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Full Steam Ahead On Medtech Value-Based Business Models

DAVID FILMORE david.filmore@informa.com

US health-care policy is headed for some potentially big changes, but that is not causing medtech executives to signal big changes of their own to how they approach the market. In particular, industry's move to adopt new value-based business models seems to be continuing at pace, according to interviews and comments at the JP Morgan Healthcare Conference and satellite meetings in San Francisco last week.

Not only is the Affordable Care Act under threat of repeal under the incoming Trump administration, but some payment and delivery reforms that have been rolled out by the US Centers for Medicare and Medicaid Services in recent years are vulnerable, as well. Those CMS reforms force the hands of health-care providers to adopt practices that reduce costs, and maintain or improve outcomes.

Tom Price, the Georgia Republican congressman who has been nominated by President-elect Trump to run the Department of Health and Human Services, is a vigorous opponent of these types of mandatory programs, including the recently launched bundled, episode-of-care payment programs for joint replacements and cardiac procedures. *(Also see "Fierce Critic Of Obamacare, Medicare Delivery Reforms Tapped To Run HHS" - Medtech Insight, 29 Nov, 2016.)*

But these political signals are not changing plans by device firms to bet big on the types of incentives that such payment reforms create. This is because the push away from volume-based care to value-based approaches are already sufficiently entrenched in the health-care market. And it is a global trend, so the market impact of any policy adjustments in the US is muted.

J&J'S CAREADVANTAGE

Case in point, Johnson & Johnson announced on Jan. 10, the first day of the JP Morgan meeting, a new branded offering of value-based service offerings and risk-sharing opportunities for hospitals for its entire medical device business. The *CareAdvantage* program is designed to offer hospitals a clear opportunity to contract with J&J, not just as a supplier, but to provide services that allow use of its devices and after-discharge care in a more efficient and effective manner.

Specifically, the firm cited the current HHS goal to have 90% of Medicare fee-for-service payments directed toward value-based purchasing approaches by 2018. A particular set of services J&J is offering for orthopedic procedures responds directly to CMS' recently launched

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UK health technology body NICE will wait for the government to finalize its life-sciences strategy before deciding whether to go ahead with its plan to levy a fee for technology appraisals. Medtech companies say the delay will allow more time for their concerns over the proposal to be explored.

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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
MARION WEBB @MEDTECHMARION
marion.webb@informa.com
SUE DARCEY @MEDTECH_INSIGHT
sue.darcey@informa.com
FERDOUS AL-FARUQUE @MEDTECH_DANNY
danny.al-faruque@informausa.com
ELIZABETH ORR @ELIZABETHJORR
elizabeth.orr@informa.com
CATHERINE LONGWORTH @MEDTECHCATE
catherine.longworth@informa.com
ASHLEY YEO @ASHLEYPYEO
ashley.yeo@informa.com
MAUREEN KENNY @SCRIPREGMAUREEN
maureen.kenny@informa.com
NEENA BRIZMOHUN @SCRIPREGNEENA
neena.brizmohun@informa.com
VIBHA SHARMA @SCRIPREGVIBHA
vibha.sharma@informa.com
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

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GE Healthcare Extends Portfolio With First App-Based Ultrasound Device

CATHERINE LONGWORTH catherine.longworth@informa.com

GE Healthcare has extended its ultrasound portfolio with the launch of a new-generation handheld device with wireless capabilities.

Vscan Extend joins the company's Vscan family and is the first app-based ultrasound device to use wireless connectivity to integrate with hospitals DICOM systems. The portable device weighs 406g and includes two ultrasound probes built into the transducer head which is connected to a touchscreen smartphone interface.

The device has been designed for a number of clinical uses, including assessing heart failure patients and measuring bladder volume. Dr Guy Lloyd, Head of Echocardiology at Barts Heart Center in London, told *Medtech Insight* the wireless functionality made it a "key differentiator in the market."

"This device is a complete game changer. We've been using GE Healthcare's Vscan family for years but they've always had major limitations," said Lloyd. "Other devices have not been able to communicate with hospital systems and consequently it's difficult to build the device into a care pathway. Vscan Extend reinvents that because it moves imaging into an integrated imaging platform on DICOM so the machine can communicate with hospital systems on a universal platform anywhere. Any hospital in the world can take this format of imaging and integrate it into their hospitals information system, so you can start to have whole pathways joined up in which images are available."

Lloyd said this wireless communication could lead to more rapid diagnostics. "It's ideal for when patients have a binary question like yes or no that needs to be answered. For example, is the heart function good or bad? Or, is there fluid around the heart?" he explained.

"When we can answer these questions rapidly it helps with reducing the number of inappropriate and false scans that are carried out and gets people out the hospital faster. It's also financially good as you can then deploy your resources where its most valuable."

Lloyd said the device's main limitations were that it was only valid for systems with DICOM configurations and required further training for complex clinical questions. "If you're wanting detailed questions on heart function, then you need to have people using it with appropriate training to understand and interpret the image. Understanding what you are looking at and understanding the limitations of what you can't do on this sort of device is absolutely vital."

"We are developing further training programs for this platform. The technology comes first and how to really appropriately deploy it sometimes runs a bit later. In a sense it can only guide the diagnosis so far. However, there's really good evidence to show that if you add in handheld ultrasonography with clinical history and ECG you will get much closer to an accurate diagnosis even if its carried out by relatively inexperienced people. So as long as your care model is right you can take this device anywhere you go with a broadband connection."

He continued that due to Extend using a smartphone platform, there is potential for education and referencing apps to sit alongside it. "Not only can the images be reviewed elsewhere easily but they can be taken to meetings and used for auditing quality and reliability."

GE Healthcare told *Medtech Insight* earlier Vscan generations had already generated substantial interest from healthcare providers in rural territories due to the portability. The company now envisions Extend improving patient management in remote locations.

"We can see this technology moving out of hospitals and into the community where you could be offering some form of community diagnosis with expert review done remotely so it kind of explodes the possibilities of handheld ultrasonography," Lloyd added.

"If you were running a heart failure service in a remote environment and you needed to know who you should see urgently to pick out the bad ones, you could easily deploy somebody with expertise to go round in a car and scan people, then beam back the images to a hospital and make a decision."

With internet security threats increasingly occurring, GE Healthcare said data security had been of "critical importance" when designing the device. It said Extend had the highest level of encryption to ensure security and privacy. Patient images were also kept anonymous and patient information database encrypted to FIPS 197 standard.

Vscan Extend is CE marked and now commercially available in Europe and will launch in the US at the end of Jan.

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Comprehensive Care for Joint Replacement (CJR) and the Surgical Hip and Femur Fracture Treatment (SHFFT) bundled-care models, which put providers on the financial hook for the cost and quality of episodes-of-care, extending from a procedure through after-hospital rehabilitation. *(Also see "Cardiac Care Bundled Pay Models Preserve New Tech Add-Ons, But Still Make Medtech Nervous" - Medtech Insight, 5 Jan, 2017.)*

"There are three things that are raised around the foundation of the Affordable Care Act … the 'triple aim' of improving patient outcome, improving patient satisfaction and improving cost. Those truths will happen no matter what administration is in power," Gary Pruden, worldwide chairman of J&J's medical device business, told *Medtech Insight* in an interview during the JP Morgan meeting.

"Offering solutions that help solve those basic three problems are going to be an opportunity no matter what happens," he stressed.

CareAdvantage is J&J's effort to bring together the service capabilities of its vast businesses under a coordinated, branded framework. It's intended as a go-to mechanism for hospital systems to engage with the company as more of a strategic partner, Pruden explained.

To illustrate, he described a meeting he had with the CEO of a large US hospital system several years ago. "The CEO said, 'You know, until today, I never realized that J&J was our largest supplier,'" Pruden relayed. "He said, 'In the past you came at me with 20 different brands of individual companies. If I actually knew that you were my largest supplier, maybe we could have worked together in a different way. Maybe we could think about how we become partners.'"

Under CareAdvantage, J&J will work with interested hospitals in coming up with solutions to improve care efficiency and effectiveness, potentially across its orthopedic, surgery and cardiovascular device businesses. But the firm is laying out the most details about its offerings in the orthopedic space, where its program is designed to match up with the recently launched Medicare bundled-payment programs. J&J says it can offer hospitals pre- and post-orthopedic surgery services, including a cloud-based digital platform, to help guide patients through surgery and recovery; Depuy Synthes' *Patient Athlete*coaching-based program to prepare patients for surgery; data analytics support for tracking patients' hospital and post-discharge episode-of-care; infection risk management support; and hip-fracture care.

> "There are three things that are raised around the foundation of the Affordable Care Act … the 'triple aim' of improving patient outcome, improving patient satisfaction and improving cost," J&J's Gary Pruden says. "Those truths will happen no matter what administration is in power."

J&J will also enter into risk-sharing agreements specifically linked to the bundled-payment spending and quality targets set by the new CMS programs.

BREADTH AND SCALE

Pruden says the breadth and scale of the J&J device business is a core factor in making the CareAdvantage program attractive to hospitals. Because the firm is the No. 1 or 2 supplier for many customers, it is worth their while to arrive at the most efficient way to employ those products. Also, he says the experience J&J has in its other businesses – in particular, the consumer business – contributes to its value-based offering.

"We are looking to leverage some of the learnings that we have from our consumer division in how we can engage patients in a better way," Pruden said.

J&J is, of course, not alone among the larger medtech firms in making a shift to value-based models. Medtronic PLC has emphasized its transition to a solutions-based company for several years, and, in 2013, it launched a dedicated Hospital Solutions business unit, principally to contract with hospital cath labs, to improve efficiency. In November 2016, Medtronic inked its first Solutions agreement in the US, with the Cleveland-based University Hospitals system, with a focus on implementing new models to optimize workflow in the system's cath and electrophysiology labs.

The other big players are accelerating their emphasis on these approaches, as well.

Robert Ford, who heads Abbott Laboratories Inc.'s medical device business, which just expanded greatly to include St. Jude Medical Inc., says risk-sharing has become routine among medtech players, and he doesn't expect that to change.

"I don't think it's extremely differentiated that you're saying to a customer, 'Listen, if you don't get this outcome, I'll give you … 45% of the cost back,'" Ford told *Medtech Insight* at JP Morgan. "From a differentiation standpoint on that value-add, I think there are other elements that will be important here."

He noted: "I think you do need to surround disease states with a service and a value proposition that goes just beyond, 'Hey, I've got this great device that all of your implanters and surgeons really want to use.'"

Abbott's acquisition of St. Jude provides new opportunities for the company

to target those types of opportunities, he suggested. For instance, he explained, Abbott can work with hospitals to improve overall care of heart-failure patients by bringing together the combined firm's technology and know-how in cardiac resynchronization therapy, heart-valve repair, ventricular-assist devices and *CardioMEMS* remote monitoring.

Ford said Abbott will also be exploring opportunities in multiple businesses to offer services to hospitals, leveraging the vast quantities of data produced by the firm's devices.

NOT JUST FOR BIG MEDTECH

But it is not just the big companies that are accelerating efforts toward value-based models. Industry experts say it is crucial for small, mid-sized, and large firms alike to understand the full value proposition for devices in development and use that understanding to drive how they approach customers. That has not historically been standard practice in industry.

One start-up that is making this approach central to its business model is Bruin Biometrics, a wireless sensor-focused device firm founded out of the University of California, Los Angeles, in 2009.

"We develop sensors ... for areas that are very deficient in diagnostic standards," CEO Martin Burns told *Medtech Insight* during a discussion at the JP Morgan conference. The firm's first focus is in wound care; specifically, pressure ulcers.

Bruin's *SEM Scanner*, available in Europe, is a handheld, portable device that assesses the layers below the skin to detect changes in sub-epidermal moisture (SEM), a biophysical marker of tissue damage. The idea is to identify previously unspecified pre-stages of pressure ulcers before they reach the level of being more difficult and expensive to treat.

The firm says it is having early success with risk-sharing agreements in places like the UK, and it is about to expand on that approach in a big way. By the end of the month, Bruin plans to announce a risk-sharing agreement with a UK health-system partner that will include 60,000 to 80,000 patients. "We are very much putting our skin in the game," Burns said.

> "Some of the policies we enjoy the benefit of sits underneath the Affordable Care Act. Most of it, however, doesn't," says Martin Burns, CEO of Bruin Biometrics.

The firm plans to take the same basic approach in the US. Bruin is going to submit for FDA approval under the *de novo* pathway by the end of the current quarter and plans to be on the market in 2017. Burns acknowledges that there are differences in the US market and that a shift is coming with the Trump administration that his firm will need to monitor closely. But similarly to J&J's Pruden, he says the fundamentals will stay the same.

"Some of the policies we enjoy the benefit of sits underneath the Affordable Care Act. Most of it, however, doesn't," Burns said. For instance, pressure ulcers in stages three and four are designated as "never events," meaning Medicare won't pay to treat when they are acquired in a hospital. That policy came before ACA, and he doesn't believe it is going away.

"The other part that is not under jeopardy," Burns said, "is that, if you are negligent, you should pay for your own negligence. There is a focus on not having certain events occur within a care setting, and I can't see that changing."

VALUE-BASED ROADMAP

But not all companies, in particular, start-ups, are as prepared to address these types of value-based incentives. AdvaMed says it is trying to improve that situation. The device trade group is currently putting the finishing touches on two "value frameworks," one for medical devices and another for diagnostics.

Andrew Fish, who runs the AdvaMed-Dx arm focused on diagnostics, spoke about the tools, which the group plans on releasing soon, at the Medtech Showcase meeting Jan. 10 in San Francisco. (Medtech Showcase is run by EBD Group, an Informa company. Informa also publishes *Medtech Insight*.) He says they will be practical roadmaps designed to help firms think about the value proposition for their products, starting in the R&D phase, and how that value can be presented to different stakeholders, including patients, clinicians and hospitals.

"What we have seen is some manufacturers have historically brought products to market because they could, they had the technology, the ability to iterate … but they had not necessarily thought enough about what the ultimate clinical value of that was," Fish said. "The value framework that we put together really helps companies state vigorously from the very beginning what the value of the product is and how to demonstrate it, long before you get to that point of trying to get market traction."

AdvaMed traditionally has focused its efforts on changing government policy, which it will continue to do, but its work on the value frameworks is another sign pointing to the importance of incentives coming from the health-care system and private payers in setting market dynamics, Fish suggests.

"This value framework is in part an exercise in communicating to a wide range of stakeholders in the private marketplace, Fish said. "That is really a change in perspective for us, because it is a recognition that that is one of things our companies are grappling with."

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New PIP Court Ruling Sends Further Shockwaves Through EU Medtech Sector

AMANDA MAXWELL amanda.maxwell@informa.com

EU notified body TÜV Rheinland LGA Products has been ordered by the commercial court in Toulon, southern France, to pay €60m ($64m) in compensation to 20,000 women implanted with the defective PIP breast implants,

On Jan. 20, the court ordered the German notified body to pay €3,000 to each plaintiff, according to news circulating in Europe. This is apparently an initial compensation, with the final assessment yet to be determined.

One lawyer representing some 13,000 women, Olivier Aumaitre, is reported to have said the outcome was inevitable.

TÜV Rheinland, meanwhile, states that the court ordered payment of provisional amounts to persons claiming to be former foreign distributors of PIP breast implants/foreign clinics/sales representatives of PIP/and plaintiffs who allege having received PIP silicone gel breast implants.

It is planning to appeal the ruling; it is hopeful of success, given the precedents, and that the European Court of Justice's final ruling – still to come – will be in its favor. TÜV Rheinland has also filed a criminal complaint against PIP and its former managers.

There has been a great deal of controversy over whether the German notified body should be found liable for these products after the manufacturer of the PIP breast implants went bust. The French manufacturer, Poly Implant Prothèse, had replaced the approved medical-standard silicone gel with industrial-standard silicone gel – a substance with unknown medical risk – in its implants. It is not clear whether notified body responsibilities would have covered action that could have uncovered such fraud.

HERE WE GO AGAIN?

There is a sense of déjà vu with this news.

In 2013, the Toulon court had ordered TÜV Rheinland to pay €53m to 1,700 recipients of the PIP implants and to six foreign distributors of the implants.

But that ruling was overturned in 2015 by an appeal court in Aix-en-Provence. TÜV Rheinland is counting on the same happening again.

The numbers of plaintiffs in this case have grown more than tenfold, compared with the 2013 case, and the women in this latest case have reason to be hopeful that they will gain financially whatever the eventual outcome. This is because TÜV Rheinland had paid the 1,700 plaintiffs in 2013 some €3,400 each before the ruling had been overturned. It seems that they have not sought to recoup this money.

WHY THE INITIAL RULING WAS OVERTURNED

In the 2015 ruling, the appeals court in Aix-en-Provence considered that TÜV Rheinland had been misled by the French manufacturer of the defective breast implants. In every other

The German Federal Supreme Court (BGH) referred this issue to the European Court of Justice on April 9, 2015. The BGH has asked for guidance on the responsibilities of notified bodies under EU medical devices legislation. The opinion of the advocate general at the EU Court of Justice could have an impact on whether the ECJ, in its final ruling, finds TUV Rheinland liable and on whether it is ordered to pay further damages.

What EU Rules Say About Notified Body Liability

The current Medical Devices Directive 93/42/EC (MDD) says very little about the criteria that must be met by notified bodies. These are spelled out in a single page in Annex XI of the directive. In terms of insurance, the directive simply states that the notified body must "take out civil liability insurance unless liability is assumed by the state under domestic legislation or the member-state itself carries out the inspections directly." The extent of that insurance is not regulated in the MDD, nor is it clear under what circumstances a notified body could be found to be liable. Civil liability insurance is coverage against civil claims for damages such as harm caused through negligence, product liability or some other form of consumer redress.

Meanwhile, the near-final text of the forthcoming Medical Devices Regulation is much more detailed about criteria that must be met by notified bodies.

The question of liability insurance is dealt with in Annex VI, 1.4 of the MDR text, "Requirements To Be Met By Notified Bodies." This section repeats the wording of the MDD, but talks of "appropriate liability insurance" instead of "civil liability insurance." Crucially, it goes further, stating, "The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates." But the regulation says nothing about potential liability with regard to patients, as is relevant to the TÜV Rheinland PIP case

respect, the appeals court found, the notified body had fulfilled its obligations and could not be held responsible for failing to detect PIP's undercover operations. The court lay the blame for the faulty implants firmly and solely with the Poly Implant Prothèse.

Having found itself back at square one in the Toulon court, TÜV Rheinland lawyer Cécile Derycke said that the court was persisting in ignoring very clear findings of the PIP case that establish that TÜV Rheinland "performed its mission … diligently and in total compliance with the applicable regulations."

She added: "In such circumstances, granting provisional amounts and the preliminary enforcement of the judgments are irresponsible and shall be firmly challenged before the Court of Appeal."

WHAT THE WHOLE CASE RESTS ON

TÜV Rheinland has long held that its role was only to inspect the manufacturing process and not to check the actual implants.

And this is the issue on which the whole case – which is also before the European Court of Justice – is likely to be decided.

What exactly had been the full legal responsibility of notified bodies at the time the PIP breast implants were being manufactured and before the Recommendation on notified body audits and the Implementing Regulation on the designation and supervision of notified bodies, published in September 2013, tightened up the requirements for notified bodies and their oversight?

The Toulon court in this case is reported to have said that if TÜV staff had carried out "the slightest unannounced inspection... the fraud would have been easily detected."

This matter of liability is still being reviewed by the European Court of Justice.

ANOTHER REASON FOR NOTIFIED BODIES TO EXIT THE MEDTECH SECTOR?

The German notified body will be shaken by this ruling and it will send shockwaves through the medtech sector and particularly through all notified bodies operating in this field.

Many notified bodies are struggling to manage the much tighter requirements that have been imposed on them since the emergence of the PIP breast implant scandal; and some are questioning whether they have the resources to cope with additional challenges that will come with the forthcoming Medical Devices Regulation.

The specter of this kind of liability, and of the inevitable hike in liability insurance associated with the outcome of this ruling, may make some notified bodies think even more carefully about remaining in this sector.

And what makes matters potentially worse is that the case comes at a time when notified body capacity is already too thin on the ground, and demand for notified body services is growing more than ever. Moreover, that demand will soar once the Medical Device and IVD Regulations are adopted, expected in March.

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South Africa Medtech Regulations Published – Vital Next Steps Still Awaited

ASHLEY YEO ashley.yeo@informa.com

South Africa's long-awaited "Regulations relating to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs)" were signed off by minister of health Aaron Motsoaledi, on Nov.14, 2016, and published in the *Staatskoerant* on Dec. 9. The emergence of this piece of dedicated medical technology legislation is a victory for stakeholders across the industry, and a testament to the patience and attentive follow-up of its supporters.

One group pressing for the legislation – which adds to and is part of South Africa's centerpiece health industry legislation, the Medicines and Related Substances Act 1965 (Act No. 101 of 1965) – is SAMED, the national medical technology industry association. SAMED executive officer Tanya Vogt has lobbied for dedicated medtech legislation that recognizes the differences with medicines for several years *(Also see "Wait goes on for regulation in South Africa" - Medtech Insight, 10 Sep, 2010.)*. Last fall, the first really positive news emerged from a Medicines Control Council workshop *(Also see "South Africa Finally Gets Medtech Regulations Over The Start Line" - Medtech Insight, 21 Sep, 2016.)*.

At that point, Vogt was guarded but optimistic about the progress being made. Almost more than anyone else, she is aware that potential barriers lie ahead, and the path yet to follow will require industry to work closely with the regulator to ensure the right outcome. The dedicated medtech regulatory system will only be complete once SAHPRA, the new regulatory body, is up and running. That was due to be as of March 2017, but there is a sentiment that this date, floated at the same MCC meeting, might now seem too ambitious.

Late last year, the MCC also set a timeframe within which medtech manufacturers/establishments were to have applied for a license – and also include a list of their products – with the MCC. It set a deadline of Feb. 28, but it now seems that this original date was only penciled in and in fact is to be superseded. The public will be notified of the new date in a future issue of the government gazette. The industry is now urgently seeking clarification of the procedures and timelines that companies should adhere to.

MCC registrar Joey Gouws says the government gazette notice should provide for a six-month period during which medical device establishments must secure licenses. And this notice will be

published upon publication of the overall body of the General Regulations for Medical Devices. This will effectively introduce a regulatory system in South Africa based on the principles of the International Medical Device Regulators Forum.

There is apparently more work to do yet. Nevertheless, as it stands the new Regulations relating to Medical Devices and IVDs keep the momentum going. They establish a framework that covers all technical product- and company-related issues for medtech companies within 28 content items. The key elements are the rules on:

- Obtaining a license to manufacture, import, export, or act as a distributor or wholesaler of medical devices or IVDs; and the period of license validity.
- The classification of medical devices and IVDs and registration certificates.
- Conducting clinical trials and clinical investigations.
- Adverse event reporting and vigilance.
- Labeling and IFU (which must "at least" be in English)
- Rules for custom-made medical devices.
- Recordkeeping for implantables and custom-made medical devices.
- Transitional arrangements for unlicensed manufacturers, distributors and wholesalers – and unregistered medical devices and IVDs.

DETAILS ON...PRODUCT REGISTRATION

The Regulations state that a person residing and doing business in South Africa may apply for the registration of a medical device or IVD, including the particulars of the authorized representative (AR) in South Africa who will be responsible for interacting with the MCC.

Products must comply with the Essential Principles for Safety and Performance of Medical Devices, which include requirements for quality, safety and performance, as determined by the MCC. An application for registration of a medical device or IVD must be accompanied by a declaration of conformity by the AR. Applications must be made in respect of each individual medical device or IVD, or medical device or IVD group or family.

Where a device or IVD is registered by a regulatory body outside South Africa, the applicant is to additionally supply: a certified copy of the certificate of registration or pre-market approval; IFU; and information on the conditions of registration.

Additionally, the MCC may require a device or IVD to comply with additional requirements with a view to ensuring the product meets its own Essential Principles.

...CLASSIFICATION OF DEVICES AND IVDS

Medical devices and IVDs will be one of: Class A, low risk; Class B, low-to-moderate risk; Class C, moderate-to-high risk; and Class D, high risk, the scale having been determined based on risk to the patient, user or to public health.

All devices, except custom-made, must be registered with the MCC before they may be sold or used in South Africa. The MCC determines the classification of medical devices and IVDs in accordance with the classification rules.

For Class D implantables and high-risk, custom-made devices, a permanent record must be kept on the premises by the institution or professional where the medical devices are sold to the patient.

...TRANSITIONAL ARRANGEMENTS

Manufacturers, distributors and wholesalers who were legally selling medical devices or IVDs in South Africa at the time of the commencement of the new Regulations are considered to be trading legally. The MCC is to make a call in the government gazette requesting the licensing of unlicensed establishments, including timelines. Similarly, unregistered device or IVDs at the time of the new regulations taking effect are considered to be sold legally on the same basis.

The MCC will issue notices in the gazette calling for the registration of certain types of devices and IVDs, stipulating the Class being called for registration and the conditions and time periods for application for registration.

In the spirit of continually educating the market and device users, SAMED and its IVDs counterpart SALDA are to host a regulatory forum with the Global Medical Device Nomenclature agency on Feb. 2, 2017, at which GMDN agency technical lead Barry Daniels will give an overview of GMDN, and Gouws will discuss why the South Africa has chosen to use the GMDN system.

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FDA Cracks Open Door For More Manufacturer Communications

ELIZABETH ORR elizabeth.orr@informa.com

US FDA issued two question-and-answer format draft guidance documents, on Jan. 18 that attempt to clarify the agency's stance on manufacturer communications in a range of circumstances.

The first draft guidance explains how FDA expects manufacturers to discuss investigational products with insurance companies and other payers. The second reviews the agency's thinking on how firms should communicate information that isn't contained in FDA-cleared labeling, but still relates to cleared uses.

The draft guidance on communications with payers lays out types of information that FDA will let manufacturers share when discussing unapproved products, as long as it's true and not misleading. This information includes basic product data such as a device's design and price; information about the indication being sought, such as the planned clinical study protocol, including the endpoint being studied as well as the patient population under investigation; factual presentations of trial results; and planned marketing strategies or product-related services.

In addition, FDA strongly suggests manufacturers clearly inform payers that the product is still under investigation. The communication should include the product's development stage, and be updated as needed, FDA says.

Meanwhile, the guidance on communicating information that isn't in the labeling notes that the area requires manufacturer caution. While information consistent with product labeling doesn't prove a new intended use, FDA says, "a communication that is consistent with a product's FDA-required labeling could nonetheless misbrand the product and subject a firm to enforcement action if the representations or suggestions made in the communication are false or misleading in any particular."

Under the guidance, information is considered "consistent" with approved labeling if it passes a three-pronged test. The key questions are whether the information differs from the labeling in areas such as indication for use or suggested patient population; whether it could cause a greater health risk than the approved labeling; and whether the approved directions for use allow the product to be safely used in the way suggested in the communication.

Potential appropriate topics for these communications include additional information on the product's long-term safety, context about adverse reactions or information about the product's use in a specific patient subgroup.

Overall, the documents are a "positive step" that should offer manufacturers more clarity on the agency's communications policies, says Anne Walsh, an attorney and director at Hyman, Phelps & McNamara.

"They include more overt leniency about some statements and claims industry can make," Walsh, who was previously associate chief counsel at FDA, says. "For example, they consistently suggest that you could make a statement about the onset of benefits even if that wasn't allowed in the labeling because it was before the trial endpoint."

She also noted that, because the documents are in draft form, manufacturers will be able to comment and change any trouble spots. But she sees little cause for concern so far.

"Before these drafts came out, there wasn't enough clarity on this issue, just a lot of questions," she said. "This makes it easier to see where FDA is headed."

Trade group AdvaMed is still reviewing the documents, but the association is generally supportive of FDA's efforts to help stakeholders understand its policies and improve scientific discourse addressing the public health, said Khatereh Calleja, senior vice president, technology and regulatory affairs.

"As the agency has acknowledged, the public health can be served with truthful and non-misleading scientific and medical information on medical products," she said.

FDA will accept comments on both guidance documents at Regulations.gov until April 18, for the payer guidance under docket FDA-2016-D-1307, and for the consistent communications guidance under docket FDA-2016-D-2285.

OFF-LABEL DOCKET REOPENED

Both documents specifically exclude off-label communications, but the agency is re-opening a comment period on communications about off-label uses that was opened in conjunction with a November hearing on the subject." At the meeting, the agency heard both from manufacturers frustrated that they couldn't get pertinent information to physicians and patients, and patients who feared off-label uses would pose health risks. *(Also see "US FDA Hears Competing Messages On Off-Label Communications" - Medtech Insight, 11 Nov, 2016.)*

The docket is being reopened, FDA says, "to allow interested parties an opportunity to review the two draft guidances before submitting comments to any of the relevant dockets." As part of the reopening, FDA released a new memorandum giving additional background on key issues FDA is considering in reviewing its policies on off-label marketing. The memorandum looks at how FDA tries to find a balance between First Amendment rights and protecting the public health.

The off-label communications docket is open at FDA-2016-N-1149 until April 10.

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Q&A: AdvaMed Gears Up For 2017

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

As the administration of Donald Trump takes the White House, JC Scott, head of government affairs at AdvaMed, sat down with *Medtech Insight* to talk about the trade group's ongoing lobbying to repeal the 2.3% medical device excise tax and how it hopes 2017 will shape up under a new president and Congress.

Also, several names have been floating as potential candidates to lead FDA but Scott declined to name any preferred nominee stating he hopes the cultural shift that has taken place at the agency the past few years continues.

LISTEN
Listen to the full Jan. 18 interview at http://bit.ly/2jZvjwM


Photo credit: AdvaMed

JC Scott

"We've seen now a better trajectory at the agency over the last couple of years, more specifically under Dr. [Jeff] Shuren's leadership at the device center," he said. "We've seen what I would call some degree of cultural change that goes all the way down to the individual reviewer level and what we hear increasingly from companies is more positive interactions, better communications, better predictability.

"We would hope that whoever comes into the role as commissioner would want to continue that positive trajectory, would want to continue that work that's been ongoing now for the last few years at the device center," added Scott.

Listen to the full Jan. 18 interview in the player, or scroll below for a full transcript.

Medtech Insight: First of all we'll just dive right in, you are still on the offensive to try permanently repeal the medical device tax. We've already reported on much of that. Will you tell our listeners what steps are next?

JC Scott: We are very much continued to be focused on repeal of the medical device tax. As you all have reported on before, the tax was suspended at the end of 2015. That suspension expires at the end of this year so for us it's critically important that it be fully repealed and that that happens early this year. I'll say as a starting premise we're really appreciative that Congress suspended the tax in 2015, we've seen a lot of good outcomes as a result of that. Companies have put money back into research, back into innovation and we've been trying to share those stories on Capitol Hill with policy-makers. It's important often times to connect the dots between a policy-outcome and the real-world outcomes that flow from them.

But all of these positive outcomes of the device tax suspension are really in the nature of short-term investments because there's no certainty on what's going to happen next. The short-term suspension is not going to accomplish the same goal as a permanent repeal in terms of unleashing job growth, unleashing future innovation. And individual companies are already making important planning decisions for the years ahead. I think you know this because you've been around the industry for a long time but it's like a ten-year proposition to get a new innovation from the bench to the bedside.

> "The short-term suspension is not going to accomplish the same goal as a permanent repeal in terms of unleashing job growth, unleashing future innovation."

So to sustain a viable R&D pipeline, companies have to budget differently and that means they can't create permanent jobs based on a temporary policy. So medical device tax continues to be something we're focused on as a top priority on Capitol Hill. We're continuing to tell that story and hopeful that sooner rather than later perhaps as part of this Affordable Care Act reconciliation exercise that it'll be an opportunity to do away with the tax completely.

Do you guys currently have a headcount on how many lawmakers are on

board with you and what is your confidence level on the device tax repeal?

Scott: We're operating with a high degree of optimism that there's broad awareness of the negative impacts of the medical device tax as a policy but you never take anything for granted. And your question always becomes one of context and vehicle when you're talking about decisions that they make up on Capitol Hill.

I can give you some numbers just for additional context. So in the House, as something of an exercise in just reaffirming the support that exists for repealing the device tax, we saw congressman Erik Paulsen of Minnesota, Ron Kind of Wisconsin, reintroduce their standalone repeal legislation. That's up to 235 co-sponsors at this point. Senators [Orrin] Hatch and [Amy] Klobuchar introduced similar legislation just last week in the Senate, 10 co-sponsors on that now.

And then you could look back over the last couple of years right? The bill in the last Congress had 283 co-sponsors. They had a vote on it in the House. It passed with 280 aye votes in the House. And I would just note on the side I think there were about a dozen supportive members who were actually out of town that day. It was right around the same time as the unfortunate shootings down in South Carolina so some folks had to miss that vote.

But it tells you with those members in town you would have been over a veto-proof majority. All that is to say broad strong bi-partisan support for doing away with the tax, now it's just a question of how and where that occurs.

So beyond this tax, what are some Congressional priorities, some priorities maybe in regards to FDA that you have in this coming year?

Scott: I certainly don't want to leave anyone with the impression that we are a single-issue association. If you'll bear with me a little I'll give you a little bit of color, commentary, on it.

As you look at the medtech innovation ecosystem in areas where we need to see policy changes in order to strengthen that ecosystem, sometimes it's helpful to look at it through some of our smaller and start-up companies. So there are what roughly 7,000 medtech companies in the United States, many of those are the smaller operations where the true new innovations are really being done. Fundamental to their ability to succeed is their ability to attract capital in order to sustain funding through the course of getting their product from that initial development stage to the point where it's being delivered to providers and to patients. And as I mentioned earlier, getting that initial R&D done, getting through the FDA review and approval process, getting some kind of coding and coverage decision out of CMS, you're in the neighborhood of at least 10 years for one of these newer PMA type of devices. Layer in a policy like the medical device tax at the tail-end of that, meaning that your very first dollar of revenue is taxed on your very first sale, it's making it more and more unattractive for venture capital investors to put money into these companies.

We just put out some data at the end of last year that we've seen some negative trends in that space. Since the early 1990s, VC investment in the industry has gone from about 13 percent in total VC dollars to about 4 percent in recent years. When you talk about the really early stage start-ups that are really dependent on that seed capital, it's gone from about 10 percent in the 90s to 3 percent in recent years, so it's going in the wrong direction. All that is to say there are a number of places where we need a better policy environment to have a better ecosystem for those companies to attract capital and to be able to develop product right. So that means continuing to see improvements in the way FDA operates, that means improving the CMS process to make it more predictable and transparent and certainly it means tax policies like the medical device tax.

Some of that can be done legislatively and some of it can be done through the administration. In terms of our Capitol Hill agenda I just highlight one piece of that ecosystem and that's on the FDA side because you asked about that specifically. We're in the midst of that five-year cycle where we have to reauthorize the user fee (MDUFA IV) agreement with the FDA.

We just completed that negotiation last year. We feel really good about the outcome of that negotiation in terms of what we agreed to with the agency, what we're putting forward to Capitol Hill because we think that it builds on the success we saw in the last user fee agreement and finally kind of righting the ship, if you will, at the device center at the agency and it's going to help us take that next step in continuing that trajectory. So we're hopeful that the Hill is going to be ready to act on that in the first half of the year and can get that reauthorized and continue onwards on that path with FDA.

Speaking of reauthorization with a new administration, do they have any concerns that they'd want to renegotiate any part of MDUFA IV before it goes to Congress?

Scott: We haven't seen any indications of that at this point and our message to policymakers has been very consistent. We continue to be committed to the agreement as we negotiated it. That's what we want to see move forward on Capitol Hill.

Well, as the new administration prepares to take the helm, how do you think that could change the way that you do your job and is there anything you're concerned with based on any sort of interaction with them?

Scott: No concerns. Part of the answer is, it's just too early to say right. We're a few days out from the swearing in. The new guys and gals are not yet even in place in their positions but I always look at these transition moments as opportunities. Opportunities to reset the conversation with the FDA, with

CMS, with some of these other agencies, and to go in and educate people what some of the historic challenges have been and how they might be able to do things differently.

So stepping back toward FDA and the new administration, couple of new names have been floating around for the potential next FDA commissioner. Based on your work, do you have any preference and qualities that you're looking for in the next commissioner?

Scott: Not specifically. But I would say, going back to an earlier part of our conversation, we've seen now a better trajectory at the agency over the last couple of years, more specifically under Dr. Shuren's leadership at the device center. We've seen what I would call some degree of cultural change that goes all the way down to the individual reviewer level and what we hear increasingly from companies is more positive interactions, better communications, better predictability.

We would hope that whoever comes into the role as commissioner would want to continue that positive trajectory, would want to continue that work that's been ongoing now for the last few years at the device center.

Another big position that might get filled is that of HHS secretary with Tom Price. Do you have any thoughts on his ability to lead the department, do you have any questions for him as his nomination is discussed?

Scott: Obviously he has some natural qualifications in the health-care space because he is a physician by training and I think that many people are aware that in the past he has expressed some concern with some of the movement toward the new value-based payment model, some of the payment reforms we've seen as part of the Affordable Care Act. And I would say from the industry perspective we want to make sure those are set up in the right way, but this is also where the industry is going as well right? It's no longer about just, for example with the CJR [Comprehensive Care for Joint Replacement] demo, selling the implant; it's about everything leading up to the procedure, it's about the post-surgery infection control and patient monitoring and all of the other services that medical technology companies are now bringing to the table when they're going to the hospital to sell their services as part of a procedure.

So we actually support that move to value-based purchasing and looking at outcomes because that's where the industry is headed; so we'd hope we'd have an opportunity to work with the new secretary if it's Dr. Price or someone else about what's good and what's not working as well in those arrangements.

> "I always look at these transition moments as opportunities. Opportunities to reset the conversation with the FDA, with CMS, with some of these other agencies."

Finally, if there is one lesson you want industry to take away as you continue your work over the next year, what would it be?

Scott: It's a fairly basic answer: If you don't engage you're not going to be heard.

And what we've seen I think resonates very well for us, going back to the device tax conversation through the course of the last year, is that individual companies were willing to stand up and say, "This is how the suspension of the medical device tax has impacted us in a positive way, let us tell you in a really concrete detailed way what we've been able to do with that revenue.

I can tell you from personal experience that is resonating on Capitol Hill, connecting those dots from the policy change to the outcomes gives policymakers something to ground their future decision-making in. So I would just encourage everyone in our space to continue to be engaged and be willing to stand up and have their voices heard.

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NICE Cost-Recovery-Plan Pause Is Welcome News For UK Industry

VIBHA SHARMA vibha.sharma@informa.com

UK pharmaceutical and medtech industry associations say they welcome the decision by health technology assessment body NICE to put on hold controversial plans to charge companies for technology appraisals until the government finalizes its strategy for the life sciences sector.

The pharmaceutical industry association, the ABPI, said it was pleased that there would now be more time for its concerns to be fully considered. It noted that it had raised a number of important points about the workability of the proposals. *(Also see "As Appraisal Fees Loom, NICE Says No To Industry Calls For Reform" - Pink Sheet, 22 Sep, 2016.)*

The ABPI's medtech industry counterpart, the ABHI, also welcomed NICE's decision to postpone the proposed HTA fee. It said a similar approach should be taken to fees proposed by the Medicines and Healthcare products Regulatory Agency. *(Also see "New UK Market Surveillance Levy Could Cost Medtech Companies Millions Each Year" - Medtech Insight, 3 May, 2016.)* "[Both] NICE and MHRA are world class organizations and should be critical assets for the UK in its ambition to become the destination of choice for the Life Sciences industry. Ensuring they are adequately resourced needs to be an integral part of a reinvigorated industrial strategy," the ABHI said.

NICE said discussions with industry bodies regarding its proposals had been constructive, but both the ABPI and the ABHI told *Medtech Insight* they had concerns about the negative impact the proposed HTA fee would have on small- and medium-sized enterprises. The proposal involves levying a fee of £142,000 (around $179,000) for all single and highly specialized technology appraisals; £210,000 for standard multiple technology appraisals; £282,000 for complex multiple technology appraisals and £99,000 for abbreviated technology appraisals.

Paul Catchpole, the ABPI's Value and Access Director, believes that introducing a flat-fee structure with high costs paid up-front would be "regressive" as it would place a disproportionate burden on SMEs. "This will potentially create inequalities in access to some medicines, including smaller population medicines for NHS patients. The time given for this consultation has not allowed us to work up alternatives, so we would propose that this is included in the next phase of review," Catchpole said.

The ABHI has concerns among other things over the affordability of the proposal in comparison to other countries, particularly for small-to-medium-sized companies. In addition, it said there was lack of clarity on what the HTA process would be for companies "that do not wish to pay fees." It further warned that the fee proposals by NICE and the MHRA to fund their core activities would increase the cost of doing business in the UK, saying such proposals ran counter to other initiatives, such as the development of the life sciences strategy that aims to support growth in the sector.

LIFE SCIENCES STRATEGY IN SPRING?

NICE said it had agreed with the Department of Health to wait for the government's life sciences strategy to be completed before any further action is taken regarding its fee proposal. In the meantime, it said it would continue to test its fee proposal against "the suggestions and challenges" identified by stakeholders during the consultation process. It chose not to elaborate, saying only that it was "considering a number of our proposals in light of our conversations with the industry representatives."

The ABPI understands that the strategy will be completed by spring. "NICE can play a key role in supporting a healthy life sciences industry in the UK and it makes sense [for NICE] to wait until the strategy is completed before finalizing, in insolation, the proposal for charging for appraisals," Catchpole said.

The ABHI explained that the forthcoming industrial strategy was expected to contain recommendations for the future role of NICE. The medtech association said it had submitted its views to the government on this front.

NICE explained that if and when it decides to go ahead with the fee proposal, the proposal would "need to be agreed by the Department of Health and Treasury before regulations are laid before Parliament and then implemented by NICE."

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COMPLIANCE CORNER:

Have Tech-Savvy People In Place For 'Live' FDA Inspections

SHAWN M. SCHMITT shawn.schmitt@informa.com

As more and more US FDA investigators conduct so-called "live" facility inspections, one industry insider is urging device manufacturers to make sure they have appropriately skilled individuals fetching and handling electronic information to be handed over to the auditors.

During a live inspection, the traditional process of hardcopy record review is circumvented when agency investigators request a live review of documents.

That means "FDA will be reviewing trending reports for quality metrics and quality data live during the inspection. This is very easy if you're in a sterile facility to look at the trending for environmental monitoring, for example, electronically. And FDA will review electronic documentation and records live in your IT system during the inspection," said Teresa Gorecki, practice lead at consulting firm Compliance Architects.

"The inspectional front room has to be able to manage live information, which means you have to have people who know the IT tools and how to navigate them, and how to find things quickly and explain them," she said. "And they must be familiar enough with the work that goes on in the IT tool that they can answer basic questions, and facilitate the conversation and the review of the document that is projected live on the wall.

"Because once the information's on the wall and it's live, the questions from the investigator are going to come," Gorecki continued. "If you're sitting there with that live view on the wall and you don't know the answer, then you must decide, well, do we go onto the next document? What do we do next? In this live inspection environment, your ability to be fast on your feet will be really, really, really important."

Gorecki formerly worked at Johnson & Johnson for 27 years, holding a variety of quality and compliance leadership roles.

"One of the lessons I learned in my last live inspection right before I left the industry was that it was important to find the right person to run IT tools well enough that they can orient the FDA investigator to what they're seeing on the computer screen," she said.

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"In some ways, you have to have empathy for an FDA investigator. They walk into 25 companies over a defined period of time. They might see the same electronic tool, but device firms have the ability to configure those things differently; all of the screens look different; firms put things in different places on these screens," Gorecki said.

"So, think about how, before you even open that first electronic record, you're going to have a person in the room and/or maybe an inspection aide that's been prepared to say, 'Here's the data initiation. Here's the data closure. Here's where you find this. Here's where you find that.' I think it's really important to be able to orient the investigators to what they're seeing on the screen."

During her final FDA inspection while at J&J, Gorecki witnessed an employee excel at using one type of software but flounder when using another.

"I watched someone who was very capable one day of using particular software with one type of record, and the investigator was relaxed, and it was a really calm environment. But on the second day we opened another type of record from a different electronic system. That same individual was nervous. It's not that they didn't have the expertise, but they were nervous, and their ability to calmly explain and orient FDA to what they were seeing was just not as strong," she said.

"On the second day of that inspection I remember leaving at lunchtime, walking into the lady's room, and looking at some of the people from the inspectional back room who were in the lady's room too, and I said, 'This was a rough morning.' It was a rough morning because that individual was nervous and had a tough time orienting FDA to what they were seeing," Gorecki said.

"Maybe if she had a job assist, maybe if we had selected another individual, then that morning would have gone a lot more smoothly and been a lot less frustrating."

Gorecki says if she was part of a live inspection nowadays, "and we were looking across most of the major quality systems, I'd make sure that in my back room I'd have a person who could run my change control module; my CAPA [corrective and preventive action] module; my nonconformance or deviation module; and all my different IT tools or pieces of tools in the QMS [quality management system]. I'd make sure I had the right folks there."

Comments from Gorecki came during a panel discussion at the 11th annual FDA Inspections Summit in Bethesda, Md.

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Atlas Genetics Fundraising Pulls In New Chinese Investment

CATHERINE LONGWORTH catherine.longworth@informa.com

UK point-of-care diagnostics developer Atlas Genetics Ltd. has raised $35m from an investor syndicate to finance US clinical trials and commercialization of Atlas' second diagnostic product, a combined chlamydia and gonorrhoea test that runs on the company's *io* electrochemical sensor technology.

The io platform relies on test-specific disposable cartridges and a small benchtop instrument to deliver results within 30 minutes. Atlas Genetics said the equity would also be used to expand cartridge manufacturing at **Bespak**, Atlas Genetics' cartridge manufacturing partner.

The investors include Consort Medical PLC, Novartis AG, Johnson & Johnson, which have all invested in Atlas before, and a new Chinese investor, **Wondfo Biotech Co. Ltd**. Wondfo is a Chinese in vitro diagnostic company based in Guangzhou, Guangdong Province. It was founded in 1992 as a research based company on the campus of South China University of Technology in Guangzhou and now develops a range of diagnostic assays including several POC tests.

Atlas received a CE mark for its first product, the *io CT* chlamydia trachomatis test in February 2016 *(Also see "Atlas First In Market With 30-Minute POC Molecular Test For Chlamydia" - Medtech Insight, 5 Feb, 2016.)* and expects it to be earn US FDA approval around the end of 2017. Atlas markets the test for primary care clinics and physician offices to increase the number of patients treated for the sexually transmitted infection. It was the first molecular POC test for an STI to enter the market and the first in Atlas Genetics pipeline of products.

In January, the company announced positive results its US beta study for CT on its rapid diagnostic platform. The beta site study aimed to assess the performance of the compared to a laboratory nucleic acid amplification test (NAAT), and to evaluate women's attitudes to rapid testing and willingness to wait for testing results. The study determined the company's test was more accurate than laboratory systems.

Atlas Genetics said it plans to roll-out new assays over the next few years. It plans to use its infectious disease platform to extend beyond STI's to a range of clinical areas and become a stronger player in the diagnostics market. *(Also see "Atlas Genetics Ready To Play Its Part In The POC Workflow Revolution" - In Vivo, 21 Dec, 2016.)*

Founded in 2005 as a spin-out from **Osmetech Plc** and the University of Bath, Atlas Genetics has a head office and laboratory facilities near Bath in the UK and a commercial office in Boston, MA. Prior to the Series D funding round, Atlas Genetics closed a $20m Series C round in January 2015, from first-time backer RMI partners and existing investor.

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US Sales Of Sinclair Pharma's Silhouette InstaLift–Off

CATHERINE LONGWORTH catherine.longworth@informa.com

Aesthetics company Sinclair Pharma PLC sales are growing rapidly following the US launch of its facelift product *Silhouette Instalift*. The non-surgical "one-stitch" facelift is performed under local anaesthesia and involves inserting a series of threaded biodegradable cones into the face to gently tighten and lift the skin.

Instalift launched in August 2016 via Sinclair's distribution partner **Thermigen**, the aesthetics subsidiary of pharma group Almirall SA.) The procedure aimed to complement Thermigen's existing aesthetic offering *ThermiTight* - a micro-invasive, single procedure for the neck and other body areas.

The company reported year-on-year headline growth of 51% with sales of £37.8m in 2016, compared to £25m in 2015, the company reported Jan. 17. Instalift was originally earmarked as a potential major revenue growth driver for Sinclair but exceeded analyst's expectations in 2016 with recorded sales of £1.3m. London advisory firm Peel Hunt forecast sales of £0.3m for InstaLift in 2016.

"We've had extremely good feedback from doctors. It started with key opinion leaders in the US showing enthusiasm for the product which led to large stocking orders," Andy Crane, Head of Investor Relations at Sinclair Pharma told *Medtech Insight*. "This strong interest from physicians shows the potential for further growth in 2017. We currently have 160 doctors in the US trained on using InstaLift and aim to increase that number significantly this year."

Sinclair have indicated interest in eventually regaining the distribution rights to Silhouette Instalift. "Depending on the outcome of sales and our agreement with Thermigen, we could buy back rights to enter the US market by 2019," Crane said.

The company also has other products in the pipeline, including *Ellansé*, a next-generation collagen stimulator which the company hopes to launch in 2019. Under the terms of the agreement, Thermi were granted four-year distribution rights for the US market until mid-2020. Sinclair also retained an annual option, after year three, to repatriate the rights.

More details of Sinclair Pharma's sales and earnings will be released on 21 March.

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Abionic's New POC Sepsis Test On Rapid Move To Market

CATHERINE LONGWORTH catherine.longworth@informa.com

Swiss start-up Abionic SA, has secured CE marking for two point-of-care (POC) tests assessing sepsis risk and iron deficiency.

The two tests will sit on Abionic's testing platform *abioSCOPE,* a CE marked analyzer. A round disk cartridge that holds up to eight small, transparent capsules is inserted into abioSCOPE. The capsules contain nano-chambers, where specific proteins present in drops of blood from the patient are quantified. Results are then displayed on a touch screen and saved on a SD card.

Photo credit: Abionic

Nicolas Durand, CEO of Abionic, founded the start-up in 2010 with colleague Iwan Märki after completing PhDs at research institute EPFL in Lausanne, Switzerland. "We began with developing three abioSCOPE devices – a green, blue and red one," Durand told *Medtech Insight*. "The green one is a screening device which is intended for pharmacies and drug stores. The blue device is a diagnostic one for experts on site doing quantitative measurements so that medical doctors can get the same quality results directly as ones obtained from laboratories. Then finally the red device is intended for emergency use in hospitals."

The company began commercialization by demonstrating traction of the green device in pharmacies in Switzerland and selling the blue one to medical doctors in Switzerland and emerging countries such as Algeria. Abionic now intends to launch the red abioSCOPE in emergency rooms in 2018 with sepsis as the first application.

"Our clinical trials have demonstrated that the device is working well so we want to position it in emergency rooms," said Durand. "When people enter the emergency room physicians need a very quick answer about whether someone is developing sepsis or not in order to take the decision to send the patient to the ICU or whether the patient should stay in the waiting room for the next 2-3 hours."

Sepsis, is the most common cause of mortality in intensive care units and characterized by an overwhelming systemic response to infection, which 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.

Abionic's sepsis test uses a new biomarker PSP (pancreatic stone protein) to diagnose the condition with results given in five minutes from one drop of blood. "More than 10 different independent clinical trials have shown PSP as being superior to the current gold standard – the PCT test. Our test is giving results much faster than what is currently existing," explained Durand.

The company is aiming for a 2018 launch of the sepsis test and red device so they have time to conduct usability studies to improve the product for clinical use. Meanwhile, Abionic's CE marked iron deficiency test was launched in January in Switzerland. The test measures ferritin levels in blood to determine the amount of available iron stored within the body. It is designed for routine screening for iron deficiency at pharmacy or doctor's offices. "We have just started in Switzerland but are now looking for distribution partners to launch in different European countries," said Durand.

Photo credit: Abionic

Abionic CEO, Nicolas Durand

To date, Abionic has raised CHF12m ($12m) from angel investors and early stage venture capital firms and recently opened a new fundraising process. "We are looking for an additional CHF20m for the development of future tests," he said. Abionic aims to develop new applications for a range of clinical indications including diabetes and cholesterol.

Durand said: "The competition is quite difficult in this field because the principal of screening disease from a drop of blood

is not new. "The technology out there either allows very high concentration of applications in a very short amount of time or very low concentration within 2-3 hours. Our technology is combining both advantages of being both very fast and using a very low concentration –just one drop of blood. The only similar competition we have really on the market is the *LabGeo* from Thermo Fisher Scientific."

Abionic hopes the rapid sepsis test will greatly improve chances of survival from sepsis and minimize the use of antibiotics when they are not needed. "The idea with our system is really to be able to guide the physician about the risk of developing sepsis and if the measurement is high the physicians can really take advantage of giving immediate antibiotics," said Durand.

"Physicians are often disagreeing about when to use antibiotics. With this system you can really say 'Ok this is now a good time to start' and monitor the effect of antibiotics. You can even guide the physician about when to stop the antibiotics. In reality, the medical community know that it is really bad to take antibiotics for no reason or to be take it for too long so it's a little bit like reinventing a modern thermometer."

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J&J Taps Aspect Biosystem's 3D Printing Tech For Meniscus Implant

REED MILLER reed.miller@informa.com

Johnson & Johnson's orthopedics business DePuy Synthes will use **Aspect Biosystems Ltd.**'s *Lab-on-a-Printer* 3D bioprinting platform to develop a bioprinted tissue device for surgical knee meniscus replacement.

Aspect CEO Tamer Hohamed told *Medtech Insight* that Lab-on-a-Printer is highly differentiated from other 3D-printing technologies because it offers the unique capability of creating complex multi-cellular 3D tissues at "industrially relevant throughput." It has a microfluidic print-head capable of rapidly manipulating and sequencing multiple biomaterials, including living cells, extracellular matrix content, growth factors, bioactive compounds, and other "bio-inks." The results are three-dimensional heterogeneous, structurally accurate, functional tissues, Hohamed explained.

Injuries to the knee meniscus, which transmits load and absorbs shock, are among the most common knee injuries. The currently available treatments for a damaged meniscus involve complete or partial removal of the meniscus, which may relieve acute pain but increases the risk of osteoarthritis, Hohamed explained.

Julia Hwang, DePuy Synthes's Director of Advanced R&D, told *Medtech Insight*: "Recently we've recognized that there are new innovations in 3D printing of soft tissues specifically, which may provide another path for a technology that may allow the body to heal and preserve the meniscus." She explained that technologies that create an artificial meniscus-replacement with a mold, scaffolding process, and other traditional techniques, cannot achieve the complexity of 3D printing, which is often called additive manufacturing when applied on an industrial scale.

"The meniscal tissue in general … has a very complex architecture, as well as different gradations of chemistries," Hwang explained. "So really, the hypothesis we're trying to test is, are those scaffolds that are currently in development sufficient to be able to regenerate the tissue? Or is it going to require this complex architecture and chemistry that only 3D printing may allow, and will it do it in an easier fashion that will ultimately result in a better product?"

This is just one of many collaborations with small companies J&J maintains, including several others with companies specializing in 3D printing, such as **Carbon 3D**, which it is working with to develop custom surgical devices with its Continuous Liquid Interface Production (CLIP) technology. *(Also see "J&J Announces New Device Collaborations" - Medtech Insight, 7 Jan, 2016.)* According to a 2014 *SmarTec Markets* report, the market for 3D-printed medical and dental products is worth more than $2bn and expected to grow 330% annually through 2024. *(Also see "3D Printing: Will Personalized Medical Devices Be The Next Big Thing?" - Medtech Insight, 15 Jun, 2015.)*

These deals are "part of an overall plan we have in place [to] to establish key partnerships across this technology space," Joe Sendra, Johnson & Johnson's VP of Manufacturing Engineering and Technology, told *Medtech Insight*. "We have over 50 partnerships – academic and commercial – for complementary technologies and materials, and we line them up with the right product offerings that match what those capabilities are."

Neither company would speculate on when the collaboration will yield a commercial product, but Hohamed said: "By combining our platform and expertise with the domain knowledge at leading organizations, we could quickly realize the full potential of Aspect's broadly applicable 3D printing technology. Johnson & Johnson brings significant expertise in orthopedic applications and a world-class portfolio of orthopedic products. We are very excited to work closely with the innovative team at Johnson and Johnson on this application and look forward to building a long-term relationship."

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Adherium Brings In MicroDose Co-Founder As Senior VP

CATHERINE LONGWORTH catherine.longworth@informa.com

SmartInhaler developer Adherium Ltd. has appointed Scott Fleming, the co-founder of MicroDose Therapeutx Inc., as Senior Vice-President Business development, Europe.

Fleming will replace pharma industry veteran John Tarplee, who stepped down at the end of December 2016 to pursue a new venture. Tarplee previously joined Adherium in April 2016, to head up its newly established European subsidiary. *(Also see "Adherium Sets Up EU Base With Tarplee As Head" - Medtech Insight, 5 Apr, 2016.)*

Fleming is a veteran of the drug delivery world, with 25 years covering strategy, device development, sales and marketing and big pharma. He co-founded Microdose in 1997, developing the first totally digital piezo driven dry powder inhaler. At MicroDose he led strategy and licensing and development collaborations with companies including, Bristol-Myers Squibb Co., Novartis AG, Merck & Co. Inc. and Gilead Sciences Inc.

He played a key role in selling Microdose to Teva Pharmaceutical Industries Ltd. in 2013, and joined the company as Global Brand Lead for eConnectivity – part of Teva's respiratory franchise. During this role he was responsible for the commercial and branding strategy and supporting the development and future launches of products.

As Senior Vice-President business development, Fleming will be tasked with developing Adherium's partnerships within the key European markets. He will be based at Adherium's European Operations site in Amsterdam, Netherlands.

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AXREM Names Siemens Healthineers MD As Chairman

CATHERINE LONGWORTH catherine.longworth@informa.com

UK trade association AXREM (the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care) has appointed Peter Harrison, the UK managing director of Siemens Healthineers, as chairman for the 2017-18 period.

Harrison holds over 20 years of experience across the Siemens business, assuming the role of managing director of Siemens Healthcare in the UK in 2012. He transferred to Siemens Healthcare Services (SHS) Ltd in 2002 and headed up Siemens' Imaging and Oncology solution business from 2004.

Previously, Harrison served as chair for AXREM during 2007-08. His other board experience includes serving as an industry representative on the Clinical Radiology Faculty Board of the Royal College of Radiologists and non-executive board member of an NHS Mental Health Foundation Trust. Harrison was also director and chair for Metier Healthcare from 2002 to 2008.

AXREM was originally formed as the Association for X-ray Equipment Manufacturers, but now represents suppliers of diagnostics medical imaging, radiotherapy, IT and care equipment in the UK.

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Dexcom First To CGM Reimbursement Finish Line

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

Dexcom Inc. will benefit from a new ahead-of-schedule ruling from the US Centers for Medicaid and Medicare Services providing coverage for continuous glucose monitors (CGM) defined as therapeutic by the agency. The firm says its *G5 CGM* is currently the only CGM on the market that meets CMS' requirement that the device can be used to make treatment decisions.

"This landmark CMS ruling will make available the most important technology in diabetes management to the Medicare population," Dexcom President Kevin Sayer said. He says over the next few months the firm will work with CMS to implement the rule.

Immediately after an FDA advisory committee in July overwhelmingly recommended approving the test as a replacement for finger-stick glucose meters for patients aged 2 and older, Dexcom VP Steven Pacelli told *Medtech Insight* that the firm was working aggressively to gain reimbursement. But the first step to getting coverage was getting US FDA approval. *(Also see "FDA Panel Overwhelmingly Votes For Dexcom CGM to Replace Finger Sticks" - Medtech Insight, 21 Jul, 2016.)*

"It's somewhat up to CMS," he said at the time. "We'll work with CMS to decide whether they want us to go immediately to a national coverage decision … or in some instances CMS will advise you to go on more regional basis first, and then

come back for a national decision. My hope is we have reimbursement sometime in 2018."

Last month, FDA approved the Dexcom's test, stating it could reduce the burden of disease management. *(Also see "Dexcom Glucose Test System Approved For 2-Year-Olds" - Medtech Insight, 20 Dec, 2016.)*

"FDA recently approved expanding the indications of one CGM product to include replacement of blood glucose monitors for diabetes treatment decisions," states CMS in its ruling. "This ruling addresses whether 'therapeutic' CGMs, which provide information that can be used to make diabetes treatment decisions, meet the definition of DME. For the purpose of this ruling, all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as 'non-therapeutic' CGMs."

CMS says the fee schedule for CGMSs such as the G5 will range from $236 to $277 per device.

"This coverage decision is well ahead of expectations … and we believe it positions the company for potential upside to just-issued 2017 sales guidance of $710M to $740M," said Leerink analysts Danielle Antalffy and Rebecca Wang in a Jan. 13 research note.

Analysts caution it will take time to negotiate with regional Medicare Administrative Contractors. The reimbursement scheme isn't expected to be implemented until the middle of this year.

Nonetheless, the ruling gives Dexcom a leg up over competitors Medtronic PLC and Abbott Laboratories Inc.

"[Abbott] is pursuing a dosing claim for its already-filed *Libre*, but we believe sensor accuracy will have to improve ... before one is granted," the Leerink analysts state. "And as far as we know, [Medtronic] is not pursuing a dosing claim as of yet for any of their sensors or integrated pump systems."

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Zimmer Biomet To Settle Overseas Bribery Charges With US DOJ

ELIZABETH ORR elizabeth.orr@informa.com

Zimmer Biomet Holdings Inc. will pay $30.5m to settle allegations that the company's actions in Mexico and Brazil violated the Foreign Corrupt Practices Act (FCPA), the US Department of Justice announced Jan. 12.

The payments stem from allegations that Biomet Inc. paid bribes to Mexican government officials and violated the FCPA's internal controls provision in Mexico and Brazil. In addition, the company's actions breached a 2012 deferred prosecution agreement between the Department of Justice and Biomet. The agreement had been set to expire in 2015, but DOJ extended it based on allegations of ongoing misconduct. *(Also see "Biomet Still Under Scrutiny For Overseas Bribery" - Medtech Insight, 30 Mar, 2016.)*

The company's behavior forced DOJ to move ahead with criminal charges, said Leslie Caldwell, assistant attorney general of the Justice Department's Criminal Division.

"Zimmer Biomet had the opportunity to avoid criminal charges, but its misconduct allowed the bribes to continue," she said. "…In appropriate circumstances the department will resolve serious criminal conduct through alternative means, but there will be consequences for those companies that refuse to take these agreements seriously."

DOJ says that Biomet kept using a Brazilian distributor that was known to have bribed government officials on Biomet's behalf, even after the deferred prosecution agreement. Biomet also didn't put adequate internal accounting controls into place at its Mexican subsidiary, Biomet 3i Mexico S.A. de C.V., even though the government warned that the subsidiary appeared to be paying bribes. The subsidiary was bribing customs brokers and sub-agents so they would let Biomet 3i import contraband dental implants that lacked proper registration or labeling, which violated Mexican law.

In addition to a $17.4m criminal penalty, Zimmer Biomet signed a new deferred prosecution agreement that requires it to maintain an independent corporate compliance monitor for three years. Meanwhile, subsidiary JERDS Luxembourg Holding S.ár.l. agreed to plead guilty on a charge its actions caused Biomet and Biomet 3i to violate the books and records provision of the FCPA.

Zimmer Biomet is also set to pay $13m to the Securities and Exchange Commission to resolve a cease and desist order. The settlement includes a disgorgement of $6.5m and a civil penalty of $6.5m.

In a statement, Zimmer Biomet said it was "pleased" to reach the resolution but noted that all the violations occurred before Zimmer's 2015 purchase of Biomet. *(Also see "Zimmer, Biomet Sell Off Some U.S. Assets As They Finalize A $14 Bil. Merger" - Medtech Insight, 25 Jun, 2015.)*

The payments won't affect Zimmer Biomet's financial outlook, the company said.

The Zimmer settlement was one of two health-care-product-related settlements announced by DOJ on Jan. 12. In the second, Baxter Healthcare Corp. agreed to pay more than $18m to resolve allegations the company violated good manufacturing practices in its North Carolina IV drug manufacturing operations.

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Appeals Court Rejects False-Claims Approach To FDA Off-Label Cases

ELIZABETH ORR elizabeth.orr@informa.com

A holiday-season opinion from the US Court of Appeals for the First Circuit suggests manufacturers can't be convicted of violating the False Claims Act solely on allegations that their application for FDA approval was misleading.

The decision, attorneys Anne Walsh and Andrew Hull said in a post to Hyman, Phelps & McNamara's FDA Law Blog, should allow companies faced with an allegation of what's called fraudulent inducement to "breathe easier."

The ruling arose from a whistleblower suit brought by Jeffrey D'Agostino, a former sales rep for defendant ev3 Inc. ev3 manufactured an artificial liquid embolic called *Onyx*, while fellow defendant and ev3 subsidiary Micro Therapeutics Inc. made another embolic product called *Axium*. FDA approved Onyx to treat brain arteriovenous malformations but limited its use to physicians with specific training. But the company marketed it for off-label uses, provided off-label training, and sold the device to physicians who weren't properly trained, D'Agostino alleged. The 2010 qui tam suit said the defendants' FDA application to market Onyx overstated how much physician training the company would provide and omitted important product safety information.

In the past, courts have cited the doctrine of pre-emption to block other attempts by individuals to sue manufacturers for defrauding the FDA, Walsh and Hull said. So D'Agostino's case took a different tack, alleging ev3's misrepresentations during the approval process had influenced FDA's decision and thus led to false claims being submitted to government health programs.

But that theory didn't stand up under First Circuit scrutiny. In the court's opinion, Judge Jeffrey Howard wrote, "If the representations did not actually cause the FDA to grant approval it otherwise would not have granted, CMS would still have paid the claims. In this respect, D'Agostino's fraudulent inducement theory is like a kick shot in billiards where the cue ball 'could have' but did not in fact bounce off the rail, much less hit the targeted ball."

The court also ruled that D'Agostino's allegations didn't meet the standards for a False Claims Act case. First, federal healthcare programs kept reimbursing for Onyx even after D'Agostino had filed suit. Second, FDA hasn't taken any enforcement actions such as recalls or relabeling against Onyx since the lawsuit was filed. The fact FDA hadn't withdrawn the product meant D'Agostino couldn't show that FDA's approval was falsely obtained, Howard said.

A district court had already dismissed D'Agostino's claims. The appeals court's ruling means that decision will stand, and D'Agostino cannot amend his complaint against ev3.

Walsh and Hull applauded the decision.

"To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so," Walsh and Hull wrote. "The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings."

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