ROTH Capital Partners

FULL REPORT: **Innovation 101 – Technology & Innovation in the Medical Device Industry**
Washington, DC – *September 13, 2012*
Matt Dolan, Senior Research Analyst, ROTH Capital Partners, LLC

Introduction

Over the past few decades, the Medical Device (aka, Med Tech) industry has positively impacted the quality of US health care in a cost effective manner. In addition, the industry provides substantial contributions to the economy through innovation, quality jobs, higher earnings, and sales.

Today, the Med Tech industry faces a number of challenges, most notably unpredictable regulatory and reimbursement environments, which have led to reductions in early stage investing in the space. Into 2013, the industry looks to another obstacle in the form of the 2.3% tax on US sales imbedded in the Affordable Care Act (ACA).

In the following report, we strive to (1) outline the impact the Med Tech industry has on the US economy and the US health care system, (2) argue that the premise behind taxing the Med Tech industry may not be justified, and (3) identify the negative effect the Medical Device tax will have on an industry that otherwise delivers positive contributions to the health care system and the US economy.

I. Med Tech State of the Union – Why Med Tech Matters

A. The US Med Tech industry ships $136 billion in products, pays $25 billion in salaries, and employs well over 400,000 individuals.

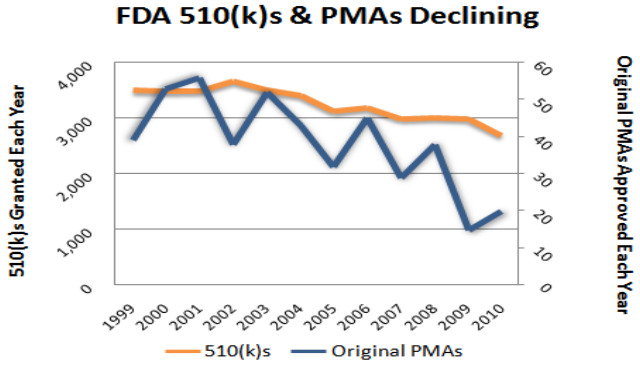
- *Investment in quality health care has provided positive economic returns and improved patient outcomes:*
  - Death rates are down 16%,
  - Life expectancy has increased by over 3 years (+4%), and
  - Disability is down 25%. [1]
- *Medical Technology is cost effective:* Prices grew slower than Consumer Price Index (CPI) and remained consistently only 6% of national health expenditures. [2]
- *Smaller companies account for innovation and jobs*: 80% of Medical Device companies have fewer than 50 employees and 98% have fewer than 500.
- *More jobs, earnings, and sales*: Each medical technology job generates an additional 1.5 jobs in a given state, as well as 90% more earnings and sales. [3]

[1] *Estimates of Medical Device Spending in the United States, King, Donahoe*
[2] *The Value of Investment in Health Care, MEDTAP International.*
[3] *State Economic Impact of the Medical Technology Industry, June 7, 2010, The Lewin Group.*

B. *Why is Med Tech already suffering?*

53% of companies cite an unpredictable regulatory environment as the biggest challenge in the medical device business today.

- Unpredictability in the regulatory environment: 53% of companies cite this as biggest challenge in running their business today[4].

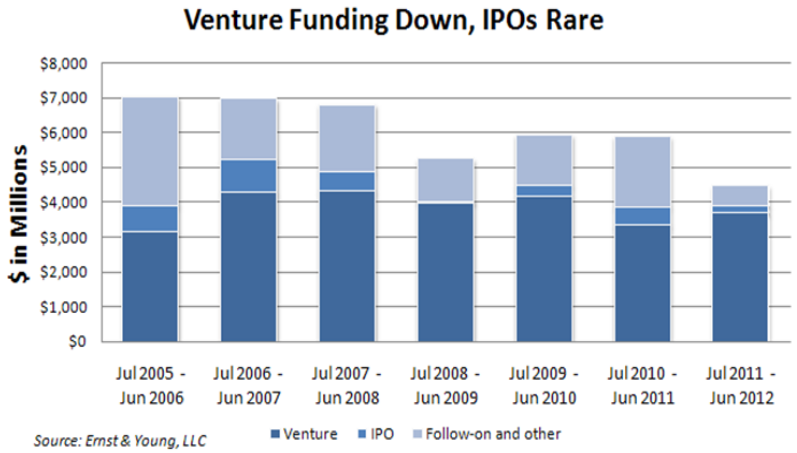


Source: www.fda.gov; FDA Impact on US Medical Technology Innovation, November 2010

- Uncertainty of reimbursement has reduced investment in the category.
- Existing businesses impact by hospitals pushing back on pricing and volume.

Venture Capital (VC) investment is already on the decline, particularly for early stage companies. This is a good indicator for the health of an industry. Med Tech appears to be plagued mostly by regulatory uncertainty.

Furthermore, Med Tech Initial Public Offerings (IPOs) have been virtually non-existent in the past four years, which serves as another indicator of a change in the industry's health.

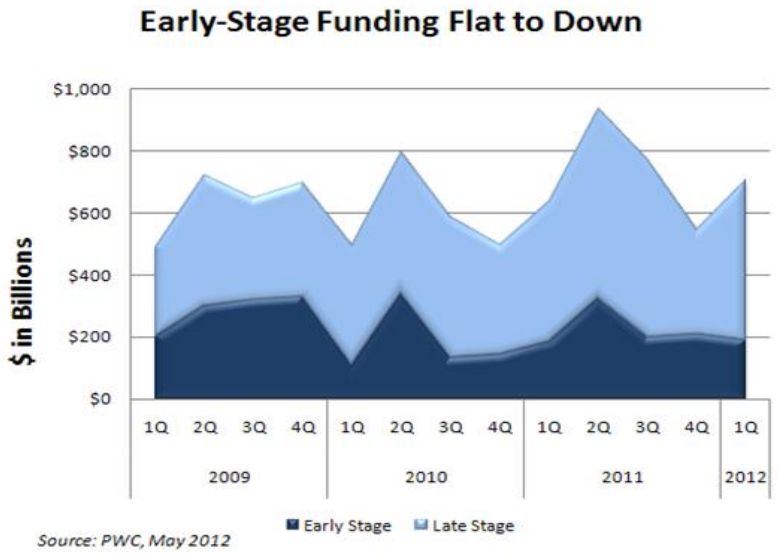


Source: Ernst & Young, LLC

Early stage, "Series A" funding is projected to shrink again in 2012. We view Series A funding as a leading indicator of innovation in any industry, as it typically targets those new, and often more innovative ideas, that provide bigger opportunities for economic development and job growth.

---

[4] *Emergo Group; 2012 Medical Device Industry Survey, n = 198*



Affordable Care Act

Today, the biggest topic of conversation surrounds the Affordable Care Act (ACA).

- Imposes a 2.3% excise tax on medical device sales in the United States.
- Tax on all sales occurring on or after January 1, 2013, even though coverage for the newly insured begins in January 2014.
- Based on top line sales, not profit.

As of September 2012, the industry has not received guidance on how the tax will be implemented or collected.

The primary justification for the tax appears to be the expectation for an increase in volume (aka, windfall) of newly insured patients for medical device companies.

II. What Windfall? How ACA Should Affect the Med Tech Industry

In this section, we argue that perhaps the basis for the Device tax might not prove as straightforward as previously thought, once we take a deeper look at its rationale.

- Newly insured patients much younger than medical device users.
- Hospital purchasing appears to be getting worse, not better.
- Real world example: Universal health care in Massachusetts.

A. Consequences of ACA Have Been Difficult to Estimate

The Congressional Budget Office's estimates for the impact of ACA on the budget have been revised a number of times. It seems to us that the effect of ACA should be constantly evaluated as we get more data and that the bills intended consequences may be less predictable than originally anticipated.

B. Incoming Patients Not Typical Medical Device Users [5]

Bringing this concept back to the Medical Device industry, one major argument for a tax on medical devices is driven by the assumption that Med Tech manufacturers would be beneficiaries of a windfall of formerly uninsured patients now insured under ACA.

However, when one compares the average age of a medical device patient and that of the uninsured, we find a stark contrast. We chose five large medical device categories in this slide, with the average age being well into the 60s for many devices and even 70s for others.

Average Age of Patients by Medical Device:

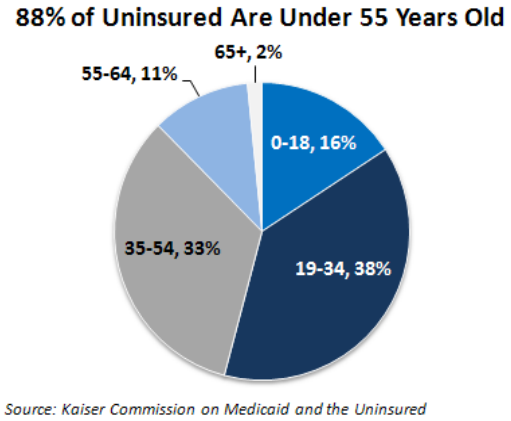
Medical Device	*Average Age*
Heart Valves:	70
ICDs (Implantable Cardiac Defibrillators):	60's
Cardiac Stents:	62
Knee Implants:	64
Hip Replacements:	75.1

If we compare that age group to that of the uninsured, that will become insured under ACA, we find a stark contrast to the prior chart. Eighty percent of uninsured patients are under 45 years old and 88% are under 55, well below the average device user. Only 2% of the uninsured are over 65 years old.

[5] *Heart valve data – MDT; ICDs – European Heart Journal; Stents – European Society Cardiology Study (1,234 patients); Knees – Dartmouth- Hitchcock; Hips – JAMA 2007-08.*

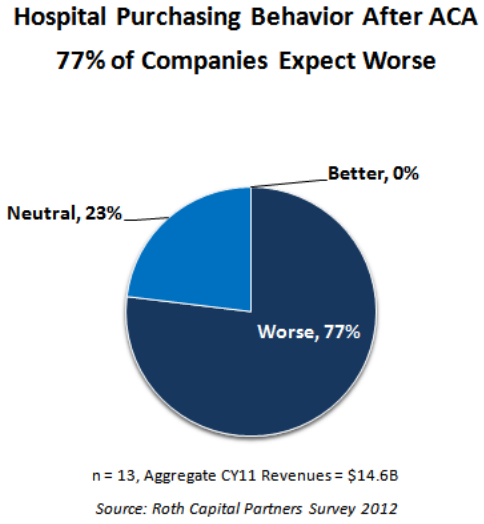
80% of uninsured are under 45 years old, and 88% are under 55 years old.

The average Medical Device user appears to be at least in their 60's.



C. Hospital Purchasing Behavior Getting Weaker, Not Stronger

Medical device customers (i.e., hospitals) are attempting to reduce utilization and pricing in the future. Anecdotally, this has been a consistent trend in the past few years.



In the past few weeks, we ran a survey gathering input from what medical device companies were hearing from their hospital customers. In our survey of 13 companies representing just over $14.5 billion in industry revenue, 77% expected purchasing behavior to worsen, and notably none anticipated a better environment.

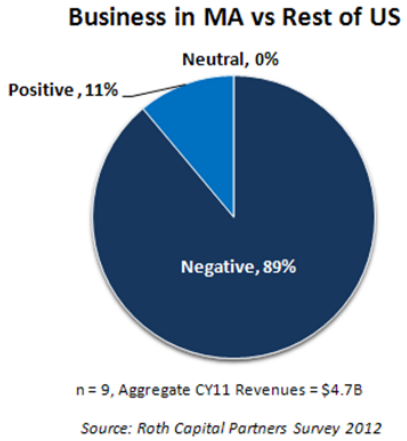
We believe this further refutes the concept of a windfall.

D. Real-World Example: Universal Health Care in Massachusetts

Universal health care was legislated in Massachusetts in 2006 and implemented through 2011. In our evaluation of ACA and the basis for the Medical Device tax, we investigated if universal health care in Massachusetts provided a windfall to medical device companies' businesses in that state relative to the rest of the country.

The following outlines our early findings, suggesting that revenues and volumes in Massachusetts may not have benefited and perhaps were negatively impacted as a result of universal health care in that state.

8 out of 9 companies experienced negative comparative growth rates in Massachusetts as compared to the rest of the US following the implementation of universal health care in that state.

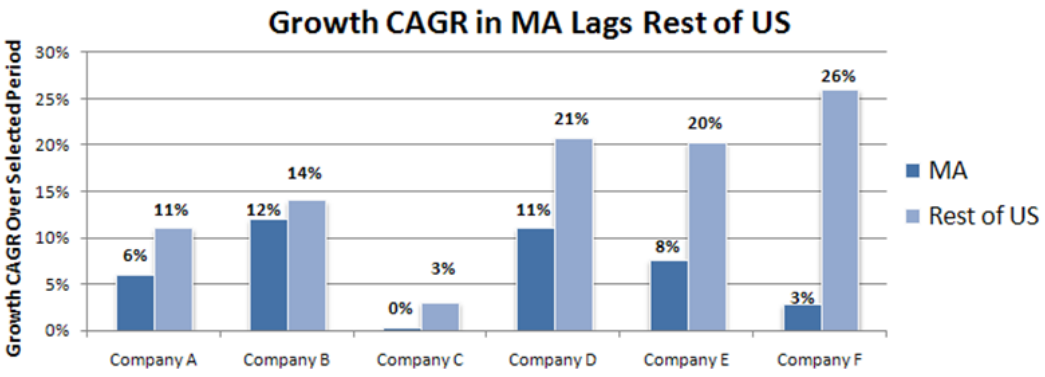


In our analysis, 8 out of 9 companies experienced negative or neutral comparative growth rates in Massachusetts as compared to the rest of the US following the implementation of universal health care in that state.

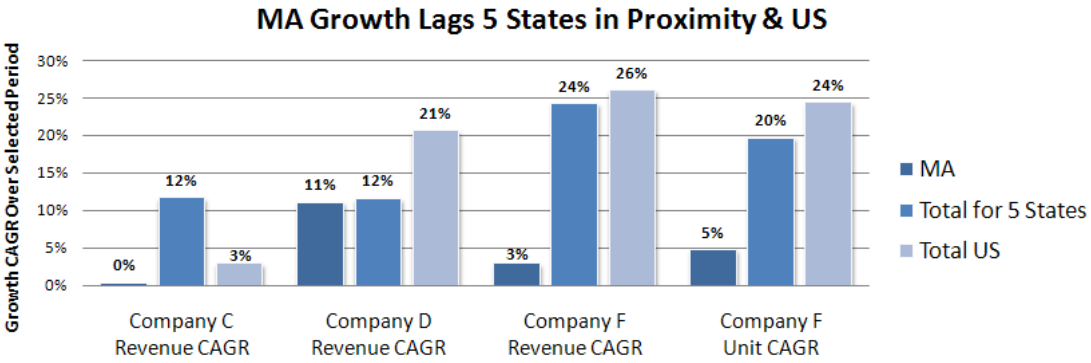
Massachusetts Case Studies: Represent Aggregate Revenue >$1.75B

Using the six case studies (below), we see that trends in Massachusetts, contrary to an expectation for higher medical device utilization rates, actually lagged the rest of the US in the years following the legislation of universal health care.

Using these six case studies, we see that trends in Massachusetts, contrary to an expectation for higher medical device utilization rates, actually lagged the rest of the US in the years following the legislation of universal health care.

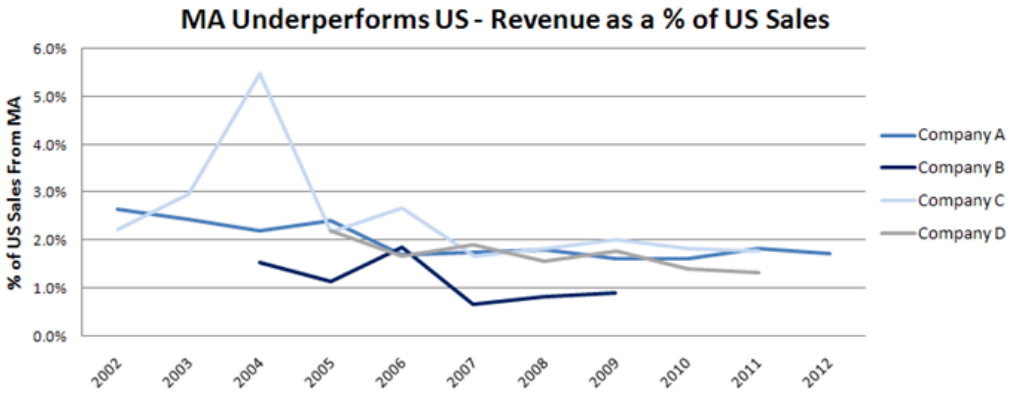


When possible, we also compared growth in Massachusetts to that of five states in close proximity to Massachusetts, in an effort to control for any geographic variability (second chart). Again, the trend was the same: Growth in Massachusetts lagged that of the states in geographic proximity.

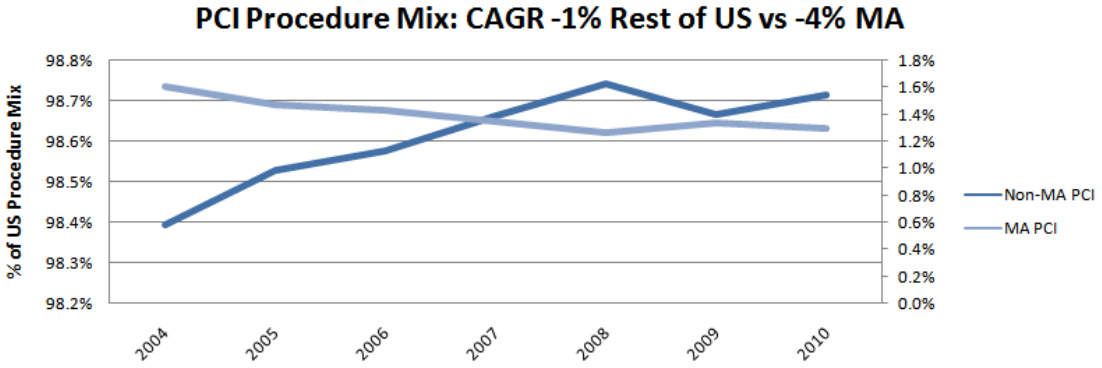


Looking at this trend annually, we see that the percentage of revenue out of Massachusetts between the 2002-04 through 2009-12 timeframe declined, suggesting no windfall was experienced in these businesses.

Although preliminary, we believe these studies provide evidence against any apparent windfall to medical device utilization levels associated with universal health care and perhaps ACA.



Similarly, percutaneous coronary intervention (PCI) volumes followed a similar negative comparative trend in Massachusetts versus the rest of the US.



Although preliminary, we believe these studies provide evidence against any apparent windfall to medical device utilization levels associated with universal health care and perhaps ACA.

III. Negative Impact of Device Tax on the Industry's Financial Health

Surveys of Med Tech companies in the past year support this claim, with the majority anticipating the Medical Device tax to carry a negative effect.

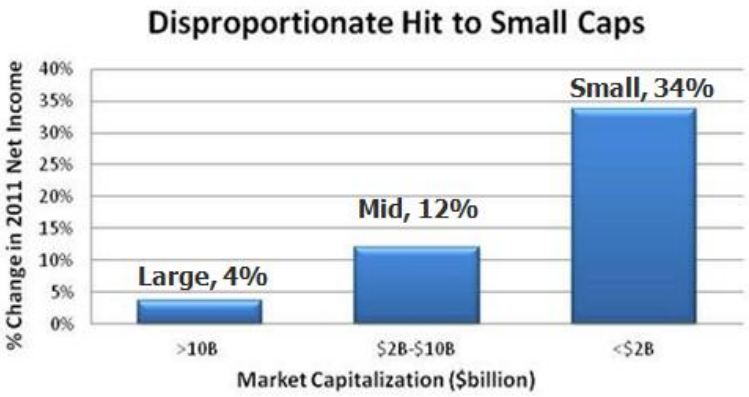
Our analysis below also points to another notable theme: smaller companies, typically the industry's innovators and job creators, take a disproportionate hit to profits as a result of the Medical Device tax.

A. What impact will a scheduled 2.3% excise tax on device sales in the US have on your business?

Greater than 70% expect a somewhat to very negative impact (n = 198).[6]

Of the 18 small-cap companies used in this analysis, we calculate an approximate average earnings decline of 34% on an aggregate basis. All 14 large-cap companies had less than a 10% decline in earnings, a stark contrast from the small cap group where only one of 22 companies had an earnings decline under 10%.

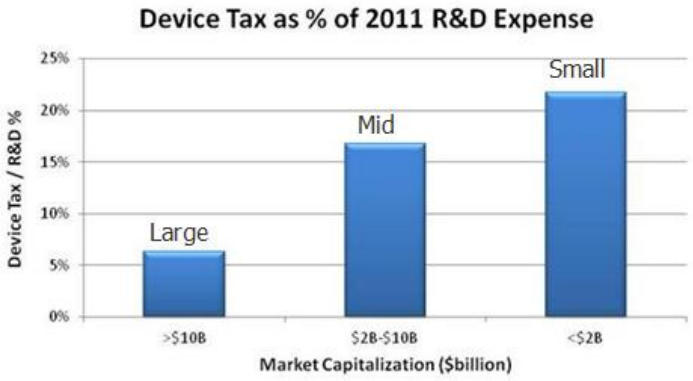
Smallest Companies Take the Biggest Hit



Source: Roth Capital Partners; Moody's Investor Services

Of the 18 small-cap companies used in this analysis, we calculate an approximate average earnings decline of 34% on an aggregate basis, versus 4% for the large-cap cohort. All 14 large-cap companies had less than a 10% decline in earnings, a stark contrast from the small cap group where only one of 22 small-cap companies had an earnings decline of less than 10%.

Greater than 70% expect a somewhat to very negative impact from the Medical Device tax.



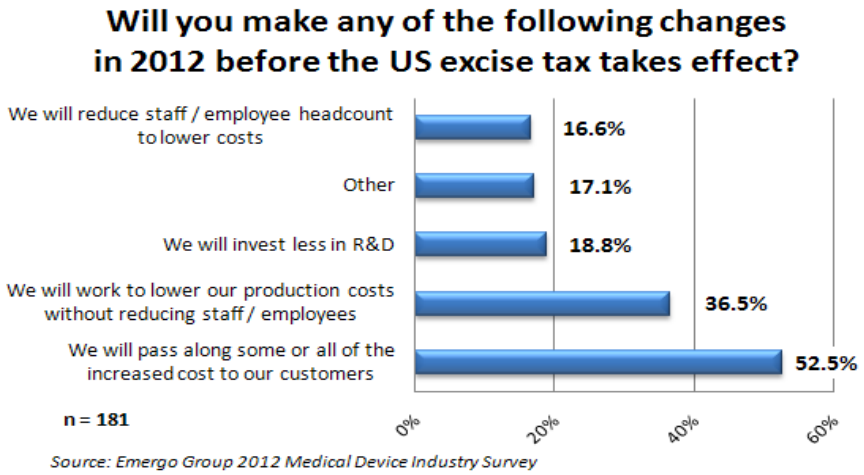
Source: Roth Capital Partners; Moody's Investor Services

[6] *Emergo Group; 2012 Medical Device Industry Survey*

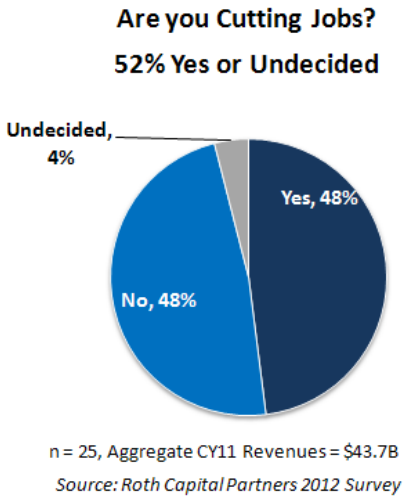
We also look at the tax as a percentage of R&D, considering (1) R&D often represents the most flexible spending line within a company and (2) is often an indicator of innovation and future growth. Again, we find an escalating hit to R&D budgets of smaller companies.

IV. The Device Tax Hurts Jobs & Innovation

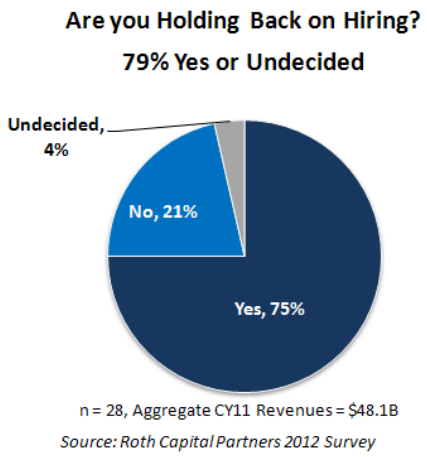
The Med Tech industry is one of fierce competition and many times disagreement, but this is one issue where feedback has been remarkably consistent.



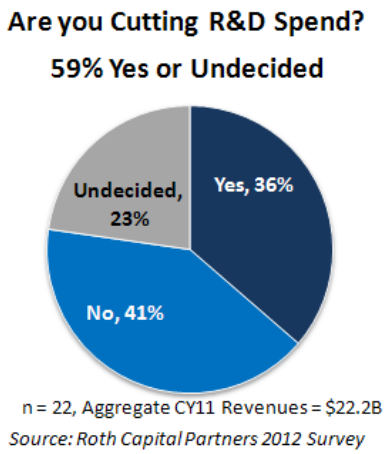
Considering this data was likely collected in late 2011, we also surveyed companies on their latest plans to manage through the implementation of the Medical Device tax next year. We determined that (1) over 80% would either cut jobs or forego new hires and (2) more than 75% would either cut or forego new R&D projects as a result of the tax. See the following series of charts.



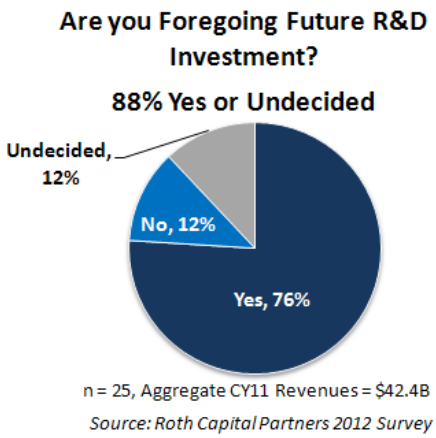
Greater than 80% indicated jobs would be cut or new hires would be foregone.



Greater than 80% indicated jobs would be cut or new hires would be foregone.



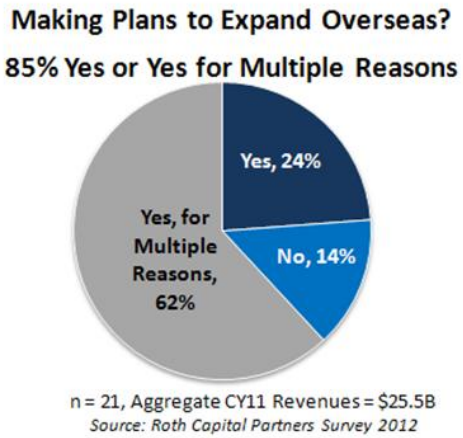
Greater than 75% indicated R&D spending would be cut or new projects would be foregone.



More than 75% indicated R&D spending would be cut or new projects would be foregone.

Expansion Already Being Directed Overseas

We found that plans to direct expansion overseas was already a common trend within the Med Tech industry, with many responses indicated that the tax was one of many reasons to do so.



V. Conclusions

A. Medical Technology cost effectively provides better patient care and quality of-life.

The Med Tech industry has been a contributor to improved patient care (i.e., longer lives and reduced disability), and has provided these benefits in a cost effective manner.

B. The industry is already facing pressure. A tax on Medical Devices would exacerbate this trend.

Reduced Med Tech investment due to an unpredictable regulatory and reimbursement environments, as well as softer pricing and utilization trends at the hospital level, have already begun to impact the Med Tech industry negatively. A tax on medical devices would exacerbate this trend.

C. Initial data suggests the rationale behind the Medical Device Tax appears unjustified.

The assumption that insuring the uninsured will provide a financial benefit to Med Tech companies does not appear to be well justified, based on a number of analyses. Uninsured patients are typically much younger than medical device patients and hospital purchasing and utilization appears to be getting weaker, not stronger, going forward. Perhaps most striking in this report, our preliminary analysis of trends in Massachusetts suggests that medical device revenues and procedures trended negatively through the implementation of universal health care in that state.

D. If implemented, the Medical Device will result in a direct hit to US jobs, R&D innovation, and quality of patient care.

Our latest surveys and analyses indicate that the 2.3% Medical Device tax will have a negative effect on jobs, R&D / innovation, and the pursuit of new opportunities within the US. Considering the positive health care and economic benefits the Med Tech industry has provided in recent decades, we believe this trend will also have long-term implications on the nation's quality of patient care.

Matt Dolan, Senior Research Analyst, ROTH Capital Partners
mdolan@roth.com
949-720-5796

Chris Lewis, Research Associate, ROTH Capital Partners
clewis@roth.com
(949) 720-7163

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject industry. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

For important disclosures please contact: The Director of Research at (800) 678-9147 or write to: ROTH Capital Partners, LLC, Attention: Director of Research, 888 San Clemente Drive, Newport Beach, CA 92660

The material, information and facts discussed in this report other than the information regarding ROTH Capital Partners, LLC and its affiliates, are from sources believed to be reliable, but are in no way guaranteed to be complete or accurate. This report should not be used as a complete analysis of an industry or security discussed in the report. Additional information is available upon request. This is not, however, an offer or solicitation of securities. Any opinions or estimates in this report are subject to change without notice. No part of this report may be reproduced in any form without the express written permission of ROTH. Copyright 2012. Member: FINRA/SIPC.