Medtech Industry Trends 2012 and Beyond

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Medtech **Risk Aversion**

- "We live in a culture that somehow seems to forget that if we want [medical miracles] to happen, we have to be prepared for both reasonable cost and reasonable risks. [The public needs to] stop looking for simple one-line solutions to the healthcare problem and stop listening to the two extremes in our political system, neither of which is offering a realistic assessment of the situation."

- **Dean Kamen, Great Innovators Roundtable, MD&M East, May 2012**

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Why would you ever choose the medtech business?

+ Medtech **Market Size**

- The U.S. is the largest medical devices market, with estimated sales of roughly $95 billion in 2010."
  - **Medical Devices Industry Outlook,** Zacks Equity Research, April 2011

- The global medical device market is expected to grow to $348.6 billion in 2015.
  - **Medistat Worldwide Medical Market Forecasts to 2016,** Espicom Business Intelligence, June 2011

+ Medtech **U.S. Policy**

- Affordable Care Act
  - Supreme Court finds ACA constitutional.
- Medical Device Tax
    - 2.3% tax on sales
    - Expected to cost between $20 billion and $30 billion
  - Bills to Repeal
    - H.R. 436—House passes 270–146 on June 6, 2012; not expected to pass in the Senate.

My Prediction: The Medical Device Tax is *NOT going to be overturned. If you don't already have a game plan for implementation, you might be in trouble.

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Medtech **Regulation**

- Safety and Innovation Act (FDASIA)
  - User fees more than double from $277 million in 2008-2012 to $609 million from 2013-2017.
  - Will add about 200 full-time equivalents (FTEs) involved in device approvals by 2017.
  - Allows FDA to reclassify (Class I, II, II) devices through administrative order.
  - Extends FDA Sentinel initiative (safety standards, methods for tracking) from drugs to devices.
  - Unique Device Identification gets a boost with refined recall processes.
  - Medical apps guidance within 18 months.
  - Harmonization

+ Medtech **Purchasing Policies**

- Hospital Purchasing
  - Hospitals are changing they way they buy devices.
  - This means sales tactics in hospitals are shifting. Sales go through administration, rather than through MDs.
- New promotional channels
- Medicare and private insurance carriers are changing coverage policies.
  - They will demand information on comparative effectiveness of devices (requiring more clinical data).
  - Comparative effectiveness: direct comparison of existing healthcare interventions to determine which work best for which patients and which pose the greatest benefits and harms.

Medtech **Healthcare Consumer**

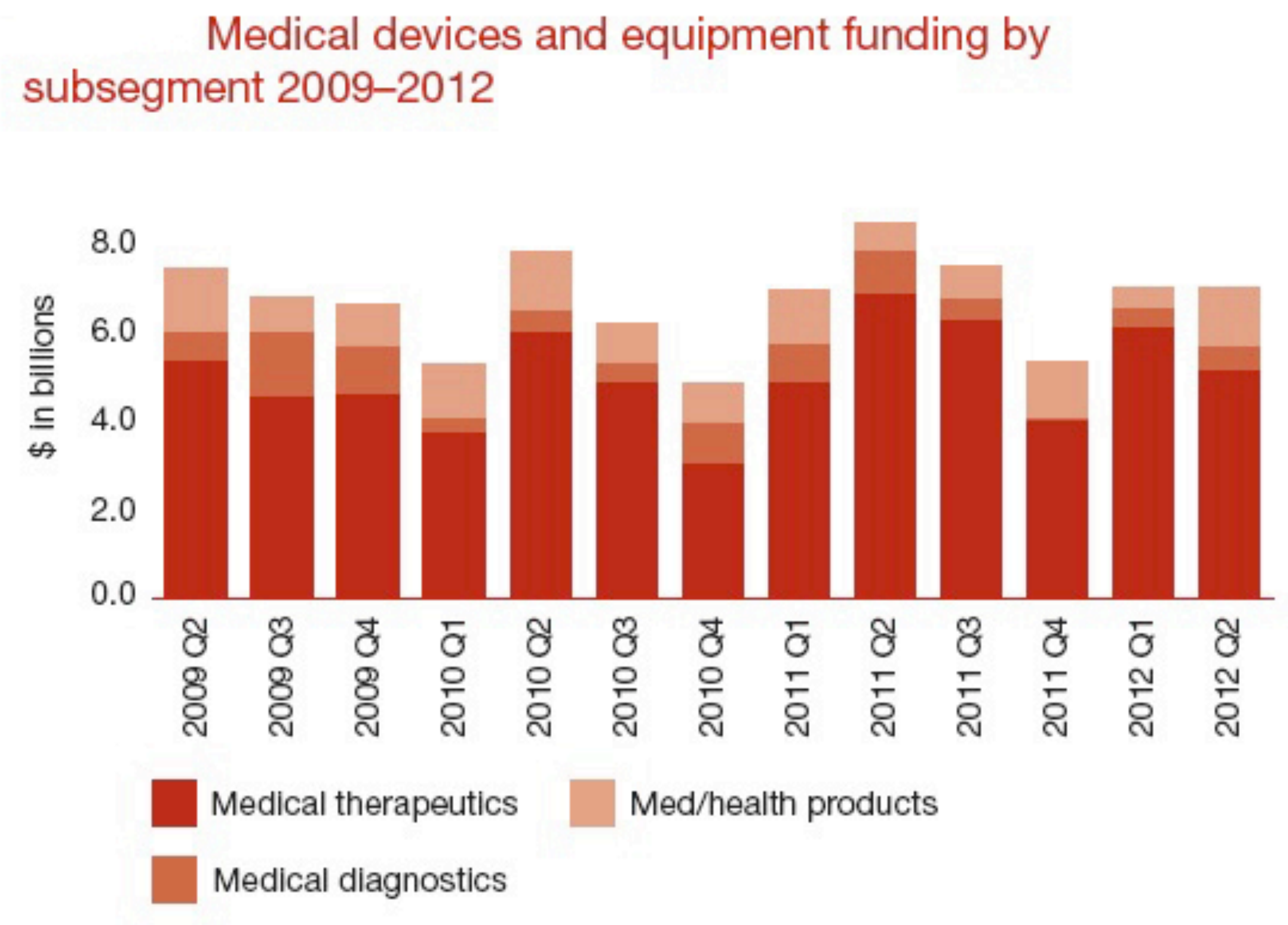
- By August 2012 there will be more than 13,000 iPhone health apps available for consumers.
  Mobihealthnews

- Design of consumer devices will require improved user interfaces, extremely simple operation plans (e.g., intuitive use), and failure-proof security, safety, and efficacy.

Medtech **Consumer Devices**

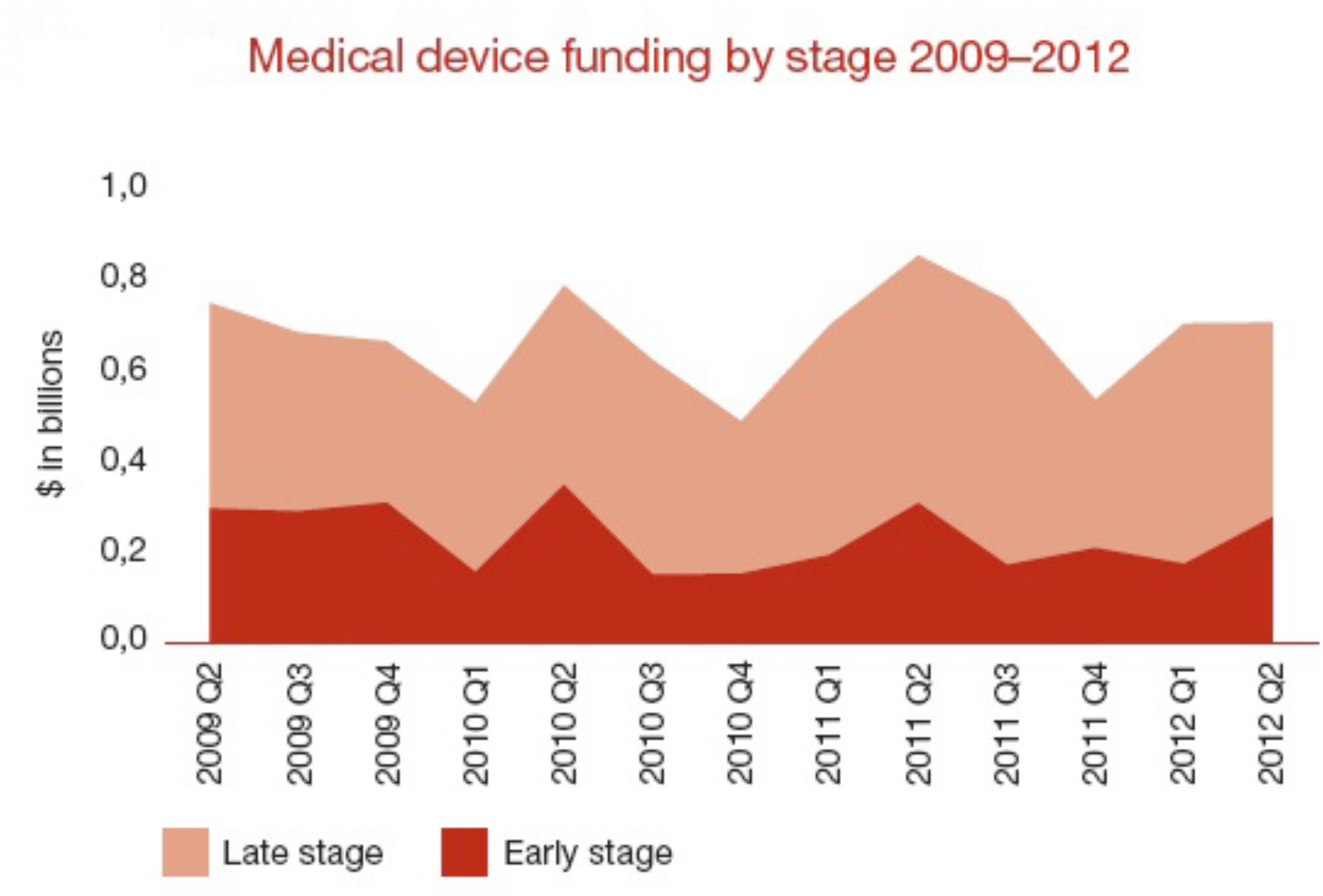
- Disease management, weight loss, preventive health, diagnostics
  - Vitality Inc. Glowcaps
  - fitbit
  - Alivecor
  - Sotera Visi Mobile

+ Medtech VC Funding



Source: "***Dollar drought," August 2012, PriceWaterhouseCoopers***

Medtech VC Funding



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+ Medtech **Funding**

- VCs and Angels are no longer interested in the long lead times and risks associated with funding medical device technologies. Any who do remain in the space are those that are really interested—not fair-weather friends. However, new technologies will not find homes unless they have an incredibly solid schedule and value proposition.

However…

- Companies have liquid capital. And they are using it to make strategic alliances (e.g., fill gaps in their own technology or purchase complimentary tech).

- A record number of transactions were initiated in 2011, including some very large purchases (J&J buys Synthes). From this point, we've seen some slowing, but it should pick up in the second half of 2012.

- Some VCs are not only staying, but reinvigorating their investment in medical tech. These are groups that really understand the space and can make educated decisions about technology.

Medtech **Global**

Medtech **China**

Strengths

- Almost endless supply of cheap labor.
- Controlled economy.
- Double-digit growth in healthcare revenue.
- Rapidly expanding middle class.

Weaknesses

- Slowing growth.
- Copycat me-too business culture.
- Insufficient R&D resources
- Wage inflation.
- Inadequate IP protection.

Opportunities

- Expanding middle class demanding improved healthcare.
- Inadequate domestic R&D and MFG of high-end medical equipment good for MNCs.

Threats

- Competition among domestic players.
- Corruption.
- Other countries with better value (lower wages; more sophisticated skillset)
- Shipping costs.
- Price controls.

+ Medtech **China**

- $7.5 billion in 2012, growing to $11.4 billion by 2015
  - UBM Canon
- The medtech market will achieve annual growth of 19% and be valued at RMB 420 billion (€53 billion) by 2016,
  - Liu Dao Zhi, President, Pudong Medical Devices Association; Senior VP, Emerging Business, Microport Shanghai Co., Ltd.
- MIIT 2012 goals to boost China's medtech prowess

Manufacturers are beginning to adopt a China-first mentality. Devices are then brought back to the US and Europe.

Medtech **India**

Strengths

- Educational and business support for high-tech industries.
- Rapidly growing middle class.
- Health insurance and hospital administration growth

Weaknesses

- Long approval process.
- Difficult to ID key Indian players/partners.
- Very price sensitive.
- Protective market, not too much import or export.
- Low-priced local products not competitive.

Opportunities

- Improved regulatory environment.
- Promising private care infrastructure.
- Insurance expansions for

Threats

- Weak legal framework and ineffective IP enforcements.

+ Medtech **India**

- Market size was $3 billion in 2010, with a projected 5-yr CAGR of 16%
- Device sales are growing 30-40% annually. Review times for devices are estimated to be 5x faster than in Europe.
- India Medtech market: "We can expect 12%–16% annual growth over the next 10 to 15 years. All the risk factors put together are just irritants, which at most can bring growth to 8%–9%. This is still significantly higher than the 2%–3% growth that developed, Western markets are currently experiencing." —Annaswamy Vaidheesh, managing director of Johnson & Johnson Medical India

Medtech **Brazil**

Strengths

- Largest market in Latin America.
- Well established medical device industry.
- Second largest private healthcare insurance sector in the Americas.
- Emerged quickly from global downturn.

Weaknesses

- Poor infrastructure.
- Dependant on commodity exports.
- Protectionist.
- Domestic production geared towards local market.

Opportunities

- Growing private sector.
- Diagnostic imaging apparatus, followed by orthopedics and consumables are the largest market sectors.
- Hospitals regularly modernize and upgrade equipment.

Threats

- Inflation could threaten investment into the medical device sector.

+ Medtech **Brazil**

- In 2011, Brazil's medical market was valued at $3.6 billion.
- Imports are high-tech devices not produced locally, 68% are supplied by US and EU.
- Import growth rate is about 34%.

Key Insights for 2013

- Device makers are under increasing pressure to demonstrate better outcomes, efficiencies, and cost to appeal to cash-strapped hospitals and ACA.
- Device supply chains are going to be squeezed, and suppliers will continue to consolidate.
- 2013 will be an implementation year to handle the device tax.
- A restricted industry represents an opportunity to weed out and refine the industry to its strengths.
- Manufacturers must start designing for efficiency to compete with opportunities in BRICs and globally.
- Medical sales teams will further specialize. Soon, PhDs may be "selling" devices to hospitals.

Thank You!

Questions?

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