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NEW AT MEDTECH EUROPE:
Bisazza Spotlights Industry's EU Regulatory Challenges

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Although Oliver Bisazza has only stood at the regulatory helm of Medtech Europe for a couple of months, he is no stranger to the medtech regulatory scene and the ongoing reforms. Now in his key role at the EU's largest medtech trade association, Bisazza is ready to advise the medical device and IVD sector on when to press the stop and start buttons as the new EU regulatory machinery starts to splutter into operation.

The implementation process for the new Medical Device and IVD Regulations (MDR/IVDR) is still in its infancy, but there is no time for companies to be complacent, Bisazza said in an interview. The association is advising its members to focus compliance efforts on whatever they can do now, he said.

Bisazza is already a well-known figure in the sector, having previously worked as director of Europe, Middle East and Africa regulatory policy at Medtronic. Medtech Insight caught up with him several days before he was due to speak in London at the annual regulatory conference of the UK Association of British Healthcare Industries (ABHI), on October 5. He provided an overview of how MedTech Europe is currently approaching the labyrinthine task of understanding and explaining to its members the ins and outs of the new MDR and IVDR, now several months after the new regulations formally took effect in May.

Industry should be gap-assessing the new regulations against their existing company situations, updating their quality management systems, mapping out their economic operators and starting portfolio planning, among other activities, he said.

These are important areas where companies should already be active, he warned, because once the secondary legislation supporting the new regulations starts to arrive, there will be new material to absorb, gap-assess and implement.

That is the bottom line, but what is the main focus of Bisazza's daunting workload, and how will the industry association prioritize its efforts? Bisazza provides a picture in the Q&A below.

Oliver Bisazza *was appointed as director of regulatory and industrial policy in the summer, replacing the post left vacant by John Brennan. Brennan left the association after nine years to become secretary general of the EU biotech association, EuropaBio.*

Medtech Insight: What are the three regulatory issues that are of most concern to MedTech Europe right now, and why?

Oliver Bisazza: Our overwhelming focus right now is on the new EU IVD and Medical Devices Regulations. MedTech Europe's members are working intensively on what I call 'technical implementation,' i.e., deep diving into the texts, to identify and resolve challenges of legal interpretation. This is essential work for unraveling all the things companies need to do in practice, to make a success of the compliance deadlines.

Beyond this internal technical work, we remain engaged with the European Commission and member states regarding important "building blocks" of the new regulations. These building blocks include things like the transition

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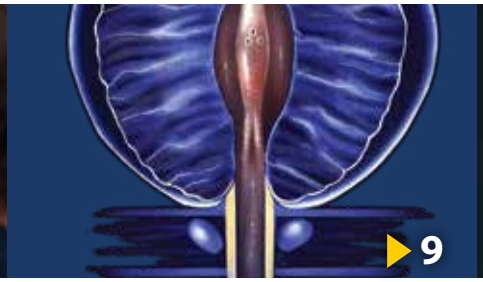

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LivaNova On The Mend With Stronger, Sharper Focus

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Damien McDonald likes fixing things and **LivaNova PLC** , it would be fair to say, was a fixer-upper when he joined the group nearly a year ago.

LivaNova was formed in 2015 following the merger of Sorin and Cyberonics, two companies with a collective history of nearly 90 years and both leaders in their respective fields of cardiovascular disease therapy and vagus nerve stimulation. While some questioned the rationale of combining two seemingly disparate businesses, supporters of the deal maintained that the merged entity would have the scale to push a broader product offering deeper into the market, and thus accelerate top-line growth, drive synergies and open new avenues for innovation. However, revenue growth post-merger proved slow. Total sales from LivaNova's three key businesses – cardiac surgery, neuromodulation and cardiac rhythm management (CRM) – barely increased by 1% in the first two quarters of 2016. While Q3 2016 saw a slight improvement of 3% growth, revenue took a big tumble in the final quarter, declining 2.3%. The particularly weak fourth quarter led to 2016 revenue being almost flat for LivaNova's first full fiscal year, increasing just 0.8% from the previous year to $1.22bn. The promised synergies also didn't materialize in LivaNova's 2016 income statement, with an operating margin of 18%, significantly lower than its medtech peers.

It was in this context that McDonald came to LivaNova. He joined the company as COO in October 2016, and only a month later – "a little quicker than I expected," he admits – was named successor to outgoing CEO (and former Sorin head) André-Michel Ballester. Some two weeks after the CEO-transition was announced in November, McDonald was speaking at the Jefferies Global Health Care Conference, where he maintained that the Sorin-Cyberonics merger was "still the right thing to do", offering "geographic synergies and a more customer-centric focus," among other things. LivaNova's building blocks, McDonald reassured investors at the meeting, were "very solid" and there was a lot of runway for more substantial growth. *(Also see "JEFHCLON16: Growth Strategies And What's In Store Post-US Election" - Medtech Insight, 17 Nov, 2016.)*.

Photo credit: LivaNova PLC

***Damien McDonald, CEO of LivaNova PLC**, set out four strategic pillars to support LivaNova's transformation: growth, profitability, talent, culture.*

This belief in LivaNova's potential has not proved groundless and, today, since McDonald officially took the helm on Jan. 1, LivaNova seems to be on the mend. The company's top-line growth this year to date has been modest but at least it is moving in the right direction. The first quarter of 2017 reported a slight year-over-year revenue decline of 0.7%, at $285.1m, but this improved in the second quarter to a 0.1% revenue increase, at $321.4m. The third quarter – the results of which the company will announce on Nov 2 – is expected to see a more substantial jump. Based on the average estimate of five analysts covering the company's stock, LivaNova is forecast to report Q3 revenue in the range of $295.4m-300.48m, a 1.8% growth, year-over-year. Others have an even more optimistic outlook, like Jefferies analyst Raj Denhoy, who forecast revenue growth of 2.3% for Q3 and further improvement into Q4 at a predicted growth of 2.5%. Indeed, Denhoy's calculations project a continued upward trajectory for LivaNova in the coming years: "We model [annual] sales growth improving to around 4% by 2020, from the current 0.8%," he wrote in a Sept.8 research note.

McDonald attributes this achievement to having "a team that is passionate about fixing something that has so much promise." "The opportunity [at LivaNova] is really tremendous in terms of the three or four major disease states where we have competitive advantages but were not being exploited," he tells *Medtech Insight* in an interview during the company's London investor meeting on Sept 20.

Unlocking opportunities and accelerating growth in billion-dollar businesses – large organizations that run the risk of being too unwieldy – is something McDonald knows a thing or two about. He had cut his teeth at diversified health care group Johnson & Johnson, where he worked across the different medical device franchises, including leading the marketing for Ethicon, a $2bn-plus company. Just before he joined LivaNova, he was group executive and corporate vice-president at Danaher; there, he led the $1.4bn-group of dental consumables businesses.

"I was lucky enough to be exposed to these various operating systems and industry leaders who, for various reasons, have been successful and one of the great things I have been able to do is bring the best bits of what I know into this role [at LivaNova]. So, J&J, I really believed, had tremendous strategy. Danaher was great at executing. Those companies each provided a different learning opportunity for me," says McDonald.

And it's people with such similar broad experiences – of portfolio management, accelerating growth and driving revenue while streamlining operations to improve margins – that McDonald has brought into the organization. For example, among the new faces in LivaNova's senior management team is Thad Huston,

who stepped into the role of CFO in May. Huston spent over 25 years at J&J and was most recently CFO of the group's medical devices division. Then there is Alistair Simpson, who joined LivaNova in April to oversee the company's biggest division, cardiac surgery. Simpson's background overlaps that of McDonald and Huston, having come from one of Danaher's dental consumables subsidiary, Kerr, and is part of the J&J alumni.

LivaNova's new senior executives are charged with executing the four strategic pillars McDonald had set out for the company: growth, profitability, talent and culture.

"These four pillars all hang together. It was very clear to me that we were growing, but just not fast enough; we were profitable, but there was no focus on really driving that profitability. The talent was definitely there, but needed to be unlocked and enhanced. And culturally, [at LivaNova], there wasn't the mentality of needing to continuously improve, needing to be accountable and there certainly wasn't a sense of teamwork, right from the top down," says McDonald.

These strategic pillars will bring that all-important focus underpinning LivaNova's transformation. This focus needed to be strong and clear to support the LivaNova story – what the company is about and what its goals are – and get buy-in from its stakeholders, not just its customers or its investors who might have lingering reservations about the Sorin-Cyberonics merger, but also the people working in the organization.

"When I came to LivaNova, it wasn't clear what we wanted to be. As I went around the company and talked to people, asking them 'what do we want LivaNova to be, how do we get there, what do you need me to do, how can I contribute', these things were not easy for people to see," says McDonald. "That's why we talk about the four strategic pillars that we need to focus on. If you can't map your activity back to these four pillars somehow, then either we haven't helped you understand your job or you are doing things in your job that are not helping the story line. That clarity made an incredible difference."

LivaNova was and still is essentially a "head and heart" company, but it does not want to be everything to everyone, McDonald asserts.

SHARPENED FOCUS

So what exactly is LivaNova about? How has its story line changed in the last year? LivaNova was and still is essentially a "head and heart" company, but it does not want to be everything to everyone, McDonald asserts. Its focus is now sharpened on legacy areas of strength and market leadership, which, it has been determined, does not include cardiac rhythm management.

LivaNova announced Sept. 14 that it was exploring strategic options for CRM, the smallest of the three business groups (accounting for 20% of H1 2017 revenue). CRM sales declined 4% in 2016, as the business – which has about 2-3% of global market share, according to Jefferies' figures – struggled to compete in a space dominated by heavyweights like Medtronic, Abbott and Boston Scientific. But it did have strengths in certain geographies and "a great pipeline", McDonald told attendees of the Sept 20 London investor meeting – CRM just no longer fits strategically in LivaNova's portfolio and its long-term growth plans. "This is a $250m-ish business, with good strengths in Europe and Japan, and has interesting science and tech to back it," he said, adding that there was potential for good growth opportunity if it went to someone who could give the CRM business the required attention and funding. "If it weren't for the other parts of [LivaNova's] business, I'd keep and fix [CRM] as I like fixing things. But it isn't the right portfolio fit," the CEO maintained.

This leaves LivaNova to further nurture and build on cardiac surgery, where Sorin's legacy *S5* heart-lung machine has been a market leader for 40 years, and neuromodulation, where Cyberonics was a pioneer of VNS therapy, especially in epilepsy.

While LivaNova already has market leadership positions in these two areas, there is still plenty of room for growth. Customer visibility is now a critical component in LivaNova's tactics to ensure its leading products do not lose share to competitors, as well as to drive demand and grow sales for its other offerings. For example, in the cardiopulmonary business, LivaNova has a 70% share of the heart-lung machine (HLM) market, with its S5 system. By introducing a database of its HLM customers, with information on where the customers are, the age of the HLMs they have, when the systems are reaching the end of their life cycle, LivaNova's sales team can use this data to identify their targets more effectively. Additionally, increased customer visibility enables the sales team to better leverage LivaNova's HLM footprint to boost sales of the company's oxygenators (an important component of HLMs) and address the discrepancy in market share of these two products (LivaNova only has 30% oxygenator market share).

The source for LivaNova's other significant near-term growth opportunities within its existing portfolio is multi-directional. This includes, among other things:

- A recent US CMS approval for a new technology add-on payment code on its *Perceval* minimally invasive aortic valve, the only sutureless heart valve on the market. This NTAP code

LivaNova's Shots On Goal

During the London investor meeting, LivaNova outlined three strategic portfolio initiatives that are expected to drive growth in the longer term:

1. VNS for treatment-resistant depression: TRD is a bit of sensitive area as Cyberonics had unsuccessfully sought US reimbursement for this indication not just once but twice, in 2007, then in 2013. LivaNova is still betting on the TRD market for VNS, but it is now focusing its efforts in the EU. It has started a pilot trial in Germany, where there is a favorable reimbursement environment for VNS-TRD, and LivaNova is planning a scaled launch in other European countries where the company already has approval and reimbursement for this indication. It is still in dialogue with the CMS with the hope of getting that all-important thumbs up for the US market.
2. Transcatheter mitral valve replacement: LivaNova first invested in Caisson International in 2012 and in May this year, it bought the company outright, thus bringing in-house the Caisson TMVR technology. Currently, only Abbott's *MitraClip* is available on the market for TMVR, but other cardiology giants – Medtronic, Abbott, Edwards Lifesciences – are racing to bring to market their respective technologies. Caisson's TMVR is said to be the only TMVR system designed to be delivered through a single venous access, and implanted using a trans-septal approach. The system comprises a proprietary delivery system as well two-part, anchor-and-valve implant. LivaNova just initiated the INTERLUDE study, a North American/EU clinical trial, in July of last year, the results of which will be used to support CE marking, hopefully in 2019.
3. VNS for heart failure: Probably the longest shot out of the three strategic portfolio initiatives. The company would not be the first to explore the use of VNS for this indication, and clinical evidence of its effectiveness has been mixed. However, CEO Damien McDonald said the company "knows it works" and that LivaNova – with its combined expertise in both vagus nerve stimulation and cardiology – has the advantage of "a real understanding of the clinical pathway" involved. Having looked at other VNS-HF studies that have failed, the CEO said at the London investor meeting that he believes LivaNova can overcome the issues that led to those studies' failure. In its ongoing trial of VNS for heart failure, the firm already has "very powerful" results from the first 60 patients. "We're in a really good spot here," McDonald assured.

means CMS will now reimburse hospitals up to an additional $6,000-plus for Perceval procedures, which would help drive penetration of the device in the US market and boost its current 20% global market share; and

- The expanded US approval of the implantable VNS system to cover use of the therapy in pediatric epilepsy patients as young as four years old. As epilepsy is often diagnosed at a young age, allowing treatment with VNS in pediatric patients should yield better results, further strengthen the clinical evidence supporting the use of this therapy and ultimately boost adoption, which still remains very low (out of a pool of 350,000 possible epilepsy candidates for VNS in the US, 65,000 are implanted with LivaNova's *Aspire* device. Outside the US, just 35,000 patients have been treated with this VNS therapy.)

M&A TUCK-INS

But growth won't just come organically. LivaNova is actively looking for tuck-in acquisitions. The company already made an acquisition in May this year, buying Caisson International, whose clinical-stage transcatheter mitral valve replacement device is one of LivaNova's longer-term shots on goal (See box, "LivaNova's Shots On Goals").

McDonald underlined that the company will be taking a "very disciplined" approach to its M&A activity, and – similar to the Caisson transaction – it would be about bolting on LivaNova's head-and-heart remit. McDonald tells *Medtech Insight* that the firm has a very active funnel and, so far, he has been very encouraged by the opportunities. However, by taking a very disciplined view on each candidate's internal rate of return, the company has already walked away from a couple of deals "as it wasn't in the window that we liked. "People would have loved the assets, but I think they would have questioned our legitimacy if we paid those prices," he says. Elaborating more on the type of technologies that would appeal, the CEO says it has to be something that "surrounds a disease state or a call point." "I don't want to be selling a widget for the sake of selling a widget. I'm looking for things to tuck into our growth strategies."

These acquisitions will hopefully give LivaNova that additional boost to its growth trajectory over the next three years and beyond 2021, the company expects these acquired businesses to start driving incremental growth.

So, has LivaNova really picked itself up and turned the corner?

McDonald diplomatically replies that "it's way too early to declare victory." However, change – for the better – has happened and this is just the beginning, he believes. "If we look at our growth in the last two quarters, you'll see a slight change in the growth profile. We've started changing our profit profile – our gross margin and adjusted operating income. Culturally, we've begun the journey well and certainly in terms of market valuation, what we've seen in the last few months is people being very receptive to our story," he says. "On multiple levels, we are seeing the embers of the journey I want the company to take."

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'Super Office' To The Rescue: FDA's Device Center Is About To Undergo A 'Total Product Life Cycle' Makeover

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US FDA's device center is moving quickly on a major reorganization that will essentially dissolve and replace the Office of Compliance, Office of Surveillance and Biometrics, and Office of Device Evaluation into one "super office" that would fulfill a "Total Product Life Cycle" (TPLC) scheme the agency has long envisioned.

The yet-unnamed office would have jurisdiction not just to review and greenlight products in the pre-market stage, but continue to assess them and the manufacturers that make them after they've hit shelves, too. *(Also see "US FDA Device Center Pushes 'Total Product Life Cycle' Concept; 'Reorganization' Coming, Says Compliance Chief" - Medtech Insight, 19 Apr, 2017.)*

CDRH Director Jeff Shuren announced plans for the TPLC office Sept. 28 during AdvaMed's 2017 Medtech Conference in San Jose, Calif. Shuren announced the planned changes to FDA staff about two weeks ago, he told *Medtech Insight* in an interview following his announcement.

Bill Maisel, deputy center director for science and acting director of the Office of Device Evaluation, will head the new super office. And the current heads of the Office of Compliance (Robin Newman) and the Office of Surveillance and Biometrics (Thomas Grossman) will retain management over those functions under the new structure, he suggested.

CDRH Director Jeff Shuren took industry questions at AdvaMed's Medtech Conference

Photo credit: Ferdous Al-Faruque

TAKING A TEAM APPROACH

The concept of total product lifecycle -- where device development is viewed as a feedback loop of devices being developed, approved and marketed, and then new iterations being approved again, and so on – is not a new one to CDRH. It was the basis for forming the Office of In Vitro Diagnostic Device Evaluation and Safety (now the Office of In Vitro Diagnostics and Radiological Health) in 2000 as an office that handled pre-market review, post-market surveillance and quality issues for diagnostics.

Now, the center is more than doubling down on that approach, says Shuren. The new office would completely upend the center's traditional bureaucratic structure and instead encourage a "team approach" to pre- and post-market product oversight, he said.

"It will look very different because it will no longer be branches or offices," he told conference-goers. "The lowest level will be divisions, everything else is teams. A lot of changes going on with this office that we think will allow us to be far more efficient and effective, but also invest more in the professional development of our staff.

"I will say one thing though: Anything like this will always have hiccups, so cut us some slack," he added. "There may be some bumps here and there, but overall the intent is when we're done we'll have a much better working organization."

Shuren says the super office will address issues such as information-sharing, which he acknowledged may be challenging at times under the current regime as products are handed off between different offices. Instead, the new office will be designed to ensure the right agency experts are dealing with the products at the right stage. It will move agency officials away from sending consults to figure things out that may lead to unnecessary paperwork between offices.

Manufacturers, however, can expect to have the same reviewers, said Shuren, but product reviews will be performed in a way that helps the center stay better informed while being more fluid to adjust for workloads and technology changes.

ADDRESSING STAFFING CHALLENGES

The new office is also meant to help with staffing challenges, which is a topic that Shuren has been especially keen to address. He has long raised the alarm that FDA cannot offer the same career advancements and salaries that the private sector can. Speaking to *Medtech Insight*, he said often FDA becomes too focused on user fees and other work, and not focused enough on spending resources on employees.

FDA staff "often find that if they want to advance professionally they have to look for other jobs," said Shuren. "We're trying to address that all in the TPLC office."

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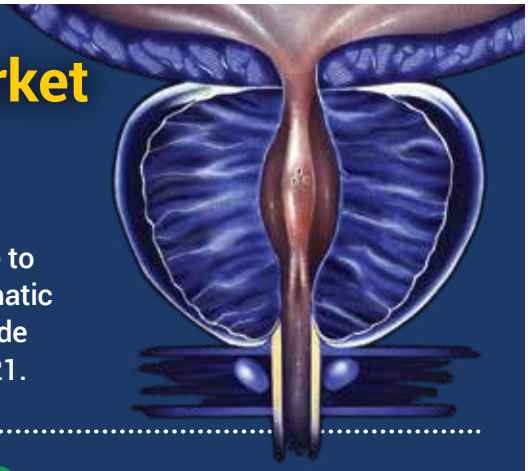
BPH and Prostatitis Device Market Will Grow As Population Ages



Over the next five years, the aging of the population, patient awareness, and increasingly sophisticated therapy will combine to increase the number of patients seeking treatment for symptomatic benign prostatic hyperplasia (BPH) and prostatitis. The worldwide market for these therapies is expected to reach $586.1m by 2021.

The worldwide market for device and pharmaceutical therapies to relieve BPH symptoms is growing, driven mainly by growth of laser-based treatments and implants.

Worldwide

2016	421.0m
2021	586.1m

30m

Number of men diagnosed with moderate to severe BPH each year in the world

>100m

Possibly the real incidence of BPH, which is underdiagnosed in many countries

GEOGRAPHIC BREAKDOWN BY COUNTRY/REGION

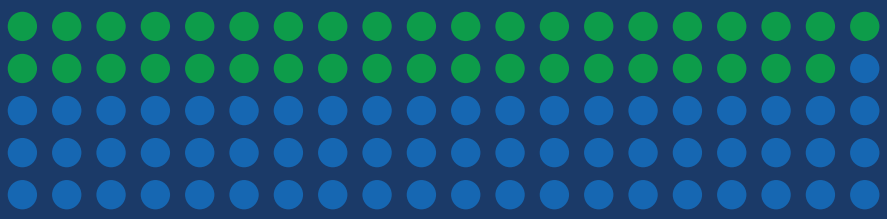
2016 2021

US	5EU	Japan
10.3m	12.3m	6.2m
11.5m	13.5m	6.2m

20-25%

Percentage of men suffering from BPH who may seek help

39% PROBABILITY OF MEN OVER THE AGE OF 60 YEARS WITH OBSTRUCTIVE BPH SYMPTOMS UNDERGOING SURGERY



Source: Meddevicetracker's Report on The Benign Prostatic Hyperplasia and Prostatitis Device-based Treatments Market

Will Reshuffle Extract Sluggish Dentsply Sirona's Potential?

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Dentsply Sirona Inc.'s leadership is in flux following the resignation of the company's top-tier personnel – executive chairman Bret Wise, CEO Jeffrey Slovin, and president and COO Christopher Clark. Replacing the outgoing executives – with immediate effect but on a temporary basis – are Mark Thierer, who assumes the position of interim CEO, and Bob Size, who will be interim president and chief operating officer. Board director Eric Brandt has been appointed non-executive chairman.

Dentsply Sirona stated that the leadership changes were "intended to better position the company to achieve its potential," while Brandt added that new leadership was "critical" to the enable the Salzburg-headquartered group to achieving its business objectives.

Thierer has over 30 years' experience in the health care industry, mainly in the pharmacy services sector. His track record includes overseeing a number of mergers; first as president, CEO and chairman of SXC Health Solutions, which merged with Catalyst Health Solutions to create Catamaran, then as chairman and CEO of Catamaran which merged with OptumRx in 2015.

Size, on the other hand, brings to the table his internal knowledge of Dentsply, both pre- and post-Sirona merger, having served as senior VP of the company for a decade between 2007 and 2017.

Dentsply Sirona said it is in the process of identifying a permanent CEO and COO.

The management shakeup comes about 18 months since Dentsply International completed its merger with Sirona Dental Systems in February last year. When the deal was first announced in September the year before, eyebrows were raised at the merger terms, which saw a stock-swap that did not entail any premium over Sirona's then share price. *(Also see " Sirona Forfeits Premium For Significant Benefits Dentsply Merger Will Bring" - Medtech Insight, 21 Sep, 2015.)*. Jeff Slovin, who was Sirona's CEO at that time and late took the helm of the merged entity, had assured investors there was "so much upside" to combining the two companies, and that integrating the operations to offer a broader product line and create more cross-selling opportunities will result in expected annual pre-tax synergies of at least $125m in the third year following completion of the deal.

However, the pace of change has been sluggish while there are still no signs of the promised synergies, and the combined company's stock price post-merger has been underperforming significantly against its peers, noted Jefferies analyst Brandon Couillard. "From our vantage, [Dentsply Sirona] struggled to integrate the two legacy organization, which impaired its ability to begin capturing the $125m of targeted deal synergies remain elusive, while costs ballooned," he wrote in an Oct 3 research note.

The analyst approved the leadership stand-ins, saying that Thierer's "dental industry outsider" perspective would enable him to make hard integration decisions without legacy ties. He also said Size was "a logical choice," with his experience leading Dentsply [International's] global efficiency program, which led to impressive ROIC gains in 201/15."

While the company's stock price had plunged to a 52-week low in August following poor Q2 results which showed declining sales, Couillard maintained that the leadership change is not an indication that more weakness is expected in the second half of the year. "The decision was more due to past performance and not related to 2H results (as evidenced by the reiteration of the 2017 EPS guidance. We believe the 2Q17 debacle (guide down & impairment) likely sealed the deal and suspect the move had been in motion for many weeks. With XRAY on-track to meet its 2H guide, we see no reason to view '18 as a 'transition year' with muted growth prospects."

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New CEO To Lead Atlas Genetics' Commercial Phase

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Atlas Genetics Ltd. has appointed Jeffrey Luber CEO. He succeeds John Clarkson, who founded Atlas Genetics and who will now take on the role of executive chairman. Current chairman, Neil Butler, will remain with UK company as a non-executive board director.

Luber has led both public and private companies; he was most recently with **Good Start Genetics** where he restored growth to its core business, expanded its reach into consumer markets, and forged partnerships with multinationals like Roche and Amazon. He oversaw the sale of Good Start Genetics to **Invitae Corp**. In his role at Atlas Genetics, Luber will lead the expansion of the company's commercialization activities.

Atlas currently has two products on the market: a chlamydia trachomatis test and a combined chlamydia and gonorrhea test, both of which run on its *io* electrochemical sensor platform.

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US FDA Approves Medtronic's HVAD For Destination Therapy

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US FDA approved **Medtronic PLC**'s *HeartWareHVAD* left-ventricular assist device system as a "destination therapy" for patients with advanced heart failure who are not candidates for heart transplants.

The approval will allow Medtronic to market HVAD to the same population eligible for **Abbott Laboratories Inc.**'s *HeartMate II* LVAD. HeartMate II earned the long-term destination therapy indications in 2010 and it has proven to be an important advantage over HVAD in the US market. *(Also see "HeartWare HVAD Meets Primary Endpoint For Destination Therapy" - Medtech Insight, 21 Apr, 2015.)*

FDA approved the new labeling for HVAD based on results from the ENDURANCE and ENDURANCE Supplemental trials, which enrolled about 1,000 destination-therapy patients. ENDURANCE randomized 446 patients in need of a destination therapy to either HVAD or a VAD already approved by FDA, including HeartMate II. The primary endpoint of the trial was stroke-free survival at two years, and 55% of the HVAD patients achieved the endpoint, showing non-inferiority. Among 200 patients implanted with a newer version of HVAD, upgraded in 2011 with a sintered titanium inflow cannula, 57.5% attained the primary endpoint. *(Also see "Clinical Data Double-Boost Supports Medtronic's HeartWare Investment" - Medtech Insight, 11 Apr, 2017.)*

However, the two-year stroke rate in the HVAD group was 29.1%, compared to just 12.1% in the control group. Because elevated mean arterial blood pressure proved to be a significant independent risk factor for strokes, the investigators ran the ENDURANCE Supplement trial in 446 patients to evaluate the impact of enhanced blood pressure management on the outcomes of patients treated with HVAD. The results showed that a reduction in mean arterial blood pressure reduced the rate of stroke and transient ischemic attack in patients receiving an HVAD by 24.7% compared to the rates in ENDURANCE.

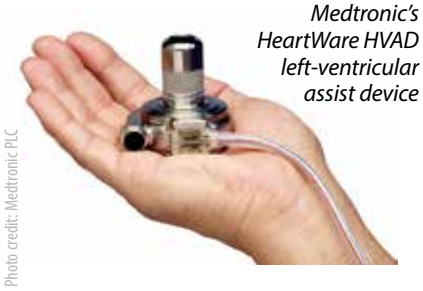

Photo credit: Medtronic PLC

Medtronic's HeartWare HVAD left-ventricular assist device

The primary endpoint of the ENDURANCE Supplemental trial – the incidence of neurologic injury at one-year with HVAD compared to HeartMate II – missed the non-inferiority criteria, but HVAD was superior to HeartMate II for one-year survival free from disabling stroke, death, device malfunction requiring exchange, removal of the device or urgent transplant.

Analysis of outcomes for the sickest patients in ENDURANCE treated with HVAD – 95 patients in the trial classified as INTERMACS level 1 or 2 – showed they had similar outcomes to the rest of the patients treated with HVAD. Most previous VAD trials have shown worse outcomes in patients with the worst INTERMACS scores.

HVAD earned a CE mark as a bridge-to-transplant for patients eligible for heart transplants in 2009 and then the FDA approved it for that indication in 2012. It earned a CE Mark that same year for patients at risk of death from refractory, end-stage heart failure.

Medtronic acquired HVAD when it bought **HeartWare International Inc.** in 2016 for $1.1bn, about a year after **St. Jude Medical Inc.,** now part of Abbott, bought HeartMate-developer **Thoratec Corp.** for $3.4bn. *(Also see "Medtronic Set To Compete With Abbott/St Jude In VADs After Buying HeartWare " - Medtech Insight, 27 Jun, 2016.)* Both deals gave the bigger companies an LVAD to market alongside their other heart-failure therapies, and provided much needed R&D resources in the LVAD space.

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Roche Launch First Cancer Care Clinical Decision-Support Tool

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Roche has launched a new digital, cloud-based software tool for managing tumor boards and streamlining oncology care collaboration. The *Navify* digital tumor board solution is the first decision-support product launched by Roche and will be available in the US, UK, Germany, Spain, Sweden and Switzerland.

Tumor board reviews are established meetings in clinical care in which specialists come together from different disciplines to jointly review an oncology case and then agree on treatment options for the patient. The process can be time-consuming for health-care providers as extensive patient information must be gathered manually before the meeting.

"The reality of tumor boards is that in many cases the physicians don't have the time to prepare for it well. If some of the core documents are missing there isn't really the right type of informed decision making which is needed and what the patients deserve," Tim Jaeger, Head of Roche Diagnostic Information Solutions told *Medtech Insight*. Jaeger said as the diagnostic complexity of oncology cases increases, clinicians need tools to support the comprehensive review of patient data.

"The complexity of medicine is going far beyond what we have seen before. We now know there are 30/40 different kinds of breast cancer or 40/50 kinds of lung cancer and really beginning to understand the complexity of disease and biology," he said. "Roche diagnostics want to help clinicians navigate the complexity of disease, the diagnosis and essentially the way a good treatment decision is reached. At the same time,

we want to support those interdisciplinary care teams in jointly getting to the best possible decision."

The new workflow tool allows clinicians to collect data such as patient medical history, biomarkers, tumor information, radiology images, pathology reports and electronic medical record notes from multiple sources and collate in one digital dashboard. In addition, the software can be used to coordinate logistics, prepare for the meeting and document meeting outcomes.

While developing the software, Roche worked with clinicians across European and US sites to pilot the application. "The great feedback we received is that Navify helps clinician's tumor boards become a lot richer in information," Jaeger said. "With the software, they are able to review maybe 3 or 4 times more documents around a specific case than they would manually which makes the quality of the discussion so much better and optimizes decision-making."

Jaeger said Navify can help physicians manage large patient groups by increasing the frequency of tumor board discussions and accelerating patient treatment. "We have seen in many hospitals and leading academic centers that they are struggling with long patient waiting lists and solutions like this can help care teams work more efficiently," he said.

"Clinicians always needed to collate this type of information but only now clinicians have a tool to support this process," he said. "We have even seen that clinicians that were hesitant to use technology actually switching quite quickly to this type of software. Physicians are won over when they understand how they will get to better quality decisions for their patients and we can provide evidence of that."

The workflow solution is the first decision-support product launched by Roche but is the first of many according to Jaeger. "We have taken the decision to expand our product offering into clinical and lab decision support to really augment our offering," he said. "We are already providing a range of diagnostic tests across IVD so we wanted to bring in our understanding of medicine, the complexity of health-care routines and converge and enrich those data points into a much more comprehensive offering to the clinicians so you can expect to see more of these types of products from Roche coming to market."

"We're not disrupting how clinicians work, we're simply augmenting and supporting what they already do. We are not planning in any shape or form to replace clinicians with the products we provide," Jaeger said. "Navify is there to support them in very complicated, daily routines and we want to make sure clinicians feel comfortable and in charge."

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Abbott Gains Go-Ahead For First 'No-Fingerstick' CGM

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Abbott Diabetes Care Inc.'s mobile *Freestyle Libre Flash* continuous glucose monitoring system was approved by US FDA as the first CGM that can be used by adult diabetes patients to directly make treatment decisions without calibration from a blood sample.

Dexcom gained approval last year for its *G5* system for non-adjunctive treatment decisions without regular fingersticks in pediatric and adult patients, but that device still requires fingerstick blood samples for calibration. *(Also see "Dexcom First To CGM Reimbursement Finish Line" - Medtech Insight, 17 Jan, 2017.)*

"FDA is always interested in new technologies that can help make the care of people living with chronic conditions, such as diabetes, easier, and more manageable," said Donald St. Pierre, acting director of FDA's diagnostics office. *(Also see "Dx Departure: US FDA's Diagnostics Chief Gutierrez Steps Down" - Medtech Insight, 28 Sep, 2017.)* "This system allows [diabetics] to avoid fingerstick calibration, which can be painful, but still provides necessary information." Use of the device is indicated for those with diabetes, age 18 and older, according to the company and FDA.

LIKELY WILL BE PRICED AT $35-$40 FOR 10-DAY SUPPLY

While the company could not confirm precisely what they will charge for the device in the US, a spokeswoman said it will be similar to the cash cost for the device in Europe. That means the price for 10 days would come to about $35-$40. The Freestyle Libre system is now being used by more than 400,000 across 40 countries, and Abbott has secured partial or full reimbursement in 17 countries, including France, Japan, and the United Kingdom.

The company has applied for, and expects to receive Medicare reimbursement for the Freestyle Libre, but the process to do so could take as long as 90 days, according to a market analyst's report.

"We'd note about 50% of Libre patients OUS are 'cash pay,' which suggests to us that the product should be attractive in the US even if reimbursement is challenging," Wells Fargo analyst Larry Biegelsen says.

SELF-APPLIED SENSOR WIRE INCLUDED

The Freestyle Libre, about the size of cell phone, relies on a small sensor wire inserted below the skin's surface that continuously measures and monitors glucose levels, according to FDA. The insertion procedure with an applicator leaves behind a small cylinder of plastic that is about the size of two stacked quarters, Abbott explained.

While there is no fingerstick testing, the sensor itself is "self-applied" and consists of "a small filament [sensor wire] that is insert-

ed just under the skin and held in place with a small adhesive pad," an Abbott spokeswoman told *Medtech Insight*. Patients apply the sensor wire themselves via a spring-loaded sensor insertion part that uses a small needle to insert the tiny filament, and may feel a slight prick when doing so.

To take a reading of glucose levels after the filament is in place, the user takes a one-second painless scan with a small, dedicated, handheld reader over the sensor. The sensor identifies glucose level trends as "high, low, or stable" with a directional arrow and can review eight hours of glucose history, the company stated. The subcutaneous sensor wire stays in place for 10 days, before another one must be applied.

DEVICE CAN'T BE USED WITH MRIS, CT SCANS

Contraindictions and warnings supplied with the device note that it requires a prescription, that the sensor wire should be removed before MRIs, CT Scans, X-rays or diathermy treatments, and that it is not approved for pregnant women, persons on dialysis, or the critically-ill population.

Further, sensor placement is not approved for sites other than the back of the arm, and standard precautions for transmission of bloodborne pathogens should be taken.

STUDIES SHOW USERS SPEND LESS TIME HYPOGLYCEMIC

Some of the benefits of the device is that it reduces the time diabetics spend in a hypoglycemic mode, said Tim Dunn, principal clinical research manager of Abbotts Diabetes Care.

He summarized some of the studies performed on the Freestyle Libre in an interview with *Medtech Insight* earlier this month, noting that the studies – undertaken around 2014-2015 – captured performance and outcomes data. "In type 1 diabetes, it dramatically showed that over six months, these patients who were well-controlled from an average glucose perspective were able to dramatically reduce their time in hypoglycemia," Dunn said.

For type 2 diabetes patients – those that require insulin – "they've also been able to increase the number of times of day they check their glucose, and with that information, they've been able to reduce their time in hypoglycemia without worsening their hb1c, compared to people who used a standard, finger-stick regimen," Dunn remarked.

The trials were both randomized controlled trials, "that were really strong at showing the outcome benefits for people who adopted the system," he added.

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START-UP SPOTLIGHT: Peripal, Easing Peritoneal Dialysis For ESRD

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Peritoneal dialysis (PD) offers many end-stage renal disease (ESRD) patients a way to take their renal replacement therapy into their own hands at home, liberating them from lengthy sessions hooked to machines at hemodialysis centers. But connecting oneself to the dialysis equipment can be difficult and risky. Zürich-based startup **Peripal AG** has developed a connector it hopes will eliminate that barrier to PD — and potentially boost a niche market for home dialysis care.

"Home care is such an important trend in the entire health care industry. We will be on the top of that wave," says CEO Sandra Neumann. "We hope that we can support, as well, with the transition from hospitals to the home, where the health care system actually wants to foster that."

GROWING MARKET

Patients using PD first undergo surgery to implant a permanent catheter into the abdominal cavity. For dialysis, the patient connects his or her catheter to fresh dialysate fluid, and for several hours, waste exchange takes place across the peritoneal membrane in the abdomen. Then the connection is broken and the fluid is drained and disposed. The modality is popular with younger patients, in part because it frees them from the rigid schedule of a hemodialysis center. It is also less expensive than hemodialysis and is better tolerated by some patients.

While PD still accounts for a small share of the total dialysis market, its popularity is growing. The PD market segment is worth just $3.0bn globally, according to a 2016 annual report from home dialysis specialist **NxStage Medical Inc.** , compared with

TABLE 1

Growth Of The PD market, 2010-2022

YEAR	PERITONEAL DIALYSIS MODALITY SHARE (%)
2010	7.9
2011	8.4
2012	9.3
2013	9.8
2014	10.4
2015	10.2
2016	9.9
2017	10.2
2018	10.5
2019	10.8
2020	11.1
2021	11.4
2022	11.7

Source: Citi Research, "Fresenius Medical Care (FMEG. DE). NXTM acquisition – Homerun or Homewrecker?" Patrick Wood and Catherine Tennyson

$10.1bn for in-center hemodialysis. But an Aug. 8 report by Citi Research projects a healthy growth rate, with patient penetration rising to 11.7% in 2022 compared with 9.9% in 2016. (See Table 1.)

In 2014, according to the United States Renal Data System, some 9.3% of US patients with new ESRD were started on peritoneal dialysis, and 50% more such newly-diagnosed people were using the modality in 2014 than in 2000. For people with ongoing ESRD, the rise in PD use was 71% over the same period.

The numbers could climb much higher. In Hong Kong, for example, which has had a PD-first policy since the 1980s, 3 out of 4 dialysis patients use PD, with only 1 in 4 using hemodialysis. Dialysis giant **Baxter International Inc.** , for one, has placed major bets on PD, halting development of its home hemodialysis platform *VIVIA* in 2016 in favor of its *Amia Automated PD System* and *Sharesource Connectivity Platform*.

REMOVING PD HURDLE

PD carries a substantial risk of infection, however, with peritonitis being the most serious complication and the most frequent reason PD fails. Daytime PD requires four to six exchanges a day, and each connection offers bacteria a route into the body. In addition, the connection step can be prohibitive for patients with hand tremor or poor eyesight. The *Peripal System* is a coupling device intended to make this step easier, safer, and less burdensome.

"We created a system where the patient would never actually open the catheter manually by themselves. Whenever you open your catheter and are exposed in a certain way to infection, this is only done within the device so you're protected," Neumann says. "You cannot actually fumble in there with your fingers."

The device resembles a box which, when opened, contains several channels into which the catheter and dialysate tubing can be laid. The patient inserts these, closes the box, and moves a lever and presses buttons to make and break the connection. (See Figure 1.)

A biochemist by training, Neumann was formerly General Manager, Renal, for Baxter AG in Switzerland; she has also worked as a medtech business development consultant, and as a strategy consultant with McKinsey & Company Inc.

FIGURE 1

The Peripal System

The device offers patients a lower-risk method to attache their PD catheter to dialysate tubing

Photo credit: Peripal AG

Working with the Federal Institute of Technology in Zurich, Switzerland (ETH Zurich), she became interested in how eye-tracking technology could help device designers pinpoint what confuses patients. Neumann and Peripal co-founder Stephan Fox, an ETH PhD candidate, studied PD patients' behavior with this system and incorporated extensive feedback from patients during the design phase.

In July this year, Peripal completed a series A1 round, of which financial details were not disclosed; participating in the round were two Swiss banks in addition to previous investors StartAngels and other business angels. The funds will help the company take its device through ongoing clinical studies and up to CE mark approval. Peripal is aiming to get the CE mark in 2018, then launching the product in Europe before moving onto the US to work on getting FDA approval. The firm is also seeking IP protection via a pending PCT application.

Production is "currently ramped up until end of the year" in Switzerland and Germany, according to Neumann. She is proud of the speed with which it has moved. "From idea to market, in two and a half years, for a medical device is quite okay," she says. The company also plans to target emerging global markets, where many countries, including Thailand and Colombia, have PD-first policies.

In charge of R&D project management at Peripal is Jean-Claude Gröbli, PhD, a physicist who previously worked in Operations and R&D at **QIAGEN Instruments AG**. Barbara Jeroncic, also a medtech veteran, worked at regulatory affairs at Tecan, among other companies. She heads up Quality Assurance and Regulatory Affairs at Peripal.

In future, Neumann believes the Peripal System could move into other home-care markets, assisting patients who manage their own vascular access for conditions like cancer and interventions like total parenteral nutrition or antibiotics via PICC line — "wherever you have a patient who is a layperson taking care of themselves in a chronic disease," Neumann says.

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Contact: Sandra Neumann, PhD. CEO

Industry Segment: Nephrology

Business: Peritoneal dialysis peripherals

Founded: June 2015

Founder: Sandra Neumann, PhD

Employees: 6

Financing to Date: Seed, series A, and series A1 rounds, amount undisclosed.

Investors: Start Angel, Zürcher Kantonalbank, Aargauische Kantonalbank.

Board of Directors: Reto Koch, Chairman of the Board; Erich Platzer, MD/PhD, Member of the Board; Sandra Neumann, PhD, Member of the Board

Scientific advisory board: Peter Rutherford, MD, PhD, Vice President, Integrated Market Access, Quintiles, and former medical director and EMEA head

TRADE SALE EXIT?

With regard to an exit strategy, Neumann envisions a move from either a large dialysis-products company, like **Fresenius Medical Care AG & Co. KGAA** or Baxter,

or a hospital supplier. "This could be a very nice, very profitable add-on to their portfolio," she notes. "We're not restricting ourselves too much at the moment because we see that it's going to be a very attractive, profitable product in its niche."

Peripal investor Erich Platzer, MD/PhD, predicts an exit via M&A, thanks to Swiss law that frees individual investors, but not corporate investors, from capital gains taxes. But, he stresses, "we are not impatient—it's not like we are seeking an exit tomorrow…We first want to build success and build value."

Platzer, an oncologist and business angel whose experience includes a business directorship at Roche, says his decision to invest was based in large part on his admiration for Neumann, whom he calls "an absolutely convincing person."

But, he adds, the product itself carries an attractive risk profile.

"This company has mostly market risk, execution risk," he notes. "Compared to some of the other stuff I have [in my portfolio], it's relatively low technological risk, but it has, I think, a lot of potential benefit for patients." Hurdles may include getting physicians to make the switch from tried-and-true in-center hemodialysis to the less familiar PD option.

"If you put somebody on peritoneal dialysis, and the patient doesn't handle the device well, and then encourage an intraperitoneal infection, there's a medical risk involved, and as a doctor, you shy away from that," Platzer says. But he hopes that if Peripal can reduce the risk of infection, a reduction in PD failures could follow, and perhaps a wider uptake of this treatment option.

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He said the challenge is that FDA staffers are in high demand, and the agency is at a disadvantage in the amount of compensation it can offer or the experts it can hire.

"I can't offer the same salaries or other opportunities that you can in the private sector," he said. "By the same token, there are some very capable people in the private sector that I can't bring into the FDA either because of the big salary cuts they have to take, or because they own stocks and that's their retirement. And I have no opportunity just to say let's wall it off for that one company depending on the job they have to divest."

The TPLC office would also allow CDRH to "flatten the organization" so it can figure out solutions without having to dig through bureaucratic layers, which in turn can free up technical managers who can focus on big-picture topics and personnel issues, Shuren said.

Shuren says all this will be done with resources FDA already has and is really just a matter of placing people in positions that align with the work they already do in the new office structure, while also giving them the opportunity to expand their career opportunities.

In parallel to the major reorganization, Shuren says CDRH is also stepping up efforts to improve engagement with industry (based on findings from a working group that the center is starting to implement) and it is updating its outdated IT systems. He added that the agency is in discussions to consider solutions such as using cloud-computing.

ON LEAST BURDENSOME, CONGRESS FELL SHORT

One ultimate goal of the super office is to further expand the least-burdensome paradigm, according to Shuren. "Least burdensome" was clarified in the 21st Century Cures Act. But in the agency's perspective, Shuren says, "Congress didn't go far enough, not even close."

"Our view is that 'east burdensome' is the fundamental operating principal of what we do," Shuren told attendees. "We believe it applies across the total product lifecycle for everything we do and we think it is a broader concept than what is written in the statute."

He noted that Congress stated everyone in the pre-market review process should be trained on the least-burdensome concept, but he thinks the concept is must-training for all staff, whether focus on pre-market, post-market or compliance.

Another factor to consider with regard to the TPLC approach is categorizing how data is gathered and analyzed, especially in the context of the new National Evaluation System for health Technology (NEST).

"We talk about 'clinical trials' and 'real-world evidence'; I'd love to take both terms and get rid of them. We should only talk about clinical evidence," he said. "It's irrelevant if it's a traditional clinical trial or if it came out of an observational study from a registry – who cares? What matters are the two factors we laid out in the final guidance in August on real-world evidence: Is the evidence relevant to the question we have to answer, and is it sufficiently reliable that we can use it to make a decision?"

He said that clinical trial experts and real-world evidence epidemiologists will get "smooshed together" into the new super office, allowing them to take an agnostic approach to clinical evidence.

EXPECTATIONS FOR INDUSTRY

But it's not just FDA that should apply the least-burdensome approach; industry must also do so, Shuren said, by only offering up information that is relevant to the issue at hand.

"This is what we view as 'least burdensome': the minimum amount of information necessary to adequately address the right regulatory question, and issue through the most efficient manner at the right time," said Shuren. Similarly, he said industry should use that approach instead of throwing the "kitchen sink" at FDA when they submit their pre-submission application.

"Do you think you're going to get a timely review if you throw stuff at us that really isn't relevant? No, that's not going to happen," said Shuren. "Maybe IBM Watson could do that, but we can't."

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LISTEN

Listen to our full interview with Jeff Shuren from The Medtech Conference at http://bit.ly/2xZBmlz.

CONTINUED FROM PAGE 1

periods, the governance system, and the availability and capacity of notified bodies. For the IVD and medical device sectors alike, it's essential that we work together to get these elements right in a timely manner.

A third key area of our regulatory work is in the area of chemicals and environmental legislation. While the new IVD and Medical Devices Regulations are our focus, horizontal EU legislation like the REACH Regulation, the Biocidal Products Regulation, the RoHS Directive and so on, all remain important to our members. On 26 September, we co-organized a life sciences industry roundtable, to explain to the Commission and relevant EU agencies some of the unique challenges the REACH Regulation pose to industries such as ours.

What do you think will be the three regulatory issues that most concern the association in 12 months' time, and why?

Bisazza: I see the three activity areas just described as long-term challenges and we're in for the long haul. This time next year, however, I certainly expect that things will have moved on with the IVD and Medical Devices Regulations and the three "building blocks" I mentioned.

Think, for instance, about notified bodies. Right now, we're still waiting for 26 November 2017 to arrive when notified bodies can first apply to be designated under the new medical device regulations. By this time next year, however, we'll be well into the designation process and can gauge whether progress has been satisfactory.

In 12 months' time, we'll also be well into the 3- and 5-year transition periods for the MDR and IVDR, respectively. The transitional provisions of the regulations are quite complex, and can change depending on things like the timely availability of the EUDAMED medical device database. Building EUDAMED is a major priority for the Commission, but also a highly ambitious task, so we'll all be taking stock of the progress made in 12 months' time.

Finally, by September 2018, the new governance system will be well and truly up and running. This includes not only the Medical Devices Coordination Group (MDCG) and the Competent Authorities for Medical Devices (CAMD), which will both comprise authority representatives, but also the various sub-groups that we expect will be the main vehicles for drafting documents like secondary legislation and interpretive guidance. It is essential that these groups work regularly, in earnest, and substantively involve industry and other stakeholders from beginning to end.

How optimistic are you that the notified bodies will be designated in good time, and can you explain your views and what you are advising your members?

Bisazza: The timely availability and sufficient capacity of notified bodies is absolutely critical for the medical technology industry and for the success of both regulations. We are stressing to the Commission and member states that they will need significant ambition and investment of resources to make a success of this task.

Eventually, however, companies will need to start CE marking their IVDs and medical devices under the new regulations, and for most products this will depend on notified bodies being available. If a notified body only becomes available 12 months before the compliance deadline, instead of 18-24 months, for instance, this difference can have a major impact on companies' internal planning and implementation efforts.

In the interest of continued business certainty and overall confidence in the new system, MedTech Europe is, therefore, in constant dialogue with the Commission and member states about the need to get notified body designation right the first time, and early on.

How important is the Commission/CAMD roadmap in ensuring that implementation of the various parts of the Regulations are achieved, and achieved in a timely way?

Bisazza: We see the Commission/CAMD roadmap as an important insight into the new governance system, the elements of the regulations on which the authorities will focus their efforts, the implementation timeframes that authorities will target, and the extent to which industry and other stakeholder will be meaningfully involved.

Numerous experiences show the benefit and importance of involving stakeholders early on and in detail, rather than merely posting draft documents for final public consultation.

Why is the finalization of that roadmap important to MedTech Europe and its members?

Bisazza: For MedTech Europe and for our members, the roadmap will bring clarity on the governance system and structure on the implementation of the regulations. This will allow our members to properly plan and implement their own compliance activities.

Both the Commission and member states have stressed a need to focus their resources on implementing the most essential elements of the new regulatory system, and this means that official interpretive guidance may not be available for all topics for some years.

As with all EU regulations, however, we need to ensure genuinely EU-wide interpretation and enforcement of the new rules. This is needed for those parts of the regulations which industry (and not just authorities) consider essential. A routine manufacturer task, like labeling, for instance, is hugely resource-intensive for industry, but is not always an immediate focus area for authorities when they consider the topics on which to write guidance.

The roadmap is therefore an important tool, to help industry understand which elements authorities might priv-

ilege for implementation, and which gaps might therefore remain, for industry associations like MedTech Europe to address via its own guidance.

Do you have concerns about standardization? If so, what are they?

Bisazza: Harmonized standards are a critical part of the EU regulatory system for IVDs and medical devices. MedTech Europe welcomes the European Commission's effort to ensure the harmonization of standards under both the current directives and the new regulations.

The planned steps recently presented by the European Commission include the issuing of a streamlined standardization request (formerly known as the standardization mandate) to CEN/CENELEC, based on a priority list of standards that will first undergo harmonization under the new regulations.

For MedTech Europe's members, the horizontal standards applicable for both the IVD and medical device sectors, such as those related to labeling, quality management systems and risk management would be high priorities for early harmonization under the new process.

The Commission has also outlined an action plan to address the situation of standards that have been proposed to be published in the Official Journal under the directives, but remained in the pipeline for several months. MedTech Europe hopes that this process can start resolving the existing backlog and get the whole standardization system back on track and MedTech Europe is fully committed to giving constructive input, to help make this effort a success.

Where is MedTech Europe needing to focus most of its resources within its regulatory program and why?

Bisazza: Beyond the issues already discussed, we are focused on tasks like supporting our members in strengthening their knowledge and understanding of the regulations, through training and educational toolkits. Our aim is to provide our members with quality training on areas important to them. For instance, we recently published flowcharts, one on the MDR and one on the IVDR, giving a high level overview of the CE marking process under both regulations.

[We are also] conducting an impact assessment on the new regulations. The goal of the impact assessment is to collect and analyze quantitative and qualitative information on the impact of the new regulations - such as value costs, increased demands on company resources, and any potential impact companies expect.

Do you think some companies are going to abandon the EU market because of fears over its stringency?

Bisazza: Within the industry, patient safety remains at the core of the work therefore we welcome efforts, such as the new IVDR and MDR regulations, to further strengthen the reputation and value of CE Marking. At the moment, we don't expect companies abandoning the EU market based on concerns of more stringent rules.

There is much talk about the US becoming more favorable for innovative companies from a regulatory point of view and fears of the EU losing such companies. What are you advising your companies?

Bisazza: It's still too early to know the full impact of the new regulations. The co-legislator clearly intended to raise the bar in terms of both notified body requirements and manufacturers' clinical evidence requirements. That said, CE marking still serves as a 'passport' to 30+ European markets, and is also widely recognized in emerging markets around the world, e.g., to support product registrations, facilitate customs clearance, or satisfy tendering requirements.

With the new regulations, one would expect the reputation of CE marking to improve even further. Our advice to companies is, therefore, clearly, to stay engaged with the EU regulatory system. The investments needed may indeed be going up, but the rewards for success remain great.

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Will EU Common Specifications Get In Way Of International Standardization?

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Common Specifications already exist in the EU's IVD Directive but rolling them out to cover medical devices too is raising questions about how they may impact not only EU standards, but, even more so, international standards agreements.

Common Specifications (CS; originally known as Common Technical Specifications or CTS) are conceptually like standards but go into further technical detail and are specific to certain product types. Although they are voluntary, in practice they are quasi mandatory; where manufacturers choose not to use CS, they must demonstrate that they have adopted equivalent solutions. The new EU Medical Device Regulation (MDR) is broadening the role of CS to devices.

During the standards seminar convened by the EU standards bodies CEN/CENELEC in Brussels on September 21, some disquiet was voiced about Common Specifications.

Industry representatives were not against CS per se, but there is concern about the implications if the different standardization regimes with which Europe is allied start to deviate.

Underlying question raised by stakeholders: What if a common specification is written and it deviates from an existing standard? Do you then have to revise that existing EU standard? What implications will that have on an international level?

In a nutshell, companies are worried that these common specifications would put the EU at odds with the content of the large number of international medtech standards to which the EU has contributed and signed on to.

The risk is that there would be two regimes in product or topic areas where there is currently common international standard. As a result, businesses would need to follow one set of standards in Europe, and another set elsewhere.

It is hard to see, in terms of an international standard, how you would persuade the Chinese, Brazilians, Australians or Americans, for example, to automatically agree to revising an internationally agreed standard to support changes that are going on in the EU alone, sources suggest.

Questions are also being raised about the reverse situation, for example, what would happen if an international or European standard changed on a particular topic and impacted a Common Specification. How and when would that Common Specification then be updated?

The new EU MDR states in Recital 24 that Common Specifications should be developed after consulting the relevant stakeholders and taking account of European and international standards. How this will work in practice is the key issue industry stakeholders are trying to work out.

CS AND THE MDR

The new MDR opens the door for the Commission to adopt CS, which detail general safety and performance requirements (Annex I), technical documentation, clinical evaluation and post-market clinical follow up or requirements regarding clinical investigation where no harmonized standards exist or relevant harmonized standards are not sufficient (Article 7.1). The Commission would introduce, through implementing acts, CS "where no harmonized standards exist or where relevant harmonized standards are not sufficient, or where there is a need to address public health concerns."

However, where CS exist for a given Class III device or implantable, this may allow the companies to avoid the otherwise mandatory requirement to perform clinical investigations. This is the case as long as those devices are already compliant with the current medical device directives and the clinical evaluation is based on sufficient clinical data, and the device is compliant with the relevant CS where available (Article 49, 2ab).

Moreover, it is not necessary to carry out clinical investigations under the MDR in the case of sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors if the valuation is based on sufficient clinical data and is in compliance with relevant product-specific CS.

Turning to manufacturers of products that do not have an intended medical purpose listed in Annex XVI, they must comply with the relevant CS that will be developed in this area to address, at a minimum, risk management and, where necessary, clinical evaluation regarding safety. CS for Annex XVI products must be adopted by May 26, 2020, and apply from six months after the date of their entry into force or from May 26, 2020, whichever is the later.

Also, the MDR requires that reprocessing must be performed according to CS, which cover:

- Risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing;
- Validation of procedures for the entire process, including cleaning steps;
- Product release and performance testing;
- Quality management system:
- Reporting of incidents involving devices that have been reprocessed; and
- Traceability of reprocessed devices.

CS FOR IVDS

Under the current IVD Directive, the following are covered by CS:

- Tests for determining blood groups: ABO system, Rhesus (C,c,D,E,e), anti-Kell;
- Tests for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV1 and 2), HTLV I and II, and hepatitis B, C and D; and
- Tests for vCJD – added in 2009.

A new CS is being considered for HIV self-tests.

While clinical evidence, referred to as performance evaluation, is currently not required for the vast majority of IVDs, it is required in the context of the CSs where appropriate evaluation criteria is established.

CS UNDER FUTURE IVD REGULATION

Under the new IVD Regulation, some assays that are being up-classified to the highest risk, class D, under the new classification rules, may be subject to CS and it is the EU reference laboratories that will verify compliance with CS for Class D IVDs.

The Regulation states that for innovative class D device (where there is no similar device) and no CS exists, notified bodies should in addition to ensuring lab testing by a reference laboratory, also request expert panels to scrutinize the performance and evaluation assessment reports.

This consultation of the expert panels in relation to performance evaluation is intended to lead to a harmonized evaluation of high-risk IVD by sharing expertise on performance aspects and to developing CS on categories of devices that have undergone the consultation process.

Once these CS exist, this will avoid subsequent products of the same nature needing to go through this process.

It is also possible for member states to request the Commission to designate EU reference laboratories to ensure the verification of the performance claimed by the manufacturer and the compliance of class C devices with applicable CS when available.

WHAT DO CS ADDRESS UNDER NEW REGS?

Already existing CS are meant to address: performance evaluation and reevaluation criteria; batch release criteria; reference methods; and reference materials.

But under the new Regulation, the Commission intends that the scope of CS should be widened so that CS can also be adopted regarding the following regulatory aspects:

- General safety and performance requirements;
- Technical documentation;
- Clinical evidence; and
- Post-market follow-up.

The still-to-be-established Medical Device Coordination Group will contribute to the development of CS, as will the expert panels and expert laboratories that are also tasked to contribute to the maintenance of the CS.

It will be the role of the notified body to assess a manufacturer's compliance with the CS, just as it is with standards.

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QUALITY ON THE BRAIN: FDA Maturity Pilot Aims To Shift Industry's Compliance Mentality To A 'Quality Mindset'

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Becky Fitzgerald has quality on her mind, and she wishes that more medical device manufacturers did, too.

In the industry, "there's a bit of a gap, if you will, between the compliance perspective" – device-makers wanting to make sure they meet US FDA regulations – "and the quality mindset," Fitzgerald said. "There is a great need to shift the way work is performed at device firms from a compliance mindset to a quality mindset."

The longtime Michigan-based consultant believes an upcoming voluntary pilot program from FDA in conjunction with the Medical Device Innovation Consortium (MDIC) will be the perfect vehicle to help drive a compliance-to-quality culture change at firms. To be stood up in early 2018, the pilot will see manufacturers use third-party Capability Maturity Model Integration (CMMI) assessors to measure the maturity of their quality systems and manufacturing processes.

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How a company views quality "boils down to behavior. It's a cultural thing. It's the way people do their work. And if they're doing their work effectively and efficiently, that results in the best possible outcome. A strong quality system equals strong output. So, the better the quality system, the better the outcome," said Fitzgerald, principal and cofounder of Two Harbors Consulting.

The soon-to-be CMMI pilot, she says, "represents a shift from neat baseline compliance requirements to build better quality systems and better quality devices."

After all, Fitzgerald would know. She was the CMMI lead appraiser who helped design and conduct proof-of-concept activities and pre-pilot maturity appraisals for the joint FDA/MDIC venture.

CMMI is a framework that allows appraisers to score where manufacturers fall on a five-tiered maturity scale, with "1" denoting beginner efforts by a firm, and "5" signifying that a company is self-correcting, effectively manages quality and is continuously improving. 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.

"Maturity" in the context of manufacturing means that companies have adequately developed practices and processes to ensure that quality is pervasive throughout their organization.

Under the pilot, results of a manufacturer's CMMI assessment will be shared with FDA. The agency will then use the information to help shape its regulatory, compliance and enforcement decisions.

And device-makers will benefit, too, Fitzgerald said. Manufacturers "will realize performance benefits. They will realize better efficiencies and effectiveness in the way they do their work," she said. The CMMI "framework has been used for years [in other industries] with evident outcomes. So, there is an expectation that firms will receive benefits by taking a look at the way they do their work from something other than a purely compliance perspective."

Companies that play in the pilot will also "look at how rigorous and disciplined their approach is to quality," Fitzgerald said. "The more rigorous they are and the more disciplined they are in their approach, then the better, more effective and more efficient their outcomes will be."

Fitzgerald's comments to *Medtech Insight* come as FDA gears up for an Oct. 10 public workshop, during which the agency will lay bare a maturity model appraisal framework and a plan for implementing the pilot. *(Also see "US FDA Maturity Model Pilot Program Gets October Meeting Date" - Medtech Insight, 24 Jul, 2017.)*

FDA will formally announce the pilot in December and begin recruiting manufacturer volunteers soon after. Sean Boyd, deputy director of the Office of Compliance within the agency's device center, said at a Case for Quality workshop in May that FDA's goal is to collect data from firms via CMMI appraisals throughout 2018 and to have a fully realized program operational by 2020. *(Also see "Gifts For Industry: From Waived Inspections To Pre-Market Leeway, US FDA Woos Firms For Maturity Pilot" - Medtech Insight, 25 May, 2017.)*

"We don't know for certain how many manufacturers are going to participate or who's going to play. But because we've been able to bring together FDA and industry, and experts from CMMI together to work on this in a very thorough and rigorous and thoughtful way before the pilot program is even announced, we're building the credibility of the program before we even launch it," MDIC Program Director Stephanie Christopher said.

The pilot "is a way for all of us to come together to incentivize quality and to make sure that we get high-quality products into the hands of patients who need them, and to create a system where, rather than focusing simply on compliance, we focus on quality," Christopher told *Medtech Insight*. "And I think that's a message that resonates with the medical device industry members that are participating."

But Fitzgerald acknowledged that moving beyond simple compliance with FDA rules to having a more robust quality system and quality mindset won't happen overnight for manufacturers.

"All of that takes time," she said. "But industry, through the proof-of-concept and early pilot activities – through that very first dip-your-toe-in set of activities – already realizes the benefits from participation. The CMMI program will be one of those things where momentum for it builds by evident outcome."

CMMI's Five Maturity Levels

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)

SURVEY TURNS UP MOSTLY POSITIVE RESULTS

MDIC conducted three separate pilots in late 2016 with one small, one medium and one large device firm to gauge whether CMMI was the best maturity model for the device industry to use.

Aside from their size, the three companies were chosen based on the variety of products in their portfolios. "We wanted to make sure that the devices they made were diverse, including devices with software components, hardware components – you name it. We really looked for even the materials and components to be diverse amongst those three firms," said Vizma Carver, founder and CEO of Carver Global Health Group in Ashburn, Va., and co-leader of those early-on pilots and proof-of-concept activities with Fitzgerald.

A survey of 26 employees from the three firms, conducted late last year, support Fitzgerald's notion that the device-makers saw organizational benefits following their CMMI appraisals.

A whopping 96% of survey respondents – people who were involved in the pilots at their firms in some way, shape or form – said the appraisal process identified "areas or processes that could improve how work is performed to increase product quality." (See Figure 1, Q1.)

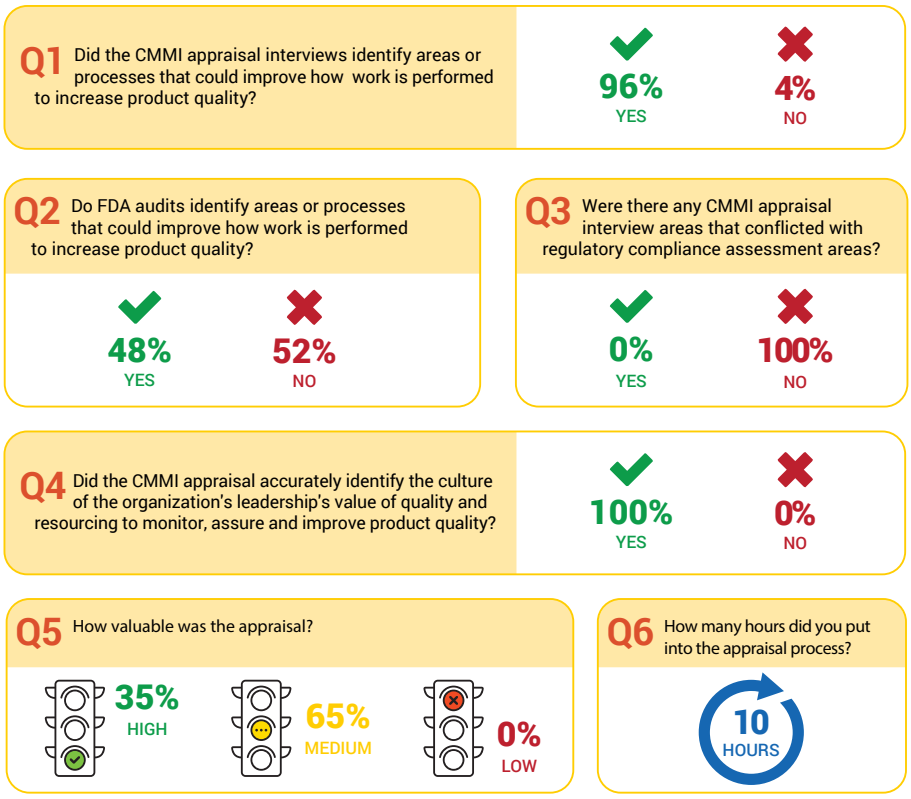
Further, all of the survey-takers said "CMMI appraisal interview areas" didn't conflict with "regulatory compliance assessment areas," and that the appraisals accurately identified how leadership at their firms viewed the concept of quality. (See Q3 & Q4.)

Overall, 35% said the maturity appraisal was a very valuable experience, while 65% deemed it to be somewhat useful. (See Q5.)

Carver told *Medtech Insight* that she isn't concerned that more participants didn't find the experience to be of high value.

FIGURE 1

CMMI Survey: Pre-Pilot Feedback



Source: Survey conducted by MDIC of 26 employees at three device firms enrolled in separate pre-pilot CMMI pilots

She believes – as time goes on, and more appraisals are conducted and changes are seen – that those participants will eventually see more benefit in the process.

"Some will look at the CMMI model for the first time and say, 'Oh, they're talking about requirements; they're talking about risk management – well, that's a no-brainer. There wasn't anything 'a-ha' about that,'" she said, surmising that's why more survey-takers didn't grade the process higher.

But, Carver said, the CMMI process can be a slow-burn that causes big changes to happen over time. "That's why those numbers should eventually shift from 'medium' to 'high' in future surveys. And that will be an indication of whether the program is working."

She pointed out that, in the end, the maturity pilot is all about patient safety.

"The purpose of the [pilot] is for organizations that embrace quality to be recognized for doing that," Carver said. "And, most importantly, it ultimately becomes a benefit to the patient. I want readers of *Medtech Insight* to know that there has been no meeting [about the pilot] that I have been a part of where the patient and how this benefits the patient hasn't been the central part of the conversation. This is all about us honing in on the patients and everyone saying, 'What can we do to do it better?'"

10 HOURS

It took an average of 10 hours per employee to participate in the CMMI appraisal, MDIC's survey of the three piloted firms shows. (See Figure 1, Q6.)

Because that's an average, consultant Carver said she would expect some employees to spend perhaps only a few hours participating in an appraisal, while others could spend up to two full days.

"For example, your project manager is going to sit through most of your appraisal sessions. So, that individual, who is kind of scheduling everything, *etcetera*, may have more time invested in it," Carver said. "Meanwhile, your contracts manager might attend one or two brief sessions – so that person will use a smaller number of hours."

FDA Inspections & Quality

The MDIC survey found that less than half of respondents – 48% – believe that FDA inspections pinpoint areas or processes that could be improved to increase the quality of their products. (See Figure 1, Q2.)

"That question was asked because we wanted to identify activities that help the industry move toward a continuous process improvement," consultant Vizma Carver said.

"We wanted to know: Do FDA inspections help with quality, or is the nature of the audit one that actually puts the organizations on defense, and thus really doesn't help?" she said. "Inspections are more about a presentation. But CMMI appraisals aren't about presentations – rather, they're about a facilitated dialogue amongst people who are actually doing the work so they can identify the areas that have attributes for success – but also discover areas where they can improve.

"So, that's the difference. That's what we're trying to identify: When firms have an FDA investigator come in, do they get that CMMI-type of experience of working toward better quality? Most people who took the survey don't think so."

INCENTIVES, NOT 'GIFTS'

FDA is offering incentives to manufacturers that participate in the pilot program. The agency says it will put off regularly scheduled facility audits and waive pre-approval inspections, and will allow firms more leeway for 30-day notices and pre-market submissions.

Further, FDA will engage with troubled companies enrolled in the pilot rather

than quickly dashing off a warning letter or using some other type of enforcement. Other incentives are also being considered.

In a May story on the pilot, *Medtech Insight* labeled the incentives as "gifts for industry," but consultant Fitzgerald doesn't necessarily see it that way.

Manufacturers that volunteer to open their doors to FDA under the pilot are more transparent, she said, which means the agency has more confidence to give those firms access to such generous benefits.

"If you're willing to show how your quality system is operating and how your company is operating, then FDA is saying, 'Look, that's more information for us, and that will help us identify where we need to focus our attention and our efforts. In return, we can support you in going faster through the process because we know more about you, frankly,'" Fitzgerald said.

"So, keep in mind that it's not 'gifting' – those firms will work hard for those incentives from FDA, which they'll receive because of their transparency and the maturity of their operations."

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Lab Industry Says PAMA Reimbursement Rates Not Really Market-Based

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Draft reimbursement rates published under the Clinical Laboratory Fee Schedule (CLFS) Sept. 22 do not truly reflect market-based charges for laboratory tests, as promised under the Protecting Access to Medicare Act (PAMA), the American Clinical Laboratory Association argues.

"ACLA has conducted an initial review of the draft PAMA rates. With few exceptions, these rates are not market-based … [and] if finalized, will inflict severe cuts – well beyond those envisioned by Congress. ACLA believes the impact will be unprecedented and far reaching," said ACLA President Julie Khani in a Sept. 22 statement.

On Sept. 27, ACLA released a new economic analysis, compiled by economists John Dunham & Assoc.,showing that the 37,000 laboratories across the US operated by independent firms, hospitals, physician offices, inpatient and outpatient medical facilities, pharmacies and other medical sites, that would be affected by the clinical lab fee schedule cuts, typically provide 276,978 direct laboratory jobs, and 115,449 supplier jobs to the economy.

FEES BASED ON MARKET RATES WERE PREFERRED

Several years ago, then-ACLA President Alan Mertz cheered the changes to the PAMA law enacted in 2014, saying it would "avoid another potential round of indiscriminate, across-the-board payment cuts." *(Also see "Medicare Dx Payment System Will Be Market-Based, More Transparent Under New Law" - Medtech Insight, 3 Apr, 2014.)* It was also thought that such a system would allow more opportunities for test-makers to make the case for the economic value of their tests, and provide some protections – due to provisions in PAMA that limit drops in payments for a specific test to 10% per year, at least through 2019.

But three-and-a-half years later, laboratory groups including ACLA, AdvaMedDx, the American Association of Clinical Chemistry and others, said labs found collection of the necessary market data laborious, and begged CMS for more time to complete the task.

In late March, CMS ultimately gave laboratories two more months – until May 30, 2017 – to report their private-payor pricing data to the agency, leaving the agency sufficient time to use the data to serve as the basis for a new fee schedule over the summer. *(Also see "Labs Have Two More Months To Report Private-Payer Data, CMS Says" - Medtech Insight, 31 Mar, 2017.)* Then on Sept. 22, the agency released its preliminary determinations of the CLFS payments for 2018 on its "Annual Laboratory Public Meeting" page, saying it would take public comment on the rates until Oct. 23.

Some of the proposed payment rates will be higher in 2018 than in 2017, but most will decrease, CMS stated In an executive summary.

For example, the agency said that the payment amounts would work to lower Medicare Part B payment rates overall by about $670 million for calendar-year 2018, by making the following changes:

- For approximately 10% of the HCPCS (Healthcare Common Procedure Coding System) codes on the clinical lab fee schedule, the weighted median of the private-payer rates for 2018 is an *increase* over the 2017 CLFS national limitation amount; the NLA is defined as 100% of the median of the local fees for tests listed on the schedule;
- For approximately 75% of the HCPCS codes on the CLFS, the weighted median is a *decrease* from the 2017 CLFS NLA; and
- About 58% of HCPCS codes will receive phased-in payment reductions in 2018, 2019 and 2020, rather than the full private-payer rate-based payment amount.

CMS also noted that the top 25 HCPCS codes, when ranked by CLFS 2016 spending, accounted for about 63% of total CLFS spending.

The agency said its next steps for development of the 2018 rates include collecting comments through Oct. 23 in response to its preliminary determinations on which codes should be "gapfilled" or "crosswalked," and the on the preliminary CLFS rates for 2018. It plans to publish final rates by November 2017, and the rates will take effect on Jan. 1.

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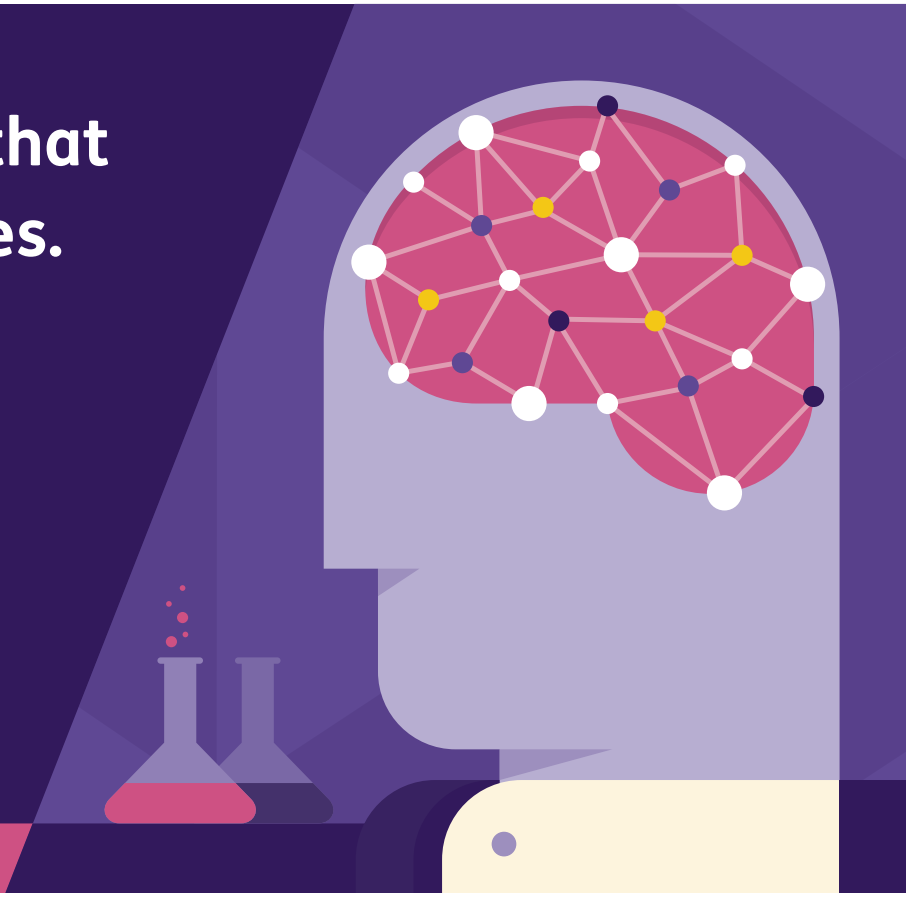

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