Medtech Insight
Issue 13
medtech.pharmamedtechbi.com
Pharma Intelligence Informa
October 10, 2016

Firms Must Submit The Good, Bad, And Ugly Trial Data On Devices Under Clinical Trials Rule

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A ClinicalTrials.gov final rule and related policy document posted by the US HHS and the National Institutes of Health on Sept. 16 could have several significant downsides for device companies, industry attorneys told *Medtech Insight*. Language in the final rule warns of the legal consequences for device sponsors who do not submit appropriate trial data to ClinicalTrials.gov – which is run by NIH – before the regulatory deadlines.

The final version of the rule was issued almost two years after NIH released a proposed version in November 2014 calling for expansion and faster release of clinical trial data for devices and drugs, as required by the FDA Amendments Act of 2007. The rule is aimed at improving public access to information about trial results that can't be found through other public sources.

In addition to widening the range and types of clinical device trials and trial data that would have to be submitted to the public-facing ClinicalTrials.gov website, the rule also puts the onus on industry to make declarations about what part of their clinical trial data they consider to be confidential business information that it is not releasable to competitors.

Attorneys who have read the new rule closely told *Medtech Insight* that in addition to imposing new reporting burdens, the final rule could draw unwanted attention from FDA to newer versions of devices that companies ultimately reject for the marketplace because a trial uncovers some flaw, or from enforcement authorities such as the US Department of Justice. Additionally, product liability attorneys will be looking very carefully at the postings on the ClinicalTrial.gov website to search for adverse events revealed by trials, they said.

"The full impact of these reporting requirements will likely not be fully appreciated for some time," remarked Jennifer Henderson, counsel, Hogan Lovells US LLP.

DELAYING DATA RELEASE

After the rule goes into effect in January 2017, the standard disclosure deadline for trials data to be posted on the public database will be one year after a clinical trial is completed. But the regulation permits a delay of up to two years for firms to submit their trial data for public posting if their device or new indication is still in development. But companies will have to "be proactive and certify this so as to delay" study data that will be posted on ClinicalTrials.gov, said Mahnu Davar, a partner with Arnold & Porter.

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FROM THE EDITORS OF: **THE GRAY SHEET, CLINICA, START-UP** AND **MEDTECH INSIGHT NEWSLETTER**

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The view beyond LASIK
http://bit.ly/2dwxT8C

LASIK continues to hold a dominant share of the refractive surgical market but limitations in current technologies are stymying further growth. However, a tide of innovative refractive correction is coming that, over the next few years, could accelerate growth and fully capitalize on the huge and yet undertapped opportunity known as presbyopia.

EU unannounced audits
http://bit.ly/2dSgert

The European Commission wants notified bodies to conduct unannounced audits at least once every third year. But Germany says that timetable can be extended to every five years for some products and it wants Europe to follow its lead.

Medtech Europe Q&A
http://bit.ly/2dxeuUL

John Brennan of device trade association Medtech Europe reassures industry that a plan of action is in place and that the sector's voice will be heard in an interview with *Medtech Insight*.

Abbott gets flash
http://bit.ly/2de25Uk

US FDA has approved Abbott's *FreeStyle Libre Pro* flash glucose monitoring system, intended to provide health-care providers with an easy-to-read visual summary of a diabetic patient's glucose data. Abbott has also filed for approval with FDA for a consumer-targeted version of the device.

Device Week
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Medtech insight

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The UK's head of devices stresses the need for collaboration, increased manpower and solutions around notified bodies.

20 UK MHRA Presses For Leading Global Role PostBrexit – The UK MHRA believes it has a valid and vital role to play on the global regulatory stage even after the UK leaves the EU.

21 CDC Whistleblower Says Test Misses Too Many Zika Cases; US Special Counsel Calls For Review – The US CDC-promoted Trioplex Zika virus test that won an FDA emergency-use authorization in March is nearly 40% less sensitive than a rival CDC Zika test called Singleplex, a CDC microbiologist whistleblower told superiors in April. A review of his complaints by HHS and CDC did not substantiate that, and CDC demoted him. The US Special Counsel sent a letter to the White House this week asking for further review.

COMMERCIAL

8 How To Avoid Profit Cuts? Sharpen Your Pricing Strategy – Findings from an industry survey forecast profit declines for medtech companies, among other things, if they do not take stock of weaknesses in their pricing strategy and fully tap into the profit potential of their new products.

10 Intuitive Surgical, Fosun Pair Up For Lung Cancer JV – Intuitive Surgical is setting up a China-based joint venture with its distribution partner Fosun Pharma that will develop robotic-assisted, catheter-based devices for diagnosing and treating lung cancer.

10 Colibri Enters TAVR Joint Venture With Venus Medtech Focusing On Emerging Markets – US firm Colibri Heart Valve and China-based Venus Medtech have formed a venture to commercialize two heart valves in China and other emerging markets: a balloon-expandable version created by Colibri and a self-expanding version developed by Venus using tissue processed by Colibri.

11 KO'd By Allergy Failure, Circassia Looks To Respiratory Pipeline For Second Wind – Circassia is shifting its focus on its respiratory portfolio following the disappointing Phase III results of its cat allergy drug in June, which saw the company's share price plummet by more than 60%.

12 Sunshine Heart Changes Course Again: Pauses Neuromodulation To Focus On Aquadex – The company has switched from pursuing a counterpulsation technology to focusing on a fully implantable neuromodulation device, and is now directing its full attention to the recently acquired Aquadex FlexFlow ultrafiltration system for heart failure, all in a period of about three-to-four months.

R&D

13 From Military To Medicine, Owlstone Medical Targets Lung Cancer With Its Breath Analysis Tech – Owlstone Medical is on a mission to "save 100,000 lives and £1.5bn in health-care costs by 2020" by applying a gas sensor technology, originally developed for military defense purposes, for early stage detection of lung cancer.

US FDA Approves First 'Artificial Pancreas' In Medtronic's MiniMed 670G

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A major milestone has been met in diabetes. US FDA announced Sept. 28 the approval of **Medtronic PLC**'s *MiniMed 670G* hybrid closed-looped automated insulin delivery system.

It's the first hybrid closed-loop insulin delivery system approved anywhere in the world, according to the company, making it the first so-called "artificial pancreas," says FDA.

Medtronic, however, says it will not begin commercializing MiniMed 670G until the spring of 2017 to provide time to ensure payer coverage, market and manufacturing readiness, and the training of employees, clinicians, educators and patients.

Photo credit: Medtronic PLC

MiniMed 670G system

MiniMed 670G features Medtronic's *SmartGuard HCL* algorithm and the *Guardian* glucose sensor. It continuously delivers insulin at a variable rate in response to the patient's blood-glucose levels to maximize the time the glucose levels are within the target range. It requires minimal input from the patient. The user only has to enter information on their mealtime carbohydrates, accept bolus-correction recommendations, and periodically calibrate the sensor, Medtronic explains.

The FDA approval labels MiniMed 670G for patients with type 1 diabetes who are 14 years of age or over. The company is sponsoring a trial of the system in younger patients.

Medtronic believes it is at least three years ahead of any competitor in the development of an artificial pancreas. Wells Fargo analyst Larry Biegelsen says the approval is a big win for the company. "We expect the 670G system to help drive acceleration in Medtronic's US diabetes growth from the low-single-digits seen in the fiscal first quarter [reported Aug. 25]," the analyst writes in a Sept. 28 research note. "We currently model US diabetes growth of 10% for the second half of fiscal 2017, driven primarily by the 670G launch."

KEEPS PATIENTS IN TARGET GLUCOSE RANGE

At the American Diabetes Association conference in New Orleans in June, Richard Bergenstal of the Park Nicollet International Diabetes Center near Minneapolis presented data from a 123-patient pivotal trial that supported the FDA approval of MiniMed 670G.

Following a two-week control period during which the system's hybrid closed-loop functions was turned off, the patients used the MiniMed 670G for three months with the hybrid closed-loop functions operating as frequently as possible (a median of 87.2% of the time). No serious adverse events, diabetic ketoacidosis or severe hypoglycemia (low glucose levels) were reported during the study.

A comparison of the patients' sensor glucose levels at baseline and during the study phase of the trial showed that patients using the hybrid closed-loop system spent more time with sensor glucose between 71 and 180 mg/dL, less time with sensor glucose at 70 mg/dL or lower, and less time with sensor glucose at 50 mg/dL compared to baseline. Sensor glucose variability measured by coefficient of variation decreased from 0.38 to 0.35, a statistically significant improvement. Also, the patients' average glycacted hemoglobin decreased from 7.4 to 6.9, a significant improvement.

As a condition of approval, FDA is requiring Medtronic to sponsor a post-market study to better understand how the device performs in real-world settings. Once the device is launched in 2017, patients using Medtronic's earlier-generation *MiniMed 630G* system will be eligible to get a MiniMed 670G through a Priority Access Program. Medtronic says it expects regulatory approval of the MiniMed 670G in territories outside the US in the summer of 2017.

FDA SPEEDED PROCESS ALONG

Medtronic gained approval for a closed-loop system quicker than many would have expected several years ago. According to both FDA and the company, the US agency has devoted outsized time and resources to working with Medtronic on planning trial designs and other matters for this and precursor systems.

In conjunction with this approval, FDA touted its role in working with a range of stakeholders, including multiple companies, to speed development of artificial pancreas device systems.

"The FDA has been working together with diabetes patient groups, diabetes-care providers, medical device manufactures, and researchers to advance the development of an artificial pancreas," the agency explains. "FDA's efforts include prioritizing the review of research protocol studies, providing clear guidelines to industry, setting performance and safety standards, fostering discussions between government and private researchers, sponsoring public forums, and finding ways to shorten study and review time."

On the same day as approval of the 670G, FDA also approved **Abbott Laboratories Inc.**'s *FreeStyle Libre Pro* continuous glucose monitoring system for health-care professionals.

Published online 09/28/16

Boston Scientific Buys EndoChoice, Mulls De-FUSEing Potential Weakness

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Shutterstock: Maya2008

Boston Scientific Corp. has inked a $210m deal to acquire EndoChoice Holdings Inc., a specialist in gastrointestinal endoscopy products and services; the move is intended to broaden its product offerings to gastroenterologists.

Under the terms of the agreement, Boston Scientific will pay $8 in cash per EndoChoice share. While this offer represents a hefty 90% premium over EndoChoice's closing share price of $4.22 the day before the Sept. 27 deal announcement, it is less than half the $16-17 range at which the Alpharetta, Georgia-based company's stock was trading in the early months after its initial public offering in June 2015.

EndoChoice is a relatively young company founded in 2008. It has built itself a sizeable portfolio in gastroenterology that does not overlap much with Boston Scientific's existing offerings of stents for treating strictures in different parts of the gastrointestinal tract, biliary devices and endoscopic ultrasound-guided devices, among other things.

EndoChoice's flagship technology is the *Full Spectrum Endoscopy System (Fuse)*, intended for visualization of the gastrointestinal tract and related therapeutic interventions. The system comprises colonoscopes and gastroscopes, as well as accessories for image processing and management. The Fuse colonoscope is designed to offer a 330° view of the colon, instead of the 140° to 170° view offered by standard colonoscopies. The firm says Fuse has been clinically demonstrated to identify 69% more precancerous polyps compared to standard endoscopes. EndoChoice's portfolio also includes a wide range of single-use devices, such as resection and retrieval devices, needles, graspers and infection-control kits, products which Boston Scientific does not currently offer.

The EndoChoice acquisition will also add GI pathology and scope repair services to Boston Scientific's offering and with this, new customers, according to a Boston Scientific spokesperson. "In particular, this agreement will strengthen our leadership and presence in Ambulatory Surgery Centers," she told *Medtech Insight*. EndoChoice offers a pathology lab specifically focused on GI pathology with GI-trained pathologists and histotechnicians on staff "to provide rapid, high quality diagnostic services for gastroenterologists and their patients, which is a significant growth area for the Boston Scientific ASC customer base." She added that the infection control portfolio enhances the safety of GI procedures for patients and healthcare providers and helps Boston Scientific customers achieve compliance with multiple infection control guidelines, notably guidelines from the Centers for Medicare and Medicaid Services and from the Society of Gastroenterology Nurses and Associates.

FUSE SALES STRUGGLE

The company reaches out to more than 2,500 customers in the US and uses distribution partners overseas. For the full-year 2015 it recorded revenue of $72.3m, an 18% increase from the previous year. More recently, in its second-half 2016 results, EndoChoice reported revenue of $37.7m, a more modest 7% year-over-year increase. While revenue from GI pathology services during this period increased by a solid 33% to $8.4m, revenue from sales of GI equipment barely grew, up just 1% to $29.3m. The company blamed poor device sales on weakness in the European markets and delays in converting existing customers to the latest-generation Fuse product; it subsequently lowered its revenue guidance for full-year 2016 from $82m to $80m.

The acquisition by Boston Scientific could allow EndoChoice to leverage its buyer's established sales infrastructure and commercialization know-how and to address these troubles, which could potentially snowball if addressed by a company with less experience and resources.

Indeed, Boston Scientific stated in the acquisition announcement that it intends to "evaluate strategic options" for the Fuse colonoscope and "expects to provide further clarity at or around the time of transaction closing," which is slated for the fourth quarter of this year.

Wells Fargo analyst Larry Biegelsen noted that the Fuse colonoscope is "a piece of capital equipment, unlike many of [Boston Scientific's] endoscopy products that are single-use." He estimates that Fuse accounts for around $20-30m of annual sales, a significant portion of EndoChoice's revenue – for now at least.

On completion, the acquisition is expected to have no net impact on Boston Scientific's adjusted earnings per share in 2017, and to be accretive thereafter. The transaction is expected to be less accretive (or dilutive, as the case may be) on a GAAP accounting basis, due to amortization expenses and transaction and integration costs.

Published online 09/27/16

US Health-Care Enforcement Focus Continues To Expand, Officials Say

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The types of health-care activities and payments under enforcement scrutiny by the US Department of Justice and HHS Office of Inspector General (OIG) continue to expand. That was the message from government officials and attorneys at a Sept. 27 panel discussion at the Food & Drug Law Institute annual Advertising & Promotion Conference in Washington, DC.

Efforts by manufacturers to encourage payers to reimburse their products, for instance, are recently getting more attention.

"A big trend is a greater focus on reimbursement-support activities," said Jennifer Bragg, a partner with Skadden, Arps. "There are more resources put into making sure products get paid for now, but historically that's an area where there haven't been as many compliance controls created."

For example, the OIG is now examining many patient-assistance programs, including those run by nonprofits, said OIG senior counsel Mary Riordan. She added that the office has issued advisory opinions "blessing" several such arrangements.

In addition to reimbursement-support efforts, other financial arrangements that traditionally might have gone unscrutinized are capturing notice, Riordan said. For example, she cited a $370m Novartis AG settlement related to allegations of kickbacks to specialty pharmacies – not, she said, "a traditional area of focus." Reportedly, the pharmaceutical company tried to boost refill rates on two Novartis drugs by pressuring the pharmacies to have nurses contact patients about the drugs.

SPOTLIGHT ON INDIVIDUALS

It's been frequently reported that DoJ is putting more attention on charging individual executives, and not just corporations, under the Park Doctrine. Officials have been signaling this approach for at least the past six years.

The policy, also called the Responsible Corporate Officer Doctrine, allows executives to be held individually responsible under a misdemeanor without requiring the government to prove they intentionally broke the law. The strategy got a further boost in a 2015 memo from US Deputy Attorney General Sally Yates encouraging government prosecutors to pursue charges against individuals more frequently. And recent criminal cases have established that executives may be prosecuted even if they didn't intend to break the law.

However, Michael Blume, director of the Department of Justice's consumer protection branch, disputed claims that the Yates memo has led to any major changes for his office. While the memo reemphasized the need to look for individual liability, he said that finding responsible parties has always been part of his office's process in considering enforcement actions.

What's changed, he said, is the way investigations are planned. "Instead of starting by figuring out what a company is doing, now we start by looking at the individual actors," he said. "So Yates may change our focus, but I don't think it changes who we've charged."

Blume noted that DoJ believes citing individuals may be more effective than citing corporations as a whole because corporate behavior only changes when people change.

OIG cannot bring charges, but it has excluded several medical technology executives from participation in Medicare in recent years, Riordan said. She noted that sometimes it's hard to decide who to hold to account in corruption cases.

"We want to hold the right individuals accountable," Riordan said. For example, if someone raised a compliance concern but was shut down by upper management, that person probably wouldn't be sanctioned. In part, she said, that's because punishing someone who tried to come forward could send the wrong message.

RECENT DEVICE SETTLEMENTS

The recent investigation of **B. Braun Medical Inc.** may provide another hint at future enforcement directions, DoJ's Blume said. In that case, the company paid $7.8m in May to settle allegations that it continued distribuing contaminated syringes manufactured by a contractor despite what the government says were repeated warning signs and a high risk of patient harm.

"We believed, given the facts of the case, that there were sufficient signals flashing that should have alerted B. Braun to the fact there were problems with these syringes," he said. "Whether you manufacture a product yourself or you hire another company, it's the same analysis."

The panelists also discussed recent trends in corporate integrity agreements (CIA) routinely signed by companies as part of fraud settlements. For example, Riordan noted that the CIA signed by **Olympus Corp.** in the wake of this spring's $646m False Claims Act settlement included several of innovative clauses to protect against future misbehavior. The company allegedly plied physicians with kickbacks including grants, trips, payment for leisure activities such as golfing, and gifts or free use of Olympus equipment to encourage the sale of Olympus endoscopes.

The CIA signed by the company requires Olympus' board of directors to sign a statement annually affirming that they have reviewed the company's overall compliance policy and found no problems. In addition, key managers are required to sign off certifying individual corporate divisions are compliant. Requiring this kind of internal risk mitigation is becoming standard in CIAs, she said.

Published online 09/29/16

How To Avoid Profit Cuts? Sharpen Your Pricing Strategy

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Amidst increasingly oppressive market conditions, medical device companies are turning to new product-launches to keep their top-line buoyant. However, less-than-optimal pricing strategies still persist across the sector and many medtech manufacturers are not achieving their planned price increases, thus putting themselves at risk of seeing their bottom lines shrink.

These are some of the key findings from the Global Pricing Study 2016, a biannual industry survey conducted by strategy and marketing consultancy Simon-Kucher & Partners (SKP) in collaboration with the Professional Pricing Society. The survey received nearly 2,200 responses from senior executives across 16 different industries and of these, 97 responses (about 5% of the total sample) were from medtech companies in Europe, the US and Asia.

While pricing pressures in the medtech sector are not new, the situation has intensified – mainly due to the arrival of low-price competition and customers' increasing negotiation power – to the extent that one in every two medtech companies are now engaged in a price war, the survey results showed. Additionally, companies have to deal with cost increases, which are driven by a mix of factors including higher personnel costs, higher cost of goods, currency fluctuation and inflation.

However, these companies, on average, have achieved only 83% of the price increase that they planned to implement. This shortfall is not enough to offset cost increases and profits are set to decline this year, SKP analysts predict. *(See Figure 1.)*

Survey respondents revealed that one of the top methods medtech companies are using to counter these challenges is to introduce new, innovative or differentiated products which can command premium prices.

But pervasive inadequate pricing practices mean that the profit potential of these new products are not fully capitalized. A third of respondents in the survey said less than half (up to 40%) of products introduced to the market within the last five years met their profit targets, while half of the respondents said 40%-80% of new products met profit expectations. Only the remaining 20% said 80%-100% of the new product launches were successful.

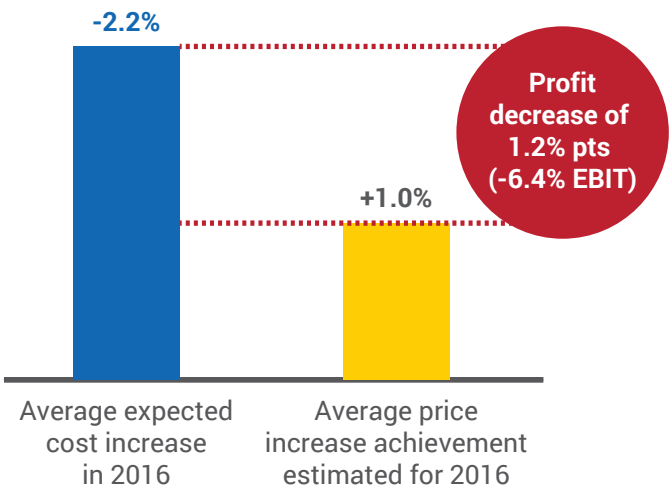
As to the reason behind this lackluster performance, the survey found that companies that neglect pricing and marketing activities around these new products were less likely to realize the profit potential of these innovations. Digging deeper, the study findings showed that the share of successful product launches increases by nearly 20% when a company takes pricing into account continually – from the start of the product development process through to the launch – rather than neglecting or ignoring them until right before the launch. *(See Figure 2)*

Joerg Kruetten, head of SKP's global life sciences practice, told *Medtech Insight* why factoring pricing early in a product's life-

FIGURE 1

Estimated impact on return on sales

Profits are set to decline by 1.2 percentage points, as insufficient price increases are unable to mitigate cost increases

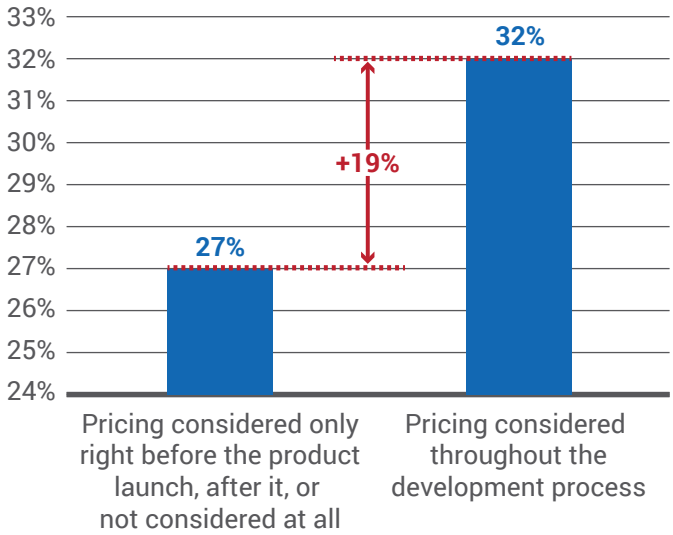


Source: Simon-Kucher & Partners

FIGURE 2

Share of new products that meet profit targets

By taking pricing into account throughout the development process, the share of successful product launches increases from 27% to 32%



Source: Simon-Kucher & Partners

cycle is critical. "Firstly, when you are making a business case to get that initial funding to develop new technology, you need to have a good understanding of that product's price potential and its reimbursement potential. It's important to consider before signing off on any R&D investment, whether you can get any reimbursement and whether you will get a sufficiently high price for the product.

"Secondly, along with the R&D process, having a good understanding of the end customer price and what your margin expectations are will help you to define a target cost and ensure that you do not exceed this cost. Thirdly, once you know the price potential and you know the value buttons that you need to push to convince payers and providers, this will help you design your clinical trials in such a way that they are meaningful – not only from a product approval perspective but also from a marketing point of view. So you will have a clear marketing message from the start," said Kruetten, noting that the medtech industry could take some lessons from its pharma cousins on that aspect.

"For pharma, pricing and market access goes in parallel with R&D. For each project, there are pricing/market access checkpoints. If the company does not see sufficient market access [that would make the product commercially viable], they kill the project. And when pharma companies perform clinical studies, they use it to get regulatory approval, as well as to build their messages to stakeholders."

Aside from ensuring pricing considerations are taken into account early and continuously from a product's development through to launch, what factors actually make up an effective pricing strategy?

Findings from the survey showed that the "best" medtech companies – defined as such because they fulfilled SKP's criteria for best pricing practices – placed high importance on three factors in particular: having the right systems, processes and sales skills.

For companies struggling to hit their pricing targets, Kruetten advises getting the right processes in place first by assigning clear pricing roles, and responsibilities and then ensuring this is well understood and executed by the sales organization. Once the "basics are in place, then incorporating the right systems – such as using dedicated support software to monitor and guide pricing – can then be the second or third step," he said.

"There is still no clear guidance in many companies for sales people about which price they should sell which product, at which level they should give discounts – this guidance often does not exist. So the salesperson makes the decision based on what they think is right. It is a very individual and opportunistic way of selling devices compared to other industries," said Kruetten.

Price monitoring is also something that is not that common, even though there are pricing support tools available that can facilitate this. Kruetten pointed out the benefits of more bespoke pricing software, which "best" companies use more frequently than other less competitive companies, as the survey revealed.

Seven Steps To Take Now To Escape Price Pressure And Boost Profits

- **Priorities:** Make price strategy and price management your top priority – no price cuts without specific approval.
- **Ambition:** Set more ambitious price targets.
- **Proprietary pricing approaches:** Develop a tailor-made pricing strategy rather than rely on off-the-shelf solutions.
- **Empowerment:** Increasing prices almost always comes with volume risks, and vice-versa. Make sure that your incentives not only push volume, but also support price performance.
- **People and organization:** Invest in building up pricing departments and pricing competence, clarify roles and responsibilities for pricing activities.
- **Leadership:** Dedicate a fixed slot in your management meetings to price decisions.
- **Digital-ready:** Challenge whether your price model is still appropriate in the digitalization age.

Source: Simon-Kucher & Partners

"What we are seeing is that best-in-class companies have their own software developed and they integrate it into their other systems rather than relying on off-the-shelf software. They have something more sophisticated to fit their needs," said Kruetten.

Having these systems in place give these companies a better understanding of pricing decisions as they create transparency on the value of the product they are offering, know which prices to set for new product launches and implement the price targets planned. "With the digital solutions that are available right now, you can do much better price steering. When you are at a point of sale with a customer, you can discuss a certain deal and get online guidance on what price to sell it and what room there is to maneuver in terms of providing discounts. It can facilitate quicker and more effective price decision-making because you have the tools to allow you quicker access to the relevant data."

While the medtech industry appears to be lagging behind other industries when it comes to adapting their pricing strategies to the changing market environment, "there is a lot of movement in the right direction," Kruetten believes. "There is room for improvement … but given that we have seen a lot of price erosion in the medical device world, the attention to pricing has increased and the need for action is becoming more urgent."

For more information about the Global Pricing Study 2016, contact Nora Neuwinger of Simon-Kucher & Partners at nora.neuwinger@simon-kucher.com

Published online 10/05/16

Intuitive Surgical, Fosun Pair Up For Lung Cancer JV

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Intuitive Surgical Inc. is expanding its presence in the lung cancer space through a joint venture it has set up with **Shanghai Fosun Pharmaceutical Group Co. Ltd.**

The deal expands the two companies' relationship, which was first forged in 2011 when Fosun Pharma's subsidiary, **Chindex Medical Ltd.**, became a distributor of Intuitive's flagship product, the *da Vinci* system for minimally invasive, robotic-assisted surgery, in China.

Intuitive and Fosun Pharma will contribute up to $100m to fund the JV, which will focus on developing, manufacturing and selling robotic-assisted catheter-based devices for the "early diagnosis and cost-effective treatment of lung cancer." Intuitive will provide the IP on which the technology for the new products will be based, and the Sunnyvale, Calif., US firm will also be responsible for distributing the finished products outside China. The Shanghai-registered JV will focus on the R&D and manufacture of the devices, as well as distribution in China.

Lung cancer is one of the most commonly diagnosed forms of cancer in the world and China has one of the highest incidence of the disease. Some da Vinci systems are used by surgeons for lobectomy procedures, although the technology is used primarily in gynecologic surgery, general surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery.

"Today lung cancer biopsies are a trade-off between either serious complications or the risk of reduced assurance of a diagnosis," explained Paige Bischoff, vice-president of global public affairs at Intuitive Surgical. "A major goal of the joint venture is to offer physicians and patients an option which combines improved safety with a higher probability of diagnosis."

The company told Medtech Insight that as initial work on development of the new technology progresses, the timing of when the first products from the JV will become available on the market will be assessed.

Published online 09/29/16

Colibri Enters TAVR Joint Venture With Venus Medtech Focusing On Emerging Markets

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A new joint venture between Colorado-based **Colibri Heart Valve LLC** and the HangZhou, China, device firm **Venus MedTech** has been formed to bring two transcatheter aortic heart valve replacement (TAVR) devices based on Colibri's "dry" tissue technology to market in China and other emerging markets, including India.

Colibri's novel "dry" porcine pericardium processing technology allows for the manufacture and packaging of a transfemoral aortic valve system that can be shipped to the customer premounted on the delivery system and ready to use. By contrast, other TAVR devices are delivered "wet," requiring staff at the procedure site to rinse off the sterilant and mount the valve on the delivery system. This makes Colibri's system potentially well-suited to emerging markets where setting-up training systems for new users of TAVR devices can be especially difficult, according to Colbri CEO Joe Horn.

He said the procedure for implanting Colibri's valve is similar in many ways to implanting a coronary stent because it does not require any preparation at the procedure site. "The complexity of training a lab in an emerging market is difficult enough, and finding somebody to teach them how to deliver the heart valve, the right location, and the patient safety are big issues," Horn told *Medtech Insight*. "[With a pre-mounted valve], when [the trainers] go into train someone, they won't have to train them on how to clean the valve, etc. That's a big win for the Chinese market, which currently has very little TAVR use."

The terms of the agreement that created the **Colibri-Venus Medtech JV**, announced Sept. 13, call for Colibri to provide tissue to Venus, which will use it to create a self-expanding TAVR device based on its A-Valve delivery technology. In addition, Colibri will provide a balloon-expandable version of the valve, which Venus will also market in emerging markets, especially China and India, Horn said. Colibri maintains the exclusive rights to market valves based on its proprietary technology in established markets in Europe, Japan, and North America.

The joint-venture will be the only company marketing both balloon-expandable and self-expanding TAVR systems in China and other emerging Asian markets, the firms say.

Horn said the choice between balloon-expandable and self-expanding usually comes down to the preference of the individual surgeon or interventional cardiologist running the procedure. "**Edwards** [**Lifesciences Corp.**'s line of *Sapien* TAVR systems] has 65% of the worldwide market, so clearly the market has spoken and says that balloon-expandable is what they want to put in," he said. "[But] the way we look at it is that Venus has a complementary system to ours. [so] we will supply the cardiologist and/or surgeons with both and let them choose."

Venus will fund a first-in-man trial of the self-expanding ver-

sion of the valve in China or another emerging market to support eventual approval by China FDA. Horn expects that trial to begin within the next 60 days. Venus will also fund pilot studies of both the balloon-expandable and self-expanding versions of the valve in Europe with goal of securing CE marks for both systems. Horn expects the European trial of the balloon-expandable system to begin by the first-quarter of 2017 and the European trial of the self-expanding system to begin soon thereafter.

"So we have non-dilutive funds paying for our CE-mark study," Horn said. "And, for us, that was a big win."

In conjunction with the formation of the joint venture, Venus, along with several undisclosed investors, has contributed an undisclosed amount to Colibri's Series C financing, thereby providing the company with "significant financial stability," according to Colibri. Also, Colibri says that it has been operating debt-free since it converted its senior notes earlier this year.

Published online 10/03/16

KO'd By Allergy Failure, Circassia Looks To Respiratory Pipeline For Second Wind

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UK biotech firm **Circassia Pharmaceuticals PLC** says it's ready to bounce back from the recent high-profile clinical trial failure of its key cat allergy treatment by pouring efforts into its respiratory pipeline and expanding commercialization of its respiratory devices.

The company's lead product, a cat allergy vaccine called *Cat-SPIRE*, flopped at the final hurdle in June when top-line results from the Phase III study showed a high placebo response rate in 40-60% of patients. This placebo effect – which was expected to impact only 20-30% of subjects – prevented a treatment effect being shown. The results showed that there was a huge improvement in allergy symptoms and a reduction in rescue medication use in all arms of the study. Circassia's share price plunged by more than 60% in the aftermath of this trial failure.

Now, three months later, CEO Steve Harris has outlined the company's change in direction in conjunction with the release of its first-half 2016 results on Sept 27. Harris told *Medtech Insight* that Circassia has "evolved to be a specialty pharma business" based around its respiratory pipeline after the disappointing results of Cat-SPIRE.

Circassia diversified its business beyond allergy in 2015 with the acquisitions of respiratory companies Aerocrine for around £88m ($114m) and Prosonix for up to £100m. Swedish company Aerocrine gave Circassia its asthma diagnosis platform *NIOX* and a commercial infrastructure with established channels targeting allergy and asthma specialists. The acquisition of Prosonix added a respiratory pipeline of asthma and COPD drugs under development and the technology to develop further products.

The NIOX VERO device is used by physicians to measure allergic airway inflammation by measuring exhaled nitric oxide. The result determines if the patient will benefit from steroid treatment. At present, Circassia sells NIOX directly in the US and Germany, as well as through worldwide distributors. According to the company's H1 2016 results, sales of NIOX increased 21% to £11.1m, showing growing demand for the products, Circassia believes.

Harris said Circassia would be focusing on expanding their direct sales force to the UK and also to China where respiratory disease is a huge problem, making it an "attractive market." France and Italy held other opportunities for a direct sales force as distributor agreements had recently been terminated.

As for its respiratory drugs activities, Circassia has initiated negotiations for the return of EU rights to *Fliveo,* their recently approved substitute **GlaxoSmithKline PLC**'s asthma inhaler *Flixotide*, among other things.

He said Circassia's expanding commercial infrastructure will also be a real asset for advancing other respiratory products, which would be sourced externally and added to Circassia's portfolio. "We're looking to use our commercial infrastructure to sell products that other people have developed so we're not looking to add lots of research and development to increase costs but we're looking at other products to add sales. That may be through acquisition but it may be partnering or licensing."

CAT-SPIRE IN THE BACKSEAT

As for the cat allergy drug Cat-SPIRE, Harris said development of this has taken a backseat. A subset of patients from Cat-SPIRE will be followed up for a second year to determine if the placebo effect might wane and a large-scale field study into a house mite allergy treatment is due to complete in spring 2017.

Commenting on investor sentiment, Harris admitted he thought shareholders were feeling "a bit sore" following the disappointing Cat-Spire results. "They've lost money from their investment in Circassia, that doesn't make me feel good and I'm sure that doesn't make them feel good but they're also realistic as they knew there was a risk of failure at Phase III, and that's the nature of the business," Harris told *Medtech Insight*.

He said the focus now for Circassia was to build itself back up from the disappointment of the study and look to the future.

"They've said to me, 'Don't worry about where you've come from.' Now it's, 'Where are you going?'"

Published online 09/28/16

Sunshine Heart Changes Course Again: Pauses Neuromodulation To Focus On Aquadex

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Sunshine Heart Inc. announced a major shift in its overall focus for the second time in the last four months.

Under the "strategic realignment" announced Sept. 29, the company says it will pause clinical development of an implanted neuromodulation device to treat heart failure and focus resources instead on commercializing the Aquadex FlexFlow Aquapheresis system. Sunshine Heart acquired Aquadex Aug. 8 from **Baxter International Inc.** for $4m in cash and 1 million shares of Sunshine's stock.

"Aquadex was an important strategic investment, which allows Sunshine Heart to strengthen its presence in the heart-failure market," Sunshine Heart CEO John Erb says in a Sept. 29 release. "We have been very pleased with the reception and enthusiasm we have received from many current and former Aquadex customers that depend on Aquapheresis therapy to manage fluid overload, including patients with congestive heart failure."

Aquadex Flexflow is 510(k)-cleared in the US for up to eight hours of ultrafiltration treatment in patients with fluid overload who have failed diuretic therapy, and extended ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

The company says the realignment will help it reduce its cash burn from the $2m-per-month rate it recorded in the fourth quarter of 2015 to around $800,000 per-month by the fourth quarter of 2016. Sunshine Heart hopes to attain an annualized revenue run-rate for the Aquadex business of $5m by the end of 2016, reaching $10m by the end of 2017. The company also says it is continuing "ongoing review of potential partnerships, strategic alliances and the pursuit of financing alternatives."

NEUROMODULATION DEVICE PLANS PROVE SHORT-LIVED

The end, at least for now, of Sunshine Heart's neuromodulation project comes just a few months after its initiation. In July, Sunshine Heart announced that it would drop its long-running development of the C-Pulse counterpulsation aortic balloon cuff for heart failure and would instead focus on a new neuromodulation technology for heart failure.

C-Pulse's days were numbered for some time. In December 2015, then-Sunshine Heart CEO David Rosa told *Medtech Insight* that the COUNTER-HF pivotal trial of C-Pulse had been struggling to enroll patients, partly due to a lack of resources. With the company's stock languishing, Rosa left the company several weeks later. He was replaced by John Erb.

Sunshine Heart said clinical data from early experiences with C-Pulse showed that the device was providing greater benefits to patients than what can be explained by hemodynamic action of the aortic cuff alone, and that it discovered that the primary mechanism of action of the device was a "neuromodulatory effect due to the counterpulsation balloon placement on the ascending aorta and its activation of the aortic baroreceptors with each expansion." The company said a fully implantable neuromodulation device would provide a more cost-effective and faster path to commercialization for the company than C-Pulse and that it would provide "broader access to the NYHA class III heart failure market."

"We believe a neuromodulation-based therapy will ultimately be more impactful to both patients and physicians than our original C-Pulse System. We are confident that we are on the right track," Erb said during the company's second-quarter earnings call on Aug. 9. "In fact, we believe that the development and ultimate approval of a fully implantable neuromodulation device can be achieved in half the time and at half the cost of our original system. Our unique approach targets easy-to-find anatomical structures, which provide an immediate and measurable response when stimulated. In addition, the mechanism of action is direct and well understood."

At that time, Erb said the company would soon launch a 20-patient first-in-man acute study of an external pulse generator and prototype electrodes to demonstrate the potential hemodynamic benefits of the neuromodulation approach.

Sometime in 2017, Sunshine Heart expected to launch a six-month, 30-patient clinical trial of a proprietary, fully implantable neuromodulation system to support a CE mark and a US FDA investigational device exemption. Also during the earnings call, Erb said, "I am pleased with the progress we are making on both of these clinical initiatives," noting that clinical sites in Europe and Australia were already lined up to run the first-in-man study, and that the company was in "active discussions with some of the leading medical device companies in the neuromodulation space and negotiations are on track to secure mutually beneficial partnerships."

Erb also said during the call that "Aquadex system is highly complementary to our focus on treating heart-failure patients. Aquadex not only allows us to strengthen our presence in the heart failure market, it will also help us build and expand our relationships with key physician groups, which will be strategically beneficial as we pursue the development of our core neuromodulation technology." Now it appears to be no longer complementary to the company's focus, but its only focus.

Published online 09/29/16

From Military To Medicine, Owlstone Medical Targets Lung Cancer With Its Breath Analysis Tech

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Lung cancer has one of the worst prognosis among the different cancers, especially when detected at a late stage. According to figures from the NHS, in the UK alone around 44,500 people will be diagnosed with lung cancer this year and 35,200 will die. If detected at stage 1, the five-year survival rate for lung cancer is 54%, but this drops to just 4% if the cancer is detected at stage 4.

Owlstone Medical, a Cambridge-based diagnostics company, is aiming to bring to market a breathalyzer test that can improve lung cancer outcomes by identifying patients with early stages of the disease.

The breathalyzer test incorporates proprietary technology from Owlstone Medical's parent company, Owlstone Inc. The latter was founded in 2004 by three researchers from Cambridge University after they developed a microchip sensor technology called *FAIMS* (Field Asymmetric Ion Mobility Spectrometer). The microchip has the ability to detect and identify multiple chemicals in a gas flow at very low concentration (parts per billion). The sensor can then be reprogrammed to detect new gases through software while the hardware remains intact.

Post-9/11, there was a drive for technology to detect explosives and toxic gases, says Billy Boyle, one of the founders of Owlstone Inc. The company's primary focus for FAIMS was therefore on defense and security applications and it won military contracts and received "millions of pounds'" worth of funding and investment to advance their technology.

Then few years ago, the firm started working with clinicians and academics to explore whether that same technology could be used for diagnosing disease. "It turns out that it can," Boyle tells *Medtech Insight*.

In March this year, Owlstone Medical was spun out – with Boyle appointed CEO of the new company – to focus on developing a breathalyzer that incorporates the FAIMS microchip software, reprogrammed to detect volatile organic compound biomarkers in patients' breath that can be linked to specific diseases.

ReCIVA (Respiration Collector for In Vitro Analysis) is Owlstone's CE-marked breath sampler

Owlstone Medical's LuCID, (Lung Cancer Indicator Detection) project was originally funded by a £1m ($1.3m) grant from SBRI healthcare, an NHS England-funded initiative, for Phase I and II development stages. After the spinout, the company has raised more funds, completing a $7m venture capital round in June led by Medtekwiz Advisory Ltd. This new capital will be used to support the company's clinical activities.

Phase I of LuCID has already been completed, where 12 markers of lung cancer were shown to be detectable by FAIMS technology. An expansion of the Phase II trial was announced in September, which will target the development of a customized breathalyzer suitable for use in a doctor's surgery or hospital, and clinical validation of the method.

How does FAIMS work?

FAIMS utilises an oscillating electric field to separate different gaseous analyte ions based on their differing ion mobilities. Gaseous analytes for detection by Owlstone's FAIMS technology undergo three processes; ionisation, filtration and detection. The gas under analysis is introduced into the ionisation region where its constituent molecules gain either a positive of negative charge. The analyte ions are then filtered and separated as they pass between pairs of plates in an asymmetric oscillating radio frequency electric field. The ions become separated depending on their differing mobilities in the RF field. A varying compensation voltage (CV) is applied to the RF waveform that allows ions with different mobilities to be steered towards a detector, generating spectra of ion current as a function of CV. Separate spectra are obtained for positive and negative ions. The separation of ions can be enhanced by increasing the amplitude of the applied RF waveform.

Source: Owlstone Medical

To validate biomarkers in the clinical trial, an analysis of chemicals in patient's breath will be compared against the patient's CT scans and biopsy results, says Boyle. Three-thousand patients have been recruited to take part in the study across 25 different sites in the UK and Europe.

"The project will be looking at a population of lung cancer patients at late stages, but what we're looking at is how well can you transfer the diagnostic algorithm to early stage cancer" says Boyle. "But to do this we need to see more patients, as only a small fraction of patients has early stage cancer."

Boyle says the breathalyzer would provide health-care professionals with an easy, noninvasive and quick method for early stage cancer detection. "The way we envisage it being used is in primary care-type settings. So if someone is at risk of lung cancer, like someone with a smoking history or over the age of 55, the doctor would take a breath sample, send it off for analysis, and if you see suspicious biomarkers you then refer them for follow-up CT imaging."

Owlstone Medical's test entails the patient breathing into a breath collection device, *ReCIVA* (Respiration Collector for In Vitro Analysis), over an extended period of time and then the sample is sent away for analysis. "The lungs are just an extremely good way of exchanging chemicals from blood to the airways so what we're able to do with our breath sampling technology is collect chemicals stored in breath. Once every minute, your entire blood flow circulates round your body so by sampling over that period of time, you're able in essence to sample a lot of chemicals in the blood. It's a bit like doing an analysis of blood."

Boyle admits that he was skeptical when the company started out. "Part of the skepticism that I had when we started looking at this field was that the challenges of breath detection are not just around the sensor itself but also how do you collect a good sample?"

In response, Owlstone Medical has developed ReCIVA, a CE-marked breath sampler that uses internal, fast response CO2 and pressure sensors. ReCIVA can monitor patient breathing patterns in real time using supplied software. The device can be configured to select a particular part of the patient's breath for collection (e.g. alveolar or bronchial fractions) by turning its sampling pumps on or off based on the measured pressure and CO2 level in the mask. Selected volumes and fractions of exhaled breath VOCs can either be sent directly to an analytical instrument for analysis in real time or collected on sorbent packed tubes for later analysis.

ReCIVA is currently being used in the LuCID lung cancer detection project and is being commercialized for research use.

Owlstone Medical believes the breathalyzer test could go beyond lung cancer and be used to diagnose a broad range of diseases: In February, the company was awarded a contract, worth up to £10m in investment, under the Innovate UK Stratified Medicine SBRI, to adapt its disease breathalyzer technology for asthma. The technology would be used to stratify asthma patients and match them to the right treatments.

Published online 10/3/16

CONTINUED FROM PAGE 1

Davar said "[There] is a concern by industry that they're going to be at a competitive disadvantage, and their proprietary rights are going to be at a disadvantage, if they have to disclose results from studies which could have sensitive information, prior to them having a device that will be approved or cleared."

"Particularly in spaces where this is a lot of intense competition, which it's [replacement] hips and knees, or cryoblation, or something else … any innovation of any product that's really going to be a market disruptor, for companies that are doing research and getting results from research, they always want to keep a lid on that clinical trial data as long as they can," Davar remarked.

CHILLING EFFECT ON INNOVATION?

For products in the research and development stage that the company ultimately decides not to launch, the new trial-reporting clients can be a burden and have other negative implications, said Henderson.

"In addition to the obvious administrative burden on device firms – particularly small firms – of having to comply with these reporting requirements for medical devices that will ultimately never see the light of day, one potential downside could very well be a chilling effect on the pursuit of innovative research, as companies consider their clinical study strategies," Henderson remarked.

She added that the clinical trial data for products not launched "could negatively impact FDA's review of a marketing submission for the next generation device that the company does seek to market."

ADVERSE EVENTS REPORTING REQUIREMENT

Among the data elements that must be reported to ClinicalTrials.gov under the rule are adverse events; the full trial protocol and statistical analysis plans; and race and ethnicity data on trial participants in analysis of baseline measures. The final rule goes into detail on how adverse events are to be reported, says a Sept. 23 advisory on the rule by Arnold & Porter, stipulating that the sponsor provide three tables: one on serious adverse events occurring during the trial; a second on information relating to other adverse events that occur more often that 5% within any trial arm; and a third reporting all-cause mortality data.

> "For device firms in a very competitive space, "they want to keep a lid on that clinical trial data as long as they can," says Arnold & Porter Partner Mahnu Davar.

The adverse-event reporting requirements illustrate "part of the public health concern that underpins the push toward this transparency," said Davar. "A company could be aware of a safety signal through early stage research, or post-market research, and not disclose it in a timely manner." He added that the adverse-events reporting fits with a trend of state attorneys general and the Justice Department calling on firms to report all their study data about a product, even when the outcomes are negative.

> "Because of a concern that companies sometimes bury bad studies, while promoting good ones, repercussions for firms hiding bad news about a device could be serious.

FDA is also focused on better alerting the public about early warning signs or safety signals with devices that pose safety issues, and last December issued a draft guidance, "Public Notification of Emerging Postmarket Medical Device Signals."

"There's a concern that companies bury the bad studies, and promote the good studies," Davar added. The repercussions for a company could be serious, he warned.

"If a company isn't disclosing a particular adverse event, but it's conducting a clinical trial that shows a particular implant has a high likelihood of [producing] a particular adverse event, this could now allow a product liability law firm to say, 'you are misleading your physicians and your patients, and they are being harmed' by the product."

This could occur even if the product is never launched, Davar said.

"I think that from the legal and regulatory liability standpoint, the real issue would come about if the product eventually makes it way to the market, and there's data that hasn't been disclosed."

PEDIATRIC SURVEILLANCE DATA TO BE REPORTED

The regulation also serves "as a required guidance" under FDAAA on how companies must submit trial data on post-market surveillance of their pediatric devices. For those firms that are running Sec. 522 post-market surveillance studies on devices used for children that were initiated after Sept. 27, 2007 (when FDAAA went into effect), now will be considered "applicable device clinical trials," even if they are only observational in nature, the rule says, according to Danielle Humphrey, a senior associate at Hogan Lovells.

"For such studies, HHS has indicated in the preamble to the final rule that it was 'unable at this time' to articulate results information that would be relevant across all pediatric post-market surveillance studies that are not clinical trials," she said.

"Accordingly, the final rule requires submission of the final study report that was submitted to FDA. However, the final rule

does allow the responsible party to redact certain information from the report, including names, addresses, and other personally identifiable information, as well as any proprietary Information," including trade secrets, Humphrey added.

RULE MAKES IT DIFFICULT TO AVOID POSTING ALTOGETHER

While the two-year delay on public posting some study results can be helpful to firms, in the long run the trial data will be revealed, Davar noted.

"I think it's possible to thread the needle through the trial's requirements, without disclosing something that's confidential, and I think if a company cannot avail itself of the two-year delay, then it's going to be tricky to make the argument that the study shouldn't be posted at all," he said.

Davar added that some clients had come to him in the early days of the ClinicalTrials.gov when it was first proposed, to ask, "Is there an argument for us to make to not have to post the study *at all?*"

"And I think with the final rule out now, it makes it very clear that if you are engaging in research, and it's a covered study, there's no argument that lets you avoid posting – except for the two-year delay."

Published online 09/30/16

House Subcommittee Reaffirms Health-Care Fraud Focus

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Health-care fraud remains a major concern despite ongoing deterrence efforts, members of the US House Ways and Means Subcommittee on Oversight said during a Sept. 28 hearing.

Estimates show that about 10% of the country's $60bn Medicare budget goes to fraud and abuse – an amount that committee member Tom Reed, R-N.Y., said was twice the budget of the National Institutes of Health and three times that of NASA.

The Department of Justice has recovered $1bn in False Claims Act settlements each year since 2000, said Barbara McQuade, US Attorney for the Eastern District of Michigan, during the hearing. The amount rose to $2bn in 2015, and McQuade predicted that will be matched or exceeded this year. Enforcement, she said, is at an all-time high. In June, charges were filed against 301 individuals, including 61 medical professionals, in a single scheme involving $9bn in false payments.

McQuade, along with HHS Office of the Inspector General Special Agent Abhijit Dixit, testified about a several large enforcement actions, including the $646m settlement paid by Olympus Corp. to settle kickback allegations, which is a record amount for the device industry. But the officials expressed skepticism as to whether enough was being done to identify fraud early, as opposed to chasing it down after large amounts had already been paid out.

"We remain concerned that CMS continues to rely too much on pay-and-chase, rather than preventing potentially fraudulent payments from going out the door," said Rep. Peter Roskam, R-Ill., who chairs the subcommittee.

CMS is the US Centers for Medicare & Medicaid Services.

Roskam noted that credit card companies report fraudulent payments at a rate of less than 1%, and those firms can alert users to suspected fraud within hours. The congressman questioned why CMS can't do the same. "They tell me that Medicare claims are more complicated," he noted. "But if Medicare claims are more complicated, it should also be more complicated for fraudsters to make it look legitimate."

"We remain concerned that CMS continues to rely too much on pay-and-chase, rather than preventing potentially fraudulent payments from going out the door," says Rep. Peter Roskam, R-Ill., who chairs the subcommittee.

In response to questioning, Special Agent Dixit surmised that less than half of health-care fraud is detected and prosecuted. And while improving data analytics is helpful, he said, the technique has to be combined with intelligence efforts to prove fraud. For example, data analysis might show one home-health agency was an outlier in terms of utilization, but it would take witness interviews to prove that the agency was receiving physician kickbacks.

Representatives also asked what further tools would help to better fight fraud. Scott Ward, senior VP of Health Integrity LLC said Medicare program integrity contractors such as his company would benefit from further access to Internal Revenue Service and State department records as a way of more quickly identifying and stopping payment on fraudulent claims. For example, he cited a physician who was found to have been in Dubai for several months even as he continued to bill to see patients in Texas.

McQuade, meanwhile, asked for additional funding to publicize DoJ's enforcement efforts and build out health-care databases. For example, Michigan's prescription drug database, which is important in tracking opiate abuse, is incomplete, she said.

The hearing is a continuation of subcommittee work to understand the causes and solutions of Medicare fraud, Roskam said. It was not tied to any specific proposed legislation.

Published online 09/29/16

Global Device-Makers Want India To Harmonize Standards

PENELOPE MACRAE

India is already one of the world's 20 biggest medical device markets and Asia's fourth-largest after South Korea. Thanks to an expanding middle class, aging population, widening insurance coverage and government universal health-care initiatives, the country's device industry could be worth $25-30bn or even more by 2025, up from $3.7bn in 2014, predicts a new report.

The Indian market is growing at a healthy 15% CAGR, far eclipsing the global industry figure of 4-6%. On top of demographic drivers, domestic manufacturing, exports and sales from local innovations could also spur the sector.

"With an enabling policy framework and ecosystem support, industry estimates indicate a potential to grow at around 28% to $50bn by 2025," consultancy Deloitte says in the report entitled *"Making in India - A Leap For Indian Healthcare."* India's devices industry now represents some 1.3% of the US-dominated global medical devices market of $335bn.

However, for that rosy scenario to materialize, what analysts have described as India's "archaic" medical device regulatory landscape needs to become "clear, unambiguous, transparent and predictable," Abby Pratt, VP of global strategy at AdvaMed, a leading US-based global medical technology trade group, told *Medtech Insight*.

"Harmonizing with global standards just makes it that much easier for companies to manufacture in India and be part of the global supply chain," said Pratt. "Not having separate regulations appropriate for medical devices is a stumbling block for companies to design, develop, test and launch a product in India."

REGULATORY ENVIRONMENT

Currently, India's medical device industry and drug market is governed by the Drugs and Cosmetic Act of 1940, onto which medical device regulation was bolted later and the sector remains highly unregulated, raising questions about safety and effectiveness.

Shutterstock: Lima-Junior

> "Industry estimates indicate a potential [for the device sector] to grow at around 28% to $50 billion by 2025." - Deloitte

India's government, led by Prime Minister Narendra Modi, who is seeking to overhaul an ossified bureaucracy to spur the economy, has identified medical devices as one of its priority "Make in India" sectors to boost manufacturing and create employment.

Right now, the country imports at least 70% of its medical devices – from implantable devices to robotics – and there are fewer than 60 domestic medical device-makers out of around 750 with annual revenues of more than $10m.

Washington, DC-headquartered AdvaMed, which represents companies across the US, Europe, India, China, Brazil and Japan, is urging Indian lawmakers to grasp the regulatory nettle and realize the country's medical device potential.

"If India aligns itself to global standards, it's easier for foreign companies to invest in India and the other way round for Indian companies looking to sell their products abroad. It's helpful all way round … a win-win," Pratt said.

BIG POTENTIAL FROM LOW SPENDING

Deloitte calls the market opportunity "significant." India's per-capita spend on medical devices is the lowest among the BRIC countries at $3 compared with $7 in China, $21 in Brazil, and $42 in Russia, while in the US it's $340. Nearly all the top 40 global medical devices firms have an Indian presence, but most have their production base outside India and import their products for the Indian market.

In June, after struggling to get an amended Drugs and Cosmetic Act through parliament, the government dropped the bill and said it would draw up new legislation to cover the latest medical advances.

There's some question now about whether the revamped legislation will in-

volve two acts – one for drugs and the other for medical devices – or be just a single bill. G.N. Singh, the national drug watchdog, told Indian magazine *Business Today* in July, "We are trying to sort this out."

He said it was agreed there should be "separate verticals" to handle medical devices and drugs. But he noted that "globally medical devices are under the jurisdiction of drug regulators" and said "a similar system will be in place here."

Chemical and Fertilizer Minister Ananth Kumar, under whose remit medical devices fall – confusingly health matters are split among several ministries – said in a Sept. 2 speech that he would "hold discussions with the health minister" on the industry's call for a separate medical devices law to help the industry be globally competitive.

"This is a sunrise industry… We will look at bringing in whatever is the appropriate legislation," he said.

NOTIFICATION SYSTEM

Meanwhile, the government has drafted new medical device rules that can be "notified" swiftly rather than needing the nod of India's fractious parliament. The new rules on which it has invited industry comment would introduce a system of third-party auditing, stipulate educational levels for staff overseeing manufacturing, and classify devices from A to D based on the severity of risks.

The draft rules stipulate the quality requirements for 22 types of medical devices – and align to an international standard – but still leave thousands of medical devices out of the regulatory net.

In the longer term, "we hope they [the government] will go the full mile and create a separate act for medical devices," said Pratt. If they remain under the drugs act, "medical devices will ultimately still be treated as drugs – that's why we are encouraging the health ministry to introduce a separate act."

She notes that drugs with their 20-year patents are very different from devices, which change every 18-to-20 months with upgrades.

HARMONIZATION TO SPUR PRODUCTION

One of the biggest gains from introducing wide-ranging, globally harmonized regulations would be economic, by facilitating growth of domestic manufacturing and production of affordable devices that can compete at a global level, experts say.

The government's twin goals of "Make in India" and "Skills India" would be beneficiaries and foreign players would be incentivized to take advantage of the 100% automatic direct investment route in the sector introduced by Modi's government in 2015.

> "We hope [the Indian government] will go the full mile and create a separate act for medical devices," AdvaMed's Abby Pratt says.

New Delhi believes there's big potential – both for domestic consumption and for exports – for lower-priced locally made devices like X-ray machines, telemedicine units and patient monitoring systems, especially with India's tradition of what's known as "frugal engineering." This involves reducing the complexity and cost of production as well as "jugaad," a Hindi word referring to Indians' capacity for innovative and inexpensive solutions.

As part of its drive to boost the sector, the government is establishing medical device manufacturing parks. Chemical Minister Kumar said these parks could slash manufacturing costs by 30% through pooling facilities.

The government's introduction of a goods-and-services tax that could be implemented by April will reduce taxation in the sector by 12%, Kumar said, adding that an inverted duty structure that has made some imports cheaper than manufacturing them in India is being corrected, and the government will look at "whatever tariff incentives are required."

RANGE OF CHALLENGES

But the industry still faces problems of lack of engineers, product designers and researchers. There are other issues too. Lack of rigorous intellectual property protection for novel technology in India is a drawback for companies envisaging investing. Absence of a local quality certification authority lowers export opportunities as many manufacturers need a certificate from the country of origin.

Right now, local manufacturers must get US or European certification to supply some segments of the domestic market and other parts of the world, and this approval takes time, impacting speed to market. The national government aims to set up the first state-owned medical device testing laboratory in the western state in Gujarat by yearend, Gujarat drugs commissioner H.G. Khoshia recently announced.

Affordability is another key issue with 61% of medical care paid out-of-pocket and hundreds of millions of Indians still living on less than $2 a day. The challenge "for companies in India is to produce medical devices that are both cost-competitive and effective to increase penetration," noted Deloitte.

Another problem is the absence of an adequate ecosystem to support medical device manufacturing locally as a big part of the component supply chain is imported. And despite the Modi government's efforts to reduce red tape, India still lags behind most countries in ease of doing business, with the World Bank ranking it 130 out of 189 nations.

"There are a lot of issues for companies to consider when deciding to invest anywhere abroad. They want to know how long it will take for their product to be approved, what's the regulatory situation. They're looking at investing a lot of money, they want to know what the process is going to be like," Pratt said.

The 2016 Deloitte report suggests India could take a page out of China's book to spur its medical device industry. China, which is a domestic consumption and manufacturing hub, allows fast-track approval of locally produced "innovative" medical devices and has reduced corporate tax for the sector to 15% from 25% as it is an "encouraged industry."

Published online 09/28/16

UK Regulator Wants To See Medtech Legislation Implemented Appropriately

Getting the manpower in place to bring about the successful implementation of the future Medical Devices Regulation and IVD Regulation is going to be tough, admits John Wilkinson, head of the devices section of the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

Speaking at the London Annual Regulatory Conference of the Association of British Healthcare Industries (ABHI) on Sept. 28, Wilkinson said he had "some concerns about the aggregate capacity of the sector" to deal with all the issues related to implementation of the two new regulations, which are likely to be adopted during the first quarter of 2016. "The sheer number of people needed is a problem," he stated.

"We thought the negotiations were hard work," the regulator stated, "but implementation is going to be something else." He should know; having headed the European medtech trade association and now as head of devices at the MHRA, he has the insight of both the industry and the regulator.

It was good to see Wilkinson address a large audience again after a long period of being publicly less prominent.

Behind-the-door negotiations on the future regulations, and political uncertainty post-Brexit, have made it difficult for him to talk openly. And while broader Brexit issues remained off-territory, on Sept. 28 Wilkinson was able to comment on how the MHRA is planning the first steps toward implementation of the regulations, and on what he sees as the major challenges.

Wilkinson is a particularly well-respected communicator and coordinator who has injected the UK message of moderation into EU discussions. His public resurgence, Medtech Insight notes, will no doubt be welcomed by those wanting leadership during the challenging period ahead of implementing the immensely complex texts, whatever the status of the UK in the EU.

The UK's vote to leave the EU means no one quite knows what that will ultimately mean for the medtech sector mid-long term, but the MHRA's priorities in terms of safeguarding patients remain the same, he told the meeting. "Until we have executed Article 50 and gotten out of the EU, we are full members and we will be energized in making sure that the legislation that we shaped is correctly implemented," he told the conference.

Wilkinson did not shy away from admitting what a huge task lies ahead for all those involved in implementing the forthcoming rules; like many other speakers at the meeting, he stressed the need to break up planning into bite-sized pieces, as well as the need for cooperation and collaboration at all levels to create a mutually understood strong basis to move forward.

In planning, it is important to remember, he said, that there are no discrete clusters of topics in themselves, but rather a series of interrelated topics and overlaps in the regulations.

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"Collaboration is key," he stressed. "We need to get working groups together across member states to get things organized and coordinated, otherwise matters may become fragmented."

Toward this end, Wilkinson will be meeting up with his EU device competent authority counterparts shortly within the context of the Competent Authority for Medical Devices Group in Bratislava, under the Slovakian Presidency of the Council of the EU on Oct. 17-19. There the aim will be to identify those priorities that need dealing with first.

Wilkinson also stressed that whatever comes out of discussions needs to be "proportionate, sensible and balanced" – words that have characterized the UK regulatory approach that has proved popular and persuasive at EU level.

NOTIFIED BODIES AND THE TRANSITION PERIOD

Two particularly critical areas in terms of the successful implementation of the new regulations will be the redesignation of notified bodies and the length of time that their certificates can remain valid.

Getting notified bodies redesignated in time is going to be the biggest single challenge ahead, Wilkinson noted. The good news, he said, is that the European Commission has indicated that there may be some flexibility in cases where the notified body has just been audited. In such cases, there may be a lightweight way of redesignating them, he suggested.

There is also the question of whether notified bodies can operate under both the directives and the regulations at the same time. "I can't see why they shouldn't," Wilkinson said, adding that this may help smooth the transition to the new regulations.

Another big issue around notified bodies that needs to be addressed is the competition element between them and the fact that all notified bodies will want to be among those that are redesignated in the first wave, Wilkinson said.

In conclusion, Wilkinson is no stranger to the enormity of the tasks ahead. The current directives offer a "pretty decent legislation, but are not fully effective" and have fallen into some "disrepute," he said.

This means that the changes on the horizon are "absolutely necessary," he stressed, adding that the majority of planning will need to be done over the next few months to ensure the regulations are implemented effectively. The UK regulator, he said, is keen to talk with industry – through the national trade association or other representative organizations – to ensure its voice is heard.

Published online 09/29/16

UK MHRA Presses For Leading Global Role Post-Brexit

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The UK medical device regulator, the MHRA, has had a leading role in the regulation of medical technology – in the EU and globally – over many years, and there is no reason for that to change in the wake of the UK's referendum vote to leave the EU.

That is the view of MHRA medical devices director John Wilkinson OBE, speaking to packed house at the Association of British Healthcare Industries' Annual Regulatory Conference 2016 (September 28) in London. Packed, because the EU Medical Device Regulation and In Vitro Diagnostic Regulation have only recently been published, and this was the first opportunity for SMEs and MNCs alike to get some context around them and also an idea of what extra demands will be placed on them – and when.

But like a great shadow over the industry – or indeed the much-referred-to elephant in the room – there was no dodging the thirst for information about any sense of direction being taken over Brexit, in spite of conference chair Shuna Mason's opening message that Brexit was not an agenda item.

Mason is a partner at CMS Cameron McKenna.

Deciding to address the theme early, Wilkinson said the MHRA has assembled its own Brexit team in view of the importance of engaging with all stakeholders – in and outside the UK. "We hope to have influence wherever we can," he said, adding that nothing is guaranteed, and not all of the MHRA's work in this direction can be made public.

In these early days, where positions are still being worked out, the MHRA director admitted that he could not reveal much, and politely declined further Q&A on the theme of Brexit from Medtech Insight. Suffice to say that so far, the MHRA considers that no regulatory change or a whole batch of new regulations for the UK are equally unlikely.

For UK life-sciences regulation, the likely route ahead lies in "shades inbetween" these opposite ends of the spectrum, and the MHRA's approach to whatever regulatory option eventually emerges for the UK needs to be contextualized by what is best for patients, R&D and the medtech industry, he said.

Keeping a level head in these uncertain times is an unspoken part of the brief. Wilkinson said that regulatory priorities have not been altered by the Brexit vote given that "technological regulatory challenges do not change." Putting a positive complexion on matters, he said that the UK should also take the chance to ensure it creates an environment that is innovation-friendly.

Returning to the central theme of the day – the MDR and how to respond to it – Wilkinson was critical of the fact that it took a full eight-and-a-half years to refresh core EU legislation (the MDR). "It's not helpful. We need to speed things up."

But the UK remains a member of the EU and will be active in progressing the legislation and pressing for it to be effectively implemented. That stands, regardless of the UK's future relationship with the EU27 and its ability or otherwise to keep in force legacy EU legislation – at whatever level or extent.

Published online 09/28/16

CDC Whistleblower Says Test Misses Too Many Zika Cases; US Special Counsel Calls For Review

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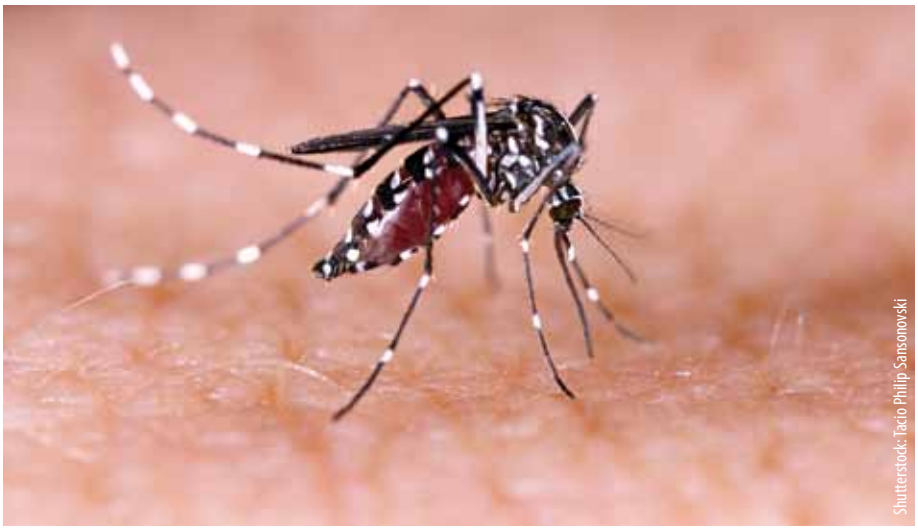
Officials at the US Centers for Disease Control and Prevention and HHS have investigated and dismissed a CDC laboratory chief's allegations this past summer that the agency is promoting a Zika virus detection test, *Trioplex*, that is substantially less sensitive than CDC's older *Singleplex* laboratory-developed test. CDC said it chose Trioplex because it can also detect two other related viruses. Nonetheless, on Sept. 27, the US Office of Special Counsel asked the White House in a letter for further review of the whistleblower's disclosures on the Zika tests.



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The Trioplex test missed 39% of Zika infections detected by Singleplex, said whistleblower Robert Lanciotti, who is chief of the CDC's Diagnostics and Reference Laboratory at the agency's Arbovirus Diseases Branch. "There was clearly enough data to warrant a pause in the recommendation of Trioplex [by CDC] until an extensive comparison could be performed," he said.

HHS referred the case to the Office of Special Counsel, which did its own review. "As the agency contemplates additional improvements or changes to the Zika testing protocol, I encourage CDC to review Dr. Lanciotti's comments, respond to each of his concerns, and utilize his experience as the agency works to ensure it is implementing the most effective test methods in response to this public health emergency," concluded Special Counsel Carolyn Lerner.

Her Office of Special Counsel forwarded a letter and CDC's report to the White House about its investigation of Lanciotti's complaints.

"The CDC conducted a thorough investigation in Dr. Lanciotti's allegations, and its findings appear reasonable," Lerner stated in her letter. "However, Dr. Lanciotti raises serious concerns about each of the CDC's findings, including the methodology for discounting his research and that conducted by [independent laboratory] BSRI, both of which suggest that the Trioplex may detect fewer Zika infections than the Singleplex."

Lerner also disclosed in a Sept. 27 release that after Lanciotti complained to CDC officials and to state public health officials about his concerns on the Trioplex tests, the lab director "was reassigned to a non-supervisory position within his lab" in May. Lanciotti then filed a whistleblower retaliation claim alleging that CDC's action to diminish his duties from lab chief to a non-supervisory position was reprisal for his disclosures.

After the investigation, the Office of Special Counsel secured an agreement from CDC to reinstate Lanciotti as chief of his lab.

ALLEGATIONS ABOUT TRIOPLEX

Among Lanciotti's allegations, said the Special Counsel, were that use of Singleplex in a clinical setting would result in an additional 39% of acute-phase Zika infections going undetected. He reached this conclusion after analyzing results of a multi-assay comparative study performed at his laboratory and reviewing summary data compiled by the Blood Systems Research Institute, which is a separate, independent lab.

Lanciotti provided this evidence about Trioplex's lower rate of sensitivity to the CDC's Emergency Operations Center (EOC), which makes decisions for the agency about which tests should be used in response to the Zika outbreak as it has escalated. In April, the EOC continued to recommend use of Trioplex. Ultimately, the whistleblower said, public health labs approved to use Singleplex began preferentially using the Trioplex "based on the incorrect belief that it is the superior method" for detecting Zika-virus RNA.

CDC answered Lanciotti's charges: "There is insufficient statistically robust, definitive data to reach an evidence-based conclusion that use of Trioplex assay over the Singleplex in clinical practice will result in 39% of Zika infections being missed."

Agency investigators added that while Lanciotti's study showed that Trioplex was less sensitive, a CDC laboratory in Puerto Rico found the two tests had approximately the same sensitivity for detecting Zika, and that "inconsistencies in

how the assays were performed and in data reporting precluded making a statistically valid conclusion."

In response to Lanciotti's second point that EOC continued to recommend Trioplex, CDC stated, "Sharing inconclusive performance data showing a conflict between CDC laboratories would have provided little actionable information to external laboratories" and "had the potential to create considerable confusion during an ongoing emergency response."

SINGLEPLEX LDT VERSUS FDA-AUTHORIZED TRIOPLEX

The microbiology debate pits a single-target, laboratory-developed test (Singleplex), which some local public health labs had been given a protocol for by Lanciotti's CDC reference lab and were relying upon to detect Zika virus cases, against the heavily validated, triple-targeted (Zika, dengue and chikungunya) Trioplex diagnostic that CDC developed over the past year. CDC obtained an emergency-use authorization for Trioplex from FDA in March, and has been asking public health laboratories to use ever since.

CDC argued in its investigatory report on Lanciotti's charges that there was an internal debate over which tests to submit to FDA for an EUA submission. The agency said it had solid reasons for picking the Trioplex, including:

- There was added clinical utility of testing for three different viruses;
- Testing for all three viruses on a single test would be more efficient and reduce burdens;
- The preliminary work had already been done to prepare the assay for 510(k) submission, which laid the groundwork for submitting an EUA application; and
- Dr. Jorge Muñoz-Jordán of CDC's Puerto Rico laboratory was willing to guide the test through the submission process.

After FDA's authorization of the Trioplex, CDC recommended that state and local health departments use that test, and "clearly supported its use and dissemination," the agency's report stated.

> "Dr. Lanciotti raises serious concerns about each of the CDC's findings ... which suggest that the Trioplex may detect fewer Zika infections than the Singleplex" – Special Counsel Carolyn Lerner

However, it added, "at no time did CDC instruct states to stop running the Singleplex or any other Zika virus real-time RT-PCR assays."

The Singleplex LDT was designed in Lanciotti's lab during a 2007 Zika virus outbreak in Micronesia, and used by his laboratory thereafter, according to the CDC/HHS report on his complaints. It is designed to detect Zika virus RNA only, and does not detect genetic material from any other viruses. The assay is not cleared, approved or authorized by FDA, but may be run in appropriately certified Clinical Laboratory Improvement Amendment (CLIA) laboratories.

As the diagnostics and reference activity chief, Lanciotti worked with partners in state and local health departments so they could run a version of the Singleplex assay to detect Zika in their labs. He also provided the external labs with a two-page protocol that provided information on deploying a version of Singleplex, and provided positive control material to help run the test.

The Trioplex assay came into play when CDC started developing an alternative to Singleplex in an effort led by CDC laboratorians Lanciotti and Muñoz-Jordán of the agency's dengue branch in San Juan, Puerto Rico, in fall of 2015. The goal was to make a multiplex assay that tested for Zika, dengue and chikungunya viruses and to generate the extensive validation data needed to bring the Trioplex assay through an FDA 510(k) submission and review.

However, by winter of 2015, the worsening Zika outbreak induced the urgency to quickly complete development of the assay and seek an expedited regulatory review from FDA to allow distribution to state, local and territorial public health laboratories.

RECENT UPDATES TO TRIOPLEX

One positive result that may have come out of Lanciotti's whistleblower complaints is that the agency is now tweaking its Trioplex test to ask for a larger-than-standard input volume for the test.

According to the Special Counsel's letter to the White House, on Aug. 22 the CDC submitted a substantial amendment to the Trioplex EUA for FDA approval seeking authorization to use larger sample volumes in the assay. Lanciotti acknowledged that the CDC's proposed amendment to the Trioplex EUA may increase the Trioplex's analytical sensitivity, although he also said that when primers directed against multiple pathogens are combined in one test, the sensitivity of the assay is inherently reduced.

Lerner also mentioned that on Sept. 27 she transmitted the CDC report, and whistleblower Lanciotti's comments on it, to the chairmen and ranking members of the Senate Committee of Health, Education, Labor and Pensions, and to the House Energy and Commerce Committee.

Published online 09/29/16

Short-Term US Funding Bill Passes With $1.1bn In Emergency Zika Funds

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Congress approved an additional $1.1bn in emergency funding to fight the spread of the Zika virus on Sept. 28 as part of a fiscal year 2017 continuing resolution measure that keeps government agencies, including FDA, running at current spending levels until Dec. 9, after the US election.

"This is a necessary bill that will keep the government open and operating, provide resources for our service members and veterans, and address critical needs across our country related to the Zika virus, the opioid epidemic, and the recent disastrous floods," said House Appropriations Chairman Hal Rogers, R-Kent.

Senate Appropriations Committee ranking member Barbara Mikulski, D-Md., also praised the resolution, saying, "The bill fights the Zika virus with $1.1bn of emergency funding without objectionable riders restricting funding."

Recent mosquito control and other Zika virus prevention efforts in Florida have kept the number of pregnant women who were infected in that state at bay, the Centers for Disease Control and Prevention (CDC) said in a recent update. But the agency is still testing for additional Zika cases and trying to prevent the disease, which can cause microcephaly and other illnesses in newborns, from spreading in other states.

NO EMERGENCY DOLLARS FOR FDA

Approved by the Senate on a 77 to 21 vote, and agreed to by the House late last night by a margin of 342 to 85, H.R. 5325's $1.1bn appropriation includes no money earmarked for FDA, which has been working hard to turnaround emergency-use authorizations for newly developed Zika virus tests as quickly as they come in, FDA device director Jeff Shuren said recently.

According to lawmakers, the money will be cut five ways:

- **$394m to the CDC** to support Zika-carrying-mosquito eradication, disease surveillance, and laboratory testing via several CDC and private company tests authorized by FDA in emergency use authorizations (EUAs). CDC will also use its dollars to support education and outreach, and to reimburse state and local public health departments.
- **$397m to the National Institutes of Health (NIH) and Biomedical Advanced Research and Development Authority (BARDA)** to support advanced R&D of diagnostics, vaccines and therapeutics.
- **$141m to support health-care services,** including contraceptive services and maternal and child health services, to prevent the spread of Zika. This amount includes at least $126 million for Puerto Rico – which has been hit hard by the Zika outbreak – and the territories.
- **$145.5m to support international health-care services**, including vector control activities, diagnostics, vaccines and building up the health-care infrastructure.
- **$30m to the State Department and US Agency for International Development** for personnel costs, including evacuation and care for ill American diplomatic and developmental workers.

MEDICAL GROUPS PRAISE FUNDING

The American Medical Association and other health-care groups praised Congress for passing the emergency Zika funding. "With the threat of the virus continuing to loom, this funding will help protect more people – particularly pregnant women and their children – from the virus' lasting negative health effects," AMA President Andrew Gurman said.

The Infectious Diseases Society of America also welcomed the additional $1.1bn, but the medical society also said it is "disappointed that the package fails to replenish resources redirected from other public health needs, including from funds allocated to ongoing impacts of the 2014 West Africa Ebola outbreak."

In addition to tapping $117m in leftover Ebola outbreak funding to pay for the emergency Zika funding package, Congress is using $168m originally intended to help US territories set up Affordable Care Act exchanges, and $115m in total rescissions from unobligated balances in prior disaster funding originally intended for the Federal Aviation Administration, the Department of Transportation, and the Federal Emergency Management Administration, among other agencies.

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