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Full Steam Ahead On Medtech Value-Based Business Models

by David Filmore

Federal health-care policy in the US, at least, is potentially in for a major transition, but that is not having much of an impact on the fundamental business models of medtech firms and their ever-accelerating focus on value-based and risk-sharing business models. Emphasis on value strategies was a significant medtech theme at this year's JP Morgan Healthcare Conference bonanza.

US health-care policy is headed for some potentially big changes, but that is not causing medtech executives to signal big changes of their own to how they approach the market. In particular, industry's move to adopt new value-based business models seems to be continuing at pace, according to interviews and comments at the JP Morgan Healthcare Conference and satellite meetings in San Francisco last week.

Not only is the Affordable Care Act under threat of repeal under the incoming Trump administration, but some payment and delivery reforms that have been rolled out by the US Centers for Medicare and Medicaid Services in recent years are vulnerable, as well. Those CMS reforms force the hands of health-care providers to adopt practices that reduce costs, and maintain or improve outcomes.

Tom Price, the Georgia Republican congressman who has been nominated by President-elect Trump to run the Department of Health and Human Services, is a vigorous opponent of these types of mandatory programs, including the recently launched bundled, episode-of-care payment programs for joint replacements and cardiac procedures. (Also see "*Fierce Critic Of Obamacare, Medicare Delivery Reforms Tapped To Run HHS*" - Medtech Insight, 29 Nov, 2016.)

But these political signals are not changing plans by device firms to bet big on the types of

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incentives that such payment reforms create. This is because the push away from volume-based care to value-based approaches are already sufficiently entrenched in the health-care market. And it is a global trend, so the market impact of any policy adjustments in the US is muted.

J&J's *CareAdvantage*

Case in point, *Johnson & Johnson* announced on Jan. 10, the first day of the JP Morgan meeting, a new branded offering of value-based service offerings and risk-sharing opportunities for hospitals for its entire medical device business. The *CareAdvantage* program is designed to offer hospitals a clear opportunity to contract with J&J, not just as a supplier, but to provide services that allow use of its devices and after-discharge care in a more efficient and effective manner.

> *"There are three things that are raised around the foundation of the Affordable Care Act … the 'triple aim' of improving patient outcome, improving patient satisfaction and improving cost," J&J's Gary Pruden says. "Those truths will happen no matter what administration is in power."*

Specifically, the firm cited the current HHS goal to have 90% of Medicare fee-for-service payments directed toward value-based purchasing approaches by 2018. A particular set of services J&J is offering for orthopedic procedures responds directly to CMS' recently launched *Comprehensive Care for Joint Replacement* (CJR) and the *Surgical Hip and Femur Fracture Treatment (SHFFT)* bundled-care models, which put providers on the financial hook for the cost and quality of episodes-of-care, extending from a procedure through after-hospital rehabilitation. (Also see "*Cardiac Care Bundled Pay Models Preserve New Tech Add-Ons, But Still Make Medtech Nervous*" - Medtech Insight, 5 Jan, 2017.)

"There are three things that are raised around the foundation of the Affordable Care Act ... the 'triple aim' of improving patient outcome, improving patient satisfaction and improving cost. Those truths will happen no matter what administration is in power," Gary Pruden, worldwide chairman of J&J's medical device business, told *Medtech Insight* in an interview during the JP Morgan meeting.

"Offering solutions that help solve those basic three problems are going to be an opportunity no matter what happens," he stressed.

CareAdvantage is J&J's effort to bring together the service capabilities of its vast businesses under a coordinated, branded framework. It's intended as a go-to mechanism for hospital systems to engage with the company as more of a strategic partner, Pruden explained.

To illustrate, he described a meeting he had with the CEO of a large US hospital system several years ago. "The CEO said, 'You know, until today, I never realized that J&J was our largest supplier,'" Pruden relayed. "He said, 'In the past you came at me with 20 different brands of individual companies. If I actually knew that you were my largest supplier, maybe we could have worked together in a different way. Maybe we could think about how we become partners.'"

Under CareAdvantage, J&J will work with interested hospitals in coming up with solutions to improve care efficiency and effectiveness, potentially across its orthopedic, surgery and cardiovascular device businesses. But the firm is laying out the most details about its offerings in the orthopedic space, where its program is designed to match up with the recently launched Medicare bundled-payment programs. J&J says it can offer hospitals pre- and post-orthopedic surgery services, including a cloud-based digital platform, to help guide patients through surgery and recovery; Depuy Synthes' *Patient Athlete*coaching-based program to prepare patients for surgery; data analytics support for tracking patients' hospital and post-discharge episode-of-care; infection risk management support; and hip-fracture care.

J&J will also enter into risk-sharing agreements specifically linked to the bundled-payment spending and quality targets set by the new CMS programs.

Breadth And Scale

Pruden says the breadth and scale of the J&J device business is a core factor in making the CareAdvantage program attractive to hospitals. Because the firm is the No. 1 or 2 supplier for many customers, it is worth their while to arrive at the most efficient way to employ those products. Also, he says the experience J&J has in its other businesses – in particular, the consumer business – contributes to its value-based offering.

"We are looking to leverage some of the learnings that we have from our consumer division in how we can engage patients in a better way," Pruden said.

J&J is, of course, not alone among the larger medtech firms in making a shift to value-based models. *Medtronic PLC* has emphasized its transition to a solutions-based company for several years, and, in 2013, it launched a dedicated Hospital Solutions business unit, principally to contract with hospital cath labs, to improve efficiency. In November 2016, Medtronic *inked its first Solutions agreement* in the US, with the Cleveland-based University Hospitals system, with a focus on implementing new models to optimize workflow in the system's cath and electrophysiology labs.

The other big players are accelerating their emphasis on these approaches, as well.

Robert Ford, who heads *Abbott Laboratories Inc.*'s medical device business, which *just expanded greatly* to include *St. Jude Medical Inc.*, says risk-sharing has become routine among medtech players, and he doesn't expect that to change.

> ***"You do need to surround disease states with a service and a value proposition that goes just beyond, 'Hey, I've got this great device that all of your implanters and surgeons really want to use,'" says Robert Ford, Abbott's device business head.***

"I don't think it's extremely differentiated that you're saying to a customer, 'Listen, if you don't get this outcome, I'll give you ... 45% of the cost back,'" Ford told *Medtech Insight* at JP Morgan. "From a differentiation standpoint on that value-add, I think there are other elements that will be important here."

He noted: "I think you do need to surround disease states with a service and a value proposition that goes just beyond, 'Hey, I've got this great device that all of your implanters and surgeons really want to use.'"

Abbott's acquisition of St. Jude provides new opportunities for the company to target those types of opportunities, he suggested. For instance, he explained, Abbott can work with hospitals to improve overall care of heart-failure patients by bringing together the combined firm's technology and know-how in cardiac resynchronization therapy, heart-valve repair, ventricular-assist devices and *CardioMEMS* remote monitoring.

Ford said Abbott will also be exploring opportunities in multiple businesses to offer services to hospitals, leveraging the vast quantities of data produced by the firm's devices.

Not Just For Big Medtech

But it is not just the big companies that are accelerating efforts toward value-based models. Industry experts say it is crucial for small, mid-sized, and large firms alike to understand the full value proposition for devices in development and use that understanding to drive how they approach customers. That has not historically been standard practice in industry.

One start-up that is making this approach central to its business model is Bruin Biometrics, a wireless sensor-focused device firm founded out of the University of California, Los Angeles, in 2009.

"We develop sensors ... for areas that are very deficient in diagnostic standards," CEO Martin Burns told *Medtech Insight* during a discussion at the JP Morgan conference. The firm's first focus is in wound care; specifically, pressure ulcers.

Bruin's *SEM Scanner*, available in Europe, is a handheld, portable device that assesses the layers below the skin to detect changes in sub-epidermal moisture (SEM), a biophysical marker of tissue damage. The idea is to identify previously unspecified pre-stages of pressure ulcers before they reach the level of being more difficult and expensive to treat.

The firm says it is having early success with risk-sharing agreements in places like the UK, and it is about to expand on that approach in a big way. By the end of the month, Bruin plans to announce a risk-sharing agreement with a UK health-system partner that will include 60,000 to 80,000 patients. "We are very much putting our skin in the game," Burns said.

> *"Some of the policies we enjoy the benefit of sits underneath the Affordable Care Act. Most of it, however, doesn't," says Martin Burns, CEO of Bruin Biometrics.*

The firm plans to take the same basic approach in the US. Bruin is going to submit for FDA approval under the *de novo* pathway by the end of the current quarter and plans to be on the market in 2017. Burns acknowledges that there are differences in the US market and that a shift is coming with the Trump administration that his firm will need to monitor closely. But similarly to J&J's Pruden, he says the fundamentals will stay the same.

"Some of the policies we enjoy the benefit of sits underneath the Affordable Care Act. Most of it, however, doesn't," Burns said. For instance, pressure ulcers in stages three and four are designated as "never events," meaning Medicare won't pay to treat when they are acquired in a hospital. That policy came before ACA, and he doesn't believe it is going away.

"The other part that is not under jeopardy," Burns said, "is that, if you are negligent, you should pay for your own negligence. There is a focus on not having certain events occur within a care setting, and I can't see that changing."

Value-Based Roadmap

But not all companies, in particular, start-ups, are as prepared to address these types of value-based incentives. AdvaMed says it is trying to improve that situation. The device trade group is currently putting the finishing touches on two "value frameworks," one for medical devices and another for diagnostics.

Andrew Fish, who runs the AdvaMedDx arm focused on diagnostics, spoke about the tools, which the group plans on releasing soon, at the Medtech Showcase meeting Jan. 10 in San Francisco. (Medtech Showcase is run by EBD Group, an Informa company. Informa also publishes *Medtech Insight*.) He says they will be practical roadmaps designed to help firms think about the value proposition for their products, starting in the R&D phase, and how that value can be presented to different stakeholders, including patients, clinicians and hospitals.

"What we have seen is some manufacturers have historically brought products to market because they could, they had the technology, the ability to iterate ... but they had not necessarily thought enough about what the ultimate clinical value of that was," Fish said. "The value framework that we put together really helps companies state vigorously from the very beginning what the value of the product is and how to demonstrate it, long before you get to that point of trying to get market traction."

AdvaMed traditionally has focused its efforts on changing government policy, which it will continue to do, but its work on the value frameworks is another sign pointing to the importance of incentives coming from the health-care system and private payers in setting market dynamics, Fish suggests.

"This value framework is in part an exercise in communicating to a wide range of stakeholders in the private marketplace, Fish said. "That is really a change in perspective for us, because it is a recognition that that is one of things our companies are grappling with."

From the editors of The Gray Sheet