CLARKSTON CONSULTING

2015 Medical Device Trends

The value-based healthcare model is pushing life science companies towards precision medicine, which requires extensive data analysis, technology integration and industry collaboration. Within the medical device industry, there are notable partnerships forming between diagnostics and Big Pharma, device companies and tech and biotech, and small and medium-sized organizations looking for scale and negotiating power. As the use of wearables, mobile medical applications and patient monitoring devices increases, leading companies will determine how to strategically address data management and security, and regulatory uncertainty, while driving innovation.

01 | STRATEGIC PARTNERSHIPS

The industry saw the largest number of acquisitions last year since 2011, as medical device companies focus on developing their product portfolios globally with new and innovative technologies.[1] As our healthcare system increases in complexity, the growing power of Group Purchasing Organizations drives M&A activity among small and mid-size medical device manufacturers who want to strengthen price negotiation positions. Hospitals will utilize economies of scale to ensure best prices, causing smaller manufactures to face downward pricing pressures and smaller margins.[2] Additionally, as consumers embrace the digital health movement, industry partnerships between medical device, tech and biotech companies will only increase.[3]

02 | DIAGNOSTICS & BIOTECHNOLOGY

With the focus on precision medicine, the dynamics between diagnostics and biotechnology is evolving. Previously, diagnostics were just used to identify which patients have a disease; now, they can forecast the progress of a disorder and identify which patients are most likely to respond favorably to a particular treatment. Many global pharmaceutical companies are incorporating diagnostics early in the R&D process to improve therapy development. In the field of oncology, Thermo Fisher Scientific and Illumina are working with Big Pharma to develop next-generation sequencing (NGS)-based companion diagnostics; Thermo Fisher is collaborating with GlaxoSmithKline and Pfizer,[4] and Illumina has announced partnerships with Merck, AstraZeneca, Sanofi and Janssen Biotech.[5]

03 | DATA & ANALYTICS

Device performance and patient data are more easily available to healthcare providers, improving patient monitoring and the overall quality of care. Medtronic, for example, launched a tool in 2010 that augmented their cardiac devices to securely transfer device data to doctors.[6] In addition, companies are integrating and sharing medical device data with their internal ecosystems (e.g., EMR) and partners to improve transparency and collaboration.[7] As this shift occurs, disparate data types and systems will require additional data processing ahead of analysis. And, as consumer wearables become more commonplace and data volumes increase,[8] companies must consider proper data management, warehousing and security.

04 | WEARABLES & MOBILE MEDICAL APPLICATIONS

In 2014, there was a 125% increase in digital health investments, including health monitors, glasses and wearables. While these devices are overwhelmingly marketed to track personal health and activity, they are critical tools for remotely monitoring chronic illnesses and the safety of children and the elderly. Much of the innovation in this space has come from technology companies unfamiliar with the healthcare landscape, which do not have experience managing time-consuming and costly regulatory processes. While the FDA has released some guidance for low risk devices and mobile applications, they have been unable to keep pace with these advances.[9,10] As such, regulatory uncertainty and data security remain primary concerns.

05 | THERAPEUTIC VALUE

Providers and payers are turning to therapies with proven patient data to determine which treatments and devices to utilize. Medical device companies that excel in this landscape will realize new ways to prove their value. DePuy Synthes (a Johnson & Johnson subsidiary), for example, has launched a health and wellness platform that leverages direct consumer interaction to improving patient outcomes. The Patient Athlete program helps joint replacement patients better manage pain reduction before and after surgery. Through video-based training, patients said they felt quicker recovery times and increased confidence.[11] Other companies are partnering with health providers and academia to develop, track & measure therapeutic value.

06 | MEDICAL DEVICE TAX

Republicans are currently a majority in Congress and a large number of Democrats hail from states heavily supported by the medical device industry.[12] As such, the two-thirds vote required to override a veto seems possible. The delay seems to be deciding on the source of the lost tax dollars. States caught in between are resorting to creative solutions like covering the federal tax with a state tax credit. While the possibility of repeal seems positive, there is uncertainty around the actual timeline; so, companies should continue to budget for the tax until a decision is clear. To bridge the revenue gap, some companies are increasing their focus on emerging markets.

References

1 Silicon Valley Bank Financial Group. “Trends in Investments and Exits 2014.” Revised July 2014.

2 Son, Anna. “Manufacturers Brace for the Impact of Healthcare Reform.” IBISWorld. April 9, 2014.

3 Hartford, Jamie. “5 Medical Technologies to Watch in 2015: Mobile Medical Apps.” Medical Device and Diagnostic Industry. December 15, 2014.

4 Lawrence, Stacy. “Thermo Fisher to develop ‘universal’ oncology companion diagnostic with GSK, Pfizer.” FierceMedicalDevices. September 25, 2014.

5 “Illumina Announces Strategic Collaboration with Merck Serono to Expand Companion Diagnostics for Oncology.” FierceMedicalDevices. March 10, 2015.

6 “Medtronic Launches New Cellular Accessory for the Medtronic CareLink® Network.” Medtronic website. May 10, 2010.

7 The Economist Intelligence Unit. “Value-based healthcare: The implications for pharma strategy.” March 2014.

8 Davies, Michael. “Wearable Tech Can Extend Clinical Analytics.” InformationWeek. August 12, 2014.

9 U.S. Department of Health and Human Services Food and Drug Administration. “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff.” February 9, 2015.

10 U.S. Department of Health and Human Services Food and Drug Administration. “Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff.” February 9, 2015.

11 Lawrence, Stacy. “J&J launches wellness platform with DePuy pain reduction program.” FierceMedicalDevices. February 27, 2015.

12 “The Medical Device Industry in the United States.” SelectUSA website.

CLARKSTON

Headquarters
2655 Meridian Parkway
Durham, NC 27713
Phone: 800-652-4274

