Medical Device Pressures and Opportunities: Now is the Time to Invest

by Gavin Phillips

A recent Health Imaging article by Evan Godt, Survey: AdvaMed members feel pinch medical device tax, tells us that that the Affordable Care Act’s medical device excise tax is having a direct effect on the medical device industry within a year of its approval. According to the Advanced Medical Technology Association (AdvaMed) survey, the excise tax resulted in loss of jobs and restrained R&D efforts.

Unfortunately, the 2.3% excise tax is not the only thing forcing massive change at medical device companies. Even as the medical device industry grows as a result of increased demand in the US and around the world, there are many additional forces at work changing the industry. Companies should not wait for the pressure to alleviate; they should find opportunities now to adapt with innovative business models, mobile connectivity and emerging markets.

Downdraft Pressures

Industry Consolidation. The healthcare system in the US is in a stage of major consolidation. The industry is experiencing more hospital mergers, GPO alliances, and medical device mergers and acquisitions than ever before. Medical device manufacturers need to better understand new and adapting customers, pricing strategies, and value propositions to larger institutions. Consolidation activity is driving prices down, and in turn lowering margins for device manufactures. As a result, many organizations are restraining revenue that would have otherwise been invested in R&D growth opportunities.

Regulatory Environment. The FDA’s UDI requirement, 510(k) approval changes, REACH, RoHS, and other components of the Affordable Care Act are here to stay.

Price Pressures. Medical device payer organizations have continued to drive down product pricing in the medical device industry, while also expecting better clinical outcomes for patients. This is a tall order to fill, with thousands of payer organizations across the globe creating thousands more individual organized contracts between payers and medical device institutions. The Centers for Medicare and Medicaid (CMS) are baseline drivers behind medical product pricing. The pricing set by CMS, along with the continued initiatives of the Affordable Care Act (ACA), does not bode well for anyone that is expecting these pricing pressures to alleviate.

Updraft Opportunities

Some organizations might argue that the increased industry pressure is merely a temporary phase that ebbs and flows with the status of the economy and regulator stringency. I could not disagree more. Medical device organizations need to work harder and smarter than ever before. They need to invest in new business models that bring value to their customers, they need to leverage growing technology opportunities in the global marketplace, and most importantly, they need to take a strong look at their NPD and portfolio management processes.

Here are some important opportunities to help offset the downdraft pressures:

- Explore alternative business models that leverage mobile/wireless technologies, telemedicine, and at-home patient care
- Build new product business cases around clinical and economic outcomes data
- Track patient outcomes and patient satisfaction data in a way that can be leveraged with payer organizations
- Implement and maintain a streamlined yet flexible new product development process incorporating needs from all customer segments (i.e. patients, payers, physicians, etc.)
- Do not underestimate the opportunity in the emerging global markets - the world is becoming smaller and smaller with mobile/wireless technologies and networks

While many organizations are twiddling their thumbs and blaming government and regulators for the current, pressure-filled environment, now is the time for action. Explore the global marketplace, leverage cutting-edge technology, and innovate your organizational processes. As Evan Godt stated, the results of the medical device excise tax “...should serve as a wake-up call.” Regardless of which updraft opportunities you take advantage of, investing in them now will help you get to the front of the pack.

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