POLICY & REGULATION
Unannounced audits in EU not obligatory, p. 8

COMMERCIAL
Hologic buys into aesthetics, p. 17

R&D
Efferent eyes research market first for "living" biosensor, p. 20

Medtech Insight
Issue 32
medtech.pharmamedtechbi.com

Pharma Intelligence Informa

February 27, 2017


Shutterstock: grapestock

More Manufacturers Sign Up For Single Audits As MDSAP Becomes Operational

VIBHA SHARMA vibha.sharma@informa.com

Regulatory authorities from around the world participating in the Medical Device Single Audit Program (MDSAP) have seen a "rapid increase" in requests from medtech manufacturers about the program after its pilot phase closed on Dec. 31, 2016.

The number of device manufacturing sites participating in the program rose from 158 at the end of the pilot phase to approximately 200 as of Feb. 14, 2017.

"The rate of requests for participation has significantly increased since the end of the pilot," said Fábio Pereira Quintino from Brazil's regulatory agency, ANVISA, and the current chair of the MDSAP Regulatory Authority Council (RAC).

MDSAP was conceived by the International Medical Device Regulators Forum to allow device manufacturers to undergo a single audit that will satisfy the quality requirements of the five participating nations – the US, Australia, Brazil, Canada, and Japan – instead of having to undergo individual inspections from different regulators. Pereira Quintino told *Medtech Insight* that regulatory agencies from several other countries have also expressed interest in joining the program; a policy for admitting new members is currently under discussion.

Under MDSAP, companies can appoint an accredited auditing organization to conduct a single audit. The concept was piloted in several regions until the end of last year. By the end of the pilot phase, the consortium of MDSAP regulators had established the program's main policies, procedures and underlying quality management system.

"Data generated during the pilot is still being collected and analyzed and a formal 'Proof of Concept' report will be considered by the MDSAP Regulatory Authority Council before the end of 2017," Pereira Quintino said.

To date, MDSAP regulatory authorities have received 138 audit reports; 90 of those reports are from audits conducted in the US. The auditing organizations that submitted these reports were given feedback on the quality of their audit reports and, based on the experience gained, improvements have been made to the audit report requirements.

The audit reports submitted under MDSAP have generally been useful for participating regulatory authorities in the issuance of good manufacturing practice certificates or to support their decision to grant a marketing authorization, Pereira Quintino noted. A formal review of the au-

CONTINUED ON PAGE 7

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

MDMA FDA Forum: PMA/510(k) Workshop

MARCH 8-9, 2017 | PALO ALTO, CA

Confirmed Speakers Include:

William Maisel
Deputy Center Director for Science and Chief Scientist, CDRH, FDA

John Sheets
Director, Office of Devices, CDRH, FDA

Thinh Nguyen
Director, Office of Combination Products, FDA

Bakul Patel
Associate Director for Digital Health, Office of Center Director, CDRH, FDA

Murray Sheldon
Associate Director for Technology and Innovation, CDRH, FDA

Marjorie Shulman
Director, Premarket Notification [510(k)] Program, Program Operations Staff, ODE/CDRH/FDA

John Weiner
Associate Director for Policy and Product Classification Officer, Office of Combination Products, FDA

Barbara Zimmerman
Deputy Director, Premarket Program Management, Office of Device Evaluation

MDMA's popular FDA Forum will be held in **Palo Alto, CA from March 8-9, 2017**.

The FDA Forum will focus on unique insights and strategies to govern the 510(k) and PMA regulatory pathways, as well as what changes to expect with the recently negotiated user fee reauthorization, FDA reform efforts and more. Numerous interactive panels will be led by FDA officials, industry leaders and policy experts.

This popular MDMA conference has over 100 attendees, and great networking opportunities for you and your colleagues.

REGISTER TODAY to gain valuable insights and network with top medical technology experts and to learn the latest on how to successfully submit a 510(k) or PMA in this evolving regulatory environment.

- MDMA Member: $595
- Non Member: $895

REGISTER NOW AT *MEDICALDEVICES.ORG*


cover

8

20

explore more:

exclusive online content

EU regulations
http://bit.ly/2kMlnbo
Exclusive details about the transition periods for the new Medical Device Regulation and how long CE marks awarded under the current system will apply.

Making infusion pumps safer
http://bit.ly/2mlDO2X
Why are infusion pumps, which are used abundantly in hospitals, vulnerable to errors and what are the big players doing to address the problem? Get answers in this market intelligence feature.

Russia reads
http://bit.ly/2loNZ9s
Look for a series of three articles on what's happening in the medtech regulatory and policy sphere in Russia.

Siemens Healthineers builds one-stop digital shop
http://bit.ly/2lv8kYZ
Siemens is building a digital ecosystem that will bring together providers and tech-solutions specialists to enable the digitalization of health care.

Compliance 360°
http://bit.ly/2lvCyv3
Compliance 360° is an eight-part podcast series from Medtech Insight on US FDA compliance and enforcement issues. In the third installment, former FDA investigations branch director Ricki Chase explains how your firm can build trust with agency investigators during a facility inspection.

medtech.pharmamedtechbi.com

inside:

Medtech insight

DAVID FILMORE @MEDTECHDAVID
david.filmore@informa.com

TINA TAN @MEDTECHTINATAN
tina.tan@informa.com

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

REED MILLER @MEDTECHREED
reed.miller@informa.com

AMANDA MAXWELL @MEDTECHAMANDA
amanda.maxwell@informa.com

SUE DARCEY @MEDTECH_INSIGHT
sue.darcey@informa.com

DANNY AL-FARUQUE @ALFARUQUE
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

JANET HANIAK SENIOR DESIGNER

GAYLE REMBOLD FURBERT DESIGN SUPERVISOR

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

PHIL JARVIS MANAGING DIRECTOR

Editorial office:
52 Vanderbilt Avenue, 11th Floor, New York, NY 10017
phone 240-221-4500, fax 240-221-2561

CUSTOMER CARE:
1-888-670-8900 OR 1-908-547-2200
FAX 646-666-9878
clientservices@pharmamedtechbi.com

▶ join the conversation

We are tweeting, chatting, liking and sharing the latest industry news and insights from our global team of editors and analysts — join us!

@Medtech_Insight

£9m NHS Savings With HeartFlow 'Virtual FFR' Gets NICE Nod

REED MILLER reed.miller@informa.com

A new guidance from the UK's National Institute for Health and Care Excellence (NICE) recommends HeartFlow Inc.'s *HeartFlow FFR$_{CT}$ Analysis* non-invasive cardiac imaging system for the diagnosis of coronary artery disease in stable patients with chest pain. NICE was convinced the device could save £214 per patient and save the National Health Service in England more than £9m by 2022 by avoiding invasive investigation and treatment.

"Overall, the committee concluded that HeartFlow FFR CT should be considered for use as a non-invasive investigation for diagnosing angina in patients with stable, recent onset chest pain of suspected cardiac origin, and that it provides the clinician with additional functional information to determine which coronary lesions are responsible for myocardial ischaemia," the guidance concludes. The new guidance augments the new chest pain guidelines issued by NICE in November 2016. The guidelines recommend non-invasive coronary CT angiography for the initial diagnostic test for patients with stable chest pain.

HeartFlow FFR$_{CT}$ Analysis is a software system that turns cardiac computed tomography (CT) data into three-dimensional images of the cardiac anatomy, including a map of the coronaries that includes measurement of fractional flow reserve (FFR). FFR, the ratio of maximal blood flow in a diseased arteries compared to normal flow, is traditionally measured with an invasive catheter-based instrument. It is superior to angiography alone, because it shows where blood flow in the coronaries is actually restricted, whereas traditional angiography, which just shows the shape of the coronary lumen, can only provide an indirect and often inaccurate picture of blood flow. *(Also see "TCT 2015: Heartflow's FFR CT Could Bring Costs Down By One-Third" - Medtech Insight, 14 Oct, 2015.)*

> "The evidence showed high diagnostic accuracy and increased specificity with HeartFlow FFR$_{CT}$ compared with cardiac computed tomography angiography alone," the NICE guidance states.

HeartFlow FFR$_{CT}$ Analysis was CE marked in 2011. US FDA cleared the system in Nov. 2014 based on three validation studies comparing the FFR$_{CT}$ device to invasive FFR and conventional angiography. So far, it has only been evaluated in patients with stable, recent-onset chest pain, so that is the only indication NICE examined.

In developing the guidance, the committee reviewed of data submitted by HeartFlow and an external report prepared by the King's Technology Evaluation Centre (KiTEC), a collaboration between several King's College, London departments and the Medical Physics Departments of Guy's and St Thomas' NHS Foundation Trust and King's College Hospital. A first draft of the guidance was released in August 2016.

In its evaluation of HeartFlow FFR$_{CT}$ Analysis, NICE's Medical Technology Advisory Committee looked at 26 studies, but "the committee considered the evidence from the PLATFORM study to be most relevant to the decision problem," according to the guidance. PLATFORM was an observational study that compared invasive and non-invasive coronary artery disease screening tests in 584 symptomatic patients without known coronary disease.

PLATFORM showed that screening stable chest-pain patients with CT and selective FFR$_{CT}$ instead of invasive angiography saves money and produces equivalent clinical outcomes and patient quality of life, according to one-year follow-up data published in the *Journal of the American College of Cardiology* in August 2016.

"The evidence showed high diagnostic accuracy and increased specificity with HeartFlow FFR$_{CT}$ compared with cardiac computed tomography angiography alone," the guidance explains. "It also noted promising results from the PLATFORM study, in a population which closely matches that in the scope. The evidence was sufficient to conclude that HeartFlow FFR$_{CT}$ has a high diagnostic accuracy for coronary artery disease, and that its use has the potential to reduce the need for invasive coronary investigations."

The cost-savings estimate – £214 per patient – is derived from cost-modelling performed by KiTEC and supported by expert testimony. According to the NICE guidance, HeartFlow FFR$_{CT}$ now costs about £700 per test.

The committee considers HeartFlow FFR$_{CT}$ Analysis to be an innovative tool for simplifying screening for coronary disease in patients presenting with chest-pain, a process that is otherwise "a complex patient pathway." Clinical experts testified to the committee that they are confident in the diagnostic accuracy of HeartFlow FFR$_{CT}$, and that it could provide an effective early rule-out test for coronary artery disease. This would reduce the need for ICA and invasive FFR measurement, and potentially reduce radiation exposure."

The committee also discussed the relative importance of per-patient versus per-vessel diagnoses and, based on expert testimony, concluded that per-patient diagnostic accuracy is more important for an initial diagnosis, while per-vessel assessment provides additional information to help manage the patient. "The committee concluded that per-patient level figures were the most reliable and relevant to the diagnosis of coronary artery disease," the guidance states. "Further clinical studies would be helpful to clarify the wider applicability of HeartFlow FFR$_{CT}$ in routine clinical practice."

Published online 02/16/17

Ethicon-Sponsored Trial Shows Bariatric Surgery Improves Diabetics' Outcomes

REED MILLER reed.miller@informa.com

New results from the Surgical Treatment And Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) trial demonstrate that bariatric surgery can do much more for patients with type 2 diabetes than just help them lose weight by improving their glycemic control and reliance on medications.

The five-year follow-up results from STAMPEDE are now published by the *New England Journal of Medicine*. STAMPEDE is sponsored by **Johnson & Johnson/Ethicon Inc**., LifeScan Inc., the Cleveland Clinic, and the National Institutes of Health.

"STAMPEDE brought bariatric surgery and the surgeons performing these radical operations out of the closet of black magic and into the scientifically valid light," says Elliott Fegelmen, Ethicon.

"STAMPEDE, as the first randomized controlled trial in the bariatric space, brought bariatric surgery and the surgeons performing these radical operations out of the closet of black magic and into the scientifically valid light," Elliott Fegelman, Ethicon's Therapeutic Area Lead for EndoMechanical and Metabolics, told *Medtech Insight*. "It demonstrated the significant clinical impact that bariatric surgery was having. It cannot be over emphasized how critical this first step has been to the overall improvement in the quality of science in the bariatric space."

STAMPEDE randomized 150 patients who had type 2 diabetes and a body-mass index of 27 to 43 to either intensive medical therapy alone or intensive medical therapy plus a Roux-en-Y gastric bypass surgery or sleeve gastrectomy using surgical instruments provided by Ethicon-Endo Surgery. Roux-en-Y gastric bypass surgery creates a small gastric pouch (20-50mls), and then separates and reconnects the small bowel to bypass about two meters of bowel. The smaller stomach pouch causes the patient to feel full after eating less than they would have before the surgery, and bypassing much of the small intestine prevents the body from absorbing so many calories. The sleeve gastrectomy procedure is called that because it removes about 90% of the stomach's volume, leaving just a sleeve-shaped gastric tube.

Of the 150 patients who underwent randomization, 134 completed five years of follow-up. The primary endpoint was a glycated hemoglobin level of 6% or less.

After five years, 5% of the patients who received medical therapy alone achieved the endpoint, compared with 29% of the patients treated with Roux-en-Y gastric bypass and 23% of the patients treated with sleeve gastrectomy. The patients treated with surgery had significantly greater average percentage reduction in glycated hemoglobin level from patients than the patients treated with medical therapy only (2.1% vs. 0.3%).

The surgery patients also showed significantly greater weight loss – 23%, 19%, and 5% in the gastric-bypass, sleeve-gastrectomy, and medical-therapy groups, respectively – and greater reduction in triglycerides, high-density lipoprotein cholesterol levels, use of insulin, and quality-of-life scores on the RAND 36-Item Health Survey. There was only one reoperation among the surgery patients, and no major late surgical complications.

"Weight loss alone will improve insulin sensitivity, but there is a weight-loss independent effect that is likely manifested through hormonal and neuronal signals that are being actively pursued," Fegelman explained. "The most important aspect of this report [of five-year STAMPEDE results] is demonstrating the durability of surgical intervention in health benefits."

In recent years, several devices marketed as a less-invasive alternative to bariatric surgery or sleeve gastrectomy have taken market share, including Ethicon's *Realize* adjustable gastric band, GI Dynamics Inc.*EndoBarrier*, and Apollo Endosurgery Inc.'s *Lap-Band*. But Fegelman maintains, "the sleeve and the bypass are simply more efficacious operations and are durable, as this study demonstrates. The less invasive procedures can be very effective as well, but they typically require more engagement from the patient postoperatively. We hope that the health benefits demonstrated by STAMPEDE will help patients and their physicians to believe more in the long term health benefits of weight loss surgery."

"These results demonstrate that they can have significant health improvements following weight loss surgery, and it is not only diabetes which improves, but hypertension, sleep apnea and many other chronic conditions," he said. However, third-party payer coverage for these procedures is still "highly variable," he said. Cut Ethicon is optimistic that "results like these will demonstrate to payers and employers the excellent return on investment that weight loss surgery can offer to those who pay for patient health care."

These results from STAMPEDE are the result of Ethicon's Metabolic Applied Research Strategy (MARS), a collaborative research program between Ethicon, the Massachusetts General Hospital, and the University of Cincinnati that began more than a decade ago. "These pre-clinical discoveries gave us reason to believe that results studied in the rodent model, and observed in the clinical, setting could be proven definitively in a study such as STAMPEDE," Fegelman said.

The patients in STAMPEDE will be followed in ARMMS (Alliance of Randomized trials of Medicine versus Metabolic Surgery in type 2 diabetes), along with patients from three other trials, to assess the impact of their surgery out to at least then years.

Published online 02/16/17

CONTINUED FROM COVER

dit reports will also be added to the proof-of-concept report.

In addition, efforts have commenced to develop a web-based portal over the next two years that would enable "sharing of information and evidence on which regulators may base their market authorization decisions," he added.

MDSAP entered its full implementation phase on Jan. 1, 2017, and all participating regulatory agencies have established formal legal mechanisms, where required, to use the outcomes from MDSAP audits within their respective regulatory schemes.

The use of the MDSAP work products varies for each participating regulator, in accordance with the constraints of their regulatory scheme, and is further explained in a Q&A document. *(Also see "Device Firms Invited To Join MDSAP Ahead Of 2017 Full Launch" - Medtech Insight, 14 Sep, 2016.)* "The program respects the sovereignty of each country for their regulatory decisions," Pereira Quintino added.

Canada has committed to replace its Canadian Medical Devices Conformity Assessment System (CMDCAS) with MDSAP certification to support the licensing of medical devices. The full launch of MDSAP in January also marked Canada's start of a two-year transition phase that will result in the nation ceasing to recognize CMDCAS certification from Jan. 1, 2019. *(Also see "Manufacturers' Worries Grow Over Canada's MDSAP Deadline" - Medtech Insight, 12 Oct, 2016.)*

ARE THERE ENOUGH ACCREDITED AUDITING ORGANIZATIONS?

Pereira Quintino said that 13 auditing organizations, with presence all over the world, are currently participating in MDSAP. However, not all of these organizations are fully accredited to carry out independent audits.

As per MDSAP procedures, the first three audits conducted by an auditing organization have to be witnessed by regulatory authority assessors. Pereira Quintino explained that while two auditing organizations have met all recognition criteria and may conduct independent MDSAP audits, nine are authorized to conduct MDSAP audits under supervision, and two have not yet completed all prerequisite requirements to achieve the first stage of authorization to conduct MDSAP audits. In addition, an application from a 14th auditing organization was recently received and is being processed.

Now that the pilot phase has ended, more auditing organizations should be able to apply for accreditation. Pereira Quintino explained that during the pilot phase, applications from auditing organizations to be accredited under the program were restricted to those who were already enrolled in Health Canada's CMDCAS program, i.e., CMDCAS registrars. The full implementation of the program now permits participating MDSAP regulatory authorities to accept applications from other potential candidates that have experience with regulatory audit programs, he added.

Regulatory authorities, for their part, have contributed significant resources to the program, in the expectation that the collaboration will help provide effective oversight of auditing organizations and, in turn, medical device manufacturers. "Participation [of regulatory authorities] in the program also aids in the convergence of requirements for the regulation of medical devices and builds an understanding and confidence in each other's regulatory schemes," Pereira Quintino said.

He expects regulatory authorities will continue to use their experiences from the program to drive continuous improvements to MDSAP. While the program was devised by the IMDRF, it is now being overseen by the MDSAP Regulatory Authority Council, whose governing body comprises of senior representatives of each participating regulatory authority. The council is currently chaired by Brazil's ANVISA.

Pereira Quintino pointed out that MDSAP has its own governance, procedures and policies. He explained that the MDSAP council would consult with the IMDRF on any proposals that might significantly change the original model and policies for MDSAP to ensure that any implementation is consistent with agreed requirements.

Published online 02/16/17

Unannounced Audits In EU Not Obligatory, Commission Confirms

AMANDA MAXWELL amanda.maxwell@informa.com

Shutterstock: Gajus

The European Commission has confirmed to Medtech Insight that a recent European Court of Justice ruling means that unannounced audits of medtech manufacturers by notified bodies are not compulsory under the Medical Devices Directive (93/42/EEC).

The Commission was referring to the ECJ judgment of Feb. 16, concerning the involvement of German notified body TÜV Rheinland LGA Products in overseeing the French producer of the fraudulently manufactured PIP breast implants.

The judgment clarifies that "notified bodies are not under a general obligation to carry out unannounced inspections or to examine devices or manufacturer's business records," the Commission said, confirming earlier suggestions that this judgment applies currently and should not be read in the historical context of the PIP case. *(Also see "EU Court Ruling Throws Confusion On Need For Notified Body Unannounced Inspections" - Medtech Insight, 17 Feb, 2017.)*

It emphasized, however, that "when there are reasons to be alerted, notified bodies need to adapt the surveillance of manufacturers accordingly."

DE FACTO MANDATORY

Some may argue that these unannounced inspections were never mandatory because the Medical Devices Directive does not make them so and because the Commission emphasized the importance of doing them through a formal "recommendation" rather than a regulation.

But they have been made *de facto* mandatory since the general message from the regulatory authorities around Europe has been that notified bodies were required to comply with the recommendation or risked losing their designation.

LIABILITY QUESTION LEFT TO NATIONAL COURTS

The ECJ statement regarding unannounced audits answered the second and third questions put to the European Court by the German Federal Court of Justice concerning the potential liability of TÜV Rheinland with respect to its auditing of the PIP breast implant manufacturer. (See box.)

In responding to the first question about whether a notified body is liable towards the patient, the ECJ stated that while notified bodies act to protect end users of devices, the Medical Devices Directive does not regulate liability of notified bodies towards third persons.

The ECJ stated that it seems "entirely appropriate that those bodies should in principle be capable of bearing liability under national law to those patients and users for a culpable failure to fulfil their obligations, provided that the principles of equivalence and effectiveness are always respected. That will be a matter for the national court to determine."

The Commission noted to *Medtech Insight* that the ECJ also held that notified bodies monitoring the quality systems of medical device manufacturers fulfill their duties arising from EU product safety rules also with a view to protecting patients and that "this finding can be of significance for the liability of notified bodies under German law."

CHANGE ON UNANNOUNCED AUDITS WITH MDR

The ECJ ruling will only apply to notified bodies until they become redesignated under the oncoming Medical Devices and IVD Regulations.

The MDR, which is in its near final state and likely to be adopted over the next month or two, states:

The notified body shall randomly perform, at least once every five years, unannounced on-site audits to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors,

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample from the production

Three Questions Germany Asked the ECJ Regarding Class III Devices

1. In the case of a culpable infringement of an obligation, does the notified body have direct and unrestricted liability towards the patient concerned?
2. Is the notified body subject to a general obligation to examine devices, or at least to examine them when there is due cause?
3. 3) Is the notified body subject to a general obligation to examine the manufacturer's business records and/or carry out unannounced inspections, or at least to do so where there is due cause?

or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation; and

Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation.

But even within the current EU regulation, there is some confusion as one of the recitals at the beginning of the text states: "The national authority responsible for notified bodies may, in addition to regular monitoring or on-site assessments, conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance."

Furthermore, the MDR also states that the Commission may, by means of implementing acts, set out the minimum frequency of unannounced on-site audits and sample checks conducted by notified bodies (Article 42, 10).

The present EU Recommendation states that unannounced on-site audits should take place every three years.

Published online 02/20/17

Unlocking Legalities: Gorsuch's Impact May Be Felt On Free Speech, Preemption

ELIZABETH ORR elizabeth.orr@informa.com

President Trump's nominee for the Supreme Court, Neil Gorsuch, offers promise for the medtech space in legal areas of off-label communications and preemption, but there are some question marks.

The US Senate has scheduled confirmation hearings for Gorsuch to begin on March 20 with opening statements, followed by questioning of the judge and other witnesses starting on the next day. Overall, the hearings should take about three to four days. Sen. Chuck Grassley (R-Iowa), who chairs the Senate Judiciary Committee, announced the hearing plans on Feb. 16.

If the schedule holds, Gorsuch's confirmation hearings will start a year and five weeks after Justice Antonin Scalia's death on Feb. 13, 2016. And while Gorsuch has been widely reported to be a conservative in the mold of Scalia, his appointment – combined with Republican control of the presidency and both houses of Congress – could mean some changes for the better for device manufacturers.

In general, Gorsuch's confirmation "obviously wouldn't represent any dramatic difference from what we had when Justice Scalia was still alive," American University professor of law Lewis Grossman said in an interview. However, he noted that the picture gets more muddled if – as many anticipate – Trump gets a chance to appoint one or more additional conservative justices during his presidency, creating a conservative majority.

Neil Gorsuch
10th US Circuit Court of Appeals

"[Gorsuch's] dissatisfaction with the Supreme Court's tortured approach to express preemption in medical device product liability cases is very clear," says Reed Smith attorney James Beck.

One area where these changes might show up is in regulation of commercial free speech, Grossman said. In recent years, a handful of lower court rulings have called into question FDA's ability to prevent manufacturers from engaging in off-label speech if it's truthful and not misleading. *(Also see "Vascular Solutions Case (Partially) Points Way Forward For Off-Label Marketing" - Medtech Insight, 6 Apr, 2016.)* But FDA has historically settled or otherwise resolved the cases before they reached the high court, so justices have not directly addressed the issue.

But if the Trump administration chooses to pursue it, Gorsuch and other conservative justices could lead the Supreme Court to a "strong First Amendment decision," Grossman said.

Gorsuch has also ruled in favor of device-makers in preemption cases. For example, in 2015 he sided with Medtronic PLC in *Caplinger v. Medtronic*, in which a patient said she had been injured by Medtronic's *InFuse* spinal bone-graft device. Plaintiff Caplinger said that, because the PMA device had been inserted through her back rather than through her front, it had been used off-label and was not subject to the standard PMA preemption protection. The US Court of Appeals for the 10th Circuit disagreed. The opinion written by Gorsuch concluded that federal law didn't distinguish between on- and off-label uses.

The Supreme Court rejected Caplinger's request for an appeal in January 2016. *(Also see "High Court Won't Hear InFuse Off-Label Preemption Case" - Medtech Insight, 14 Jan, 2016.)*

"[Gorsuch's] dissatisfaction with the Supreme Court's tortured approach to

express preemption in medical device product liability cases is very clear," said attorney James Beck of Reed Smith said in a post on the Drug & Device Law blog. "We are cautiously optimistic that he will be inclined to do away with the 'general vs. specific' and 'parallel claim' exceptions to express [Medical Device Act] preemption."

Such exceptions to federal preemption for PMA-approved devices came out of the 1996 Supreme Court decision in *Medtronic v.Lohr*. Beck believes Gorsuch "would be content to interpret that broad preemption language" in the federal Medical Device Amendments "in accordance with its terms, leaving Congress to amend the statute if it does not like the scope of its own language."

REGULATORS V. COURTS

But, unlike Scalia, Gorsuch is known as an opponent of the *Chevron* doctrine. The doctrine takes its name from a 1984 Supreme Court case in which the court said that if the judiciary disagreed with a federal agency on how a regulation should be interpreted, the agency's opinion should take precedence. Gorsuch, however, thinks that judges should have the final say. This opinion is often seen as conservative or libertarian, but Cornell University law professor Michael Dorf noted it didn't fit neatly into any political alignment.

Experts interviewed by *Medtech Insight* couldn't point to any cases imminently headed to the Supreme Court that would require it to revisit the *Chevron* decision. In addition, it's unclear whether Gorsuch's opinion would be enough to tilt the nine justices to move away from the *Chevron* precedent.

But ending the assumption that agencies have the last word "would be quite disruptive for many regulated industries," Dorf said. As an example, he says revoking *Chevron* might mean a company could follow FDA rules in putting a product on the market, but later learn the court wouldn't defer to the agency's decision. "Later in litigation, a court could pull the rug out and say that FDA got the meaning of a statute wrong, their regulation is invalid, and [a company] are not allowed to market this," he noted.

Overall, a change to *Chevron* would make it harder for agencies to provide guidance, or for regulated parties to rely on guidance that was issued, he said. Dorf also noted that federal agencies typically give regulated parties more notice of changing requirements than the courts do, thus making it easier for companies to follow changing regulations.

But Grossman said that even if Gorsuch ends up shifting court opinion on *Chevron*, it's difficult to say what that would mean for medical device manufacturers without seeing a specific case. "[An FDA] rule that a court may or may not give deference to, could be a rule that is increasing or decreasing regulations of medical devices," he said. He further noted that it would be unusual for the high court to take on and reverse a relatively recent decision such as *Chevron*.

PATENTS

The *National Law Journal* reported that Gorsuch's rulings on intellectual property issues, such as patent law, have typically been sophisticated but relatively limited. In a 2008 case, he upheld a $20m award against medical device manufacturer Ballard Medical Products Inc. for infringing trade secrets, despite Ballard's defense that it held a patent on the information. Gorsuch said that, while the patent might help the inventor establish his case, the trade secrets suit hadn't raised a question of federal patent law. In another case, he specifically noted that a ruling that found images created for car advertisements couldn't be copyrighted might not apply in future cases.

Several attorneys cautioned against reading too much into Gorsuch's past rulings in considering his impact on the Supreme Court.

"Other than in cases of first impression, you can't really tell what a lower court judge will do when he or she doesn't have the Supreme Court looking over his shoulder, since most judges faithfully follow precedent as they interpret it," said Jeffrey Wasserstein of Hyman, Phelps & McNamara. "One case probably doesn't signal how they might affect industry."

Published online 02/20/17

CMS Nominee Seema Verma Urges Caution On Competitive Bidding Program

SUE DARCEY sue.darcey@informa.com

Seema Verma, Trump's nominee to head the US Medicare and Medicaid reimbursement agency, CMS, revealed very little about what changes she might make to those programs, but did caution that the agency needs to take care that its competitive-bidding program for medical suppliers does not impact beneficiary access, or cut providers out.

"A federal, one-size-fits-all approach doesn't always work," Verma said before the Senate Finance Committee at her Feb. 16 confirmation hearing. "And I think what you are bringing out with that competitive bidding program example, is we are sometimes seeing that rural providers are being paid at a rate, that may be more appropriate for an urban area," she told Sen. Mike Enzi, R-Wyo.

Enzi had complained that beneficiaries and suppliers in his sparsely-populated state of Wyoming may not be getting what they need out of CMS' planned expansion of its durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive-bidding program. *(Also see "CMS Expands Competitive Bidding To Include Insulin Pumps, More CPAP Areas" - Medtech Insight, 3 Feb, 2017.)* The program sets the amount Medicare pays for certain devices and medical equipment like wheelchairs based on market-bid prices in certain re-

gions. DMEPOS "is currently saving over $2bn per year" for Medicare, acting CMS Administrator Patrick Conway said Jan. 31, promising a ramp-up to cover more areas in 2018-2019.

But, Verma cautioned, "We need to understand how that program will impact a rural provider on the front end, and having that discussion is the way to do it. If we are having issues, then we need to respond to that. We need to be sure that we are not impacting beneficiary access.

"We don't want to do that [with a program], where we are actually preventing providers from participating, or losing providers who don't want to leave Medicare beneficiaries behind. We have to be very careful, that we are not pushing providers out," she said.

She noted that attracting more providers into the Medicare program would be a good way to give seniors more choices.

Verma is a former consultant and architect of Indiana's state Medicaid alternative, Healthy Indiana Plan, or "HIP," which most Republicans and some Democrats tout as highly successful.

Verma was asked by the Finance panel's ranking member Ron Wyden, D-Ore., if she prefers Medicare's older 'fee-for-service' policy over payment reforms that reward high-value rather than high-volume care. While Verma said she *does* have concerns about fee-for-service, she added that some rural health care providers "aren't ready to take on the risks that some of these payment innovations propose."

Other questions came up at the hearing about the former health-care consultant's opinion on a rule proposed at CMS by the Trump administration on Feb. 15. It is aimed at easing the marketplace standards for insurance plans that could serve as alternatives to Affordable Care Act plans, but Verma said she wasn't yet familiar with the proposed regulation and the quality of the coverage it might supply beneficiaries.

According to CMS, the proposed rule would make changes to special enrollment periods, the annual open enrollment period, guaranteed availability, and actuarial value requirements – which address how many benefits a typical plan would cover.

Verma fielded one question from Democratic Sen. Debbie Stabenow of Michigan, however, who claimed that under the proposed rule, women would probably have to pay extra for maternity care – a cost that is fully covered at no extra charge under ACA. "Should women have to pay more for maternity care?" Stabenow asked.

Verma answered, "Some women may not choose to have maternity care as part of their health plans – I want to give them that choice."

Published online 02/17/17

China To Get Tougher On Recalls Beginning In May

NEENA BRIZMOHUN neena.brizmohun@informa.com

Stricter rules governing medical device recalls in China that will expand the scope of what constitutes defective products and introduce larger fines for manufacturers who refuse to implement a recall are set to kick in on May 1, 2017.

The new rules, which the China Food and Drug Administration adopted last month, will mean that more types of defects will be subject to a recall, according to Katherine Wang, partner at the Shanghai office of law firm Ropes & Gray.

Also, the maximum penalty for failure to recall a device, subject to a mandatory recall order from a local FDA, will rise from three times the value of a device, to up to ten times its value, Wang said.

The new requirements will on May 1 replace the recall rule promulgated in 2011. A public consultation on a proposed version of the new rules was held in September 2016. *(Also see "China Proposes Stricter Rules And Higher Penalties For Recalls" - Medtech Insight, 20 Sep, 2016.)*

The new rules follow the current basic regulatory framework in that recalls are divided into mandatory recalls (imposed by local FDAs) and voluntary recalls (initiated by device manufacturers), Wang noted. Depending on the severity of the product defect, recalls are classified into one of three levels.

However, the scope of what constitutes defective products is expanding.

Wang noted that under the current definition, defective products that should be recalled are devices that pose "unreasonable risk of potentially damaging human health or life safety when used under normal conditions."

She said that the new rules enlarge the definition by adding three more types of defective products:

- Products that do not conform to compulsory standards, or to the product's technical specifications registered or filed with the CFDA;
- Products that pose unreasonable risk due to the failure to comply with the applicable quality management rules for device manufacture and supply; and
- Products that for other reasons must be recalled.

The latest rules also clarify who is responsible for the recall. "For domestic products, the holder of the product's registration license is responsible for recall … [and] for imported products, the designated regulatory agent of the foreign device manufacturer in China is responsible for recall," Wang said. If a foreign manufacturer initiates a recall outside China for a product also marketed in China, its local agent must report the recall-related information to the CFDA in a timely fashion, she added.

Published online 02/17/17

Australia To Make Access To Unauthorized Products Faster And Less Bothersome

NEENA BRIZMOHUN neena.brizmohun@informa.com

Australia's Therapeutic Goods Administration has issued proposals on how it can make it easier to use two of its existing programs to provide patient access to unapproved drugs and medical devices.

The proposals, contained in a consultation document, comprise changes the regulator wants to make to its Special Access Scheme (SAS) and Authorised Prescriber (AP) Scheme so that patients can receive products under either scheme faster and with less bother. Unapproved goods are only meant to be accessed in exceptional circumstances, where products on the Australian Register of Therapeutic Goods are not clinically suitable for a patient.

The change proposed for the SAS seeks to make it easier to prescribe certain unapproved medicines, biologicals or devices for patients with non-life threatening conditions, which fall under "category B" of the scheme.

Here, the agency wants to replace the existing, but burdensome, approval process required for SAS category B products with a simple notification process for certain products. It has also proposed criteria to identify which SAS B products would be appropriate for the notification process and it plans to create a list of eligible products.

The TGA expects the notification system to eliminate a great deal of the administrative burden currently involved with applying for and processing the approximately 20,000 SAS category B applications it receives every year, 99.7% of which are approved. Processing these applications can involve extensive consultation with practitioners to ensure sufficient information is available to support an approval decision, the agency explained. In addition, it notes that because such a small percentage of SAS category B applications are rejected, such products on the whole are unlikely to pose a risk to public health and safety.

The criterion for products that would make it on the new SAS category B list could be met, for example, by medicines, biologicals and devices demonstrating a history of use in Australia or overseas without significant safety concerns during the preceding three-year period, the TGA suggests.

The agency would update the list periodically to include additional therapeutic goods or remove products as needed. A decision to include a product on the list would not be appealable, it said.

The regulator stressed that only products that are not substantially similar to products already in the Australian Register of Therapeutic Goods (ARTG) would be eligible for SAS category B notification. "This ensures that the criterion can only be applied to goods where no appropriate therapeutic good is on the ARTG," it explained. "For example, in situations where a smaller pack size of the same therapeutic good exists, the large pack size product from a competitor will not be able to be notified to the TGA."

> "Only those devices that can be specifically and consistently identified would be suitable for inclusion on the [Special Access Scheme] listing," Australia's Therapeutic Goods Administration says.

There may be limitations to including medical devices on the notification list, the regulator added. "The identity of medical devices often lacks the clarity that would allow precise discrimination between different devices that have similar uses. Only those devices that can be specifically and consistently identified would be suitable for inclusion on the listing."

The consultation document suggests that SAS category B products not on the list would continue to require an application. The notification process for SAS category A (which covers patients with life-threatening conditions) would also remain unchanged.

AUTHORIZED PRESCRIBER UPDATES

For the AP Scheme, the TGA wants to streamline the parts of the application process that could be considered burdensome to practitioners and that slow timely patient access to products.

The AP Scheme allows approved prescribers to prescribe a specific therapeutic good to a class of patients under their care.

The current process involves an assessment of a clinical justification by both the TGA and either a human research ethics committee (HREC) or a specialist medical college. The TGA no longer wants to have to approve the clinical justification for the use of products. "Instead we will rely on the HREC/college expertise, which will improve the efficiency of the scheme."

The agency is also proposing to extend the duration of an AP approval for up to three years for a medical device and up to five years for a medicine, provided there is a history of established use of the product. This will lessen the regulatory burden on applicants, who currently have to seek re-approval after one or two year, for devices and medicines, respectively.

The TGA noted that an analysis of AP data from 2015 identified that less than 1% of applications are rejected by the agency, and those rejections arose because there was an alternative product included in the ARTG obviating the need to use an unregistered product.

Regarding compliance with the SAS and AP Scheme, the TGA said it intends

to improve how it monitors use of the schemes to ensure that they work efficiently and effectively. It is also planning to develop an online system for AP applications and SAS applications and notifications, which it said would allow users to enter information directly into the system, reduce any unnecessary administrative burden on health-care practitioners and sponsors, and provide real-time monitoring of applications and notifications in the system. In the meantime, the existing paper-based application/notification processes will be maintained.

The proposals for improving the SAS and AP Scheme are part of the government's September 2016 response to the Medicine and Medical Devices Regulation (MMDR) review, which made recommendations aimed at streamlining the TGA's processes and improving timely access by Australian consumers to medicines and medical devices. *(Also see "Australia Accepts Three Approval Pathways, Defers Registry For High-Risk Devices" - Medtech Insight, 19 Sep, 2016.)*

The deadline for submitting feedback to the consultation is March 29, 2017.

Published online 02/16/17

Unusual False-Claims Settlement Cites GMP Issues

ELIZABETH ORR elizabeth.orr@informa.com

Manufacturing problems were behind last month's False Claims Act civil settlement between the US Department of Justice and Baxter Healthcare Corp. And while the $2.16m fine imposed was small, the cause of action is raising eyebrows among some industry observers.

Baxter allegedly sold IV solutions made at a facility that was not in compliance with current good manufacturing practices to the Department of Veterans Affairs. The government argued that this was a FCA violation because the VA requires that products it buys abide by the federal Food, Drug & Cosmetic Act, and good manufacturing practice (GMP) issues put manufacturers out of compliance with the FD&C Act. So, in violating the FD&C Act, Baxter caused false claims to be submitted.

Case documents don't say that patients were injured or the product itself was harmed by Baxter's GMP woes. Instead, the company violated GMPs by neglecting maintenance in the clean rooms fitted with high-efficiency particulate absorption (HEPA) filters in which the IV solutions were made in. A whistleblower alerted the government that five of the 120 filters had failed testing and needed to be replaced. However, no excessive mold was found in the cleanroom or products themselves. *(Also see "The Case of Baxter's Moldy HEPA Filters" - Pink Sheet, 26 Jan, 2017.)*

Anne Walsh, an attorney at Hyman, Phelps & McNamara, said in a post on the company's blog that she was aware of only two FCA settlements tied to GMP issues. In both cases, the products were impacted by the company's failure to abide by cGMP. For example, drugs involved in a 2010 settlement with GlaxoSmithKline PLC "had no active ingredient or no controlled release mechanism, higher or lower amounts of the active ingredient, non-sterile product, or product that contained microorganisms," she wrote.

Walsh argues that FDA has broad discretion to enforce GMP compliance, including the ability to issue warning letters, take products off the market, or stop a company from making products until the agency is satisfied with compliance efforts. Having DOJ and the VA step in for GMP enforcement, she said, is "disturbing."

Shutterstock: Brian A Jackson

Although this case involves drug cGMPs, similar questions about the potential for FCA liability based on alleged violations to the device Quality System Regulation have been raised. Some courts have decided that GMP/QSR violations alone can't be the source of an FCA claim because companies are not making a "specific representation" about QSR compliance to Medicare, but only to FDA. *(Also see "FCA Liability After Escobar: Challenges And Opportunities For Device Companies" - Medtech Insight, 12 Oct, 2016.)*

"We hope FCA cases based on cGMP compliance remain a rarity," Walsh wrote. "At any given time, a company can be cited for not satisfying the requirements of cGMP; by its very nature, 'current' practices are constantly evolving. This is FDA's statutory purview under the FDC Act, not the FCA."

In fact, FDA issued a warning letter to Baxter about the moldy filters in May 2013.

In addition to the $2.16m civil settlement, Baxter also agreed to pay $16m and sign a 30-month Deferred Prosecution Arrangement as part of a criminal settlement. The government is also requiring the company take advanced compliance measures.

Published online 02/16/17

New Bill Aims To Bring Consistency, Transparency To US FDA Inspections

SHAWN M. SCHMITT shawn.schmitt@informa.com

Two US senators have drafted a bill they say will bring more transparency and consistency to FDA device facility inspections.

Sens. Johnny Isakson, R-Ga., and Michael Bennet, D-Colo., introduced the legislation, S. 404, on Feb. 15. It calls for adopting a uniform FDA inspection process to ensure parity between foreign and domestic audits, notifying manufacturers in advance of records that will be requested during an inspection, and specifying a window of time for investigators to conduct their onsite inspections, among other requirements.

"There is a lack of transparency and consistency concerning inspections … which leads to inefficiencies and inconsistencies, and undermines confidence in United States standards," the bill states.

While FDA's Quality System Inspection Technique offers firms a structure for how investigators will inspect with the goal of increasing audit consistency, many investigators stray from the technique, industry experts have told *Medtech Insight*. Investigator deviations from the technique mean less predictable audits and, quite possibly, unfavorable inspection outcomes for companies. *(Also see "FDA Investigators Play Fast And Loose With Quality System Inspection Technique, Experts Say – But Is It Par For The Course?" - Medtech Insight, 12 Dec, 2016.)*

The new legislation complains that inspections of foreign device firms are "conducted more efficiently" than those for their US counterparts.

Indeed, FDA foreign facility audits are typically completed within a brisk three to five business days, while inspections of domestic firms can last for weeks, with investigators leaving for several days at a time before returning to continue their work.

"The frequency and nature of inspections of device establishments are not consistently risk-based, and a comprehensive, transparent, risk-based approach to inspections would result in greater focus on the more significant risks to public health while reducing the burdens on establishments with a strong track record of compliance," the bill states.

"While FDA's Quality System Inspection Technique offers firms a structure for how investigators will inspect with the goal of increasing audit consistency, many investigators stray from the technique, industry experts have told *Medtech Insight*.

The law, if enacted, would require FDA to inform companies "of the type and nature of [an] inspection." The agency would also have to announce the audit "within a reasonable time before such inspection."

The bill also calls for FDA to provide device firms with "a reasonable estimate of the timeframe for [an] inspection."

If enacted, the bill would require a draft guidance to be penned that would:

- Provide "standardized templates" for communication between FDA and industry;
- Establish "a standard timeframe over consecutive days that is applicable to both domestic and foreign inspections, to which each inspector shall adhere," unless the investigator has cause for taking additional time to inspect; and
- Identify "practices for investigators and device establishments to facilitate the continuity of inspection."

LETTERS TO FOREIGN GOVERNMENTS

Finally, the legislation would allow manufacturers to keep their certificates to foreign governments if the firms can prove to FDA that it has a plan to correct problems found during a facility inspection.

Such certificates allow companies to export products overseas. Rarely does the agency pull a firm's certificate, but it does happen, typically after a corporate warning letter is issued.

Corporate letters are an enforcement

tool intended to force top company executives at large firms to address systemic quality systems at all of their manufacturing facilities. Along with denying recipients certificates to foreign governments, the letters impose limitations on pre-market approvals.

AdvaMed came out early in support of the new bill. Scott Whitaker, president and CEO of the device industry trade group, noted Feb. 16 that a robust FDA inspection process is a must, pointing out that the agency's current process "suffers from a lack of consistency, predictability and transparency."

The legislation "will help modernize FDA's inspections process through a risk-based approach that will focus the agency's limited resources on facilities that have the most potential to impact public health, improving overall patient safety," Whitaker stated.

The bill was referred to the Senate Help, Education, Labor and Pensions Committee. Its prospects of passage remain to be seen, but the device user-fee reauthorization bill, which must pass this year to keep the user-fee program from expiring, offers a potential near-term legislative vehicle.

"Scott Whitaker, president and CEO of AdvaMed noted Feb. 16 that a robust FDA inspection process is a must, pointing out that the agency's current process "suffers from a lack of consistency, predictability and transparency."

WHAT ABOUT PROGRAM ALIGNMENT?

It is not clear if or how the legislation would affect FDA's in-the-works "program alignment" inspection initiative.

Under program alignment, facility inspections performed by the Office of Regulatory Affairs (ORA) will be restructured along commodity-specific product lines – a historic change for the office, which conducts all of the agency's field activities. One of the plan's goals is to make inspections more predictable and consistent for investigators and manufacturers.

Program alignment calls for the agency's five regional offices to be replaced by three distinct districts within the US. *(Also see "Kiss Your FDA Regional Office Goodbye: Big Changes Afoot Thanks To ORA's Inspectional Program Alignment" - Medtech Insight, 21 Mar, 2016.)* Further, Boston, Florida and Los Angeles will likely be home to new FDA divisions dedicated to coordinating inspections of device manufacturers under the initiative. *(Also see "Podcast: FDA's Inspection 'Program Alignment,' New Guidance Docs Top QA/RA Hotspots In 2017" - Medtech Insight, 1 Feb, 2017.)*

Published online 02/16/17

House Panel Plans Oversight On Device Tax, MACRA, Trade Negotiations

SUE DARCEY sue.darcey@informa.com

The House Ways and Means Committee agreed to a two-year oversight plan, covering everything from overseeing device excise tax repeal and other reforms to the Affordable Care Act, to review of trade agreements with Asia-Pacific countries and the EU.

The committee agreed to the agenda during a Feb. 14 hearing. Much of the hearing was taken up by a two-hour debate over an amendment offered by Rep. Lloyd Doggett, D-Texas, to have the Treasury Department require President Trump to release his tax returns. This amendment was defeated.

COMMITTEE PROMISES REFORMS TO HEALTH SYSTEM

But Committee Chair Kevin Brady, R-Texas, found time to lay out the committee's two-year plan, commenting that the oversight scheme "highlights an opportunity to make progress to reform our healthcare system."

Other goals include carrying out "comprehensive tax reform to create a fairer, simpler tax code built for growth," and "eliminating inefficient and counter-productive government regulations."

One tax burden that the committee's Republican majority has questioned in the past, and is likely to view as "counterproductive," is the medical device excise tax. Brady promises to carry out oversight of the device tax, as well as other ACA tax provisions, including the individual mandate and the employer mandate to purchase health insurance. Last June, Brady, along with House Speaker Paul Ryan, promoted a new "Better Way" tax system that includes repeal of the ACA taxes. *(Also see "Industry Praises GOP Tax Reform Policy For Global Profits Treatment, End To Device Tax" - Medtech Insight, 28 Jun, 2016.)*

Among other reforms detailed in the committee's oversight plan are reconsideration of the Independent Payment Advisory Board and CMS's Center for Medicare and Medicaid Innovation (CMMI), both created under ACA, and a reexamination of physician payment reforms enacted by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Among the physician payment reforms advanced last year by CMS's CMMI under MACRA were the Comprehensive Care Joint Replacement model*(Also see "Total Joints: Bundled Payments Driving Procedural Innovation" - Medtech Insight, 26 Apr, 2016.)* and the Cardiac Rehabilitation Incentive Payment model, which each test-bundled payments and quality mea-

House Ways And Means Members

In 2017, the House Ways and Means Committee lost some members and gained some new blood based on election results and new appointments. New members are in bold; members in italics sit on the Health Subcommittee.

REPUBLICANS	DEMOCRATS
Kevin Brady, Texas, Chairman	Richard Neal, Mass., Ranking Member
Sam Johnson, Texas	*Sander M. Levin, Mich. (Ranking Member, Health Subcommittee)*
Devin Nunes, Calif.	*John Lewis, Georgia*
Pat Tiberi, Ohio (Chair, Health Subcommittee)	Lloyd Doggett, Texas
Dave Reichert, Wash.	*Mike Thompson, Calif.*
Peter Roskam, Ill.	John B. Larson, Conn.
Vern Buchanan, Fla.	*Earl Blumenauer, Ore.*
Adrian Smith, Neb.	*Ron Kind, Wis.*
Lynn Jenkins, Kan.	Bill Pascrell, NJ
Erik Paulsen, Minn.	Joseph Crowley, NY
Kenny Marchant, Texas	Danny K. Davis, Ill.
Diane Black, Tenn.	Linda Sanchez, Calif.
Tom Reed, NY	*Brian Higgins, NY*
Mike Kelly, Pa.	*Terri Sewell, Ala.*
Jim Renacci, Ohio	**Susan Delbane, Wash.**
Pat Meehan, Pa.	**Judy Chu, Calif.**
Kristi Noem, SD	
George Holding, NC	
Jason T. Smith, Mo.	
Tom Rice, SC	
David Schweikert, Ariz.	
Jackie Walorski, Ind.	
Carlos Curbado, Fla.	

sures for episodes of care associated with hip and knee replacements, and cardiac procedures, respectively. *(Also see "Cardiac Care Bundled Pay Models Preserve New Tech Add-Ons, But Still Make Medtech Nervous" - Medtech Insight, 5 Jan, 2017.)*

"The committee's oversight plan lays out our continued commitment to robust congressional oversight of federal programs," including the Medicare proposals, Brady said at the Feb. 14 hearing.

TRADE DEAL OVERSIGHT PROMISED

The oversight plan agreed to by Ways and Means promises to "fully exercise Congress' oversight responsibilities regarding existing and new trade agreements." The US had negotiated the Trans-Pacific Partnership (TPP) under the Obama administration, but the Trump administration issued a presidential memorandum to the US Trade Representative in late January pulling the US out of the TPP agreement. *(Also see "Trump Dumps Industry-Supported Trans-Pacific Partnership" - Medtech Insight, 24 Jan, 2017.)* In his decision to pull out of the TPP, Trump said he prefers to negotiate trade by the US with other countries on a one-on-one basis. Negotiations had also been ongoing with Europe for a Transatlantic Trade and Investment Partnership (TTIP), but it's unclear if that will move forward under the new administration.

Other trade agreements the committee is likely to weigh in on include the CAFTA-DR – an agreement between the US, several Caribbean-region countries and Korea and Peru; and the North America Free Trade Agreement (NAFTA) between the US, Canada and Mexico, which President Trump argues should be renegotiated.

During the session, Brady welcomed several new members to the Ways and Means Committee that have joined the panel in the last month and half, primarily due to election changes. In addition, former committee member Tom Price, R-Ga., is now Secretary of HHS, and former member Xavier Becerra, D-Calif., was sworn in as California's Attorney General in mid-January. *(Also see "House Ways And Means Committee Membership, 115th Congress" - Medtech Insight, 16 Feb, 2017.)*

Published online 02/16/17

Q4 Recalls Snapshot: Numbers Dip Slightly But Remain High; Sterility Troubles Bubble To Surface

SHAWN M. SCHMITT shawn.schmitt@informa.com

Despite falling slightly, the number of medical device recalls remained high in the fourth quarter of 2016.

"Q4 2016 saw the second largest number of recall events since Q4 2013. There were more recalls last quarter than this quarter. However, both Q3 and Q4 were high quarters for recall activity," said Michael Good, VP of commercial & client services for consulting firm Stericycle, which gathered its recalls data from FDA Enforcement Reports.

The company's detailed analysis of recall events, shared with *Medtech Insight*, found that there were 339 recalls in Q3 2016 (July-Sept.) and 313 in Q4 2016 (Oct.-Dec.). That represents an 8% decrease. (See Figure 1.)

"There are many factors that play into that, and we certainly see normal fluctuations across industries from quarter to quarter. But while advancements are undoubtedly providing many benefits for patients, they can lead to added challenges and complexities, and in some cases, additional recall activity," Good said.

"As technological advances increase, and we see more connected medical devices, we can expect software issues will continue to cause recalls," Stericycle's Michael Good says.

It should be no surprise that trouble with software was the No. 1 reason for device recalls in Q4. Seventy-two recall events were related to software last quarter, which is down a bit from the 85 events linked to software in Q3 2016, when it was also the top reason for a recall.

"Generally, software issues occur in products that feature a diagnostic device or a display screen. As technological advances increase, and we see more connected medical devices, we can expect software issues will continue to cause recalls," Good said.

Along with software, mislabeling problems caused the most headaches for manufacturers in the fourth quarter of 2016. While there were 72 recalls (23%) related to software, 53 (17%) were due to mislabeling. (See Figure 2.)

"Some common mislabeling issues include incorrect size, product name and

quantity within the package," Good said. 'We also see issues where a piece of information in the instructions either doesn't match the product or was meant for a different product."

Meanwhile, problems with sterility crept back into the top 5 reasons for a recall, landing at the No. 3 spot.

The sterility issue "was fifth in Q1 and Q2 [2016], and sixth in Q3 [2016], so it's usually near the top five," Good said. "The uptick only happened in Q4, so it's definitely something we'll keep an eye on to see if this is a one-quarter blip or part of a larger trend."

RECALLED DEVICE UNITS

The number of recalled device units fell in Q4 2016. In Q3 there were 115,954,287 units recalled, while in Q4 there were 63,102,245 – a 45% decrease.

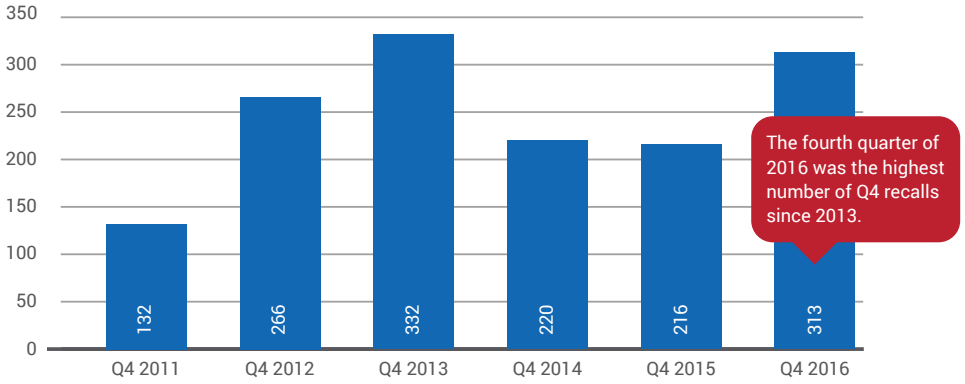
"Although it is a big drop, that's mostly because Q3 saw such a large number of recalled units. We don't always see a drop between Q3 and Q4, and for added context, the number of units recalled in Q4 is more than was recalled in Q1 and Q2 combined, and is more than 13 of the last 16 quarters," Good said.

Stericycle's breakdown of Q1 2017 data won't happen until shortly after March 31. It will then take the firm a month or so to fully analyze FDA's recalls data.

Published online 02/16/17

FIGURE 1

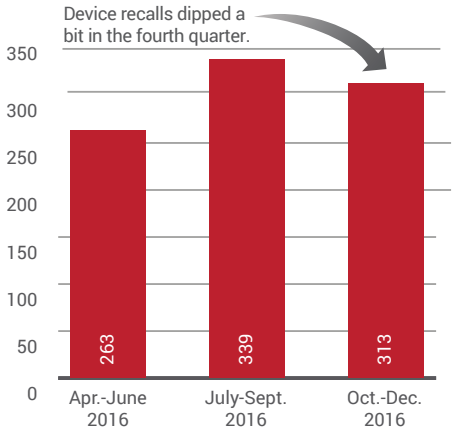
Number Of Recalls, Q4 2011 - Q4 2016



Source: Stericycle analysis of recalls data listed in FDA Enforcement Reports

FIGURE 2

Number Of Recalls, Q2 2016 - Q4 2016



Top 5 Causes For Recalls, Q4 2016

Source: Stericycle analysis of recalls data listed in FDA Enforcement Reports

Integra Aims To Bolster Neurology Portfolio With J&J Codman Buy

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

Integra LifeSciences has made a billion-dollar bid for **Johnson & Johnson**'s **Codman Neurosurgery** business. Integra says deal would give it a larger global reach and acquire products that add to its already existing portfolio of neurosurgery devices.

Codman is owned by J&J subsidiary **DePuy Synthes**. On Feb. 15, Integra formally made a $1.045bn bid to acquire the company, which produces products ranging from steerable guide wires and catheters, to electrosurgical generators and various neurosurgery kits. The offer is open until May 15, but could be extended to Aug. 14, according to the company's report to the US Securities and Exchange Commission.

Integra states Codman's existing portfolio includes advanced hydrocephalus, neuro-critical care and electrosurgery products that complements its own pipeline of tissue ablation, dural repair and cranial stabilization products. The company says the products they are hoping to acquire through the buy generated about $370m last year alone.

Codman's "innovative portfolio and global reach will enable us to enhance our position in the neurosurgery market, while also building a global infrastructure that will benefit Integra as a

whole," said Integra CEO Peter Arduini.

Integra has so far been active on the M&A front in 2017. It acquired the tissue-regeneration company **Derma Sciences Inc.** at the start of the year. The company paid $204m for Derma. At the time, Integra said the addition of Derma's amniotic tissue-based products would broaden its regenerative technology offerings and accelerate is advanced wound-care strategy. *(Also see "M&A Analysis: Feeble Start To 2017" - Medtech Insight, 3 Feb, 2017.)*

Larry Biegelsen, an analyst with Wells Fargo, said the Codman acquisition is Integra's largest ever.

"Together with the Derma Sciences acquisition that was announced in early January, the recent acquisitions will represent nearly a third of pro forma IART 2018 revenue," Biegelsen said in a Feb. 16 research note. "Given the size of the deals, we believe that the integration poses some level of risk."

If the Codman deal goes through, more than 600 Codman employees would join Integra. The New Jersey device-maker says the acquisition would accelerate its goal of reaching $2bn in revenues, although there is likely to be some initial disruption in the first year after the buy. After that, Integra expects an initial 3% growth rate and 6% growth in the long term.

Integra is scheduled to hold a 2016 Q4 investor call on Feb. 23.

Published online 02/16/17

Hologic Stitches Medical Aesthetics Into Women's Health

REED MILLER reed.miller@informa.com

Hologic Inc. plans to acquire **Cynosure Inc.** for about $1.65bn to add medical aesthetics products to its existing range of OB/GYN and women's health technologies.

Hologic will pay $66 per share in cash for Cynosure, a 28% premium over Cynosure's closing price before the deal was announced. Net of cash, the enterprise valve of the deal, expected to close by April, is about $1.44bn. Cynosure's 2016 revenue was $433.5m, a 28% increase over 2015.

"This deal checks many of the boxes that we have discussed related to M&A. It's additive to our top-line and bottom-line growth rates. It provides good economic returns as measured by return on invested capital and it's immediately accretive to EPS on a non-GAAP basis," Hologic CEO Stephen MacMillan said during a Feb. 14 conference call.

"It also adds a completely new growth platform to our business while leveraging our scientific and commercial strengths. And while it is a larger deal than we expected at this point, the unique nature of Cynosure prompted us to act," he said. "We will leverage our commercial channels in women's health, especially our broad coverage of OB/GYNs, while simultaneously expanding Cynosure's market."

Cynosure markets a range of laser systems for aesthetic indications and is the exclusive distributor for **DEKA**'s *Mona Lisa Touch* CO2 laser for vaginal rejuvenation. we believe Cynosure is the best-in-class player in the space, and a unique asset. "Not only are they the market leader, they have the broadest portfolio of differentiated products in key categories, including body contouring, hair removal, skin revitalization, and women's health," MacMillan said.

> "This deal checks many of the boxes that we have discussed related to M&A. It also adds a completely new growth platform to our business while leveraging our scientific and commercial strengths," says Stephen MacMillan, Hologic.

Hologic believes Cynosure's customer base complements Hologic's better than that of any other medical aesthetics company because 60% of Cynosure's business comes from physicians who are not dermatologists or plastic surgeons, including the many of the same OB/GYNs that buy Hologic's diagnostics, mammography, breast biopsy equipment and other women's health products. However, Cynosure's penetration into these sales channels is low and represent a significant growth opportunity, according to Hologic.

Hologic's entry into medical aesthetics via Cynsosure comes just a day after **Allergan PLC** announced plans to boost its growing medical aesthetics business by acquiring **Zeltiq Aesthetics Inc.** for $2.475bn. *(Also see "Allergan Pays $2bn-Plus For Zeltiq, Expanding Aesthetics Business" - Medtech Insight, 13 Feb, 2017.)*. Zeltiq's flagship product is the *CoolSculpting* body-contouring system and MacMillan especially highlighted the growth potential of Cynosure's *SculpSure* body-contouring product as one of Cynosure's most attractive assets. However, MacMillan said that the timing of the two deals was a coincidence, because the deal for Cynosure has been in the works for a while.

Hologic identified medical aesthetics "as an attractive adjacency in our strategic planning process last summer. Even at that time, Cynosure rose to the top of the list of potential targets," he said. Cynosure recently received an unsolicited inbound offer from another unnamed company which led Cynosure to reach out to Hologic to discuss a possible merger, MacMillan said. The deal started to come together after Hologic sold its blood screening busi-

ness to **Grifols SA** for $1.85bn at the end of 2016, "which significantly increased our financial flexibility and our ability to consider a deal of this size," the CEO explained. *(Also see "Blood Brothers No More: Hologic Unloads Blood-Screening Business To Partner Grifols" - Medtech Insight, 15 Dec, 2016.)*

At the time of the Grifols deal, Hologic said it was looking to boost its revenue growth through acquisitions. Cynosure "provides access to a large, growing opportunity," MacMillan said, pointing out that the medical aesthetic device market exceeded $2bn in 2016, and will probably grow in the low double digits for the next several years.

"The growth in the overall aesthetics field is being driven by a number of demographic and customer trends," MacMillan said. "While many baby boomers and Gen X'ers have the disposable income needed for aesthetic procedures, they also have a strong preference for non-invasive methods that avoid anesthesia, surgery, and downtime."

Echoing a point Allergan execs made while explaining the Zeltiq acquisition, MacMillan said Hologic sees a benefits in relying on consumers who are willing to pay for their own procedures rather than the third-party payers who pay for most medical devices. "Many physicians, including many of our current customers, are looking for new ways to supplement their income and diversify their practices away from declining insurance reimbursement toward more cash pay procedures."

Hologic says that the Cynosure deal coupled with the divestiture of the blood screening business adds about 150 basis points to its revenue growth rate will push earnings-per-share growth into the double-digits over the next five years. Cynosure expects to deal to be immediately accretive to its top and bottom lines, and expects the deal to produce annualized cost synergies of approximately $25m by 2019, a net present value of over $0.5bn, and a low-double-digit internal rate of return.

Published online 02/15/17

Efferent Labs' Living Biosensor Could Save Pharma, Device Firms Money

TINA TAN tina.tan@informa.com

The buzz around organ-on-a-chip technologies – microfluidic cell-based diagnostic devices that mimic the human organ structure and function in a lab for use in drug development research – has become louder in the last few years as the flow of products entering the mainstream increases. Furthermore, companies are continuing to make significant advances in this area; last year in June, a consortium composed of CN Bio Innovations, Continuum and the Massachusetts Institute of Technology unveiled the world's first seven-organ "human-on-a-chip".

Efferent Labs, a Buffalo, New York firm, is also looking to offer a cell-based diagnostic device to the research market. However, in contrast to organ-on-a-chip's in vitro approach, Efferent's CytoComm "living" biosensor is designed to be implanted in the animal subject or human patient to measure cellular interactions in vivo.

"No one is doing it in vivo like we are, that's a key differentiator between us and organ-on-a-chip companies. It was important for us to develop something that can be put inside a living animal and living human and see the interactions in real time and give the feedback if necessary to physicians," Bill Rader, CEO of Efferent, told *Medtech Insight*, adding that the company has patents issued around the in vivo aspect of its technology.

Photo credit: Efferent Labs

Efferent Labs CEO Bill Rader describes CytoComm as "sticking a microscope inside a person".

Rader describes CytoComm as "sticking a microscope inside a person." The implant, which measures approximately 3.5mm in width and 25mm in length, comprise a biosensor that has living cells inside it. The cells are kept in place by a membrane that allows interstitial fluid or blood to enter into the sensor, but do not allow the cells to pass out of the device. "So that means we can keep the environment healthy and not contaminated externally."

The cells are stimulated by pulses of specific light waveforms emitted by the sensor. The cells react to the interrogation and the device captures this response, which is transmitted wirelessly to Efferent's cloud-based data analytics software.

"We're looking at the patient's cells through a micro-MEMS photonic sensor,

monitoring how those cells are interacting with the different pharmaceutical products by measuring their photonic response, and then determine – based on these photonic readings – how the body is reacting to the drugs," explained Rader. By analyzing the body's reaction to the drugs, the optimum dosage or treatment regime for different diseases, such as chemotherapy for cancer, can be assessed. Additionally, CytoComm could be used as a monitoring tool for at-risk cardiac patients, programmed to look out for biomarkers such as BNP, epinephrine, troponin, that are linked to heart failure and to send out a warning signal before an adverse cardiac event happens. Depending on what the sensor is used for, different cells will be used in the implant to monitor the target interactions.

When asked what the technical hurdles were when developing CytoComm, Rader said a major challenge was getting around apoptosis. "When we first announced we were doing this many years ago, one of the big companies said you're never going to keep the cells alive over a few days or even a week. But we've been very successful in overcoming that – it's all in the design of our sensor and how it works. We're now heading up to three months in managing to keep our cells alive in our sensor. That's our goal – to have three months of cell life without having to refresh the cells at all."

Other hurdles included making the photonics small enough to slip into the device and being able to capture the photons that these cells are emitting. However, Rader said the company succeeded in overcoming these challenges in "about 24 months".

The firm's immediate focus is to start commercializing CytoComm in the preclinical market where the implant will be used in animals. Efferent believes its biosensor can help keep clinical study costs down in a number of ways. Firstly, as CytoComm is able to gather multiple data points from the same animal for the duration of a study, fewer animals would be required. Also, as the data collected by the sensor is automatically transmitted to the cloud-based platform and each implants has an RFID tag which allows researchers to keep track of each animal subject, this reduces the need for individual handling of the test animals, cutting down on labor costs.

"When we first announced we were doing this many years ago, one of the big companies said you're never going to keep the cells alive over a few days or even a week. But we've been very successful in overcoming that," says Bill Rader, Efferent Labs.

How it all started

The idea for a device like CytoComm came from Efferent Labs' chief medical officer, Spencer Rosero, who is a practicing cardiologist. As a physician, Rosero would hear from his patients that they "just don't feel right" and while he would conduct a battery of tests, nothing conclusive would show up. Then 2-3 weeks later, these patients would show up having suffered a heart attack. "So he started wondering, with these patients there was something going on biologically that we weren't able to measure easily: how do we monitor them in real-time to see what's happening and make a determination in these high-risk patients that they might have an event? If we can do this, we can correct this before it even happens," explained Rader. Rosero started looking at using cells as a sensor and over a decade on, Efferent now has a technology, with "patents that are solid through the mid-2030s.

In January, Efferent signed on its first partner, German drug discovery and development specialist Evotec, for CytoComm in the preclinical research market. The multi-year deal will see CytoComm used to help with work on optimizing and validating targeted pathways, and Rader said that since the agreement was sealed, Efferent has already engaged with other potential partners, including "one major pharma and one medical device company". "We have interest there for partnering. We're a small company, and we have a limited amount of bandwidth due to funding, so we're taking this one step at a time," the CEO said.

These preclinical research partnerships would hopefully generate the revenue that would support Efferent's efforts to move CytoComm into the clinical-phase research market, where the technology would need to get regulatory approval, most likely under a de novo classification. Rader estimated that it would take the company about 24 months to get to the clinical research market.

Efferent to date has been financed privately by angel investors and the company's management. The firm has also won research grants and a $500,000 prize from coming second in a global business competition, 43 North. "To date, we've got just under $3m in investment but one of the big pharma companies said it would have cost them about $15m to get as far as we have," said Rader.

Efferent is halfway through a bridge round of funding at the moment, and is hoping to move into a Series A by mid-year. This Series A will be for $10-12m and should support the company through preclinical research commercialization and into the de novo approval phase to move into the clinical research market.

Published online 02/20/17

Intensix Data Analytics Demo High Accuracy In ICU Sepsis Detection

CATHERINE LONGWORTH catherine.longworth@informa.com

A new study has shown that an analytics platform developed by Israeli company Intensix has a high accuracy for detecting and predicting sepsis in the ICU.

The study, conducted at the Mayo Clinic in the US sought to test the Intensix platform for sepsis detection in ICU, compared to the gold standard observation of a sepsis sniffer and additional manual review.

"Most patients admitted to ICU are in a bad condition and deteriorating very quickly so it's vital for clinicians to be able to monitor and detect this early," Intensix CEO Gal Salomon told *Medtech Insight*. "The results from this study showed our platform's performance is comparable to manual review for detecting sepsis. It demonstrated high reliability and the ability to process flow of data needed for algorithm execution."

Intensix's platform correlates anonymized ICU data collected from different patients with mathematical algorithms to create models for predicting clinical outcomes. It can be used as a standalone app or used with existing systems. The company revealed the positive results at the Healthcare Information and Management Systems Society (HIMSS) conference in Orlando, Florida.

"The platform can be integrated as part of the clinician's workflow using three different data points," said Salomon. "The first one is data from the vital signs, including heart rate and pressure. The second type of data is the medication that the patient is using, and finally results from the patient's tests, including CT and MRI scans. All this information can give us an estimation of a patient's status in critical care."

Sepsis is the most common cause of mortality in intensive care units and can rapidly lead to vital organ dysfunction, and death. It accounts for 40% of total ICU expenditure, with 18 million individuals dying each year from the condition.

Intensix CEO Gal Salomon

"Sepsis is the most common cause of mortality in intensive care units and can rapidly lead to vital organ dysfunction, and death. It accounts for 40% of total ICU expenditure, with 18 million individuals dying each year from the condition.

The study included 782 patients and showed a sensitivity of 90.5% and specificity of 88.5%. The positive predictive value of the Intensix system was 71.5% and negative predictive value of the system was 96.7%.

The company will now be conducting additional studies to improve and validate the system. "We need to be able to judge the system in several different categories," explained Salomon. "Firstly, it has to be able to discharge a patient faster from the ICU compared to manual review. It then has to improve costs dramatically and lower the usage of expensive medication. We need to see all those priorities evidenced in clinical trials."

Most recently, Intensix completed an $8.3m Series A financing round led by Pitango Venture Capital. Salomon said the funds would be used to expand and accelerate the development of the platform. "We are planning to increase our development team as we need to double the team in less than year. We also need to support different clinical studies going on, we started in the US market but we're progressing towards Europe. These funds will also help us to start building our commercial team including sales and marketing. So we're going from being a small startup which is focusing only on R&D to a company that is ready to do business from next year."

The Israeli start-up is also conducting an interventional study in Tel-Aviv Medical Center. Results from the prospective study showed that the platform could recognize deterioration before medical staff.

Salomon said: "We're taking the time in 2017 to conduct clinical trials in as many hospitals as we can and the idea is to install the system and let the team work at collecting more information so we are ready for commercialization which we plan to aim for 2018."

Published online 02/20/17

‘Selective’ JDRF Backs Israeli Injectable Blood Glucose Monitor

CATHERINE LONGWORTH catherine.longworth@informa.com

An Israeli start-up developing a long term injectable blood glucose sensor for diabetics has scored $1.9m from the Juvenile Diabetes Research Foundation (JDRF) to bring the product closer to in-human clinical trials.

GluSense’s *GlydeCGM*, a miniature implant injected under the skin, is expected to last for one year, taking blood glucose measurements continuously and transmitting the data wirelessly to an external wearable device. Calibrated glucose measurements are then displayed on the wearable device and transmitted to a smartphone application.

The technology is still at an early stage but the firm – which emerged from the Israeli incubator Rainbow Medical – has already attracted several investors. To date, it has raised around $15m including financing from four Chinese investors - Ping An Ventures, ZTE, Keytone Ventures and Rongan.

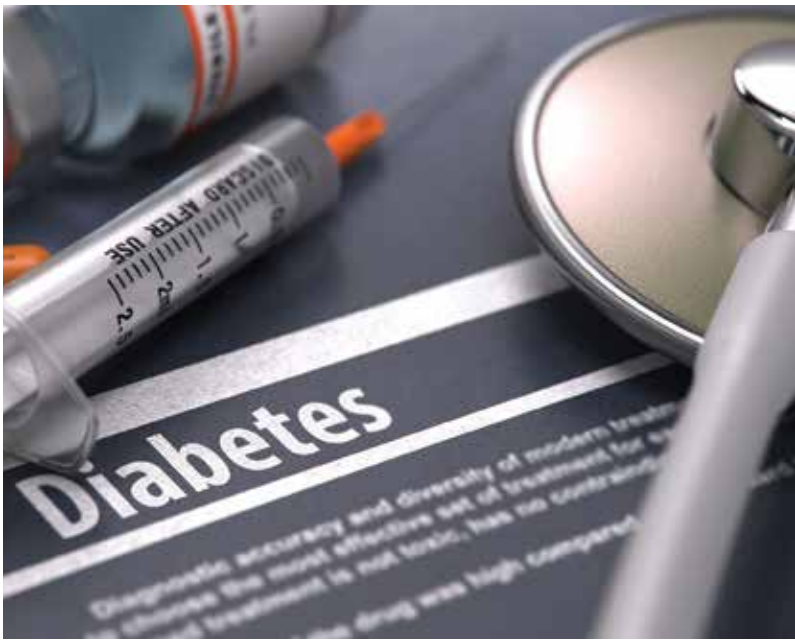
“This [latest JDRF] investment is a huge recognition for us and our technology,” GluSense CEO, Boaz Brill told *Medtech Insight*. “The JDRF are very selective and it took time for us to convince them that this technology would really work. There was almost 10 months of due diligence until we got the green light so this is a huge win. Our main focus now is getting the product ready for clinical studies and this investment will help push the product out to humans.”

The JDRF T1D fund is a new venture philanthropy fund dedicated to supporting early-stage Type 1 diabetes treatments. Early animal tests of the device showed that the technology was able to provide high-accuracy measurements and long-term viability. The firm is now aiming to begin further pre-clinical studies in late 2017, then move to human studies in 2018. “The end goal is to have at least a one-year implantation, but we will start smaller with three months and six month studies,” said Brill.

“Hundreds of startup companies have tried to develop noninvasive glucose sensors and have all failed. The reason is because all of them had a very small, unspecific signal and were not able to deal with the noise of real life measurements. On the other hand, currently marketed Continuous Glucose Monitors (CGMs) are also inherently limited - they use an enzyme that takes up the glucose and creates electric charge based on interaction between glucose and oxides,” Brill explained. “But after some time you have issues when the glucose oxidase runs out or the tissue gets blocked or the oxide diffuses too slowly, which all affect the measurement.”

“The model GluSense is developing is completely different, it’s not based on an electrical measurement. Instead, we are setting out to provide a long term glucose sensor using an optical measurement, based on a fluorescent molecule.”

Glyde’s glucose detection uses a fluorescent protein that is sensitive to glucose and consists of three parts - two fluorophore groups and a glucose binding domain. As the glucose binds to the glucose domain of the fluorescent protein, the optical properties of the biosensor changes using the Fluorescent Resonant Energy Transfer (FRET) effect.



Shutterstock: Brian A Jackson

To overcome the challenge of maintaining long term sensor functionality, the device has been designed to include engineered live human cells that continuously replenish the fluorescent protein, ensuring fresh biosensor is always available. “We’re designing this product without any expiry date so we’re trying to make everything work if possible without any limitation,” said Brill.

The stable biosensor aims to free diabetics from the multiple calibration finger pricks currently needed for glucose measurement in CGM’s. “There are many products on the market right now for diabetes but they must be replaced frequently and require having to prick your finger repeatedly. This is a very limited way to manage diabetes long-term for patients and our technology would minimize this need for frequent calibrations.”

A physicist by education, GluSense CEO Boaz Brill, completed a PhD in Physics from the Weizmann Institute of Science in Israel and spent several years in the semi-conductor industry before heading into medical devices. “I was looking for a new adventure and medical technology seemed to me like the most interesting and fulfilling thing and the best way to apply my skills and experience in developing high accuracy measurement tools,” he said.

“We believe that we have a really groundbreaking technology that could be viable for very long-term use and now with the help of the JDRF we can finalize development to help improve the life of people living with diabetes.”

Published online 02/16/17

Over 100 event types

Over 100 catalyst types

Over 5,000 products

Meddevicetracker
Pharma intelligence | informa

Double the Power

Meddevicetracker with Medtech Insight reports is a new interactive real-time source of in-depth medical technology market intelligence

Meddevicetracker brings you closer to the medtech market, helping you to:

- Identify upcoming device regulatory events/filings
- Search for medtech clinical trial starts and data
- Find historical and forecasted procedure volumes data
- Monitor drug delivery technologies and identify partnership opportunities
- Quantify the market size for devices or diseases
- Discover forecasted market share of devices by type
- Understand the device competitive landscape and identify unmet clinical needs

Request your free demo today:
please visit - **www.meddevicetracker.com**