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Medtech Insight
Issue 42
medtech.pharmamedtechbi.com

Pharma Intelligence Informa

May 8, 2017

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John Brennan

Q&A: With New EU Regs Taking Effect, What Can Industry Do To Be Proactive?

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Industry wants the European Commission and competent authorities to organize a workshop – preferably in June – to air outstanding issues associated with the implementation of the Medical Devices and IVD Regulations, which are expected to take effect within the next six weeks.

Such a gathering would help in the development of a program to quickly address implementation complications, says John Brennan, director of regulations and industrial policy at industry trade group MedTech Europe.

Brennan, who plans to leave the device and IVD trade association in mid-June to join EuropaBio, spoke with *Medtech Insight* about next steps and what medtech companies should be focused on as the new regulations take effect.

Brennan says that a scheduled workshop would be a critical opportunity for the regulatory authorities, notified bodies and industry to identify and prioritize shared concerns that need urgent attention, but may not be addressed in the roadmap that is in the works by the Commission and national authorities, set for release in June. Such a meeting would help all parties, including the Commission and the authorities, and the notified bodies and device companies, to plan better and to more fully understand the framework and challenges, he noted.

Among the topics that would need to be discussed at the workshop, Brennan said, are solutions to ensure there is sufficient and timely availability of notified bodies in the transition to the new regulations. Concerns about the capacity of notified bodies to handle the changes have been widespread.

Brennan had a lot more to say about where companies should direct their vigilance now that the system will start to come together and industry will need to

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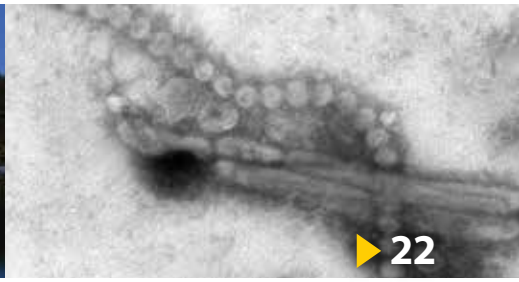
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The rising diabetes epidemic is fueling significant innovation in next-generation, automated artificial pancreas systems and miniaturized, less-invasive wireless technologies This feature takes a close look at potentially groundbreaking new technologies, as well as the competitive landscape.

Alibaba AI
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When China's e-commerce giant Alibaba flexes its muscles, this time in personalized health care using artificial intelligence, everyone takes note.

Medtech multitudes in Congress
http://bit.ly/2qsiv5y

A bumper-crop of bipartisan, mostly industry-supported legislation seeking to streamline compliance, improve access or otherwise reduce burdens in the medical device space has surfaced in recent months in the US Congress.

US FDA quality system
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The head of the Center for Devices and Radiological Health's compliance office says it wants to be in the "tent together" with medical device manufacturers by creating a quality system for its own internal operations that will be based on international standards.

Device Week
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his supervisor that violated anti-kickback law and could pose a risk to patient safety.

9 **Stent Leaders Pull Out Of India Amidst Price Cap Storm –** The storm in India over price caps on stents has not shown any signs of abating, with foreign firms seeking to pull back certain key brands and the pricing regulator resolute about maintaining market equilibrium. The slugfest also appears to have opened up the Indian market for Chinese firms, among others.

POLICY & REGULATION

16 **The Patient Perspective: Upcoming US FDA Device Center Studies Put Device-Users In Front Seat –** A patient's point of view is paramount as the Center for Devices and Radiological Health embarks on a plan to conduct patient-perspective studies to ascertain what device-users want and value when it comes to health care. But don't call it a survey – "this is real research," CDRH compliance chief Robin Newman says.

17 **New Bill Would Regulate Third-Party Device Servicers –** A new US House bill seeks to even the playing field so that third-party service providers are subject to similar FDA oversight to what manufacturers face when servicing their own devices.

18 **Legislation Would Streamline Risk-Classification For Device Accessories –** A bill introduced in the US that industry stakeholders want to be added to the "must-pass" user-fee reauthorization bill would create a tailored approach to classifying or reclassifying device accessories, following up on change made last year that requires accessories to be classified separately from parent devices.

19 **Sen. Klobuchar Forming Coalition To Push For Both Device, Cadillac Tax Repeal –** Sen. Amy Klobuchar, D-Minn., is putting together a coalition of lawmakers who favor repeal of both the device excise tax and the Affordable Care Act's so-called "Cadillac tax" on high-expense health-care plans.

20 **Unapproved Indications Guidance Proves Controversial Companies –** US FDA has collected more than 100 comments on a pair of draft guidance documents about manufacturer speech relating to unapproved devices or information not listed in device labeling. A document allowing manufacturers to disseminate some information not in the labeling drew fire from patient groups and trade groups, for different reasons.

22 **HHS Pressured By Lawmakers To Release Pandemic-Flu Plan –** Two House Committee leaders are asking HHS Secretary Tom Price about the current status of an overdue pandemic influenza preparedness plan, including diagnostic advancements, that was promised last August.

A New NEST: MDIC Leaders Discuss Relocation, National Evaluation System And More

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The Medical Device Innovation Consortium, a public-private partnership focused on regulatory science with deep FDA involvement, has been busy lately helping to start the Coordinating Center for the Medical Device National Evaluation System for health Technology (NEST), moving its headquarters from Minneapolis to the Washington, DC, area and continuing to facilitate collaborative research and development for better approaches to running medical device clinical trials.

The US FDA recently committed to spend $30m from device industry user fees to pilot NEST as part of the MDUFA IV reauthorization that will roll out at the start of FY 2018, and MDIC has been tasking with setting up the NEST Coordinating Center to get the effort off the group. NEST is envisioned as a network of registries and databased collecting real-world device data that can support device approvals and post-market surveillance. The industry and agency stakeholders contributing to NEST have already agreed to set-up at least two three-year pilot projects to show how NEST work. *(Also see "Pilot Of New US Evaluation System Will Include At Least Two Devices" - Medtech Insight, 31 Oct, 2016.)*

MDIC recently moved its headquarters from Minneapolis – where it was close to the headquarters of many major medical device manufacturers – to just Arlington, Va., so that its staff can interact more regularly with the FDA, trade groups, and contributors from outside the US. And, on April 12, MDIC announced that Rachael Fleurence – previously the Patient-Centered Outcomes Research Institute (PCORI) Program Director for Research Infrastructure and director of PCORnet, the National Patient-Centered Clinical Research Network – will serve as the first ever Executive Director for the NEST Coordinating Center.

To catch-up on these and other developments, *Medtech Insight* Deputy Editor Reed Miller sat down MDIC CEO William Murray and VP for Technology Innovation Dawn Bardot during a break in the sessions at the recent Design of Medical Devices Conference at the University of Minnesota in Minneapolis.

Dawn Bardot, MDIC Vice President, Technology Innovation

"We've built some momentum in the last year I think in the diagnostic area ... and we're starting to see some real interest from the digital-health community," says Dawn Bardot, MDICs VP for Technology Innovation.

Medtech Insight: MDIC moved its head office from Minneapolis to near Washington, DC this fall. How is that working out so far?

William V. Murray: I relocated to Washington to set up headquarters in October of last year. We still have operational offices here with some of our project managers. Most of our projects have participants from our member organizations, and they can be anywhere in the country. I'm in Washington, and Dawn is there a lot too, because the FDA is one of our major stakeholders and a big reason a lot of people engage with us is because we're working on regulatory science.

William V. Murray, MDIC President and CEO

Dawn Bardot: And we have international members as well too. DC is just a more workable location as a hub.

What can you tell us about the development of the Medical Device National Evaluation System for health Technology, called NEST?

Murray: A big thing right now is that we just announced that Rachel Fleurence was hired as the first executive director

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Emerging Markets Welcome Rise Of Robots, But UK Skeptical

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New research from Pricewaterhouse Coopers (PwC) finds that emerging economies are more willing to embrace the use of artificial intelligence (AI) and robotics in health care, compared to more-developed Western European countries.

PwC's report, "What Doctor? Why AI and Robotics Will Define New Health," is based on a survey of more than 11,000 people from 12 countries across Europe, the Middle East and Africa. The survey found that more than half of the respondents (55%) said they would be willing to use advanced computer technology or robots with AI that can answer health questions, perform tests, make a diagnosis and recommend treatment.

UK patients were found to be the most skeptical about health care via AI and robotics, with 39% saying they would engage with AI/robotics, in contrast to other European countries, such as the Netherlands and Germany (55% and 41% respectively). Brian Pomering, PwC health-care partner, told *Medtech Insight* that the UK figures were encouraging from a "glass-half-full perspective."

"It's easy to focus on the figures showing that the UK is the most skeptical, and there's not an opportunity here, but actually if you think about it, the UK spends over £100bn a year on health care, not to mention its spend on social care," said Pomering. "If 39% are willing to adopt this technology, which is a big number on a big scale, then it's a huge market opportunity for the industry."

"In the UK, we spend a lot of time dismissing the NHS, but it has an unbelievably good reputation globally and is looked at as a beacon of health care. We get amazing health outcomes, yet we only spend about 7.5% of our GDP on health care, which is a relatively low percentage spend on health care," said Pomering.

In March, the UK government pledged £17.3m ($22m) to fund research in artificial intelligence and robotics developed by UK tech companies and universities.

The UK spends over £100bn a year on health care, not to mention its spend on social care...If 39% are willing to adopt this technology, which is a big number on a big scale, then it's a huge market opportunity for the industry," says Brian Pomering, PwC health-care partner.

The pledge was announced as part of the government's strategy to put the UK at the forefront of pioneering the technology.

African countries were also identified as a huge opportunity for AI/robotics, with 94% of patients in Nigeria saying they would engage with the technology, and 82% in South Africa. Further, in the operating theatre, respondents in Nigeria, Turkey and South Africa were the most willing to undergo minor surgery performed by robots (73%, 66% and 62%, respectively), with the UK the least willing (36%).

"The largest correlation we've seen in these results is to do with patient access to care," explained Pomering. "If you look at the various countries like those in Africa that are most willing to engage with artificial intelligence and robotics, they are the countries where people don't have huge access to good quality health care and facilities now, and any care is considered better than no care at all."

"Mobile phone coverage has boomed rapidly in African countries and transformed services where they didn't have existing infrastructure in place," he said. "There's been a digital revolution, and I think we will see a similar thing with robotics and AI in African countries."

The survey found younger generations were more likely to embrace technological changes (55%) compared to older generations (33%), highlighting the generational shift in attitudes toward new technology. Despite the reluctance and skepticism felt by many, Pomering said companies and health systems need to turn their attention to improving medical technology generally to ensure success and innovation continue. "In addition to robotics and AI, companies need to be tapping into the potential of personalized medicine. These three areas together mean we'll be able to deliver much better care to more people," he said.

"Looking back in history at the industrial revolution, there was a lot of people who looked cautiously at the convention of the steam engine and electricity, and said it would never catch on. Those were the businesses that very quickly failed when they didn't adopt it. The genie is out of the bottle with AI/robotics, and I don't think we're going to stop the constant development of these tools and techniques," Pomering said.

"Unfortunately, one of the inevitabilities of life is we are all deteriorating creatures, and at some point in our lives we will all need access to caring, compassionate, good, quality care. We like people and we are emotional and spiritual creatures, as much as we are anything else, so that balance is always important. What I think robotics can do is enable our clinicians to meet more demand and to deliver more care to more people, high quality which will make their jobs very fulfilling."

Published online 04/25/17

Medical Device Startups Shine At AXA PPP Health Tech & You Awards

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Startups from across the healthcare spectrum gathered at the Design Museum in London to showcase their new technology as part of AXA PPP Health Tech & You 2017 awards exhibition in London. The exhibition, was held at the Design Museum in London showcased the latest innovation in health technology and personal health.

In advance of the awards, *Medtech Insight* met with finalists about new technologies. Winner of the Health Tech & You challenge was London based startup Entia (formerly known as Eva Diagnostics) which has developed *Affinity,* a connected device for cancer patients to monitor their blood cell counts from home. Low blood counts are a common side effect of chemotherapy and can result in serious infection and problematic delays to chemotherapy treatment. The device was developed in collaboration with the Royal Marsden and Imperial College for patients to use at home in between chemotherapy and can identify blood cell count from a finger prick test in five minutes.

"What we want to do with Affinity is simplify blood tests and through that offer a better health experience for individuals," CEO and co-founder of Entia, Toby Basey-Fisher told *Medtech Insight*. "Underpinning much of what we are doing is taking core analytical concepts found in laboratories and miniaturizing them so that pretty much anyone can access them in the community, home or doctor's office. Accessibility is key to what we are trying to achieve."

The home monitoring system is connected to health workers so that every time a test is done by the patient, the information on the blood cell count is shared via the Cloud to health workers so they can make decision of when they should be interacting with patients. "Around 1 in 5 people when they come to back hospital to receive their next dose of therapy take a blood test and are then sent home because their blood count hasn't recovered sufficiently. It's estimated somewhere around £35m is wasted every year on these appointments so there's a financial burden. But the biggest burden is with the patient as there is all the stress and anxiety of coming in expecting treatment and then getting delayed," said Basey-Fisher.

He added: "The system has many benefits. The first is it can be used to schedule appointments for when the patient needs to be there, the second is it can measure adverse effects – it gives quantitative evidence of rapid change in blood cell count to bring patients in earlier, and timing is incredibly important in treatment."

The device is currently in clinical evaluation for the next year and a half with the Royal Marsden. Entia estimates it will be available to other UK healthcare trusts by the end of 2018.

Winner of the Trending award was GSK's *MyAsthma*, a medical device app for asthma management. The app is designed to help people living with asthma better understand and manage their condition. The app was devised by GSK with asthma researchers at the Nottingham Respiratory Research Unit and digital marketing company Earthworks. Smartphones and technologies have changed so much so we wanted to try and capitalize on that. MyAsthma is the first medical device app for asthma. It tries to help patients understand what their potential triggers are, track their attacks and medication use," said Kai Gait, digital director at Earthworks.

The app uses an asthma control test (ACT) that helps people understand how well controlled their asthma is by tracking medicine usage and asthma attacks to help communication between themselves and their doctors. It also connects to the user's everyday life; learning what triggers their asthma from location, weather and air quality. MyAsthma is the first pharma-supported Grade 1 Medical Device as a smartphone app

Nominated for the Health Tech Age Award category was *MonitorMe*, developed by company Sanandco. The device is a landline telephone that captures vital signs using special sensors integrated into the handset. The vital signs are then sent via telephone lines to a digital patient record that compares the patient's vital signs with previous records and raises an alert to medical professionals if changes are identified. The phone can capture heart rate, oxygen saturation level, temperature, ECG and blood pressure via a cuff included with the phone.

"The target demographic for MonitorMe is the older generation," said Julian Holmes, director of Sanandco. "The device makes earlier hospital discharge possible and introduces a new way to provide long-term care of the elderly and vulnerable in their own homes. Elderly and frail people are more likely to be using a telephone so we took the temperature sensors used on a smart phone and incorporated them into the handset. We wanted

AXA PPP Health Tech & You 2017 Award Winners

Challenge Award
Affinity

Trending Award
MyAsthma

Future Award
sensewear

Professional Award
uMotif

Health Tech & Age Award
MIRA Rehab

Wow! Award
HealthUnlocked

it to be an ordinary landline connection as we believe that is more secure than a wireless connection and doesn't depend on people having additional services like broadband."

Clinical professionals would provide patients with a MonitorMe phone and via a portal set the frequency of automated calls. The automated call includes a health questionnaire tailored to patient's condition which can be responded to by using the key pad on the phone. Intervention would then be triggered should the vital signs fall outside defined parameters. The company hope to receive CE marking in July 2017 as a Class IIA device so it can commence clinical trials.

Other medical device technologies recognized by the awards included *Inspair*, a smart inhaler developed by French device company Biocorp. The smart sensor is designed to be attached to regular asthma inhalers and works with adaptors designed to fit the mouthpieces of normal inhalers and records data on the number of inhalation. The sensor then provides daily feedback on inhaler use and misuse to patients, as well as information on environmental factors. In addition, the sensor measure the breath-hand co-ordination, speed of inspiration and doses inhaled by the user so they can improve their inhalation technique. Biocorp has already partnered with several major pharma companies to roll out the sensor and aims to extend its reach further in 2017.

The winners of were announced at the Health Tech & You award ceremony at the Design Museum IN Kensington, London 27.04.17.

Published online 04/28/17

Calif. Jury Awards $25m In Device-Maker Whistleblower Case

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A Los Angeles county jury has awarded a total of $25m to a man who accused his former employer, coronary and vascular device manufacturer **Cardiovascular Systems Inc.**, of retaliation and unlawful termination.

The jury's award to Steven Babyak includes $22.4m in punitive damages for whistleblower retaliation and wrongful termination, and a further $2.7m in compensatory damages. Babyak worked for the company as a regional sales manager for almost three years before he was suddenly fired on June 1, 2015. He filed suit later than year, on Nov. 16.

Babyak's attorneys say he was terminated after repeatedly telling executives, human resources and company attorneys about patient safety concerns as well as violations of laws including the Anti-Kickback Act, Sunshine Act and Sarbanes-Oxley Act.

Specifically, Babyak says his manager asked sales staff to collect patient information via their relationships with referring physicians, then offer the information to surgeons if they agreed to use the firm's products. Babyak reported the scheme to company officials, and an internal investigation allegedly corroborated his account. The manager then received a written warning, court records say.

His attorneys, Tamara Freeze and Robert Odell of the law firm Workplace Justice Advocates, PLC, say that, before Babyak was terminated, Cardiovascular Systems took retaliatory actions against him that included limiting his territory and imposing a higher sales quota, which reduced Babyak's compensation and bonuses.

Babyak also said that the harassment and retaliation violated California's anti-discrimination Fair Employment and Housing Act.

Freeze and Odell called the $25m reward "a complete vindication" of Babyak. "We hope that CSI's Board of Directors will take decisive action against the executives who terminated Mr. Babyak and then tried to cover it up," they added.

Cardiovascular Systems announced plans to challenge the verdict in an April 26 filing with the US Securities & Exchange Commission. "The Company strongly believes that this case was incorrectly decided as to liability, the amount of compensatory damages, and the appropriateness and amount of punitive damages," the statement reads.

Published online 04/28/17

Stent Leaders Pull Out Of India Amidst Price Cap Storm; Opportunity For 'The Dragon'?

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Months after India capped prices of coronary stents, three leading foreign suppliers of these devices – **Abbott Laboratories Inc., Medtronic** and **Boston Scientific Corp.** – have sought to pull out certain brands from the Indian market.

Abbott appears the most forthright of the three, mincing no words on the reasons for its decision. The US multinational said that following India's National Pharmaceutical Pricing Authority's (NPPA) price ceiling decision, it "examined and reexamined" whether there is a "sustainable" way to make available in India two of its latest stent technologies, the [Xience] *Alpine* drug eluting stent and the *Absorb* dissolving stent, considering their higher manufacturing costs and other associated costs.

"We have determined it is not sustainable, and we have applied to the NPPA to withdraw these two stents," Abbott told *Medtech Insight*.

The company underscored that while it is aligned with the government's intent for broad access to care, it is disappointed by the NPPA's declaration that there is "no differentiation in coronary stent technology."

Abbott, however, is not completely writing off the Indian market for the two stent brands – at least not yet. "We will continue looking at future opportunities to bring back Alpine and Absorb, if it becomes commercially viable," it added.

PRICE CAPS

The NPPA had, on Feb 13, capped the prices of stents in India in two broad buckets – bare metal stent prices were capped at INR7260, while prices of drug eluting stents (DES) including metallic DES, and bioresorbable vascular scaffold (BVS)/biodegradable stents were capped at INR29,600.

The price caps were clearly stinging for the foreign firms; Absorb was estimated to be available at around INR190,000 ($2,948) and Xience Alpine at around INR150,000, prior to the price cap, while Medtronic's *Resolute Onyx* was said to be available at around INR165,000. No official confirmation on the pre-cap price tags were immediately available; nor did any of three firms provide details of comparable prices of these products in other Asian markets.

MEDTRONIC, BOSTON SCIENTIFIC POSITIONS

On plans to take Resolute Onyx off the Indian market, Medtronic maintained that it regularly reviews its product portfolio "as part of normal business operations."

"Based on this review, we have submitted an application for withdrawal of Resolute Onyx under the provisions of Drug Prices Control Order. We will continue to supply Resolute Onyx till we get the required permissions from the authorities. Our decision to withdraw or introduce products is made only after taking into consideration all guidelines and norms set by the government," it explained.

Medtronic said it will continue to work toward increasing access of cardiovascular therapy to patients in India and cater to different needs of patients and physicians while providing them with a choice of "clinically proven and globally certified" stents like Resolute and *Resolute Integrity*.

Resolute Integrity, the first US FDA-approved drug eluting stent to have the additional indication for patients having diabetes mellitus with symptomatic ischemic heart disease, continues to be available in India, it specified.

Similarly, Boston Scientific, which is seeking to withdraw its *Synergy* and *Promus Premier* brands, told *Medtech Insight* that since the price control order in February 2017, it has been in a constant dialogue with the government bodies under various legal provisions.

"We have sought the possible reliefs available under the law and also submitted details on the superior clinical attributes of our stents Synergy and Promus Premier. Any decision to discontinue

these next generation stents may be taken as a part of the corporate sustainability review. In such case, Boston Scientific's other drug eluting stents shall continue to remain available in India as per guidelines and norms set by the law."

The NPPA website lists nine cases (including those pertaining to Boston Scientific's stents and other non-device products) that were up for discussion on April 19, but could not be completed and is scheduled to continue to be heard on May 2.

Significantly, Boston Scientific's India website also suggests that the import of its *Taxus Liberte* and *Liberte* stent brands has already been discontinued due to "global end of manufacturing" and that the current price information displayed therein is applicable "only till the time stocks exists in India." Boston Scientific declined to further comment on the issue.

None of the three companies specifically commented on whether they would facilitate the availability of brands that they propose to withdraw, for patients who may require these products and willing to pay a non-India price.

NPPA TWEETS

Interestingly, within days of news that some foreign firms had sought to withdraw their stent brands largely on account of the unviable pricing scenario, NPPA's Twitter handle appeared to resurrect previous notices to Abbott and Medtronic aimed at ensuring that these firms comply with the price caps set and maintain uninterrupted supply.

The notices include directions to the firms to maintain production/import/supply of the coronary stents and to submit a weekly report on coronary stents produced and distributed.

"They will also submit a weekly production plan for the next week to NPPA and DCGI [Drugs Controller General of India]," the Feb. 21 notices to Abbott and Medtronic respectively said.

It's not immediately clear why the price regulator chose to tweet these notices sent out on Feb. 21 to the companies at this juncture (on April 24), but it was seemingly enough to add more fuel to the fire.

While some industry watchers say the regulator's "hostile" approach did little to bridge the trust deficit with industry, others suggested that regulator was merely reminding the firms, in a transparent manner, on the need to stay compliant. NPPA chair Bhupendra Singh, who is rather active on Twitter, is seen as an intrepid regulator and someone who is seemingly liked and scorned in equal measure on both sides of the pricing debate divide in India.

The Medical Technology Association of India (MTaI), which represents research-based medtech companies in the country, said that it is not against price control on stents but only for categorization so quality and innovation are rewarded to keep that segment attractive and viable.

"The NLEM [India's national list of essential medicines] concluded that the later generations of stents are not superior to earlier generations. Based on this, the NPPA decided on one price for all drug-eluting stents. So, if all the DES are the same, the industry should have some freedom in deciding which stents to market, as long as a broad range still stays available. If in hindsight, the authorities feel that some DES are better than others, then there is a case for categorization of stents which is, by the way, the main point which we made to the NLEM, and continue to submit," MTaI said in an April 25 statement.

Last year, NPPA set out modalities for firms wanting to stop supplies of certain essential medicines in the country, though industry claims that these are beyond the regulator's remit and underscored how a lopsided pricing approach can lead to potential shortages. *(Also see "India Specifies Terms For Ceasing Supplies Of Essential Drugs" - Pink Sheet, 3 Oct, 2016.)*

ENTER 'THE DRAGON'?

Meanwhile, some industry officials tell *Medtech Insight* that the ongoing price cap storm for stents has potentially thrown up interesting growth opportunities for regional players, especially those from China.

Some mention potential opportunities for Chinese firm firms like **MicroPort Scientific Corporation** in India, though a leading cardiac surgeon in Mumbai contacted by *Medtech Insight* said that he had "no experience" so far using Chinese stents for his patients.

Some industry officials though referred to a significant influx of stents from Chinese firms, at sharp discounts, over the recent past. MicroPort could not immediately be reached for an official comment on the India opportunity.

Last year, MicroPort Scientific Corporation announced the official establishment of its subsidiary in India registered as MicroPort Scientific India Private Limited. On Feb. 15, MicroPort said that a case using its *Firehawk* Rapamycin Target Eluting Coronary Stent System was successfully completed in the HJ Doshi Ghatkopar Hindu Sabha Hospital based in Mumbai, India. It marked the first clinical use of Firehawk in India and a milestone in MicroPort's market development in the country, the Chinese company said at the time.

Published online 04/25/17

CONTINUED FROM PAGE 5

for NEST, and Rachel comes to us from PCORI where she was program director for Research Infrastructure. So we're excited by that for multiple reasons. Rachel has also been the PCORI representative on our board, so Rachel has a board-level understanding of MDIC and she comes in with some context and understanding of MDIC, and a deep understanding in developing networks, having established through PCORnet, relationships and expertise in how to execute on a national network.

So we're very excited by that, and I think her skills are complimentary to what Dawn and I bring, which is much more depth in the medical device community and our unique needs and requirements.

Since the change in presidential administration in January, have you picked up on any notable changes at FDA so far?

Murray: Based on my discussions with [CDRH director] Jeff Shuren, we are continuing on our strategic path in our day-to-day operational directions. So we don't see anything right now indicating a change. That's obviously not guaranteed, but that's the operating assumption.

Dawn Bardot: One exciting evolution is that people are beginning to engage on NEST and to understand what is possible. And even in a model and in a simulation session today [at the Design of Medical Devices Conference] that was on systems levels modeling, there was a discussion of how databases and real-world evidence are being pulled into the analysis and design of medical devices, and we had a real-world evidence example shared from **Abiomed Inc.**

Are you getting more and more interest in what you're doing? Are more companies getting involved? What are you doing to reach out to stakeholders to contribute to MDIC and where do you stand in terms of engagement?

Bardot: The interest level continues to be strong. We've always had very strong interest level from the traditional medical device community, especially the manufacturers of class III and more-complex class II devices. We've built some momentum in the last year I think in the diagnostic area as well, and we're starting to see some real interest from the digital-health community.

Murray: There's two areas that are of strong interest. One – and this sounds obvious – is NEST, because obviously the real-world evidence and the work there is obviously of interest to them. And the other area where there's real opportunity is in our Case for Quality Initiative. Having good data is necessary for having a robust system in the post market, so there's an interest from that community in that area, as well.

Are there any other broad areas that we should be paying attention to that MDIC is involved with?

Murray: We don't have anything specific yet [but] that would be in the whole cybersecurity area. There's an interest in that area for obvious reasons. So we're not quite sure whether or not there's a project for us in that area yet, but it's an area that our members tell us is important to them.

And then the other one, which is critically important, but we're still trying to figure out how to really approach it, is the reimbursement area – not from the policy side, but more … the reimbursement science work can we do to help support and make reimbursement more efficient and more predictable. The same things we're doing with FDA – can we do it with private payers and CMS?

"We're still trying to figure out how to really approach ... the reimbursement area – not from the policy side, but more ... the reimbursement science work can we do to help support and make reimbursement more efficient and more predictable," William Murray says.

Bardot: I think there's some real dovetailing there with NEST as well, because this is all really about evidence, and evidence in clinical [experience], not so much in a clinical trial, so NEST is a direct portal into answering those questions.

Murray: It's especially important to understand the patient perspective for those therapeutic or disease areas where there's preference-sensitive attributes. And what we're trying to do is bring some scientific rigor to that as opposed to just having the last person you talk to be the voice that you remember in that process.

Bardot: I think the other component that may add value here is looking at routine clinical care as being your source of evidence. I think that's an area where, as opposed to a clinical trial, there may be value because you're not creating artificial inclusion/exclusion criteria. You are actually taking patients as they are in clinical care. So that's an area where clinical science from routine clinical care may be more powerful in some instances than a randomized clinical trial itself.

We've written several articles in the past on MDIC's work with experts from industry and government to create "virtual patient" computer models that may make clinical testing of new devices more efficient. What's the latest on that project?

Bardot: We have heard from sponsors that we have approved statistical analysis plans that include virtual patients. [On April

17] we have an MDICx webinar on the virtual patient, which includes two FDA speakers.

But what's really great is we'll be able to hear FDA's interest in Bayesian [statistical] methods, we'll be able to hear industry examples of retrospective analyses that worked for them, and we even have one of our speakers talking about how you brief an FDA-advisory panel if you're going to use virtual patients.

Murray: We have now eight retrospective analyses that have been done where sponsors went back and looked at prior clinical trials and said 'If we were to incorporate this statistical model into our trial design, what would be the impact?' And now what we have is two statistical analysis plans … that have been submitted to FDA where FDA has accepted that plan as part of the clinical study, which means the opportunity is for a clinical trial to have fewer actual patients enrolled, but still all the power and the significance associated with a traditional trial.

And I think that is the opportunity, and that's the value proposition that MDIC brings when we talk about the cost of innovation, gaining access to patients that are safe and effective, maintaining the rigor and confidence in the performance of the product but making it more effective and efficient.

A company might ask, "'I know how my product's going to work, but how do I make sure that the data that we're getting from the health-care system really represents the product performance?' It's not easily attainable today in many cases," Murray says.

Bardot: What MDIC has done – and the value proposition that MDIC provides to the ecosystem – is that we can help with the development of these methods, and we can help with how you operationalize and de-risk these methods. So by creating the mock submission, then by creating the retrospectives, we're showing that there's the proof in the pudding. We're showing how the rubber hits the road so that when sponsors pick them up and use them prospectively, they can have higher confidence in how you use it and how it will be viewed.

And then what we, as an organization, want is for those sponsors to come back and tell us about their experiences, because that's how we'll be able to both improve the method and learn how the method's actually working in practice. And that means that those sponsors have to share that with us.

In terms of companies sharing and their willingness to work with other companies on these projects, is that going pretty well? Is there still some reluctance, or has everybody bought into that?

Murray: 'Everybody' is too a strong statement, but I think there's a significant percentage of our members that have realized that to accomplish what we need to accomplish, and for the overall health of the ecosystem, they've got to change some of the methods and means. So there's been more openness and more collaboration than maybe there was in the past, where everybody did everything themselves, but they just realized that the cost of innovation has become so high. The pain points have kind of driven it to this approach.

Bardot: And on these shared pain points where we're talking about regulatory science, we can collaborate and help all boats rise with the tide.

In terms of the overall cost and difficulty facing companies trying to run clinical trials to support regulatory approval, would you say it's getting better or getting worse?

Murray: I'll tell you what I hear broadly here. I think there's genuinely strong alignment that, from an FDA regulatory perspective, the process has improved significantly under Director Shuren's leadership and specifically as it relates to predictability and engagement. Starting with engagement and predictability, reimbursement is a conundrum, and especially if you need a new code, our system is still very challenging [and makes it hard] to figure that out. And that's the area that is probably, from an environmental perspective, the most vexing.

Bardot: That's the most adverse situation right now.

Murray: Well, what I would say on that point, this gets back to the real-world evidence. So if you look at many of the payers and the health-care systems, they aren't fully aware of how the product performs longitudinally, right? Especially for hospital-based systems, once that patient leaves the hospital the long-term connectivity of that patient to the initial procedure is a challenge, right? And that is also true for the payer side of it, right? So I think that's where, if you will, the interest from a large strategic player like Medtronic with real-world evidence is, for them to do this risk sharing, they've got to have robust ways of knowing how the product performs over the product's lifecycle.

All this data is not easily collectible on a cost-effective, efficient way, so as Medtronic is thinking about, in this case, their business strategy, they have to ask "How do I know what the appropriate risk model would be? I know how my product's going to work, but how do I make sure that the data that we're getting from the health-care system really represents the product performance?" It's not easily attainable today in many cases.

If it's hard for a company with as many resources as Medtronic, how can a small company survive in this environment?

Murray: Well, I think that over the long-term – the near term is a different question – this is the vision for NEST, because we

want to put a national system in place. And this is what Jeff Shuren talks about too. But really, the opportunity is [to create a new expectation] where clinical research is part of routine clinical care. So if you have that and you have long-term data that you can look at and it's not exponentially more expensive to get that level of insight, then you have an opportunity for all-comers to have a playing field where they can innovate and have risk-sharing models. But, right now, that's not a cost-effective scenario for most, or certainly for a startup company.

"The very next announcement you'll hear from us is the establishment of the governing committee for NEST, and for the NEST Coordinating Center, and that's the key additional ingredient that we need," Bardot says.

Bardot: But unlocking that story is the value proposition for NEST.

Murray: Right. Now having said that, I think that's also where some of the digital-health companies and the disruptive startups might look going outside of the traditional system, with sensors and different methods and means for getting that information than what we have today.

Bardot: The future isn't going to be registry-based, for example. At least, the future isn't going to be *only* registry-based.

What would you say are your big priorities for the next year, as an organization?

Murray: I'll start with the coordinating center in NEST. The first one is I hired Rachel Fleurence, and now we're going to start up the governance structure for NEST. We have to work to get that established.

We're also in the middle of completing a landscape analysis on real-world evidence, and that will be used to inform our demonstration projects. And those projects need to start to show value in how real-world evidence can be used and start to build the case for the application of real-world evidence in a more comprehensive way.

We'll end up going out and requesting proposals [for those demonstration projects], and that's why we have to have the governance structure in place, because the minute we ask, we're going to get a lot of ideas, and we need to have a process for that.

Bardot: The very next announcement you'll hear from us is the establishment of the governing committee for NEST, and for the NEST Coordinating Center, and that's the key additional ingredient that we need before we can start collecting demonstration project proposals.

Who will be represented on that committee?

Murray: We're going to have a broad stakeholder representation, so there'll be industry representation, government representation, healthcare systems, healthcare providers, and there's going to be some digital IT folks too.

Bardot: And patients.

Murray: —and patients. There's a group of patients that are not only patients but have developed expertise in clinical trials and some of the considerations for the science behind engaging in patients. So it's not just somebody that uses a product. It's not a huge group, but we only need a few to be part of that.

Anything else going on that you want stakeholders to know about?

Murray: Our clinical trial science work and the virtual patient work, that area, that's going to be highly impactful, I think, for the ecosystem.

Bardot: Stay tuned. We'll soon have some good discussion points on early feasibility studies.

Published online 04/27/17

CONTINUED FROM PAGE 1

review its regulatory compliance. Check out the conversation in the following Q&A with *Medtech Insight*'s Amanda Maxwell.

Medtech Insight: The texts have been adopted. What top three things would you advise companies to be doing right now?

John Brennan: Make sure that you read the texts and identify the gaps between what you are doing now for regulatory compliance and what will be required in future. Talk to your notified bodies to find out their positions. And make sure that the senior management in your company know that this is a business issue rather than simply a regulatory issue. Also, someone needs to be appointed to oversee the implementation – a good project leader who recognizes that this is very much a cross-functional job.

"Notified bodies, and when or whether they are available or not, is the most important issue in terms of the whole system working."

How would you like to see the European Commission and competent authorities preparing now, and is this happening? What evidence do you have of progress?

Brennan: We are very eager to see the next version of the roadmap which is being developed by the European Commission along with the Competent Authorities for Medical Devices (CAMD) group. This is due out during the first week of June, after the draft version was discussed at the Commission and CAMD stakeholder meeting on March 9.

We know that, within the roadmap, the Commission is already working on plans specifically focused on IVD guidance and NBOG [Notified Body Operations Group] codes for IVDs, amongst many other projects. We also know that groups are ... working on how to set up the new and much-expanded version of the Eudamed medical device database. These are among subjects that we also consider to be priorities.

We are hoping that the Commission/CAMD roadmap will also feature timeframes. This is one of the vital things that companies need to understand as quickly as possible ... to implement the different aspects of the regulations.

There are some challenges around understanding the transition period timeframes because of the many derogations in both texts and it is difficult to determine what these will ultimately mean in terms of implementation.

The reason for the possible derogations around the timeframes for compliance with the requirements related to the Eudamed database, for example, exist because of the long delays experienced with the earlier version of the database.

What advice would you offer manufacturers who are seeking earliest possible compliance or, if manufacturers are going to wait to seek compliance at a later stage, what are the pitfalls of which they should be aware?

Brennan: It is not our role to advise companies whether they should be aiming for early or late compliance. It would be impossible to do this well because there are so many different types of businesses making different types of products There is no right answer. Each business will have to assess that question for itself.

I would, however, recommend that companies examine the texts and see what has changed so they know how much they need to adapt. This is likely to be a particularly challenging for IVD companies as, for some 80% of companies, the use of a notified body is new.

"Companies need to examine their own technical files, see if there are any gaps, and, if so, how they will fill them ... They need to look at the question of whether they "remediate, replace or retire" their products."

What are you advising your companies in terms of the notified body options, given that the 22 members of the notified body association, TEAM-NB, will be making an early request for designation?

Brennan: In our view, notified bodies, and when or whether they are available or not, is the most important issue in terms of the whole system working. We have been asking our members and national associations to let us know of any issues they are facing and have already been hearing about notified body capacity issues and delays. Companies and our members know they should be letting their authorities know those issues so the authorities are aware of what is going on and can consider what should be done.

On a more individual level and in terms of companies having assurance that their notified bodies are going to continue operating in this sector, it's important for each company to talk to its notified body to find out their intentions.

How many of the other 35 or so remaining notified bodies designated at present under the Medical Devices Directives that are not members of TEAM-NB will be seeking designation under the MDR?

Brennan: We have heard from TEAM-NB that their 22 members are definitely going for designation; that does not mean the others aren't too. But we don't know of any details yet.

We don't have any solid data on whether it is all of them or fewer of them. The authorities and the Commission are aware there are concerns about the lack of information here.

What would you recommend in terms of action now for companies with high-risk medical devices subject to scrutiny and where new organizations, such as the expert panels, reference labs, and the Medical Devices Coordination Group (MDCG), have a role to play but still need to be set up?

Brennan: The key thing for companies that fall into this area is for them to read and understand the new requirements as laid out for the clinical part for IVDs and medical devices.

Companies need to examine their own technical files, see if there are any gaps, and, if so, how they will fill them and make decisions based on that. They need to look at the question of whether they "remediate, replace or retire" their products, to repeat a phrase that I heard from some companies in recent conferences. I would advise companies to work through their files like that, and to look at their post-market surveillance data. If that data is not sufficiently relevant, then they need to adjust it to ensure they get the relevant data.

It was mentioned at the March 9 stakeholder meeting that we would like to see the how governance around the new structures is going to work as early as possible. How will the organization be set up, when will they be set up, how will they run, who makes their decisions, who is on them, how do they communicate with each other?

When it comes to expert panels, the Joint Research Council already has rules on how to set those up, but are those the ones we are going to use this time?

Although there are some 80 delegated and implementing acts still to be drafted, there are apparently 14 that are considered urgent. Could you give an indication of what is happening here, please?

Brennan: I have heard that there are 14 priority acts but I have not seen the list and the dates beside them.

To my knowledge, the Commission has mentioned that among the priority implementing acts are those dealing with the notified bodies system and the setting up of all of that; the reprocessing of single use devices; the Eudamed database; the MDCG; and the regulation of aesthetic products.

Have you any guides ready yet for your members or for industry?

Brennan: We have subgroups working on best-practice guides for our members in all the main areas. That work continues now that we have the final text – due to be published imminently – and we will reread our work to make sure we are up to speed with the very last version of the texts. We will also check them against the roadmap and see if there are any additional items that need addressing or items that need to be worked on in a different order.

Areas where we are working on guides for our members include, in the devices area, notified bodies transition and clinical requirements, and, in the IVD area, classification, conformity assessment and clinical evidence. Those are the areas where our members are most concerned and where we are seeking to quickly get down on paper what the best-practice compliance route would be.

> "There is no next. There is what we have currently and that is implementation."

What are your top three tips to companies for avoiding bottlenecks?

Brennan: Plan, plan, and plan again! Remain vigilant as to what is going on at your national associations, and with us at the European level. Many member states are starting to produce national programs looking at the implementation or workshops of discussions, so keep an eye on those.

SMEs will tend to get the information they need at the national level. It should be funnelling down from the work the Commission and competent authorities are doing and MedTech Europe. But it needs to be a two-way communication. It is highly important that we get information from our national associations about concerns on the ground, including on notified-body issues.

The larger countries are trying to put support in place, such as a conferences, or setting up a consultation meeting like in Germany, to get the information from the text at EU level to verbal information, so manufacturers, importers, distributors, authorized representatives can begin to understand and ask questions.

What should the sector be looking out for next?

Brennan: There is no next. There is what we have currently and that is implementation, the secondary legislation and guidance to be developed and put into place. We are now heavily focused on the whole implementation program.

We have to stay vigilant for any of the potential bottlenecks that might happen, especially around of the database, notified bodies and the governance structures. We have to be very vigilant about bottlenecks and tackle them before they become a problem or serious problem.

Published online 04/28/17

The Patient Perspective: Upcoming US FDA Device Center Studies Put Device-Users In Front Seat

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Engaging with patients continues to be a top priority for US FDA's Center for Devices and Radiological Health as it tries to determine what device-users want and value when it comes to health care.

Robin Newman, director of the Office of Compliance within CDRH, says "the only way we're really going to know is by partnering with patients and asking them. As an agency and as a center, we've come to realize: partnering with patients is key."

Newman's comments came at FDAnews' 14th Annual Medical Device Quality Congress in Bethesda, Md.

"When it comes to working with our patients, we want to promote a culture of meaningful – and 'meaningful' is an important word – patient interactions between the people at CDRH and the patient groups, patients themselves, advocacy groups, *et cetera*," she said.

To that end, the center is launching patient-perspective studies that will be sliced into two categories: patient-preference information (PPI) studies and patient-reported outcome (PRO) studies.

In a PRO study, a patient's health status is reported by the patient without physician involvement. And during a PPI study, a patient's views on products, and the tradeoffs of benefits and risks, are recorded.

"This is not about just sending out a survey. This is about bringing patients in, talking to the groups face to face, having people at the agency sit down and listen to a patient's story. That's what 'meaningful' is. That's what we're trying to do," Newman said.

Patient-perspective studies can provide valid scientific evidence regarding patients' risk tolerance and perspective on benefit, the agency says. The studies also can inform FDA's evaluation of a device's benefit-risk profile during the premarket approval (PMA), humanitarian device exemption (HDE) application, and *de novo* request review processes.

"This is not about just sending out a survey. This is about bringing patients in, talking to the groups face to face, having people at the agency sit down and listen to a patient's story," CDRH compliance head Robin Newman says.

"We're trying to increase the transparency we have in getting patient input so we really know what it is that they're thinking and how they're experiencing their product, and then letting that, hopefully, impact our decision-making in a very positive way," Newman said.

She said device center staff is researching best ways to put the patient-perspective studies together.

"The agency is very, very good at quantitative research. We understand that well. But some of [the patient-perspective studies] will involve qualitative research, new methodologies and new ways of thinking," Newman said. "We're looking at really logical soundness [and] good integrity to these studies that we're doing."

CDRH also wants to conduct collaborative PPI research related to obesity, neurology, oncology, pediatrics and women's health.

"We're looking across a pretty broad spectrum of not only pathophysiologies, but different patient populations. We're trying to reach out across a variety of different demographic groups to reach the right groups," Newman said.

The center will also review research linked to patient-reported outcomes for traumatic brain injuries, urology and women's health. "This is research that's planned and is in various stages of getting kicked off. So, again, this is real research – not just a survey," she noted.

FDA has been pushing hard on the notion of putting patients first and gaining their perceptions.

CDRH identified increasing meaningful patient engagement and improving use of tools such as patient-reported outcomes as one of its top 2016-2017 strategic priorities. *(Also see "CDRH Prioritizes Leveraging Real-World And Patient-Preference Data, Enhancing Quality" - Medtech Insight, 15 Jan, 2016.)* And efforts to advance use of PRO and PPI are specifically tagged for increased funding under the MDUFA IV user-fee agreement inked with industry last summer, and now before Congress for approval. *(Also see "MDUFA IV Takes Shape: A Catalogue Of Draft Commitments" - Medtech Insight, 29 Aug, 2016.)*

The agency launched the Patient Preference Initiative in 2012 "to develop a systematic way of eliciting, measuring and incorporating patient-preference information, where appropriate, into the medical device Total Product Life Cycle."

Since then, FDA has increased its focus

on developing tools for formally incorporating patient input into regulatory decisions. *(Also see "FDA Validates Tool For Incorporating Patient Preferences In Regulatory Decisions" - Medtech Insight, 30 Sep, 2013.)*

FDA finalized a guidance document last August that outlines how the agency will use patient-preference information when reviewing device applications. *(Also see "Final Guidance Encourages Use Of Patient Preference In Device Applications" - Medtech Insight, 25 Aug, 2016.)*

Patients are also playing an ever-increasing role in how the agency approaches its compliance and enforcement priorities, former FDA investigations branch director Ricki Chase said in a Compliance 360° podcast from March. *(Also see "Compliance 360° Part 8: Patient Influence On US FDA's Enforcement Strategy" - Medtech Insight, 27 Mar, 2017.)*

"Patients are at the heart of everything we do," compliance chief Newman said. She pointed out that 63% of CDRH staffers engaged with patients in some way, shape or form in 2016, besting a goal of 50%.

"But we're not finished. This is just a good start – this is changing the tone of how we think about things," she said.

For example, the Office of Compliance recently invited a cancer patient to speak with agency officials about her healthcare experiences.

"Do you think her benefit-risk perspective is a little bit different, perhaps, than a patient who is going to have an elective procedure? The answer is yes," Newman said. The patient "talked to us about how she takes risks as a cancer patient, knowing what those risks are … because the alternative is a completely unacceptable one.

"This is a very powerful process, and I think it changes the way our people think about our mission and why we come to work every day."

Published online 04/25/17

New Bill Would Regulate Third-Party Device Servicers

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Third-party medical device servicing companies could be regulated by US FDA if a new bill proposed in the US House is signed into law. The bill's sponsors argue it is intended to improve patient safety, and help FDA keep track of the servicers and their work.

Reps. Ryan Costello, R-Pa., and Scott Peters, D-Cali., introduced the bill, "Ensuring Patient Safety through Accountable Medical Device Servicing" (H.R. 2118), on April 24. The lawmakers plan to present the bill on May 2 to the House Energy and Commerce Committee along with other device-related bills, including legislation, also from Reps. Costello and Ryan, to streamline the review of new imaging device indications that rely on established contrast agents; one to make device-facility inspections more consistent and transparent; and one that would make some hearing aids available over the counter.

Each of the bills has the potential to be added to the MDUFA IV device user-fee reauthorization legislation that is currently moving through Congress.

"Right now there is no registration system to track third-party contractors who work on medical devices and imaging machines," said Peters in a statement to *Medtech Insight*. This is an issue that affects both patients and manufacturers, many of whom are at the center of the innovation economy in my district in San Diego. This bill is first and foremost about ensuring patient safety by creating a registry at the FDA so we can know who is working on these machines."

The bill has already received support from the industry lobby group the Medical Imaging & Technology Alliance, which argues that currently only medical device servicing performed by the original device manufacturers are regulated by FDA. The group says the proposed bill will level the playing field by requiring similar regulatory oversight of third-party vendors.

"If a device fails to perform in a safe and effective manner due to improper servicing by an unregulated, third-party organization, it could potentially put the patient at risk for serious physical injury or result in low image quality – which could lead to a delayed or missed diagnosis," MITA said in a statement. "A survey conducted by KRC Research in 2016 found the majority of Americans believe proper servicing and maintenance of all medical and radiation-emitting devices is crucial to protecting patients, and agree that FDA should extend regulatory oversight, including minimum quality, safety and regulatory requirements, to all entities servicing medical devices."

MITA Executive Director Patrick Hope says the bill is a "…reasonable, commonsense solution that will not be costly or burdensome to third-party organizations, but will protect patients who rely on the safety, effectiveness and reliability of our technologies."

The subject of third-party device servicing also gained attention in lawmaker questioning of FDA Commissioner-nominee as part of the confirmation process. *(Also see "Gottlieb Wants Timely Approval Of User Fee Bill, Balanced LDT Plan" - Medtech Insight, 27 Apr, 2017.)*

And the agency itself is weighing adjustments to its current policies. Last year, FDA issued a docket asking for comment on whether it needs tighter oversight of device servicing and repair practices *(Also see "Focus On Refurbishing: FDA Seeks Input On Practices That Extend The Life Of Devices" - Medtech Insight, 3 Mar, 2016.)*, and it convened a meeting in November on the topic. *(Also see "Device Users Stress Need For Proper Manuals, Training To Support Refurbishing" - Medtech Insight, 2 Nov, 2016.)*

Published online 04/28/17

Legislation Would Streamline Risk-Classification For Device Accessories

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Following provisions in the 21st Century Cures Act to separate US FDA review of accessories from their parent device, a bill proposed in the US House would create a new streamlined regulatory pathway for accessories. The bill is being hailed by industry lobbyists as an "important legislation" that would save the agency resources while stopping regulators from unfairly categorizing the products.

Device-industry advocates hope to add the legislation, which was introduced in the House and referred to the House Energy and Commerce Committee on April 25, to the medical device user fee reauthorization bill, or MDUFA IV, which is currently moving through Congress and must pass by July to avoid layoff-planning notices to go out to FDA employees. *(Also see "Risks Of Missing Reauthorization Deadline Highlighted At User-Fee Hearing" - Medtech Insight, 21 Mar, 2017.)*

Industry groups have long griped to regulators that FDA's approach to classifying accessories based on their parent device is unfair and a disincentive for manufacturers to update accessories. For its part, FDA finalized a guidance in December that takes a more lenient approach to regulating accessories and to how the agency determines that a particular product *is* an accessory.

But some in industry remain dissatisfied with the guidance, stating it failed to provide clarification in critical areas and did not address the issue of classification for accessories already on the market. (In particular, attorney Bradley Thompson, who runs the industry Clinical Decision Support Coalition, complained that the guidance requires manufacturers to use the *de novo* process, which could be cumbersome for some companies. (*Also see "FDA Provides Accessories Guidance, But May Be 'Missed' Opportunity" - Medtech Insight, 4 Jan, 2017.*)

While FDA was finalizing the guidance, Congress included a provision in the December 2016-enacted 21st Century Cures Act, as part of health software regulation reforms, requiring FDA to treat accessories differently from the parent devices. *(Also see "21st Century Cures: Device Provisions" - Medtech Insight, 14 Dec, 2016.)*

The more recent piece of legislation, called the "Risk-Based Classification of Accessories Act" (H.R. 2144) was introduced by Reps. Mimi Walters, R-Calif., and Annie Kuster, D-N.H. It goes a step beyond the Cures language by providing a streamlined mechanism for FDA to classify new and established medical device accessories, providing an alternative to the *de novo* process. Specifically, the bill would establish a classification process for new accessories that would be based on a recommendation from the product sponsor that includes data or other information to support the designation.

It would also streamline reclassification for accessories that were put on the market before the Cures bill severed the necessary parent-accessory classification link. Specifically, manufacturers could recommendation a classification for such a product and FDA would have 60 days to approve or deny the recommendation, including providing an opportunity for the company to meet with agency officials about the recommendation.

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"This bill would clarify that something like a plastic tray doesn't need to be tested to the same degree as a high-powered eye surgery laser," Rep. Annie Kuster, D-N.H., who cosponsored the bill, says.

According to Walters, the bill would reduce burden on medical device manufacturers by doing away with unnecessary regulatory oversight.

"Some of the largest drivers of health-care costs are the antiquated, one-size-fits all regulations that make medical devices and new technologies more expensive to bring to market," she said in a joint statement. "This bipartisan legislation streamlines some of the excessive red tape that unnecessarily delays the health benefits patients receive from medical devices."

Kuster echoed her co-sponsor on the bill. "It is commonsense that an accessory that does not impact the safety of a device should not need to go through the cumbersome process for FDA approval required for a more sophisticated medical device," she said. "This bill would clarify that something like a plastic tray doesn't need to be tested to the same degree as a high-powered eye surgery laser."

Kuster's district includes device-maker **Smiths Medical**, which has 350 employees in Keene, N.H. In the lawmakers' joint state-

ment, Chris Swonger, senior VP for global government relations at Smiths applauded the bill.

Industry-group AdvaMed also welcomed the legislation, stating that it fills a gap left by the Cures provisions in establishing streamlined mechanisms to classify accessories. a good mechanism for implementing the provisions and addressing accessories already on the market.

"A tailored review approach for device accessories would improve FDA's efficiency and save the agency resources while ensuring patients continue to benefit from safe and effective medical technologies," AdvaMed CEO Scott Whitaker said.

UNANSWERED: ACCESSORY CLASSIFICATION STANDARD

Bradley Thompson, who practices law at Epstein Beck & Green in addition to his work with the Clinical Decision Support Coalition, has been lobbying FDA to change its oversight of accessories since 2010. The attorney says the agency's views on regulating accessories has evolved, especially with the latest guidance document, where it agreed their classification should be based on intended use. But he notes it still left out the question of what process FDA should use to regulate the products. That issue would apparently be addressed by Walters and Kuster's bill, he suggested.

"This bill picks up where 21st Century Cures left off with the premise that accessories should be classified on the basis of their own intended use, rather than the intended use of the parent device," Thompson told Medtech Insight. "What the act then seems to do is create at least three alternative pathways for accomplishing that classification, instead of the *de novo* process."

"By far the tougher issue, and the issue that this legislation does not address, is the standard for deciding the appropriate classification," attorney Bradley Thompson says.

Thompson says the new proposed pathway is progress, but he is somewhat skeptical about how big of an impact the bill could have on the status quo.

"Right now, if FDA agrees to a classification through a pre-market approval process, I don't know that there's any particular barrier to them setting up a new classification that they've already essentially acknowledged," he said. "By far the tougher issue, and the issue that this legislation does not address, is the standard for deciding the appropriate classification."

The biggest issue for Thompson is figuring out what level of evidence FDA will require of accessory manufacturers to determine the product's risk class. Essentially, that issue is skipped in the new legislation and is deferred to FDA.

Published online 04/27/17

Sen. Klobuchar Forming Coalition To Push For Both Device, Cadillac Tax Repeal

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In an effort to strengthen the appeal of repealing the device tax, Sen. Amy Klobuchar, D-Minn., is forming a coalition of senators willing to work to end both the 2.3% excise tax and the Cadillac tax, both enacted in the 2010 Affordable Care Act.

Klobuchar discussed the plan at the Medical Device Manufacturers Associations' annual meeting in Washington, DC, April 27.

The Cadillac tax is a 40% excise tax that will be imposed on health-care plans with annual premiums exceeding $10,800 for individuals, or $29,500 for a family, starting in 2020, to be paid by insurers.

The senator noted that after support for a Republican-led alternative ACA repeal and replace plan – the American Health Care Act – melted away in the House on March 24, "We are now at a standstill on device tax repeal."

Another vehicle for device tax repeal might have been President Trump's tax reform plan released April 26, but the short list "is kind of light on details," and didn't mention any device-tax repeal, Klobuchar told the MDMA audience as she held up the President's one-page plan.

"Here's what I'm trying to do to bring about device-tax repeal. I'm forming a coalition of Senators who are opposed to the Cadillac tax in the ACA, and those who are opposed to the device tax. If we work together, we'll get more force behind the device tax-repeal proposal," the senator said.

Klobuchar has been pushing for permanent repeal of the medical device tax – which was temporarily halted for a two-year period – for several years now in the Senate. Her latest effort is a standalone, device tax repeal bill, S. 108, co-introduced by Sen. Orrin Hatch, R-Utah, with 12 other co-sponsors. Two of the newest senators in this session of Congress, Tammy Duckworth, D-Ill., and Maggie Hassan, D-N.H., signed on to the bill in the last two months, so support is growing. But to get through the Senate, device-tax repeal would almost certainly need to be attached to a larger legislative package.

And as far back as 2015, advocacy groups including unions, and disease-focused groups like the American Cancer Society, who favor the generous health-care plans known as "Cadillac plans,"

> "I'm forming a coalition of Senators who are opposed to the Cadillac tax in the ACA, and the device tax ... if we work together, we'll get more force behind device tax-repeal," Klobuchar said.

have favored a repeal of that ACA tax – so repeal of both the taxes have been linked together before, in prior sessions of Congress. *(Also see "Two-Year Ban On Device Tax Clinched In Tax-Extenders Bill, Passage Expected Soon" - Medtech Insight, 17 Dec, 2015.)*

A likely vehicle for such a combined tax repeal effort in 2017 might be a Medicare or Children's Health Insurance package passed alongside a FY 2018 appropriations bill later this year, in September or October, Klobuchar said.

Less likely, would be attaching a combined Cadillac tax repeal/device tax repeal bill to the MDUFA IV user fees reauthorization bill – which most legislators, and device industry representatives, want to keep as clean as possible. *(Also see "Senate, House Panels Release Clean Device User-Fee Discussion Draft" - Medtech Insight, 14 Apr, 2017.)*

Published online 04/28/17

Unapproved Indications Guidance Proves Controversial

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Trade groups, manufacturers and patients alike weighed in on a pair of US FDA draft guidance documents that were issued in January to address manufacturer communications, with 110 comments collected before the April 19 deadline and posted online this week.

The agency collected 86 comments on a draft guidance on manufacturers' communications about unapproved uses of medical products, with an additional 24 comments coming in response to a guidance about manufacturer communications with payers that was issued at the same time.

The draft documents, which were written in Q&A format, explain how companies can discuss unapproved products in a manner that complies with FDA-required labeling and is truthful and not misleading. The proposed guidelines were issued in the closing days of the Obama administration, so it is unclear how the Trump administration FDA will move forward with the documents. FDA Commissioner-nominee Scott Gottlieb is known to favor broader allowances for manufacturer speech.

In any case, the draft documents were widely seen as cracking open a door to off-label communications. *(Also see "FDA Cracks Open Door For More Manufacturer Communications" - Medtech Insight, 20 Jan, 2017.)* The drug and device industries have long lobbied for broader speech protections, and multiple courts have supported that position.

UNAPPROVED-USE GUIDANCE STIRS CONTROVERSY

The unapproved use guidance would allow manufacturers to communicate certain types of information not listed in device labeling, such as long-term safety data, as long as they are "compatible with" the labeling. It doesn't apply to true off-label speech, FDA says.

The proposal sparked a broad spectrum of response. Several of the 86 comments posted so far came from citizens who say they were injured by drugs or devices used off-label, or from groups that expressed related safety concerns. For example, consumer group Public Citizen argued strongly in favor of keeping restrictions on speech about unapproved products or uses as they stand. The industry belief that FDA's speech restrictions are unconstitutional isn't supported by case law, the group says.

"History shows that after-the-fact enforcement is inadequate to protect patient safety," Public Citizen contended, and went on to refer to a 1937 disaster in which more than 100 people were poisoned by a new and unapproved drug formulation. "Rather, when an unproven assertion of safety and effectiveness is relied on, the resulting harm may be severe—even, as was the case with Elixir Sulfanilamide, irreparable. In the strongest terms, we urge the FDA to strengthen, not loosen, its restrictions on promotion of drugs and medical devices for unapproved uses."

Similarly, Pew Charitable Trust asked that FDA keep its patient safety responsibilities in mind before making any reforms. Use of products for unapproved indications had sometimes harmed patients, the Trust said. "The ability of FDA to protect the public health through its function as an independent scientific authority could be compromised if the agency could not restrict firms from promoting products for sale for uses that that have not undergone FDA review," the group wrote.

Pew also expressed concern that allowing manufacturers to discuss unapproved uses could dilute FDA's authority to require that manufacturers provide data backing any marketing claims.

In contrast, medical device trade groups largely backed the draft guidance, saying it would help, not hurt, patient safety. AdvaMed's main critique was that the guidance should be flexible enough to ensure protection for a broad range of communications about medical devices throughout a products' lifecycles.

"Unlike other medical products, medical devices are often multifaceted, with various technical features, components, and accessories," AdvaMed wrote. "The design, use, and understanding of these devices is often complex, and this necessitates educational programs and engagement with the health-care community throughout the lifecycle of the medical device."

Specifically, the association wants the document to allow man-

ufacturers to speak with medical professionals about technical developments in real time, especially when it comes to training and technical support. "Facilitating the ability of medical device manufacturers to provide truthful and non-misleading information for uses of approved or cleared products and associated risks promotes the safe and effective use of these products by health-care professionals, and should be encouraged in order to further the common goal of patient safety," AdvaMed said.

The trade group also asked FDA to more clearly explain the differences between "off-label communications" and "information consistent with labeling." The draft guidance applies only to information consistent with labeling, but AdvaMed feels the definition is both unclear and overly narrow. AdvaMed further requested changes to the guidance so it would allow manufacturers to talk to payers about anticipated approvals, and to include data on off-label uses in information sent to payers to help build risk-based reimbursement rates.

The Biotechnology Innovation Organization (BIO) also expressed support for the draft guidances, but it recommended FDA combine them into a single document. BIO also asked for greater clarity on the evidentiary standards that FDA wants to see.

BIO said the Internet made broader speech protections for manufacturers imperative because a great deal of information about unapproved uses is available online. This means that device-maker speech is especially important "to counterbalance the potential public health consequences of the proliferation of potentially incomplete and/or unreliable information in the public domain," BIO argued.

BIO also said that labeling often lags significantly behind knowledge drawn from real-world data. Companies should be able to communicate new knowledge if it's truthful and not misleading, BIO said. The biotech group has worked with the drug lobby organization PHRMA to develop a set of detailed principles on what constitutes truthful and non-misleading information, as well as a companion document laying out related bioethical concerns. These documents should inform FDA's handling of unapproved information, BIO said.

Finally, the Medical Information Working Group filed a 47-page comment letter that lays out its understanding of how the US Constitution applies to FDA's speech regulations and makes a case for several changes to FDA's regulatory framework. MWIG is a coalition of drug and device firms that lobby FDA on manufacturer communication issues. MIWG believes that FDA assumes "the First Amendment can be subordinated to FDA's regulatory preferences and policy interests." This is a flawed assumption, MIWG argues.

"The government generally may not restrict accurate speech about lawful activity in order to prevent 'bad decisions' or to influence people to make choices the government prefers," the comment states, adding that government restrictions on speech must be more narrowly drawn than those imposed by FDA. The group believes almost any speech should be allowed as long as it is truthful and non-misleading.

PUSH FOR PAYER GUIDANCE TO BE BROADENED

The draft guidance on communications with payers would allow manufacturers to share several specific classes of true and non-misleading information about unapproved or investigational products. Information protected by the draft include basic facts such as a device's design and price; the planned indication for use; planned clinical trial protocols; and planned marketing strategies or product-related services.

A coalition of more than 30 wide-ranging members in the health-care space called for FDA to create "a safe harbor for the exchange of clinical and economic information for emerging therapies prior to FDA approval."

But the lists of protected speech are too narrow, trade groups told FDA.

A coalition, including more than 30 wide-ranging members such as Celgene, the Center for Medicine in the Public Interest, Genentech and the Mayo Clinic, submitted a joint comment that calls for FDA to create "a safe harbor for the exchange of clinical and economic information for emerging therapies prior to FDA approval." For example, the coalition thinks sponsors should be allowed to tell payers about unapproved indications for devices cleared for other uses. As written, the guidance would only permit communications about unapproved products.

AdvaMed aligned with the coalition is asking that communications with a broader range of stakeholders be protected. "The guidance recognizes communications with payers, formulary committees, or similar entities," AdvaMed states. "However, the review cycle for medical device reimbursement and utilization often requires discussion with other persons within health-care systems, including health systems' budget committees and technology assessment committees. The communications described in the guidance should specifically cover all such entities."

To fix the issue, AdvaMed asked FDA to add group purchasing organizations, value committees, and stakeholder coding committees to the guidance.

The group also asked FDA to clarify how the guidance would apply specifically to medical devices. More examples or discussion of relevant principles would help, the association states. In addition, AdvaMed said the agency should outline more types of information "concerning other uses that are not approved or cleared for approved or cleared product" that weren't mentioned in the guidance.

The Washington Legal Foundation expressed general support for the guidance, saying they largely agreed with FDA's interpretations of the law. In the past, WLF has frequently sparred with FDA on First Amendment issues.

"In the past, FDA has established unrealistically narrow definitions of what constitutes 'truthful' speech, a policy that frequently has placed FDA in conflict with First Amendment strictures," the WLF comment states. "The Draft Guidance avoids that conflict by adopting a definition of truthfulness that better conforms with

the commonly understood meaning of that term." However, the foundation expressed disappointment that the guidance didn't fully reflect language in the 21st Century Cures Act that seemed to broaden a safe harbor provision applying to language about investigational products.

The guidance document also needs a more straightforward and prominent definition of what an investigational product is, the Medical Device Manufacturers' Association said. Currently, the definition is buried in a footnote. MDMA says the term should be defined on the first page to make the document more useful.

Published online 04/26/17

HHS Pressured By Lawmakers To Release Pandemic-Flu Plan

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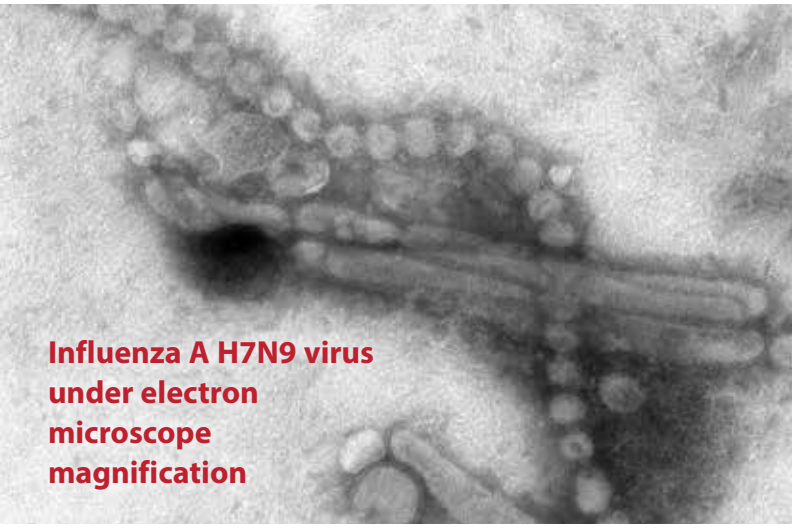

Influenza A H7N9 virus under electron microscope magnification

Two House Energy and Commerce Committee heads want to know why HHS has not yet released a new pandemic influenza plan – promised by late 2016. The lawmakers sent a letter to HHS Secretary Tom Price April 21, seeking the revised plan, which is expected to include a focus on new advances in diagnostics, among other technologies.

House Energy and Commerce Committee Chair Greg Walden, R-Ore., and Oversight & Investigations Subcommittee Chair Tim Murphy, R-Pa., said the plan is "vital," due to a potential pandemic threat posed by an H7N9 avian influenza virus that re-emerged after flaring up in 2013, and is "suddenly spreading in China."

The virus caused 918 laboratory-confirmed human infections and 359 deaths in prior outbreaks between 2013 and Jan. 16, 2017, according to the World Health Organization, Walden and Murphy told Price.

FDA GRANTED EMERGENCY AUTHORIZATIONS AFTER 2013 OUTBREAK

Following the last H7N9 influenza outbreak that reached the US in 2013, FDA granted emergency use authorizations for three diagnostics: CDC's *Human Influenza Virus Real-Time RT PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay* in April 2013; **Quidel Corp.**'s *Lyra* Influenza A Subtype H7N9 Assay, in February 2014; and **Arbor Vita Corp.**'s *A/H7N9 Influenza Rapid Test*, in April 2014. At the time, FDA reviewers took advantage a newly-passed law, the Pandemic and All Hazards Preparedness Reauthorization Act, to quickly provide those flu-test authorizations. *(Also see "FDA Puts Strengthened Emergency Authority To Use For Diagnostics" - Medtech Insight, 3 Jun, 2013.)*

The influenza strain linked to the ongoing 2017 outbreak is the same as in prior H7N9 influenza outbreaks in China and the US epidemics and, thus, should be detectable by the existing tests. But in an August 2016 letter that followed a 2015 hearing on pandemic flu preparedness, HHS promised the Energy and Committee that its new, revised pandemic flu plan "will incorporate new advancements in influenza vaccines, antivirals, diagnostics, and other surveillance and control measures."

HHS also said last August that its plan will "introduce new technologies to help treat, prevent, and minimize the impact of an emerging pandemic."

The two congressmen have asked HHS to respond by May 4 to provide:

- An update on the status of the HHS Pandemic Influenza plan and information on why it was not released in late 2016 and whether the document has been drafted;
- A response on whether HHS attempted to release the Pandemic Influenza plan before President Trump was sworn in on Jan. 20, and whether it was ready for release then and delayed;
- The target date for release of the HHS Pandemic Influenza Plan.

Chairmen Walden and Murphy also asked HHS to present a briefing about the HHS Pandemic Influenza plan to their committee staff.

FIFTH H7N9 OUTBREAK IN CHINA

An update from WHO on April 20, reported on the US Centers for Disease Control and Prevention's website this week, said that the current outbreak of H7N9 flu virus in China is the fifth epidemic of the flu type, and accounts for 595 infections. No official count of deaths from this epidemic have yet been confirmed. During previous epidemics, about 40% of people confirmed with Asian H7N9 died.

As of April 24, CDC said it "does not have any new or special recommendations for the US public at this time," and does not recommend that people delay or cancel any trips to China. But travelers to China should take common sense precautions, the agency advised, like avoiding touching birds, washing hands often, and fully cooking any poultry products while in the country.

Published online 04/25/17

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