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India's Simmering Device-Pricing Controversy – Many Hues

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India's recent regulatory action to rein in the prices of coronary stents seems to have left the medical devices segment nursing some bruises. However, there are fears that more of such action may be brewing for industry.

Part of the apprehension appears stoked by recent diktats, including a note by India's health ministry to the Medical Council of India (MCI), in response to concerns of the National Pharmaceutical Pricing Authority (NPPA) over supplies and the use of coronary stents. Furthermore, a recent data gathering effort by the NPPA to monitor the price movement of 19 medical devices seems to have piled on additional pressure on industry. *(Also see "India's Stent Price Slash Creating Climate Of Fear, Foreign Device-Makers Say" - Medtech Insight, 15 Mar, 2017.)*

The NPPA had in February this year informed the health ministry that industry, hospitals, distributors and certain cardiologists "might try creating an artificial short supply" of coronary stents citing the low ceiling price set, details in the health ministry's note to the MCI dated March 16 said. The note, which appears to have been received by the NPPA around mid-May, was uploaded by the price regulator on May 22.

"It has also been noticed that certain hospitals are providing lower valued stents to patients, while billing them at NPPA-notified prices which may lead to denial of the price benefits to needy patients and may result in health risks and some cardiologist may resort to multi-stenting or converting angioplasty cases to bypass surgeries," the health ministry's March 16 note said.

The ministry urged the MCI to issue a circular to all the medical colleges, State Medical Councils and the Indian Medical Association "to arrange for strictly adhering to the visions of the gazette notification" pertaining to the capping of prices of stents.

"The Council may also issue a notification/order for medical doctor[s] in general citing the relevant provision of the ethics regulation," it added. The MCI's response to the note could not immediately be ascertained.

NO SHORTAGE?

In February this year, the NPPA capped the prices of stents in India in two broad buckets – bare metal stent prices were capped at INR7,260, while prices of drug-eluting stents (DES) including metallic DES and bioresorbable vascular scaffold (BVS)/ biodegradable stents were capped at INR29,600.

Abbott Laboratories Inc., **Medtronic** and **Boston Scientific Corp.** had subsequently sought to pull out certain stent

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MIXIII BIOMED 2017:

Aging, Technology & Robotics In The Digital World

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People worldwide are living longer with 30% of the population in developing regions expected to be aged 60 or over by 2050. So what challenges and opportunities will this rapidly aging population provide for the healthcare system? Israel's life sciences and technology conference, MIXiii Biomed, held on May 23-25 in Tel Aviv, brought together companies, investors and academics to explore the impact of an aging population on healthcare.

First day discussions opened with how medical technology can offer solutions for the elderly. Former president of Intel Israel Shmuel Eden told the audience in his keynote address how technological advances could enable independent living for the elderly at a reduced cost compared to hospital care. He said healthcare costs in the hospital and care homes were not sustainable in an aging population and companies had a huge opportunity to address this need.

Eden joked that the increased availability of wireless implantable devices such as pacemakers, insulin pumps and gastric stimulators will see humans turn into "cyborgs." He posited in the future we could see chips embedded inside people to aid them in carrying out everyday tasks and how eventually we will have a "brain-computer interface," with the internet functioning as an extension of the human brain. "The technology is already there," said Eden. The question now is how do we implement it in an ethical fashion, he said.

Robots will also make aging easier, according to Eden. "A robotics population will complement an aging population by supporting the economy and providing care for the elderly," he said. Home care robotics formed one of the central themes of the second day's discussions, with companies presenting innovations designed to allow elderly citizens to stay at home longer and enable their families and caregivers to track their health remotely.

However, conference participants heard that many elderly people could find their user experience of robotics and digital health "frustrating." Intuitive use of digital technologies was more difficult to achieve for older users due to decline in motor and cognitive abilities and less cultural expectation and motivation to use them said Tamar Weiss, head of the laboratory for innovations in rehabilitation technology at Haifa University, Israel. She suggested companies needed to collaborate with the elderly to improve design and robotic devices should "complement human therapists" and be used within the context of an array of treatment techniques, including wearable sensors, and virtual reality. She explained it was important to increase personalized use and tailoring therapies and assistance to individuals.

Digital health start-ups presenting included, Kytera Technologies which is developing a remote monitoring system for elderly living at home. The system is based on "contextual activity analysis," which uses advanced machine learning algorithms and sensing technology to learn the routine of seniors at home to detect deviations from the routine and distress situations. Assaf Sella, Kytera CEO, said more seniors than ever were now living alone but needed tools to permit independent living in a safe environment. Kytera's technology consists of a wristband worn by the senior and sensors that are installed around the home which can then send alerts to family members remotely.

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Medtech M&A activity is at an all-time high and 2017 is on pace to be the third consecutive year with 10 or more transactions worth more than $1bn. Pre-commercial device M&A activity was also staying relatively steady, with cardiovascular, ophthalmology and orthopedic sectors experiencing the most activity, says Gil Bar-Nahum, Jefferies.

MEDTECH M&A ACTIVITY AT ALL TIME HIGH

On the commercial side of medtech, Jefferies managing director Gil Bar-Nahum told the audience despite market uncertainty, the

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Gifts For Industry: From Waived Inspections To Pre-Market Leeway, US FDA Woos Firms For Maturity Pilot

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"We want to do this pilot program so we can have increased confidence in a firm, that they are doing more than meeting the regulatory requirements and checking the boxes, if you will, in terms of meeting [FDA's] Quality System Regulation and other reporting requirements," CDRH's Sean Boyd says.

From putting off regularly scheduled facility audits and waiving preapproval inspections, to allowing more leeway for 30-day notices and pre-market submissions, US FDA wants to hand a huge gift basket to medical device-makers that voluntarily play in an upcoming pilot program.

The pilot, which aims to determine the manufacturing maturity of firms, will be stood up in early 2018. Manufacturers that take part would use a specified maturity model and work with third-party assessors to measure their quality systems and manufacturing processes. That data would then be shared with the agency, which would use the information to help shape its regulatory, compliance and enforcement decisions.

"We're engaged with MDIC right now … on using maturity appraisals to identify firms that are focused on continuous process improvement, customer service, and going above the compliance baseline," said Sean Boyd, deputy director of the Office of Compliance within FDA's device center, at a May 2 Case for Quality Metrics Workshop in Cincinnati hosted by the Medical Device Innovation Consortium (MDIC) and Xavier University.

"Maturity" in the context of manufacturing means that companies have adequately developed practices and processes to ensure that quality is pervasive throughout their organization. Conducting self-assessments using a maturity model can uncover quality baselines for where firms should be in relation to their peers in industry, and provide other types of useful information. And conducting assessments via a third party can make the data even richer, the agency says.

"Over the course of 2017 we're focused on developing this voluntary pilot program that will recognize independent assessment of manufacturing product quality through use of the CMMI maturity appraisal process," Boyd said.

Capability Maturity Model Integration, or CMMI, is software that allows companies to appraise where they fall on a five-tiered maturity scale. Under CMMI's scale, "1" denotes so-called "heroic efforts" by a beginner firm, and "5" signifies that a manufacturer is a self-correcting organization that effectively manages quality and is continuously improving. (See "The CMMI Model," below.)

FDA will formally announce the pilot program in December. But it will first hold a public meeting about it in August.

"We really see 2018 as the year where we begin to collect data and see what information we can get from maturity appraisals, and how we might use those results to inform metrics and other key performance indicators that are going to be strong indicators of quality within manufacturing or within the design processes at a firm," Boyd explained, noting that the agency will continue throughout next year to nudge manufacturers to use CMMI and join the pilot program.

"By 2020 we hope to have this program fully operational, where it becomes a regular part of how we interact with industry," Boyd said. By that time, he hopes that "industry views using maturity models … for the purpose of not only meeting regulatory requirements for FDA, but that they also see the value in focusing on maturity as a business organization, as well."

He said FDA is proposing a "regulatory paradigm shift" by leaning on maturity assessments to help make better compliance and enforcement decisions.

"We want to do this pilot program so we can have increased confidence in a firm, that they are doing more than meeting the regulatory requirements and checking the boxes, if you will, in terms of meet-

ing [FDA's] Quality System Regulation and other reporting requirements," Boyd said.

"What are firms doing that allow them to detect problems early and take preventative actions to address them as they are occurring?" he wondered. "Well, if we had access to that data, then we would have additional confidence that would change the way we interact with a particular firm."

Robin Newman, director of CDRH's Office of Compliance, agreed with Boyd's assessment.

"We're looking for tangible objectives, measurable data that tells us that the company is doing the things they need to do to give the agency a high level of confidence in their performance," Newman said. That way, "we can put our energy and efforts on the companies where there are more problems, where the products are not working well, or where patients are not being satisfied, or frankly, they're being harmed."

FDA would use third-party CMMI assessors to determine the maturity of volunteering firms.

"The idea is to develop a third-party assessment, so it's not FDA going in and assessing, and it's not a company assessing themselves," Newman said. "So the company would engage and allow us to get that third-party assessment to look at how they're doing, and over time, as we work together, [the agency] would gain a great deal of confidence in the companies and their ability to respond proactively to their quality systems."

Newman says the maturity model initiative will probably never be mandatory for manufacturers.

"Companies that want to reap some of the potential benefits of raising their confidence level and demonstrating a high-maturity quality system – those are the ones that will benefit" from the maturity model pilot, she said.

Newman is concerned, though, that small device-makers with less robust quality management systems could become lost in the shuffle.

Because of that, "we're trying to make sure we've figured out by 2019 or 2020 a way to engage with smaller companies, which is the majority of the device ecosystem, frankly. We need to figure out: How do we engage with these smaller companies? What tools will we maybe have created by then that can be of use to [small firms] that will help them do the things that are necessary to be successful?" she said.

Large companies will likely benefit the most in the pilot's early stages, Newman conceded.

Nevertheless, "we need to make this something that all companies can engage in," she said. "All companies can benefit from the ability to create a system that gives the agency enough confidence that we, frankly, are just not going to focus on you," like it would a company with clear quality system troubles.

Newman's comments on the maturity model pilot came May 3 at MedCon 2017 in Cincinnati, and March 28 at the 14th Annual Medical Device Quality Congress in Bethesda, Md.

Maturity Pilot Incentives

- Removal from US FDA's work plan for routine facility inspections
- FDA pre-approval inspections waived where appropriate
- Engagement and meetings between the agency and industry to resolve issues
- Modification of pre-market submission requirements and faster pre-market responses from FDA
- Accelerated pre-market approval path
- Competitive market around product excellence

Source: US FDA

"What if firms could do better? What if the device sector could have the same kind of reliability that's demanded, say, in the aerospace industry, where failure is absolutely not an option?" Newman says.

GOODIES GALORE FOR PARTICIPATING FIRMS

CDRH's Boyd believes maturity assessments will help drive the agency's regulatory decisions and yield a faster time to market for products. But shipping new devices to store or hospital shelves more quickly wouldn't be the only benefit for firms taking part in the pilot program.

FDA would drop pilot participants "from the routine agency work plan for surveillance inspections, such that if [firms are] participating and … engaged with CMMI, and are having maturity appraisals that are a good indicator of where they are in the process with respect to quality and compliance, we would remove them from our surveillance work plan knowing that they're working toward that goal," Boyd said.

Under the maturity pilot – and eventual program – the agency would also waive preapproval inspections for device-makers with a high level of manufacturing maturity, and engage with troubled companies rather than quickly dashing off a warning letter or using some other type of enforcement.

"When we identify problems with particular firms, we might look to take interactive approaches as opposed to traditional regulatory approaches," Boyd said. "So, instead of sending a warning letter or an untitled letter, we would sit down and engage with [the firm] specifically to hear, what is the issue, what are the steps [it is] taking to address the issue, and what is the plan to resolution, as opposed to taking more traditional regulatory approaches for resolving issues once they're identified."

Further, "for firms that are engaged in this program, we would look to allow

[them] to presume [FDA] approval for a manufacturing site change or a 30-day notice, specifically so they don't have to wait for FDA to review and make that decision," he said. "We've talked with several members of industry who see real value in that type of a regulatory change, where [firms] can immediately make the changes that they anticipate, so long as [FDA has] the confidence that [those firms] have the processes in place, the systems in place, to make those changes well."

But wait – there's even more for pilot program enrollees: "There may be other things we can do that we'll be looking at in the last half of this year with respect to 510(k) and other pre-market submission pathways, where we might be able to accelerate approval or not request certain types of data, so long as we have that information accessible elsewhere or have confidence in your ability to provide that and collect that information," Boyd said.

The agency is offering the incentives with an eye on making manufacturers aware that there's a return when they invest in above-par quality systems and processes.

"It's a business decision at that point, not only for promoting patient safety, but for identifying yourself as a leader within industry that is able to proactively address and identify those customer service issues that you have to meet," Boyd said.

THE CMMI MODEL

Developed in the 1990s by Carnegie Mellon University's Software Engineering Institute in Pittsburgh, and now administered by the CMMI Institute, CMMI is based on the Capability Maturity Model. CMM was also developed at SEI-CMU – by software engineer Watts Humphrey – in 1988.

In 2013, when FDA first bandied about the idea of using maturity models in industry, the agency eyed using the Quality Management Maturity Grid. That approach, created in 1979, ranks manufacturers on their ability to meet quality requirements, but it was eschewed by FDA in favor of CMMI. *(Also see "Measuring Manufacturer Maturity As A Quality-Improvement Tool" - Medtech Insight, 13 Nov, 2013.)*

"MDIC did a lot of research when we first propositioned it to think about what would be the best assessment tool out there. There's a varied amount of assessment maturity tools that are available," Francisco Vicenty, a program manager in CDRH's compliance office, said at the May 2 Case for Quality Metrics Workshop.

> "I'm not asking you to change all the things that you put in place to comply. I'm asking you to look at, is it working well for you?" CDRH's Francisco Vicenty says.

"There was an assessment and evaluation done, and for the purposes of what we wanted to do, [CMMI] was the most flexible. So, this is the one we chose to start with," Vicenty said. "Now, that doesn't mean that as the program evolves there might not be potential for more incorporation [of different maturity models], but we have to start learning somewhere, and [CMMI] gave us the best flexibility to get there."

The five maturity levels of CMMI are:

1. **Initial** (processes are unpredictable and not controlled)
2. **Managed** (processes are reactive)
3. **Defined** (processes are proactive)
4. **Quantitatively Managed** (processes are measured and controlled)
5. **Optimizing** (continuous process improvement)

"'Heroic efforts' is how Level 1 is referred to – the company is just trying to get a product out the door. It doesn't have a quality system, frankly, at that level," CDRH compliance chief Newman said. "Most companies are probably functioning somewhere around Level 3 if they've been around for a while, which means they have a good, reliable quality system, *et cetera*.

"But what if firms could do better? What if the device sector could have the same kind of reliability that's demanded, say, in the aerospace industry, where failure is absolutely not an option?" she asked.

Vicenty stressed that FDA, by using the maturity model, is not looking to "redefine" the Quality System Regulation.

The QSR "exists. That's already out there. It establishes your baseline. [CMMI] doesn't redefine what's going on at your facility," he said. "I get that question a lot. I'm not asking you to change all the things that you put in place to comply."

Rather, "I'm asking you to look at, is it working well for you? Is it delivering what you need for the patient?" Vicenty said. "And then, from an agency standpoint, when looking hard at ourselves, are we asking the right questions? Are we enabling that, or are we driving it in other directions, or not really allowing it to evolve and make use of what it's intended to do, which is … driving that continuous improvement within your organization and for the patient?"

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US FDA's Gottlieb Wants Safety Built Into New Medtech Products, But Budget Will Be Cut To Surveil Older Ones

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US FDA Commissioner Scott Gottlieb told a House Appropriations subpanel May 25 that there is no need to speed up or improve medtech product approval times at the agency because the Center for Devices and Radiological Health is already very efficient at approving products.

However, FDA does need to do a better job at intervening earlier, when devices are under development, to make certain companies are truly baking safety and efficacy features into their products so they won't need to be recalled once marketed, Gottlieb said.

"Are we doing all we can about the safety and efficacy of products in the development process?" is the real question that should be asked to address product performance prior to market release, the commissioner commented.

Rep. Rosa DeLauro, D-Conn., pointed to examples of serious device problems, including those with **St. Jude Medical Inc.** defibrillators with a history of battery issues resulting in the products' failure to operate *(Also see "St. Jude Warns Of Battery-Depletion Issues With Some ICDs" - Medtech Insight, 12 Oct, 2016.)*, and release of **Bayer Healthcare AG**'s *Essure* sterilization coils into the market that initiated 60,000 adverse event reports to FDA by 2016. *(Also see "Expect Bayer To Get Heat At FDA Advisory Panel Over Essure Adverse Events, Doc Training" - Medtech Insight, 23 Sep, 2015.)*

She asked Gottlieb: "Why does FDA refuse to pull faulty devices such as these off the market? When will you use your mandatory recall powers? I know you want to speed up [the approval process]."

DeLauro also decried cuts to the agency in the Trump administration's proposed budget released May 23 that will hamper and slow down FDA's post-market surveillance efforts *(Also see "Trump Budget: 71% Of US FDA Device Funding Would Come From User Fees" - Medtech Insight, 23 May, 2017.)*, and asked: "What other regulations will you pull back?"

"I think we don't need to think about speeding up the process, or speeding up review times," Gottlieb responded. "I think the question we need to be asking is about the overall efficiency and speed of the [device] development process itself."

He asked: "Do we have the right tools, are we asking the right questions, to make sure that part of the process isn't just efficient, but also produces safe products?"

> "Are we doing all we can about the safety and efficacy of products during the development process?" is the most important question to ask to circumvent post-market device recalls, Commissioner Gottlieb commented.

PLAN FOR INDUSTRY TO PAY HIGHER USER FEES CRUSHED BY CONGRESS, INDUSTRY GROUPS

Other questions that DeLauro and other subpanel members raised at the budget hearing centered on the Trump administration's insistence in its May 23-released budget that the device and drug industries pay substantially higher user fees to support FDA activities, but at the cost of deep cuts in the agency's budgetary authority from Congress. *(Also see "Trump Budget: 71% Of US FDA Device Funding Would Come From User Fees" - Medtech Insight, 23 May, 2017.)*

She and Subcommittee Chairman Robert Aderholt, R-Ala., both flatly told Gottlieb they had "no intention" of approving such a drastic budget change, but Gottlieb said the budget proposal had been written "without my input," and added he "wasn't involved in formulation of the budget."

Device industry representatives also made clear this week they will not support a doubling of industry user fees to shore up FDA's overall budget. "Any renegotiation [of FDA user fees] at this point could significantly delay any final user-fee legislation, resulting in substantial layoffs at the agency," AdvaMed President and CEO Scott Whitaker told *Medtech Insight* May 24.

MDMA President Mark Leahey also said his group was content with the user-fee authorization agreement as it stands, noting that it "was the result of over two years of thoughtful negotiation" between FDA and industry.

REMOVAL OF HIRING FREEZE WILL HELP AGENCY

Gottlieb also used the Agriculture/FDA Appropriations Subpanel hearing as an opportunity to announce that the hiring freeze at FDA had been lifted by the White House the morning of May 25. *(Also see "A Burning FDA Hiring Freeze Question: What About User-Fee-Supported Staff?" - Medtech Insight, 24 Jan, 2017.)*

He remarked: "The hiring freeze was lifted as of 9 a.m. this morning," which frees up the agency to hire more experts for device, drug and food reviews, and to help ensure product safety. Gottlieb noted that the inability to hire new staffers at FDA was a barrier, adding: "I don't want to go back there."

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Biomarker Is King In Latest US FDA Cancer Drug Approval

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FDA's approval of Merck's *Keytruda* (pembrolizumab) for use in any patient with a solid tumor with a particular genetic mutation is the first of its kind and could be the herald of a new approach to treating cancer.

The agency announced the accelerated approval of the PD-1 inhibitor May 23, noting "this is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated."

The new indication, Keytruda's ninth, is for adult and pediatric patients with unresectable or metastatic solid tumors that have been identified as having microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and specifically in colorectal cancer patients with the biomarkers that have completed earlier lines of treatment (*see box*). Labeling cautions that pediatric patients with MSI-H central nervous system (CNS) tumors have not been adequately studied.

"This is an important first for the cancer community," said Richard Pazdur, director of FDA's Oncology Center of Excellence. "Until now, the FDA has approved cancer treatments based on where in the body the cancer started – for example, lung or breast cancers. We have now approved a drug based on a tumor's biomarker without regard to the tumor's original location."

MORE TO COME?

Multi-histology or tissue-agnostic approaches have mostly been viewed as a mechanism for low-incidence tumors, but in this case, it also means finding the subpopulation more likely to respond to immunotherapy in a tumor type that generally hasn't been receptive.

"Basket" trials that assign patients to therapy based on molecular signatures are an increasingly popular clinical trial design, with high-profile efforts like the National Cancer Institute's MATCH study, the American Society of Clinical Oncology's TAPUR trial and **Novartis AG**'s SIGNATURE protocol. *(Also see "Genomics-Driven Trials Built To Be Fast And Flexible" - Pink Sheet, 21 Sep, 2015.)*

But while their ability to speed research and improve targeting is clear, the regulatory path has been less clear. The closest example was the approval of Novartis' *Gleevec* based on a histology-independent trial that included more than 40 uncommon cancers with high unmet need; the FDA issued four indications for specific tumor types from that pivotal trial. *(Also see "Gleevec: A Groundbreaking Example" - In Vivo, 27 May, 2014.)*

The Keytruda approval clearly demonstrates FDA's openness to this approach. With a recent spate of breakthrough designations (BTD), including for Keytruda's new indication, the agency has guided a few drugs through late-stage development for treatment of cancer patients based on molecular signatures, as opposed to the traditional paradigm focused on tissue of origin.

Keytruda first received a BTD for MSI-H colorectal cancer, then added another for MSI-H non-colorectal cancers.

Loxo Oncology Inc.'s larotrectinib and **Ignyta Inc.**'s entrectinib both hold BTDs for tissue-agnostic indications. Loxo's larotrectinib, a selective inhibitor of the *Trk* family of receptor tyrosine kinases, is currently in the Phase II NAVIGATE basket trial, potentially supporting a late 2017 or early 2018 NDA filing for NTRK fusion-positive solid tumors. Ignyta's entrectinib, which also targets the Trk family, has the Phase II STARTRK-2 basket trial under way with a possible 2018 NDA filing for NTRK fusion-positive solid tumors.

New Indication

Microsatellite Instability-High Cancer: For the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient.

- Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment
- Colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

- Limitation of Use: The safety and effectiveness of Keytruda in pediatric patients with MSI-H central nervous system cancers have not been established.

Loxo's larotrectinib is also in Phase I studies for sarcoma, while Ignyta's entrectinib is in Phase II trials for NSCLC and colorectal cancer as well.

Datamonitor Healthcare analyst Jared Wolffe said that the approval for Keytruda "certainly sets a precedent that it can be done."

HOW MERCK GOT IT DONE

Merck's approval was based on a collection of patients with MSI-H or dMMR solid tumors from across five uncontrolled, single-arm clinical trials. Some of the trials were solely in biomarker-selected populations, but in other trials, a subgroup was built of patients who tested for MSI-H or dMMR after treatment began. In total, there were 15 cancer types among 149 biomarker-positive patients across the five trials; the most common cancers were colorectal, endometrial and other gastrointestinal cancers, FDA noted.

Of the 149 patients who received Keytruda in the five trials, 39.6% had a complete or partial response and the response lasted six months or more in 78% of those patients.

Merck is conducting additional studies in patients with MSI-H or dMMR tumors to meet the accelerated approval requirements for confirmatory trials.

Both MSI-H and dMMR mutations affect the natural processes of DNA damage repair inside the cell. According to FDA, the biomarkers are most commonly found in colorectal, endometrial and gastrointestinal cancers and less commonly in other cancers, including breast, prostate, bladder and thyroid gland. "Approximately 5% of patients with metastatic colorectal cancer have MSI-H or dMMR tumors," the agency reported.

Bristol-Myers Squibb Co.'s PD-1 inhibitor *Opdivo* (nivolumab) is under review at FDA for MSI-H colorectal cancer only with an Aug. 2, 2017 review goal. *(Also see "Keeping Track: Teva's Austedo Clears US FDA, Merck Sitagliptin CV Outcomes Labeling Draws Complete Response" - Pink Sheet, 7 Apr, 2017.)*

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IVD UK SPRING MEETING:

The Costly But Necessary Route To IVDR Compliance

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Many challenges are facing UK IVD manufacturers, but the EU In Vitro Diagnostics Regulation (IVDR), which officially came into legal force on May 25, will dwarf all else as companies battle with compliance to a very tight deadline.

Addressing the spring meeting of the British In Vitro Diagnostics Association (BIVDA) earlier this month, association chairman Simon Richards took pains to stress that compliance with the four-risk-category IVDR will require effort, planning and patience. It will attract significant extra cost, to the extent that some manufacturers will decide to discontinue supporting some of the older products in their portfolios.

Companies are only now just getting a feel for the extra costs ahead, and of the waiting game that both they and notifies bodies (NBs) will have to play within the IVDR's five-year transition period. *(Also see "EU's New IVD Regulation: Key Dates And Deadlines To Shape Your Strategy" - Medtech Insight, 16 May, 2017.)* NBs cannot be designated to work under the IVDR until the end of November – six months and 20 days following the May publication in the Official Journal of the European Union, although those ahead of the game will be ready as of day 1. *(Also see "Interview: How Are EU Notified Bodies Preparing For Designation Under New Regs?" - Medtech Insight, 17 May, 2017.)* IVD manufacturers must then wait a further unspecified period while undergoing joint audits – by European Commission staff and two other NBs.

So, companies cannot file product applications until possibly as late as 18 months into the transition period, which raises capacity and bottleneck issues. The number of NBs that IVD companies can work with, meanwhile, is dropping. As of May 2017, there are 22 NBs designated under the current EU IVD directive, but some expect that number to fall to as few as 11 under the IVD Regulation. *(Also see "More EU Notified Bodies Bite The Dust" - Medtech Insight, 17 May, 2017.)* The NBs themselves must also manage potentially acute staffing issues, although a certain amount of qualified staff would come onto the market as a function of dwindling notified body numbers.

> Alere expects its ratio of files that can be self-declared versus those that require notified-body oversight to flip from 92:8, under the legacy directive, to 4:96, under the new IVDR.

A NEW LEVEL OF REGULATORY CHALLENGES

Richards, **Alere Inc.** VP for regulatory affairs for Europe-Middle East, discussed the main IVDR challenges as he and his group see them. The first issue is the upgrading of risk classification for products that were self-certified under the Medical Device Directive (MDD) – for example, a syphilis test will be up-classified from "self" to class C. This implies notified body oversight for this and related products.

A large company like Alere expects its own ratio of files that can be self-declared versus those that require notified-body oversight to flip from 92:8, under the legacy directive, to 4:96, under the new IVDR – that is, NB oversight will be needed in 96% of Alere's files. It is estimated that a major company with, say 800 IVDs to re-register, will likely be spending in the region of $30m to ensure full compliance with the IVDR.

The BIVDA chairman coined a new acronym – MAID (Manufacturers-Authorized Representatives-Importers-Distributors) – for the commercial economic operators (other than the NBs) that will be impacted by the IVDR. New duties will fall on each part of the supply chain, Richards stressed.

Importers and distributors will need to verify information such as CE-markings, with liability now extending across the chain. It will necessarily mean more interaction between players, bigger relationships between manufacturers and distributors, and "a lot more checking than in the past," Richards said. Factor in the unannounced inspections by NBs that are already required under the MDD, and the workload might seem daunting.

Some manufacturers will be forced to consider how to manage some of their products off the market. This will be an inevitable consequence of the fact that that there is no grandfathering – all IVDs must undergo the process of re-registration. The cost of supporting older products will rise, and, for some of them, it will inevitably be the end of the line.

More costs will come from the need to state an IVD test's scientific validity, and from the increased requirements for clinical data. Also, under the oncoming Unique Device Identification requirements, each IVD will need a unique bar code for track and trace purposes. There will also be new IFU (instructions-for-use) language requirements. And the NB's name must appear on the product label.

The IVDR will increase transparency across the board. The transparency changes extend to class C and D IVD product manufacturers, who will be required to summarize the main safety and performance aspects of their products and make both that and a performance evaluation publicly available.

EU companies will see time-to-market lengthen. They will need to supply training for some products, for example, point-of-care tests. They will also need, for the first time, to CE mark products that facilitate "testing at a distance." Elsewhere, vigilance and post-market surveillance (PMS) will become law, previously having been governed by MEDDEV guidance; relevant reporting times will be cut from 30 to 15 days.

Country authorities will also be able to levy fees for the regulatory services they provide (alongside the increasing charges due to the NBs), in the way that Ireland already has done *(Also see "Ireland, UK working on new fee proposals for medtech industry" - Medtech Insight, 9 Jul, 2015.)* and the UK has considered more than once in recent years. *(Also see "UK MHRA Postpones April Target Date For New Device Fees " - Medtech Insight, 10 Feb, 2016.)*

The IVDR implementing and delegated acts have yet to be written. Those could advance further compliance timing complications for manufacturers. Some topics, like documents addressing product classification, will be prioritized. But the full picture will not become clear until the end of 2018.

The regulatory requirements apply across the EU. In the UK, a "hard" Brexit, which would entail no access to the single EU market and no participation in the customs union, would require IVD manufacturers to appoint authorized representatives to be legally responsible for their products within the EU territory.

So, for UK IVDs manufacturers looking stay competitive in the EU market, speed, awareness and preparedness will be vital qualities as the five-year transition starts to tick down.

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This is one of two stories covering the BIVDA spring meeting. Check out "IVDs UK Spring Meeting: Diagnostics Get New Market Access Tools – But At A Price" (http://bit.ly/2smpPwP) for a look at new opportunities for easier and more predictable market access.

Malaysian Regulator Seeks Feedback On Conformity Assessment Expectations

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Manufacturers seeking to register their products in Malaysia must have a post-market surveillance system in place to ensure continued conformity to the essential principles of safety and performance for medical devices, the country's Medical Device Authority says in a draft guideline on conformity assessments.

This means that for classes B, C and D medical devices, manufacturers must document, maintain and implement processes relating to complaint handling, distribution records, mandatory problem/adverse event reporting, field corrective actions, and recalls, the document says.

The draft guidance, which is open for consultation, provides an overview of MDA's expectations regarding conformity assessments of medical devices. It deals with manufacturers' responsibilities when it comes to providing evidence to demonstrate that their product is safe and performs as intended.

It also covers the responsibilities of the authority or conformity assessment body (CAB), whose job it is to confirm whether the necessary conformity assessment elements are properly or adequately applied by the manufacturer. It notes that conformity assessment becomes more stringent as the risk of the medical device increases.

Outlining the elements of conformity assessment, the draft guideline explains that for medical device registrations, a CAB is required to assess the manufacturer's post-market surveillance system, quality management system (QMS), technical documentation and declaration of conformity.

CABs can consider any relevant existing QMS certification and, if not satisfied, may carry out an on-site audit of the manufacturer's facility, the draft document says. The guideline deals with the criteria for acceptance of existing QMS certification – for example, QMS certificates issued by certification bodies from recognized countries (US, Canada, Australia, Japan, EU). It also clarifies that QMSs carried out on behalf of the manufacturer by third parties "shall remain the responsibility of the manufacturer and are subject to control under the manufacturer's QMS."

The draft guideline contains tables summarizing the conformity assessment elements that apply to class A, B, C and D devices, as well as a checklist for conformity assessments by CABs.

Comments on the draft guideline must be submitted by June 9, 2017 to shahrezza@mdb.gov.

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European Commission Makes Final Decision On Cranberry Products

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The European Commission's Regulatory Committee on Medical Devices has ruled that cranberry products cannot be regulated as medical devices. This is an important ruling for industry because it is the first time that the European Commission has used its "borderline" product decision-making authority.

In making its ruling, the committee voted in favor of an earlier draft commission decision. The decision was made in response to a request from French authorities. *(Also see "Fruitful Use Of EU Reg Loopholes Or Farce? How The Cranberry Is Dividing Opinions" - Medtech Insight, 23 Feb, 2016.)*

The legal basis for the decision is Article 13(1)d of the Medical Devices Directive, which allows the commission to take a decision, at the request of an EU member state, on whether a product or a group of products falls within the definition of a medical device.

French authorities invoked the article after several companies started selling cranberry capsules with medical device claims, including French food supplements firm Arkopharma, with its *Cys-control Gélules* (Class IIa medical devices) and Medical Brands with *Cranberry-Active* (Class IIb medical devices). The approach may have been considered a more straightforward alternative to seeking approval for health claims through the EU Nutrition and Health Claims Regulation.

THE CRANBERRY DILEMMA

There have been various arguments put forward about whether the action of cranberries in the urinary tract represents a medical and physical action, which would mean that companies could claim that cranberry products, including capsules, are medical devices.

While the commission found that the principal intended action of these products is achieved through inhibiting adhesion between P-fimbriated *E. coli* and mucous membrane cells in the urinary tract, it did not agree that this action means the product is a medical device, noting that benefit is achieved by "pharmacological, immunological or metabolic means."

The formal adoption and publication of the final decision is expected within the next few months.

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What the Medical Device Regulation (MDR) Says

Under the new regulation, which enters into force on May 25 and fully applies in 2020, the European Commission will be allowed, on its own initiative or at the duly substantiated request of a member state, to decide on a case-by-case basis whether a specific product, category or group of products falls within the MDR. In doing so, it must consult the EU Medical Device Coordination Group.

When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the commission should ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as appropriate.

Medtronic Hits Targets In 'Solid' Fiscal 2017

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Medtronic PLC saw annual revenue grow 5% to $29.71bn and net income widen to $4.02bn for fiscal 2017, beating market forecasts in what chairman and CEO Omar Ishrak described as "a solid year" for the company.

A strong fourth-quarter helped to bring the fiscal year to a positive end. In Q4, Medtronic posted worldwide sales of $7.91bn, up 5% on a reported and constant currency basis. This was largely driven by continued double-digit growth in emerging market sales during this period, despite taking a small hit from negative currency effects ((+13% reported, +11% constant currency, at $1.06bn). Q4 US sales, which still make up the lion's share of total revenue at just over 56%, grew 4% to $4.40bn, while non-US developed market revenue grew 2% (+4% constant currency) to $2.45bn.

In the company's earnings conference call on May 25, Ishrak highlighted Medtronic's focus on expanding its global presence beyond the US to ensure the group maintains its position as industry leader. "In addition to ongoing traditional market development, we are executing on differentiated strategies namely structuring partnerships with both governments and the private sector as well as optimizing our distribution channels. We believe that these initiatives will not only position us for a long-term leadership in emerging markets, but also will accelerate growth and lead to sustained market and performance."

Ishrak acknowledged facing persistent challenges in the macroeconomic environment in the Middle East, causing Medtronic's revenue to decline in the mid-single digits, but noted that the largest market in that region, Saudi Arabia, has produced stable sequential revenue. China, Latin America, and Southeast Asia continued to deliver double-digit growth, while Eastern Europe saw high single-digit growth. "Overall, the consistency of our emerging market performance benefits greatly from geographic diversification, reducing dependence in any single market. We continue to believe that the penetration of existing therapies into emerging markets represents the single largest opportunity in medtech over the long term," Ishrak told analysts and investors during the earnings call.

PRODUCT MARKET GAINS

All four of Medtronic's business groups saw roughly mid-single-digit revenue growth. (See table below). Bright spots include its transcatheter aortic valve repair franchise within its Cardiac and Vascular Group, which delivered +30% growth. Ishrak said the company increased its transcatheter aortic valve market share sequentially in both the US and Europe – where **Edwards Lifesciences Corp.** is its arch rival – on the continued launch of the *CoreValve Evolut R* 34-mm valve. Medtronic expects to soon earn FDA intermediate-risk indication for *CoreValve Evolut R*, an indication that Edwards' TAVR systems already have. *(Also see "ACC 2017: SURTAVI Supports Intermediate-Risk Intervention For Medtronic's CoreValve" - Medtech Insight, 21 Mar, 2017.)*

While the company had been seeing declines in US sales of its drug-eluting stents, it indicated its optimism in turning this around in fiscal 2018 with the recent FDA approval of the Resolute Onyx DES.

Revenue from the Diabetes Group was the one business unit that came off a little light in terms of meeting market expectations. The company had seen the US FDA approval of its new *MiniMed 670G* hybrid closed loop system in September last year and as it prepared for the full launch of this latest-generation insulin pump in spring 2017, Ishrak said the sequential slowdown in Diabetes revenue growth had been expected.

Medtronic gained insulin pump share in both the US and international markets driven by strong clinician and consumer demand for Medtronic's "6 series" pumps. In the US, direct pump shipments to consumers grew over 20%, continuous glucose management grew in the low-20s, and the demand globally remains strong as more patients transition to our sensor-augmented pumps, he said.

Medtronic is preparing for a broader launch in June for the more than 20,000 pump users enrolled in a Priority Access Program.

COVIDIEN CONTINUES TO PAY OFF

Over two years since its landmark merger with Covidien, Medtronic said the integration of the two companies continues to progress as planned. The bulked up group has now realized over $600m in synergies savings and Ishrak said it remains on track to hit its goal of $850m of total cost savings by the end of the next fiscal year. "This operational productivity, coupled with our revenue growth, were key contributors to delivering double-digit EPS growth and generating over $5.5bn of free cash flow," he added.

Despite having forked out $47bn for Covidien, Medtronic continued to dig into its pockets in the last fiscal year. It invested approximately $1.5bn in several strategic investments and five tuck-in acquisitions, and Ishrak said these acquisitions are expected to further enhance its revenue growth and improve returns over time.

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For a complete breakdown of Medtronic's 2017 sales by business group, visit the online version of this article at https://tinyurl.com/y9at2ne8

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brands from the Indian market; In April, this year, the NPPA turned down their requests. Companies wanting to discontinue any product on India's national list of essential medicines need to meet certain conditions set out in the regulations, including the issue of a public notice in this regard. The Government may, in public interest, direct the manufacturer to continue with the "required level of production or import" for up to one year, from the intended date of such discontinuation within 60-days of receipt of such intimation.

Industry sources claimed that there is no shortage of stent supplies by the key foreign players (and at price levels specified by the NPPA, they assert) and that stock, distribution records etc. as sought by the pricing regulator are being provided, though there is some disquiet around the timing of the latest upload by the NPPA of the ministry's note of March 16. MedTech Insight could not, however, immediately separately verify the claims on stent supplies in the market.

On April 28, the NPPA had emphasized that all manufactures/importers/marketers of coronary stents need to follow the directive of India's Department of Pharmaceuticals and submit a weekly report on coronary stents produced and distributed. In addition to maintaining production/import/supply of these stents, manufacturers were asked to submit a weekly production plan to the NPPA and the Drugs Controller General of India (DCGI) – the order is valid for six months and regulators would review the situation two weeks ahead of expiry of the specified period.

'FOOTPRINT' IN THE MINDS OF PEOPLE

An industry pundit with a foreign firm told *Medtech Insight* that the NPPA is "quite within its remit" to try to curb the prices of life-saving devices such as stents and other devices. However, he added that while the "sentiment" is right – [patients do need a "vigilant" regulator to ensure that they receive the best value for money- as with most government decisions, he says] – "the chronology is not."

Government agencies, he explained, are often tempted to treat the symptoms and 'leave a footprint' in the people's minds.

"Political capital is to be made more from perceptions of reform than from actual reform which in most cases is long-winding and gradual," the pundit underscored.

Industry watchers acknowledge that there has been some chest-thumping by the government around the stent price cuts, but underscore that the fact remains stent prices have come down by over 75% in India. And with celebrations to mark three years in office of the NDA government led by Prime Minister Narendra Modi commencing on May 26, "achievements" such as these, or even more in store, are likely to be flaunted, they add. On May 26, India's department of pharmaceuticals tweeted that savings on account of the price cap on coronary stents was estimated at INR44.50bn.

Besides, there's also been support for the price action from domestic firms - the Association of Indian Medical Devices Industry (AiMED) has backed the price cap on stents.

In an article published by the local press Rajiv Nath, forum coordinator of AiMED and joint managing director of Hindustan Syringes and Medical Devices Ltd, noted how high priced imported stents had enjoyed an "unfair competitive advantage" over equivalent Indian products and were favored because of the more lucrative margins they offered to the hospitals. AIMED has sought a "game-changing" national medical devices policy to turn 'Make in India' a reality. Its suggestions include a "Buy Indian and preferential purchase policy" for medical devices that are made locally.

Significantly, on May 24, India's Cabinet, chaired by PM Modi, approved a broad policy for providing preference to 'Make in India' in government procurements, though details on the scope and applicability across sectors could not immediately be ascertained. PM Modi's pet "Make in India" initiative, launched in 2014, aims to make India a global manufacturing hub, thereby upping the contribution of the manufacturing sector to the country's gross domestic product. Procurement by the government is "substantial in amount" and can contribute towards this policy objective, the May 24 statement noted.

> A May 12 office memorandum by the NPPA stipulated that all medical device manufacturers/importers and marketers would need to submit certain data – including date of launch of the product, specification of the product as per the approval from the Drugs Controller General of India, the maximum retail price (MRP) of the product – in a prescribed format in respect of the 19 medical devices "irrespective of their classification."

NEGATIVE SENTIMENTS

But the pharmaceutical and medical devices industry has long maintained that pricing of products cannot be viewed in isolation in the access debate. Affordable healthcare, they assert, is not only about the price of a medicine or a device but also associated costs of care - diagnostics, hospital charges, doctor fees, sometimes unnecessary tests etc. pile up costs for patients.

The industry pundit cautions that excessive government involvement into

business creates "negative sentiments". And, if that involvement is seen to be addressing only one part of the problem, then it is likely that accusations of becoming "anti-industry" crop up, he maintains.

"Up until now, there is no indication that either hospitals or other stakeholders in the healthcare continuum will be under pressure as much as the industry is."

Health activists, though, suggest that broader reform will take time; they also referred to NPPA's proactive approach in examining alleged overcharging complaints against hospitals pertaining to stents.

MONITORING PRICE MOVEMENT

Meanwhile, the devices industry also appears somewhat nervous over the recent data gathering effort by the NPPA. The pricing authority aims to monitor the price movement of 19 medical devices of the 23 devices notified as "drugs" under the Indian Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

A May 12 office memorandum by the NPPA stipulated that all medical device manufacturers/importers and marketers would need to submit certain data in a prescribed format in respect of the 19 medical devices "irrespective of their classification".

The regulator has sought details such as the date of launch of the product, specification of the product as per the approval from the DCGI, the maximum retail price (MRP) of the product from April 2014 to 2017, price to the stockist/ distributor and separately to the hospital/retailer as of April 2017.

Typically, the NPPA regulates prices of scheduled drugs - those that are in India's national list of essential medicines (NLEM) and attract price caps. Non-scheduled products, which include the specified 19 devices in question for which data has been sought, are those that typically don't figure in India's NLEM and whose prices are not capped. The regulator can, however, monitor the prices of such non-scheduled drugs and ensure that the increase in their MRP does not exceed 10% of the MRP prevalent during the preceding 12 months.

> The pricing mechanism for medical devices "should not strangulate" the flow of innovative and critical care devices in the country - Medical Technology Association of India

SOLID CLINICAL AND HEALTH ECONOMICS OUTCOMES

Industry, however, appears uneasy with the level of price detail sought by the regulator and one official with a foreign firm told *Medtech Insight* the regulator appeared to be "preparing a case" for more price caps. There is also concern around "mixing of issues", with details around "specifications as per DCGI approval" being sought.

"The regulator's price monitoring effort should ideally be around the MRP," the official said.

The May 12 office memorandum said that a series of meetings had been held with the medical devices industry and associations aimed at arriving at a consensus on the format to be used for collecting data for the monitoring exercise.

"However, based on the feedback received from the members of medical devices associations, it has been found that reaching a consensus on classification may not be possible due to diverse opinions about the classifications among the medical devices industries. In view of this, a new format based on Form-V prescribed under DPCO, 2013 has been prepared," the office memorandum said.

The Medical Technology Association of India (MTaI), whose founding member companies include **Johnson & Johnson**, **Bausch & Lomb**, **Smith & Nephew**, and Boston Scientific, among others, did not respond to specific queries on the NPPA's price monitoring effort, but told *Medtech Insight* that the pricing mechanism for medical devices "should not strangulate" the flow of innovative and critical care devices in the country.

"MTaI is for greater patient access and proposes a systems-based approach and the revitalizing of the Medical Technology Advisory Board (MTAB) to judge matters pertaining to medical device pricing, and arrive at decisions based on surgical therapy needs and solid clinical and health economics outcomes," it said.

India has proposed setting up a MTAB in the Department of Health Research that would recommend technologies (drugs, devices, method of treatment, etc.) in the area of health after evaluating them on their efficacy, appropriateness and cost effectiveness. The latest position on this is not immediately clear.

END-TO-END COST STRUCTURE

The industry pundit quoted previously explained that India is a very cost-sensitive market and companies end up competing on price.

"Demanding an end-to-end cost structure is tantamount to laying bare that competitive benefit of a company, and is not something most will be happy to comply with. While the regulator might do this with an aim to price right, I don't think it is their prerogative to dictate prices," the pundit said.

He also added that if the regulator's objective is to "break up any cartels" that device companies may have potentially formed, there are other market mechanisms to do so.

"However, these mechanisms may not offer instant gratification and therefore may not generate the political capital that is sought. Advertisements that appeared in national dailies congratulating the Prime Minister for thinking about the health of the citizens of India makes it clear that the move is political in nature, and the ruling party was quick to grab credit".

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industry on the whole should feel encouraged. Medtech M&A activity is at an all-time high and 2017 is on pace to be the third consecutive year with 10 or more transactions worth more than $1bn he said. Pre-commercial device M&A activity was also staying relatively steady, with cardiovascular, ophthalmology and orthopedic sectors experiencing the most activity. Bar-Nahum said that early stage medical device companies "selling the dream" to acquirers were also achieving higher valuations than FDA approved companies. Figures showed pre-FDA approval companies achieved on average $398m per acquisition, compared to an average of $320m for post FDA approved companies. However, these early stage deals were occurring at a lower frequency compared to later stage companies as the market is more discerning about price.

Bar-Nahum said significant acquisition and consolidation in the medtech sector were being driven by several factors. Firstly, the market was seeing a decline in growth rates of the two largest markets, cardiology and orthopedics from double-digit growth to low single-digit growth. In addition, there is a slower, high risk regulatory process and a shift in balance of power from device companies to hospitals/payers. Greater pressure on product pricing for medical device companies and a shift to value-based reimbursement in the US were all also having an impact on medtech M&A, said Bar-Nahum. "Medtronic has carried out 12 acquisitions in past five years totaling $50bn, while Stryker has had 11 acquisitions [over the same time period]," he said. "There has been a strong consolidation in recent years so we are now seeing a reduced pool of medtech buyers remaining."

Tax reform and cash repatriation under a Trump administration could be positive factors for M&A activity in 2017 but a repeal of the Affordable Care Act and the strengthening of the dollar, could all impact company earnings negatively.

He added cost effectiveness would be a key driver of funding in the future, with point of care testing devices, personalized medicine and digital health all earmarked as being at the forefront of the industry in future.

That said, it has not stopped innovators from innovating and Israel has traditionally been, and continues to be, fertile ground for the development of cutting-edge technologies.

The conference hosted a start-up competition, of which the winner was E-Shunt, which has developed a drainage device to treat glaucoma, a disease that causes intraocular pressure to rise to the point where it can damage eyesight and ultimately cause blindness.

The implant is based on a nano-electro-spinning technology that channels pressure deeper into the eye socket, releasing the pressure on the optical nerve. The implant process takes less than 10 minutes and is designed so ophthalmologists who are not glaucoma specialists can perform the procedure. E-Shunt's Founder and chief medical officer, Gilad Levin told *Medtech Insight* he wants the device to put the "ease of use for surgeons as a priority and recovery process for the patient is minimal." He said by the end of the process, the patient should be free from dependence on medication, and the disease's progress stops.

Below is a summary of the companies that were also presenting at MIXiii Biomed.

Medical Technology Companies Showcased At MIXiii Biomed

COMPANY	DEVICE AREA	TECHNOLOGY	PRODUCTS
MeMed	IVD	Diagnostic IVD platform for distinguishing between bacterial and viral infections based on the patient immune response to different infection types.	*ImmunoXpert* – a CE marked assay test.
Kytera Technologies	Digital health/Activity monitoring	Remote monitoring system for elderly. Uses advanced machine learning algorithms and sensing technology to learn routines of senior in the house and detect deviations from the routine and distress situations.	Wearable wrist device
Chronisense Medical	Digital health/Patient monitoring	Wearable wrist ICU device for continuous measurement of vital signs.	Wearable watch, with four sensors. Platform connected to smart phone.
EarlySense	Digital health/Patient monitoring	Continuous patient monitoring system.	*EarlySense System*
MicroMedic	IVD	Cancer diagnostics.	*CellDetect* – for bladder cancer, prostate cancer and prostate cancer
Nucleix	IVD	Epigenetics biomarker cancer test. Includes a panel of 15 DNA methylation biomarkers for detection of bladder cancer. A bioinformatics tool enabling rapid and systematic development of biomarker panels for a wide range of clinical tasks.	*Bladder EpiCheck*

COMPANY	DEVICE AREA	TECHNOLOGY	PRODUCTS
Intensix	Critical care monitoring	Predictive big data analytics platform. Applies machine learning with predictive modelling and analytics techniques to provide healthcare professionals with warnings in ICU management to avoid disease deterioration.	*Intensix* platform for critical care monitoring
Belong	Cancer management	Mobile app for cancer patients to help manage treatment. Patients can organize and manage medical records and share with family and healthcare professionals.	*Belong* app
iFeel	Respiratory disease management/Digital rehabilitation	Respiratory digital therapy for asthma and COPD patients. Helps users improve their breathing technique and lung function while playing a variety of popular mobile games like Candy Crush.	Wearable pulse sensor and mobile app.
XACT Robotics	Surgical robotics	Robotic needle steering for use in minimally invasive interventional procedures such as biopsies and ablations	*XACT 5 degrees-of-freedom robot.*
Enopace Biomedical	Neuromodulation	Early-stage device company developing an aortic neuromodulator for treatment of heart failure.	*Harmony System,* a catheter-based neurostimulator device
NanoRetina	Ophthalmology	Miniature bionic retina for restoring vision lost due to retinal degenerative diseases.	Miniature implantable chip and a set of eyeglasses worn by patient.
EyeOn Medical	Ophthalmology	Minimally invasive ophthalmic devices.	*Hyper-CL*, a therapeutic contact lens for treating corneal edema,

Qualcomm: A New Kind Of Medical Device Company

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When you hear "medical device company," the first name that comes to mind probably isn't Qualcomm. But if the company has its way, it'll likely be a major player in the medical device industry for the foreseeable future.

A mobile-technology company, Qualcomm has been making big waves in the health-care sector by using its wireless chip technology and unorthodox partnerships to change how treatments are delivered and how physicians keep tabs on their patients.

In an interview with *Medtech Insight*, Rick Valencia, president of Qualcomm Life, a subsidiary of Qualcomm, says the company's goal is to be the "connective tissue" that bonds patients, physicians and their treatments, in the hopes of providing the best outcomes for the best cost.

Rick Valencia

RIDING THE DIGITAL HEALTH WAVE

It all started about a decade ago, in what Valencia describes as "evangelism" by some in the company to use their mobile technology to improve health-care delivery. Eventually that idea spawned into Qualcomm Life – about six years ago – and now the company seems to have entrenched itself with partnerships across the health-care sector.

Over the past few years, a number of well-known companies that are not traditionally in the medtech space, such as Apple, IBM and Verily Life Sciences (formerly Google Life Sciences), have made big investments in the health-care industry. They've been partnering with device and pharmaceutical companies to meld their traditional background in communication and data technology with products offered by traditional health-care companies to develop a new field in the health-care sector called "digital health." *(Also see "Wearables: A World Of Pharma Partnership And Potential" - Scrip, 8 Aug, 2016.)*

The transformation has been noticed by stakeholders across industries, in-

cluding the medical device lobby group AdvaMed, which last year launched AdvaMed Digital to represent new digital-health companies, such as those mentioned above and Qualcomm. The issue has led the group to make digital health the cornerstone of its upcoming annual medical device industry conference, being held in San Jose, Calif. – near the headquarters of many digital health companies on the US West Coast.

Qualcomm, based in San Diego, is one of these companies in the new digital-health arena, and seems to be working to corner the market with their mobile chip technology. The company has ramped up efforts over the past couple of years with several high-profile partnerships. Notably, it is partnering with medical device giant Medtronic, and pharmaceutical companies including Novartis and Roche. *(Also see "BEHIND THE DEAL: Why Medtronic And Qualcomm Are Teaming Up On Diabetes" - Medtech Insight, 31 May, 2016.)* and *(Also see "INTERVIEW: Qualcomm's digital health expansion plan sees Novartis, Roche tie-ups" - Scrip, 9 Feb, 2015.)*

Besides collaborations with drug and device companies, Qualcomm has also partnered with about 2,000 hospitals to build what Valencia calls "the internet of medical things;" a play on the term "Internet of Things," or IoT, which is used to describe a trend in the consumer industry to connect everyday products with customers through the web.

Qualcomm is also working with UnitedHealthcare on a project to track the health and wellness of employees of the insurance company to figure out a way to reduce health-care costs. If successful, it could be a model for the insurance industry to find ways to reduce costs.

"We're trying to create something similar to the mobile network, but in health care. We're trying to create this ubiquitous, open platform that we partner with everybody in industry," said Valencia. "What you'll notice if you look at our customers – now partners – is that a lot of them are direct competitors in the industry when they go to market, but they compete on the uniqueness of their medication or diagnostic device, or whatever."

Valencia notes that Qualcomm technology can be found in virtually every mobile device, whether it's modem, processors, or even licensing of their chips in wireless devices. He says this allows them to play a neutral role in the market so their partners can compete for the best product using their services as a base.

"What we offer is more like a utility that they plug into and they don't have to worry about it, so we're able to act as this intermediary that acts like Switzerland because we're new," said Valencia. "We haven't been in this for a long time, we're not heated competitors of any of these folks, and so they've been very welcoming to Qualcomm in this space."

One big area where Qualcomm has blurred the lines between traditional drug and device products is by using their technology to not only help patients improve how drugs are administered, but also to track the long-term safety and efficacy of drugs.

The company has been partnering with pharmaceutical companies developing new drugs to monitor their effects on patients through diagnostic and monitoring devices so that patient data is directly streamed to researchers and physicians. Drug-makers and Qualcomm say this is intended to improve clinical trial recruitment and compliance, while also reducing potential for human error when logging the patient data.

"If it's coming directly off the device straight into the research database, then the chance of getting there faster and with less errors is very high, and it enables them to get a drug to market faster," said Valencia.

Ultimately, he says, these partnerships are creating a new health-care sector called digital pharmaceuticals.

Pharmaceutical companies "are creating drugs that will be prescribed with a digital element that will help their customers with [dosage compliance], and giving feedback to their doctors, and how they are taking the medication, and maybe even at some point how the body is reacting," said Valencia. "You can imagine a patient not only taking medication, but they might be wearing some sensors, or maybe a patch that's taking their heart rate and respiration rate, and maybe eventually even blood pressure and blood glucose, and feeding that information back, noting that when I take this drug, this is how my body reacts to it, and whether or not they should change the prescription as a result of it. And that part of the business is really taking off."

MOVING TO A VALUE-BASED HEALTH-CARE MODEL

Valencia says this is leading to a new value-based health-care model that is replacing the traditional fee-for-service model that has been in effect in the US. He says the current volume-based health-care system is too costly and unsustainable in the long run.

"If you're really, really sick, you have some really strange disease or condition, day-in day-out primary care is double the cost in the US than it is anywhere else in the developing world; over 20% of GDP, and we have worse outcomes and lower life expectancies than any other developed country," said Valencia. "The cost of care has to come down for a good health-care system to be sustainable, [and] we think that value-based care delivery and payment is the best mechanism to get there."

And the problem isn't just in industrialized health-care systems. As developing countries are growing their middle class, Valencia says that will push greater demands on their health-care systems.

"We're hoping they don't end up making the same mistake we made and go straight to a sustainable model that we believe is value-based care, where we're really focused on conditions and costs associated with an individual condition as opposed to a procedure, as opposed to a department, as opposed to a facility," said Valencia.

In response to what he sees is an inevitability, Valencia coauthored a recent report at the World Economic Forum in Davos, Switzerland, for its Value in Healthcare project outlining what steps governments and other stakeholders need to move the volume-based health-care systems into value-based systems.

Among the main objectives of the project is to develop shared standards for health outcome metrics.

Qualcomm isn't the only player pushing for adoption of value-based health-care models. AdvaMed recently also published a document outlining considerations for the medical device industry in value-based health-care models that the group says is a wave that is coming, and one that the industry needs to have a voice in. *(Also see "AdvaMed: Medtech Needs Voice in Value-Based Health-Care Models" - Medtech Insight, 15 May, 2017.)*

Valencia says in the end, it all comes down to aligning costs and outcomes so patients get the best treatment for the best price, and that's where a company like Qualcomm can make a major impact.

"To make health care more sustainable and deliver on value-based care, you're going to need to have a system with tighter connection with the patient. Imagine a patient who has just been discharged," he said. "They're at a very fragile point in their lives, and having that tether for a period of time as they're getting well is important."

But Valencia admits getting countries around the world to adopt value-based health-care models is no easy feat considering the disparities in how care is delivered across systems and the political baggage that comes with trying to change those systems. He says if they can overcome the various political hurdles, the regulatory regimes will catch up.

However, the most important thing right now, Valencia says, is developing agreed upon proof points among health-care stakeholders to prove the value of treatments using sound science. Further, Qualcomm is planning several pilot projects around the world in health arenas such as congestive heart failure and diabetes to find what the best treatments are that deliver value.

DATA-SHARING IS CRITICAL

The real audience of the report, according to Valencia, are policymakers, and a good first step for US lawmakers would be to consider requiring data-sharing. While he says it would be good to have data from patients, that's not the most important type of data that is needed right now. Instead, Valencia says, the health-care system needs data on physicians, hospitals and medical procedures, and how much those procedures cost and how well they perform.

"Health care right now is a bit of a black box in terms of what things cost, in terms of the quality of an individual care provider, the results or outcomes of a specific procedure," he said. "So one of the things that we need to do is, if we're going to identify value based on a specific condition, there's going to be procedures that are required to treat that condition, we need to know how they're done, whether not they are done well, how long they take, and we need a lot of that sort of data."

However, he says, currently there is not a lot of incentive for that kind of data to be shared, and overcoming aversion to sharing that data is the first step in creating a value-based health-care model.

Beyond selling industry stakeholders on a value-based health-care system are also basic logistical hurdles, including making sure medical devices are not vulnerable to potential cybersecurity threats and that they can store and transmit data that protects patient privacy.

Valencia says Qualcomm already has experience storing and transporting data that goes beyond compliancy requirements and the Health Insurance Portability and Accountability Act (HIPAA), and the firm has been active in ensuring their chips are secure from malicious hackers.

"One of the things we've been doing for twenty-odd years is creating secure communications all the way down into the chipset," he said. "In fact, we have a small business at Qualcomm that a lot of people don't know about that is a cybersecurity business where we provide all of the secure communications to the US government, so we know a thing or two about that."

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DEVICE DEBUTS:

Spinal Innovation From NuVasive, Life Spine; Teleflex Targets EuroPCR For Arrow AC3 Optimus; Abiomed Pushes 3-G Impella

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Device Debuts is a regular *Medtech Insight* feature highlighting new products introduced into the market for the first time, important new iterations of existing products, or launches of existing products into new markets for the first time. This month's edition includes a series of spine surgery devices and mechanical circulatory support devices launched at major medical meetings this spring.

NUASIVE ANNOUNCES SERIES OF NEW SPINE HARDWARE

NuVasive Inc. announced April 19 that it launched the *Reline Trauma* portfolio to coincide with the American Association of Neurological Surgeons meeting in Los Angeles the following week. The company expects Reline Trauma to address the US spine trauma fixation market, which is currently worth about $100m and growing 5.6% annually.

The company says the Reline Trauma is the first spine trauma system designed to allow surgeons to customize their approach during the procedure, be it a traditional open procedure, a minimally invasive surgery, or a hybrid approach. Reline Trauma allows surgeons to "dial-in" fraction correction through a dual rack system achieving independent lordosis restoration and parallel compression/distractions for ligamentotaxis. This allows the procedure to be complete by a single surgeon, rather than needing two, which should cut costs. *Reline Trauma Fracture Frame* instrumentation allows controlled fracture correction throughout the procedure, with or without a rod present in the construct and gives surgeons the ability to place various rod diameters and materials before or after fracture correction, which makes it easier to reduce fractures, according to NuVasive.

Reline is intended to integrate with NuVasive's computer assisted technologies in the *Integrated Global Alignment* that lets surgeons to calculate, correct and confirm spinal alignment throughout the procedure.

The first version of the system earned a 510(k) from the US FDA in 2014, but the current version of the system, Reline 4.5-5, earned a 510(k) in March.

"Reline Trauma is now the most versatile trauma system on the market, designed to provide surgeons the flexibility to customize their approach intraoperatively, including traditional open, maximum access surgery or hybrid procedures depending on pathology the patient needs," NuVasive CEO Gregory Lucier said during the company's April 25 earnings call. "In collaboration with our surgeon partners, we succeeded in creating a platform designed not only to improve clinical outcomes, but also to reduce the total cost of care."

Also during the first quarter, NuVasive launched its first two expandable interbody devices for lumbar fusion surgery, *MLX* and *TLX*. Lumbar fusion remains the largest part of the spine market. NuVasive also recently relaunched the *XLIF* (*eXtreme Lateral Interbody Fusion)* lateral access spine surgery system in Japan. In March, the US FDA 510(k)-cleared NuVasive's *CoRoent* small interbody system, the only cervical cage system cleared by the FDA for fusion of up to four contiguous levels.

NuVasive expects these spine technologies to be among the drivers of revenue growth in the second half of 2017, along with the Unyte system, a magnetic growth rod technology that earned a 510(k) in April for treating open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions, or limb lengthening of the tibia. Lucier said a series of cases with Unyte will soon be published in the *Journal of Orthopedic Truama*, which will show surgeon's its potential. "We believe Unyte will bring some of the most significant innovation with the potential to 'obsolete' the $800m external fixation market," he said.

LIFE SPINE FULLY LAUNCHES PROLIFT

Also just in time for the AANS meeting, Huntley, Illinois-based **Life Spine LLC** announced the full commercial launch of the *Prolift* lordotic expandable interbody solution on May 16. Prolift is designed for in-situ disc height restoration, with minimally invasive posterior lumbar interbody fusion, transforaminal lumbar interbody fusion, and oblique approaches, to allow restoration of normal spinal pelvic parameters with the multiple lordotic options. Prolift earned a 510(k) in March 2016.

Prolift features the company's *Osseo-Loc* geometric surface architecture that provides an osteoclastic environment that recruits osteoblasts to assist healing and solid fusion.

Life Spine claims to have the broadest, fastest growing suite of expandable products in the market. In February, privately held Life Spine announced its revenue grew 38% in 2016, led by the launch of 27 new products during the year and six 510(k) clearances. The new devices including multiple expandable interbodies like the *Longbow* lateral expandable spacer system, which offers controlled in-situ expansion for maximum endplate coverage, minimal anatomical disruption, and post-packing capabilities.

Teleflex Launches New Arrow ACR Optimus IABP At EuroPCR

Teleflex Inc. introduced its *Arrow AC3 Optimus* intra-aortic balloon pump (IABP) at

the recent EuroPCR conference in Paris, France on May 16-19.

Arrow AC3 Optimus IABP delivers circulatory support to a broad range of patients, even those not previously considered candidates for IABP therapy, according to the company, including patients with the most severe arrhythmias or with heart rates as high as 200 beats per minute. Arrow AC3 Optimus IABP has a third-generation *AutoPilot Mode* with proprietary algorithms that automatically adjust timing and triggering parameters, including exclusive algorithms like *WAVEInflation Timing*, *Deflation Timing Management*, and *Best Signal Analysis*, to optimize key functions of the IABP, according to the company.

The device is CE marked and has launched in India and parts of Europe.

Earlier in May, Teleflex announced the FDA 510(k)-cleared the Arrow AC3 Optimus IABP. The company showcased it at the American Association for Thoracic Surgery and American Society of Extra-Corporeal Technology annual meeting in Boston April 29 to May 3.

"AC3 Optimus IABP global launch marks a major milestone for Teleflex," Teleflex CEO Liam Kelly said May 2. "This highly anticipated launch will enable the Company to become a more significant player with a product that can enhance patient outcomes and make it easier for clinicians to deliver IABP therapy."

Arrow AC3 Optimus is one of the products Philadelphia-based Teleflex when it acquired **Vascular Solutions Inc.** for $1bn in February. The Vascular Solutions deal was latest in a series of moves over the last decade that has transformed Teleflex from a diversified industrial conglomerate into a medical device company. *(Also see "Teleflex Buys Vascular Solutions For $1bn To Improve Growth" - Medtech Insight, 6 Dec, 2016.)*

Teleflex says it now offers the full line of products interventional cardiologists need to handle both routine and complex cases, including balloon pumps, catheters, and guidewires.

Abiomed Shows-Off Third-Gen Impella CP At SCAI

Abiomed Inc. unveiled its *Impella CP-Third Generation* heart pump at the Society for Cardiovascular and Angiography Interventions annual meeting New Orleans May 10-13.

The third generation Impella CP is a member of the Impella family of heart pumps, along with the *Impella 2.5*, *Impella 5.0*, and *Impella LD*, designed to support high-risk patients undergoing cardiac interventions. Impella CP's earned PMA supplementary approval in March 2016 to provide up to four days of circulatory supportfor patients suffering from cardiogenic shock. *(Also see "US FDA Approves Abiomed's Impella For Cardiogenic Shock Ahead Of Schedule" - Medtech Insight, 8 Apr, 2016.)* In December, the agency expanded the indication for the Impella CP to include high-risk percutaneous coronary interventions (PCI).

There are several new features on the latest generation Impella CP that simplify patient management, according to Abiomed, including the ability to enable higher flows, including peak flows above 4 liters/minute for patients whose hearts need additional pumping support, and a new guidewire re-access sheath that allows clinicians to re-access the femoral artery and rapidly escalate care if necessary. Impella CP Third-Genteration new insertion kit has a unique 25 cm introducer sheath to help insert the device in challenging or tortuous femoral vessels. The introducer sheath can be removed with a simple peel-away technique that is not possible with any other kind of introducer, according to Abiomed.

In the US, Impella CP has been placed at 1,016 hospital sites for a penetration rate of 73% of total hospitals, and the survival rate of acute myocardial infarction complicated by cardiogenic shock (AMICS) has improved 14% compared to the year before the FDA approval, according to Abiomed. However, of the 89,000 AMICS cases nationwide in 2016, only 6% were supported by Impella heart pumps. Abiomed hopes that making the device easier to deploy will increase that percentage.

"The ability to introduce the Impella device simply and swiftly even in the presence of challenging femoral or iliac arteries will be valuable for interventional cardiologists caring for high-risk patients during PCI and for those in cardiogenic shock," Abiomed Chief Medical Officer Seth Bilazarian explained. "Enhanced flows will be very useful, as will the new guide wire repositioning unit which expands the options for access site closure or device exchanges."

During the company's fourth-quarter earnings call on May 4, Abiomed CEO Michael Minogue mentioned that a version of Impella CP with an fiber optic sensor recently received a CE mark and will begin rolling out in Germany in the next two quarters. The company hopes to launch this version in the US by the end of the year. The optical sensor allows provides real-time sensing of the location of the Impella pump relative to the aortic valve during the procedure. "And that's really important to maximize the flow," he said. "It's definitely an ease-of-use aspect for patients that are in the ICU. And it will also give us in the future more ways to do smart pumping, so we can actually help wean the patient off and maximize the opportunity of heart muscle recovery."

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