



Keystone
Heart™

*Protecting the Brain;
While Treating the Heart*

**Management of Early and Middle Stage Companies:
When to transition from inventor/founder to professional management**

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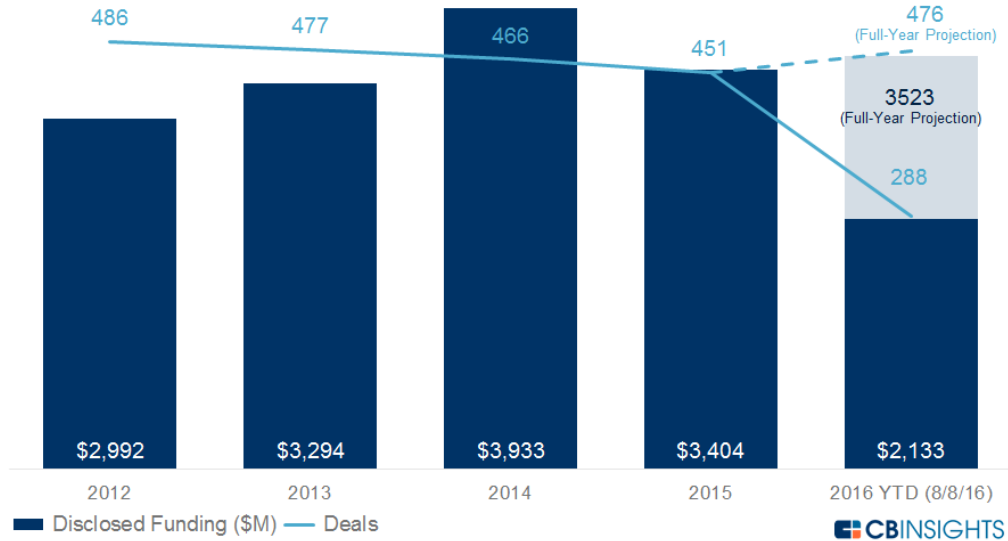
National Health Expenditure Projections 2015-2025 Forecast

•Patient Access to Care How accessible is care?

- For 2015-25, health spending is projected to grow at an average rate of 5.8 percent per year
- Health spending is projected to grow 1.3 percent faster than Gross Domestic Product (GDP) per year over this period;
- In the US Healthcare of GDP is expected to rise from 17.5 percent in 2014 to 20.1 percent by 2025.
- Health spending growth is expected to accelerate and average 5.7 percent for 2017 through 2019 as a result of gradual increases in economy-wide and medical-specific prices.
- Focus on costs and cost-effectives in the device approval and coverage process - As there is an increased focus on reducing costs of medical care and as new devices are becoming more expensive there will be a renewed focus on cost and cost-effectiveness of new technologies. Likely this will effect not only coverage decisions but eventually device approval as well.

MEDICAL DEVICE ANNUAL GLOBAL FINANCING HISTORY

2012 - 2016 YTD (8/8/16)

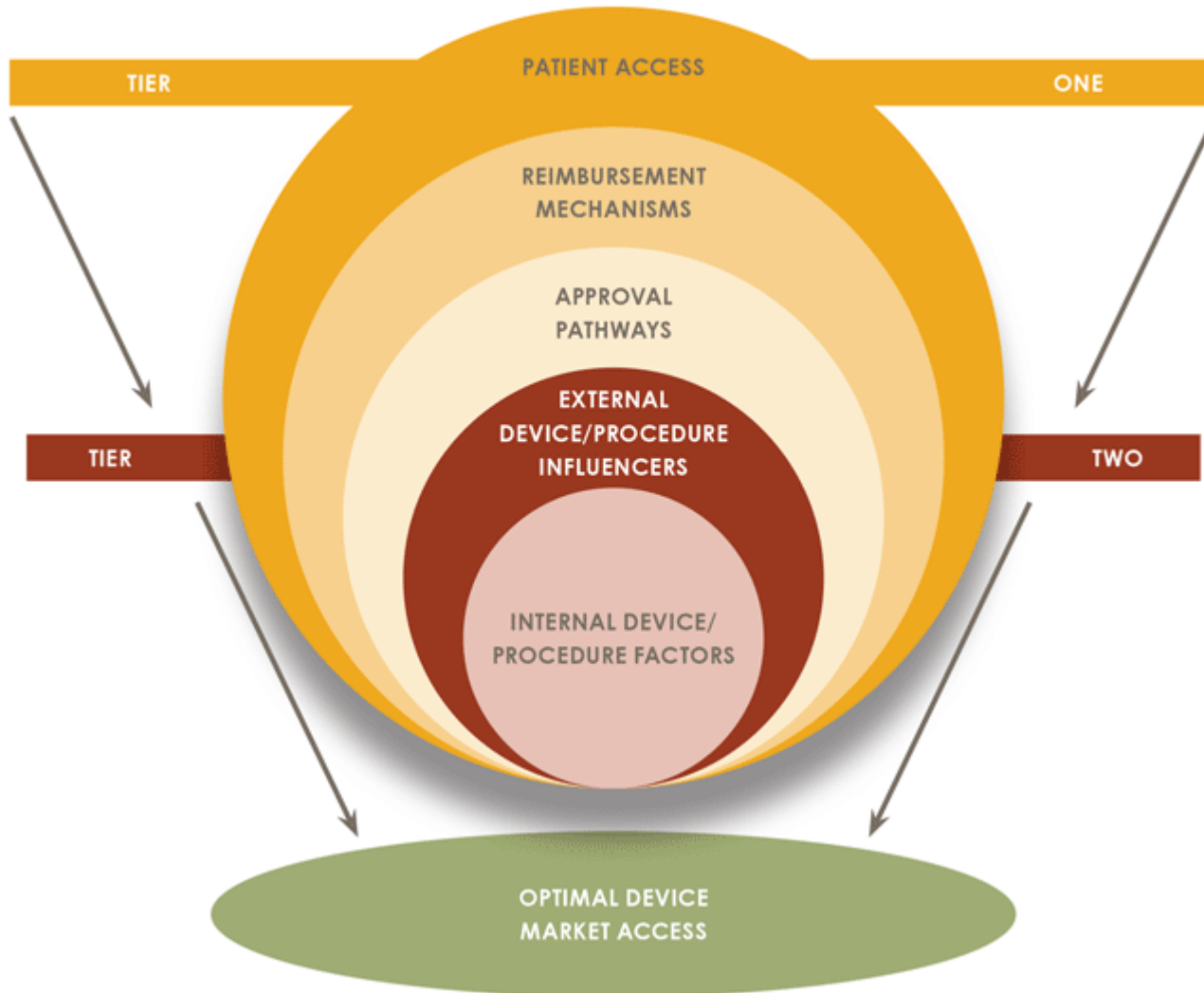


Most Active Medical Device Investors 2012-2016 YTD (8/8/2016)

Rank	Investor
1	New Enterprise Associates
2	Versant Ventures
3	High-Tech Gruenderfonds
4	Johnson & Johnson Innovation
5	OrbiMed Advisors

There are more than 4,000 biotech companies and 6,000 device manufacturers in the world. It can take more than a Decade and hundreds of millions of dollars to prove that a drug or device is safe and effective.

FIGURE 1: MARKET ACCESS ATTRACTIVENESS FRAMEWORK



•Patient Access to Care

How accessible is care?

Transitioning to a ***value-based future, from a volume/cost based model*** requires more than just collaboration among providers; it requires rethinking of the core elements of practice organization (physicians as employees) and developing complimentary levels of clinical, operational, financial, and *cultural alignment* that further advance the respective participants' shared incentives with objectives that support the entire enterprise. The transformation of our healthcare system from volume to value-based payment is proving to be particularly perilous for many providers.

[AdvaMed expresses dismay at India's capping of coronary stent prices](#)

An order has been issued by India's National Pharmaceutical Pricing Authority capping prices of bare-metal coronary stents at approximately \$109 per unit and of metallic drug-eluting stents and bioresorbable vascular scaffold or biodegradable stents at approximately \$442 per unit effective immediately. AdvaMed said the order could discourage manufacturers from introducing new products in India and advised the authority to address larger problems and inefficiencies in the country's health care ecosystem.

Medical Device Start Up Fundamentals

•Medical Device Start Up Success is determined *Early* in the Process

- 1. Fill the need in a Large and Growing Market** (*Founder/Inventor*)
- 2. Secure a Robust IP Portfolio** (*Founder/Inventor*) – *Professional Management*
- 3. Plan your Fund Raising/Financial Partnerships Wisely** (*Cash is King*)
- 4. Build a Deliberate Team** (*Dedicated, Motivated, Company Branding*)
- 5. Consider Your Exit Strategy** (*M&A, IPO*)
- 6. Reimbursement Planning & Continued R&D are Crucial** (*Profitability*)
- 7. Maintain Focus** (*Balance Resources with Product Establishment*)
- 8. Create a Sustainable Value Proposition** (*Must Adapt or Die*)



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