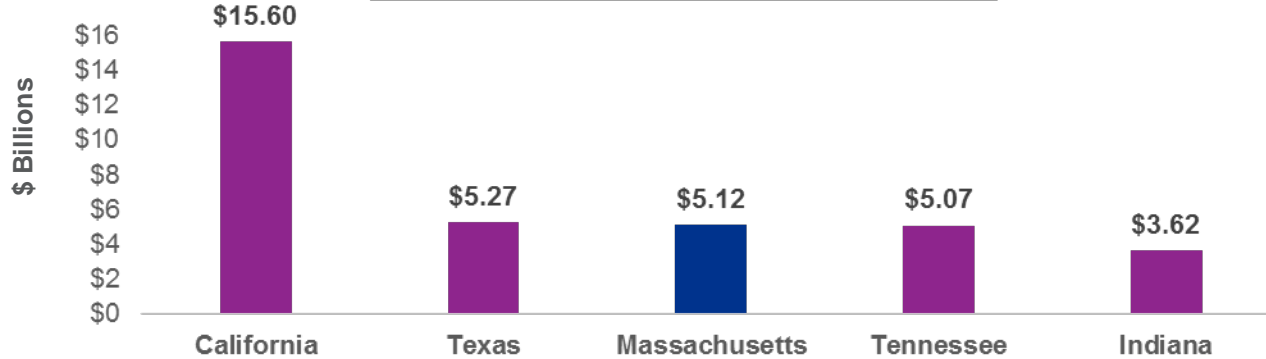
Massachusetts Industry Employment

- MassMEDIC 2015 Survey, 20% of respondents cited MDET as having impact to employment / headcount reduction.

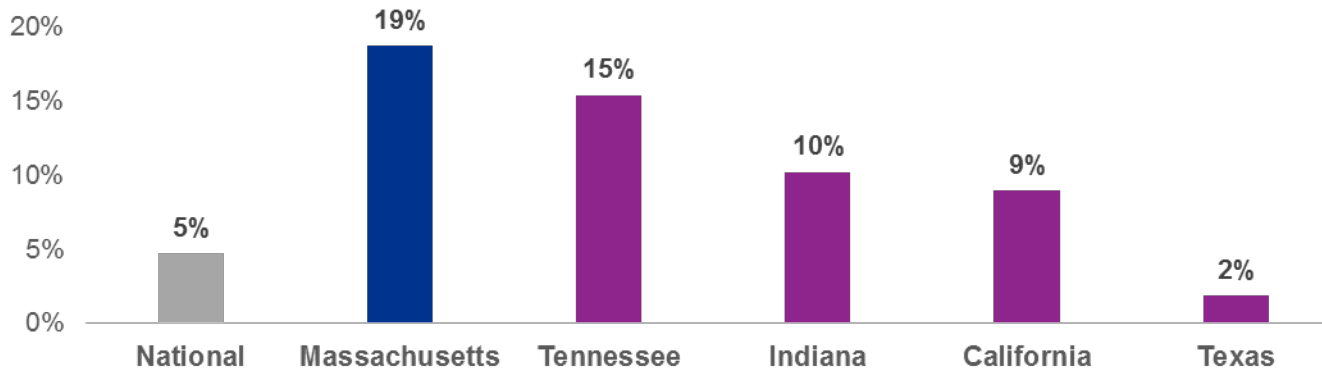
Source: U.S. Census Bureau, 2013 Annual Survey of Manufactures; 2012 County Business Patterns

Massachusetts exports more Medical Devices per dollar of total exports (19%) than any other top five Medical Device export state.

Medical Device Exports – Top Five States



Medical Device Exports % of Total State Exports – Top 5 States



U.S. Medical Device Exports

- From 2008–2014, U.S. Medical Device exports have grown at a CAGR of 4.5%.
- Medical Device exports reached \$44 billion in 2014 representing a 1.6% increase from the previous year.

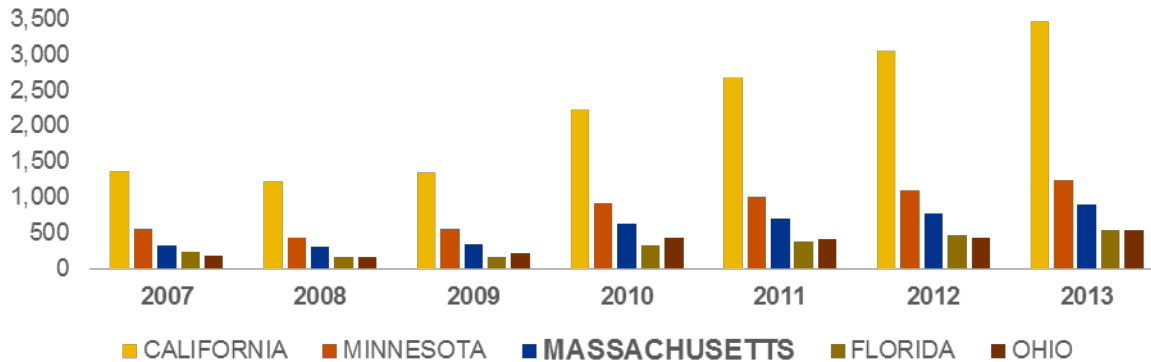
Massachusetts Medical Device Exports

- In 2014, Massachusetts ranked #3 in overall Medical Device exports, but #2 per capita.
- Massachusetts ranks #1 in Medical Device exports as a percentage of total exports across all industries.

Source: U.S. International Trade Statistics, U.S. Census Bureau
 “The Medical Device Market: USA” Espicom Report dated December 12, 2014

Massachusetts ranks #3 in overall number of Medical Device patents approved, and #2 in 510(k) and PMA approvals.

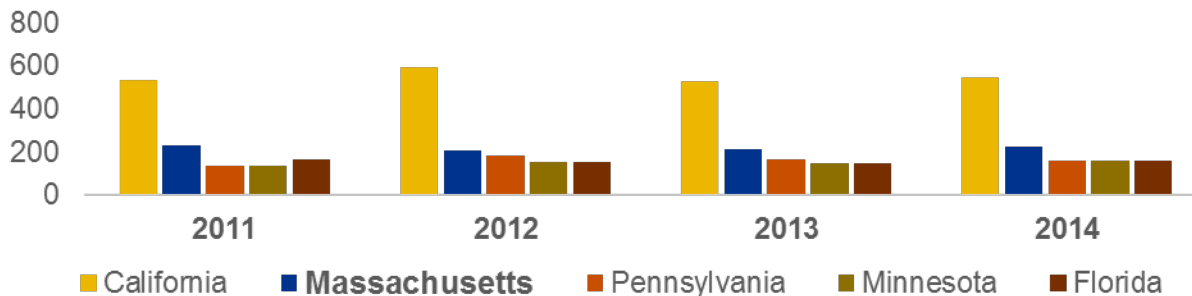
of Patent Approvals – Top 5 States



Patent Approvals

- U.S. Medical Device patents have increased every year since 2009 with a 5-year average annual growth rate of 21% (versus 9% across all industries).
- Massachusetts ranks #3 in overall patents approved, but #2 per capita.

of 510(k) Approvals – Top 5 States



510(k) and PMA Approvals

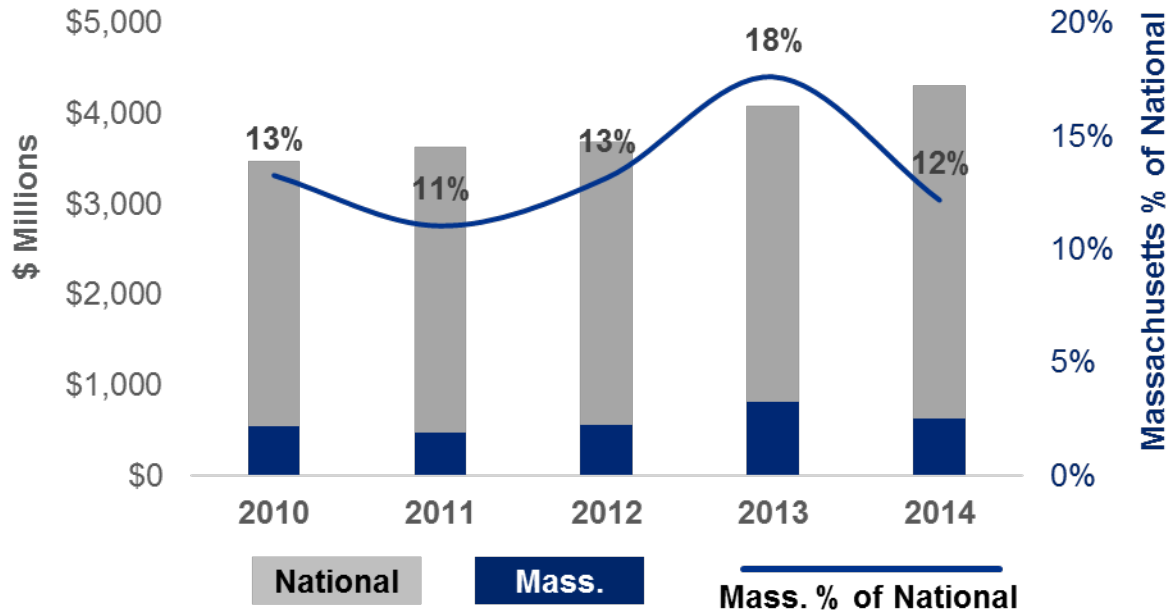
- Massachusetts ranks #2 in overall 510(k) approvals, but ranks #1 on a per capita basis.
- Massachusetts ranks #2 in PMA approvals with 19 PMAs from 2008 – 2012.
- California leads with 34 PMAs from 2008 – 2012.

Sources: Food and Drug Administration, March 2015; U.S. Patent & Trademark Office, PTMT, March 2015 'Stake Your Claim in the Medical Device Patent Gold Rush' MDDI Article dated May 16, 2014 Massachusetts Technology Collaborative, The Massachusetts Innovation Economy Annual Index 2014

Massachusetts ranks #2 in VC funding and number of VC deals.

Four deals accounted for 36% of 2013 total value

Massachusetts vs. National Medical Device VC Funding



U.S. VC Funding

- Massachusetts ranks #2 in overall VC Funding and number of VC Deals behind California, but #1 per capita.

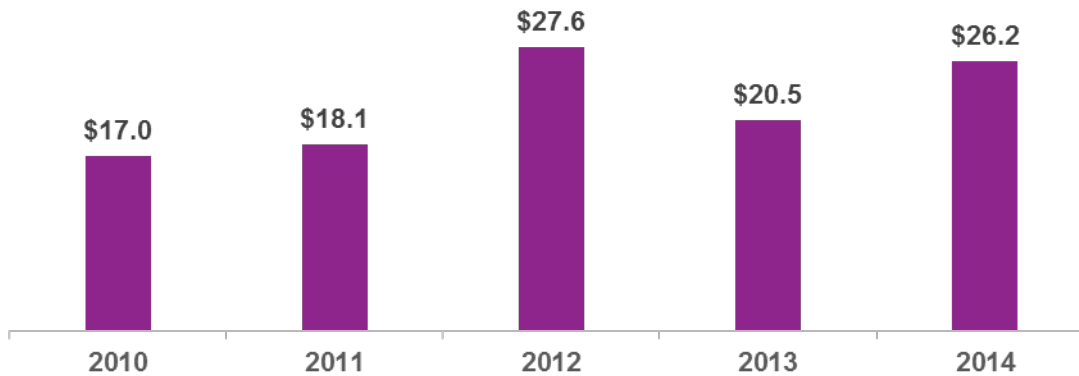
Massachusetts VC Funding

- Top 10 Massachusetts VC Deals in 2014:
 - Orthopedic Synergy
 - Fractyl / Mithril Capital Mgmt.
 - NinePoint Medical / Corning
 - Auris Surgical Robots
 - Cheetah Medical / Fletcher Spaght
 - Dimension Therapeutics
 - OMNIlife science
 - Daktari Diagnostics
 - Medrobotics
 - Quanttus / Khosla Ventures

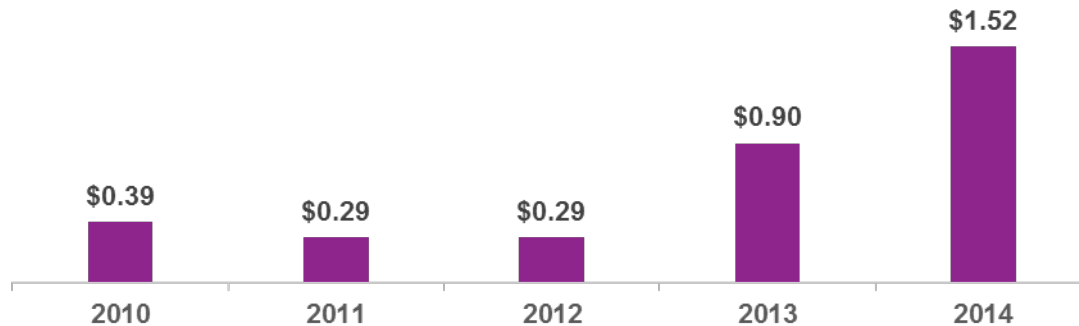
Source: Pitchbook, 2015 (<http://pitchbook.com/>)

Medtronic – Covidien and Thermo – Life among recent largest Medical Device mergers and acquisitions.

U.S. M&A Deal Values (\$ Billions)



U.S. IPO Amount Raised (\$ Billions)



U.S. Medical Device M&As and IPOs

- In 2014 there was a strong Medical Device M&A and IPO environment including megamergers as well as acquisitions of VC-backed companies.
- There were 16 acquisitions worth more than \$50M – 10 of them of venture-backed companies.

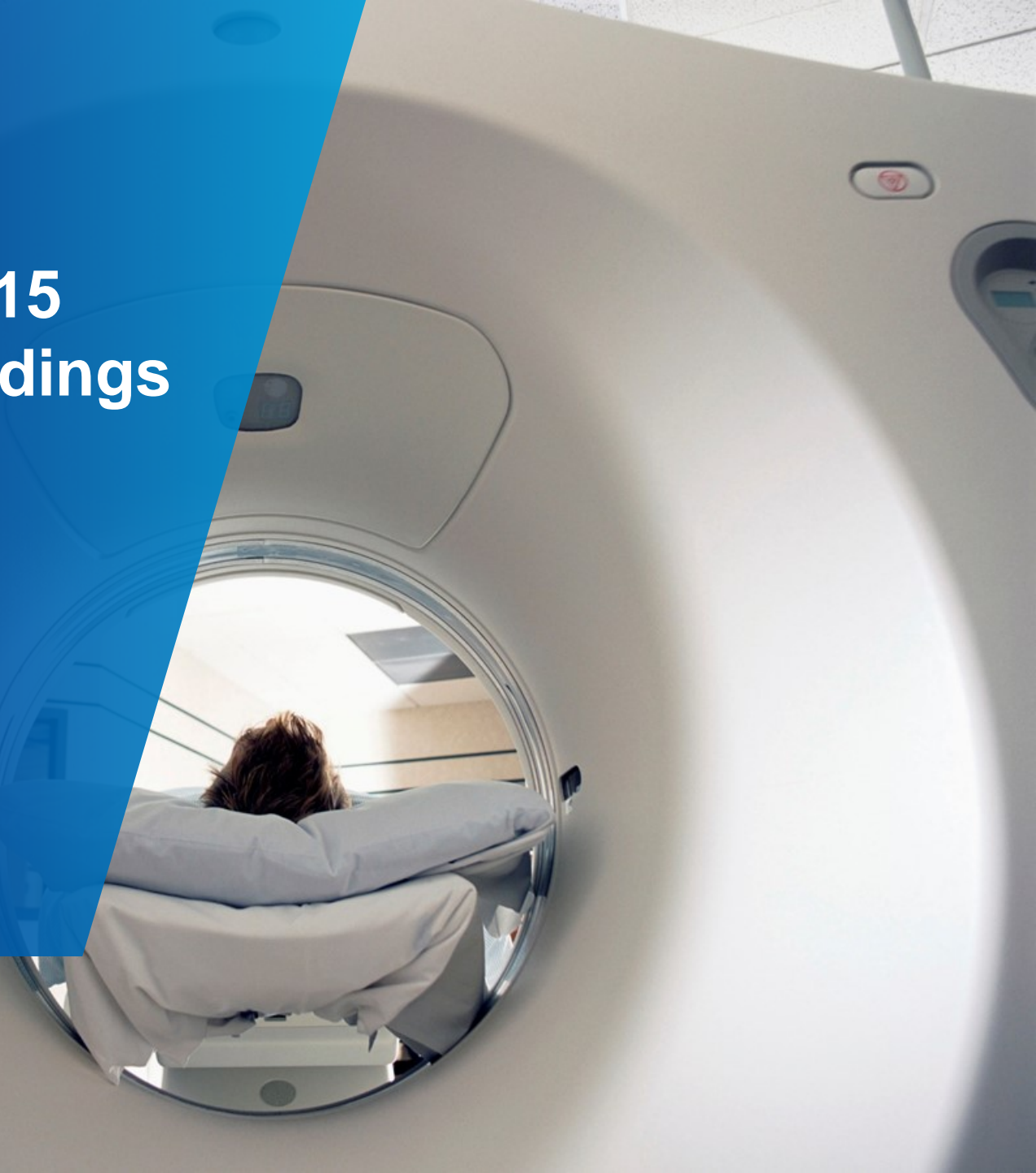
Massachusetts M&As and IPOs

- Massachusetts has had two of the largest recent U.S. M&A deals:
 - Medtronic and Covidien (U.S. HQ: Mansfield, MA) for \$42.9B in 2015
 - Thermo Fisher Scientific (Waltham, MA) and Life Technologies for \$13.6B in 2014
- Ocular Therapeutix (Bedford, MA) IPO raised \$75M, among U.S. largest in 2014.

Source: Pitchbook, 2015 (<http://pitchbook.com/>)

“Med tech exits pick up in 2014, momentum to continue into 2015” FierceMedicalDevices Article dated, January 6, 2015

MassMEDIC 2015 Survey Key Findings



Objective

Our intention in conducting this survey is to provide a snapshot of the Massachusetts Medical Device industry perspective on strategic focus areas and the financial and regulatory climate.

Methodology

The survey was conducted between March 4 and March 16, 2015. A total of 52 Medical Device industry professionals participated.

The survey was e-mailed to the Primary Member list maintained by MassMEDIC, which includes 165 companies that are primarily engaged (>50%) in manufacturing or components directly used in the production of Medical Devices.

Company Demographics

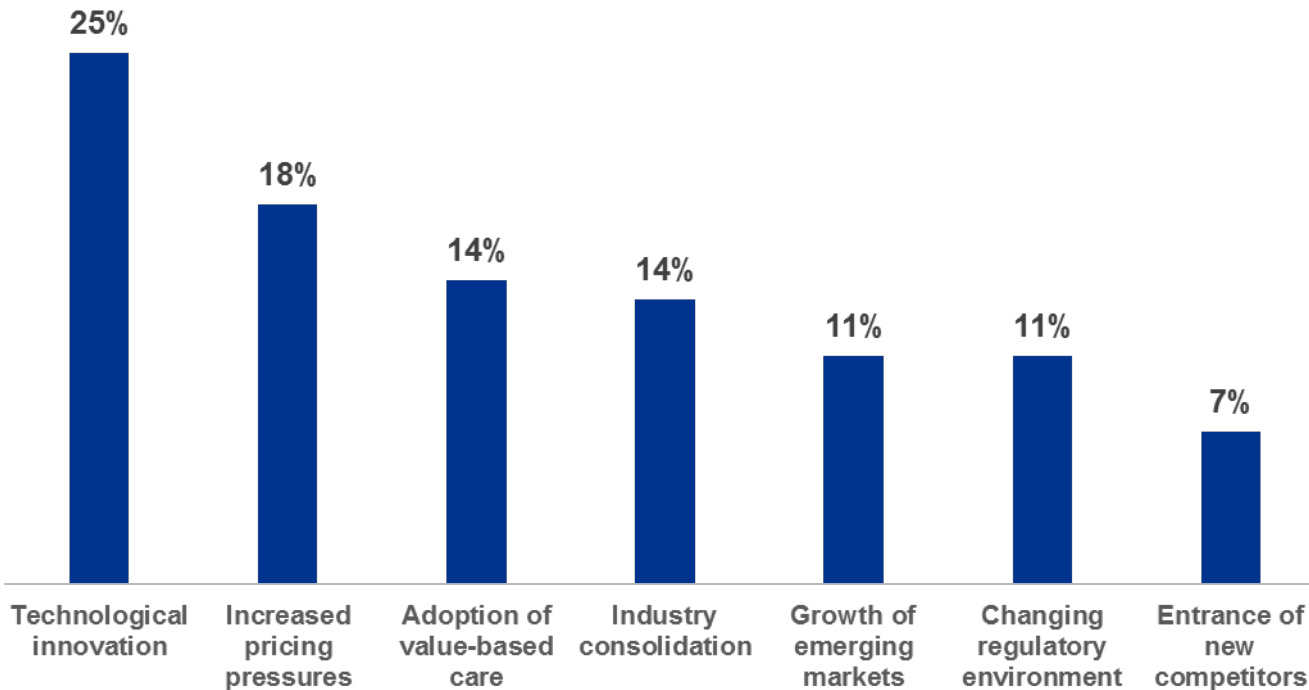
■ Private	91%
■ Public	9%
■ Less than \$10 million	55%
■ \$10 million to \$50 million	17%
■ \$50 million to \$250 million	4%
■ \$250 million to \$1 billion	11%
■ More than \$1 billion	9%
■ Unknown / Not Commercialized	4%

Participant Demographics – Area of Responsibility

■ President / CEO / COO / Managing Director	53%
■ Sales / Marketing / Business Development	21%
■ Engineering / R&D / Product Management	8%
■ Regulatory / Quality / Clinical	8%
■ Other / Miscellaneous	10%

MassMEDIC 2015 Survey

What do you expect will be the top drivers of transformation for your business for the next 3 to 5 years?



Leading Transformation Drivers

- **Innovation:** The “consumerization” of Medical Devices, or “medicalization” of consumer devices, such as the emergence of new technologies (e.g., smartphones and social media), has gained momentum in recent years leading to increased investment in patient-empowering technologies.
- **Increased pricing pressures and Value-based care:** Emergence of a consumer-centric, value-based health care marketplace have led to purchasing decisions being made on the basis of the convergence of cost, outcomes, and other quality factors.

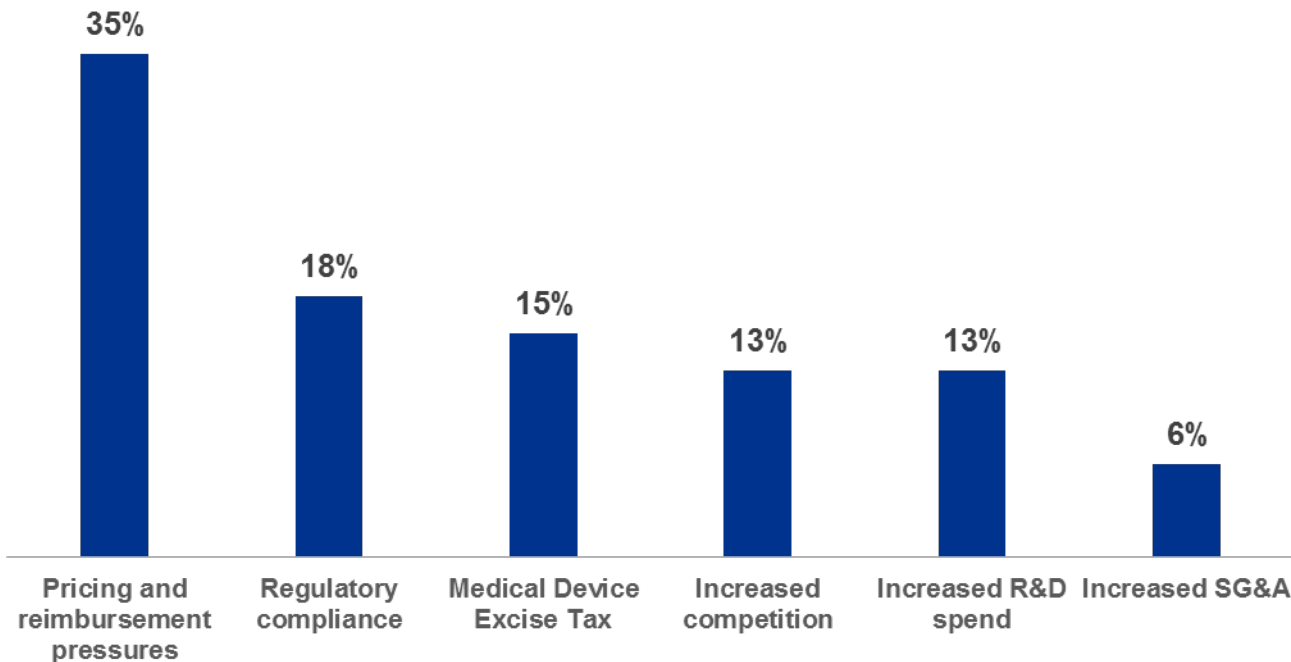
Source: MassMEDIC 2015 Survey

“Five Trends Transforming the Device Industry” Medical Devices Summit Article, June 2014

“New Buying Behaviour Provides Value Creation Opportunities for Medical Device Manufacturers” Marakon Article February 2012

MassMEDIC 2015 Survey

What do you view as the biggest challenges to company profitability in 2015?



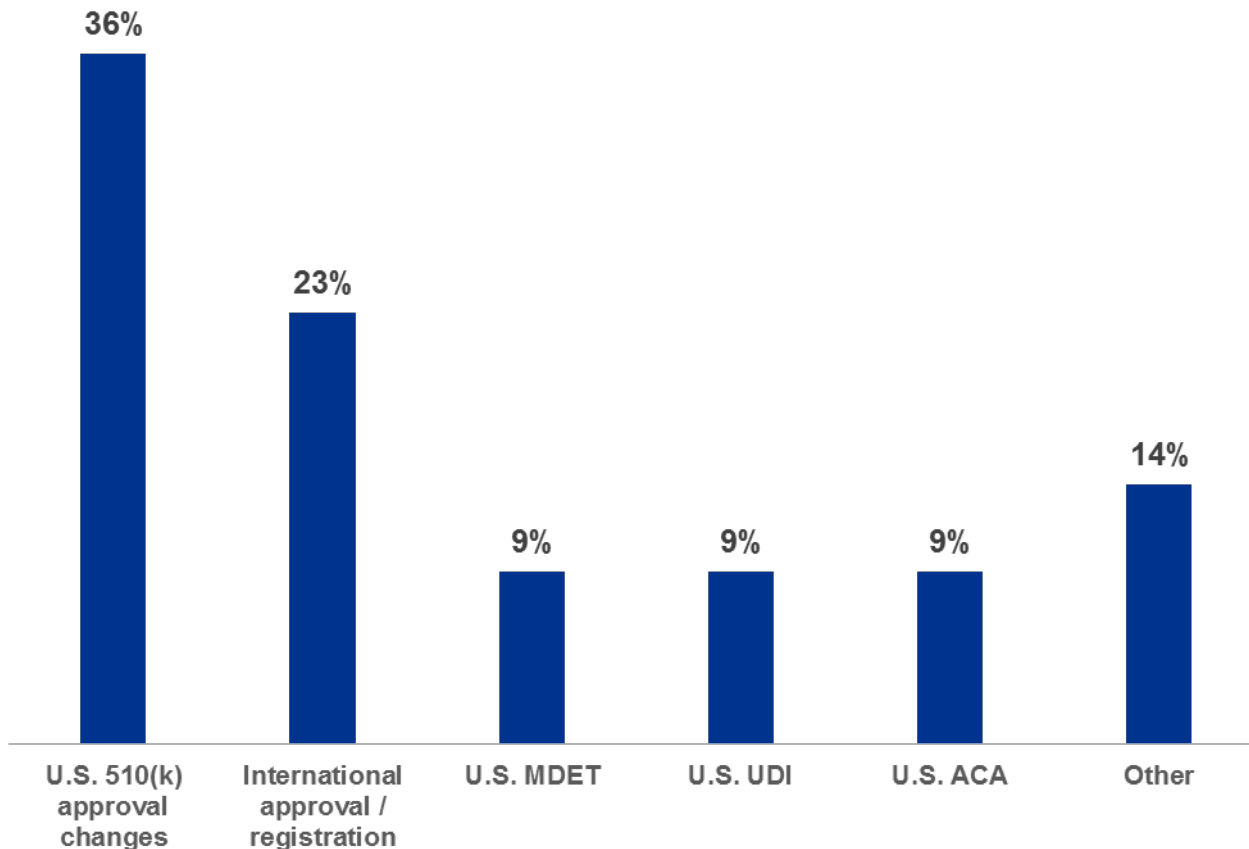
Leading Profitability Challenges

- **Healthcare Provider Consolidation:** Consolidation of healthcare delivery has led to changing sales models due to growth of GPOs and decreasing margins and increased competition.
- **Regulatory Environment:** Major regulations include FDA Unique Device Identification (UDI) legislation that went into effect in 2013, and China policies which will favor domestic manufacturers.
- **MDET:** Since implementation in 2013, MDET has led to companies lowering the prices of their products to remain competitive, and additionally has reduced resources for capital investments, R&D, clinical trials, manufacturing improvements, and investments in startups.

Source: MassMEDIC 2015 Survey
 "The State of the US Medtech Industry" Anchin Report, January 2015

MassMEDIC 2015 Survey

What is the greatest regulatory challenge that will impact your business in 2015?



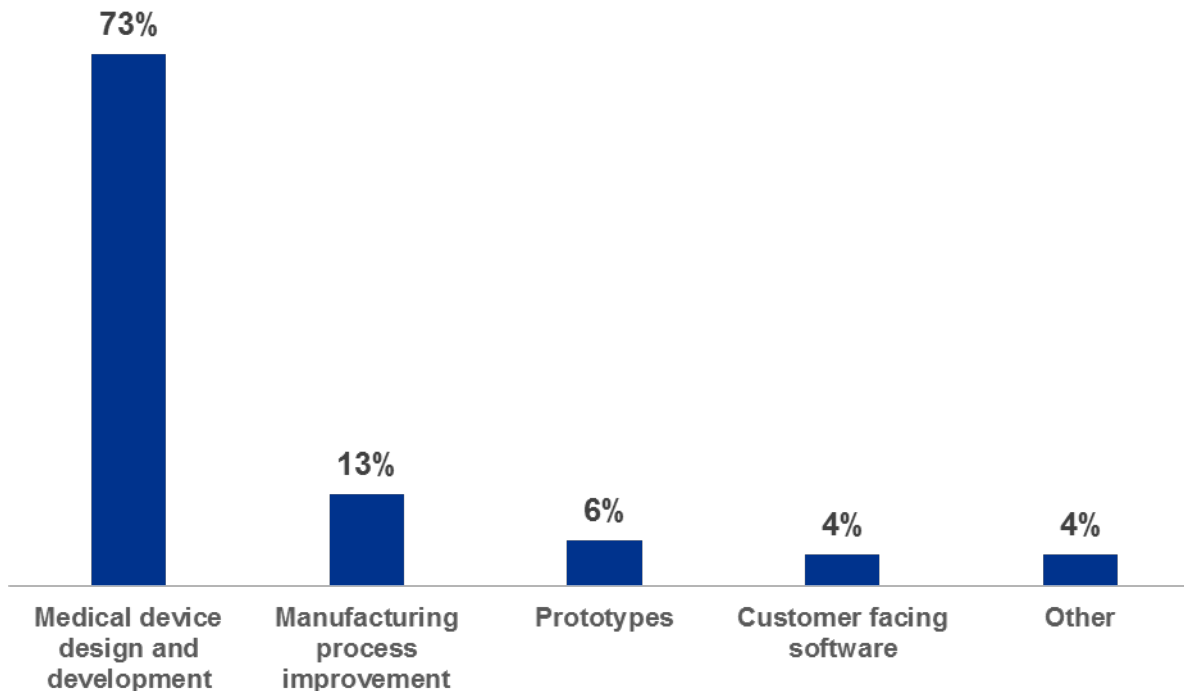
Regulatory Challenges

- Regulatory approval and registration changes and complexities in the United States and other markets such as China, Japan and Brazil.
- Although companies' MDET compliance efforts have been underway over the last few years, ACA and MDET will continue to have effects on U.S. sales and job growth.
- The FDA UDI legislation that went into effect in 2013 affects areas such as labeling, master data management, and marketing, and initial due dates have passed.
- Other regulatory challenges cited were the U.S. PMA approval process, and Medical Device vigilance reporting requirements.

Source: MassMEDIC 2015 Survey

MassMEDIC 2015 Survey

In what area does your company incur the majority of the R&D expenditure?



Commonly Missed R&D Tax Credit Opportunities

- **MassMEDIC 2015 Survey:** 40% of respondents are currently claiming R&D tax credits.
- **Customer Facing Software:** New rules allow for R&D credit to be claimed for activities enabling interaction with customers and other third parties, as well as software to support administrative functions.
- **Manufacturing Process Improvement and Prototypes:** Costs that are currently part of costs of goods sold or fixed asset accounts may qualify as R&D costs.
- Companies are able to retroactively claim R&D credit using alternative simplified and more favorable credit calculations.

Source: MassMEDIC 2015 Survey



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