

Medical Device Trends

In today's rapidly changing business climate, understanding the regulatory and demographic environment of the medical device industry is only part of the challenge. The real struggle for medical device companies is defining the right strategy, developing an appropriate business plan, and then efficiently executing against them. Firms that are able to adapt quickly, taking advantage of the transformative nature of the industry, will become inherent market leaders.

We will highlight four trends shaping the medical device industry, providing guidance on how medical device leaders can successfully navigate each.



Increased Regulation

Obamacare is being implemented in full force. How is your company responding?



Healthcare Provider Consolidation

With increasing consolidation, is your go-to-market approach changing?



Aging Population

Is your company aligned to take advantage of this megatrend?



Emerging Markets

This is both a threat and an opportunity. Is your company capitalizing on the opportunity?



Increased Regulation

With the increased involvement of industry stakeholders and consumer advocacy groups, along with widely publicized safety concerns and product recalls, regulatory agencies are being forced to act. Beginning with the Patient Protection and Affordable Care Act, the government's goal is to shift the focus of US health-care from quantity to quality. This tenet carries over into the modification of the 510(k) process, the end result of which will more effectively protect patients and promote the health of the public.¹ The recent UDI legislation furthers this protection, ensuring that devices are identifiable and secure at all points within the supply chain.

Patient Protection and Affordable Care Act (ACA)

In 2010, the Patient Protection and Affordable Care Act was signed into law, which included a \$20 billion dollar tax on the medical device industry. In 2013, a 2.3 percent excise tax on the total revenue of medical device companies went into effect. With the excise tax on revenue instead of profit, medical device companies are experiencing a significant increase in their overall tax burden.

Due to the high cost of R&D at start up, many smaller medical device companies will struggle to survive the taxation. While large medical device companies can rely on a range of products to provide a dependable revenue stream, there is concern that the medical device industry will begin to mirror the pharmaceutical industry's fondness for mergers and acquisitions.

510(k) Submission Process

One of the fastest and most widely employed regulatory paths for medical devices is the FDA 510(k). In reviewing the current 510(k) clearance process, the Institute of Medicine (IOM) found the current process flawed, and suggested

that the FDA develop a "regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle."² Involving industry stakeholders in the change process, the FDA is considering a range of policy options, including risk management, design controls, and risk-based stratification.

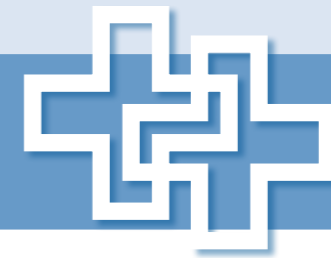
Unique Device Identification (UDI) System

The timeline for UDI implementation started on September 24, 2013, with compliance of all devices expected in 2020. The legislation mandates that most medical devices distributed in the US include a unique device identifier, which will not only allow the FDA to isolate product problems more quickly and ensure patient safety, but will also establish consistency and security for a global distribution network.

Navigating this Trend

- Familiarize yourself with the details of the regulation and the excise tax, understanding how they apply to your company
- Build an internal competency built on understanding new regulations, which will position your company to win in an increasingly regulated environment
- Seek acquisition opportunities where smaller, niche players may not have the resources to keep up with increased regulation
- Streamline current operating costs to maintain profit margins, allowing the flexibility to pursue key opportunities when they arise





Healthcare Provider Consolidation

In addition to increased regulation, another decade long trend is the consolidation of healthcare delivery. Hospitals are being acquired by major healthcare delivery organizations, and independent physicians are slowly joining these larger organizations. In an environment where margins are slim and government regulation is high, a larger size is beneficial, particularly if economies of scale can be gained. Representing this shift, the number of hospital mergers and acquisitions that have occurred over the past two years is at an all time high; additionally, the ratio of independent hospitals to hospitals in larger health systems has gradually decreased over the past ten years.

Evolving Sales Model

Healthcare providers are increasingly interested in providing high quality care at lower costs. To do so, many are working more closely with their group purchasing organizations (GPOs), while others are investigating the GPOs that provide the best value. Larger hospital systems lead to larger sales, so hospital financial organizations (e.g., CFOs) will begin to have more weight in supplier selection. With this transition, sales personnel will need to understand and clearly articulate the clinical value and financial impact of their devices.

Due to this consolidation, the selling approach of medical device companies will continue to evolve. Sales organizations will shift their focus from building relationships with individual physicians to a more value-driven model – one that directs sales conversations to the GPO. Additionally, account planning is becoming more prevalent, and leading firms are investing in tools and methodologies that will support strategic, as opposed to transactional, selling.

Decreased Margins & Increased Competition

Medical device companies are also likely to realize falling margins on medical devices, due to pricing pressure from larger healthcare providers and GPOs that are purchasing in bulk. With independent hospitals joining larger systems, the customer pool for medical device companies will decrease. This will increase industry competition, potentially driving hospitals to demand more, such as improved levels of support and trial periods for healthcare products.

Navigating this Trend

- Research and develop concise models that directly tie products and services to measurable health outcomes
- Leverage existing contacts to develop better relationships with larger healthcare providers and payers
- Invest in hiring personnel with strategic selling skills, which will facilitate proactive organizational account planning and team-based selling
- Invest in tools, methodologies, and sales processes that support strategic selling





Aging Developed World Population

From 2000 to 2011, the population over the age of 65 in the United States has increased 18 percent from 35 to 41.4 million.³ This trend is consistent across the more developed areas of the world, with the percentage of the population aged 60 years or over expected to increase from 23 percent to 32 percent by 2050. When examining these countries as a whole, in fact, the 60 and over population has already surpassed the youngest cohort (15 years and younger), and will only increase over the coming years.⁴ Globally, aging populations will continue to drive demand for medical devices. However, this increase is not likely to result in the standard diversification of the purchasing population, which is normally seen in consumer products.

Telemedicine

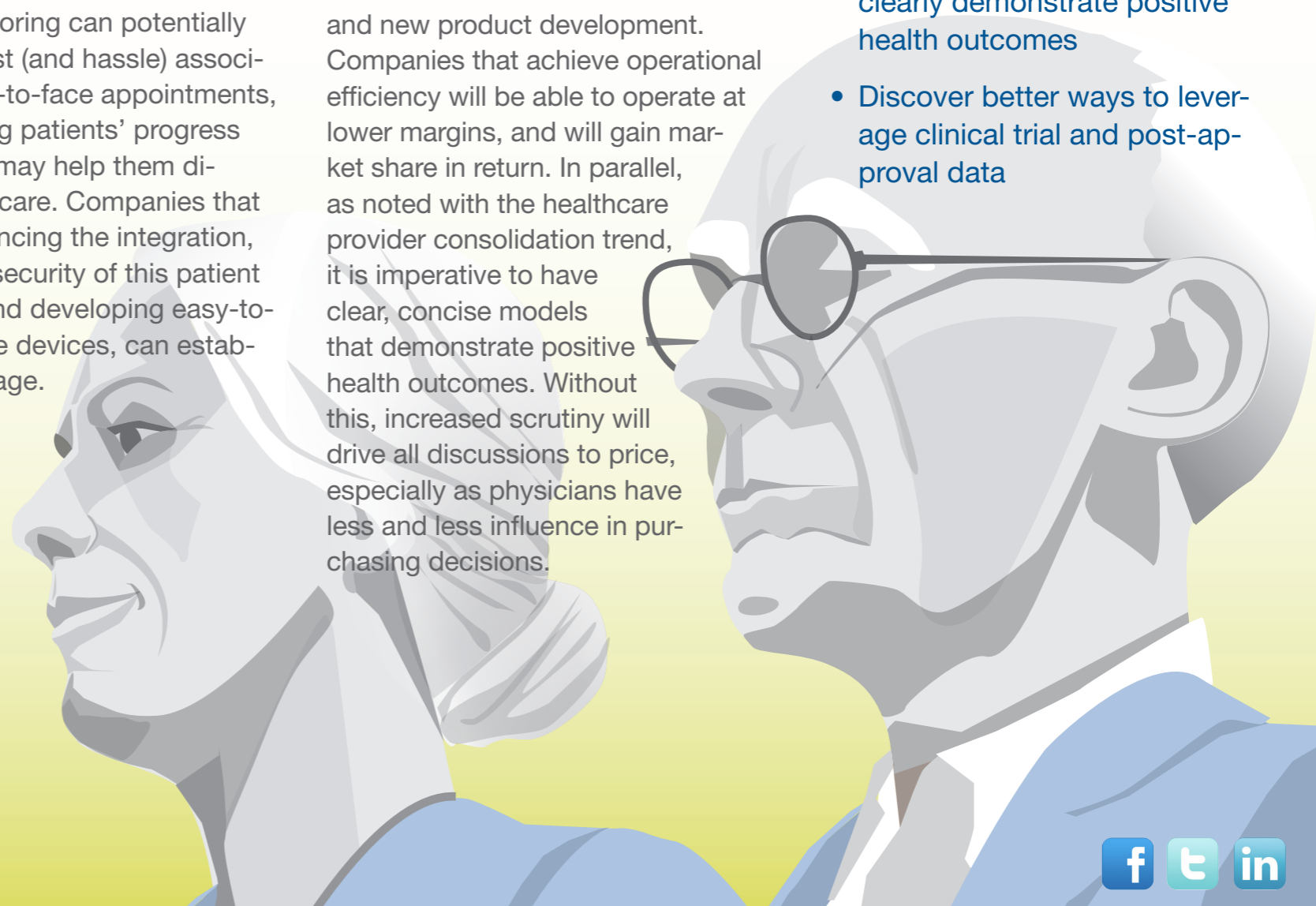
Telemedicine has gained traction by dramatically improving access to clinical care and reducing Emergency Department (ED) visits for some of the world's most vulnerable populations. Increasingly, similar technologies are being developed and used to manage chronic diseases and disorders in the elderly, along with tracking vital signs, sleep patterns, or medication use. Telemonitoring can potentially reduce the cost (and hassle) associated with face-to-face appointments, and by tracking patients' progress in real time, it may help them direct their own care. Companies that focus on advancing the integration, analysis, and security of this patient information, and developing easy-to-use, interactive devices, can establish an advantage.

Government-Subsidized Healthcare

Due to government-subsidized healthcare for the elderly, a larger portion of medical device spending will come from the government – and at lower margins. Justification of health outcomes is the only way that companies will be able to protect their margins while continuing to make crucial investments in research and new product development. Companies that achieve operational efficiency will be able to operate at lower margins, and will gain market share in return. In parallel, as noted with the healthcare provider consolidation trend, it is imperative to have clear, concise models that demonstrate positive health outcomes. Without this, increased scrutiny will drive all discussions to price, especially as physicians have less and less influence in purchasing decisions.

Navigating this Trend

- Develop products in areas that target aging populations, such as telemedicine and wireless
- Invest in operational efficiency to maintain profitability in higher volume, lower margin environments
- Invest more heavily in patient research to create models that clearly demonstrate positive health outcomes
- Discover better ways to leverage clinical trial and post-approval data



Emerging Markets



Many medical device companies are turning to emerging markets like China, Brazil, and Mexico, to create consistent, single-digit revenue growth. With China's 2020 goal for universal health-care, the market in China has grown substantially. In close proximity, Mexico offers another promising trading partner for U.S. medical device companies because of North American Free Trade Agreement (NAFTA) regulations and medical tourism. As the demand for medical devices grows in these emerging markets, U.S. companies can leverage their brand position, but must be wary of varying regulations and business procedures.

China

China is the third largest market for medical devices in the world, and is expected to rise to the second largest in the next few years, importing the largest portion (31 percent) of medical devices from the United States.⁵ Although local medical device companies have joined the competitive landscape, consumers in China are willing to pay a premium for western brands, as they view them as higher quality, more dependable devices. When seeking to enter the Chinese market, however, companies should be aware of the business landscape, which can present a range of regulatory hurdles and preference towards state-owned enterprises (SOE).

Mexico

As the Mexican economy grows, local hospitals and clinics are increasing their demand for quality products. Additionally, due to lower pricing, more people are crossing the border into Mexico to have medical procedures completed. Since Mexico does not enforce high tariffs or importation licenses requirements for every shipment, like Brazil, the country continues to attract U.S. medical device companies. U.S. medical device companies also have a competitive advantage because their brands signify high quality, positive after sales service, and reasonable price points compared to products of similar quality from other countries.⁶

Navigating this Trend

- Be prepared to rethink current business models and distribution strategies, as they may not be ideal in new markets
- Consider how to best relate to local R&D, talent and potential business partners, as establishing local operations may be a requirement for winning government tenders
- Capitalize on the reputation of U.S. medical device companies in emerging markets to maintain target profit margins
- Consider how your products will compete with, or complement, local products, and how to interact with local competitors and R&D



Continue the Discussion



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Increased Regulation

- Insights Paper: FDA's Medical Device Marketing Clearance Process
- What's Next for UDI? Webinar



Healthcare Delivery Consolidation

- Case Study: Sales Reporting and Analytics Solution
- Case Study: Smooth Transition and Better Planning with SAP BPC



Emerging Markets


- VIEWpoint: Optimizing Financial Planning and Consolidation for Global Expansion

References

- 1 Institute of Medicine. Public Health Effectiveness of the FDA 510(k) Clearance Process. 2013.
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- 5 The American Chamber of Commerce in Shanghai. "Healthcare in China: Diagnosing the Challenges and Opportunities in the China Market." 2011.
- 6 International Trade Administration. Medical Devices. 2012.

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