**POLICY & REGULATION**
US CMS downsizes bundled-payment programs, p. 9

**COMMERCIAL**
Hindsight 20/20: Raymond Cohen, p. 5

**R&D**
LimFlow gets a foot in market for endovasc limb ischemia treatment, p. 13

Medtech Insight
Issue 58
medtech.pharmamedtechbi.com

Pharma Intelligence Informa

August 28, 2017

# MDUFA IV (AND MORE) IS LAW: Trump Signs A Health-Care Bill

**SUE DARCEY** sue.darcey@informa.com
**DAVID FILMORE** david.filmore@informa.com

President Trump quietly signed the FDA Reauthorization Act Aug. 18, authorizing about $1bn in device user-fee collections over the next five years and a range of reforms and enhancements the agency's review programs.

The signature came with no signing ceremony, and was largely unnoticed amid news about the departure of Steve Bannon from the White House staff and other controversies. But his signature means Trump can take some credit for getting at least one piece of major health care legislation passed his first year in office, following the failure to repeal and replace the Affordable Care Act. *(Also see "Senate To Consider User Fee Bill Soon, As Hopes For BCRA Passage With Device Tax Repeal Fade" - Medtech Insight, 19 Jul, 2017.)*

FDARA reauthorizes the prescription drug, medical device, generic drug and biosimilar user-fee programs for another five years, beginning Oct. 1, and also makes other, largely industry-supported reforms to FDA.

The lack of fanfare and Trump waiting to sign the bill just hours before it would have been enacted by default anyway (the president has 10 days to sign or veto a measure after it is delivered to the White House) may signal tepid support for the measure, which attracted overwhelming majorities in Congress. *(Also see "Senate Approves FDA User Fee Reauthorization Bill On 94-1 Vote" - Medtech Insight, 3 Aug, 2017.)* The White House previously proposed to scrap the prescription drug, medical device, generic drug and biosimilar user-fee agreements inked last summer with the Obama administration and instead make company fees cover FDA's entire pre-market review budget, but lawmakers resisted the pressure. *(Also see "Trump Budget: FDA-Regulated Firms Should Pay 'Their Share' In User Fees" - Medtech Insight, 16 Mar, 2017.)*

The enactment is an unambiguous victory for the device industry. Implementing the MDUFA IV device-user-fee has been the sector's top overall FDA priority, and finally the agency has the statutory go-ahead to do so.

The reauthorization will mean increased fees for pre-market submissions – a total of $320.5m (plus inflation) extra over five

CONTINUED ON PAGE 20

TABLE 1

## Select New MDUFA IV Performance Goals

| CATEGORY | GOAL DESCRIPTION |
|---|---|
| PMA – Shared Outcome Goal | A ramp-down in three-year total-time-to-decision averages, from 320 days to the FY 2016-2018 receipt cohort, to 290 days for the FY 2020 to FY 2022 cohort. |
| 510(k)s – Shared Outcome Goal | A ramp-down from 124 total days for FY 2018, to 108 days for FY 2022 |
| Pre-submissions | FDA will provide written feedback to a pre-submissions request within 70 days of receipt or five days before a meeting, whichever is first. The goal will be reached for 1,530 submissions in FY 2018, and ramp up to 1,950 in FY 2022. |
| *De novo* Classifications | 150 "FDA-day" review standard for 50% of submissions in FY 2018, incrementally increasing to 70% performance in FY 2022 |
| CLIA Waivers | A 180-day standard for 90% of dual 510(k)/CLIA waiver submissions; a 150-FDA-day standard for 90% of CLIA waiver by applications without an advisory panel meeting; a 320-FDA-day standard for 90% of CLIA waiver by applications with an advisory panel meeting. |

# MEDICAL TECHNOLOGY EXECUTIVE FORUM

## SEPTEMBER 15, 2017

**CROWNE PLAZA CABANA HOTEL**
**PALO ALTO, CA**

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

**MDMA's 10th Annual Medical Technology Executive Forum** will be held on September 15 in Palo Alto, CA. The agenda is now available and includes multiple interactive panels with top industry experts and government officials.

### TOPICS INCLUDE

- The Future of Med Tech Innovation
- Raising Capital
- CEO Perspective: "Do's and Don'ts" for Successful Leaders

### CONFIRMED SPEAKERS INCLUDE

- **Mike Carusi**, General Partner, Lightstone Ventures
- **Jeff Dunn**, President & CEO, Si-Bone, Inc.
- **Thomas Fogarty**, Physician, Inventor & Founder of Fogarty Institute for Innovation
- **Marc Galletti**, Managing Director & Founder, Longitude Capital
- **Mir Imran**, Founder, InCube Labs
- **James Mazzo**, Global President, Ophthalmic Devices for Carl Zeiss Meditec AG
- **Casey McGlynn**, Partner, Wilson Sonsini Goodrich & Rosati (moderator)
- **Reneé Ryan**, Vice President, Venture Investments, Johnson & Johnson Development Corporation
- **Jeffrey Shuren**, MD, Director, CDRH

**REGISTER TODAY** to ensure your spot and network with over 150 med tech executives!

**MDMA Members $395**

**Nonmembers $595**

**TO VIEW THE AGENDA AND REGISTER, VISIT *WWW.MEDICALDEVICES.ORG***




## explore more:

exclusive online content

**Expanding medtech's toolbox**
**http://bit.ly/2vmjX7K**
Three years in the making, FDA has released a final guidance for medical device development tools that could help manufactures move to market more quickly.

**EU challenges**
**http://bit.ly/2v5DNcc**
The EU Medical Device and IVD Regulations may yet have a devastating effect on the EU's speedy access to innovation in general, and on small companies in particular, according to one Swiss medtech CEO.

**Eye on drug delivery**
**http://bit.ly/2iq3oql**
The market for ophthalmic drugs is expected to exceed $30bn in 2020 and more effective drug delivery systems are being developed to fully capitalize on this growth. Read about the latest innovations in ocular drug delivery technologies that are in the pipeline.

**Starts & Stops**
**http://bit.ly/2h1QXQS**
Find out which clinical trials were initiated, suspended and completed in the previous month.

**Device Week**
**http://bit.ly/2v0IJtS**
In the latest episode of our weekly podcast, *Medtech Insight* journalists discuss M&A trends. In the next episode, we'll address what the enactment of the FDA Reauthorization Act means for medtech.

medtech.pharmamedtechbi.com

# inside:

# Medtech insight

**DAVID FILMORE** @MEDTECHDAVID
david.filmore@informa.com
**TINA TAN** @MEDTECHTINATAN
tina.tan@informa.com
**SHAWN M. SCHMITT** @MEDTECHSHAWN
shawn.schmitt@informa.com
**REED MILLER** @MEDTECHREED
reed.miller@informa.com
**AMANDA MAXWELL** @MEDTECHAMANDA
amanda.maxwell@informa.com
**MARION WEBB** @MEDTECHMARION
marion.webb@informa.com
**SUE DARCEY** @MEDTECH_INSIGHT
sue.darcey@informa.com
**FERDOUS AL-FARUQUE** @MEDTECH_DANNY
danny.al-faruque@informausa.com
**ELIZABETH ORR** @ELIZABETHJORR
elizabeth.orr@informa.com
**CATHERINE LONGWORTH** @MEDTECHCATE
catherine.longworth@informa.com
**ASHLEY YEO** @ASHLEYPYEO
ashley.yeo@informa.com
**MAUREEN KENNY** @SCRIPREGMAUREEN
maureen.kenny@informa.com
**NEENA BRIZMOHUN** @SCRIPREGNEENA
neena.brizmohun@informa.com
**VIBHA SHARMA** @SCRIPREGVIBHA
vibha.sharma@informa.com
**JANET HANIAK** SENIOR DESIGNER
**GAYLE REMBOLD FURBERT** DESIGN SUPERVISOR
**RICHARD FAINT** HEAD OF MEDTECH
richard.faint@informa.com
**PHIL JARVIS** MANAGING DIRECTOR

Editorial office:
52 Vanderbilt Avenue, 11th Floor, New York, NY 10017
phone 240-221-4500, fax 240-221-2561
**CUSTOMER CARE:**
**1-888-670-8900 OR 1-908-547-2200**
**FAX 646-666-9878**
**clientservices@pharmamedtechbi.com**



## ▶ join the conversation

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

@Medtech_Insight

the market due to reports that blood clots and occlusions may form inside the graft when it's used to treat blunt traumatic aortic injury.



### R&D



### POLICY & REGULATION



# Hindsight 20/20: Raymond Cohen

**TINA TAN** tina.tan@informa.com

*Raymond Cohen, CEO of Axonics Modulation Technologies, Inc.*

With around three decades of experience in the medical device industry, Raymond Cohen is recognized for having led several start-ups developing disruptive, technological innovations to growth and has also sat on the board of various publicly-listed entities. He is currently CEO of Axonics Modulation Technologies Inc., a California company developing a rechargeable sacral neuromodulation technology to treat urinary and fecal dysfunction. He recently took the firm through a $35m series C financing round. He was previously CEO of other neuromodulation companies including renal denervation firm Vessix Vascular Inc. , which was acquired by Boston Scientific for $425m in 2013.

Cohen's experience stretches beyond the US, having been on the board of directors of several European firms in the cardiovascular intervention space, among other things.

**Medtech Insight: What are the biggest mistakes you see young companies make over and over again in their clinical strategy?**

**Raymond Cohen:** This is a complex topic which can be looked at from various perspectives. Early-stage device companies trend towards two major mistakes - they often go into a clinical study with a prototype device and they tend to overcomplicate and outsource.

Going to the clinic for a human study with a product that is not a commercial-grade product fundamentally guarantees that you will have problems and have you hope that none of the compromises you made affect patient safety. The easiest way to kill a company and dampen investor support is to have a safety issue. And besides, do you really want to spend time making excuses for the ugly duckling product?

Study designs tend to have objectives that are beyond what is required as an initial step. This is sometimes a function of an executive being advised by overzealous clinical/regulatory consultants or investors. The thing I hear often is "that's just the way it's done." Hogwash. Sure, there are some rules. However, clinical and regulatory folks often work off of what they heard or learned – good or bad – at their last company and have a tendency to spit it back out as gospel. You have to ask yourself – is there really anything more to prove in this first study other than that the product is safe and works as designed? Of course, you want to see efficacy, but that will be there assuming the device works.

I have also observed folks engaging CROs on the assumption that "this is the way it's done," or that a CRO is necessary, or that the CRO will bring expertise that the early-stage company may not have on the team. Hiring a CRO is a sure-fire way to ensure a study will be expensive since CROs bill by the hour. The entire study process, from filings with Ethics Committees, etc. will, no doubt, take longer than desired and be more complex. There's a role for CROs but it shouldn't be the first thought. CROs are great for monitoring, but they don't drive enrollment and won't be able to handle physician investigators who will want to enroll patients that they feel will benefit from the therapy even if it doesn't quite meet up with the inclusion/exclusion criteria.

Bottom line: No third party is going to care more about your product and your patients than the company and its representatives. My advice is to hire good people and do the majority of the tasks yourself. A virtual clinical department is, in my view, a fantasy and turns out to be much more expensive. When you do things yourself, you will learn everything there is to know about how folks use the product and how patients react.

**Financing is always an issue with start-ups, but in which area(s) would you advise companies absolutely not to skimp on with the budget and why?**

If you are going to play the game, it's going to take money. And a lot more than you imagine. My advice is to forget dilution and raise as much money as you can, as early as you can. Time is of the essence and velocity is important. In terms of where to invest – it should be all about end-user research and product development. You need to understand what you are going to build from a design standpoint – form, function, features – before you build it. If you don't have a great concept and an embodiment that is a winner from both a functionality and design standpoint, then all the "other stuff"' is not going to get you to the promised land.

**Some venture-backed companies opt to take the IPO route. In your experience, aside from the stock market conditions, what factors must be considered to assess whether the time is ripe to go public or not? And what factors enable a company to thrive in the public markets?**

An IPO is a well-worn approach. However, to attract institutional investors to execute the IPO typically requires a few

years of commercial sales showing positive momentum and solid growth. This is more applicable in US than in certain European jurisdictions. Whilst going public is a good way to raise a large sum of money, it has its downsides. In particular, once you are public, sales need to grow quarter after quarter and it becomes quite challenging. Early-days product problems or market adoption issues will guarantee that the company gets punished. Public investors are, by definition, "fast money" players and will easily lose interest, accept losses on their shares and sell out their position. If you can effect a trade sale – it's never too early to sell– then that's the best way to ensure an ROI on your time and your investors' money.

**If you had to put together a dream team to help you take your company's disruptive, white space-targeting technology from bench to market, what attributes/skills/expertise would you be looking to recruit?**

First, I want an experienced operating person who understands the medical device business and can sell the vision to lead the company. Second, I want the most diligent and intelligent product development person that has a track record of solving complex technical problems and has access to a bench of engineering talent. Third, I want a subject matter expert who understands the clinical application perfectly.

Fourth, I want the most creative regulatory professional who knows how to get things done, Fifth, I want an in-house intellectual property attorney on staff. Sixth, I want a clinical person who knows how to run clinical operations. And finally, I want a finance person who can do modeling and manage the finances. Lastly, I want to engage two outside groups – a stable of KOLs in the field to provide input from the medical side of things and a great industrial design firm who can do the end-user research and then help translate that into the actual product design. What you don't need is sales or marketing talent to start with.

**Share with us your experience of a particular crisis you encountered either as part of the management or on the board of a company. How was the crisis averted and what do you think could have been done differently to avoid the problem ever arising in the first place?**

Success is far from a sure bet in the medical device business, and I have yet to meet anyone in our business who has not experienced crisis situations. There's no doubt that handling a crisis is much easier when your company is privately held. For a publicly-traded company, when things go bad, the dirty laundry is hung out for all to see and the punishment from the market is typically quite severe in terms of loss of share price, credibility and market capitalization. A downward spiral many times results in law firms launching "investigations" claiming malfeasance by management, share prices falling below $1 and running afoul of listing requirements.

## 3 IN 30:
## Three quick-fire questions in 30 seconds

**What do you do to help unwind from the stresses of your job?**
On a regular basis, I enjoy socializing with friends and following major league baseball. My favorite activity is fly fishing which is a wonderful way to clear one's mind.

**Who, outside the medtech industry, do you see as a role model and why?**
As a young person, it was hall of fame baseball player, Roberto Clemente. In addition to being a great player, he was a true gentleman who was deeply involved in charity work. His humanitarian efforts ultimately cut short his life at 38 years old when he died in a plane crash en route to help earthquake victims in Central America.

From a business perspective, given I'm a huge fan of great product design, I'd say Steve Jobs.

**If you weren't running medtech companies, what would have been your career Plan B?**
I'm not much for Plan Bs but my fantasy job is to be the general manager of the Los Angeles Dodgers. Although running a minor league baseball team would be fun!

I have recently lived through such a crisis in my role as a chairman in one publicly-listed company. It's a cautionary tale where two major mistakes led to the elimination of $200m in shareholder value. The first mistake stemmed from management not being clearheaded about the usability of the product, and the second was going too wide and too soon in its US market adoption strategy. Clearly, the board of directors bears responsibility for strategy, however, the board is not management and must rely on the folks operating the business to understand the product pros and cons, competitive landscape and market dynamics.

The result of pursuing this strategy was a cash burn of around $50m in two years. Anytime you introduce a new product into a market, especially one as big at the US, one should focus on a specific geography or region to ensure that you gain proper market feedback before dozens of sales and field support personnel are hired. In this story, management was ambitious and overconfident. They learned too late that the product, while performing quite well clinically, was not as easy to use as demanded by the market. This resulted in the need to "re-work" the part of the implant delivery system – never a quick solution – and forced a complete retreat from the US market and a retrenchment back to the company's roots in the UK. It's an unfortunate story since over a hundred

good people lost their jobs through no fault of their own and shareholders lost money.

The company is alive today based on a strategic partnership with a large international medical device firm that provided much needed capital, so the final chapter is yet to be written and the company, while diminished, and under new management, lives to fight another day.

This company is not alone and I am surprised to see quite a few companies make the same mistakes, driven by many factors and, in my experience, by ambition to a large extent. The moral is, don't let the demands to grow your business get in the way of ensuring your product is "hardened" and you have covered all your bases before you go wide with an expeditionary force in a large and unwieldy market such as the US.

*Published online 08/18/17*

# India Strikes Pricing Blow To Knees After Stent Cuts

**PENELOPE MACRAE**

The Indian government has cut prices of knee implants, after a regulatory report found that importers, distributors and hospitals were earning hefty and unjustified trade margins ranging from 67% to as much as 449% on knee implants. The government also capped the prices of specialized cancer treatment implants.

"The government will not remain a mute spectator and will not allow this illegal and unethical profiteering," chemicals minister Ananth Kumar, whose department has responsibility for price regulation, told reporters.

"Osteoarthritis is likely to become the fourth leading cause of disability by 2020, according to the World Health Organization," Kumar added, and declared that India with its 1.3bn population was "likely to be one of the leading countries with such immobilized citizens in terms of number. Preventing such a scenario is essential in individual as well as (in) national interest."

This latest move has stoked rising tension among the multinational firms that dominate the country's $5bn medical technology sector and who are already upset over cardiac stent cost caps. The stent price curbs have also riled Congressional leaders who see them as being among sore spots in trade deals between India and the US.

Shutterstock: baur

## UNREASONABLE MARGINS

The report by the National Pharmaceutical Pricing Authority (NPPA) showed in the case of an "insert" — used to replace a damaged bone or cartilage in knee replacement surgery — the average total trade margin was 449%. On a "total knee system," the total margin was 313%. Apart from the substantial trade margins, the analysis showed a huge disparity in the "landed" price of imported knee implants and retail prices. In the case of a total knee system, the "landed" price, which includes freight costs, was around INR65,800 ($1,024) while the retail price was INR413,000 ($6,430).

"Orthopedic knee implants are having unjustified, unreasonable and irrational high trade margins leading to their exorbitant prices… (and leaving patients) suffering in pain," said the NPPA order which took effect immediately. According to the NPAA, there are 15 million to 20 million patients who need knee implants. But only 120,000 to 150,000 knee surgeries take place in India each year. The authority estimates that the price controls would save INR15bn annually.

Under the new price regime, the price of the most widely used total cobalt-chromium knee implant, which has an 80% market share, was fixed at INR54,720 plus Goods and Services Tax (GST), marking a reduction of 65% from an earlier average price of INR158,324. The new retail price of the special metal titanium and oxidized zirconium was fixed at INR76,600 plus GST, down by 69% from an average INR249,251 plus tax. High flexibility implants will now cost INR56,490 plus tax, also a 69% cut. The price of specialized implants in cancer cases was reduced to INR113,950 from prices ranging from INR400,000 to INR900,000.

## PRICE CAPS FUEL TENSIONS WITH MEDICAL DEVICE INDUSTRY

The curbs are part of the government's election campaign promise of providing "affordable health care" in a country where over 60% of medical spending is out-of-pocket and 80% of the 1.3bn population has no insurance. However, the government's push has fueled tensions with MNCs and drug-makers that have been also subject to stiff price curbs.

The government in February imposed a 75% price cut on stent prices following a health ministry study showing devices being sold at margins ranging from 270% to around 1,000%.

India, which has a soaring caseload of cardiovascular disease and a rapidly growing incidence of arthritis, is seen as a rich growth prospect by device manufacturers. The government argues given the huge pool of patients and growing needs, foreign companies will remain in India and "make in India" to cut costs and remain competitive in the domestic market. But MNCs have said technology innovation transcends boundaries and to maintain its free flow, price curbs and any other protectionist measures will only sow doubt in global investors' minds.

While India's government was vocally pro-business in its first two years in office, it's now sounding a much more populist note as it courts a still heavily poor electorate ahead of general elections looming in 2019. Prime Minister Narendra Modi has billed the government's control of prices of many essential drugs and medical devices as proof of the government's commitment to reduce health-care costs that push tens of millions of Indians into poverty each year.

"Affordability hinges on other things such as procedures, room charges. Unless there's a way to control that, we'll be squeezing the tube at one place and it'll be bulging at the other"

## MORE PRICE CAPS ON DEVICES MAY BE COMING

In March, the NPPA cut prices of 54 generic cancer, hypertension, diabetes and other "essential" drugs by as much 55% and the pricing regulator chairman Bhupinder Singh has said the government is "working in the direction of bringing other medical devices under price control," such as pacemakers, consumables such as catheters, and intraocular lenses. The NPPA recently engaged in a data gathering effort to monitor prices movements of nearly 20 other medical devices.

Still, despite PM Modi's talk about creating greater medical access, critics note that India's health outlay badly lags many other nations. Health spending as a percentage of GDP has stagnated at around 1% – far below a world average of close to 5.99%, according to India's Economic Survey.

The Medical Technology Association of India (MTaI), made up of multinationals with significant investments in the country, declined immediate comment on the knee implant curbs, saying the subject was "intricate" and it was "reviewing" the decision.

However, after the one-price-fits-all stent price controls in February, the industry slammed the decision, saying the government was headline grabbing and avoiding meaningful reforms of India's deeply ailing health care system that would make patient care truly more affordable. **Medtronic PLC** and **Abbott Laboratories Inc.** , at the time, sought to withdraw some premium stents after the price curbs, but the government said they had to give six months' notice. Boston Scientific Corp, meanwhile, asked that the price ceiling be raised.

India and other emerging nations loom large in the sights of international medical device firms; while developed countries still account for most sales, developing markets offer faster expansion. India's per capita medical device spend is the lowest among BRIC countries at $3 and represents "a sizeable growth opportunity," a Deloitte report said, projecting India's medical device market growth will accelerate by at least 15% a year to $8.6bn in 2020, outstripping a forecast global growth rate of 4-6%.

A senior multinational executive, who asked to be unidentified, told *Medtech Insight* even though the government had flagged its knee-implant price curb plans, the industry was in talks with the NPPA and had hoped the regulator would hold off on summary action. He conceded there were "anomalies" in knee-implant pricing but said the industry had been pushing for self-regulation and should be given "its own chance to reform."

Also, "affordability hinges on other things such as procedures, room charges. Unless there's a way to control that, we'll be squeezing the tube at one place and it'll be bulging at the other," the executive said. The Association of Indian Medical Device Industry, which represents locally based manufacturers which have been pushing for more government incentives, backed the price caps. But it too said unless hospital procedure costs drop, "this move will not give the required result to the needy citizen."

Nearly all of the top 40 global medical devices companies have a presence in the India with a share of 40%-to-50% in consumables and instruments and appliances and as much as 80%-to-90% in other sub-segments, the Deloitte report said. However, most MNCs have their production outside India and import products for the Indian market.

"The domestic companies don't have the deep pockets and neither do they have a continuous technology inflow so the industry's dependent for innovation largely on MNCs. But MNCs might think if the government continues like this, the sector is becoming too straitjacketed. We're for strait-lacing and we'll do better but straight-jacketing will lead to asphyxiation," the MNC executive said.

*Published online 08/18/17*

# Could CMS Changes To Bundled Pay Models Stifle Medtechs' Value-Based Pay Plans?

**SUE DARCEY** sue.darcey@informa.com

While newly-proposed changes to bundled payment programs linked to orthopedic and cardiovascular procedures from the US Centers for Medicare and Medicaid Services (CMS) may signal a step away from mandatory value-based payment models, medtech companies say such models will continue to improve efficiencies in costs and patient care.

CMS on Aug. 15 proposed rules to reduce the number of geographic areas participating in its "Comprehensive Care for Joint Replacement" (CJR) payment program, and would totally eliminate its Episode Payment Models and the Cardiac Rehabilitation incentive payment model scheduled to begin on Jan. 1, 2018, the agency stated. The agency said it was making the changes so that hospitals and providers could participate on a "voluntary" basis and would have more flexibility.

"Changing the scope of the models allows CMS to test and evaluate improvements to reduce costs and ease burdens on hospitals," said CMS Administrator Seema Verma. She said CMS wants to allow "maximum flexibility to test other episode-based models."

The orthopedic and cardiac bundled-payment models were initiated last year by CMS' Innovation Center to reward efficiency and quality, rather than frequency, of care. They aim to make providers more financially accountable for the costs and outcomes episodes of care that extend beyond a hospital stay. The CJR model addresses hip and knee replacements, as well as hip/femur fracture treatments. The cardac model would have targeted heart-attack and bypass surgery interventions, as well as a cardiac rehabilitation.

Shutterstock: Stock-Asso

Bundling programs like CJR have the potential to lower costs and improve quality of care, AdvaMed's Don May says.

## DEVICE FIRMS SUPPORT BUNDLED, VALUE-BASED PROGRAMS

While most device firms are still reviewing the proposed CMS changes, some companies told *Medtech Insight* they are not worried, despite their preliminary investments in service and consulting businesses, including **Johnson & Johnson**'s value-based *CareAdvantage* program, and **Medtronic PLC**'s similar *Hospital Solutions*, intended to respond to new value-based incentives. *(Also see "Full Steam Ahead On Medtech Value-Based Business Models" - Medtech Insight, 16 Jan, 2017.)* The company programs, which follow CMS's prior lead in rewarding physicians and hospitals for thorough and thoughtful patient care to prevent readmissions, were started during the Obama administration, when the drive was strong to move away from the volume-based payment approach to care.

At that time, HHS's stated goal was to have 90% of Medicare fee-for-service payments directed toward value-based purchasing approaches by 2018.

But device firms have not given up hope on bundling and value-based payments. "The CJR payment model is just one of many value-based payments models," said Monica Kendrick, VP of corporate communications for **Zimmer Biomet Holdings Inc.** Zimmer launched its *Signature Solutions* program in 2016. *(Also see "Zimmer Biomet Rolls Out Comprehensive Episode-Of-Care Program" - Medtech Insight, 12 Aug, 2016.)* The program provides software and consulting services to help hospitals take advantage of the orthopedic surgery industry's ongoing transition from fee-for-service to value-based payment models.

"Both government payers (e.g., Medicare) and commercial/self-insured payers will continue to be focused on value-based models that drive cost efficiencies and improved patient outcomes," the Zimmer Biomet spokeswoman added.

## ADVAMED SAYS BUNDLED PROGRAMS DRIVE EFFICIENT CARE

AdvaMed is still examining CMS's proposed changes, but in general supports the bundled payment programs, said the group's Don May, executive VP, payment and health care delivery policy.

"Though we have not previously weighed in on whether such programs should be mandatory or voluntary, bundling programs like the CJR program – if done right and implemented correctly – have the potential to lower costs and improve quality of care by placing a premium on quality and efficiency, and improving provider coordination and collaboration," May commented.

"These goals can enhance the market for technology-based solutions, such as telehealth, and medtech that is less invasive and reduces hospital readmissions and length of stay."

In addition to supporting bundling, "our members want the option to be official collaborators in these payment goals," the AdvaMed VP added.

One factor that AdvaMed and other industry groups have criticized about ongoing Medicare value-based programs is that they don't sufficiently account for longer-term value benefits from new, often expensive medical technology. *(Also see "CMS Current Quality-Pay Programs Unlikely To Reward Device Innovations" - Medtech Insight, 12 May, 2016.)*

Allowing more provider participation also appears to be one of Seema Verma's goals. The CMS Administrator said, "Stakeholders have asked for more input on the design of the models," and noted that moving forward, CMS expects to increase opportunities for providers to participate in voluntary initiatives rather than large, mandatory episode payment model efforts.

## HOSPITAL GROUP WORRIED ABOUT LACK OF REPLACEMENTS...

Meanwhile, hospital groups such as Premier Inc. expressed some disappointment in the CMS proposal.

"While we appreciate CMS making an effort to address stakeholder concerns about large-scale mandatory models, we are disappointed with the proposal to cancel EPM and cardiac rehabilitation models without offering alternatives to replace them," said Blair Childs, senior VP of Public Affairs of the hospital group purchasing organization Premier Inc.

"We hope that the promise for a future program that builds on the Bundled Payments for Care Improvements program is quickly followed upon with a fuller, specific proposal," Childs added.

## ...BUT ACC SAYS VALUE-BASED MOVEMENT WILL NOT BE SLOWED

A physician specialty group, the American College of Cardiology, also said it finds the path forward "challenging," but was willing to work with CMS.

"As we move from volume-based care to value-based care, the path forward is challenging, and we must work together to find solutions," said ACC President Mary Norine Walsh.

Walsh added, "While this proposed rule may change current opportunities for some cardiologists who could have participated in an Advanced APM under the Quality Payment Program in the near term, the ACC does not believe the overall movement from volume-based to value-based care will slow down."

*Published online 08/16/17*

# Zimmer Faces HHS Inspector General Subpoena

**ELIZABETH ORR** elizabeth.orr@informa.com

Federal investigators are looking at **Zimmer Biomet Holdings Inc.**'s health-care consulting deals, the orthopedics giant said in an Aug. 8 public filing.

The quarterly filing with the US Securities & Exchange Commission says that the Department of Health & Human Services Office of the Inspector General in June requested "a variety of records primarily related to our health-care professional consulting arrangements (including in the areas of medical education, product development, and clinical research) for the period spanning January 1, 2010, to the present."

Zimmer doesn't know exactly what the OIG may be looking for, "beyond reference to possible false or otherwise improper claims submitted for payment."

False claims are a common enforcement area for OIG. In one recent case, **Shire Biologics Inc.** agreed to pay $350m to resolve allegations the manufacturer paid physician kickbacks in forms including lavish dinners, entertainment and medical equipment and supplies to encourage providers to use its *Dermagraft* human skin substitute. *(Also see "Shire To Pay Record-Setting Device FCA Settlement" - Medtech Insight, 12 Jan, 2017.)*

"We are in the process of responding to the subpoena. We cannot currently predict the outcome of this investigation," Zimmer said in the SEC filing.

There's no reason to think the scrutiny is industry-wide. No other major orthopedic manufacturers have mentioned OIG subpoenas in recent filings, and representatives for **Medtronic PLC** and **Stryker Corp.** told *Medtech Insight* that the companies have not received similar requests.

*Published online 08/16/17*

# Cook Removes Indication, Pulls Sizes From Market Following Graft Recall

**ELIZABETH ORR** elizabeth.orr@informa.com

A blood clot risk lead **Cook Medical Inc.** to recall the *Zenith Alpha Thoracic Endovascular Graft* and yank certain sizes of the device off the market, US FDA announced Aug. 16. The agency has identified the recall as class I, meaning use of the product could pose a high risk of death or serious injury.

In total, the company estimates 4,500 devices will be relabeled, while 500 are being removed from the market as a result of the recall. Cook spokeswoman Marsha Lovejoy declined to comment on the financial impact of the action.

"What I can tell you is that when we make the decision to recall a product, patient safety comes first – period," she said.

The Zenith graft is used to treat isolated lesions in a major blood vessel that carries blood through the chest. Previously, it was indicated to treat blunt traumatic aortic injury (BTAI), among other indications. But blood clots may form inside the device after implantation when it's used to treat BTAI, FDA's safety alert says. Cook Medical also reported cases where the graft became blocked or closed when used to treat BTAI. Patients can die if a clot or occlusion forms inside the graft, FDA stated.

The device-maker sent safety alerts alerting affected customers to the potential risk on March 22 and June 22. The June 22 communication told customers that the device's indication for use had been updated to remove BTAI as an indication. In addition, the company is removing Zenith grafts with a proximal or distal diameter of 18-22-mm from the market because they would likely be used only for the treatment of BTAI.

Grafts involved in the recall were manufactured April 10, 2015, through Jan. 3, 2017, and distributed from Oct. 29, 2015, through March 10, 2017.

*Published online 08/18/17*

# Novacyt Full Of Eastern Promise, Following Strong H1 Sales

**CATHERINE LONGWORTH** catherine.longworth@informa.com

Cervical cancer screening specialist **Novacyt SA** is focusing on broadening market penetration in Asia-Pacific following a spike in sales in the region in H1 2017. The Anglo-French firm posted €7m ($8.1m) in sales for the first six months of 2017, up from €5m in H1 2016. At constant exchange rates, this represented a 53% year-over-year increase, with the results benefitting from its 2016 acquisition of UK firm Primerdesign. "We're very pleased with the progress we've made consistently since the reverse merger with Lab21 in 2014," Novacyt CEO Graham Mullis told *Medtech Insight*.

The company has three main trading divisions within its group - Primerdesign, a DNA molecular testing business; Novaprep, cytology tests for cervical cancer diagnosis; and Lab21, a laboratory services group. "The Lab21 group is a well-established business and a lot of infrastructure from that part of our business is being used to help and support nurturing of our two fast-growing businesses, Novaprep and Primerdesign," said Mullis.

Sales of Novaprep, increased 29% to €1.1m, while Primerdesign sales grew 3% to €2.6m and Lab21 sales rose 17% to €3.3m. Asia-Pacific represented the group's fastest growing region, with sales of Novaprep up by 243% to €0.35m in H1 2017, compared with H1 2016. An emergence of cancer screening programs in China, Indonesia, Vietnam and Thailand has made the APAC region an attractive growth opportunity for the diagnostics company, with the total market in the region estimated at approximately two billion people. In 2016, Novacyt enlisted MDL Asia to take charge of its product distribution across APAC, excluding Greater China. *(Also see " Novacyt Enlists MDL Asia To Step Up APAC Liquid Cytology Sales" - Medtech Insight, 16 Feb, 2016.)* Using the distributors sales channels helped to increase Novacyt's installed base of instruments of both Novaprep and Primerdesign's genesis q16.

"The challenges of Asia Pacific are understanding the specific requirements of each market," explained Mullis. "It's not a generic region, there are very different markets there with different infrastructure and different regulatory requirements and of course geographically very large too. Being able to prioritize is key and knowing which markets to focus on and identify again the right partners is also very key. I have personal experience of living and working in Asia-Pacific and you can spend a lot of time and money not getting anywhere unless you choose the right distribution and marketing partners in each of the key territories."

In addition to robust sales, the company received China Food and Drug Administration (CFDA) approval for Novaprep for non-gynecological cancer testing, adding to the earlier approval of the system for cervical cancer. To accelerate global market penetration, Mullis said Novacyt will be identifying acquisition opportunities. "We currently only have a direct sales operation in one country today which is in the UK. We would probably be looking to add sales through a combination of direct investment ourselves and also through acquisitions; we would be looking at mainland Europe and Asia Pacific [and] at the US market too, so pretty much expanding globally where it makes sense."

"We would probably be looking to add sales through a combination of direct investment ourselves and also through acquisitions; we would be looking at mainland Europe and Asia Pacific [and] at the US market too, so pretty much expanding globally where it makes sense."
– Graham Mullis, CEO, Novacyt

The company has received US FDA approval for its Novaprep HQ+ Orange vial as a Class I medical device for cytology or molecular use. Although the US market is the largest for cervical cancer screening, Novacyt currently has no presence in the market. "We are exploring partners in the US as we speak. Novacyt recently presented at the AACC meeting in San Diego and I was very pleased with the reception and the interest we received primarily with Novaprep business but also about Primer design. There are active discussions ongoing.

"First and foremost, we are interested in acquiring sales distributors because we believe we have good products and good technologies already established within the group. So we would be looking to penetrate various key markets across the world faster and more effectively and the best way to achieve that is through a direct sales channel and quality acquisitions. In addition to this, we are looking for acquisitions that would add revenues, products and be at least a break even position going forward so we don't see a dilutive impact of any acquisitions on the strong financials we are currently enjoying."

Novacyt is currently listed on the EURONEXT Paris exchange, but believes an additional listing on the UK AIM market of the London Stock Exchange in 2017 will help accelerate growth of the group further. "We are on a trajectory towards profitability and we expect to reach breakeven point quite soon," said Mullis. "We are very close to that and pleased with where we find ourselves. Our focus now is keeping commercial momentum going. We have also made it quite clear that we see a dual listing with the UK AIM market as a key next step for us, so expect to hear more news from us on our eventual IPO AIM this year."

*Published online 08/18/17*

## START-UP SPOTLIGHT:

# LimFlow, Endovascular Treatment For End-Stage Critical Limb Ischemia

**REED MILLER** reed.miller@informa.com

**LimFlow SA** expects the US pivotal trial of the *LimFlow* percutaneous deep vein arterialization (PDVA) system for treating end-stage critical limb ischemia to begin in 2018, building on the encouraging results from a pilot trial.

The company was founded in 2012 in France to develop a percutaneous system for deep vein arterialization of the foot for the treatment of end-stage critical limb ischemia in patients whose peripheral artery disease is so severe that traditional endovascular or surgical revascularization procedures are no longer an option.

"If you get to the point where you have ischemic wounds of the foot and no endovascular surgical option, you're headed to amputation," LimFlow CEO Dan Rose told *Medtech Insight*. "Our goal was to go after that segment that is untreated and not a competitive segment with what anyone else is doing, but it's a big segment of patients. There are a lot of these patients out there who have no option, either because they've been repeatedly treated with balloon angioplasty – although that's not great – or they're coming so late that by the time they're seen, that their disease is so advanced that they can't get a wire down there or there's no surgical target."

The LimFlow system restores blood flow to the lower extremity in these patients by creating an arteriovenous fistula that diverts blood around the diseased part of the artery and into the tibial vein to supply high flow of oxygenated blood to the ischemic foot. The procedure uses ultrasound to guide a venous catheter and an arterial catheter into place to create the arterio-venous crossing and then the LimFl covered stent is implanted connect the artery and the vein. The LimFlow system comes with an arterial ultrasound catheter with needle, a venous ultrasound catheter, a covered nitinol stent in a 7F compatible delivery system, and the LimFlow valvuotome, which opens the venous valves to allow arterial flow.

**LIMFLOW SA**
95bis Boulevard Pereire
Paris, France 75017
+33 638 747 190

2934 Scott Boulevard
Santa Clara, CA 95054 USA
888-478-7705

www.limflow.com

**Contact:** Yahia Tahiri, Global Marketing Director, ytahiri@limflow.com, +33.7.54.81.68.92

**Industry:** Peripheral vascular intervention for patients with end-stage chronic limb ischemia

**Business:** The *LimFlow* system restores perfusion to the ischemic foot with a unique percutaneous procedure to relieve ischemic pain, promote wound healing, reduce amputations and restore mobility for patients.

**Founded:** September 2012

**Founders:** Martin Rothman, Tim Lenihan, MD Start

**Employees:** 12 currently; expected to be 15 by end of year

**Total financing:** $23m

**Investors:** MD Start, BPI France, Balestier

**Board of directors:** Martin Rothman, Barts Health NHS Trust; Philippe Boucheron, BPIfrance; Lynda Ong Bee Yong, Balestier; Dan Rose – CEO, LimFlow

A first-in-man study enrolling seven "no-option" critical limb ischemia patients in Singapore. Results of the study, led by Steven Kum of Changi General Hospital were published in the July 12 *Journal of Endovascular Therapy*. The LimFlow procedure was technically successful in all seven patients and all of the patients showed symptomatic improvement with formation of granulation tissue, resolution of rest pain, or both. At six months, five of the seven patients avoided amputation for at least a year after the procedure. Four of the seven patients showed complete wound healing by six months and five were completely healed by 12 months. Average perfusion increased from 8 mmHG pre-procedure to 59 mmHG by the time of healing.

"PDVA is an innovative approach for treating no-option critical limb ischemia and represents an alternative option for the 'desert foot,' potentially avoiding major amputation," Kum et al. explain. "Our results demonstrate its safety and feasibility, with promising early clinical results in this small cohort."

In 2015, the company sponsored a ten-patient clinical trial in Europe that led to CE mark approval for the LimFlow system. Rose said the company expects to file an IDE application with the US FDA this fall and start a US pivotal trial of the LimFlow next year.

The company is currently spending its Series B funding round and plans to raise a series C in the fall to pay for both the US pivotal trial and expanded commercialization in Europe.

### PROMOTING A LONG-TERM APPROACH

"I think the most important thing that has come out of our early experience and where our mindset is today is that we can reperfuse a foot - we can take a 'cold foot' and make it a 'hot foot,'" Rose said. "And that's essential, because as long as there isn't perfusion, there's no chance of wound healing – you can't get

nutrients there or anything there to heal it. So now we have a high rate of technical success and can give these patients a second chance."

Rose said that a successful reperfusion procedure is not enough to ensure long-term healing and prevent amputation of the foot, so the company is building relationships with the vascular surgeons and interventional cardiologists who will perform the LimFlow intervention as well as the other doctors treating these patients.

"We know from our experience is that it's also important to have good wound care and a multidisciplinary approach to the diabetic foot after the procedure, because it takes some months for these wounds to heal and as long the wound is open there's a risk of infection, so we've really focused on building relationships and working on science that not only looks at it as a simple, two-hour, 'get-a-great-angiogram' procedure. This is a diabetic foot and needs to be handled and managed by a multidisciplinary team - wound care specialists, vascular surgeons, interventionalists, and podiatrists who are able to manage the care all the way until it's fully healed."

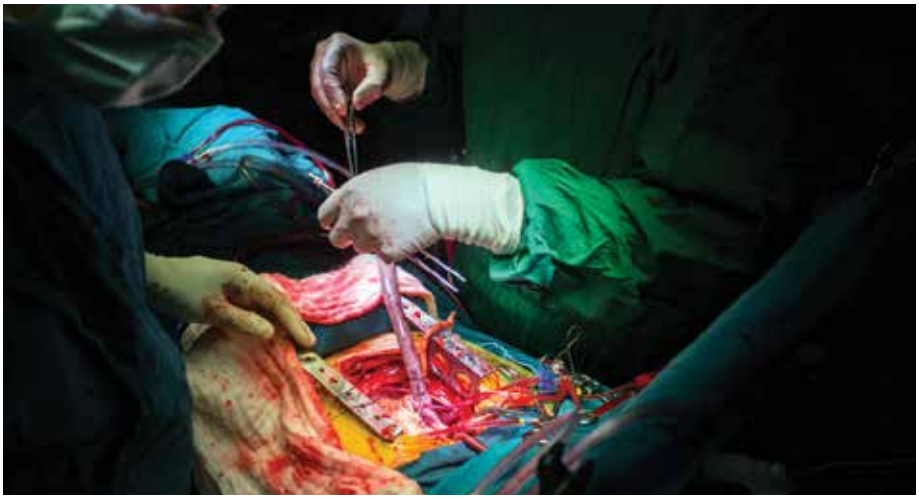

Source: LimFlow SA

Not all centers treating these patients are currently set-up to facilitate that kind of multidisciplinary collaboration, but "but once you get the people who want to make that happen, it's really successful," he said.

*Published online 08/17/17*

# Another Study Casts Doubt Over Off-Pump CABG Benefits

**REED MILLER** reed.miller@informa.com



Shutterstock: surassawadee

Off-pump coronary artery bypass graft surgery (CABG) conferred no benefits to patients over CABG on patients supported by a cardiopulmonary bypass machine in the Randomized On/Off Bypass Follow-Up Extension (ROOBY-FS) trial, offering more proof that the once-promising off-pump surgery technologies will be confined to a niche market at most and not supplant the on-pump technique for most indications.

The five-year results of the 2,203-patient, 18-center randomized trial, led by Laurie Shroyer of the Northport Veterans Affairs Medical Center in Northport, New York, were published Aug 17 in *The New England Journal of Medicine*.

The trial randomized veterans undergoing elective or urgent CABG to either the on-pump approach –the patient's circulation is supported by an extracorporeal cardiopulmonary bypass machine during the surgery – or the off-pump approach – the patient's heart continues to beat during the surgery, but the surgeon stabilizes the part they're working on with stabilizers. Off-pump CABG is also known as OPCAB or "beating heart" surgery.

After the five-year follow-up point, 15.2% in the off-pump group had died versus 11.9% in the on-pump group (relative risk = 1.28; p=0.02). The rate of major adverse cardiovascular events within five years of surgery was 31.0% in the off-pump group versus 27.1% in the on-pump group (relative risk = 1.14;

p=0.046). There were no significant differences in the rates of nonfatal myocardial infarction or death from cardiac causes. The off-pump patients were more likely to undergo a second coronary artery bypass graft surgery, but considering both surgery and percutaneous intervention, the rates of repeat revascularization were about the same for both groups.

"It appears that innovative surgical approaches — such as the more technically demanding off-pump procedure — may not always provide superior clinical outcomes," Shroyer and colleagues conclude. "Future research may identify the risk factors of the patients and the cardiac surgical processes of care that affect longer-term outcomes of coronary revascularization procedures, with the goal of increasing the rate of long-term event-free survival."

In an accompanying editorial, Eugene Blackstone of the Cleveland Clinic and Joseph Sabik of University Hospitals Cleveland Medical Center "Although the controversy about on-pump versus off-pump CABG is likely to continue, it may be time to abandon this discussion and focus on identifying which patients benefit from which procedure."

## IS OFF-PUMP OVER?

ROOBY-FS is the latest in a series of trials to cast doubt on the benefits performing coronary artery bypass graft surgery off-pump instead of on-pump, a technique that once appeared poised to dominate coronary bypass surgery.

Supporting a patient with a cardiopulmonary bypass machine during surgery requires cannulation and cross-clamping of the ascending aorta, which can knock loose atheromatous microemboli that cause strokes or transient ischemic attacks. So surgeons and manufacturers – including **Medtronic PLC** and **Guidant Corp.**(now part of **Boston Scientific Corp.**) – created stabilizers that allowed surgeons to install bypass grafts on a heart that was still pumping.

And, as off-pump CABG became more common, companies like **HeartPort** – acquired by **Ethicon** in 2001 – and **Cardica** – which changed its name to **Dextera Surgical Inc.** in 2016 – developed bypass graft anastomosis devices that promised to help make off-pump CABG a minimally invasive procedure. *(Also see "Cardica Claims Breakthrough In Endoscopic Heart Surgery" - Medtech Insight, 17 Sep, 2007.)*

"It appears that innovative surgical approaches — such as the more technically demanding off-pump procedure — may not always provide superior clinical outcomes," Shroyer and colleagues conclude.

The off-pump approach, took off in the 90s and represented 25% of all CABG operations in US in 2002 after trials in the early 2000s showed that patients with poor cardiac function or complex coexisting conditions may have better early clinical outcomes with the off-pump approach. But long-term data from randomized trials were limited and after larger randomized trials failed to show benefits of the off-pump approach versus the on-pump approach.

Results of the original Randomized On/Off Bypass (ROOBY) trial, reported in 2009, showed no significant treatment-related differences in the short term outcomes of on-pump and off-pump CABG, and no difference in the neurocognitive or health-related quality of life outcomes. But the patients in the off-pump group had worse composite outcomes and poorer graft patency than did patients in the on-pump group and there were high-risk subgroups that did better with off-pump surgery. ROOBY also showed that incomplete revascularization was more frequent with off-pump surgery than with on-pump surgery and the off-pump group showed a lower rate of graft patency. And five-year results of the OCTOPUS trial, published in 2007, found the off-pump approach offered no benefits over the on-pump approach in low-risk patients.

Also, five-year results from the CABG Off or On Pump Revascularization Study (CORONARY), reported in 2016, showed no significant treatment-related differences between off-pump and on-pump CABG.

The growth of off-pump CABG plateaued in the early 2000s and has since declined. A recent Society of Thoracic Surgeons annual report showed only 13.1% of CABG procedures in the US and Canada during 2016 were performed off-pump. "Reasons for this decline are unclear, but multiple studies have shown that off-pump CABG results in less complete revascularization and worse graft patency than the on-pump approach," Shroyer et al. explain. "Less complete revascularization is known to decrease long-term survival, and this may be a mechanism for the shorter survival that has been observed among patients who have undergone an off-pump procedure."

Blackstone and Sabik believe there may still be a subgroup that has better results with the off-pump approach. "Off-pump CABG is probably better for some patients and on-pump CABG for others, although the majority would do well with either," they argue, noting that registry data published in 2009 showed the subgroup of patients with a Society of Thoracic Surgeons Predicted Risk of Mortality score of more than 3% gained a survival advantage from off-pump CABG and results of a single-center registry reported in 2011 showed patients 75 years of age or older had a lower risk of stroke with off-pump CABG.

"Multivariable analysis involving the thousands of patients in these large randomized trials will probably identify subgroups of patients who will benefit from on-pump or off-pump CABG," Blackstone and Sabik conclude. "It is time to change the discussion and choose the procedure that is best for the patient."

*Published online 08/21/17*

# Eurasian Union For Medtech Gathers Pace, But Barriers Hamper Timely Completion

**ASHLEY YEO** ashley.yeo@informa.com

The start of 2022, in theory, should signal the replacement of the five individual medtech regulatory systems of the member countries of the Eurasian Economic Union (EAEU) with a single, decentralized system for the region. The new framework would rely on reference-member-state approval, accompanied by mutual recognition in selected member states, as set out in Article 31 of the Eurasian Economic Union Agreement of May 29, 2014.

There are many differences among the systems. Some of the EAEU members – Armenia and Kyrgyzstan – have only slight regulatory structures in place, while others (Russia) have stronger domestic industries than others, and some (Kazakhstan and Belarus) use more stringent inspection processes than the rest. Russian is the official language of the EAEU, but that might also prompt certain problems of a practical if not political nature for some member states.

In spite of the apparent lack of harmony at the outset, there was a major step forward on April 28, when Kyrgyzstan reported that it had agreed, on April 5, to protocols on the accession of Armenia to the EAEU common market for the circulation of medicines and medical devices. *(Also see "Russian Medtech Industry Wants Quicker Progress On Eurasian Bloc Plans – 2017 Now Targeted" - Medtech Insight, 24 Feb, 2017.)* This was in fact the final pollical ratification needed for completion of the medtech agreement, and it entered into force on May 6, 2017.

However, it is still not possible for companies to submit applications under the harmonized system, as EAEU member-state regulatory bodies are not yet working to the system. The intention is that, by the end of the five-year transition period, all five members will have adopted the EAEU system of medical device regulation, and their national systems – of varying levels of complexity – will have been supplanted by the Eurasian system.

The timelines for EAEU medical device regulatory approvals were set out by Andrey Ivanov, executive at the STM Group (Moscow), during Informa's recent KNect365 Life Sciences Medtech Summit. He explained that manufacturers should submit applications through their authorized representatives (ARs) to the state authority in the selected reference state. The applicant then has five working days to ensure completeness of the file, and 30 days to rectify any errors, after which it would officially enter the regulatory procedure.

Fellow KNect365 speakers Anna Harrington Morozova (Regem Consulting) and EAEU expert Alexey Stepanov stressed that local processes would no longer be allowed as of 2022. But they also suggested that, should the EAEU deadline seem impossible to meet, and there was not enough time to make the switch, the transition period would be extended. The goal is not to create bottlenecks, said Morozova, and the agencies would support an extension, should they, along with applicants, find timely compliance difficult.

## EAEU Key Second-Level Documents

- General requirements for the safety and efficacy of medical devices, the requirements for labeling and operational documentation.
- Rules for the classification of medical devices depending on the potential risk.
- Rules for conducting studies/tests to assess the biological effects of medical devices.
- Rules for conducting technical tests of medical devices.
- Rules for conducting clinical and clinical laboratory tests/studies of medical devices.
- The list of types of medical devices considered as measuring instruments during registration.
- Rules for the maintenance of the nomenclature of medical devices.
- Rules of registration and expertise of safety, quality and efficiency of medical devices.
- Rules for monitoring the safety, quality and efficiency of medical devices.
- The procedure for the application by authorized bodies of the member states of the EAEU of measures to suspend or prohibit the use of medical devices that pose a threat to life and (or) health of people, poor-quality, counterfeit or falsified medical devices and their withdrawal from circulation in the territories of the member states of the EAEU.
- Requirements for the introduction, maintenance and evaluation of a quality management system (QMS) for medical devices depending on the potential risk of use (**draft form only**).

*Source: Andrey Ivanov, STM Group (presentation at KNect365 Medtech Summit June 21, 2017, Amsterdam, the Netherlands).*

## ONLINE SYSTEM IN PLACE – AS YET UNUSED

There are certainly some barriers in place. Stepanov observed in a recent blog that on June 30 the Eurasian Economic Commission (EAC) published Decision No 78, "On Requirements for the Electronic Form of Applications and Documents of the Registration Dossier Submitted for Registration of Medical Devices." This positive move was welcomed by industry.

But a month later, there was still no indication that Eurasian harmonized medical device registration process rules were working, even though most of the Eurasian regulations have been formally enforced, he wrote.

Speaking at the KNect365 event, Stepanov said that the lack of an online system is one of the last barriers to the system working technically. The Russian regulator, Roszdravnadzor (RZN), claimed in a workshop in June that it expects electronic systems to start working by September or October this year. "The message is that as soon as the system is working technically, submissions can be filed via the electronic system," Stepanov told delegates. RZN is a strong proponent of electronic exchange of information between member states.

## QMS DOCUMENT STILL OUTSTANDING

Another piece of the EAEU puzzle yet to be put in place is the requirements document for quality management systems (QMS), which is the final outstanding document of the second-level medtech documents. (*See box,EAEU Key Second Level Documents*.)

A draft of the QMS document was available as of June 6, said Stepanov, but there appears to be issues with its finalization. Morozova observed that QMS is quite new in Russia, Belarus and Kazakhstan. Russia applies quality controls, but has had no mandatory system of QMS. It also appears there is something of a standoff between Russia and Kazakhstan – the two big players in the EAEU – on this issue.

Kazakhstan sets very high standards, but it doesn't have a very large domestic manufacturing base. As such, its inspection standards represent a high barrier for imports. Russia has almost a diametrically opposite approach. It gives a lot of support to its extensive local manufacturing industry. Indeed, it seeks to favor local manufacturers over MNCs subject to certain conditions being met, as a means of building its medtech industry infrastructure. *(Also see "Russia's Medtech Looks For Chain Reaction After Philips Partnership Deal" - Medtech Insight, 23 Feb, 2017.)*

The problem of inconsistencies in inspections needs to be overcome. "Kazakhstan and Russia adopt different approaches and they need to align," said Morozova, noting that Kazakhstan has a lot of power in the EAEU and potentially a major regulatory influence.

Nevertheless, RZN said in June that the QMS document will be released in the autumn session (as of September) and be in place by the end of the year. A likely outcome may be that the two countries would have to reach a mutual agreement, whereby Kazakhstan accommodates Russian standards on QMS, even if they do not comply with ISO 13485. It is suggested that Armenia and Kyrgyzstan may withhold from participation in any inspection activity under the EAEU.

## OTHER AREAS OF AMBIGUITY

Other potential areas of confusion include the AR needs for overseas manufacturers, and specifically whether they should they be present in just one or all five EAEU member states. Stepanov offered some clarity in that EAEU rules state that just one AR is needed in the Union for regulation purposes. But it seems open to interpretation, as post-market surveillance (PMS) rules appear to indicate that adverse reactions need to be reported to the regulatory body in that member state. As yet, there is no official statement.

Elsewhere, different member state classification systems employ different nomenclatures. EAEU nomenclature is more or less harmonized with the GMDN classification system, but the KNect 365 speakers publicly wondered how realistic this is for the EAEU. On the positive side, Russia now sits on IMDRF (ex-GHTF)'s technical committees.

Another barrier is the lack of accredited testing labs in the EAEU. A database of labs and clinical centers that are formally approved by the EAC or member-state authorities is to be made available. But, for now, the labs are not aware how they should start using standards for testing in the EAEU.

*Published online 08/15/17*

**CLICK**

For a companion article on what's ahead for Eurasian Union medtech regulations, go online: http://bit.ly/2vclwWT.

# China's Latest Cybersecurity Proposal Could Heighten Scrutiny On Device, Drug Industries

**BRIAN YANG** brian.yang@informa.com

China's Cyberspace Administration proposed a key follow-on provision to the country's Cybersecurity Law which could directly impact the medical device and biopharma industry.

The draft, Key Information Infrastructure Protection decree, was open for public comments through Aug. 10.

The proposal aims in part to further clarify the so-called Key/Critical Information Infrastructures(KIIs), which are subject to the strictest obligations under the Cybersecurity Law, which took effect June 1 *(Also see "China Cybersecurity Law Catches Pharma Firms Unawares" - Medtech Insight, 26 Jul, 2017.)*, particularly in localizing data within China and undergoing security reviews of network equipment purchases. Medical device and biopharma companies might be considered as KIIs.

Many multinationals that might need to move data across borders or purchase such equipment have been anxiously waiting for draft proposal's classifications of which industries are

The proposal, released in July, only defined in general terms the KII and proposed sectors to be included in the range of KIIs (*see* Key Information Infrastructure Security Protection Decree – Chinese language]).

Businesses will be KIIs " if their functions or networks get compromised, malfunctioning or suffered data theft will potentially damage the national security, people's livelihood and public interest," the draft says.

And the following wide range of operations should be included with the scope of protection as KIIs:

1. Government agencies, energy, finance, traffic, water transportation, health care, education, social security, environment protection and public utilities;
2. Internet, telecom, broadcasting, cloud computing, big data;
3. Manufacturing and research institutes of national defense, large equipment, chemical, food and drugs;
4. Radio, TV and news agencies; and
5. Other important units.

Shutterstock: aekkom

Foreign medical device and drug makers operating in China are potentially KIIs, Andrew McGinty, partner of global law firm Hogan Lovells's Shanghai office, said in an interview.

## DATA LOCALIZATION

KIIs are required to adopt additional specialized procedures to strengthen their security and reporting obligations.

It's not possible to reach any other conclusion than that China's legal regime for cybersecurity protection is becoming increasingly onerous, costly and potentially disruptive to business. – Hogan Lovells

For example, KIIs operating within China are required to store personal information and important data gathered during the operations inside China, and if there is a business need to transfer such data overseas, a security assessment must be carried out per Security Safety Measures, issued in May and effective from June.

Additionally, processes to maintain data must be conducted within China. If there is a reason such processes must be conducted outside the country, the organization must report this to relevant Chinese regulatory agencies and Public Security Department under the State Council.

"This raises an issue whether such arrangements will be permitted going forward," noted the Hogan Lovells lawyers in an August note to clients. Recognizing that the authorities can simply reject the plan, the lawyers pointed that "where global contracts in place, having separate local maintenance will have cost and security implications."

## EQUIPMENT PURCHASE

The KII businesses should comply by Chinese laws and regulations as well as other relevant national standards. If the business purchases network products and services that might potentially impact national security, it should seek a national cybersecurity review and sign a security confidentiality agreement with the equipment providers, the proposal instructs.

Businesses should conduct security testing prior to the launch of new software developed by a third-party and eliminate any risks if loopholes and deficiencies are discovered.

Additionally, the national cybersecurity authority may conduct random inspections on the operators of KIIs who are required to provide access to records/documents, and allow the use of testing tools and carry out testing.

"Multinational enterprises may be alarmed as to what kind of information required for such inspectors and whether their trade secrets will be at risk, not to mention cost in money and business interruption terms." noted the lawyers.

Noting no mention of cost to be borne by the government, the Hogan Lovells lawyers suggested that the cost could be adding up fast, "It's one thing to hold Chinese state-own enterprises (SOE) to the standards, it's another to hold a foreign private-owned enterprise (FIE) to the same standard, against a background of a rocketing labor costs in China."

"It's not possible to reach any other conclusion that China's legal regime for cybersecurity protection is becoming increasingly onerous, costly and potentially disruptive to business," stressed the lawyers, cautioning that cybersecurity compliance could become a "de facto trade barrier by incentivizing foreign investment in any of the (newly-expanded) list of industries that may now be designated as KIIs."

To prepare for the uncertainties, companies should conduct own risk analysis, suggested McGinty. "They should start primary analysis," and "risk factor identifications," he said.

*Published online 08/18/17*

# US FDA: BD Didn't Act On Faulty Lead Test Warning

**ELIZABETH ORR** elizabeth.orr@informa.com

US FDA's inspection of a New Jersey **Becton Dickinson & Co.** (BD) manufacturing facility found complaint handling and quality systems issues may have contributed to faulty results on tests for lead exposure, the agency announced Aug. 17.

The Parsippany, NJ, facility was inspected between May 15-July 6 as part of an ongoing investigation into **Magellan Biosciences Inc.**'sLeadCare tests, which came under FDA scrutiny after data showed the tests sometimes gave inaccurately low results when used with blood drawn from veins. *(Also see "US FDA, CDC Warn Of False Results On Lead Blood Tests" - Medtech Insight, 17 May, 2017.)* The BD plant makes some blood collection tubes used with Magellan's products.

Magellan had previously warned its customers not to use certain BD blood collection tubes with the lead tests because it believed some of the faulty testing results could be linked to changes in the tubes' design, FDA said.

A seven-observation FDA-483 inspection report states that "another manufacturer" told BD via email in May 2015 about the potential that their tubes were contributing to falsely low blood lead findings. But the finding "was not investigated, evaluated, and documented formally into your complaint handling database," the report states.

The failure to act may be tied to inadequate complaint-handling training that left staff poorly equipped to evaluate and report adverse information, FDA said. The 2015 email containing the lead test warning "was not forwarded for review and evaluation by your designated complaint handling unit, nor was it documented within your formal complaint handling software."

In addition, FDA said that BD appears to have failed to validate changes made to the design of the test tubes in question. The company's validation studies "did not utilize/collect patient blood into the tubes, and the studies did not demonstrate any clinical measurements associated with the tubes," FDA wrote.

The agency also found wider-ranging issues at the BD facility that weren't specifically tied to the test tubes. For example, FDA noted that technical support calls often weren't evaluated to see if the concerns should be reported to FDA, and the company's complaint-handling policy didn't require staff to track and trend complaint data from customer inquiry calls. In one incident, a customer reported cartridge errors and "a strong sulfurous smell" coming from a BD tube used that delayed critical test results to help detect cardiac distress. BD didn't investigate the smell or properly replicate clinical conditions during its investigation of the event, FDA said.

In addition, the 483 says BD's written Medical Device Reporting (MDR) procedures were flawed and incomplete. The firm allegedly violated MDR rules by failing to report at least five malfunctions to FDA, including one in which a nurse's finger bled after being stuck by a test-tube bottom.

However, Alberto Gutierrez, director of FDA's Office of In Vitro Diagnostics and Radiological Health, said in a statement that the agency had made no definitive link between the BD tubes and the faulty lead tests.

"At this time, we have not determined that the BD tubes or any other brand of tube is linked to the cause of the inaccurate lead test results," he said. "We are continuing to aggressively investigate the matter."

This is the second 483 FDA has released as part of the probe. An inspection of Magellen's Massachusetts facility found GMP, complaint handling and Medical Device Reporting violations, as well as indications the company had ignored early warnings on lead test accuracy. *(Also see "US FDA: Magellan Failed To Ensure Lead Test Accuracy" - Medtech Insight, 14 Jul, 2017.)*

*Published online 08/21/17*

CONTINUED FROM PAGE 1

years -- but that will come with enhanced FDA performance goals (*See Table 1, p. 1.*); more investments in things like staff expertise, digital health and real-world evidence; streamlining reforms; and formal efforts to improve review processes. (*For more details on the core user-fee agreement, check out "User Fee Facts: 10 Key Medtech Details From US FDA Agreements," p. 21.*) The trade groups that negotiated the agreement say it is a good deal for industry and that they believe FDA Commissioner Scott Gottlieb is well-suited to implement it. *(Also see "With Gottlieb Sworn In, His Focus Should Be On Quick User-Fee Passage, Industry Advocates Say" - Medtech Insight, 11 May, 2017.)*

Members of Congress on both sides of the aisle have generally championed FDARA passage. House Energy and Commerce Committee Chair Greg Walden, R-Oregon, and Ranking Member Frank Pallone, D-N.J., issued a joint statement following Trump's signature.

"We appreciate President Trump signing this critical reauthorization into law," said Walden, Pallone, and the Energy and Commerce Committee's Health Subcommittee Chairman Michael Burgess, R-Texas and Ranking Member Gene Green, D-Texas. "This law will encourage new medical innovations … and improve the regulatory review process for devices and treatments and, most importantly, provide certainty to patients and the health industry."

Sen. Lamar Alexander, R-Tenn., who chairs the Senate Health, Education, Labor, and Pensions Committee, and, Democratic Ranking Members Patty Murray of Washington also worked together on the legislation. Device Reform Provisions Address Plant Inspections, Third-Party Auditing

In addition to the core MDUFA IV agreements, FDARA includes a handful of additional device reforms heavily supported by medtech firms *(See box, Device-Reform Riders.)*.

One of those measures would require FDA to update its device facility inspection procedures to be more transparent with companies about when, why and how long a plant may be audited and to make it more difficult to deny an expert certificate to a company.

## Device-Reform Riders

- **Medtech facility inspections and export certifications (Sections 701-704)**: Requires FDA to establish a risk-based inspections schedule; provide more details to companies on the nature and planned timeframe of facility inspections; further standardize the inspections process; and allow manufacturers to keep their export certificates if they can prove to FDA there is a plan to correct problems.
- **Risk-based classification of device accessories (Sec. 707)**: Creates a tailored, streamlined approach to classifying or reclassifying device accessories, distinctly from a parent device. *(Also see "Legislation Would Streamline Risk-Classification For Device Accessories" - Medtech Insight, 27 Apr, 2017.)*
- **Over-the-counter hearing aids (Sec. 709)**: Establishes and defines over-the-counter hearing aids as a regulated category of device and mandates FDA to issue regulations and guidelines on OTC hearing aids within set timelines. *(Also see "Stakeholders Support OTC Hearing Aids At FTC Summit" - Medtech Insight, 19 Apr, 2017.)*
- **Third-party device services (Sec. 710)**: Requires a report from FDA to gather input on potential regulation of third-party servicers.
- **Pediatric devices (Sec. 502):** Requires FDA to provide more details on pediatric applications of devices and examples of data-extrapolation to support pediatric indications; reauthorizes and revises pediatric device grant provisions; and requires FDA to convene a meeting on pediatric device issues within one year.

There are also measures to streamline review of new medical imaging indications, reclassification of device accessories, and to have FDA review requirements for third-party device servicers.

### ALSO: POST-MARKET AND HEARING AID PROVISIONS

Democratic lawmakers were able to slip in on provision focused on post-market device safety into the bill. Specifically, the legislation mandates that FDA set up one or more pilot projects to apply real-world electronic data sources networked through the nascent National Evaluation System for health Technology (NEST) to support post-market surveillance. The provision acts as a parallel to an element of the MDUFA IV agreement that maps out a plan to apply NEST to speeding new devices to market. *(Also see "Pilot Of New US Evaluation System Will Include At Least Two Devices" - Medtech Insight, 31 Oct, 2016.)*

Also, a longstanding need to make well-designed hearing aids more accessible to seniors enabled congressional sponsors Sen. Elizabeth Warren, D-Mass., and Reps. Robert Kennedy, D-Mass. to attach a provision to establish and regulate over-the-counter hearing aids to the measure.

*Published online 08/18/17*

# USER-FEE FACTS: 10 Key Medtech Details From US FDA Agreements

**DAVID FILMORE** david.filmore@informa.com

The FDA Reauthorization Act is now law, and the device user fee program continues. Here are 10 important details from the underlying industry-agency user-fee agreements that medtech firms should know.

## 1 YOU'LL PAY MORE...*

***(Especially for 510(k) submissions, if your firm earns more than $100m in annual revenue)**

Device industry groups tout the MDUFA IV user-fee agreement as a good bang for a company's buck, raising an additional $320.5m (plus inflation) in user fees above the MDUFA III baseline. But that money has to come from somewhere, and the primary source will be increased submission and registration fee rates. Under the agreement moving through Congress, the year-to-year impact will be felt most dramatically by device firms in the first year of the program, FY 2018 (starting Oct. 1). The increase will be particularly sharp because FDA was forced to reduce FY 2017 rates as a result of prior-year over-collections.

Thus, the pre-inflation fee for submitting an original PMA will jump about 25% to $294,000 in FY 2018 (or $73,500 for firms that report $100m or less in annual revenue), and the annual establishment registration fee for all companies will jump about 47% to $4,978 from the FY 2017 value. But the biggest change will be for 510(k)s, the most common pre-market submission type. Due to a calculation change included in the agreement, the standard fee for 510(k) submissions will more than double, increasing from the FY 2017 rate of $4,690 to $9,996 in FY 2018. The impact will not, however, be as dramatic for smaller firms that earn $100m or less, because small businesses will now pay only one-quarter, rather than one-half, of the standard rate for 510(k)s). Qualifying firms will pay $2,499, which is only a $154 increase from FY 2017, and actually less than the FY 2016 small-business 510(k) rate. Fee rates will incrementally increase on an annual basis, by a total 11.5% between FY 2018 and FY 2022.

## 2 ...AND THERE IS NO OVER-COLLECTION REDUCTION DOWN THE ROAD

An important change in the agreement that FDA fought to include would get rid of prior user-fee-program provisions that required the agency to offset prior-year over-collections with fee reductions in the fifth and final year of a cycle (which was the cause of the FY 2017 rate drop). Going forward, "If the collections are in excess of the resources needed to meet performance goals given the workload, or in excess of inflation-adjusted statutory revenue targets, FDA and industry will work together to assess how best to utilize those resources," the commitment letter states.

On the other hand, if submission or registration volumes drop below projections, it is possible that base-fee amounts would need to be increased to make up the revenue.

## 3 *DE NOVOS'* TIME TO SHINE?

FDA is also adding one completely new fee category. Assuming the MDUFA IV agreement is approved, companies will have to, for the first time, pay a fee when submitting a *de novo* classification, which will be set at 30% of the PMA fee. (In FY 2018, the pre-inflation rate would be $88,200.) The new fee reflects growing use by companies of the *de novo* pathway, which offers a route to market for novel, but low-to moderate-risk devices, and FDA is concerned that it won't be able to keep up with the demand without targeted resources. The fee is linked to first-time FDA performance goals for *de novo* reviews – setting a 150 "FDA-day" review standard (not including time when a submission has been sent back for response by the sponsor), which the agency commits to meet half the time for FY 2018 submissions, and will ramp up to 70% performance by the time it gets to the FY 2022 cohort.

## 4 ALL E-SUBMISSIONS, ALL THE TIME?

The MDUFA IV agreement sets the groundwork for moving from what remains still a largely paper-based FDA device submissions process to an electronic one. That has big implications for improving the consistency and completeness of industry submissions, the FDA review of those submissions, and the agency's ability to track and audit its review process.

While companies must currently submit an "e-Copy" (e.g., a CD version) along with paper submissions, the device center is still in piloting stages for employing an actual electronic submission platform that companies can routinely use for pre-market submissions. The user-fee bill grants FDA authority to require all submissions, including pre-submissions, 510(k)s, PMAs and others, be submitted solely in electronic format by an FDA-designated date after the standards for an electronic template has been established in a final guidance. FDA would have until October 2020 to finalize guidance setting out such standards.

## 5 LESSONS FROM DECENTRALIZED EU APPROACH?

By no measure does this user-fee deal pass off FDA's centralized review responsibilities to outside groups, but there are several provisions in the agreement that could spark a bigger role for accredited third-parties in medtech firm's path to market; that is, more in the direction of the role of notified bodies in the EU. And, along with the electronic submissions sections mentioned above, these approaches might support

a more globally harmonized pre-market process in the years to come.

There are two parts of the agreement worth highlighting, in particular, on this theme. One is new authority for FDA to establish a conformity assessment scheme, in which accredited "testing laboratories" will be designated to review, in FDA's stead, a company's conformance to recognized consensus standards used to help support/streamline a firm's pre-market submissions. FDA says it will trust the laboratory rather than engage in conformance-standard scrutiny of its own during pre-market reviews.

The other relevant provision addresses planned efforts to revitalize FDA's long-running, but lightly used third-party 510(k) review program. The user-fee reauthorization bill would give the agency more flexibility to make decisions on what devices should be eligible seeking 510(k) review by an accredited third party rather than FDA. Under the agreement, the agency will also establish a plan to cut down on its need to "re-review" third-party assessments, which can eat up a lot of time, and clearer standards for accrediting, training, suspending and auditing the third parties.

## 6 PERFORMANCE GOALS: SHARED OUTCOMES, PROCESS PRECISION

Another point-of-interest in the latest user-fee agreement: For the first time, FDA and industry did not adjust measures for the core performance goal categories that have been with the device user-fee program since it began about 15 years ago: the number of "FDA days" to complete PMA, PMA supplement and 510(k) reviews. Those goals will remain unchanged from the FY 2017 MDUFA III levels for the next five years, as will the in-review-process "substantive interaction" goals that were previously established in the program.

What is changing? For one, FDA and companies are committing to more reductions in so-called "shared outcome goals," which count the time an application spends in both the agency's and the sponsor's hands. Also, a few more in-process goals are being added to more precisely target potential trouble spots of a review. In particular, FDA has agreed to issue a PMA decision within 60 days of an advisory committee meeting being held on the application, and to issue a PMA decision within 60 days of a sponsor responding to an FDA "approvable" letter.

Two areas that will get enhanced end-process performance goals are pre-submissions and CLIA waiver reviews. Even so, no user fees have been linked directly with either of these submission types.

## 7 GUIDANCE DOCUMENTS

FDA has committed to producing four completely new guidance documents in the user-fee agreement, on: *de novo* reviews, electronic submissions, a new accreditation scheme to streamline FDA's reliance on consensus standards and the third-party 510(k) review program. Meanwhile, the agency agreed to specific revisions to five existing guidance and to finalize one draft guidance, on software modifications.

## 8 DIGITAL HEALTH DIVISION

Part of the MDUFA IV user-fee funds will be supporting FDA's efforts to stay on top of digital-health developments, specifically as the agency defines it, both "software as a medical device" (SaMD) products and "software inside of medical devices" (SiMD). The upshot of that funding, according to the commitment letter, will be a new central digital health unit within CDRH's Office of the Center Director, with the charge to "ensure proper coordination and consistency" digital-health reviews across the agency. In addition, FDA says it will put special attention to establishing novel pre-market pathways for digital devices and engaging in international harmonization efforts on the issue.

One important piece of context: since FDA and industry signed on to the MDUFA IV agreement last August, Congress pass provisions in the 21st Century Cures Act that remove several categories of software products from the agency's authority. That will certainly have some implications for how the device center rolls out its digital-health plans, although the agency says it still plans to implement a system of surveillance for the exempted software products or functions.

## 9 SUMMARY MALFUNCTION REPORTS

FDA agreed in the deal to allow more device malfunctions ("for most, if not all, device procodes") to be reported by companies on a quarterly basis, in summary form, rather than individually and in real-time. There are exceptions, of course, including the need to report a new, previously unknown type of malfunction for a device individually, but the change could significantly streamline companies' Medical Device Reporting responsibilities. This commitment is included in FDA's letter under the "Real World Evidence" heading, pointing to, perhaps, its primary purpose for FDA: summary versus individual malfunction reports can provide the agency with a more comprehensive picture of how a device is actually performing in clinical practice.

## 10 COMBINATION PRODUCTS

And it's not just the MDUFA agreement that device firms should heed. The Prescription Drug User Fee Act (PDUFA VI) includes provisions targeting combination products that are important for some medtech players. In a rare move, the PDUFA deal will send some funds directly to the device center as part of an overall plan to streamline combination-product reviews, adding on to other efforts from Congress and FDA to improve what are widely recognized inefficient processes for certain products that include a device, and drug or biologic.

Pharma intelligence

informa

# Intelligence with a Global Perspective

## The Premier Resource In The Life Sciences Industry

- Biomedtracker
- Datamonitor Healthcare
- In Vivo
- Meddevicetracker
- Medtrack
- Medtech Insight
- Pink Sheet
- Pharmaprojects
- RxScorecard
- Scrip
- Sitetrove
- Trialtrove

Pharmaintelligence.informa.com

Over 100 event types

Over 100 catalyst types

Over 5,000 products

Meddevicetracker
Pharma intelligence | informa

# Double **the Power**

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

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

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

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