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Comply With EU MDD Or MDR? Your Multi-Year Decision Is Beset With Hazards

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The latest text of the EU's new Medical Devices Regulation (MDR) makes it clear that it is possible to CE-mark medical devices under the current Medical Devices Directive (MDD) for another three years, and for these products to remain on the market until 2024, seven years from now.

Deciding whether this is the better option is left to manufacturers themselves to decide.

Companies will be able to continue to CE-mark their devices up until full application of the new regulation in three years' time – in Q2 2020 (based on adoption of the MDR in Q2 2017). These products will then be able to remain on the market beyond the time when notified bodies have begun to issue certificates under the MDR, and when full application of the MDR is necessary for new products coming onto the market.

This option should alleviate some of the pressure on the system, but manufacturers should think very carefully about the pros and cons of relying on the MDD system during the transition period, and the impact of the timing of compliance with the new regulations.

WHEN CAN YOU CLAIM COMPLIANCE AGAINST NEW REGULATIONS?

Once the notified bodies have been re-designated against the MDR, there will then be the opportunity to seek certification against the EU regulations. But when will notified bodies be able to start testing? And is this the best strategy rather than sticking with compliance under the directives?

The challenge in making a decision is the unpredictability. Firstly, while the 22 members of the EU's TEAM-NB notified body association are planning to all apply for re-designation at the same time, it is uncertain how long this process will take. *(Also see "EU Notified Bodies Prepare For En Masse Redesignation" - Medtech Insight, 21 Feb, 2017.)* Secondly, there are another nearly 40 notified bodies that are active in the medtech space that have not yet made their plans public. It is difficult to know which notified bodies are likely to continue to operate in the sector under the MDR, or even how long they will continue to operate in the medtech space.

Also, notified bodies will not be able to apply for re-designation until six months

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Trump Criticizes FDA For 'Slow' Approvals In Speech To Congress

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President Trump, in his first speech to a joint session Congress Feb. 28, criticized FDA's approval process as a barrier to new medical innovations.

In the context of praising a young woman, Megan Crowley, who had struggled all her life to overcome a rare disorder known as Pompe disease, and her father's efforts to find a cure by founding a company to help develop a treatment to fight the disease, Trump seemed to imply that FDA had blocked approval of that treatment.

"Our slow and burdensome approval process at the Food and Drug Administration keeps too many advances, like the one that saved Megan's life, from reaching those in need," Trump commented.

"If we slash the restraints, not just at the FDA but across the government, then we will be blessed with far more miracles like Megan," the president added.

Megan's father, John, founded **Novazyme Pharmaceuticals Inc.** to develop treatments for her. That company is now part of **Sanofi**'s **Genzyme Corp.**, and John Crowley is the CEO of **Amicus Therapeutics Inc.**

Some members of the rare diseases community support FDA, such as the EveryLife Foundation for Rare Diseases. The group has been seeking signatures on a letter from the patient community to President Trump, calling on him to exempt the National Institutes of Health and FDA from a recent hiring freeze the administration imposed upon domestic agencies, says a group that supports funding for the agency, Alliance for a Stronger FDA.

Trump also underlined and promoted his executive order of Jan. 30 that mandates federal agencies review their own regulations, and eliminate two rules for every one new regulation that is created. *(Also see "Trump's Two-For-One Reg Order Needs Agency Interpretation, Medtech Reg Experts Say" - Medtech Insight, 30 Jan, 2017.)* The president labeled the government regulations as "job-crushing."

However, the impact of the "two-for-one" regulatory policy and the Trump administration's short-term hiring freeze on FDA operations "may not make much difference," says a Feb. 24 analysis by the Alliance.

"We think the impact of the 'withdraw two old regulations for every new regulation proposed' is uncertain, but its impact on FDA won't be as great as first feared," the Alliance stated in a Feb. 24 advocacy analysis. The group added that the precise situation "won't become clear until FDA and OMB (Office of Management and Budget) reach consensus on which regulations are under $100 million in their impact."

As to the freeze, the Alliance states that the impact "won't last long," and there is a long list of "exemptions for employee categories relating to health, safety and biosciences."

NO MENTION OF DEVICE TAX

The president made no mention of the medical device excise tax, despite urging from industry lobbyists to do so. *(Also see "AdvaMed Pushes For Trump To Address Device Tax In Joint-Session Address" - Medtech Insight, 27 Feb, 2017.)* Device companies are pressing hard for a permanent repeal of the tax in conjunction with Affordable Care Act "repeal-and-replace" efforts. The tax is set to restart after a two-year hiatus, in 2018.

Mark Leahey, president and CEO of the Medical Device Manufacturers Association, said his group "applauds President Trump's call for a new generation of cures and therapies to improve patient care, and medical technology entrepreneurs stand ready to boost innovation and job creation."

But he said repealing the device tax, in addition to lowering corporate taxes, establishing more transparent and predictable regulations, and improving reimbursement are needed to "create an environment that allows this proud American industry to thrive."

Sen. Lamar Alexander, R-Tenn., who chairs the Senate Health, Education, Labor and Pensions (HELP) Committee, characterized the president's speech as "hopeful and well-delivered." He also praised Trump for speaking about how he would "repair the damage Obamacare" has done by replacing with an alternative health-care system.

During his speech, Trump did not go into too much detail about legislative fixes to the Affordable Care Act, but, instead, focused on broad goals, such as retaining provisions to protect people with preexisting conditions and implementing tort reforms to counteract lawsuits that "drive up the price of insurance."

Congressional Republicans insisted the president's comments signaled support for a plan that is in development in the House. *(Also see "GOP ACA-Replacement Draft: Device Tax Would Go Away; States Left To Decide Plan Coverage" - Medtech Insight, 28 Feb, 2017.)*

Sen. Patty Murray, R-Wash., critiqued Trump's speech and approach to health care, and added: "The plans to continue making empty promises while doubling down on policies and a budget that would hurt families, students, the economy and our national security."

And Democratic Sen. Ron Wyden, who is ranking member of the Senate Finance Committee, said of Trump's approach to health care: "Americans can't afford to go back to days where health care was only for the healthy and wealthy – that appears to be precisely what they'll be getting if congressional Republicans and the Trump administration have their way."

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Edwards Letting German Centers Stock-Up On Sapien 3 Ahead Of Patent Ruling

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Edwards Lifesciences Corp. appears to be preparing for the possibility that a German court may enjoin sales of its *Sapien 3* transcatheter aortic valve in that country, at least for a while, when it rules in an ongoing patent dispute with **Boston Scientific Corp.**

Wells Fargo securities analyst Larry Biegelsen wrote in a Feb. 28 research note that multiple physicians are reporting that Edwards is offering centers in Germany an option to buy six months' worth of Sapien 3 inventory in anticipation of an upcoming patent ruling in the dispute with Boston Scientific.

"It's not unusual in advance of pending court decisions for some customers to purchase additional inventory of their preferred product, and we have provided this option to our transcatheter valve customers in Germany," Edwards' senior director of global communications, Sarah Huoh, told *Medtech Insight*. Edwards is not offering a discount on the bulk order, but is letting centers that accept the deal to pay for the order over time, he reported.

Boston Scientific filed a lawsuit in Germany against Edwards alleging that the company's Sapien 3 valve infringes on Boston Scientific's "254" patent for paravalvular leak-sealing technology in October 2015. A few weeks later, Edwards filed a countersuit against Boston Scientific alleging that Boston Scientific's *Lotus* transcatheter valve system infringes two Edwards patents from the "Spenser family" related to the valve prosthesis and delivery system. *(Also see "New TAVI Tussle But It's Edwards In The Dock" - Medtech Insight, 5 Nov, 2015.)* Since then, both companies have expanded the list of patents they claim the other has infringed.

The court in Germany is expected to rule on the case by the end of March.

Meanwhile, in a related suit in the UK, a court in that country has determined that one of Boston Scientific's patents related to outer seals for transcatheter heart valves that was asserted against Sapien 3 is invalid, while a second patent is valid and infringed, Edwards disclosed March 3. Edwards is appealing aspects of the decision, which, it emphasizes, does not affect commercial availability of the Sapien 3.

While the UK decision is "good news for BSX [Boston Scientific] and negative for EW [Edwards], we are not sure the UK ruling is a good read-through to Germany," Biegelsen wrote. "In Germany, EW has counter-sued BSX, and we expect a ruling on both BSX's and EW's claims on March 9. It's unclear to us why EW did not counter-sue BSX in the UK."

Boston Scientific filed a similar patent infringement complaint against Edwards in France in April 2016, but that case is stayed, pending the outcome of the case in Germany. In both cases, the companies are seeking unspecified monetary damages and injunctive relief.

CROSS-LICENSING AN OPTION?

There is a recent precedent for a German court to enjoin sales of a transcatheter valve due to a patent dispute, but that ruling favored Edwards. In 2013, a German court stopped sales in Germany of **Medtronic PLC**'s *CoreValve* after it ruled that it infringed on Edwards' Spenser patent. However, that ban lasted less than three months, after which the court overturned the original ruling in response to a finding by the European Patent Office that the Spenser patent claims were not valid.

Biegelsen points out that even if the German court ruled in favor of Boston Scientific, the ruling may not compel Edwards to pull Sapien 3 from the Germany market. "If EW was found to have infringed on BSX's patents and BSX was found to have infringed on EW patents, we believe one scenario that could potentially play out is cross-licensing," Biegelsen says. He believes Edwards transcatheter aortic valve intellectual property is strong given how long the Sapien line of valves has been on the market and Edwards' past success defending its TAVR IP in court.

Biegelsen estimates that Medtronic lost roughly 13.5% of the European TAVR market in the second half of 2013 due to that injunction, but he also predicts that Edwards would not lose as much market share if the court rules against it, because Edwards has a much stronger market position and is favored by most clinicians.

"Ultimately, we continue to believe it is too early to conclude what will result from the Edwards-Boston Scientific litigation in Germany," Biegelsen explains. "We view Edwards's decision to offer bulk orders as a cost-free hedging option to customers in the event that the company receives a negative ruling from the courts. While there is perceived risk associated with the company's action, there is still a long way to go process-wise and too early (in our opinion) to come to the conclusion that Edwards' Sapien valves will infringe BSX patents and be removed from the market in Germany."

While the Sapien valves have been a huge success for Edwards, with sales growing nearly 40% year-over-year in 2016, Boston Scientific is looking for some good news from its TAVR business. The company recently announced a voluntary worldwide recall of all Lotus valve devices from commercial and clinical sites while it resolves a manufacturing problem that has caused a small number of the valves to malfunction. *(Also see "Boston Scientific Pulls All Lotus TAVR Systems Off Shelves" - Medtech Insight, 23 Feb, 2017.)*

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Big Pharma Helps Pour $900m Into Grail

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Barely a year after being spun out of next-generation sequencing specialist Illumina, Grail has already bagged more than $1bn in funding from both institutional and strategic pharma, medtech and tech investors such as Johnson & Johnson, Bristol-Myers Squibb, Merck, Amazon and Varian Medical Systems, among others.

Grail announced Mar. 1 that it raised $900m in the first tranche of a Series B round. The Menlo Park, Calif., company already gained a solid head start when it raised $100m in Series A financing in January 2016, following its spin-out from Illumina. *(Also see "Illumina Aims For All-Inclusive Cancer Screen Via New Start-Up" - Medtech Insight, 18 Jan, 2016.)* While this and the current $900m takes the total investment in Grail past the $1bn-mark, the firm is hoping to raise at least another $100m by the end of March to complete the Series B.

Grail was established to leverage Illumina's NGS know-how to develop a single, comprehensive cancer-screening test for asymptomatic patients. The technology, specifically, will use high-intensity sequencing technologies to sequence circulating tumor DNA in blood samples and combine this with the "vast datasets" it will be creating through its population-scale clinical trial programs, to identify cancer in the early, asymptomatic stages.

The roll call of strategic investors in Grail's Series B highlights the different disciplines – pharma, information technology, and medtech – that the company's technology calls upon. This second financing had Johnson & Johnson Innovation as the largest investor, while other corporate investors – and strategic collaborators – included Amazon, Bristol-Myers Squibb, Celgene, Merck and cancer radiotherapy specialist Varian Medical Systems. In terms of institutional investors, Arch Venture Partners – which led both the Series A and Series B rounds – McKesson Ventures and China's Tencent Holdings took part in this transaction.

Commenting on the J&J's substantial backing of Grail, Paul Stoffels, Chief Scientific Officer of the healthcare giant commented: "It takes great science to make medical breakthroughs for patients, and through Johnson & Johnson Innovation we are committed to finding transformative technologies that have the most potential to positively impact human health around the world. We are pleased to invest in the great science and technologies of Grail to help change the cancer prevention, diagnosis and treatment paradigm."

Ken Drazan, Grail's Chief Business Officer, said the second tranche will include more institutional investors in the life-science space.

GRAIL will use the proceeds of the financing to continue product development and validation of its cancer tests, including the Circulating Cell-free Genome Atlas (CCGA) study and other large-scale clinical trials that are expected to enroll hundreds of thousands of patients. The CCGA study will use high-intensity sequencing – leveraged from Illumina's NGS know-how – to characterize the landscape of cell-free DNA profiles in individuals with cancer and in healthy noncancer participants. Some of the $900m was also used to repurchase a portion of Illumina's stake in Grail; Illumina now owns slightly less than 20% of its spin-out.

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Medtronic's Solitaire Gets STRATIS Real-World Stroke Boost

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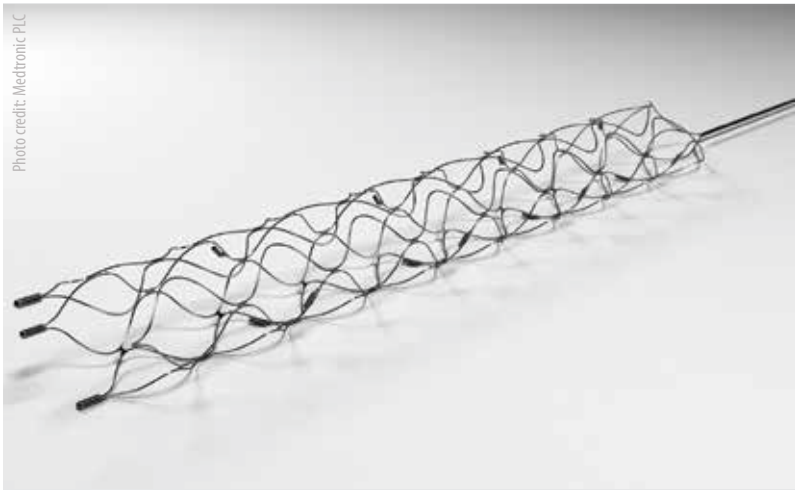
Results from the STRATIS registry shows that community hospitals can treat acute stroke patients with mechanical thrombectomy using Medtronic PLC's Solitaire stent retriever as effectively as comprehensive stroke centers at teaching hospitals. The study found that the benefits of transferring these patients to specialized centers is outweighed by the potential for additional brain damage that can result from the extra time it takes to get there.

STRATIS (Systematic Evaluation Of Patients Treated With Neurothrombectomy Devices For Acute Ischemic Stroke) is a prospective, multicenter single-arm registry designed to capture the "real world experience" of both community hospitals and academic centers in the US performing mechanical thrombectomy, without a requirement for specialized imaging, patient age limits, or specific technique exclusions. The results were presented by Nils Mueller-Kronast of Delray Medical Center in Delray Beach, Florida, and colleagues, on Feb. 22 at the International Stroke Conference in Houston.



Medtronic's Solitaire Platinum Stent Retriever

A total of 984 patients with large vessel occlusion acute ischemic stroke were enrolled at 55 sites within eight hours of the onset of stroke symptoms onset. 953 of the patients were treated with Solitaire and 31 were treated with a Mindframe Capture retriever (Mindframe Capture was originally produced by Mindframe, Inc, which was then acquired by Covidien, which was acquired by Medtronic.) The patients' average NIH stroke score was 17.3.

Medtronic believes that wider access to stent retrievers will reduce long-term disability in this patient population.

Intravenous tissue plasminogen activator tPA was administered to 63.9% of the patients and the median time from symptom-onset to arrival in the enrolling hospital was 138.5 minutes. The median time from arriving at the hospital and the start of the catheterization procedure to deploy the stent retriever – so-called "door to groin" time – was 72 minutes, and the median "groin to reperfusions" time was 37 minutes. A modified treatment in cerebral infarction (mTICI) score greater than 2b – indicating antegrade reperfusion of more than half of the previously ischemic territory – was achieved in 87.9% of the patients. Only 1.6% of the patients suffered a symptomatic intracranial hemorrhage and after 90 days, 56.6% achieved a Modified Rankin Scale (mRS) of 0 to 2, indicating nothing more than slight disability, although only 26.5% of patients 90 years or older achieved a mRS of 2 or less.

These outcomes are comparable to that of the four major pivotal randomized trials of Solitaire – SWIFT PRIME, ESCAPE, EXTEND IA, and REVASCAT, suggesting that the results with Solitaire obtained by major teaching hospitals can be replicated "in a pragmatic, real-world setting," according to Medtronic. These four trials looked at the original Solitaire FR device marketed by Covidien. Medtronic currently markets the Solitaire Platinum which also has distinctive platinum markers to provide improved imaging-visualization during the catheterization for accurate alignment and retrieval.

Importantly, the overall median time from when emergency medical services reached the patient to the start of the catheterization procedure was 152 minutes and each hour delay in this interval was associated with an 8.3% relative decline in the likelihood that the patient would eventually have a good outcome (mRS 0-2). So the "number needed to harm" was 18 per hour of delay. The highest enrolling centers – more than 30 patients– achieved significantly shorter median door to puncture times, 67 vs. 86 minutes. The study also found that interhospital transfer of these patients was associated with significant delays to treatment and significantly lower chance of that the patient would achieve functional independence within 90 days of the procedure (60.0% vs. 52.2%, p=0.02).

PATIENTS OFTEN NOT TAKEN TO BEST THERAPY

The STRATIS registry is "very much focused on underlying systems of care," Stacey Pugh, vice president and general manager of Medtronic's Neurovascular business, which is part of the Restorative Therapies Group, told *Medtech Insight*. "There's been a lot of analysis in the previous studies to show that [brain] reperfusion is a very time-dependent treatment, just like it is with acute myocardial infarction. This is the first data that actually allows you to quantify how the current delivery of patients or flow of patients is impacting patient outcomes."

The four randomized trials of Solitaire show that mechanical reperfusion improves early neurologic recovery, and functional outcomes for these patients compared to tPA alone, but requiring emergency medical services to take acute stroke patients to comprehensive stroke centers, rather than a closer-by community hospital, to undergo mechanical reperfusion delays the definitive treatment of the stroke and reduces the patient's chances of a good outcome.

Skipping the local center to take the patient to a more comprehensive stroke center might make sense if the local centers were incapable of performing the procedure nearly as well, but STRATIS shows that these community centers can achieve good results with mechanical thrombectomy if given the chance, so Medtronic maintains that wider access to stent retrievers will reduce long-term disability in this patient population.

Currently, the professional guidelines for treating acute myocardial infarction patients with a percutaneous coronary intervention set 90 minutes as the target for "door-to-balloon" time. But there currently isn't a comparable widely-accepted approach in to minimizing the delay between symptom-onset and reperfusion in acute stroke patients, even though patients with a major acute stroke lose two million neurons per minute without reperfusion and stroke is the number one cause of disability in the US, driving $74bn in expenditures, Pugh explained.

Pugh also highlighted results of a cost-effectiveness analysis of the SWIFT-PRIME trial, recently published in *Stroke*,showing that although treating acute stroke patients with stent retriever thrombectomy and tPA costs more upfront than tPA alone ($45,761 versus $28,578), the improvement in long-term outcomes, including quality-adjusted life-expectancy and reduced healthcare costs over a lifetime horizon. Study authors Theresa Shireman at Brown University in Providence, and colleagues found that the stent-retriever-thrombectomy-plus-tPA approach was associated with substantial gains in quality-adjusted life years – 6.79 versus 5.05 and a cost-savings of $23,203 per patient compared with tPA alone.

"We should be compelled to look at this – now the data suggests - not only from a humanitarian and an outcome based standpoint, but also from a cost-effectiveness standpoint," she said. "The big picture is that we now have a therapy that is shown to be highly efficacious, highly cost-effective, but it is significantly affected by the current health care system in terms of how patients are routed to these therapies."

WATCH

To see how Solitaire Platinum works, watch the video at http://bit.ly/2IDhshE

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NIH Pumps $3m Into Cell-Based Biological Pacemakers

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The US National Heart, Lung, and Blood Institute is supporting the development of "biological pacemakers," heart-muscle cells that are reprogrammed to supplement or replace the heart's natural pulse-generating function.

The $3m grant, announced Feb. 21, is intended to allow principal investigator Eugenio Cingolani and his team at Cedars-Sinai Heart Institute to "lay the preclinical groundwork for first-in-human studies of biological pacemakers as an alternative to electronic devices," according to the NIH project summary.

Cingolani told *Medtech Insight* that the grant will cover long-term safety and efficacy studies in humans, which will create data necessary to earn US FDA approval for an in-human trial, likely in three to four years. Cingolani expects that his group will need to find a commercial partner to support clinical trials.

Although biological pacemakers could eventually eliminate the need for traditional electronic pacemakers, in the short-term Cingolani envisions biological pacemakers being used in two specific populations. The first population is patients whose electronic pacemaker has become infected. A biological pacemaker could be created in their myocardium to pace their heart after the infected device is removed, and then once antibiotic drugs eliminate the infection, a new electronic pacemaker could be implanted.

The other population that needs a solution like a biological pacemaker are pediatric patients with congenital or acquired rhythm disorders. Currently, these patients need several procedures to implant new devices as they grow. A biological pacemaker that could grow with them could reduce the need for reintervention.

USING GENES TO REPROGRAM CELLS

Each heartbeat originates in the sinoatrial node (SAN), which is made of about 10,000 specialized pacemaker cells. Without the SAN, the 5 billion cardiomyocytes that make up the heart muscle cannot contract to pump blood.

In 2012, Nidhi Kapoor and colleagues at Cedars-Sinai Heart Institute completed *in vitro* studies with isolated neonatal rat ventricular myocytes and *in vivo* studies in guinea pigs showing that the T-box 18 (TBX18) gene can reprogram ventricular cardiomyocytes into working, durable SAN cells. Their paper, the first to show that a single gene could convert heart muscle cells to genuine pacemaker cells, was published in *Nature Biotechnology*in January 2013.

In 2016, Cingolani, along with Yu-Feng Hu and other colleagues at Cedars-Sinai Heart Institute, used the TBX18-transduction approach to create a biological pacemaker in seven pigs, and compared their electrocardiographic information to that of a control group of five pigs. All of the pigs were implanted with a backup electronic pacemaker.

Results of the study, published in *Science Translational Medicine,* show that after gene delivery, the TBX18-transduced pigs had a higher heart rate compared to the control group, out to at least two weeks, and the TBX18-transduced pigs achieved a higher maximal HR compared to the controls. The TBX18 group showed almost no reliance on their backup electronic pacemakers, whereas the controls relied on the backup pacemaker 8% to 40% of the time. "These findings indicate that TBX18 gene delivery successfully creates robust biological pacemaker activity, minimizing the need for backup electronic pacing," the authors concluded.

Cingolani pointed out that a major advantage of the technology developed by the Cedars-Sinai group over electronic pacemakers and some earlier attempts at biological pacemakers is that TBX18 can be delivered through a minimally invasive catheter procedure similar to a standard coronary angiogram.

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First Robotic System To Drill Into Dental Sector Gets US Green Light

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Neocis Inc., based in Miami, Florida, is hoping to cement a strong bond with dental surgeons with the introduction of its newly US FDA-cleared robotic system, said to be the first of its kind to be used in dental implantation procedures to offer physical and visual guidance to the surgeon.

The company announced Mar. 2 that it had received 510(k) clearance for its *Yomi* robotic guidance system. Veteran surgical robotics engineer and CEO of Neocis Alon Mozes, said the system fills an unmet need in the fast-growing dental implant market for robotic surgery, which he valued at an estimated $2bn for the US and at $5bn worldwide. (See Fig. 1)

The Yomi system, which incorporates haptic robotic technology, includes software that assists surgeons with preoperative planning and navigational guidance of surgical instruments during surgery.

"The surgeon can plan everything ahead (using cone-beam computed tomography (CBCT) imaging and planning software), and when it's time for surgery, the surgeon can use the drill and hold it like they normally would, but when they are getting ready to drill, the guidance arm makes sure that they drill with the proper angle, proper position and proper depth according to the plan they had in advance," explained Mozes. The procedure is being tracked in real time on a computer screen, providing the surgeon with clear visualization of the surgical site. (See Video 1).

Mozes likened the system to a "GPS system on the screen" that updates in real time. What makes Yomi different from a pre-manufactured plastic surgical guide -- which offers physical guidance according to a preset plan, but no visual guidance – is that it is flexible enough to divert from the preoperative plan during surgery.

"So if a surgeon is in the middle of surgery and changes his mind about the location of the implant or doesn't like the bone density, all they have to do is update the plan and the system will guide them to the new location right away," Mozes said. "[On the other hand,] the plastic drill guide is pre-manufactured ahead of time, so if surgeons don't like where the drill is being placed, they either need to stick with it or proceed free-hand."

He added, "With our system, the precision, accuracy, reliability and ability to change their plan are a big clinical advantage for the surgeon."

Mozes expects the biggest demand for Yomi will come from "high-volume specialists who really care about providing the highest standard of care."

The CEO, who himself helped develop software for **MAKO Surgical Corp.**'s *Rio system* for orthopedic robotics surgery, declined to say how much the Yomi system will cost, but said that the team's collective experience in developing robotic systems allows Neocis to make the robotic system at a relatively low cost, which, in turn, will make it "affordable" for the dental industry.

FIG. 1

Neocis Inc. Yomi robotic system

Source: Neocis Inc.

GOING DIRECT

Dental implant surgery remains the standard of care for missing teeth, with more than four million implants being placed in the US every year by 15,000 dental specialists and nearly 150,000 general practice physicians, according to Neocis.

Mozes takes pride in the fact that Neocis is the first to bring to market a robotic system for dentistry. "No one else has a robotic system in the dental industry," said Mozes. "And while it's certainly a different industry than orthopedics, robotic surgery is something we have great experience in, and we wanted to extend the use of robotic surgery to other markets. We identified the dental implant market as large and growing, and it lends itself nicely to robotic surgery. In many other robotic surgery markets, there is a lot of hassle with surgeons needing to go through setting up and using a robotic system. [In dentistry,] teeth are exposed and rigid, which lends itself to patient tracking and drilling into the bone, which makes it much easier to work into the surgeons' workflow."

Asked about Neocis' commercialization plans, Mozes told *Medtech Insight* that the company will manufacture the system in-house and rely on its own marketing and sales team to bring

Yomi to oral surgeons, periodontists, prosthodontists and dental specialists focusing on dental implant procedures.

Neocis was co-founded in 2012 by Mozes and fellow Mako Surgical alumnus Juan Salcedo. Salcedo was the principal robotic design engineer and main designer in Mako 's first- and second-generation robotic systems. The company raised its seed funding from industry heavyweight Fred Moll, who founded **Intuitive Surgical Inc.** Other investors include San Francisco-based investment firm Mithril Capital Management LLC, as well as Florida-based investors and former Mako employees, Mozes said.

TOO DEAR FOR DENTISTRY?

Stephen Munroe, a periodontist and owner of Hillcrest Periodontics, based in San Diego, California, agreed with Mozes that the robotic technology offers advantages. But he speculated that cost will likely put it out of reach for many oral surgeons.

"It could enhance accuracy, and, potentially, it could standardize an experience for a more predictable outcome," Munroe told *Medtech Insight*. "The biggest issue in dentistry is that new technologies are expensive and typically the biggest challenge for dentists is to maintain a standardized overhead cost."

Munroe said he uses CBCT imaging in his office -- a technology that can cost between $100,000-$200,000, plus a surgical navigation system, which runs between $20,000-$30,000 – to perform dental implant surgeries.

But Mozes argues that much of these costs above won't apply to using his system.

"We're replacing the need for the navigation system, which only offers visual guidance, and we replace the need for the plastic surgical guide, which only offers physical guidance and creates clinical challenges," Mozes explained.

John Patterson, a general dentist and owner of Patterson Dental in Phoenix, Arizona, said by looking at Neocis' YouTube video of the Yomi system, he agreed with Mozes that the robotic system looks like an enhancement to using a surgical guide, which he uses in his practice.

"It appears that the system will eliminate excessive vibration, leading to less bone trauma, less swelling and pain," Patterson said.

Mozes argues that navigation systems on the market today – such as Lansdale, PA-based company **X-Nav Technologies Inc.'s** *X-Guide Dynamic 3D Navigation system* and Canadian-based **ClaroNav's** *Navident* system -- only provide visual guidance, forcing the doctors to look at a screen for guidance. By comparison, Yomi offers surgeons both visual and physical guidance and the flexibility to change the preset plan during surgery, he added.

Asked about the company's near-term and long-term plans, Mozes said the immediate focus is to find high-volume specialists who are interested in cutting-edge technology and looking to differentiate their practice. Long-term, he said, he's entertaining multiple opportunities.

"We can expand it into the health care industry and within the dental industry," he said.

WATCH

To see how Neocis' robotic system guides dentists during dental implant procedures, go to http://bit.ly/2mtLrHM

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Pacts In Medtech: January/February 2017

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The first two months of 2017 saw a flurry of alliances that involved Asian players, whose partnerships with western counterparts have noticeably risen in recent years. This is driven by companies in the west seeking to expand eastwards into emerging markets, namely China, while Asian companies are looking to bring in innovation developed abroad to meet growing domestic demand for quality health care solutions.

US molecular diagnostics firm **Biodesix Inc**. has licensed to **Beijing Bioyong Technology Co. Ltd**. the rights to develop and sell in China its own version of Biodesix's flagship *VeriStrat* lung cancer diagnostic, a blood-based proteomic test used to assess disease aggressiveness in patients with non-small cell lung cancer.

The companies will also work together to develop mass spectrometry-based assays for cancer and other diseases. Bioyong plans to perform the new iteration of VeriStrat on its matrix-assisted laser desorption and ionization (MALDI) mass spectrometry platform. (Biodesix will transfer some of its MALDI methods to Bioyong to be used in the development of the test.) Bioyong will pay Biodesix up to $38m over the life of the collaboration.

Also in the area of molecular diagnostics, under a 15-year collaboration, **AbbVie Inc., Genomics Medicine Ireland Ltd**. (GMI), and Chinese genomics specialist **WuXi NextCODE** are teaming up to perform population genomics research in Ireland with the goal of discovering and developing new therapies and companion diagnostics for diseases in the areas of oncology, neuroscience, and immunology.

Sino-Japanese ties strengthened between Tokyo-based **Solasia Pharma KK** and its Chinese partner **Lee's Pharmaceutical Holdings Ltd.** when the former granted Lee's exclusive rights to market in China, Hong Kong and Macau the oral mucositis product *episil*. The deal does not include Taiwan, Beijing, Shanghai, and Guangzhou.

episil is an oral liquid supplied as a ready-to-use device. It is indicated for oral mucositis in patients undergoing chemotherapy or radiation. The treatment forms a bioadhesive film to protect sensitive mucosal surfaces to help heal and reduce pain. Solasia had gained Japanese and Chinese rights to episil from Camurus in 2015, and late last year, sublicensed the Japanese rights out to Meiji Seika Pharma. The deal is the second for Solasia and Lee's in the supportive cancer care market. In 2015, Solasia granted Lee's rights to sell the CINV product Sancuso in the PRC.

Below is a list of these and other key medtech industry alliances that were struck in January and February 2017:

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PLAYERS	PACT	PRODUCT SECTOR
JANUARY		
Banyan Biomarkers Inc. & bioMérieux SA (a division of Institut Mérieux)	**bioMérieux SA** licensed worldwide commercialization rights to **Banyan Biomarkers Inc.**'s traumatic brain injury (TBI) biomarkers, for use within the in vitro diagnostics market, using bioMérieux's *VIDAS* immunoassay platform. In exchange for the worldwide license, bioMérieux will take an equity stake in Banyan, purchasing approximately $7m of the private company's stock. The goal of the collaboration is to get a blood-based automated test for TBI FDA approved and on the market. The partners will additionally pursue co-development of tests within the TBI and critical care areas. Banyan's assay detects the presence of TBI using two highly brain-specific biomarkers (ubiquitin c-terminal hydrolase-L 1 (UCH-L1) and glial fibrillary acidic protein (GFAP)), which appear in the blood shortly after the occurrence of a brain injury. These biomarkers are designed to objectively diagnose TBI without the use of CT scan or other imaging methods, which can expose a patient to radiation and don't always present evidence of TBI, particularly if it's a mild-moderate injury (MMTBI). Recent clinical studies to evaluate and assess the diagnostic accuracy of UCH-L1 and GFAP, both together and individually, demonstrated UCH-L1 to perform best in the early post-injury period, while GFAP performed more reliably in detecting MMTBI across a one-week period. Through its VIDAS line of automated lab-based tests, bioMérieux offers panels in a wide range of therapeutic categories--including emergency and critical care tests to rapidly detect acute coronary syndrome, bacterial infection/sepsis, C. difficile, heart failure, HIV, myocardial infarction, and venous thromboembolism--but this will be its first immunoassay within CNS. Under an August 2016 agreement, Banyan licensed (for research-use only) the UCH-L1 and GFAP assays to **Quanterix** to incorporate into Quanterix's *Simoa* analysis platform.	IVD

PLAYERS	PACT	PRODUCT SECTOR
Beijing Bioyong Technology Co. Ltd & Biodesix Inc.	**Beijing Bioyong Technology Co. Ltd.** licensed rights in China to develop and sell its own version of **Biodesix Inc.**'s *VeriStrat* lung cancer diagnostic. The companies will also work together to develop mass spectrometry-based assays for cancer and other diseases. Bioyong plans to perform the new iteration of VeriStrat on its matrix-assisted laser desorption and ionization (MALDI) mass spectrometry platform. (Biodesix will transfer some of its MALDI methods to Bioyong to be used in the development of the test.) Bioyong will pay Biodesix up to $38m over the life of the collaboration. *VeriStrat* is a blood-based proteomic test used to assess disease aggressiveness in patients with non-small cell lung cancer.	IVD
AbbVie Inc, Genomics Medicine Ireland Ltd & Wuxi NextCODE Genomics	Under a 15-year collaboration, **AbbVie Inc., Genomics Medicine Ireland Ltd. (GMI),** and **WuXi NextCODE Genomics** are teaming up to perform population genomics research in Ireland with the goal of discovering and developing new therapies and companion diagnostics for diseases in the areas of oncology, neuroscience, and immunology. GMI will create a database containing 45k sequenced genomes from Irish volunteers. WuXi will use its integrated genomics platform to organize and mine the database. AbbVie will then use the genotypic and phenotypic data to research new molecular approaches for drug discovery and development, and to develop companion diagnostics. Such information can allow AbbVie to get a better understanding of human biology and disease etiology in an effort to identify therapeutic targets and biomarkers. AbbVie has a strong presence in Ireland, with over 600 employees.	IVD/ Therapeutics
Edap TMS SA & Medical Measurement Systems BV (a division of Laborie)	**EDAP TMS SA**, through its **EDAP TMS Japan** subsidiary, will exclusively distribute in Japan Canadian company **Laborie**'s **Medical Measurement Systems BV** (MMS) division's urodynamic diagnostic devices. Urodynamics is the study of lower urinary tract function, and assessment of bladder and urethra disorders, including urge and stress incontinence, urinary retention and frequency, nocturia, hesitancy, and storage and micturition. Laborie acquired MMS in April 2015. Its urodynamic offerings include uroflowmetry, anorectal manometry (ARM; a test to assess pelvic floor strength to detect fecal incontinence or constipation), filling cystometry, pressure-flow study, urethral pressure profiles, abdominal leak-point pressure, post-voiding residual (PVR), and electromyography measures to provide diagnostic data for these urinary tract disorders. MMS workstations used in urodynamic and anorectal manometry procedures include the *Nexam Pro* and *Solar Blue* brands, as well as the *Luna* ambulatory urodynamic recorder (to monitor bladder, urethra, and abdominal pressure). MMS also makes the *Scanmaster* 3D ultrasound bladder scanner that noninvasively measures bladder volume and PVR. The addition of this comprehensive portfolio of urodynamic diagnostic devices will enhance EDAP's existing noninvasive therapeutic ultrasound equipment offerings within urology.	Diagnostics
Laboratory Corp. of America Holdings & Sera Prognostics Inc.	Concurrent with its lead investment in **Sera Prognostics Inc.**'s $40m Series C round, **Laboratory Corp. of America Holdings** licensed exclusive US distribution rights to the company's *PreTRM* premature birth risk test. Launched in the US in March 2016, the *PreTRM* is a blood test done during the 19th or 20th week of pregnancy. It assesses risk for a premature delivery (prior to 37 weeks of gestation) using liquid chromatography-tandem mass spectrometry, which detects and measures two proteins present in the mother's blood that are predictive of preterm birth: IBP4, insulin-like growth factor binding protein 4, and SHBG, sex-hormone binding globulin. Sera will take advantage of LabCorp's expertise in women's healthcare--particularly in non-invasive prenatal testing (NIPT) and reproductive genetics gained through its July 2016 acquisition of women's health diagnostics firm **Sequenom**–as well as its nationwide network of 1.75k patient service centers, where it will now offer *PreTRM* to physicians.	IVD

PLAYERS	PACT	PRODUCT SECTOR
Mobidiag Ltd. & Wallac Oy (a division of PerkinElmer Inc.)	**PerkinElmer Inc.**'s **Wallac Oy** subsidiary will distribute **Mobidiag Ltd.**'s *Amplidiag* product line in South Africa. The *Amplidiag* brand includes multiplex in vitro diagnostics and compatible systems for detecting gastrointestinal infections using real-time PCR technology. The tests can identify the following: Helicobacter pylori and clarithromycin-resistance gene mutations; the three most frequent enteric parasites from a stool sample; five major carbapenemase groups and two vancomycin resistance markers; the toxin B gene in C. difficile while also differentiating between the hypervirulent 027 ribotype and non-027 ribotypes; bacterial pathogens; and enteric viruses (this test will be available soon). Mobidiag also offers a system that automates the nucleic acid extraction and PCR plate setup for all *Amplidiag* products.	IVD
FEBRUARY		
QT Vascular Ltd & Medtronic PLC	**QT Vascular Ltd.**licensed **Medtronic PLC**worldwide rights to distribute its *Chocolate* PTA catheter for five years. The deal term will automatically renew for two additional one-year periods. The *Chocolate* PTA catheter incorporates a nitinol constraining structure to provide predictable and uniform balloon dilatation thus reducing trauma to the vessels. The product–which is currently approved in the US, Europe, Australia, Turkey, Singapore and Hong Kong–can be used as a stand-alone treatment or adjunct treatment for stenosis in vessels above and below the knee. QT chose to partner with Medtronic because of its extensive global distribution network. QT Vascular's TriReme Medical subsidiary currently sells the *Chocolate* PTA in the US along with a distribution partner. Sales will begin transitioning to Medtronic on a country-by-country basis, beginning in the US.	Peripheral vascular
Solasia Pharma KK Lee's Pharmaceuticals Holdings Ltd.	**Solasia Pharma KK**granted **Lee's Pharmaceutical Holdings Ltd.**exclusive rights to market its oral mucositis product *episil* in the People's Republic of China (PRC), Hong Kong, and Macau. The deal specifically excludes Taiwan, Beijing, Shanghai, and Guangzhou. An oral liquid supplied as a ready-to-use device, episil is indicated for oral mucositis in patients undergoing chemotherapy or radiation. The treatment forms a bioadhesive film to protect sensitive mucosal surfaces to help heal and reduce pain. Solasia gained Japanese and PRC rights to episil from Camurus in 2015, and late last year, sublicensed the Japanese rights out to Meiji Seika Pharma. The deal is the second for Solasia and Lee's in the supportive cancer care market. In 2015, Solasia granted Lee's rights to sell Sancuso, its product for chemotherapy-induced nausea and vomiting, in China.	Cancer management

Source: Strategic Transactions

Metallurgist Admits To Stryker Bribe

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An executive with metallurgical technology company Sanova LLC has pleaded guilty to bribing a **Stryker Corp.** employee in hopes of securing a multimillion-dollar supply contract.

Sanova VP and partner Eugene Ostrovsky entered a guilty plea for violating the Federal Travel Act in Newark, NJ, federal court on Feb. 27. He reportedly paid $75,000 to Daniel Lawrynowicz, Stryker's director of engineering, between 2012 and 2013.

The criminal complaint in the case shows that the FBI recorded Lawrynowicz and an unnamed Sanova employee discussing ways to conceal the bribes during an upcoming audit.

Ostrovsky faces up to five years in prison and a fine of $250,000, or twice his financial gain or loss, and had to forfeit $1.1m as part of the guilty plea. He will be sentenced June 29. Separately, Ostrovsky is awaiting trial in Maryland for bribing a Department of Energy official in hopes of winning a $3m research contract.

Lawrynowicz, who was charged with bribery in March 2016, also faces five years in prison and a $250,000 fine.

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CONTINUED FROM PAGE 1

after the regulations take effect, and then it could take up to an additional 18 months, or longer if noncompliances are found, for them to actually be re-designated.

So, any efforts at planning to comply with the new MDR is going to be tricky for companies, and the outcomes are potentially unpredictable. There is a lot at stake. But for products whose certificates are going to be expiring, decisions will need to be made.

WOULD IT BE SAFER TO KEEP GOING WITH COMPLIANCE UNDER THE DIRECTIVES?

Manufacturers that are planning to continue compliance under the MDD into the time period when other firms must comply with the MDR need to think carefully.

Companies should be conscious of the perceived value of a certificate against the MDR compared with a certificate against the MDD, Erik Vollebregt, partner at Axon Lawyers, told *Medtech Insight*.

He pointed out that Article 120(3) of the new MDR specifies that products that are certified under the directives can be placed on the market or put into service, provided that, from the date of application of the regulation, they continue to comply with the MDD and "there are no significant changes in the design and intended purpose." Article 120(3) was added during the legal-linguist review of the MDR after the trilogue negotiations were completed last summer.

This means that no changes can be made to the MDD-certified products until they are in compliance with the MDR.

This is potentially a significant disadvantage given the normal iteration in device upgrades, and could well result in devices becoming obsolete, or at least perceived as outdated, before their certificates expire.

Also, certain markets, such as Saudi Arabia or the Emirates, for example, who rely heavily on CE-marking, may well demand compliance with the very latest regulatory requirements. These countries will want evidence of the highest level of compliance, Vollebregt suggested, and especially evidence of the highest standards of clinical data.

There also may be discrimination in tendering, or contracting, by purchasers who are keen to have devices that meet the latest regulatory standards.

It is also worth noting that for manufacturers who choose to continue complying with the directives beyond the date of application of the regulations – expected sometime in the second quarter of 2020 for the MDR – Article 120(3) still requires them to meet the regulation, as opposed to the directive, requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and devices.

> "Apart from helping companies navigate their transition into MDR compliance, my work also involves assisting strategic and industry buyers, who are already trying to see who is likely to be in trouble and where the sitting ducks for acquisition are," attorney Erik Vollebregt says.

Certificates granted to manufacturers by notified bodies and used as the basis for CE-marking will remain valid until the end of the period on the certificate, but will become obsolete, at the latest, four years after the date of application of the MDR, likely Q2 2024.

BEING PUNISHED FOR MDD CHOICE?

It is a difficult decision: Do you opt for the MDR because of the competitive advantage it may give you, or do you stay with the more established pathway of the directives?

Vollebregt suggested that companies may well prefer to continue with compliance under the directives and gradually gain knowledge and experience as others go through the MDR route, and that regulatory pathway becomes clearer and more established.

But anyone, he added, that decides to continue under the directives needs to be aware that they will already have to comply with a series of additional requirements. This includes the Article 120(3) requirements listed above, he says, but, in addition, notified bodies will be used to testing to the higher MDR standards. Indeed, when it comes to clinical data, notified bodies are already generally assessing companies against the latest clinical evaluation guideline, MEDDEV 2.7/1 rev.4. This represents a big step toward the enhanced clinical data requirements in the MDR.

Also, timing is critical. If a company wishes to gain benefit from continuing to sell a device while regulated under the directives, then it should aim to get a fresh MDD certificate a year before the transitional period of the regulations expire. The problem, however, will be the huge number of other companies that come to the same conclusion, while notified bodies deal with a bottleneck of having to transition all existing devices then on the market into the MDR system.

LACK OF REAL CHOICE AND UNFAIR DISADVANTAGES

While, at face value, there appears to be choice, in reality, manufacturers may find that options are constrained because of a lack of sufficient capacity within the notified bodies, Vollebregt warned. Indeed, this lack of capacity may even prevent a manufacturer from being audited at all – whichever option a company chooses.

And when it comes to being audited against the new regulations, even if notified bodies are accredited, will they be able to process all the certificates quickly enough, he asked, for those being assessed against the directives and the regulations?

Several competent authorities, including the Dutch Health Inspectorate, the attorney said, are concerned that there has not been sufficient communication from the European Commission about how notified bodies will act in the transition period and when the MDR notifications will be final.

There are questions, Vollebregt added, about whether notified bodies will respond to their customers on a first come, first served basis and whether some notified bodies may be notified sooner than others and be able to start issuing MDR certificates sooner. The result could be that some may suffer a "serious competitive disadvantage."

REGULATORY HIATUS WILL MAKE COMPANIES SITTING DUCKS FOR ACQUISITION

Vollebregt believes there is the risk of a huge bottleneck and that some companies will find their products in a regulatory no-man's land by the end of the transitional period: No longer compliant with the directives, nor compliant in time with the regulations. Logically, this will mean that the firm's products will no longer be legal on the market, and marketing will have to stop.

"Apart from helping companies navigate their transition into MDR compliance, my work also involves assisting strategic and industry buyers, who are already trying to see who is likely to be in trouble and where the sitting ducks for acquisition are," Vollebregt told *Medtech Insight*.

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ASIA REG ROUNDUP:

Malaysia, Vietnam & India Speed Ahead In 2017

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This is the latest entry in Medtech Insight's regularly occurring Asia Reg Roundup, spotlighting important regulatory developments in Asia with the help of local experts.

Many of the 10 Association of Southeast Asian Nations country members were able to report progress in ratifying the ASEAN Medical Device Directive (AMDD) during a December meeting of the bloc's states held in Brunei.

In an update presented by the Singapore HSA (Health Sciences Authority), the one ASEAN member that has fully implemented the AMDD, meeting delegates heard: Thailand's ratification is expected to be complete by the end of 2017; Laos is currently revising its own regulations, with AMDD adoption expected during 2017; and the Philippines, also overseeing a new national regulatory code, is on target to complete AMDD ratification by the end of 2017.

MALAYSIA SIMPLIFIES SYSTEM FOR USERS

Malaysia has completed the implementation of its pre-market process requirements associated with AMDD compliance, and expects the post-market requirements to be in place by the end of June 2017. This would pave the way for the country's ratification of the AMDD sometime in the middle of this year. *(Also see "Asia Reg Roundup: Adverse-Event Reporting, Medtech Fees, And More" - Medtech Insight, 1 Nov, 2016.)* In Malaysia, manufacturers must demonstrate device safety and performance via a Common Submission Dossier Template (CSDT), which can also be used for ASEAN system registrations.

The Malaysian Medical Device Authority (MDA) has been very good about issuing change notifications to help make its own regulatory system work smoothly, ARQon consultant May Ng told *Medtech Insight*. Applicants have not always been sure of what documents and information to submit for the product change, but, in view of the problems faced by stakeholders, the MDA recently made changes intended to alleviate and remove all obstacles in the implementation of the country's Medical Device Act (Act 737).

The MDA has also issued an advisory note on applications for Certificates of Free Sale (CFS) and Manufacturing Certificates (MCs).

Further, the authority has instructed companies on how to apply for product classifications, and decided to set a fee of MYR300 (US$64) per application. The fee was put into effect on Dec. 1, 2016.

The MDA now has a list of 16 Conformity Assessment Bodies (CABs) under the Medical Device Act of 2012 (Act 737). As of mid-January 2017, the MDA said it was in the midst of evaluating applications from more organizations to become registered CABs.

And with the AMDD, there is now a general sense of progress, even if different countries have different ways of presenting their requirements, for instance, on classifications, accreditation and organization issues. Nonetheless, some authorities are still working out their methods of approach to AMDD, says Ng. "Each country is assessing the approach that can facilitate the application and approval process in the implementation of the medical device control with AMDD requirements," she noted. "Malaysia uses CABs for conformity assessment, for instance."

The next country to address its national regulatory framework will be Thailand, she adds. But, at present, the focus in the region is on Vietnam.

VIETNAM TO THE FORE

Vietnam ratified the AMDD in 2016, and is this year rolling out its formal national regulatory system, explains Asia Regulatory Professional Association (ARPA)

secretary Jack Wong. *(Also see "Asia Reg Roundup: Vietnam Decree, Malaysia Labels And More" - Medtech Insight, 16 Sep, 2016.)* "Companies should not delay in adjusting to the new regulatory processes there," says Wong, who has been commissioned to offer training advice to the Vietnam government. "The Vietnam authorities have been smart in outsourcing product classification to institutions – this is an innovative way of dealing with a huge workload," he says.

"If a company does not know their product classification, they don't need to talk to the government, which sometimes takes a long time to answer such questions. Using third-party institution is a win-win."

The Vietnam national medical device regulations will be phased in to force, Ng observes – they take effect in June 2017 for low-risk products and by the end of 2017 for higher-risk products. Vietnam also concurrently has a local industry manufacturing plan to meet ISO quality system standards, for international purposes.

Myanmar is reportedly debating both a national law on medical devices and engaging in moves to ratify the AMDD.

INDIA MAKES A MOVE

Outside the ASEAN bloc, India has become a country to watch on the device regulatory front. India has failed to implement a comprehensive regulatory structure, in spite of several attempts, over the years. But recently the country's government published proposals for a risk-based, dedicated system for medical technology regulation, which would put an end to the current practice of regulating medical devices and *in vitro* diagnostics under rules intended for drug products. *(Also see "India Can Do More To Align New Medtech Regulations With Global Norms, Says Industry" - Medtech Insight, 6 Feb, 2017.)* The device rules would enter into force after a transition period.

India's new rules would come into effect in January 2018. "It is looking more promising that it will be implemented this time," says Ng. Wong agrees, "India this time is more realistic, so industry really does need to take it seriously."

BENEFITS OF REGULATORY CODES

Companies view these enhanced regulatory demands – national and AMDD – positively. "They give greater assurance, even if more input is required in terms of both administration and manpower. Add in the classification requirements and it's clear that there is a lot that is very new to some of the countries in the region," Ng observes.

Wong adds, "Local industry, generally speaking, likes regulation, as it helps to screen out very low quality products. The good news is that they have a positive attitude."

So ASEAN AMDD plans are largely on target, and many countries are aiming for completion of their ratification work by the end of this year (2017), instead of the original target date of the end of 2019.

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[**Editors' note:** *For Asia regional regulatory updates, check out Informa's KNect365 Life Sciences Medtech Summit, June 19-23 2017, in Amsterdam, the Netherlands. Both Ng and Wong will be speaking and hosting discussions on Asian regulatory issues as part of the Medical Device Regulatory Affairs in Emerging Markets stream. Later in the year; the AHWP annual meeting will be held in India, in November 2017.*]

RUSSIAN ICEBREAKER:

IMEDA Seeks To Keep Medtech Channels Open

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[**Editor's note**: *This is last in a series of three* Medtech Insight *articles based interviews with Moscow-based IMEDA at MedTech Europe 2016. See previous pieces addressing efforts by the Russian government to encourage localization and challenges linked to the formation of the Eurasian Economic Union.*]

"The Ministry of Health welcomes our input, but we have less than a year to come up with something" on implantable device pricing, IMEDA's Sergey Kolosov says.

Russia's International Medical Device Manufacturers Association, IMEDA, has 41 member companies. That number has remained stable in spite of – or maybe because of – the problems that Russian health-care providers have been undergoing of late.

Indeed, the remit of IMEDA's chief executive, Sergey Kolosov, is growing, and will surely become larger still as sentiment about the Russian industry generally continues to improve, and as the medtech industry in Russia increasingly recognizes the value of speaking with one voice on key issues.

Speaking to *Medtech Insight* during MedTech Europe's annual medtech forum in Brussels, Belgium, in December 2016, Kolosov said, "It's amazing how much we are dealing with." He was referring to a full plate of responsibilities that has increased exponentially since Russia developed its own modern, risk-based medical device regulatory system in 2013. *(Also see "Flurry of Russian Medtech Regulatory System Proposals Keeps Manufacturers On Their Toes" - Medtech Insight, 24 Nov, 2016.)*

That was just the start. Now there is additionally the Eurasian Economic Union's (EAEU) device regulatory system to finalize and integrate *(Also see "Russian Medtech Industry Wants Quicker Progress On Eurasian Bloc Plans – 2017 Now Targeted" - Medtech*

Insight, 24 Feb, 2017.), and Russia's drive to "localize" its medtech industry via a package of incentives. *(Also see "Russia's Medtech Looks For Chain Reaction After Philips Partnership Deal" - Medtech Insight, 23 Feb, 2017.)* The efforts to encourage local production has a flip side – it can cause barriers for overseas companies that have not invested in the Russian economic device ecosystem or have kept themselves outside pre-commercial activity locally.

Roszdravnadzor, the Russian regulator, now participates in forums hosted by the International Medical Device Regulators Forum, having upgraded from associate to full-member status in 2016.

The localization drive is focused on building the industry by favoring procurement of goods of Russian origin or services provided by Russian entities through competitive processes, auctions or other methods of procurement. The local goods and services are given priority over foreign-sourced analogs, as specified in recent legal instruments, including the 15% preference for local manufacturers (under Economic Development Order No. 155, March 2014), and, most recently, the amending Resolution 925 issued in September 2016.

And those are merely the headline issues. There are an array of other challenges for all Russian device industry stakeholders, including on issues related to value-added tax (VAT) rates for imported devices, device raw materials and components; assimilation of a new All-Russian Product Classification (called OKPD2), and its associated VAT rate implications; monitoring the impacts of Russian (and EAEU) decisions on parallel imports; and shepherding Russia's own medical device registration certificate replacement initiative (as established under Resolution 1416, December 2012).

IMPLANTABLES INTERVENTION

These are areas where IMEDA sees its value as an expert intermediary. Recent challenges faced by companies in response to the Russian government's decision to set weighted pricing for implantable devices is a good example. "Implantables was and is still a rather burning issue for us," said Kolosov, but IMEDA's interventions have secured a one-year delay to give more time for a better strategy to be devised. *(Also see "Medtechs Must Forearm For Russia's Tough Market-Access Pathway" - Medtech Insight, 8 Sep, 2016.)*

To recap, a government decree was issued in December 2015 (Resolution 1517), which listed the implantable devices that would be subject to state regulation of pricing. It took effect in January 2016, and Roszdravnadzor (RZN, the Federal Service for Surveillance in Healthcare) began requesting information from implantable-device suppliers via a survey on which to base weighted average prices.

But the survey did not reach all of its targets and the templates it used were suboptimal. The designated July 15 submission date was looking ambitious. After conceding problems with the scheme, the government deferred by one year the deadlines for manufacturers to provide the pricing information. Resolution 735 set a new deadline, Sept. 1, 2017, for the authorities to set maximum wholesale mark-ups on implantable device selling prices.

Kolosov said, "At the end of the day, the implementation of the decree was postponed. It took a lot of work, but the postponement gave us an opportunity to be fully involved in the discussions." Thus, IMEDA was able to provide expertise and possibly work toward solutions this year. But it's still a tall order. "The Ministry of Health welcomes our input, but we have less than a year to come up with something," he said.

Kolosov insists that his industry association is bidding to create a good operating environment for all companies in Russia, including domestic manufacturers. He sees the importance of identifying common ground with local companies and supporting the position of the Russian industry as a whole. The rationale is straightforward: "Doing joint work and not being separated does work; it brings results."

He added: "It is clear that this niche is quite new, as a majority of devices used in Russia are produced abroad." It seems as if the whole of the Russian medtech ecosystem is in learning mode, as Philips Healthcare observed in conjunction with recent investment projects advanced by the company in Russia. "It's not just new for us, but for ministries and the authorities too. We at IMEDA can provide assistance, as the way to go is through cooperation, providing expertise, and giving assistance," said Kolosov.

BREAKING THE ICE WITH THE REGULATOR

That also applies to working with the Russian regulator, Roszdravnadzor (RZN), which has been a challenge in the past. But, Kolosov suggests, matters are progressing. "On the communication side, there are no problems, and we have a good working relationship with the head of RZN and his subordinates." But RZN is facing staff shortages, and it is now having to deal with the pressures of the developing Eurasian Economic Union's, as well as implementing relatively fresh Russian regulations.

RZN now participates in forums hosted by the International Medical Device Regulators Forum (IMDRF), having upgraded from associate to full-member status in 2016. The management of RZN now more routinely refers to existing IMDRF initiatives linked to compliance issues, which IMEDA sees as a good sign. After the September 2016 IMDRF forum in Brazil, RZN reached out to IMEDA to discuss further details on key themes from the meeting – something of a breakthrough.

"Helping them helps industry," said Kolosov, whose diplomatic skills are evidently doing much to break the ice with. "But there's still a long way to go. We need to educate, but also to be careful how we put that over. So we call it expert opinion and assistance. That's the way to go. it's all part of the global strategy."

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FDA: Marketing Materials Encouraged Neurovascular Catheter Misuse

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Misinformation in some neurovascular catheter marketing materials could pose a risk to patients, US FDA said in a March 1 letter to providers.

The letter clarifies indication-for-use differences between neurovascular thrombus retrieval catheters and neurovascular guide catheters, both 510(k) devices. FDA has cleared thrombus retrieval catheters to remove thrombus or restore blood flow to the brain within eight hours of a stroke, while neurovascular guide catheters are indicated introducing interventional devices into the neurovasculature or as a conduit for retrievers. Unlike retrieval catheters, guide catheters aren't tested to ensure they're safe for use within the blood vessels of the brain.

But marketing materials and "recently published literature" may have spread the misconception that guide catheters are cleared to remove thrombus, FDA's letter to physicians says.

The agency became aware of the issue after receiving a complaint that claimed marketing materials for several companies implied guide catheters were newly indicated for thrombus removal, FDA spokeswoman Stephanie Caccomo told *Medtech Insight*. She declined to specify who filed the complaint or which companies' marketing was involved.

The two kinds of catheters, which are cleared under different FDA product codes, may differ in features such as length, diameter or material stiffness. Therefore, use of guide catheters to remove thrombus could cause "vessel damage, perforation or dissection when used in the most distal regions of the neurovasculature," FDA says. The agency has already received one report of a patient hemorrhaging and dying after a misused guide catheter perforated a blood vessel, and it fears other incidents may go unreported if physicians attribute the adverse events to the stroke rather than to the treatment.

The agency says it became aware of the issue after receiving a complaint that claimed marketing materials for several companies implied guide catheters were newly indicated for thrombus removal.

The agency recommends health-care providers review the marketing information for neurovascular catheters, and consider their different indications for use before performing procedures.

Stryker Corp., **Penumbra Inc.**, and **Covidien Ltd.** are among manufacturers of devices cleared as neurovascular thrombus retrieval catheters. In addition, FDA granted the first indication for use as first-line thrombus treatment to Stryker's *Trevo ProVue* and *XP ProVue* retrievers in September 2016 via the *de novo* process. *(Also see "Stryker Devices Get First-Line US FDA Go-Ahead For Stroke" - Medtech Insight, 2 Sep, 2016.)* The ProVue catheters carry a new product code and aren't referenced in the current physician alert.

Companies including **Boston Scientific Corp.**, Stryker and **Arrow International Inc.** make neurovascular guide catheters.

A search of the MAUDE adverse event database shows that FDA received 29 adverse event reports concerning neurovascular thrombus retrieval catheters in January 2017, compared to 164 for neurovascular guide catheters. It was unclear how many incidents could be traced to device misuse.

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Anti-Kickback Reforms Urged To Support Outcomes-Based System

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As device companies are betting more on business models that rely on value-based-care service partnerships with health-care providers, two trade groups say US anti-kickback law is outdated and needs to be revised to reflect a more collaborative and outcomes-based health-care system.

AdvaMed proposed anti-kickback revisions in a Feb. 27 letter to the US Health and Human Service Office of Inspector General. In it, the device industry trade group argues for broader safe harbor provisions to protect activity that benefits patients but violates some components of current anti-kickback laws.

"The breadth of the anti-kickback statute has inappropriately deterred manufacturers, providers, payers and others from engaging in beneficial value-based arrangements to improve care and reduce costs," wrote Christopher White, AdvaMed's general counsel. "This is in large part because the statute and its safe harbors were targeting behaviors that inappropriately drove utilization, cost, and other problems in a fee-for-service reimbursement environment. Many of the historical assumptions, however, are different today and the existing anti-kickback principles are simply outdated."

AdvaMed says device manufacturers could help guide outcomes-based policy due to companies' experience in collecting outcomes data about how their innovations affect patient health. But the breadth of anti-kickback statutes deters stakeholders from sharing such information, the letter states.

In particular, AdvaMed wants the OIG to provide greater clarity and protection for programs that allow manufacturers to offer rebates based on clinical outcome for bundled items and service; provide warranties that cover corrective surgery if their products don't give the desired effect; provide auxiliary services, such as follow-up lab testing, at no cost; and offer patients and providers services such as post-surgical care management if they improve outcomes. These activities align with a growing emphasis by device companies on partnering with hospitals and other providers to reduce cost and improve benefit from use of their products. *(Also see "Full Steam Ahead On Medtech Value-Based Business Models" - Medtech Insight, 16 Jan, 2017.)* So far, OIG's waivers in these areas do not include medical device manufacturers.

AdvaMed offered its comments in response to a December OIG final rule that modified established safe harbors around rebates for the needy, coupons, and some forms of remuneration. *(Also see "HHS Inspector General Rule Expands Safe Harbors For Beneficiary Remuneration" - Medtech Insight, 16 Dec, 2016.)*

HEALTH EXECS PUSH STARK, KICKBACK REFORMS

The issue of waivers to anti-kickbacks laws also received attention in a white paper issued earlier this month by the Healthcare Leadership Council (HLC), which is a consortium of executives from device and drug companies, as well as hospitals, payers and pharmacies, among others.

HLC says anti-kickback laws, including the Stark law forbidding self-referral, aren't compatible with the current movement toward an outcomes-driven health-care model. And current government waiver options are too narrow, the health-care industry group says.

Specifically, HLC wants to see anti-kickback waivers currently granted Medicare Shared Savings Program Accountable Care Organizations (ACOs) expanded so they include all ACOs and similar groups, whether they're Medicare participants or not. The group also wants broader protections around donations and training on electronic health records (EHR) software, including information-sharing technology.

HLC's white paper further proposes that the government revise the ban on setting reimbursement based on the "volume or value of referrals" to more clearly reflect an outcome-oriented health-care environment. Standards based around "fair market value" should also focus on outcomes rather than hours worked, the group says.

In addition, similarly to AdvaMed, the HLC wants HHS OIG to loosen restrictions on manufacturer giveaways. Right now, manufacturers are often limited by what's called the "one-purpose" test, which states giveaways aren't allowed if they can be seen as kickbacks. But HLC thinks device-makers should be allowed to hand out tools that could help patients follow a post-operative regimen or remember to take medications if the actions improve care and demonstrate a low risk of fraud or abuse, "regardless of whether one purpose of the arrangement is potentially problematic."

Finally, the group believes strict liability for Stark violators should be replaced by an intent-based framework or a sliding scale, allowing penalties to be aligned to the severity of the offense.

The changes could be made either via legislation, or by giving HHS increased regulatory discretion, HLC says. Its proposals were based on those of a working group formed in January 2016. *(Also see "CEOs Want Anti-Kickback, Self-Referral Law Waivers For ACO Interactions" - Medtech Insight, 19 Feb, 2016.)*

Congress has given some attention to potential Stark law reforms, in particular. The Senate Finance Committee, for instance, held a hearing last July to consider proposals to modernization the self-referral rules. *(Also see "Take Compensation Pieces Out Of Stark Law, Legal Experts Tell Senators" - Medtech Insight, 13 Jul, 2016.)*

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Thousands More Medtech Jobs At Risk If Tax Restarts, Think Tank Says

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If Congress repeals the 2.3% excise tax on device sales before the levy is scheduled to reactivate in 2018, the medtech industry will be on a path to regain the approximately 28,000 net jobs that data suggests were lost in the sector between 2013 and 2015 by about the year 2021, according to projections by the American Action Forum, a Washington, DC-based think tank.

But if tax collection is allowed to restart, an additional 25,000 jobs could be lost during a similar period, says the AAF, which identifies as a center-right organization, politically. The assessment is based on analysis of US Department of Commerce employment data and projections of tax-revenue collections from the White House Office of Management and Budget.

The excise tax, enacted by the Affordable Care Act in 2010, took effect in 2013. Congress than suspended the tax for 2016 and 2017; it is currently set to come back in 2018.

Commerce Department data suggests that the medical device industry cumulatively lost 28,800 jobs during the three years the device tax was collected. Most of that loss came in 2014, and there was actually a gain of about 2,600 jobs in 2015, when Congress passed the two-year tax suspension.

"Of course, there are also many other factors which would affect the industry, although the impact of other factors in such a short period of time is likely to be small," states the analysis, performed by health economist Robert Book.

AAF points out that its methodology would have projected a cumulative loss of 21,900 jobs during the 2013-2015 period based on the actual amount of money that has been collected by the industry from the excise tax. Using that approach, the group estimates that there will be an additional loss of 25,000 jobs by 20121 if the tax comes back as scheduled. But if the tax is repealed, the 28,800 jobs that lost are likely to be recovered within three to five years, AAF says.

Device lobbying groups have been pushing lawmakers hard to include permanent repeal of the excise in "repeal-and-replace" plans for the Affordable Care Act and in budget reconciliation discussions. *(Also see "AdvaMed Pushes For Trump To Address Device Tax In Joint-Session Address" - Medtech Insight, 27 Feb, 2017.)*

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Medtech Cybersecurity Whistleblowers: Traditional Protections, Incentives Apply

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Cybersecurity vulnerabilities that have required a US FDA safety alert and remediation from manufacturers have surfaced for several devices during the past year. While there's been no clear indication that any manufacturer has tried to cover up vulnerabilities that have reached the public view so far, employees who believe their employers are holding back information from the public about cybersecurity risks are entitled to the same protections and incentives as other whistleblowers, according to a legal expert.

Alexis Ronickher, a partner at the law firm Katz, Marshall and Banks, recently published a "Cybersecurity Whistleblower Protections" guide that looks at protections afforded to those who disclose cybersecurity vulnerabilities in different industries. *Medtech Insight* spoke to Ronickher about specific protections that are available to those in the device industry, including workers at device companies and government officials dealing with industry.

A podcast of the full interview is below:

Generally, Ronickher says cybersecurity whistleblowers are protected by several laws. The statutes that could specifically apply to

people associated with the device industry include the Sarbanes-Oxley, Dodd-Frank, Financial Institutions Reform Recovery and Enforcement, False Claims, and Whistleblower Protection Acts.

"Like all cybersecurity whistleblowers, there's not a set law that protects [medical device company employees] from retaliation, but there is a patchwork of different federal and state laws that, depending on the factual scenario for that whistleblower, are there to protect them for when they raise these issues internally and externally," she said.

According to Ronickher, whistleblowers at publicly traded companies raising concerns about cybersecurity vulnerabilities of medical devices could be protected by the Sarbanes-Oxley Act. Under that law, employees of publicly traded firms who report fraud or securities violations are protected from termination, demotion, marginalization and other forms of corporate retaliation.

Such employees could also be protected under the 2010-enacted Dodd-Frank Act if there is a securities violation.

If a publicly traded company intentionally hides cybersecurity vulnerabilities to allay potential financial repercussions, there is a whistleblower rewards program offered by the US Securities and Exchange Commission (SEC) to provide incentives to corporate employees to expose employers.

The matter, however, becomes a bit more complicated if the employee works for a private company. Even in that scenario, Ronickher says there are more than 30 states with statutes on the books to protect them, but it's important to note that each state has its own set of requirements so the level of protection will vary from state-to-state.

She also points out that one big risk from a device cybersecurity attack is that it could endanger patient privacy and, thus, violate the Health Insurance Portability and Accountability Act (HIPAA). In fact, the overwhelming majority of cybersecurity attacks on the health-care system to date have been malicious hackers infiltrating hospital systems to steal patient data and infect them with ransomware. *(Also see "Device-Makers Have Amped Up Defenses Against Hackers" - Medtech Insight, 9 Dec, 2016.)*

As previously reported by *Medtech Insight*, instead of directly attacking medical devices, a growing number of malicious hacks have been using connected medical devices as Trojan horses to infect hospital systems. *(Also see "Device Hacks Becoming More Sophisticated, Targeted, Security Firm Warns" - Medtech Insight, 7 Jul, 2016.); (Also see "Lawmakers Question FDA On Medical Device Cybersecurity Concerns" - Medtech Insight, 3 Nov, 2016.)*

Ronickher says that if an employee was fired from a device company for raising concerns about the potential HIPAA vulnerability of a device, the individual could be eligible for a wrongful termination claim.

QUI TAM CHALLENGES

If the government becomes a client of a device company in some manner, including when the company is reimbursed by Medicaid and Medicare, and it can be proved that the government has been misled about the device's cybersecurity, whistleblowers can file a *qui tam* action, allowing them to sue the company on behalf of the government and receive part of any payout.

However, no case involving a qui tam suit related to device cybersecurity has come before the courts yet. Ronickher points out that one legal challenge tied to device cybersecurity is that there aren't any specific examples of potential wrongdoings, and there aren't any specific laws or statutes in place to deal with them. She also notes that while US FDA has developed device cybersecurity guidances, those documents are nonbinding. *(Also see "'Sharing' Organizations Stay In Final Post-Market Cybersecurity Guidance" - Medtech Insight, 29 Dec, 2016.)*

"I think one of the issues here is just, it's still a relatively new issue; there haven't yet been any catastrophic or serious documented instances," she said. "So you're going to run into a bit of it being a hypothetical problem."

While FDA encourages individuals to report potential cybersecurity vulnerabilities to the agency in the post-market cybersecurity guidance issued last December, there is no financial incentive to do so, according to Ronickher. She notes that some states with whistleblower protections on the books require whistleblowers to engage in external reporting of their concerns; reporting to FDA could fulfill that requirement, which would provide more protection to the employees.

WHISTLEBLOWER PROTECTIONS FOR FDA EMPLOYEES

The protections for whistleblowers are not just for employees of device companies. Under the Whistleblower Protection Act, Ronickher says government employees concerned that their agency or department is acting in a way that is endangering the public or breaking the law are also afforded protection.

In a hypothetical scenario where an FDA employee may be concerned that the agency is not taking a potential cybersecurity vulnerability seriously enough, and/or may be protecting the interests of a company over that of the public's health, a government employee may be protected under the Whistleblower Protection Act. In such a case, the whistleblower would bring their concerns to the Office of Special Counsel, who then can investigate whether there is any merit to the claims and also whether there have been any retaliatory attempts against the government employee.

Ronickher says that when an employee is considering disclosing a device cybersecurity vulnerability that could get them in trouble with their employer, the individual should consider consulting an attorney.

She also says, although it may be counterintuitive to some, that it is important to raise such issues in writing with employers so there is a paper trail in the event an employer attempts to re-characterize the employee's communications.

"Don't report your concern and your issue at the same time as reporting other problems you have, say, with how another supervisor is treating you or another coworker is harassing you," she added. "Keep those things separate; that way the employer can't conflate different reports of issues together and say, 'Oh, the person wasn't raising an issue with the cyber-vulnerability of this medical device; they were raising workplace issues.'"

LISTEN

Listen to our interview with attorney Alexis Ronickher at http://bit.ly/2mxeoDn

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