Medtech Insight
Informa Pharma Intelligence July 29, 2019 Issue 154

International Demand For Robotic Surgery Drives Intuitive Surgical's Revenues Up 21% in Q2

REED MILLER reed.miller@informa.com

Demand for Intuitive Surgical's da Vinci robotic surgery system continues to grow.

During its earnings call on 18 July, Intuitive reported $1.01bn in total revenue for the second quarter, representing a 21% year-over-year increase. Revenue from outside the US totaled $314m, a 19% year-over-year increase and 11% increase over the first quarter of 2019.

"Q2 2019 was a solid one for Intuitive, with healthy customer interest and demand for our products," CEO Gary Guthart said during the call. "Overall, procedure growth met our expectations while capital placements exceeded them."

The total da Vinci installed base grew 13% in the second quarter to 5,270 systems. The company shipped 273 da Vinci systems in the quarter, an increase of 24% compared to the second quarter of 2018, driven entirely by the 40% growth in system sales in the US.

The use of clinical systems in the field, measured by procedures per system, grew about 3.5% year over year, which is slower than the 5% growth reported in the second quarter of 2018. But instrument and accessory revenue grew 22% year over year to $579m, reflecting customer buying patterns and increased utility of advanced instruments, according to the company.

Intuitive reported that worldwide da Vinci procedures grew about 17% compared with the second quarter of 2018. Procedure growth has been especially rapid outside the US, driven by demand in Germany, France, Japan and China. The da Vinci system was used in 20% more procedures outside the US in the second quarter of 2019 compared to the second quarter of 2018, and 4% more procedures than in the first quarter of 2019. Procedure volume in the US grew 16% year over year.

Guthart said, "In the near term, access in core markets is going to be important, and what's been nice here the last few years is the procedure base has been building, so healthy double-digit growth rates in procedures. And absolute growth numbers are starting to become substantial and making sure that those surgeons who want access to the system have it, has been important."

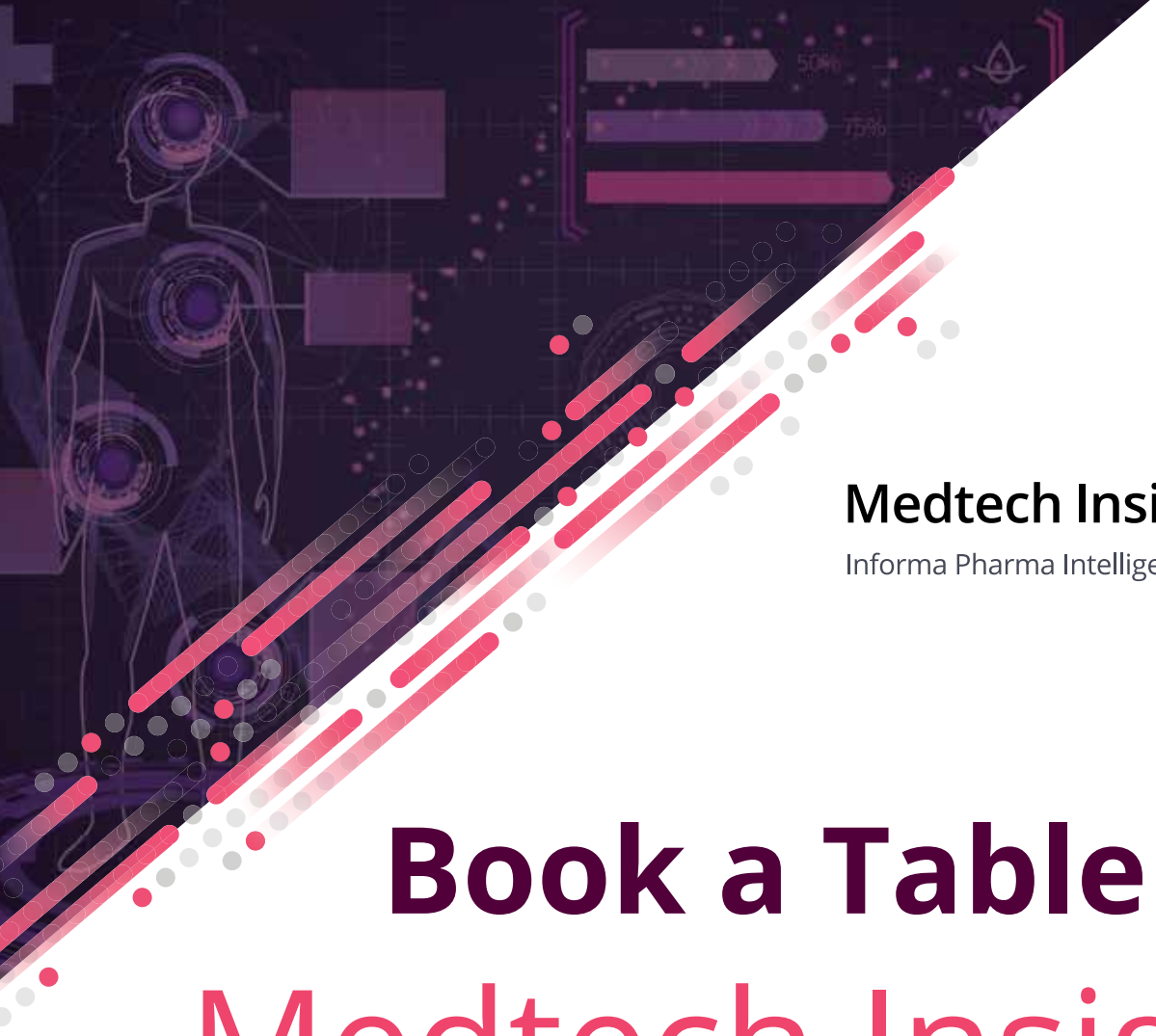
The procedure volume outside the US grew even as placements of new systems remained flat. During the quarter, Intuitive placed 80 da Vinci systems outside the US, including 30 in Europe, 24 in Japan, and eight in China. By comparison, it placed 82 systems outside the US in the second quarter of 2018 and 81 systems outside the US in the first quarter of 2019.

CONTINUED ON PAGE 22

EDITORS' PICKS
US FDA looks for help tackling ethylene oxide troubles, p. 6

POLICY & REGULATION
FDA investigator talks top process validation mistakes, p. 10

COMMERCIAL
Start-up Spotlight: SetPoint Medical eyes vagus nerve stimulation for chronic autoimmune diseases, p. 16



Medtech Insight Awards

Informa Pharma Intelligence

Book a Table

Medtech Insight Awards

Monday, September 23, 2019 | State Room, Boston

https://pharmaintelligence.informa.com/mti_awards2019

General Enquiries:

Jo Kirkpatrick | Tel: +44 (0) 20 7017 7180 | Email: jo.kirkpatrick@informa.com

Sponsorship and Table Booking Enquiries:

Christopher Keeling | Tel: +44 (0) 20 3377 3183 | Email: christopher.keeling@informa.com

Headline Sponsor ICON

In partnership with THE MEDTECH CONFERENCE Powered by AdvaMed

6


7


15

explore more:

exclusive online content

FDA and SaMDs
https://bit.ly/2GDFsd1
In a midyear update, FDA regulators say a retrospective review of companies in its pre-cert pilot program indicates that evaluating a company for excellence markers could be sufficient to let Software as a Medical Device onto the market.

EU standards
https://bit.ly/2Sznmxc
Trying to meet standards that are currently in a state of flux adds another layer of stress to medtech manufacturers already trying to comply with an incomplete regulatory structure.

Medicare coverage
https://bit.ly/2YhPsi4
The Centers for Medicare and Medicaid Services has expanded its coverage of ambulatory blood pressure monitoring.

Execs On The Move
https://bit.ly/2y4T1NJ
Renal denervation firm Ablative Solutions gets new CEO; obesity and metabolic diseases company ReShape Lifesciences hires commercial SVP; cancer diagnostics-developer Cernostics forms medical advisory board; and more.

Device Week
https://bit.ly/2GoOMkC
One of the latest episodes of our weekly podcast is all about earnings. *Medtech Insight* editors discuss how Johnson & Johnson's leadership remains optimistic despite lower device sales and how Abbott delivered a strong second quarter, beating analysts' expectations.

medtech.pharmaintelligence.informa.com

inside:

Cover / International Demand For Robotic Surgery Drives Intuitive Surgical's Revenues Up 21% in Q2 – Intuitive Surgical's worldwide da Vinci procedures were up about 17% in the second quarter of 2019 compared to the same period of 2018.

EDITORS' PICKS

5 Arthrosurface Markets First Allograft Implant To Replace Arthritic Thumb Bone – Orthopedic implant company Arthrosurface is hoping to get the attention of hand surgeons with its new allograft thumb implant to treat osteoarthritis.

6 Got A Better Idea? US FDA Seeks Help Tackling Ethylene Oxide Troubles – Regulators are reaching out to industry and the public for ideas for new sterilization methods that could reduce or replace the need for ethylene oxide.

7 Live Raccoons, Dead Possum Bring Consent Decree To Arkansas Distributor – A new consent decree requires an Arkansas distributor to stop selling medical devices and other FDA-regulated products after an inspection found rodents, insects and other animals at the company's warehouses.

POLICY & REGULATION

8 Repealing 2.3% Device Tax Not On Candidate Klobuchar's '100 Days Plan' – Democratic presidential candidate Sen. Amy Klobuchar of Minnesota has long been a supporter of medtech, fighting to repeal the ACA's 2.3% medical device tax.

8 New US State And Proposed Federal Laws Would Stop Specialists From Balance Billing – A crop of new US consumer protection state laws and proposed federal legislation is intended to stop balance billing.

10 Compliance Corner: These Are The 6 Top Process Validation Mistakes Made By Firms, According To An FDA Investigator – US FDA investigator Ben Dastoli sees medical device manufacturers making the same process validation mistakes over and over.

Medtech Insight

Informa Pharma Intelligence

CHRISTOPHER DELPORTE @MEDTECH_INSIGHT
christopher.delporte@informa.com

SHAWN M. SCHMITT @MEDTECHSHAWN
shawn.schmitt@informa.com

REED MILLER @MEDTECHREED
reed.miller@informa.com

AMANDA MAXWELL @MEDTECHAMANDA
amanda.maxwell@informa.com

MARION WEBB @MEDTECHMARION
marion.webb@informa.com

SUE DARCEY @MEDTECH_INSIGHT
sue.darcey@informa.com

FERDOUS AL-FARUQUE @MEDTECH_DANNY
danny.al-faruque@informausa.com

ELIZABETH ORR @ELIZABETHJORR
elizabeth.orr@informa.com

CATHERINE LONGWORTH @MEDTECHCATE
catherine.longworth@informa.com

ASHLEY YEO @ASHLEYPYEO
ashley.yeo@informa.com

MAUREEN KENNY @SCRIPREGMAUREEN
maureen.kenny@informa.com

NEENA BRIZMOHUN @SCRIPREGNEENA
neena.brizmohun@informa.com

VIBHA SHARMA @SCRIPREGVIBHA
vibha.sharma@informa.com

ANDREA CHARLES CUSTOM CONTENT
andrea.charles@informa.com

JANET HANIAK SENIOR DESIGNER

GAYLE REMBOLD FURBERT HEAD OF PUBLICATION DESIGN

RICHARD FAINT HEAD OF MEDTECH
richard.faint@informa.com

PHIL JARVIS MANAGING DIRECTOR

TO SUBSCRIBE, VISIT
medtech.pharmaintelligence.informa.com

TO ADVERTISE, CONTACT
christopher.keeling@informa.com

EDITORIAL OFFICE:
601 Third Avenue, New York, NY 10158 US
phone 212-520-2700

CUSTOMER CARE:
clientservices@pharma.informa.com
US Toll-Free .....+1 888 670 8900
US Toll .....+1 908 547 2200
UK & Europe .....+44 (20) 337 73737
Australia .....+61 2 8705 6907
Japan .....+81 3 6273 4260

All stock images in this publication courtesy of www.shutterstock.com unless otherwise stated

11 Hearing Implants Could Harm Shunt Function, FDA Warns – Some implanted hearing devices, such as cochlear implants, may magnetically interfere with programmable cerebrospinal fluid shunt systems, the US agency says.

11 Interview: EU Standards Hiatus Will Cost Manufacturers And Notified Bodies More Time And Resources – Delays in the work to create the standards now threaten to create even more uncertainty and further delays all around.

12 Pakistan Sets End 2019 Deadline For Filing Under New Medtech Regulations – Pakistan's health-care market is set to be unlocked when new medical technology regulations are put in place this year.

13 If Cadillac Tax Can Be Repealed, So Can Device Tax, AdvaMed Says – AdvaMed recently pointed to the 17 July US House passage of a bill to repeal the Affordable Care Act's Cadillac tax as a pathway for repealing the medical device tax.

14 Commission Offers One-Stop Shop For Vigilance Information And Offers Vital Spreadsheet – Vigilance is one area where the European Commission is sharpening up tools and practices now, with one eye on the new medtech regulations, too.

15 Siemens Cybersecurity Expert Says Medtech Industry Has 'Perverse Incentive' To Not Disclose Vulnerabilities – The fear of losing business is discouraging companies from being transparent about cybersecurity vulnerabilities.

COMMERCIAL

16 Start-Up Spotlight: SetPoint Develops Vagus Nerve Stimulation To Treat Crohn's Disease And Rheumatoid Arthritis – SetPoint Medical is developing vagus nerve stimulation technology to be a "platform technology" for treating a variety of autoimmune diseases.

18 Strong China Sales Boost Q2 Results For Philips – Dutch health giant Philips reported Q2 results 22 July, showing better-than-expected sales across its medtech businesses.

19 Abbott Delivers Strong Q2 Sales, Led By Spike In FreeStyle Libre Sales – Abbott reported worldwide sales of $8bn, up 2.7%, with medical devices highlighted as a standout division, delivering 10.5% organic growth.

20 Johnson & Johnson Growth Led By Biosense Webster And Cerenovus – Johnson & Johnson's leadership remains optimistic about the future of its medical device divisions despite reporting a 2.6% revenue decline in the first six months of 2019 compared to the same period of 2018.

21 Factory Explosion Expected To Cost Consort Millions In Profit – Consort Medical issued a profit warning following a factory explosion. The company said the incident could cut nearly $6m from its annual profits.

Arthrosurface Markets First Allograft Implant To Replace Arthritic Thumb Bone

MARION WEBB marion.webb@informa.com

Orthopedics implant maker Arthrosurface Inc. recently announced the launch of a new thumb implant to reduce pain in patients who are suffering from osteoarthritis. The SpeedSpiral carpometacarpal (CMC) implant is the first such device to replace the arthritic bone with a structurally sound, load-bearing biologic implant.

Thumb arthritis is the second most common type of arthritis in the hand and is more common in women, according to the American Society for Surgery of the Hand. Osteoarthritis, or degenerative arthritis, occurs sometime after age 40 and as the disease progresses, the pain and weakness may increase along with decreasing range of motion at the base of the thumb.

Treatment options are based on the severity of the symptoms and can involve anti-inflammatory medications, bracing, exercises, ergonomic adjustments, steroid injections and occupational therapy, the society reported. When non-operative treatment fails, surgery becomes an option.

Dori Cage, an orthopedic surgeon specializing in conditions of the hand with San Diego Hand Specialists in San Diego, CA, echoed that the first line of treatment is non-surgical and depends on the patient's symptoms.

She noted that with osteoarthritis, what the X-ray shows doesn't necessarily correlate with a patient's perception of pain. Some patients show a lot of arthritis on the X-ray, but don't have many symptoms, while others show less arthritis on the X-ray but feel a lot pain.

She said that surgery for thumb arthritis is common, especially in women, and surgeons have a lot of choice in terms of which implants to use, including metal and other materials.

Arthritis in the thumb occurs between two bones, the trapezium bone and thumb metacarpal bone, "and almost all the surgeries for that involve something to keep those two bones from rubbing together," she said. The most common surgeries involve taking out part of the trapezium bone or all of it and creating a space, and then, surgeons choose whether to place an implant or spacer (which can involve using the patient's own tendon) into that hole.

"The classic operation is the ligament reconstruction tendon interposition arthroplasty (which involves using a patient's own tendon) … but there are lots of other ways to do that surgery for thumb arthritis," she said. "No matter which of these surgeries you do, most of them work well, but once in a while there are problems with the surgery."

One of the most common complications is metacarpal subsidence where the metacarpal bone migrates into the space where the trapezium bone was taken out, she said, which may require an additional surgery, depending on each case.

Arthrosurface's CMC system uses a pre-shaped, dense, strong and flexible allograft implant to treat CMC joint pain and/or instability caused by osteoarthritis. The implant is designed to supplement and support the flexor carpi radialis (FCR) tendon, which is important to flex and abduct the hand in the wrist, and/or the capsuloligamentous structures at the thumb, while also minimizing operating room time. The implant shape diminishes the risk of metacarpal subsidence that is common to other autograft-only procedures and avoids thumb shortening, according to the company.

Lester Fehr, Arthrosurface's VP of market development, said that "there are plenty of techniques that have been around for quite some time, but all of them fail … to restore the pinch strength that you have normally when you don't have an arthritic thumb joint."

Cage said she couldn't comment on Arthrosurface's new product specifically but noted that some surgeons have used allograft to create a spacer, which involves "taking a piece of allograft and rolling it up to create a spacer – like a homemade version – and it has been used with good results."

Fehr said the SpeedSpiral CMC System is "a structural graft that's rolled and then compressed so it acts like the bone that was removed. He agreed that surgeons can buy allograft or autograft tissue and roll it, but noted that "because it's not dehydrated, compressed and made in a proprietary manner, it doesn't have structure."

Cage said given that there are no allograft spacers on the market, some surgeons would likely be interested in such a product. The big considerations are cost and the cost-benefit ratio.

"Most of the procedures that I use don't require extra equipment," she said. Cage prefers using a patient's own tendon, which eliminates extra cost.

Fehr said the Franklin, MA-based company is marketing the product to hand surgeons in private practice and academia in the US. He estimated that there are between 2,000 to 3,000 hand surgeons that will be targeted via Arthrosurface's direct sales force as well as distributors. The cost of the SpeedSpiral CMC System is "slightly below" available implants on the market, he said. Reimbursement varies but is available through Medicare and some insurers, he said.

Published online 19 July 2019

Got A Better Idea? US FDA Seeks Help Tackling Ethylene Oxide Troubles

FERDOUS AL-FARUQUE danny.al-faruque@informa.com

While American public-health officials continue to grapple with potential medical device shortages after a major ethylene oxide (EtO) sterilization facility closed this year, regulators are asking for help coming up with new methods and technologies to reduce reliance on, and emissions of, the toxic chemical.

On 15 July, the US Food and Drug Administration announced two innovation challenges to help solve its EtO dilemma, which has been a headache for the agency after medical device sterilization facilities using the chemical were asked to shut down or are planning on shutting down.

The first challenge issued by the agency is to identify alternate safe and effective methods and technologies to sterilize medical devices that don't rely on EtO. The chemical used to sterilize about half of sterilized medical devices is also known to be harmful to people in large doses.

The FDA says the method or technology proposed in the challenge needs to be compatible with a large cross section of materials used to manufacture medical devices and their packaging. Further, the proposed technology should be scalable and effective in sterilizing large volumes of devices.

Secondly, regulators are challenging stakeholders to develop strategies or technologies that are intended to reduce EtO emissions and reduce their potential environmental hazard.

"The goal of this challenge is to develop strategies or technologies to reduce emissions to as close to zero as possible from the ethylene oxide sterilization process," the FDA said.

Regulators said possible solutions to the challenge could mean changing current sterilization processes or overflow that could include changes to the supply chain, how medical devices are transported and procedural changes at sterilization sites, as well as strategies that could reduce waste from the sterilization process.

A NECESSARY DANGER

Coinciding with the agency's challenges to stakeholders, Suzanne Schwartz, deputy director of the Center for Devices and Radiological Health's Office of Strategic Partnerships and Technology Innovation, and Elizabeth Claverie-Williams, chief of the infection control devices branch at the CDRH, wrote a statement explaining the need for developing solutions to the EtO dilemma.

"While ethylene oxide sterilization is a necessary part of the manufacturing process for many medical devices, there have been concerns recently about its effects on people who are exposed (or overexposed) to it—and there are concerns about environmental emissions," the FDAers said.

They note long-term exposure to the chemical can irritate organs such as the eyes, skin and lungs, while also causing brain damage and harming the nervous system. The sweet-smelling, colorless and flammable gas damages DNA, and long-term exposure has been linked to cancer.

In February, the Illinois Environmental Protection Agency closed a sterilization facility run by Sterigenics because it exceeded the limits for how much EtO is acceptable to release into the environment. That facility was responsible for sterilizing almost 600 types of devices that the FDA is worried could spell a shortage of lifesaving products. *(Also see "Sterilization Facility Shutdowns Could Spell Medical Device Shortage; FDA Urges Firms To Assess 'Downstream Impacts'" - Medtech Insight, 26 Mar, 2019.)*

In fact, the agency later reported there was a shortage of BIVONA breathing devices for children made by Smiths Medical that were sterilized at the Illinois facility. The FDA worked with the company to change their venue for sterilizing the tracheostomy tubes to avoid further risk to children who need the products. *(Also see "There's A Pediatric Air-Tube Shortage*

Because A Sterilization Facility Was Shut Down" - Medtech Insight, 15 Apr, 2019.)

At about the same time, another sterilization facility, run by Viant in Grand Rapids, MI, was found to have the same problem and voluntarily chose to shut it down by the end of the year.

These incidents have led the FDA to reach out to industry and others to come up with better solutions for cleaning difficult-to-sterilize products without the environmental and health risks that EtO currently poses.

"The issue of ethylene oxide emissions and potential medical device shortages is a serious one," said Schwartz and Claverie-Williams. "As the FDA works with industry and stakeholders, the hope is that challenging them to present effective, efficient, and innovative solutions will help the agency prevent medical device shortages due to sterilization issues in the future."

Coincidentally, while the US sees a potential shortage of certain medical devices due to concerns about sterilization facilities being closed, Brazil has recently approved sterilization protocols that would make it easier for medical device manufacturers to clean their products with EtO in the South American country. Anvisa, the Brazilian health regulatory agency, approved the streamlined protocols that are aimed at modernizing its regulatory regime and increase domestic competition. *(Also see "Brazilian Medtech Welcomes Parametric Release Sterilization Regime" - Medtech Insight, 2 Jul, 2019.)*

Those interested in participating in the challenges presented by the FDA can submit their ideas to CDRH-Innovation-Sterilization@fda.hhs.gov by 15 October. The agency will review the submissions by 16 November.

On 13 August, the agency will also host a webinar for those interested in submitting ideas on the process and what the agency is looking for.

The agency is also planning to convene an advisory committee of external experts on 6 and 7 November to discuss the issue, although it hasn't said where the meeting will be held. Instead, the FDA says those interested should stay tuned to its advisory committee calendar.

Published online 16 July 2019

Live Raccoons, Dead Possum Bring Consent Decree To Arkansas Distributor

ELIZABETH ORR elizabeth.orr@informa.com

An Arkansas distributor must stop handling products regulated by the US Food and Drug Administration, including medical devices, after agency investigators found the company's warehouses teeming with insects, rodents, and other living and dead animals, it was announced on 18 July.

The order comes as part of a consent decree against J and L Grocery LL of Alma, AR, as well as its owner James White and manager Lori Layne, that was issued in the US District Court for the Western District of Arkansas. The decree requires J and L to stop distributing food, drug products, devices and cosmetics until the company complies with the Food, Drug, And Cosmetic Act.

The FDA discovered the unsanitary conditions at J and L warehouses during a September-October 2018 inspection. "Investigators observed multiple live and dead rodents, rodent nesting, live raccoons, live cats, a dead possum, animal feces, and urine-stained products in and around the company's seven warehouses and sheds used to store food, medical products and cosmetics," the agency said in a release.

The FDA followed the findings with two administrative detention orders on 9 and 18 October 2018. US Marshals then seized the company's FDA-regulated human and animal food products, medical devices, over-the-counter drugs and cosmetic products on 7 and 8 November 2018.

Under the terms of the consent decree, J and L cannot resume operations until it puts into place a comprehensive written sanitation-control program and gets written authorization from the FDA saying the company is in compliance with the FD&C Act. The company also agreed to destroy the seized products.

J and L stores closed after the product seizures but reopened in December 2018. But the company closed for good on 30 June, said its attorney, J. Dalton Person.

"We are sorry and would like to say thank you to everyone that has supported us, but once we sign our consent decree with the FDA it will automatically close the doors for a while and we feel in our hearts that it's time to move on to new adventures and spend some much-needed time together," reads a post to J and L's Facebook page announcing the closure.

Published online 19 July 2019

Repealing 2.3% Device Tax Not On Candidate Klobuchar's '100 Days Plan'

FERDOUS AL-FARUQUE danny.al-faruque@informa.com

Speaking to reporters at the National Press Club in Washington, DC, Democratic presidential candidate Sen. Amy Klobuchar, MN, downplayed the need for action on repealing the medical device tax as part of her "100 Days Plan" if she were to win the presidency.

"I don't think I would take any kind of action in the first hundred days, but I continue to believe it should be suspended, that it should be repealed, and I think that it could actually be done even before I become president," Klobuchar said in response to a question from *Medtech Insight*.

Newly elected incoming presidents try to use the momentum of their election win in the early days of their presidency as a mandate to make significant progress on priority issues, known as the First 100 Days. Their hope is an election victory will be treated as a mandate from the public to grease the legislative wheels for a more compliant US Congress and can be used as an opportunity to push through high-priority legislative issues.

During her 16 July talk, Klobuchar listed a number of major initiatives that tackled trade, foreign policy, climate change and health care. However, she noticeably left out repeal of the device tax, a major issue she has been championing for a long time. The 2.3% tax was put in place to fund the Affordable Care Act.

Klobuchar, who has historically been one of the top champions for medical device lobbyists, downplayed her past relationship with the industry and raised concerns about how medtech products are reviewed.

"I see the medical device industry as a strong industry in our country and it's done some good for people, but there are always issues," she said. "There are safety issues, and regulations that have to be put in place."

During her speech, Klobuchar said she would protect the ACA from Republicans who want to end the health-care law that has been responsible for helping millions of Americans obtain health insurance. However, she argued that when the law was crafted, pharmaceutical companies were treated more leniently than medtech manufacturers. That's because there were no checks placed on drug firms that would require the negotiation of drug prices and there were no limits put on industry practice to prevent generics from entering the market.

Klobuchar also said the device industry was slapped with a tax that was not thought out well and was rejected by other lawmakers, including Sen. Elizabeth Warren, D-MA, who is campaigning against Klobuchar for the Democratic nomination.

Industry lobby group AdvaMed played down Klobuchar's comments about not using her hypothetical first hundred days as president as a driver to repeal the tax.

"The good news is that a Klobuchar administration won't have to address this because we're confident the senator and her colleagues will work to enact full repeal this year," said Greg Crist, AdvaMed's chief advocacy officer and main government liaison on the Hill. "There's too much bipartisan support for this to languish any longer."

While there are a number of bills in congress to repeal the tax, if they are not successful it will go back into effect come January 2020.

Published online 18 July 2019

New US State And Proposed Federal Laws Would Stop Specialists From Balance Billing

SUE DARCEY sue.darcey@informa.com

Many state governments in the US have recently passed laws to prohibit medical specialists in emergency departments, laboratories, radiology centers and other specialty areas from balance billing patients at exorbitant rates, and now Congress is pursuing federal legislation to also stop the practice.

Passage of the state laws and proposed federal bills have been primarily prompted by sky-high bills charged by out-of-network providers, said speakers at an Alliance for Health Policy briefing on balance billing on 15 July in Washington, DC.

Also known as "surprise billing," balance billing occurs when a patient receives services from a provider in which the patient has little control over, and little ability to, choose the setting, said Al Bingham Jr., a senior consulting actuary at Wakely Consulting Group. Alternatively, a patient can face an "in-network surprise" by deliberately choosing an in-network facility and surgeon for their planned procedure or care, but then after the procedure, receiving a bill from an out-of-network provider (a laboratory or radiology center, for example) *not* chosen in advance, Bingham told briefing attendees.

EMERGENCIES IN PARTICULAR CAN LEAD TO BALANCE BILLING

New York Times reporter Sarah Kliff, who moderated the 15 July briefing, related several horror stories on balance billing she encountered when writing an investigative story demonstrating situations when fully insured adults – through no fault or plan of their own – were charged with high, out-of-network bills due to accidents that brought them to emergency rooms (ERs).

For example, Scott Kohan of Austin, TX, was violently attacked in January 2018, rendered unconscious, and brought into a hospital emergency department in the city. The first thing Kohan learned upon regaining consciousness was that he needed to undergo emergency jaw surgery that would cost him – for portions not covered by his insurance – $7,924.

Similarly, In April 2018, Nina Dang of San Francisco fell off her bike while exercising and wound up in the ER of the Zuckerberg San Francisco General Hospital and was treated for a broken arm there, Kliff told briefing participants. A few weeks later, she received a bill of $24,074 for her treatment – only $3,800 of which was covered by her insurer – leaving her with an unpaid balance of more than $20,000.

PROTECTIONS AGAINST BALANCE BILLING ENACTED IN 27 STATES

Georgetown University Health Policy Institute professor Jack Hoadley noted than more than half – 51% – of surprise and balance billings are associated with ground- and air-ambulance services, 20% with inpatient services and providers in ERs, and 9% with elective, inpatient care.

For example, out-of-network (OON) anesthesiologists in 2017 had average contracted rates at 344% of what Medicare would pay. OON ER physicians on average charged 304% of Medicare rates, and OON radiologists charged on average 204% of the Medicare rate, while all other OON specialists billed average charges at 128% of what Medicare would pay.

As of mid-July, a substantial percentage of US states – 27 – had passed either comprehensive or partial laws protecting consumers against balance billing, according to Hoadley.

He said 13 states – California, Oregon, Washington, Colorado, New Mexico, Texas, Illinois, Florida, Maryland, New Jersey, New York, Connecticut and New Hampshire – have approved laws providing comprehensive protections from balance billing for patients.

However, "While new state laws in California, New York, New Jersey and Texas would deter the practice of balance billing, providers can still send patients bills with high charges in those states," Hoadley pointed out.

Meanwhile, 14 states – Nevada, Arizona, Minnesota, Iowa, Mississippi, Indiana, West Virginia, North Carolina, Pennsylvania, Delaware, Rhode Island, Vermont, Massachusetts and Maine – have passed laws with partial protections from balance billing, Hoadley said.

FEDERAL LEGISLATION TO STOP BALANCE-BILLING ADVANCES

Problems with balance billing and out-of-network billing have now gained the attention of federal legislators because there are gaps in state-law protections, and there is no state jurisdiction over self-funded insurance coverage plans, according to the Georgetown professor. Hoadley also pointed out that when patients from a state with comprehensive protections against balance billing visit and receive health-care services in a neighboring state, they may find themselves to be *not* covered.

So that consumers will be protected by a federal law that prevents out-of-network providers from levying excessive health-care charges on patients, Congress has been moving swiftly this summer to pass surprise-billing measures with provisions to stop the practice.

The Senate Health, Education, Labor and Pensions Committee passed its anti-balance-billing proposal – the Lower Health Care Costs Act, on 26 June.

Similar legislation, the No Surprises Act, was approved by the House Energy and Commerce Committee on 17 July, with amendments calling for further study by the Government Accountability Office (GAO) on out-of-network billing, and on ground- and air-ambulance costs.

"It is critical we protect citizens from outrageous medical bills, so it's important to move this legislation forward," Rep. Jan Schakowsky, D-IL, said in June during earlier consideration of the bill by the Energy and Commerce Committee Health Subcommittee. *(Also see "US Legislators To Rein In Surprise Laboratory, Imaging, Other Health-Care Bills" - Medtech Insight, 13 Jun, 2019.)*

The proposed No Surprises measure was also endorsed by Republicans on the panel, including ranking member Greg Walden, R-OR, who said the the bill "will go a long way in protecting patients and families from surprise billing."

Walden predicted in late June that the act's provisions were written to take effect quickly, even before regulatory actions required by President Trump under an executive order he signed in June to stop balance billing can be carried out by the Department of Health and Human Services (HHS) next year.

LAB ACT COULD BE INSERTED INTO NO SURPRISES ACT ON HOUSE FLOOR

In addition, at the 17 June markup, Rep. Scott Peters, D-CA, was able to win a promise by the House panel's chair Frank Pallone Jr., D-NJ, that lawmakers would consider an amendment to the No Surprises Act, known as The Laboratory Access for Beneficiaries Act (LAB Act), on more favorable laboratory payments, when the bill reaches the House floor for consideration.

Introduced by Peters and Reps. Gus Bilirakis, R-FL, Bill Pascrell, D-NJ, Kurt Schrader, D-OR, Richard Hudson, R-NC, and George Holding R-NC, the LAB Act would delay the next round of Protecting Access to Medicare Act (PAMA) data reporting by one year to ensure that all applicable laboratories that are required to report private payer data have the necessary time to do so. *(Also see "Lab Groups Disagree With GAO That Medicare Will Be Overbilled For PAMA Test Payments" - Medtech Insight, 19 Feb, 2019.)*

Published online 17 July 2019

COMPLIANCE CORNER:

These Are The 6 Top Process Validation Mistakes Made By Firms, According To An FDA Investigator

SHAWN M. SCHMITT shawn.schmitt@informa.com

When US Food and Drug Administration investigator Ben Dastoli inspects a medical device company, he typically sees firms making the same process validation mistakes over and over.

"There are six process validation issues that have been common this year – they just continuously seem to happen," said Dastoli, who is based in Division 1 within the Office of Medical Devices and Radiological Health Operations (OMDRHO), within the FDA's Office of Regulatory Affairs.

At MedCon 2019 in Cincinnati, OH, Dastoli listed those issues and commented on each. He said manufacturers fail to:

1. Identify all processes that require validation. "As we as investigators are doing our facility walk-through, we're reviewing manufacturing instructions and we're looking at different processes that may require validation. Processes that seem to be commonly missed are gluing, layer-crimping and reagent-mixing. And keep in mind that if destructive testing is the only way to verify that specifications are met, then it's most likely a process that requires validation.

"So, I always encourage all the managers at a company to walk the entire manufacturing floor – it's a good way to identify these processes. A lot of times when investigators are pointing out these problems, I think the quality manager is just as surprised to see some of the stuff that is going on with their products.

"Another process where we see process validation issues is in the manufacture of automated soldering PC boards. When we ask if the process has been validated, the common response is, 'We 100% verify, therefore, there's no need to validate.' Verification activities usually include visual inspections, burn-in, X-ray and point-of-connection testing. But none of these are testing the solder connection. So, what else do you need to consider?

"Did you identify the risk of solder failure during design? Can the soldering joints withstand operating conditions such as vibration, heat, expansion and contraction? And are your inspections designed to capture failure modes, such as loose connections?

"So, does your automated soldering process need to be validated? The answer is, probably."

2. Identify all process variables. "Recently I was inspecting a firm that had an automated printing process. The equipment used various dyes depending on the wire gauge terminal connections. The dyes had different dials on them that could be adjusted by the operator, from one to 10, and that determined the crimp life – which also affects the crimp strength.

"Yet the firm did not consider this variable at all during validation studies. Therefore, they're inadequate validation studies. That whole situation was no good."

3. Select statistically based sample sizes. "This activity must be commensurate with the risk level associated with the failure. For example, selecting a plan allowing for one failure out of 35 for a sterile packaging operation is probably not acceptable.

"But what would be acceptable? Well, that's always the question. We're always evaluating this during an inspection.

"The validation method must ensure that predetermined specifications are consistently met, and the challenge is to repeat it enough times to ensure that the results are meaningful and consistent. Keep that in mind."

4. Identify and consider worst-case conditions. "For example, your vat size during a validation process – such as clean-treating or heat-treating – should be considering the term 'maximum load size' for processing. So, if you're validating an ultrasonic clean process and it was validated using a load size of 30, we as investigators wouldn't expect to see large load sizes during the manufacturing process, which could pose additional challenges to a process.

"Another example I recently encountered was an automated soldering operation of a PC board. The process was validated using a single-sided PC board. Well, the firm also manufactured double-sided boards in the same system – which means it had to undergo the process twice, so they didn't really challenge it. So, it wasn't the worst-case scenario anymore.

"And remember: Consider density, proximity and complexity when validating a soldering operation."

5. Identify variations in raw materials, components and equipment. "Let's say you're validating an ultrasonic welding operation for a company that uses lid seals. You should identify the variability and the fitness of the cups and the lids to understand the tolerance stack-up and evaluate accordingly.

"Additionally, you need to determine your gauge, reliability and repeatability to fully understand your worst-case stack-up conditions. For example, if a measuring tool has a 5% variability, this should be considered when establishing your acceptance criteria."

6. Address failures found during validation. "As investigators, we often come across problems that are simply dismissed for reasons such as operator error. Well, did you really investigate and determine that operator error is the root cause? And, has your sample criteria really been met now that you can eliminate certain samples? And, if you dismiss your results, do you need to make corrective actions or possibly need to revalidate?

"Those are questions you need to ask yourself."

Published online 18 July 2019

Hearing Implants Could Harm Shunt Function, FDA Warns

ELIZABETH ORR elizabeth.orr@informa.com

Magnetic interference poses a risk to patients who use certain types of implanted hearing aids alongside programmable cerebrospinal fluid (CSF) shunt systems, the US Food and Drug Administration warned in a 16 July letter to health-care providers.

The risk occurs because some implanted hearing aids, such as cochlear implants or bone conduction hearing devices, include magnets that may inadvertently change valve settings on programmable CSF shunts if the two devices are "implanted in close proximity to each other," the FDA says.

And if the change results in over- or under-drainage of CSF, patients may experience adverse events including headaches, lethargy, vomiting or difficulty walking. If not treated, the symptoms could progress to loss of consciousness, seizures, hemorrhage, or even death.

To counter the risk, the agency is recommending practitioners educate patients and caregivers about the potential issue and make sure they know when to have the shunt valve checked and what symptoms might indicate over- or under-drainage of CSF. Further, clinicians should check the valve settings after placing or adjusting other devices that contain magnets.

The FDA further recommends physicians position CSF shunts and other devices including magnets as far apart as possible. For example, if a patient has a single cochlear implant, the CSF shunt might be placed on the opposite side of the head. If a patient has bilateral hearing implants, the physician should position the shunt and the implants "at a maximum distance from each other," the agency says.

The notice also tells physicians to report incidents related to magnetic interference with CSF shunts to the FDA.

CSF shunts are used to treat hydrocephalus, which is the buildup of too much cerebrospinal fluid in the brain. The FDA had previously developed a website discussing the general risks magnetic field interference from common sources, such as security screening systems, tablets, toys and cell phones, may pose to users of programmable CSF shunts.

Published online 17 July 2019

Interview: EU Standards Hiatus Will Cost Manufacturers And Notified Bodies More Time And Resources

AMANDA MAXWELL amanda.maxwell@informa.com


Oliver Bisazza

Industry has reason to be concerned when it comes to the European Commission's draft Commission Implementing Decision on medtech standards and the delays that now look inevitable for most standards work.

Medtech Insight's Amanda Maxwell spoke to Oliver Bisazza, director of regulations and industrial policy at Europe's largest medtech trade association, MedTech Europe, to gauge his sense of how the standards request from the European Commission, in the form of the draft Commission Implementing Decision to the European standards bodies, is shaping up.

Standards are critical tools for the medtech industry to meet the requirements of the EU's new Medical Device and IVD Regulations, just as they are for meeting the requirements of the current medical device directives. However, manufacturer compliance with EU harmonized standards is not mandatory. Without standards, the manufacturer needs to demonstrate compliance by another means. But it is arguably the safest way, in both the short and long-term, to demonstrate that a product is in conformity with the essential requirements to which the standard is linked.

Medtech Insight: What are MedTech Europe's views on the standardization request enshrined in the European Commission's draft Implementing Decision to CEN and Cenelec?

Oliver Bisazza: The standardization request needs improvement. We look forward to seeing these improvements in the final version of the Implementing Decision.

What are the consequences for manufacturers if the harmonized medtech standards output is delayed?

Bisazza: Once notified bodies are finally up and running and able to conduct conformity assessments to the IVDR/MDR, manufacturers will start filing for certification. But until and unless a standard is harmonized to the relevant regulation, it legally cannot be used by the manufacturer to claim a presumption of conformity with the applicable IVDR/MDR requirements.

What does this mean for manufacturers? And does it matter if standards are voluntary?

Bisazza: The main pitfall we see is that manufacturers will need to navigate the first years of the IVDR/MDR either without this presumption of conformity or with it only existing in some specific areas where standards have first been harmonized. These manufacturers will therefore need to employ other means to demonstrate their compliance with the Regulations, and this can mean that more time is needed for manufacturers to prepare their submissions and then defend them during the certification audit.

What will the likely impact of such delays be on notified bodies?

Bisazza: Notified bodies may need to employ more time and effort to conduct these certification audits.

There are currently some 300 medtech standards, yet fewer than 100 in this standards request. Why is there such a big difference?

Bisazza: For some time now, the commission and member states have been indicating they intend to harmonize standards according to a staged approach, where a series of standardization requests can be expected, each of them covering a selected number of standards. That's precisely what we're seeing with this first request. There will be more to follow over time.

Are the standards requests being staggered in the hope that more standards will be ready on time?

Bisazza: Due to the length of the IVDR/MDR transition periods, it won't be possible to process all the existing harmonized standards on time. Re-harmonization of standards requires new Annex Zs to be drawn up showing the link between the standards and the specific requirements within the regulations. And in certain cases, it can also require a complete revision of a standard's technical content to match the new legislation. Initially, the commission had announced a staged approach, where a series of requests were to be launched, comprising a limited number of standards.

If new Annex Zs are so important, why doesn't the draft Implementing Decision make any mention of them?

Bisazza: The Implementing Decision will mandate/request the European standards organizations (ESOs) to "revise" existing standards (and to draft new standards) in support of the IVDR/MDR. The draft Implementing Decision includes some essential details for these organizations to follow in terms of scope, processes and timelines. In other words, the Implementing Decision tells the ESOs what to do, but not how to do it.

Published online 22 July 2019

Pakistan Sets End 2019 Deadline For Filing Under New Medtech Regulations

ASHLEY YEO ashley.yeo@informa.com

It is not often that the medtech regulatory world hears about progress in Pakistan, but that was one of the things that the Knect 365 (Informa) MedTech Summit brought to a large group of global regulatory delegates last month in Brussels (17-21 June).

Maham Ansari, director of regulatory affairs at Toronto, Canada-based Synaptive Medical, stressed that medtech regulation is starting to change quickly in Pakistan, "and if you don't comply really quickly, you could get locked out of the market."

The Drugs Act of 1976 was the beginnings of device law locally, but only a handful of devices were regulated under that mechanism. In early 2015, the Drug Regulatory Authority of Pakistan (DRAP) issued new medtech rules, which, however, were "very cumbersome" and accompanied by a lot of requirements. But awareness of them was low, so little actually happened, according to Ansari.

Crucially, lack of conformity assessment bodies meant the new rules could not be implemented, so after much discussion within DRAP, a new set of medical device regulations, the Medical Devices Rules 2017, was issued in January 2018. They are becoming active now, Ansari told meeting delegates. The essential changes

include an assessment and evaluation of devices by a medical device board (MDB) comprising experts from federal and provincial governments.

The more streamlined regulations also include a new fee structure to replace the convoluted system that was in place and which "had to be revised." In 2015, every class of medical device was being required to go through a design dossier submission. Now, products falling under specific categories are exempt from doing the complete design dossier. For some devices, there is a focus on specific parts only – primarily imported devices that are already registered in the US, Japan, Australia, the EU (CE marked devices that have been assessed by NANDO-listed notified bodies), and devices that are pre-qualified by the World Health Organization.

These device manufacturers should fill out form 7A, listed at www.dra.gov.pk/Home/MDMC (where all relevant forms and notices are available), which requests basic country-of-origin information and design and manufacturing details. Other registration requirements include, for manufacturers based in Pakistan, the need to obtain an establishment license issued by DRAP. For overseas manufacturers doing business in Pakistan, an import license is required to track good distribution practice. Distributors must be inspected by DRAP to secure the license. But again, many manufacturers are not aware of this, said Ansari, adding that it is important that importers and distributors in Pakistan ensure they possess this license. Both licenses are issued by the MDB.

Pakistan has no specific labeling requirements, and accepts English, which is an official language. For home-use devices, Urdu is required in addition to English. Device licenses are valid for five years and are renewable. Classification of devices is based on the A-D risk-based schedule advocated by the International Medical Device Regulators Forum. Also per the IMDRF, different types device grouping is available: single, family, system, set, IVD cluster and IVD test kit. Larger companies with various subsidiaries and manufacturing sites are allowed to use one site or the corporate HQ as the "legal manufacturer."

Implementation of the new regulations has been ongoing as of January 2018. All local manufacturers and importers were originally required to have licenses in place within six months but that deadline swiftly passed, and the authorities saw that a lot of manufacturers were struggling to comply. So they did away with that requirement and decided to use one single registration deadline of December 2019.

FILING ALONE BY DEADLINE EQUATES TO COMPLIANCE

Except for stents (which should have been registered by now), importers and distributors need to heed the December 2019 license deadline for devices of all classes. However, the applications need simply to be filed. As the DRAP is heavily backlogged, manufacturers and importers do not have to wait for approval, but can continue to import devices in the interim. "But if you don't file before that time, you will be locked out of the market," Ansari warns. Companies could then have to wait up to three years for medical device approvals, with serious implications for business continuity.

Published online 22 July 2019

If Cadillac Tax Can Be Repealed By Congress, So Can Device Tax, AdvaMed Says

SUE DARCEY sue.darcey@informa.com

On the heels of the US House of Representatives repeal of the so-called "Cadillac tax," AdvaMed is arguing that the medical device excise tax – another Affordable Care Act (ACA) tax – should also be repealed.

The so-called Cadillac tax refers to particularly expensive health care plans. In 2010 under the ACA, Congress imposed an annual 40% Cadillac tax on coverage plans with annual premiums exceeding $10,800 for individuals, or $29,500 for a family, to be paid by insurers.

Initially set to take effect in 2018, the Cadillac tax was later delayed by Congress until 2020, but in January 2018 legislators postponed the start date to 1 January 2022. Taking further action on 17 July, the House voted to repeal the tax entirely. No similar bill has been passed in the Senate.

Because the House chamber repealed the Cadillac tax, AdvaMed president and CEO Scott Whitaker said another "onerous tax," the medical device tax, should also be repealed.

MEDICAL DEVICE TAX NO LONGER HOLDS WATER

"After today's vote on the Cadillac tax, it's not possible from either a tax or health policy perspective to justify the device tax," Whitaker remarked.

"Passage of the Cadillac tax repeal opens the door to passage of the device tax repeal, which would be a win for innovation, for patients and for job creation," he added.

AdvaMed has consistently argued over the last several years that the device tax, initially put into the ACA to help fund its provisions, has been a drag on the industry's ability to expand and create new jobs. *(Also see "Medtech Groups To Blitz Congress Before Expected House Device Tax Vote" - Medtech Insight, 2 Jul, 2018.)*

Published online 22 July 2019

Commission Offers One-Stop Shop For Vigilance Information And Offers Vital Spreadsheet

AMANDA MAXWELL amanda.maxwell@informa.com

The European Commission has published an additional guidance on how the EU medical device and IVD vigilance system should work, which builds on the already existing vigilance guidance document, Meddev 2.12-1 rev 8, and starts preparing the sector for vigilance reporting under the new EU Medical Device and IVD Regulations.

Vigilance is the term that encompasses the communication of incidents related to medical devices to the authorities and the action that the authorities initiate to safeguard patients.

The additional guidance document:

- Provides further detail in relation to the area of the coordination of vigilance issues among competent authorities;
- Clarifies the differences between the EU National Competent Authority Report (NCAR) exchange and the global IMDRF NCAR exchange. (The IMDRF is the International Medical Device Regulators Forum.);
- Introduces device-specific vigilance guidance at the EU level written by members states over the years and makes all such documents available in one single place on the Commission website;
- Introduces a new Manufacturer's Incident Report and the new template for Field Safety Notice; and
- Slightly modifies some existing definitions, namely field safety corrective action and field safety notice.

ONE-STOP SHOP

The Commission's historic guidance webpage is the repository now for all information related to postmarket surveillance and vigilance.

Device-specific vigilance guidance is available there so far on cardiac ablation vigilance reporting and coronary stents vigilance reporting in additional to guidance for manufacturers on reporting device-specific incidents under the European vigilance system.

UPDATED MIR AND DETAILED, HELPFUL EXCEL SPREADSHEET GUIDE

In addition, there is an updated Manufacturer Incident Report (MIR) form and guidance in the form of a detailed Excel spreadsheet intended to help manufacturers complete the form. The updated version, V 7.2, will become mandatory for manufacturers to use from January 2020 and replace the current MIR, which had been compulsory since 1 January 2019, thereby readying them for the new requirements under the MDR and IVDR.

The spreadsheet, which features 178 rows of cells by nine columns is likely to be invaluable to manufacturers in their decision-making around reporting and in terms of accurate communication and record keeping. It contains sections covering: administrative information, medical device information, incident information derived from healthcare professional and/or user, manufacturer analysis, and general comments.

Indeed, in preparation for the future EU MDR, the new form (although not mandatory yet) introduces requirements related to use of the Single Registration Number and UDI, both fundamental communication and identification tools under the new MDR and IVDR. It also requires IMDRF terms to be filled in for identifying similar incidents.

In addition, it introduces a definition of similar incidents and requires similar incidents trend data in a tabular format.

COORDINATING NATIONAL COMPETENT AUTHORITY AND VIGILANCE TASKFORCE

There is a large section dedicated to circumstances where a coordinating national competent authority is needed, including where there is concern regarding a particular incident or cluster of incidents and where a competent authority requires the assistance of a competent authority where the manufacturers, authorized representative or notified body is located.

There is also an explanation of where a specific vigilance task force may need to be set up to take on a coordination role. This would not affect the rights of an individual national competent authority to perform its own monitoring or investigation within its jurisdiction. But communication with all parties would be vital in such cases.

Published online 18 July 2019

Siemens Cybersecurity Expert Says Medtech Industry Has 'Perverse Incentive' To Not Disclose Vulnerabilities – Might A New Law Be The Fix?

SHAWN M. SCHMITT shawn.schmitt@informa.com

A few years ago, Siemens AG's Harrison Wadsworth was in the office of his company's product security officer when a customer phone call was patched through.

"The person said: 'How come I keep getting product security bulletins from Siemens about all your security problems when this other vendor we work with has no problems?'" recalled Wadsworth, who is the director of government affairs for Siemens and the firm's cybersecurity expert.

"That's when our product security officer said: 'Well, actually, they do have problems. They're just not telling you,'" he said at a June Case for Quality forum in Arlington, VA.

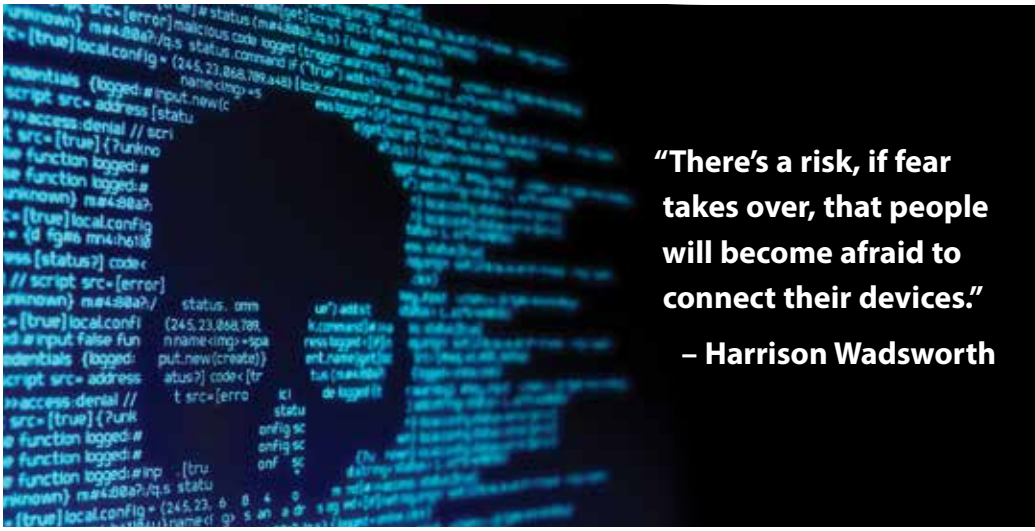
Wadsworth said the customer was so concerned about Siemens's cybersecurity disclosures that they were considering switching to a different vendor.

That fear of losing business by being transparent about cybersecurity vulnerabilities means there's "a perverse incentive in some parts of the market that encourages a lack of disclosure," Wadsworth said.

That's why the US Food and Drug Administration's Suzanne Schwartz says a new law might be the antidote to companies that willingly hide cybersecurity vulnerabilities to avoid concerning their customers.

"We certainly want to see much broader adoption of coordinated vulnerability disclosure across the entire ecosystem," Schwartz, deputy director of the Center for Devices and Radiological Health's Office of Strategic Partnerships and Technology Innovation, said at the forum.

Coordinated vulnerability disclosure is a process wherein product-makers work with cybersecurity researchers to find vulnerabilities in any software-based product – including medical devices – followed by designing a patch to fix the gap, and then distributing and deploying the patch. *(Also see "FDA Cybersecurity Forum: Manufacturers Explain Coordinated Vulnerability Disclosures " - Medtech Insight, 1 Feb, 2019.)*



"There's a risk, if fear takes over, that people will become afraid to connect their devices."

– Harrison Wadsworth

There's so much concern at the FDA about a lack of disclosure in industry that "we may be looking to require coordinated vulnerability disclosure through legislation in order to level the playing field," Schwartz said.

After all, "the companies that are demonstrating the kind of behavior that is a role model for all the ecosystem shouldn't take a hit because of their transparency and the maturity that they are demonstrating – while all the other [firms] that do have vulnerabilities and are not disclosing them" go unnoticed, she added.

Schwartz noted that a 2016 FDA guidance document, "Postmarket Management of Cybersecurity in Medical Devices," "calls out strong recommendations and encouragement of coordinated disclosure policies and processes to be adopted through industry, and we recognize the international standards that are specific to those."

In October 2018, a US congressional panel encouraged federal government agencies and private companies to embrace coordinated vulnerability disclosures, pointing to the disclosure advice in the FDA's cybersecurity guidance as a model that could work. *(Also see "US Lawmakers Praise FDA Tips On Coordinated Vulnerability Programs For Device Cybersecurity " - Medtech Insight, 25 Oct, 2018.)*

When it comes to cybersecurity and transparency, "the stakes are really high in safety-critical industries," Schwartz said. "Particularly, think about those patients with implanted devices or devices at home that they rely on for critical life functions, and what it's like to find out that information has not been disclosed in a coordinated manner. It creates a lot of fear, a lot of concern, a lot of anxiety and a lot of hysteria."

Added Wadsworth: "There's a risk, if fear takes over, that people will become afraid to connect their devices [and will develop] an overall lack of trust in connected technology and innovation.

"That's the real risk."

Published online 16 July 2019

START-UP SPOTLIGHT:

SetPoint Develops Vagus Nerve Stimulation To Treat Crohn's Disease And Rheumatoid Arthritis

REED MILLER reed.miller@informa.com

SetPoint Medical Corp. expects to address a variety of chronic autoimmune diseases with a unique bioelectric implant.

In the early 2000s, company co-founder Kevin Tracey, a neurosurgeon at the Feinstein Institute for Medical Research near New York, identified the role of inflammatory reflex and began studying how stimulation of the vagus nerve, the longest cranial nerve in the body, could treat autoimmune diseases. The company is currently focused on Crohn's disease, an inflammatory bowel disease, and rheumatoid arthritis, a chronic inflammation of the joints, but the platform may eventually be applied to other autoimmune diseases.

With proprietary pulse parameters to stimulate the vagus nerve, SetPoint's device can amplify the immunoregulation effect of the spleen by releasing specific neurotransmitters such as acetylcholine that bind to specific receptors on macrophages and monocytes and down-regulate the inflammatory cytokines.

"The mechanism of action is based on an endogenous, highly evolved reflex that has evolved over millions of years, and it's conserved across species: rodents, canines, humans," CEO Murthy Simhambhatla told *Medtech Insight*. "And it's exquisitely elegant, in that when the body senses inflammation under normal conditions, if it isn't a dysfunction, it is able to tamp down the inflammation without necessarily rendering the person immunosuppressed. If endogenous mechanism weren't around, humans would be extinct, and we wouldn't be having this conversation. We'd all be dead from either infections or inflammation, destroying a joint, causing other issues."

Drugs like Abbvie's Humira (adalimumab) also target these cytokines, but they are immunosuppressive, so they can make the patient susceptible to infections and diseases like shingles or tuberculosis. Unlike these drugs, SetPoint's vagus nerve stimulation technology does not completely shut down the cytokines, but "down-regulates" them 30% to 70%, according to SetPoint.

"There is no cure for these autoimmune diseases. These are chronic, lifelong conditions, and for the patients to be on these immunosuppressive drugs for the rest of their lives is really not something that most patients want," Simhambhatla said. "They're looking for options."

Simhambhatla also pointed out that immunosuppressant drug therapy can costs "tens of thousands of dollars per year for patients," whereas the SetPoint device is designed to last at least ten years on a rechargeable battery.

The company originally tested the potential for vagus nerve stimulation to treat autoimmune diseases with "off-the-shelf" vagus nerve stimulators already approved for other indications. For example, LivaNova's VNS Therapy device is approved by the US Food and Drug Administration for treatment of depression and reducing seizures in patients with epilepsy. Electrocore's gammaCore vagus nerve stimulation device is approved for treatment of certain types of headaches.

But SetPoint's device is miniaturized – about 2cc in volume – and is implanted directly on the vagus nerve in the patient's neck. It is programmed with proprietary pulse parameters developed and can be effective with only about one minute per day of stimulation therapy, whereas vagus nerve stimulation for traditional indications like epilepsy can require up to six hours a day, Simhambhatla said.

"All we're doing is reactivating an endogenous mechanism and then letting human physiology do the rest," Simhambhatla said. "Obviously, how you do that requires fairly well-researched algorithms, pulse parameters, the device design, and the electrode design – all of that plays into reliably activating the reflex at very low energy."

RHEUMATOID ARTHRITIS SUCCESS

Results from a 17-patient pilot trial completed in 2016, the first trial of a device that directly delivers electrical current to the cervical vagus nerve, established that vagus nerve stimulation targeting the inflammatory reflex modulates the body's production of tumor necrosis factor and reduces inflammation in patients with rheumatoid arthritis.

David Chernoff, SetPoint's chief medical officer, told *Medtech Insight*: "This is an extremely difficult patient population. The reason they were recruited was because they had no other therapeutic options."

Results from the 14-patient US pilot trial of the SetPoint device in patients with rheumatoid arthritis were presented by primary investigator Mark Genovese of Stanford University at the European Congress of Rheumatology 2019 on 17 June. All the patients in the trial had prior insufficient response to two or more biologic or targeted synthetic disease modifying antirheumatic drugs, including nine patients who failed to respond to Janus kinase inhibitors. The first three patients in the trial were enrolled in an open-label phase and stimulated for one minute, once per day. The next 11 patients were implanted with the device and randomized to one minute of sham therapy, once per day, or four stimulations per day for 12 weeks.

The results showed the implanted device was well-tolerated with no device-related adverse events through 12 weeks. Five out of 10 patients actively stimulated in the trial showed a positive clinical response, as measured by the Disease Ac-

tivity Score and the Clinical Disease Activity Index. Two of the patients achieved complete remission of the disease. The four patients assigned to sham stimulation showed no symptom improvement.

The patients treated with vagus nerve stimulation also showed greater than 30% decrease, compared to baseline, in bioassay levels of key biomarkers associated with inflammation, including IL-1β, IL-6, and TNF-α. These patients also showed improvements in bone erosion in their wrist joints, as measured by magnetic resonance imaging.

Chernoff said many rheumatoid arthritis patients need a better therapy because the current immunosuppressive drugs carry side-effect risks and are often ineffective. "The bar [for FDA-approval] is extremely low. All you have to show is that 50% of the patients have a 20% improvement. That's a pretty low bar," he said. Patients often develop antibodies to the drugs and patient compliance and persistence with these drugs outside of clinical trials, is very poor, either because the patients find them ineffective, or they cause too many side-effects, or they cannot afford to pay for them, according to Chernoff.

The company is now working with the US FDA to design a larger US pivotal trial to earn a PMA for the SetPoint system to treat rheumatoid arthritis. The endpoints will be standard measures of disease activity such as the Clinical Disease Activity Index, cytokine levels, and evidence of inflammation and bone erosion seen with magnetic resonance imaging after 12 weeks of therapy. The company expects the trial to begin by the end of 2019 and be completed by 2021.

All of the patients in the trial will be implanted with the device, but some will be randomized to having it turned off for the first 12 weeks of the trial before "crossing-over" to the treatment arm. All the patients will stay on baseline drug therapies like methotrexate. Simhambhatla said the trial will enroll patients who have shown inadequate response to at least one biologic drug or targeted synthetic drug and that the patients will remain on low-dose methotrexate or another disease-modifying antirheumatic drug while receiving vagus nerve stimulation therapy but will be "washed off" biologic drugs.

PROGRESS ON CROHN'S DISEASE

Geert D'Haens of the University of Amsterdam, the Netherlands, presented results of a 16-patient, five-center single-arm, open-label study of an "off-the-shelf" vagus nerve stimulator in Crohn's disease patients at the Digestive Disease Week conference in San Diego on 20 May.

"It was really the first time that activation of the vagus, of this inflammatory reflex, was documented in a human clinical trial to be effective with respect to other sites and other symptoms and other aspects of inflammatory components," Chernoff said.

The patients in the trial had failed to show adequate symptom improvement on biologic drugs. After 16 weeks of vagus nerve stimulation therapy programmed specifically to treat Crohn's disease, eight patients showed at least 100 points of improvement on the Crohn's Disease Activity Index, including four whose scores fell below 150, indicating remission of the disease.

The patients' average levels of serum biomarkers of inflammation, including IL-1β, TNF-α, TNF-β, and IL-12p70, were reduced during the 16 week trial, while the average level of the anti-inflammatory cytokine IL-10 increased from baseline, indicating pharmacodynamic activation of the inflammatory reflex. Seven of the 16 patients reported improvements in quality of life and 10 patients showed improvement in autonomic balance, the ratio of sympathetic to vagal tone as measured by heart rate variability.

Endoscopic investigation and biopsies also showed evidence of mucosal healing in the bowels of patients treated in the study.

MORE INDICATIONS?

Ankit Shah, SetPoint's senior director of commercialization and marketing, told *Medtech Insight* that Rheumatoid arthritis and Crohn's disease are SetPoint's "beachhead indications," but the company is also conducting preclinical research on the application of vagus nerve stimulation to other autoimmune diseases, including multiple sclerosis. This therapy may also be effective in treating other diseases currently addressed with immunosuppressant drugs, including plaque psoriasis or psoriatic arthritis, and ankylosing spondylitis, Shah said.

"It's truly a platform technology," he said.

The company is currently trying to raise money to fund the next phase of pivot trials. Its current investors include NEA, Morgenthaler, Topsin, SightLine Partners, Boston Scientific and GlaxoSmithKline's Action Potential Venture Capital.

SETPOINT MEDICAL CORP.
25101 Rye Canyon Loop
Valencia, CA 91355

Contact: Emma Poalillo, The Ruth Group. Phone: (646) 536-7024; email: setpointmedical@theruthgroup.com

Founded: 2007

Founders: Kevin Tracey, neurosurgeon, president and CEO at the Feinstein Institute for Medical Research in Manhasset, NY – part of Northwell Health

Number of Employees: Approximately 40

Financing Total To Date: More than $80 million to date in series A though D financing rounds with top-tier VC and strategic investors

Investors: NEA, Morgenthaler, Topsin, SightLine Partners, Boston Scientific, GlaxoSmithKline's Action Potential Venture Capital, and an additional leading medical device company

Board of Directors: Allan Will, EBR Systems, Chairman of the Board; Joe Biller, Sightline Partners; Chris Kaster, Boston Scientific; Josh Makower, New Enterprise Associates; Juan-Pablo Mas, Action Potential Venture Capital; Hank Plain, Morgenthaler Ventures; Murthy Simhambhatla, SetPoint Medical; and Steve Winick, Topspin Partners

Published online 18 July 2019

Strong China Sales Boost Q2 Results For Philips

CATHERINE LONGWORTH catherine.longworth@informa.com

China's growing health-care market helped boost Q2 sales for Philips Healthcare, with the Dutch company reporting strong sales performance in the country during the quarter.

During its earnings call on 22 July, company officials said the firm delivered better-than-expected sales of €4.6bn ($5.08bn) in Q2, resulting in 6% year-on-year growth. CEO Frans van Houten said the increase was mainly driven by improved performance of its diagnosis and treatment businesses.

"The diagnosis and treatment businesses delivered a 6% comparable sales growth as well, driven by strong performance in North America and the growth geographies including China," said van Houten.

"Image-guided therapy grew double-digits in both systems and devices, and ultrasound grew high single digits. Diagnostic imaging sales were in line with last year on the back of tough comparables in the advanced molecular imaging business … which had a comparable sales growth of 50% in the second quarter of last year."

Philips said it expects growing demand in China for health equipment due to the Chinese government's commitment to invest in health care. In 2016, the government published a Healthy China 2030 strategy that called for a significant increase of China's health-care provision.

"For China, we expect mid- to high-single-digit health-care market growth in 2019, mainly driven by government policies to further increase access to care in hospitals and expansion of private sector investments in health-care facilities," said van Houten.

Sales for the firm's connected care businesses also increased 6% in the quarter, with mid-single-digit growth in monitoring and analytics and sleep and respiratory care, and the personal health businesses delivered comparable sales growth of 5%, with high-single-digit growth in oral healthcare, and mid-single-digit growth in personal care and domestic appliances.

However, despite the growth, second-quarter results were met with mixed reactions from the market. In a 22 July note, Credit Suisse analysts expressed concern over margin weaknesses in the company's personal health (PH) business.

"One question we are left with is on PH margins, which missed consensus by 100 basis points, primarily due to higher advertising cost. We think this raises the question as to whether the growth is coming with higher cost attached and we look for comments on whether these costs will normalize in H219," analysts wrote. "Bottom line is that we expect management to point to Connected care orders improving in H219, but advertising costs to remain somewhat of a drag into Q319 result for personal health."

Morgan Stanley analysts echoed concerns, writing, "Overall we see the result as a mixed bag, with slightly more positives than negatives. The trends in D&T (diagnosis and treatment) on organic growth, order book and margins are encouraging as, well as top-line developments in PH and CC (connected care), however the deterioration in PH and CC margins and continued weakness in CC order book is a concern."

MEDUMO ACQUISITION

The results closely followed the news that Philips paid an undisclosed sum to acquire Boston-based start-up Medumo. Founded in 2013, Medumo develops a diagnostic patient management platform for health-care providers to deliver patient engagement and education services. The platform currently focuses on pre-procedure engagement and post-procedure follow-up by reminding and preparing patients for pre-diagnostic exam tasks prescribed by their health-care provider. The platform can be adapted to different modes of communication such as email, text message and voice.

The acquisition will expand Philips's patient management portfolio and complement its VitalHealth population health management platform, which is designed to deliver personalized care outside of the hospital.

"By combining Medumo's direct patient interaction services with Philips's diagnostic imaging systems, enterprise diagnostic informatics and operational performance management capabilities, Philips aims to deliver a patient-centric solution to our customers that helps drive their top- and bottom-line improvements by streamlining labor intensive workflows," said Matt Bierbaum, head of precision diagnosis ventures at Philips.

The Dutch health giant is focusing on carving out a leading position in health IT. In March, it acquired the IT business of Carestream Inc., a market-leading provider of medical imaging and healthcare IT solutions.

Carestream's presence across Latin America, Europe and Asia is set to complement Philips's radiology informatics footprint in North America.

Published online 22 July 2019

Abbott Delivers Strong Q2 Sales, Led By Spike In FreeStyle Libre Sales

CATHERINE LONGWORTH catherine.longworth@informa.com

Abbott Laboratories Inc. has raised its full-year profit guidance following stronger-than-expected earnings in the second quarter of 2019.

During its earnings call on 17 July, Abbott reported its worldwide medical devices division was the strongest performer in the second quarter of 2019, including double-digit growth in sales of electrophysiology, heart failure, structural heart and diabetes devices. Abbott's medical devices business grew by 6.4% on a reported basis and 10.5% on an organic basis compared to the second quarter of 2018. For the first half of 2018, Abbott's medical devices business grew 5.9% on a reported basis and 10% on an organic basis.

Based on its performance and momentum in the first half of 2019, Abbott is projecting 2019 organic sales growth of 7.0% to 8.0%, and diluted earnings per share from continuing operations of $2.06 to $2.12 and adjusted earnings per share of $3.21 to $3.27, reflecting nearly 13% growth by mid-year on a reported basis.

FREESTYLE LIBRE TAKES OFF

The biggest growth-driver was FreeStyle Libre, Abbott's continuous glucose monitoring system. The company reported worldwide Libre sales of $433 million, an increase of 72.9%. The continuous glucose monitor, which helps track blood sugar levels without users having to prick their fingers, is used by more than 1.5 million people worldwide. The next-generation device, FreeStyle Libre 2 is already approved in Europe and under review by US Food and Drug Administration.

Abbott said it will invest significantly to expand manufacturing capacity for Libre to meet demand. "The first wave of that expansion will come online in the next couple of months, followed by a cadence of incremental capacity after that," Abbott CEO Miles White said. "There's a massive population that needs help managing their diabetes and our intent is to make Libre broadly accessible to all of them."

The company said it has focused on expanding reimbursement for Libre and 75% of people with private pharmacy benefit insurance are currently eligible for the system.

"Libre offers a unique value proposition and that's by design. It provides great clinical benefits and we priced it to ensure affordability. Payers recognize that value and are increasingly providing reimbursement coverage for Libre, which helps lowers out-of-pocket cost even further for patients," White said.

MITRACLIP BOOST

Abbott highlighted other key growth drivers in its cardiology businesses. Electrophysiology growth was led by cardiac diagnostic and ablation catheters and the heart failure business by continued adoption of Abbott's HeartMate 3 left ventricular assist device following US FDA approval as a destination therapy in late-2018. *(Also see "Global Device Approvals, Weekly Snapshot: HeartMate 3 Reaches New Destination" - Medtech Insight, 22 Oct, 2018.)*

Growth in Abbott's structural heart division was led by MitraClip, Abbott's device for the minimally invasive treatment of mitral regurgitation. In March, the FDA approved a new, expanded indication for MitraClip to treat secondary mitral regurgitation because of underlying heart failure. The new indication significantly expands the number of people that can be treated with MitraClip. *(Also see "Functional MR Added To FDA-Approved Indication For Abbott's MitraClip" - Medtech Insight, 14 Mar, 2019.)*

Last week, the FDA approved MitraClip G4, the fourth generation of the device, featuring independently controlled grippers to allow the operator to grasp either one or both valve leaflets during the procedure. MitraClip G4 offers an expanded range of clip sizes, an alternative leaflet grasping feature and facilitation of procedure assessment in real time to offer doctors further options when treating mitral valve disease. *(Also see "Global Device Approvals Snapshot: 9-15 July 2019; MitraClip G4, Relievion, RAPID Imaging, ExAblate Neuro" - Medtech Insight, 15 Jul, 2019.)*

"With the rapid adoption of MitraClip and a highly under-penetrated market, as well as a pipeline of technologies targeting new growth areas that we'll launch over the next several years, our Structural Heart business is well positioned for strong steady growth for years to come," said White.

ALINITY ROLLOUT

In July, the US FDA approved Abbott's Alinity S diagnostic screening technology for blood and plasma centers. Abbott says it is faster and more efficient while taking up less space than competing systems. *(Also see "Exec Chat: John Frels, VP Of Research And Development, Abbott Diagnostics" - Medtech Insight, 1 May, 2019.)*

Abbott is in the early stages of launching Alinity instruments for hematology and molecular testing in Europe and Alinity is driving double-digit growth in Abbott's international core laboratory business.

In a 17 July note, SVB Leerink analyst Joanne Wuensch wrote that in the second quarter "Abbott did what it needed to," with revenue in line with the analysts' consensus projections. "The momentum continues for its key growth drivers and we don't believe it is slowing down any time soon as it leans into the three pillars of growth: Libre, MitraClip, and the Alinity," Wuensch wrote.

Published online 18 July 2019

Johnson & Johnson Growth Led By Biosense Webster And Cerenovus

REED MILLER reed.miller@informa.com

Johnson & Johnson's leadership is putting a positive spin on another quarter of revenue contraction from its medical device division, highlighting the strong results of its Biosense Webster electrophysiology and Cerenovus neurovascular divisions, and the signs of a rebound from its orthopedics business.

During its earnings call on 16 July, the health-care giant reported that its worldwide medical devices sales were $6.5bn in the second quarter of 2019, representing a year-over-year decline of 4.1%.

However, VP of investor relations, Chris DelOrefice, said that adjusted for the net impact of acquisitions and divestitures, J&J's medical device division grew 3.2% during the quarter. In April, J&J completed the sale of Ethicon Inc.'s Advanced Sterilization Products business to Fortive Corp. The $2.8bn deal was first announced in July 2018. J&J sold its LifeScan Inc. diabetes care business to a private equity firm for $2.1bn in October 2018. The deal was first announced in March 2018. *(Also see "J&J Offloads LifeScan To Private Equity Firm For $2.1bn" - Medtech Insight, 18 Mar, 2018.)*

Supply disruptions during the quarter negatively impacted growth by about 100 basis points, the company reported. It had to pull some lots of circular surgical staplers off the market, chief financial officer, Joe Wolk, said during today's earnings call. After remediating the problem, J&J began distributing these devices to customers again in June.

Also, a third-party manufacturer of the Surgiflo hemostatic matrix had to temporarily suspend supply to respond to questions from the US Food and Drug Administration about a change in a marketing process.

"We will continue to work with the FDA to ensure this important technology for patients is available again in the US market as soon as possible," DelOrefice said.

Accounting for these supply disruptions, J&J's medical device revenues for the quarter grew a little over 4%, "in line with last quarter and we are on track towards our goal of exceeding last year's performance," he said.

INTERVENTIONAL SOLUTIONS GROWING NEAR 20%

J&J's interventional solutions business was by far the best-performing medical device division for the company in the second quarter and first half of 2019. Revenue from the division grew 15.6% year-over-year in the first quarter on an operational basis. This division grew 16.7% in the first half of 2019, led by 20% growth in the markets outside the United States.

The interventional solutions division includes Biosense Webster Inc., which markets mapping and ablation catheters to treat cardiac arrhythmias, and Cerenovus, which markets implantable coils and revascularization devices to treat stroke, including the EmboTrap clot retrieval device, which earned FDA approval in 2018. *(Also see "J&J's EmboTrap Clot Retriever Gets US Green Light" - Medtech Insight, 16 May, 2018.)*

"Growth was strong in all regions, driven by our newer product offerings in ablation and advanced catheters contributing to atrial fibrillation procedural market growth," DelOrefice said.

The company does not officially report the results for specific products or divisions within its interventional solutions business, but Wolk said that Cerenovus grew about 35% in the quarter, representing the business' fourth straight quarter of double-digit growth.

"We are seeing improved rates from what we were experiencing 12 to 24 months ago. We're continuing on that right cadence I believe," Wolk said. "We think that has tremendous opportunity."

ENERGY DEVICES LEAD SURGERY DIVISION

J&J's largest medical devices business, surgery, reported $2.4bn in revenue in the second quarter and $4.7bn in revenue in the first half of 2019, representing year-over-year declines of 3% and 3.9%, respectively, partly due to the Advanced Sterilization Products divestiture.

Within the surgery business, the advanced surgery segment was the best performer, with 6.1% revenue growth in the second quarter and 5.9% growth in the first half of 2019, led by sales of advanced energy devices and endocutters, especially in the Asia-Pacific region.

Sales of biosurgery products were down 2% during the quarter, due to the interruption in Surgiflo supply.

Revenue from J&J wound-closure products was up about 3% during the quarter, with market share gains in both the conventional and barbed suture markets, but overall revenue for J&J's general surgery division was down 0.9% in the quarter, partly due to the field action on surgical staplers.

DelOrefice highlighted J&J's investment in "digital surgery," including robotics.

J&J agreed to buy robotic surgery start-up Auris Health for up to $5.8bn in February. *(Also see "Johnson & Johnson Diversifies Robotic Efforts With Auris Health Aquisition" - Medtech Insight, 13 Feb, 2019.)* The Auris team is developing Monarch for lung cancer and bronchoscopic surgery and is also working with the technology J&J acquired when it bought Orthotaxy SAS in 2018, DelOrefice said. J&J also has a partnership deal with Verily Life Sciences LLC to co-develop digital surgery technology. *(Also see "SAGES 2019: Spotlighting Competitive Robotic Systems And Procedures" - Medtech Insight, 3 Apr, 2019.)*

J&J and its partners are working to ensure "it's not a matter of coming to market fast, but coming to market best," DelOrefice said. "We want to make sure that we've got a differentiated product, one that competes with the current product offerings that are out in the marketplace for the next three, five, 10 years down the road."

In a 16 July note, Wells Fargo analyst Larry Biegelsen wrote "the

final U.S. hospital utilization trends for Q1 indicate that hospital admissions, as well as surgical and lab procedures accelerated sequentially and based on J&J's adjusted Q2 surgery growth it appears trends remain strong into Q2," which is also good news for Medtronic PLC, Becton Dickinson & Co. and Intuitive Surgical Inc.

ORTHOPEDICS SHOWS SIGNS OF REBOUND

Orthopedics, the second largest of J&J's medical device businesses, grew 0.6% in the second quarter and 0.7% in the first half of the year. The modest gain represents an improvement over the downward trend for J&J's orthopedics business in 2018, following the divestiture of Codman Neuroscience and the Prodisc spine business. *(Also see "Q3 Earnings Spotlight: Ortho Firms Show Mixed Results Against US Pricing Pressure" - Medtech Insight, 12 Nov, 2018.)*

The orthopedics increase during the first half of the year was driven by 3% growth in hip device sales and 1.5% growth in trauma device sales, led by US sales of new devices, including the TFN-Advanced proximal femoral nailing system.

Sales of knee and spine devices were both down slightly year-over-year in both the second quarter and the first six months of 2019 as J&J is facing stiff competition from Stryker's Mako robotic surgery system for total knee-surgery. *(Also see "AAOS Results Recap: Stryker's Knee-Surgery Robot And Miach's New ACL Scaffold" - Medtech Insight, 15 Mar, 2019.)*

"While we continued to see some stabilization of performance driven by new products such as the Viper Prime [percutaneous pedicle screw] system for minimally invasive surgery and Expedium Verse [all-in-one pedicle screw system for deformity], we continue to pursue opportunities to further improve growth, including new innovation," DelOrefice said. He highlighted the Symphony occipito-cervico thoracic system, a set of instruments and implants for posterior stabilization of the upper spine, that J&J plans to launch later in 2019.

J&J is among the orthopedics companies struggling with downward pricing pressure across the US market. J&J estimates that spine device prices fell about 4% during the second quarter of 2019 compared to the same period of 2018 and hip, trauma and knee device prices were all down about 2% year over year. However, orthopedics device prices in the second quarter were relatively stable overall compared to the first quarter of 2019, DelOrefice said. *(Also see "Market Intel: Innovation, Surgical Techniques Drive Arthroscopy, Sports Medicine Products Market" - Medtech Insight, 15 May, 2019.)*

DelOrefice said, "We continue to make progress to improve growth in this franchise and we remain committed to executing our innovation and commercial plans that aim to improve performance."

He highlighted the success of the company's Actis hip-replacement system, especially in the US, and expects new knee and spine devices to address "portfolio gaps," and restore growth to those business segments in the next few quarters.

Published online 16 July 2019

Factory Explosion Expected To Cost Consort Millions In Profit

CATHERINE LONGWORTH catherine.longworth@informa.com

Consort Medical PLC is expecting a million-dollar profit loss following an explosion at its manufacturing facility in Cramlington, UK

Consort Medical said expulsion of a chemical caused contamination of the facility. No injuries incurred, but an area of the operating plant was damaged by the explosion.

In a press release, Consort said it was too early to assess the scale of the financial impact but warned that underlying annual profits were likely to be £3m to £5m ($3.7m - $6.2m) lower than previously expected. Consort's products include drug delivery devices such as inhaler, auto-injector, nasal and ocular technologies, as well as point-of-care diagnostics products. The company has suspended all similar manufacturing processes until the cause of the incident is determined, Consort said. It added that a specialist decontamination company and safety experts will investigate the causes and compile an independent report.

Shares in Consort Medical received a boost in 2019, following US Food and Drug Administration's approval of Wixela Hub, a generic respiratory drug made by US-listed pharma group Mylan, which employs one of Consort's drug delivery systems. The company also signed a contract with an undisclosed partner for its Syrina/Vapoursoft auto-injector technology, together with a cross-divisional agreement to produce a pre-filled, nasal delivery device, Unidose Xtra.

However, FY2019 results released on 13 June showed the company had failed to produce strong year-on-year growth. It reported 1.9% increase in revenue for the year ending 30 April 2019.

Published online 16 July 2019

CONTINUED FROM PAGE 1

Intuitive's CFO Marshal Mohr said, "Placements outside of the U.S. will continue to vary as some of the OUS markets are in the early stages of adoption, some markets are highly seasonal reflecting budget cycles or vacation patterns, and sales into some markets are constrained by government limitations."

Intuitive expects full-year 2019 procedure growth to be between 16% and 17%.

SUCCESS IN ASIA

For the first time in "several quarters," da Vinci procedure volume grew slightly in China, driven by procedures performed on new systems. The China National Health Commission announced a new quota for da Vinci systems in October 2018, allowing the installation of 154 new surgical robots, including da Vinci systems, through 2020. The Chinese FDA approved da Vinci Xi Surgical system in January 2019. Shanghai Fosun Pharmaceutical Group Co. Ltd. directs operations for da Vinci products and services in China as part of a joint-venture with Intuitive. *(Also see "Market Intel: Ever Decreasing Dimensions' Snakes And Origami: The Next-Gen Surgical Robots" - Medtech Insight, 28 Feb, 2017.)*

"We are pleased with procedure performance given the recent release of systems under the new quota," Guthart said.

The company is now trying to earn Chinese regulatory approval for the new da Vinci Ion system, a robotic endoluminal platform for minimally invasive peripheral lung biopsy that the company launched earlier this year.

"We're in discussions with Chinese regulatory agencies about how best to bring it to market and timing there," he said. "We believe there are end-user opportunities and value, health-care value to bring in China and [other markets]." *(Also see "Market Brief: Global Market For Endoscopic Surgeries Will Reach $17.7Bn In 2023" - Medtech Insight, 28 May, 2019.)*

Guthart also noted the success of the new da Vinci SP single-port system, which launched in 2018.

There are now 34 da Vinci SP systems installed worldwide, including 13 installed in the second quarter. Guthart pointed out that the highest per-system use of da Vinci SP is in Korea, where it is approved for a large range of clinical applications, including urology, gynecology, general surgery, and head and neck surgeries.

Procedure growth in Japan remains "strong," according to Calvin Darling, Intuitive's senior director for finance and investor relations. But demand for da Vinci in Japan has "moderated somewhat in [the second quarter] reflecting lower growth rates in mature urology procedures as we reach higher levels of market penetration, the impact of holidays, and the anniversary of the new procedure reimbursements."

Guthart said "Japan has been a great success. [Intuitive's team there is] doing a really nice job, but it is really heavy lifting to do all the things required to build market access from partnering networks to training centers to the clinical evidence base to support additional adoption. … We have invested in them and will continue to do so."

BEATING EXPECTATIONS

Wall Street analysts are impressed with Intuitive's results in the second quarter. In a 19 July note, Deutsche Bank analyst Imron Zafar wrote, "System placements meaningfully exceeded our/Street forecasts in both the US and internationally, and continued upgrade activity was likewise encouraging.

"International procedure growth of [over 20%] outpaced our [over 19%] forecast, with Japan and China remaining the key drivers," Zafar wrote. "However, to our surprise, volume growth in the former geography did slow somewhat sequentially – but in light of the bolus of da Vinci installations over the past few quarters (including a surprisingly strong 24 systems in 2Q) in what is still a highly underpenetrated market, we do not regard this as cause for concern as the substantial recent [capital expenditure] investments demonstrate Japanese surgeons' interest in, and hospitals' commitment to, robotic surgery."

Richard Newitter of SVB Leerink wrote on 18 July that the 17% worldwide procedure growth beat Wall Street's consensus projection of 16% and he believes the company's projection of 16% to 17% procedure growth for all of 2019 will probably prove to be conservative given "ongoing momentum in US general surgery and Japan, and as more capacity expansion comes on the heels of the recently approved China quota expansion."

On 19 July, Sean Lavin of BTIG wrote "Intuitive Surgical checked all the right boxes" in the second quarter, beating Wall Street consensus projections for system placements, average selling price, procedure volume without exceeding its expenditure targets.

INTUITIVE ACQUIRES SCHÖLLY FIBEROPTIC'S ROBOTIC ENDOSCOPE BUSINESS

On 15 July, Intuitive announced the acquisition of Schölly Fiberoptic's robotic endoscope business. Over the next 18 months, Intuitive will integrate about 200 Schölly employees and manufacturing facilities in Denzlingen and Biebertal, Germany, as well as a repair site in Worcester, MA. Terms of the deal are not disclosed.

The companies have collaborated over the last two decades to design and manufacture imaging components integrated into da Vinci systems and Schölly will continue to be a vendor for Intuitive.

"In addition to bringing important aspects of da Vinci's visualization system under Intuitive, the acquisition will help strengthen Intuitive's supply chain, and increase its manufacturing capacity for imaging products," Intuitive said in a release.

INTUITIVE VETERAN BROGNA STEPS DOWN

Earlier in the week, Intuitive COO Sal Brogna announced plans to leave that role at the end of 2019. He plans to remain an advisor to Intuitive beginning in 2020. Brogna has been with Intuitive for almost 20 years in roles in operations, product development, and engineering.

"During [Brogna's] long tenure with the company, he has played key roles in developing and supplying our portfolio of surgical systems, and in developing the next generation of company leadership," Guthart said.

Published online 19 July 2019

Meddevicetracker

Informa Pharma Intelligence

Meddevicetracker: Medical Device Intelligence and Forecasts

Stay up-to-date and get a complete view of the continually evolving medtech landscape with access to real-time market intelligence on product and company developments across the medical devices, diagnostics and advanced delivery systems markets.

Anticipate upcoming filings, clinical trials dates and data, and access market size information and expert forecasts all in one place, helping you assess the competition, track key events and make better-informed decisions.

To find our more visit:
pharmaintelligence.informa.com/Meddevicetracker

Pharma Intelligence
Informa

Are you looking to reach and do business with senior decision makers in pharma and medtech?

We offer a range of marketing opportunities whether you are looking to:

- Raise brand awareness
- Produce content marketing/thought leadership content
- Generate leads
- Engage directly with potential clients as well as cementing existing relationships

To find out how our team can help visit:
https://pharmaintelligence.informa.com/marketing-services