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Unravelling Bundled Payments: A New Chapter In Reimbursement For Orthopedics

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After the US Centers for Medicare and Medicaid Services took the lead in developing new payment models, such as the Medicare Bundled Payment for Care Improvement (BPCI) and Comprehensive Care for Joint Replacement (CJR) programs, many health care provider organizations in the country have made the transition to these alternative payment systems. At this year's annual meeting of the American Academy of Orthopaedic Surgeons (AAOS) in San Diego, one of the key takeaways for attending surgeons was how they could implement strategies to meet the March 2018 deadline for submitting some type of performance year data to CMS in order to avoid penalties in income starting in 2019.

This article highlights presentations and discussions from the viewpoint of orthopedic surgeons including: what to expect from the different Medicare bundled payment models, the challenges and new developments; what it takes to make a successful transition and lessons learned during the process; and solutions that big ortho players, such as Zimmer Biomet, Stryker and Medtronic, offer hospitals and providers to better manage patients and improve outcomes.

BUNDLED PAYMENT MODELS EXPLAINED

In 2014, more than 400,000 Medicare recipients received hip or knee replacement surgeries, costing the US government more than $7bn for hospitalizations, or more than $50,000 per case, which makes these procedures one of the most expensive and common operations among Medicare beneficiaries.

AAOS presenter, David Ayers, an orthopedic surgeon in Worcester, Mass., told the audience that these numbers will continue to rise with patients under the age of 65 ranking among the fastest-growing group for total joint replacement surgeries by 2030.

Recently, CMS has taken significant steps to expand the use of bundled payments, which have been explored for several years to create financial incentives that encourage providers to coordinate care across treatment settings, and provide quality care while cutting costs related to a patient's episode of care.

However, according to published reports, general adoption of these new payment models has been slow in both the private and public sectors, due to factors including

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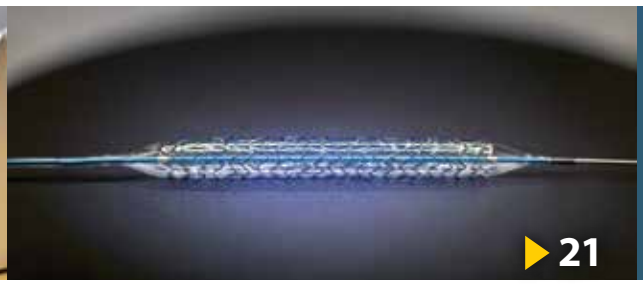
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Single Marketing Application Review For Multiple Jurisdictions On Horizon

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Members of the International Medical Device Regulators Forum are taking the model for their single-audit MDSAP initiative to the next level by exploring whether it can be used for a program that would let multiple jurisdictions rely on a single review of a marketing application.

The medical device single review program (MDSRP) is in the fledgling stage. The IMDRF discussed the initiative last month in the context of a new work item proposal (NWIP) to create new/updated guidance on the essential principles of safety and performance of devices. The idea is that the updated guidance would then be used as a foundation for creating a more harmonized premarket review process.

The "ultimate goal" is to develop a program that would allow for a single regulatory premarket review to satisfy the needs of multiple regulatory jurisdictions, according to a recently published slide presentation by US regulator Melissa Torres, who chairs the IMDRF's working group that deals with good regulatory review practices (GRRP).

MDSRP, if it goes ahead, would be modeled on MDSAP, the IMDRF's Medical Device Single Audit Program. MDSAP has already proved its value in a pilot that enabled regulators in Australia, Brazil, Canada, Japan and the US to rely on a single inspection of a manufacturer performed by a MDSAP-recognized auditing organization. Moreover, Health Canada is planning to implement MDSAP in 2019 as the sole mechanism for manufacturers to demonstrate compliance with its quality management system requirements.

As with MDSAP, MDSRP is expected to reduce "regulatory redundancies" and it could allow medical devices to reach patients faster. It would lead to greater global convergence of premarket requirements and promote consistency, predictability and transparency in the criteria for assessing premarket technical documentation for medical devices, according to Torres, who is Associate Director for International Affairs at the US Food and Drug Administration.

MDSAP, for its part, was designed to help regulators leverage their resources more efficiently by reducing the number of audits they must perform. For industry, it can allow companies to consolidate the global regulatory assessment process across multiple international locations, reducing internal costs while increasing the overall predictability of their efforts around the world.

It is still too early in the process to say exactly how the regulators plan to turn MDSRP from an idea into reality, a spokesperson from the FDA told *Medtech Insight*.

According to Torres' presentation, delivered at the IMDRF's management committee meeting in Vancouver in March, considerations that would need to be addressed to develop the program include:

- training and competency requirements for the reviewer performing the assessment;
- the types of submissions or device categories that are to be covered by the program and the establishment of specific criteria for each of them;
- the legislative framework of each jurisdiction (e.g., timeframes, flexibility, specific requirements);
- harmonization of submission requirements (e.g., IMDRF table of content);
- harmonization of the review process;
- accreditation of the entities that will perform the assessments of premarket submissions; and
- programmatic implementation aspects.

Separately, the IMDRF has already finalized a GRRP document the deals with "competence, training, and conduct requirements for regulatory reviewers." The final document (GRRP WG/N40) will be posted on the IMDRF website "very shortly," the FDA spokesperson said.

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EU Finally Adopts New Regulations Despite Sabotage Attempt

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The European Parliament voted in an April 5 plenary session to adopt the new EU Medical Device and IVD Regulations, marking the final milestone of a process which began some five years ago when the texts first came out. The adoption of the texts, already agreed by the Council of the European Union, took place at the end of a second reading.

The MDR and the IVDR will now be published in the *Official Journal of the EU* and are likely to take effect before the end of the first half of this year. This means the MDR will be fully enforceable by the end of the first half of 2020 and the IVDR by the end of the first half of 2022.

While this marks the end of a long and protracted process, it is also the begin-

Vote Counts On UKIP Proposal To Reject MDR, IVDR Texts

	MDR	IVDR
Numbers voting	703	703
In favor	66	59
Against	635	635
Abstentions	2	9

ning of another long and resource-intensive implementation stage. No one should underestimate the resources needed among all stakeholders to successfully implement these regulations in a way that does not threaten the continued availability of medical devices on the market. And no one should underestimate the additional pages still to be drafted in delegated and implementing acts, common specifications and other implementing tools which will need to take on board too.

ATTEMPT AT SABOTAGE

The vote was not without some drama. The UK Independent Party (UKIP) submitted a last-minute proposal to have the two texts rejected at the EP plenary. But it failed to sabotage the outcome. While about 10% of the votes went to rejecting the regulatory texts, the voting showed the vast majority were in favor of the texts and against UKIP's proposals:

Member of the European Parliament (MEP) Glenis Willmott, the rapporteur for the MDR text, expressed sadness that the right-wing element of Parliament had decided not to support something she believes is so important for patient safety.

The vote took place the day after the two texts were debated in Parliament, during which MEPs were given the chance to voice their views on the new regulations.

MEPs were overall very generous in their praise of the huge volume of work that has been done and the achievement of reaching this stage where the texts were ready for the final vote. German MEP Gesin Meissner of the Group of the Alliance of Liberals and Democrats for Europe said: "I have never dealt with such a protracted and complicated process."

But there were two voices that stood out during the debate who made it clear that they would not be voting in favor of the regulations – both right-wing representatives, one from the UK and one from France.

MEP Julia Reid, from the UKIP and part of the Europe of Freedom and Direct Democracy Group, made a simple statement without attempting to justify her position. She said that, although UKIP agreed with the objectives of the regulations in aiming to influence manufacturers in their production and to increase transparency, "my party and I believe this is an issue best dealt with by national parliaments, thereby avoiding unnecessary bureaucracy."

French MEP Joëlle Méline, part of the National Front in France, and a member of the Europe of Nations and Freedom Group, provided more detailed reasons why the new texts may hit problems, or be damaging to trade.

But there was some question over Méline's full understanding of how the system currently works, as she did not seem to be aware of the existence of the French notified body LNE/G-Med. This organization is not only designated under the Medical Devices Directive and the IVD Directive, but also among the likely forerunners for designation under the new MDR and IVDR.

The French MEP voiced concern that the new regulations place unrealistic demands on notified bodies and that they will ultimately lead to "a significant increase in certification costs."

Méline recognized that the highly-publicized PIP breast implant scandal was caused by the lack of supervision by a national authority, but said that cannot be used as justification to the loss of member-state prerogatives under the new regulations.

She said she was also bothered that the powers determining which products will reach the market will be transferred from national authorities to the notified bodies, turning notified bodies into some sort of policing system, and that this will lead to a privatization of the system and a significant increase in certification costs.

These regulations, she believes, could "quite quickly paralyze" the European medical device industry, in particular the French industry which has been "incapable, up to now, to have a notified body."

She considers that the regulations will lead French small-to-medium enterprises to suffer at the hands of poorer quality imports from other countries.

Ultimately, the lack of auditors would mean the European market will need to rely on imports, she said.

Companies based in non-EU countries will also have to meet the new CE marking requirements, she noted, but their profitability and prevalence on their domestic market will mean they will able to hold out for longer than those companies based in France and the EU, who she fears will be paralyzed by the new regulations.

Méline, therefore, proposed rejecting the texts. But, ultimately, no more than 10% of the vote stood behind the UKIP proposal to reject the texts.

MORE STAFF URGENTLY NEEDED

Preparedness is a key issue. With the texts now adopted, the focus should now be on how to make sure they are successfully implemented. Quite a few MEPs stressed hard the need for adequate resources to ensure effective implementation of the Medical Device and IVD Regulations

There are just 15 staff at the European Commission's Directorate General GROW working on medical devices, Austrian MEP Karin Kadenbach, part of the Group of the Progressive Alliance of Socialists and Democrats in the European Parliament, pointed out.

"This need to be raised to 40 or 45 staff members," including to cope with the implementing and delegated acts and the creation of the new Eudamed. she said, noting that recruitment is rather slow. "Without this increase in staffing," she warned, "we will not achieve the higher levels of patient safety that we are after."

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US FDA Might Face Funding Penalty For Missing User-Fee Goals

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FDA could find itself in danger of losing budget authority if it does not meet the goals in its user-fee agreements, threatening a potentially deeper funding cut than the administration already has proposed.

Sen. Richard Burr, R-NC, has floated the idea of adding a provision to the user-fee legislation that would dock taxpayer dollars from FDA if the agency fails to meet prescription drug, generic drug, medical device or biosimilar user fee terms, such as application review timing goals.

During an April 4 Senate Health, Education, Labor and Pensions Committee hearing on industry and patient perspectives on the agreements, Burr asked the representatives whether they supported "some type of claw-back mechanism if, in fact, FDA does not meet their negotiated deliverables to the industry."

Burr does not intend to force FDA to rebate user fees back to sponsors.

"I didn't say I was going to claw-back your money," he told the panel. "I'm going to claw-back our money."

Scott Whitaker, president and CEO of AdvaMed said he supported the idea. David Gaugh, senior VP for sciences and regulatory affairs at the Association for Accessible Medicines (formerly the Generic Pharmaceutical Association), also said he favored the idea and that holding the agency accountable would make sense.

Meanwhile, Kay Holcombe, the Biotechnology Innovation Organization's senior VP for science policy, demurred when Burr asked for her opinion. She said after the hearing that there already is accountability in the user-fee agreements through public program performance reporting.

"I think it's a complicated question," Holcombe said.

The possibility of another cut does not come at an ideal time for FDA. The agency's budget already is under siege by the Trump Administration, which has proposed cuts to the remaining months of fiscal year 2017, as well as a significant cut in FY 2018, which would be offset by an increase in user fee revenue. *(Also see "Trump Budget: FDA-Regulated Firms Should Pay 'Their Share' In User Fees" - Medtech Insight, 16 Mar, 2017.)*

Lawmakers have used a monetary stick with the agency previously. In 2015, the agency could have lost $20m if it did not issue final abuse-deterrent opioid labeling guidance by June, but FDA met the deadline. *(Also see "Abuse-Deterrent Opioids Could Gain Significant First-Mover Advantage Under FDA Guidance" - Pink Sheet, 1 Apr, 2015.)*

AGREEMENTS QUESTIONED

Burr also indicated during the exchange that he was not happy with the FDA-industry user-fee agreements as they are.

"We don't have to make as bad a deal as you guys can make," he told the panel.

Trump Administration officials and Capitol Hill staff also have openly asked whether the agreements could be changed, although that outcome seems unlikely. *(Also see "Trump's Budget Outline Threatens User Fee Agreements" - Pink Sheet, 16 Mar, 2017.)*

Burr previously has appeared irked by user-fee agreements that increase fees paid by industry, but do not adequately ensure FDA meets its obligations. He broached his idea with FDA during a previous HELP Committee hearing on user fees and not surprisingly, agency officials opposed returning fees for non-compliance. *(Also see "User Fees: Should US FDA Incur Penalties For Missed Deadlines?" - Pink Sheet, 26 Mar, 2017.)*

HELP Committee work on the user-feel packages could be finished later this month, with Senate floor action in May, according to Chairman Lamar Alexander, R-Tenn. He wants the bill to go to the White House before Congress' August recess to avoid forcing FDA to notify employees who could be laid off if the programs are not reauthorized.

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Gottlieb Confirmation: He's Willing To Disagree With Trump, Price

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Democrats pressed Scott Gottlieb to affirm his independence from his potential bosses should he be confirmed as FDA commissioner during an April 5 Senate hearing.

Gottlieb was asked point blank by Sen. Patty Murray, D-Wash., during his confirmation hearing before the Senate Health, Education, Labor and Pensions Committee whether he was "willing to stand up to the administration" if it tries to pressure him.

Gottlieb responded to the committee's ranking member that he is not afraid to speak up and will be guided by the science and expertise of FDA's career staff.

"For those who have worked with me, I haven't been shy about offering my unvarnished advice," he said. "I'm going to continue to offer people my very clear thoughts on whatever issues I'm asked to opine on, including [from] my bosses."

President Trump and other White House staff have made statements questioning fundamental FDA standards that have alarmed some stakeholders and lawmakers, which prompted the question from Sen. Murray.

Gottlieb also specifically separated himself from Trump on vaccines. When Sen. Christopher Murphy, D-Conn., asked whether Gottlieb would oppose a political panel researching vaccines and links to autism, Gottlieb said the issue has been settled.

"I think we need to come to the point where we can accept no for an answer around this question and come to a conclusion that there is no causal link between vaccination and autism," he said. " I have a history of not being shy … about speaking through to power and making my views known … and I will bring the same operating platform to this position."

Trump has hinted that he may create a panel to study vaccine safety that may be headed by a known proponent of the debunked idea that vaccines cause neurological diseases like autism. *(Also see "'He Is Very Pro-Vaccine': Trump Mulls RFK Jr. To Chair Commission On Safety" - Pink Sheet, 10 Jan, 2017.)*

Gottlieb also was asked whether he thought it could be left up to the market to judge efficacy in Phase III trials, an idea suggested by another candidate for the FDA commissioner post. *(Also see "Trump Meets With Two US FDA Commissioner Candidates; Third Still Lurking" - Medtech Insight, 12 Jan, 2017.)* He answered that he believed in the existing law.

"I believe in the gold standard for safety and effectiveness and I believe Congress has delineated a single standard for demonstrating that," he said.

MEASURED DISAGREEMENT ON RESOURCES

Gottlieb was more careful about disagreeing with the administration on issues like the budget.

Scott Gottlieb

When Sen. Robert Casey, D-Pa., asked about advocating against a hiring freeze and FDA budget cuts, even if proposed by the administration, Gottlieb provided a more measured response.

"I'm going to be committed, senator, to advocating for a strong FDA," he said. When Casey pressed, Gottlieb added: "I'm going to be committed to advocating for proper resources for FDA and a strong user-fee program, making sure that the mandates that you've given FDA are properly resourced and fulfill our mission."

Casey was not satisfied with the response. "That wasn't the answer I was waiting for," he said.

FDA's budget is a particular area of concern because Trump has proposed substantial cuts to the remainder of fiscal year 2017 along with an FY 2018 cut to be offset by increases in user fees. *(Also see "Trump Budget: FDA-Regulated Firms Should Pay 'Their Share' In User Fees" - Medtech Insight, 16 Mar, 2017.)*

Lawmakers also are worry about the effect of Trump's federal hiring freeze on FDA's ability to add the necessary people to meet mandates in the user fee and 21st Century Cures legislation. *(Also see "US FDA May Find Relief From Trump's Hiring Freeze" - Pink Sheet, 1 Feb, 2017.)*

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Chronic-Care Bill Would Pay Big Dividends In Telehealth Reimbursements

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Four U.S. Senators April 6 reintroduced a chronic care bill that will provide enhanced Medicare benefits for at-home patients who need telehealth services to cope with chronic-care illnesses, kidney disease, and stroke.

The Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017, S. 870, would expand access to home-dialysis therapy for patients via Medicare-covered telehealth visits with a nephrologist, and provide telehealth reimbursement benefits for Medicare Advantage beneficiaries and patients taking part in certain accountable care organizations (ACOs).

Sponsored by Senate Finance Committee Chair Orrin Hatch, R-Utah, Ranking Member Ron Wyden, D-Ore., and Sens. Johnny Isakson, R-Ga., and Mark Warner, D-Va., the bill encourages physicians and nurses to work with patients with multiple chronic illnesses at their homes, by providing additional Medicare reimbursements for telehealth visits, and home visits. A similar bill was introduced in the last session of Congress. *(Also see "Chronic-Care Bill Would Extend Pilot On Use Of Home-Care Devices, Promote Telehealth" - Medtech Insight, 28 Dec, 2016.)*

"This bill provides new options and tools for seniors and their doctors to coordinate care and makes it less burdensome to stay healthy," Wyden said. Meanwhile, Hatch lauded the bill for advancing "patient care delivery and quality without adding to the deficit."

MEDICARE ADVANTAGE PATIENTS

Under S. 870, telehealth – defined in the bill as use of electronic information and telecommunications technologies to support remote clinical health, patient health-related education, and other health-care delivery functions – could be offered under a Medicare Advantage plan to provide clinically-appropriate benefits, beyond those that currently receive payment under Medicare Part B.

Starting in 2020, telemedicine and other technologies used by MA beneficiaries would be allowed to be separately paid for by Medicare, without patients having to use rebate dollars and pay for those services as a supplemental benefit. Provisions in the legislation would permit MA plans to include the telehealth benefits in their annual bid amount.

Currently, Medicare beneficiaries may only receive paid-for telehealth services if they involve remote patient and physician/professional face-to-face services via live videoconferencing; or non-face-to-face services that are conducted through "store and forward" telecommunication services in Alaska and Hawaii.

WOULD EXPAND TELEHEALTH USE TO ACOS

Although there is nothing to preclude ACOs from providing telemedicine or other technologies that promote efficiencies in care, those services are not separately paid for by Medicare.

There is some interest in seeing if telehealth has the potential to reduce health care costs, so provisions in S. 870 would allow more use of telehealth by ACO providers by eliminating the geographic component of the originating-site requirement and let beneficiaries assigned to the approved Medicare Shared Saving Programs (MSSP) Track II and Track III, and the Pioneer ACO program, be reimbursed for telehealth services in the home.

However, this provision would also ensure that the MSSP and ACO providers would only be allowed to furnish the telehealth services as currently specified under Medicare's physician fee schedule, with limited exceptions.

TELEHEALTH BENEFITS FOR STROKES

Currently, Medicare pays for physician services provided to stroke patients under the physician fee schedule only when the patient present symptoms of stroke at the hospital emergency department, or to doctors at a distant site for a patient experiencing stroke symptoms via telehealth if it's a designated rural area.

A provision in the bill would expand the ability of patients with stroke symptoms to receive a timely consultation to determine the best course of treatment through telehealth, beginning in 2019. It would do this by eliminating the geographic restriction. Under this provision, the hospital at which the patient is present, where the telehealth consultation is initiated would not get a separate, originating-site payment.

HOME DIALYSIS

Medicare pays for beneficiaries with kidney disease to receive dialysis treatment at their homes, as long as they receive a monthly clinical assessment with their clinician (usually a nephrologist) to check for complications and discuss the effectiveness of the treatment.

Another provision in the CHRONIC Care Act would expand the ability of beneficiaries on home dialysis to receive those monthly assessments, beginning in 2019, by expanding the number of originating sites to include freestanding dialysis facilities and the patient's home. Also, these telehealth visits could be conducted from an expanded list of sites, without geographic restrictions.

ALTERNATIVE LEGISLATION ON TELEHEALTH EXPANSION

In addition to introduction of the CHRONIC Care Act by the quartet of Senate Finance Committee senators, on March 30, Sens. Corry Gardner, R-Colo., and Gary Peters, D-Mich., introduced S. 787, designed to expand Medicare beneficiary access to telehealth and remote-monitoring services.

Supported by AdvaMed, the legislation would require CMS's Center for Medicare and Medicaid Innovation to examine whether delivery-reform initiatives, such as ACOs and bundled-payment programs, can demonstrate how telehealth and remote monitoring can help providers reach program goals.

"We believe that extending coverage for these services can produce savings in the Medicare program, while increasing access and improving or maintaining quality of care," said JC Scott, AdvaMed's chief advocacy officer.

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Outbreak Triggers Senator's Renewed Probe Of Olympus Duodenoscope

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Sen. Patty Murray, D-Wash., asked **Olympus Corp.** officials April 3 for copies of all adverse events related to two *TJF-Q180V*-model duodenoscopes, in response to an outbreak of *Klebselia pneumonia* linked to the scopes and one death reported at a foreign hospital last year. The death, which occurred at an unnamed European facility, was accompanied by similar infections in four other patients. It was not reported to FDA's adverse events database until Feb. 2.

Murray, who is ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, told Olympus in the April 3 letter she needs "to understand whether the federal oversight of medical device safety in the United States is operating as it should."

In January 2016, Murray and her HELP panel staff wrote an investigational report, entitled "Preventable Tragedies," about a series of injuries and deaths tied to duodenoscopes, which also detailed a design flaw in closed-channel duodenoscopes that allowed dangerous antibiotic-resistant bacteria to linger in the device.

Olympus officials are "reviewing the letter and we have been in contact with the Senator's staff to convey our commitment to cooperating," a company spokesman said April 5.

EVENT OCCURRED WITH UPDATED DUODENOSCOPE

Details in the adverse event report on the scope-related death are sketchy and have been partially redacted, but it states that Olympus, at an unknown date in 2016, was informed that "five patients tested positive for oxa48 producing Klebselia pneumonia after having undergone endoscopic retrograde cholangiography (ERCP) using the subject device between [two unknown dates in 2016] at the facility. The facility reported that four patients are doing well except for one patient who deceased of the patient's pathology. There was no other detailed information on the cause of death at present."

In addition, the report said the "subject device" was reprocessed using a non-Olympus automated endoscope reprocessor (Solscope *Series 4)*, and the forceps elevator in the device was replaced, according to an Olympus corrective action carried out in Europe in response to an Oct. 5, 2016 European field correction notice, but completed in the US in early 2016. *(Also see "FDA Clears Redesigned Olympus Duodenoscope As Olympus Readies To Replace Old Scopes" - Medtech Insight, 15 Jan, 2016.)* The corrective action date in the Feb. 2 report suggests that the incident occurred sometime between Oct. 5 and Dec. 31; an Olympus official mentioned the event was reported in Europe.

In her most recent request, Sen. Murray also asked Olympus for copies of all documents from Feb. 1, 2016, to the present that reference antibiotic-resistant infections and any duodenoscope, and validation data "that *repaired* TJF-Q180V duodenoscopes can be reprocessed effectively."

After Murray's 2016 report was released and FDA leaned on duodenoscope manufacturers to reconsider design of the scopes, Olympus "recalled more than 4,000 closed-channel duodenoscopes used in hospitals in the United States in order to fix the design flaw that trapped bacteria and prevented effective cleaning," Murray wrote in the April 3 letter.

"However," she added, "the device involved in the most recent outbreak had undergone the same or similar modifications as the Olympus duodenoscopes in the United States, raising questions about whether the repairs are working correctly."

FDA CONTINUES TO INVESTIGATE

FDA "is aware of these reports and continues to investigate adverse events associated with duodenoscopes as appropriate," an agency spokeswoman said, adding that the agency also "communicates with regulatory partners outside of the US in order to protect the public health."

The agency responded to prior antibiotic-resistant infections tied to duodenoscopes by issuing a guidance on reprocessing them in March 2015, which also recommended redesigns to scope manufacturers. FDA also held a public meeting. *(Also see "FDA Advisors Call For New Cleaning Methods, Sterilization For Duodenoscopes" - Medtech Insight, 18 May, 2015.)* Further, it pressed the three companies who manufacture duodenoscopes – Pentax, Fujifilm, and Olympus – to revamp their reprocessing instructions for use, throughout 2015. *(Also see "FDA Endorses New Fujifilm Duodenoscope Reprocessing Instructions" - Medtech Insight, 28 Dec, 2015.)*

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23andMe Opens Up FDA Pathway For DTC Genetic Predisposition Tests

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FDA cleared the way for **23andMe Inc.** to launch the first FDA-validated direct-to-consumer intended to alert people of genetic predispositions to certain conditions with a *de novo* classification that allows marketing of DTC tests for 10 conditions, including Alzheimer's and Parkinson's, and establishes a pathway for the Mountain View, Calif., firm to launch new risk-predisposition tests without needing FDA review.

With the April 6 decision, 23andMe is preparing to launch its *Personal Genome Service Genetic Health Risk* tests for the 10 diseases or conditions. The firm had marketed the tests as part of a larger DTC gene screening service prior to November 2013, when FDA forced it off the market and demanded a pre-market review of its clinical data. *(Also see "FDA Comes Down Hard On 23andMe, Putting Consumer-Directed Genetic Testing On Notice" - Medtech Insight, 25 Nov, 2013.)*

Since then, the company and FDA have found common ground, leading to the relaunch and the establishment of a regulatory pathway for DTC carrier-screening tests in 2015, *(Also see "FDA, 23andMe Open Up Market Pathway For DTC Genetics" - Medtech Insight, 20 Feb, 2015.)* and now this latest development for genetic risk information tests.

FDA emphasized in making the *de novo* determination that these are not diagnostic tests and are only meant to notify users of potential risks. The company and FDA says the tests could help them make lifestyle choices and start discussions with their physician about the risks.

The conditions approved for testing by FDA are:

- Parkinson's disease
- Late-onset Alzheimer's disease
- Celiac disease
- Alpha-1 antitrypsin deficiency
- Early-onset primary dystonia
- Factor XI deficiency
- Gaucher disease type 1
- Glucose-6-Phosphate Dehydrogenase deficiency, also known as G6PD
- Hereditary hemochromatosis
- Hereditary thrombophilia, a blood clot disorder

Following the announcement, 23andMe CEO Anne Wojcicki said the decision will help people be more proactive about their health; she heaped praise on FDA for promoting innovation.

"The FDA has embraced innovation and has empowered individuals by authorizing direct access to this information," she said in a statement. "It is a significant step forward for 23andMe and for the adoption of personal genetics."

In a statement from the agency, device-center Director Jeffrey Shuren said the approval means consumers will have direct access to certain genetic risk information, but cautioned, "It is important that people understand that genetic risk is just one piece of the bigger puzzle, it does not mean they will or won't ultimately develop a disease."

23ANDME TESTS EXEMPT, OTHERS WILL NEED FIRST-TIME 510(K)S

FDA says it intends to exempt future 23andMe Genetic Health Risk (GHR) tests from needing pre-market review process. But other companies will be required to submit data to support first-time launch of similar GHR tests. The agency says that other developers may also be exempted from pre-market review after they submit their first 510(k). The agency says the proposed exemption for such tests could help speed the path to market for other GHR test makers.

Shuren emphasized that the special controls required by the agency will ensure consistency and accuracy in the performance of the tests. "By establishing special controls and eventually, a premarket review exemption, the FDA can provide a streamlined, flexible approach for tests using similar technologies to enter the market while the agency continues to help ensure that they provide accurate and reproducible results," the device-center director noted.

FDA has yet to publicly release the detailed special controls for the GHR tests.

The agency stressed that the regulatory pathway established with 23andMe will not be applicable to diagnostic tests, such as genetic tests for BRCA mutations, where misdiagnosing a patient could mean missing cases of breast cancer or causing women without breast cancer to undergo unnecessary treatments.

The multi-year process with 23andMe, starting with the agency seeking to assert its authority in the DTC genetics space (with 23andMe and other firms that were marketing tests without FDA approval) and evolving into a more collaborative effort has sparked public debate and forced the agency to develop its thinking on information risks, the dividing line between providing raw data and interpretation, what dissemination is protected by the First Amendment, and privacy rights. *(Also see "23andMe Has Accelerated The Consumer Genomics Debate" - Medtech Insight, 24 Feb, 2014.)*

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costs, administrative burden and a lack of consensus on how to define bundles.

But that is beginning to change.

"A lot more people are starting to look at bundles as an entity, if you will, and how to manage them, both in a quality sense as well as in a financial sense," Thomas Barber, outgoing chair for AAOS' Council on Advocacy and a practicing orthopedic surgeon at Kaiser Permanente Oakland, California, said during a roundtable discussion focusing on CJR, bundled payments, and Medicare reimbursement in the new administration.

CMS has committed to transitioning 50% of fee-for-service spending to alternate payment models by 2018. Bundled payments in hip and knee replacement surgeries among Medicare beneficiaries is expected to lead to a 2% annual decrease in medical costs alone, with expected savings of at least $700m for the industry, provided these payment models are adopted nationwide.

The bundled payment model dates back several years. On Oct. 1, 2013, CMS officially launched the Medicare Bundled Payment for Care Improvement (BPCI) initiative, an on-going voluntary pilot program made up of four models of care, which link pay for services received throughout an episode of care.

Thus far, experts say the program has gained significant traction and generated significant savings while maintaining improved quality of care.

Based on the success of BCPI, CMS last April created the Comprehensive Care for Joint Replacement Model (CJR), which is a mandatory bundled payment program, not voluntary like BCPI. Through CJR, about 800 acute care hospitals in 67 Metropolitan Statistical Areas must participate. In CJR, Medicare pays providers a single amount to cover all expenses associated with a hip or knee replacement from admission to the hospital to 90 days after discharge.

CJR EXPANSION DELAY IS WELCOMED NEWS

But the roll-out of CJR has been delayed by CMS from July 1 to Oct. 1, 2017, according to an interim final rule posted on the Federal Register. And the AAOS has commended

Thomas Barber, Chair, AAOS Council on Advocacy

CMS has committed to transitioning 50% of fee-for-service spending to alternate payment models by 2018. Bundled payments in hip and knee replacement surgeries among Medicare beneficiaries is expected to lead to a 2% annual decrease in medical costs alone, with expected savings of at least $700m for the industry, provided these payment models are adopted nationwide.

David Scott (D-Georgia) and Health and Human Services Secretary Tom Price, a known opponent of CMS' mandatory initiatives, for introducing legislation (H.R. 4848) that could postpone the program's expansion even longer, until Jan. 1, 2018. *(Also see "CMS Pushes Back Cardio, Ortho Bundled-Pay Models" - Medtech Insight, 20 Mar, 2017.)*

This delay, the AAOS stated, ensures "that physicians, hospitals, and post-acute care providers have adequate time to prepare for the onset of this complex payment system."

Barber told *Medtech Insight* that the AAOS fought hard for CJR to be included as an Advanced Alternative Payment Model (APM), which would allow qualifying surgeon participants to receive a 5% bonus for the years 2019-2024.

Currently, the majority of orthopedic surgeons in CJR qualify for the Merit-Based Incentive Payment System (MIPS) - introduced under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 – where eligible professionals must report on various quality measures. Under MACRA legislation, participants in the Quality Improvement Program have two paths to choose from: MIPS or Alternative Payment Models (APMs), with APMs offering greater potential financial risks and rewards.

Price has voiced his support for MACRA and MIPS and encouraged providers to develop Alternative Payment Models that can be adopted by CMS and commercial payers. Barber explained that there would need to be a new rule in place in order for surgeons to be able to qualify under the Advanced Alternative Payment Model in the CRJ model. *(Also see "CMS Administrator Seema Verma: What Industry Can Expect" - Medtech Insight, 20 Mar, 2017.)*

But the delay also continues to raise questions about the future of mandatory initiatives, which Price has criticized, as well as about other government initiatives.

Since MACRA legislation is bipartisan, valued-based reimbursement is widely expected to continue, though changes are likely.

KEY CONSIDERATIONS FOR PROVIDERS

"Starting now and being prepared is the key to success," Kevin Bozic, a professor and chair at the Department of Surgery

and Perioperative Care at Dell Medical School at the University of Texas at Austin, told surgeons during his presentation on MACRA at the AAOS meeting.

After disclosing that he's also a paid consultant to Medicare for developing performance measurements for bundled payment systems, Bozic told the audience, that MACRA will affect the majority of providers, and orthopedic surgeons figure prominently into MIPS and APMs.

"Success under MACRA requires preparation and attention to detail," Bozic said, and added, that providers who choose not to participate in value-based care can expect to pay a 4% penalty starting in 2019.

"The key takeaway is you'll have a positive or negative payment adjustment based on the amount of data submitted (by March 2018) from 2019 and 2024, and based on provider performance," Bozic said.

Bozic agreed with other experts at the meeting who foresee that bundled payment models will eventually be rolled out to commercial insurers as well, which makes preparedness even more imminent.

GETTING PREPARED

"This means you need to have systems in place for tracking quality and outcomes -- data transparency will be critically important, not only for us, but also for our patients as CMS moves to more data transparency on outcomes and requires increased administrative burden," he said.

Bozic also acknowledged that for many smaller practices, the financial administrative burden to make the needed investment into infrastructure and putting systems in place will be huge, which will likely lead to more consolidation into larger groups.

Barber told *Medtech Insight*, that all the solutions offered by orthopedic companies to help physicians and health care administrators (see box: *Medtronic, Zimmer Biomet, Stryker and J&J Offer Solutions for Value-Based Health Care*) won't add value unless a health system is committed to creating their own internal solutions first. He said that in order to create a value-based system, organizations need to develop four areas: standardize care among physicians, put financial management software and care management

Kevin Bozic, Professor and Chair, Dept. of Surgery, Perioperative Care, Dell Medical School at University of Texas, Austin

"Success under MACRA requires preparation and attention to detail... providers who choose not to participate in value-based care can expect to pay a 4% penalty starting in 2019. The key takeaway is you'll have a positive or negative payment adjustment based on the amount of data submitted (by March 2018) from 2019 and 2024, and based on provider performance," – Kevin Bozic, University of Texas

cost and quality of a patient's episode of care. However, provided CJR would, in the future, be included into a risk-based Advanced Alternative Payment Model, it doesn't necessarily mean that physicians would need to assume risk, Barber noted.

"Physicians don't have to assume risk, but they can, as long as the CJR program itself provides risk to the main owner of that [program] – which is the hospital," he explained. And while risk-based Advanced APMs continue to gain traction, participants must meet certain requirements to become "qualifying APM participants."

OBSTACLES

When it comes to bundled payments, many challenges prevail.

One of the major challenges for health systems and providers is the ability to capture information to analyze for performance improvement. Readiness among health care providers varies widely and larger organizations with deeper pockets tend to have more advanced technologies.

Patricia Franklin, a professor of orthopedics and physical rehabilitation at the University of Massachusetts Medical School and a principal investigator at FORCE-TJR (Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement), stressed the importance of having a web-based IT system in place to collect data from patients,

"You need to identify risk factors before, during and after joint replacement that can help you manage that bundle and (help you) understand risk for readmissions and complications," Franklin told attendees of her AAOS presentation. "Incomplete data at the end of the episode is a frustration, because surgeons will be evaluated (which can impact income and provider rankings)."

FORCE-TJR, funded by a $12m grant from the federal Agency for Healthcare Research and Quality, has built a database of more than 30,000 TJR patients since its launch in 2011, capturing how patients have fared physically and mentally since

CLICK
to find out what solutions Zimmer Biomet, Medtronic and Stryker are offering for value-based health care. http://bit.ly/2nxrYrz

their surgeries, according to a recent news report from the University of Massachusetts School of Medicine. In her new paper, Franklin discusses how leveraging the knowledge from doctors who interact with patients is essential to better outcomes.

But Barber said a big problem is that surgeons don't gain access to the real-time data they need to be real influencers in the decision-making process.

"You need real-time data every day to know how you're doing and what you're doing," Barber said. "Right now, data is coming from hospital's medical records systems or a registry, and that can take months."

Barber said working on better risk adjustment and providing doctors with more control over ownership of bundles would improve delivery of care and outcomes.

During his talk, Bozic agreed that there is a disconnect between the people who are making the decisions and the people who pay for health care.

"We have a fragmented payment and delivery system," he said. Building trust and sharing information are critical. He said that health systems also need to have processes and structural measures in place that help reduce cost and create value.

Another issue with bundled payment systems is that doctors could potentially be penalized for services or incidents that were out of their control.

Barber said during the roundtable discussion that one of his patients had a total hip replacement and did so well that she informed him she would have cataract surgery the next day, which counts as a readmission.

"My problem is she's doing too well after surgery," Barber said. "When you have physician control, you can look at some of these issues."

In other cases, when physicians deal with patients with comorbidities and high-risk, expenses go up, which is also out of the physician's control.

With the most significant opportunity to cut spending being on post-acute care, which can account for 37% of spending for joint replacement episodes, according to a study by Brandeis University, establishing relationships with post-acute providers is key, the experts agreed.

Tips for a highly effective value-based bundled payment program

- You need to have a way to standardize care among all the providers that are in the service area or in the hospital.
- You need financial management software in place.
- You need care management software.
- You need to manage relationships with skilled nursing facilities and home health-care providers.

Thomas Barber, Chair, AAOS Council on Advocacy

However, given the many variations in terms of length of stay and across post-acute facilities, providers are encouraged to choose care sites that are cost-efficient and don't lead to readmissions or complications.

One of the challenges, doctors noted, is that interests aren't always aligned here.

TRENDS

Barber foresees that more orthopedic surgeons will try to get ownership of bundles themselves. He gave the example of the American Association of Knee Surgeons, which is trying to develop its own bundled payment system.

"In a lot of venues, we see with physician leadership, you can get better quality at a better price and with better efficiency, because the physicians understand that process better," he said.

With that, he also expects that eligible clinicians will also want to participate in Advanced APMs to be eligible for the 5% incentive pay.

Bundled payments and regulation are pushing the commercial market to value-based care.

Bozic foresees that the future is also headed to managing the full episode for the condition, an effort that he's already started to implement at the University of Texas at Austin, and outlined during his talk.

"The value that you get from optimizing a procedure will only take you so far – the real value from the societal perspective and the payer perspective is to bundle for the condition," Bozic said.

In order to do that effectively, he said, doctors need to change the way they're structured in terms of delivering care. Surgeons don't merely operate; they manage teams of people who, in turn, manage the disease, "Rather than being at the end of the funnel where inefficient care has already occurred," he explained.

He said the university has reorganized its delivery system to look at common conditions patients present and created an environment where doctors don't merely look at the patient's physical health, but also their mental health, which is critical to improving outcomes.

In this "integrated practice unit," surgeons work with psychologists, chiropractors, podiatrists, and rehab specialists as a team and everyone is encouraged to push their limits on the scope of practice, which translates not only to better delivery of care, but also to greater satisfaction among team members.

Patients are actively engaged in the entire process and need to show a willingness to engage in healthy behaviors.

"I will not offer surgery to someone who isn't a 3 or 4 on the patient activation scale, so I know that the patient has engaged in healthy behavior before I even think about doing surgery on that patient," Bozic said. He said in his own studies he's found that patients who are more engaged have better functional outcomes, lower complication rates and are more satisfied.

Another trend that Barber and others predict is likely to continue to rise is the move of arthroplasties to outpatient settings.

But not all patients will be good candidates for outpatient joint replacements. Putting systems in place to have these procedures done in this less costly environment (compared to hospitals) also takes a lot of work, Barber noted.

A study that appeared in the medical journal *Orthopedics* from July/August 2016 suggests that advancements in surgical

technique, anesthesia protocol, blood loss management and rapid rehabilitation, combined with a growing need in a younger, healthy population, has decreased the need for hospitalization following total joint arthroplasty and that these procedures can be performed safely and effectively in ambulatory surgical centers with good short-term clinical outcomes in appropriately selected patients using a combined surgical and anesthesia protocol.

But Barber noted that an ideal setting requires a good team of technicians, a large recovery room with a physical therapist present and a post-acute unit where patients can recover post-surgery for hours, if needed.

His predicts that "those facilities with a small volume may have difficulties putting together systems to make it work."

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View Of The IVD Horizon: How Roche Diagnostics Sees The Sector Evolving

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Over the last few years, several players competing in the *in vitro* diagnostics landscape have been swallowed up, bulked up, whittled down or have left the scene altogether. Names like Gen-Probe and Phadia, which had featured among the top 20 IVD companies less than a decade ago have now disappeared, after entering the folds of Thermo Fisher. Beckman Coulter and Cepheid are other top names that have been acquired and helped push Danaher up the ranks. Johnson & Johnson, whose Ortho Clinical Diagnostics business was positioned within the top 10 only five years ago, is now out of the game.

Amidst this shifting scene, **Roche Diagnostics** has held on stalwartly as the world's number one IVD player. The Swiss group reported a 7% increase in diagnostic sales, at CHF11.5bn (~$11.4bn), for 2016. This was driven by 9% growth in its largest business segment, Centralized and Point of Care Solutions (formerly named Professional Diagnostics), which recorded revenue of CHF6.7bn and accounted for more than half of the diagnostic division sales.

In a recent interview with *Medtech Insight*, a month before Roche will release its first-quarter results, Jean-Claude Gottraux, head of centralized and point of care (POC) solutions, gave an optimistic forecast for the continued growth potential of this segment and the overall IVD operating climate.

"The good thing about the professional diagnostics (PD) market is that it continues to grow healthily; it's been around a 5% increase a year for more than 10 years and we can see this continuing over the next few years. The main sub-segments – serum work area [SWA], specialty testing, point of care – all contribute in a similar way to the growth of this market," said Gottraux. While he acknowledged that PD's growth has not been as high as other segments, like molecular diagnostics and tissue diagnostics – which he estimates to be expanding at between 6-11% – he said that considering PD makes up around 75% of the total IVD market, "sustaining an average 5% growth rate over such a long period of time is very impressive."

Gottraux also predicts that the overall IVD market will double over the next 10 years, driven by an aging population and an increase in non-communicable and chronic diseases in both mature and emerging markets. Indeed, the emerging markets play a significant role in Roche's growth strategy – China surpassed the US as the group's biggest market in November 2016, and Gottraux said this trend will continue.

In terms of challenges, he forecasts that further constraints will be placed on businesses in Europe, with more cutbacks in health-care budgets. Pricing pressures will also continue in the US, amid uncertainty over health-care reforms that the Trump administration is looking to implement. "We expect more reimbursement cuts in the US; I think it has been particularly dramatic in diabetes care for the past two years, wiping out a big part of the market there," he added.

Diabetes care is the second largest diagnostic business segment, after PD, for Roche but it is also a weak spot for the company, with a reported decline in sales for 2016 (-4%, at CHF2.0bn). The group isn't the only one to feel the pinch in this area. Earlier this year, Johnson & Johnson said it was exploring the sale of its diabetes care business. Would Roche also consider cutting its losses and take the same route as J&J, or does it remain committed to this space?

"Yes, we are committed to diabetes care; we've been saying for a long time that we see diabetes as a major disease and it is an interesting market going forward," Gottraux told *Medtech Insight*. "We need to ensure we adjust our internal structure to adapt to a market that is evolving, particularly in the US where there has already been some adjustment to the organizational structure. We've been in diabetes care for a long time and we are going to be in it in the future as well."

Being at the top has not only given Roche a bird's eye view of the trends that are shaping the industry, but also enables it to adapt to these changes and maintain its leadership position. In the Q&A below, Gottraux discusses in more detail changes that the company is witnessing in the IVD market – including consolidation among its lab customers, market-user trends and the impact of the forthcoming EU IVD Regulation, among other things – and how Roche has been addressing, or plans to address, these issues.

Medtech Insight: There has been a lot of consolidation among the core labs, with the labs getting bigger and offering more services. What impact has this had on Roche's dealings with these customers?

Jean-Claude Gottraux: Yes, there is a big trend towards consolidation, with labs getting larger and lab chains becoming translational and having a global importance. We can see this with the big lab chains in Germany like Sonic Healthcare, for example, which is now active in the US. What's very important here is the workflow and IT solutions, which will enable the core lab to change in the future. Increasingly, we talk about the 'connected' core lab, and growing its offerings beyond just serum work area (clinical chemistry and immunochemistry) and into areas like hematology, lab coagulation and even high-volume molecular testing such as virology and HPV. I think it is the direction that things are going. Workflow and IT is really the glue that holds it all together and we are working heavily on new solutions in this area and new transportation systems to help us own the "lab backbone," as we call it.

How does this shift towards a centralized lab approach work alongside this movement in the opposite direction towards decentralization, as seen in some countries?

Gottraux: While there is a trend towards consolidation of the big central labs, there is also decentralization as many markets are trying to reduce the burden on the hospital segment and give broader health-care access to larger parts of the population. Which is why we are working heavily on the next-generation of POC platforms with a major focus on the US. The US still makes up about 40% of the total POC market and we're working on connectivity to make sure the new POC platform have connectivity to the MRIs and to the overall platform landscape that we have within Roche. We are very bullish within POC – I expect POC to grow slightly faster than the central lab market and we need to revamp our POC offering to address this.

Jean-Claude Gottraux, Roche Diagnostics, head of Centralized and Point of Care Solutions

Could you elaborate more on what you mean by revamping your POC portfolio?

Gottraux: Our POC offering includes coagulation monitoring – self-testing in patients on anticoagulation therapy. This is a very good business, a growing business – but it is also one that is under attack to some extent because of the new generation of [anticoagulation] drugs that make this regular monitoring redundant. Another important [POC] business we have is hospital glucose, especially in the US, but it is a market that has a lower growth prospect than others.

More recently, we became involved in molecular diagnostics at point of care, with the acquisition of IQuum in 2014, where we gained the lab-in-a-tube (LIAT) technology. At the moment, we offer strep and flu tests on this platform but we are now expanding this menu.

We also want to keep growing our POC offering in other disease areas like cardiac testing and develop more high-performance immunoassays – that is where we see the largest potential for growth in the future.

IVDs are often more vulnerable to low-cost competition compared to other medical devices. How is Roche addressing this challenge?

Gottraux: There is a certain price pressures on many [IVD] parameters which are not unique. If you look at our clinical chemistry portfolio, those products do have a risk of tendency towards commoditization. But the strength of our portfolio goes beyond these parameters with what we offer in immunochemistry, which is the *Elecsys* electrochemiluminescence (ECL) franchise. There, we still have breadth of portfolio and we are still ahead of competition in terms of innovation and we should be able to continue this business over the next few years and add more to the menu.

In the US, we used to have a disadvantage over our rivals as our menu was incomplete but in the last few years, we have been catching up quickly, with the addition of tests for AMH (anti-mullerian hormone), PCT (procacitonin), high-sensitive troponin T, for example. This year, we will also have HIV in the US, once it is cleared by the FDA, and so we will be able to complete our infectious-disease panel.

I think there is a lot of opportunity for growth in the US and particularly in Asia. This is for our core business, but we also want to grow into what we call adjacencies, such as hematology and coagulation, which are segments where we were partially represented in the past, through partnerships with Sysmex for hematology and Stago for lab coagulation. In hematology, we continue to cooperate with Sysmex, particularly in Latin America, but we acquired three years ago a Boston-based company, CMI, and gained the *Bloodhound* technology. We CE marked the instrument from this platform just before Christmas 2016 and we are now busy launching it in EMEA, Europe and APAC. We'll be filing our FDA 510(k) application for the US within a month and hope to get clearance by the same time next year.

For lab coagulation, we have terminated our relationship with Stago be-

cause we are going to launch our own platform towards the end of this year in EMEA, Latin America and APAC and then later in the US.

So we are not just focusing on our core serum work area business – we are also trying to protect our leadership position by expanding and growing in adjacencies like hematology and lab coagulation. Additionally, we're working on connecting all these different disciplines through the core lab through workflow and IT solutions that we offer.

I want to touch on the new EU regulations that are to come. These will create a new environment for Roche and other IVD companies to operate in – how big an impact will the EU IVD Regulation have on Roche, in terms of product development, management of product lifecycle, its commercialization approach?

Gottraux: We have been heavily involved in the development of this new EU IVD Regulation and there is no doubt these new regulations will raise the hurdle for commercializing the products in our portfolio in Europe, as it will be for all our competitors. But I think we are well-positioned to fulfil these increased requirements. Like all other companies, we will need to reregister our entire IVD portfolio under the new regulation by the end of the transition period so this will require additional efforts in terms of personnel and additional costs. But it's raising the bar for all the companies in the field and, as the largest player, Roche will be benefiting in the end from these tighter and more strenuous regulations.

I imagine because of the sheer size of your portfolio, reregistering your portfolio will be quite an undertaking.

Gottraux: Yes, it will be and it will be costly and this has been factored into our plans in the future. We see all this as a positive trend, making it more difficult for new entrants to come in – it's a curse and a blessing at the same time. But we are not going to change our commercialization approach in the short term.

Jean-Jacques Palombo, Roche Diagnostics Lifecycle Leader, Serum Work Area Cardiac, Women's Health, Personalized Health Care Solutions

What single development do you think will have the biggest impact on the IVD sector for the next 5-10 years?

Gottraux: We talk a lot about digital transformation and this will certainly have an impact and we are looking deeply into this to see just, to what extent this digital transformation will have an impact on our operating model. The IVD business has operated on a razor/razorblade model and we believe this will continue, but there will be new streams of revenue coming forward, such as clinical-decision support tools. I think this will change the way we work; we need to develop these tools, as well as commercialize them, whereas customers today expect to receive these tools for free as part of what we offer.

It will also be critical to invest heavily in medical value, developing tests that fulfil unmet medical needs in order to justify higher pricing and to avoid the trap of commoditization.

I think there will also be new technologies, or new applications of existing technology, coming up. For example, mass spectrometry will become increasingly part of the core lab and eventually leave the dark corners of the research lab. We are working on this as well and I can see mass spec becoming part of an integrated lab solution.

WHAT THE DOCTORS ORDERED

Being able to meet the demands of your customers is critical to stay ahead of the game and beat down potential competitors. For Jean-Jacques Palombo, lifecycle leader for Roche's serum work area portfolio within cardiac, women's health and personalized health-care solutions, this entails having a good understanding of the problems physicians face when trying to diagnose a disease and being able to provide a suitable assay to resolve the problem.

A trained medical doctor himself, Palombo's role involves managing Roche's assay content and the R&D pipeline for his three portfolio areas. He told *Medtech Insight* that physicians today are facing more difficulties than ever before. One of these is the growing legal responsibility that is placed on the doctor, which changes their acceptance of risk, he said. "Doctors are less likely to take risks now; they feel less at ease with the 'gray zone.' They tend to play safe more – if they have a doubt, they will hospitalize the patients and this, of course, drives healthcare costs up. That is the evolution of the doctor's mindset that we see. What we try to do is develop tests that can give doctors the assurance that they are safely diagnosing whether a patient has A or B and they can safely make a decision from that diagnosis."

Palombo gave as an example, Roche's latest-generation high-sensitivity troponin-T test, which was recently cleared by the US FDA. *(Also see "US Approvals Analysis: Slow 510(k) Month Includes Major Cardiac Assay Clearance" - Medtech Insight, 9 Feb, 2017.)*

When a patient, who has never had a cardiac problem, presents with chest pain, they have an electrocardiogram done to see if it is an acute myocardial infarction (AMI) episode. "But EKGs are negative in half the cases of myocardial infarction, so you want a test that can give the physician a result faster and help save the patient's heart," said Palombo. "It used to take 3-6 hours for the results of standard troponin T tests to come back

and allow doctors to rule out whether patients are having an acute myocardial infarction. With our new generation of test and its new algorithm, we will be able to reduce the decision-making process to 1 hour in 78% of patients. So, one in five patients who present with these symptoms will go directly to cath lab, 50% will be discharged and the 'gray zone' will only be limited to 22% of patients. We are diminishing the gray zone, giving certainty to the physician and comfort to the patient."

As a crossover between women's health and companion diagnostics, Palombo pointed to a companion diagnostic for use in *in vitro* fertilization treatment that Roche has developed in partnership with Ferring. The *Elecsys AMH Plus* immunoassay is designed to help increase the efficiency of the IVF cycle, while diminishing the adverse effects of hormone treatment on the IVF patient. This can help doctors better tailor the treatment to the patient, as well as reduce complications.

"So we're developing precision medicine based on the own biology of the patient," said Palombo, adding that Roche's personalized-medicine strategy goes beyond the traditional area of oncology and into other spaces, such as infectious diseases, like sepsis, and Alzheimer's. "For Alzheimer's, we are developing a panel of biomarkers with the goal of enabling the doctor to administer the right therapy to the patient – when these therapies are available. There are around 20 different compounds for treating Alzheimer's that are in clinical trials right now.

"It will be the equivalent of a PET scan, which is currently the best method available for diagnosing Alzheimer's but it is a very costly imaging test. Our test will use spinal fluid aspiration and assess several biomarkers. We are expecting to launch it in the next 12-18 months," he told *Medtech Insight*.

DEFINING VALUE

While a company like Roche might have deep pockets, it is still important to spend one's resources wisely. So how does Palombo prioritize which product to the Swiss group should be betting its money on?

"For me, there are two questions which need to be answered: Firstly, am I able to create value for the patient and the payer [with this product] and secondly, am I able to capture value for Roche," he said.

To create value, one would need to be able to solve a burdensome problem that not only has enough patients who suffer from this problem, but also enough payers willing to pay to have this problem solved. "If you take a test for pre-eclampsia as an example, we sell it for, say, €30, but when the test is used it creates an economical value of €400 by reducing unnecessary hospitalizations and giving doctors the confidence to rule out pre-eclampsia; then the payback is very good," said Palombo. "You need to have a disease that is sufficiently prevalent, serving a real need, and you need to prove, through clinical data, that you are able to make the patients better or allow doctors to make better decisions. That's an example of value creation and for me, a technology has to have a check in this box."

As for the value-capture part for the company, the question Palombo would ask is, would he be able to get a high enough market share and pricing power because of this test? "Will I get a good reimbursement? If this is the case and we can own the IP for a particular indication for this test, then this will be a technology that is very interesting to me."

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VC DEALS ANALYSIS:

Big Boost From Bumper Round

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One big-buck deal can make all the difference and the $900m raised by Illumina-spinout, Grail, in March more than lifted 2017 out of the doldrums and shot the first quarter's total deal value to a five-year high. (See infographic for Q1 key facts and figures).

Some 20 financing deals of $1m-and-over passed *Medtech Insight*'s news desk in March, the same volume as February. However, last month not only saw the first nine-figure transaction of the year, there

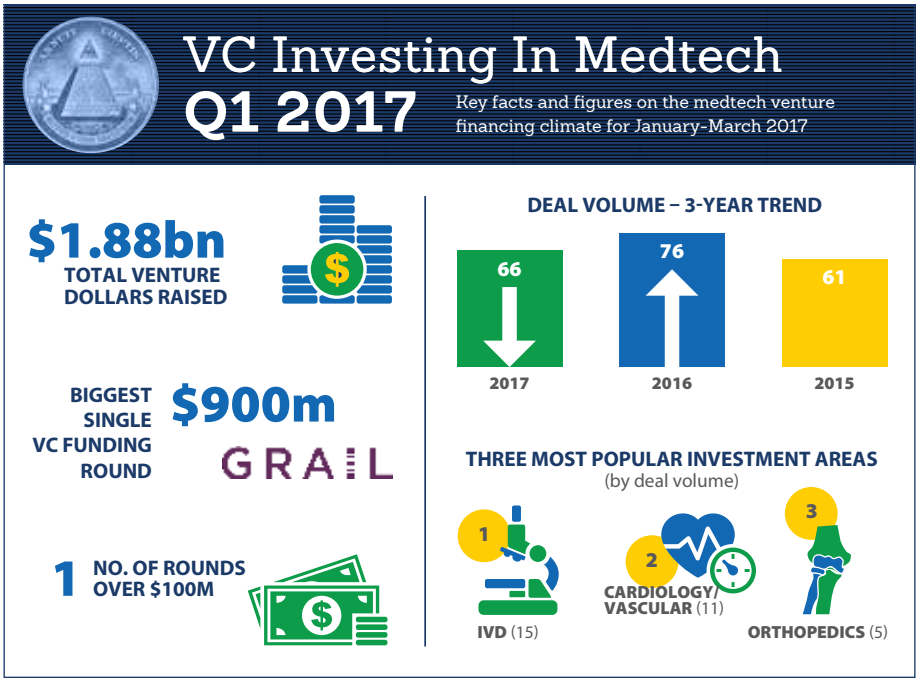
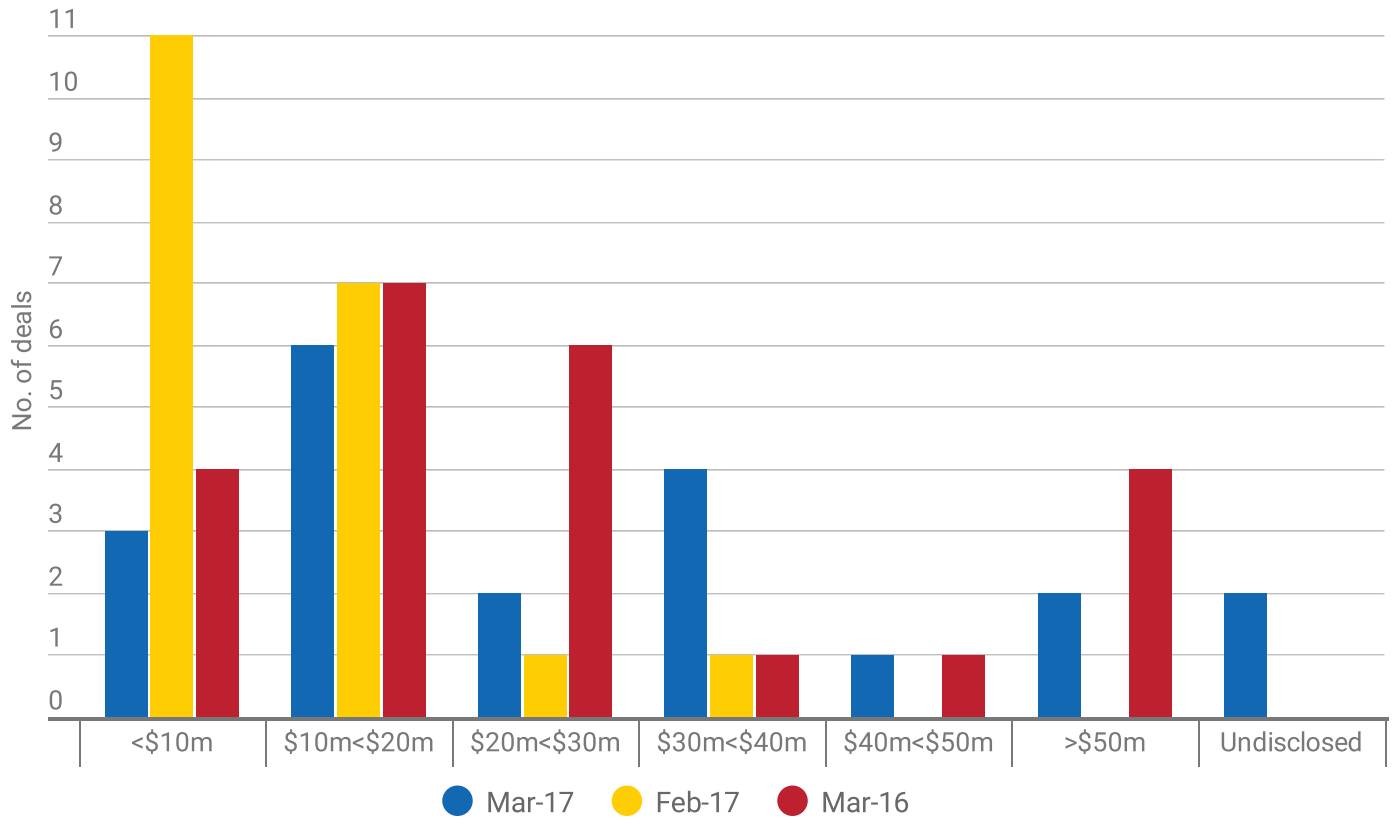


FIGURE 1

No. Of Deals By Amount Raised, Mar 2017 vs Feb 2017 vs Mar 2016



Source: Medtech Insight's VC deal tracker

TABLE 1

Q1 Total Deal Value ($m), 2013-2017

MONTH	2017	2016	2015	2014	2013
Jan	343.5	625.4	247.9	206.3	294.2
Feb	201.8	369.5	252.4	248.5	277.9
Mar	1336.5	618.1	329.9	382.4	343.7
Q1	1881.8	1612.9	830.3	837.1	915.7

were more deals towards the $30m-plus end of the value range. (See Figure 1.)

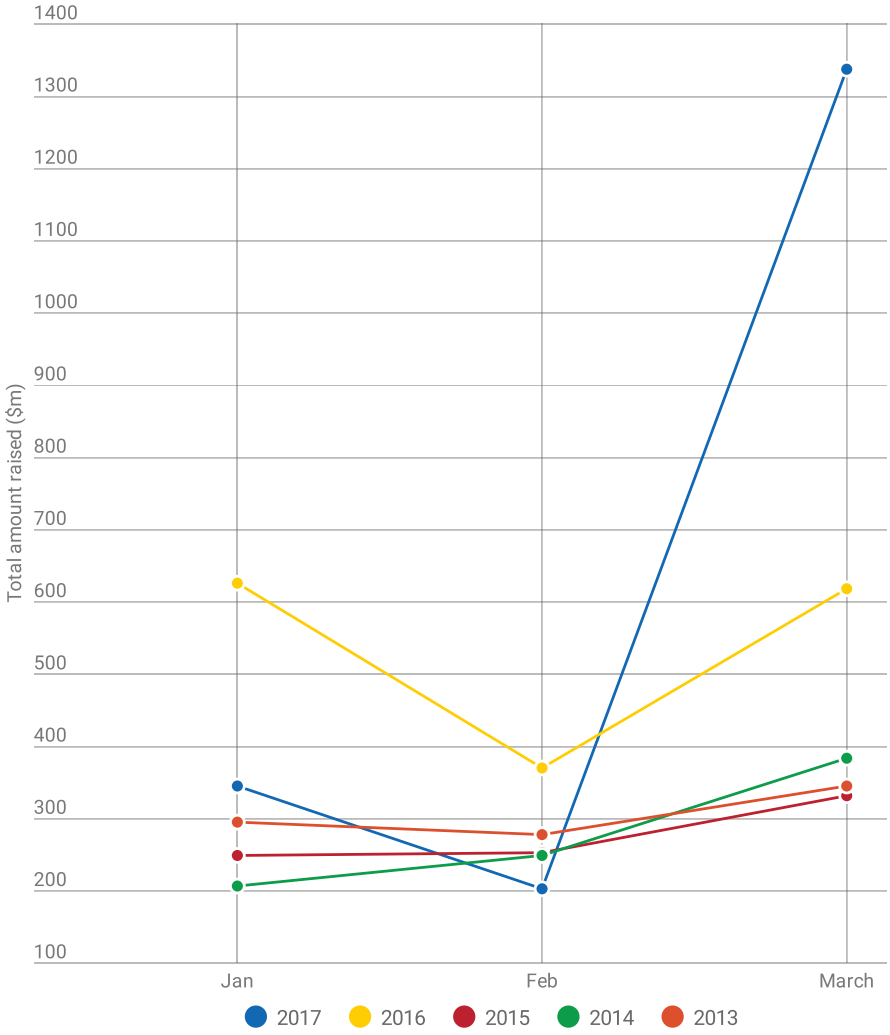
From the 18 deals that disclosed financial details, around $1.34bn was raised in total. Grail's $900m. which is the first tranche of a series B, accounted for the lion's share – but even if this was taken out of the mix, this would still leave a total deal value of $436m, beating February's total of $202m and January's $344m.

When comparing first-quarter deal value across a five-year period, 2017 rises head and shoulders above the previous years. (See Table 1 and Figure 2.)

Grail had been hoping to raise around $100m more before the end of the quarter to close the series B round at over $1bn, but as this article went to press, there had been no news of any additional funding. Johnson & Johnson Innovation was the biggest investor in the $900m first tranche, with the participation of ARCH Venture Partners, as well as certain well-known names in the pharma, tech and medtech space, such as Bristol- Myers Squibb, Celgene, Merck, Amazon and Varian Medical Systems. Of

FIGURE 2

Q1 Deal Value, 2013-2017



Source: Medtech Insight's VC deal tracker

course, Chinese players are now ubiquitous in these types of investments and Grail's investor from the East comes in the form of China's leading internet services provider Tencent Holdings.

Grail was spun out of Illumina last year, and – as its name indicates – is on the mission to develop a simple blood test that can screen for cancer at an early stage.

The second largest fundraising in March came from Freenome, which also has a similar focus to Grail, that being to develop liquid biopsy tests that use cell-free DNA circulating in the blood to allow earlier and better diagnosis of disease. What's commendable about Freenome's deal is that it was an impressive $65m series A, an unusually large amount for an early-stage round. Freenome also has some big tech names backing it, including Google Ventures.

Orthopedics attracted a lot of the big bucks in March, with three companies in this space featured in the month's top 5 biggest deals. (See Table 2).

Orthopedics, together with IVD, came in joint-second as overall most popular sector for investment in March, while companies developing cardiology/vascular-related technologies scored the most deals. (see Figure 2).

How the venture financing climate will look in the coming months is hard to predict. M&A activity this year to date has been very quiet, with many transactions

TABLE 2

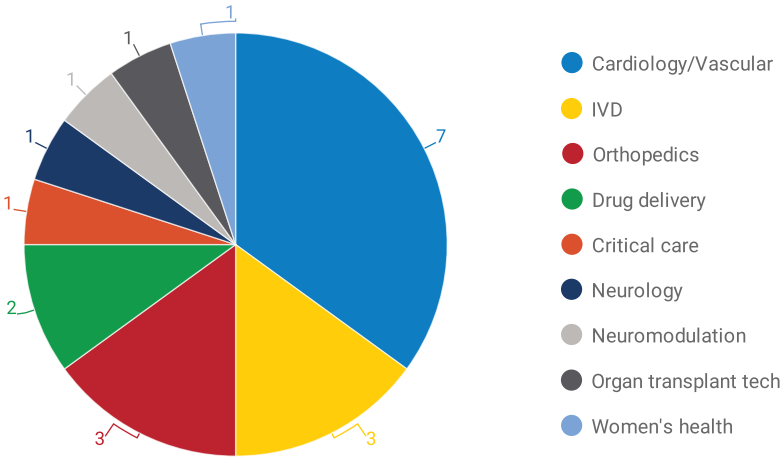
Top 5 VC Deals, Based On Amounts Raised

RANKING	COMPANY	BASED IN	PRODUCT/ THERAPY SECTOR	AMOUNT RAISED	FINANCING ROUND	TOTAL INVESTMENT
1	Grail	CA, US	IVD	$900m	Part of an expected $1bn Series B	$1bn
2	Freenome	CA, US	IVD	$65m	Series A	$70.5m
3	Moximed	CA, US	Orthopedics	$50m	Series C	$150m
4 =	Vertiflex	CA, US	Orthopedics	$40m	Undisclosed	Undisclosed
4 =	Active Implants	TN, US	Orthopedics	$40m	Undisclosed	Undisclosed
5	eGenesis	MA, US	Organ transplantation	$38m	Series A	$38m

Source: Medtech Insight's VC deal tracker

FIGURE 2

No. of VC Deals, Based On Product/Therapy Sector



Source: Medtech Insight's VC deal tracker

being more about acquisitions of mid-sized assets to consolidate the buyer's presence in its respective market, rather than a technology buy to fill portfolio gaps. That said, there is a still a lot of time for the tables to turn and if Grail does complete its series B with another $100m in the bag over the next few months, and the flow of bigger buck-deals start picking up like it did for March, 2017 may end on a better note than it started.

CLICK

For more details about VC deals in 2017 and previous years, go to *Medtech Insight*'s VC deal tracker: https://medtech.pharmamedtechbi.com/datasets/vc-funding

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US APPROVALS ANALYSIS:

Biotronik Making Its Interventional Mark

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After one quarter, **Biotronik SE & Co. KG** is leading in 2017 novel device approvals (original PMAs, panel-track supplements and *de novo* classifications) in the US. The Berlin, Germany-headquartered device firm is the only company with two original PMA approvals banked so far this year.

Biotronik gained FDA go-ahead for two different stents. In February, the firm gained approval for its *PRO-Kinetic Energy* cobalt-chromium coronary stent, Biotronik's first launch in the US coronary stent market and an important milestone in the company's plans to break into the vascular intervention market. The firm touts the device as a "new-generation" bare-metal stent with ultra-thin struts and a biocompatible coating.

"It is our intent to expand our portfolio of leading-edge vascular intervention products, and gaining FDA approval for PRO-Kinetic Energy is a first milestone in that quest," Marlou Janssen, president of Biotronik Inc., said after that Feb. 14 approval.

Biotronik followed that up with a March 23 PMA approval for a peripheral-artery stent, the *Astron Pulsar* and *Pulsar-18* stent system, approved for treating lesions in the femoral and proximal popliteal arteries. A different Biotronik stent was approved in 2015, for use in the iliac arteries.

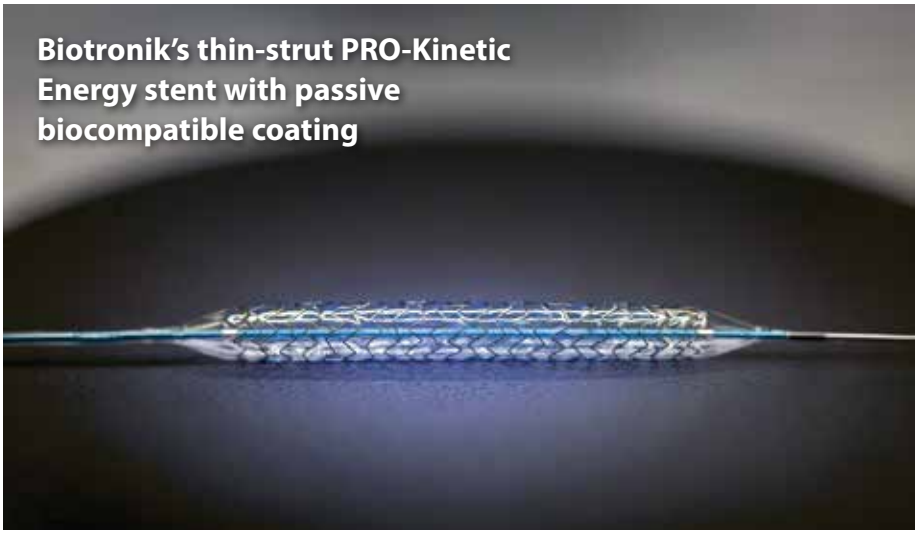


Photo credit: Biotronik

While Biotronik is making an early push into the US vascular interventional space, it has already established itself as a US competitor in the cardiac rhythm management market, albeit with much lower market shared compared to the big three players in CRM.

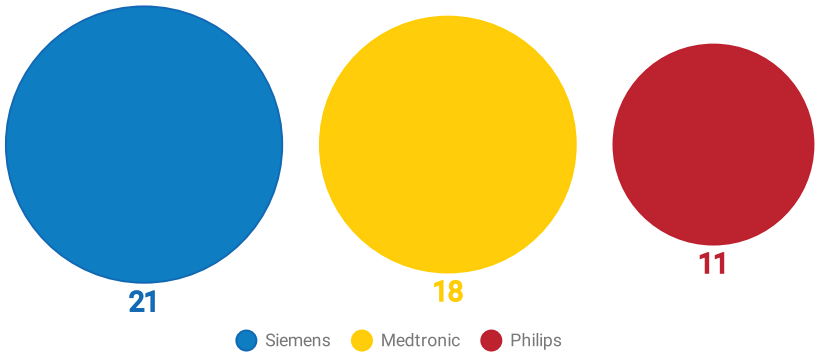
Cardiovascular devices account for nine out of the 15 devices approved via original PMAs or panel-track supplements so far in 2015. And six of those were vascular devices, including two other novel bare-

Novel Device/Indication Approvals: March 2017

DEVICE NAME	COMPANY	PATHWAY	CLINICAL SPECIALTY	APPROVAL DATE
Powerlook tomo detection software	ICAD Inc.	Original PMA	Radiology	03/24/17
Astron Pulsar Stent System, Pulsar-18 Stent System	Biotronik Inc.	Original PMA	Cardiovascular	03/23/17
Juvederm Vollure XC	Allergan	Panel-track PMA supplement	General & plastic surgery	03/17/17
Versant HCV Genotype 2.0 Assay (LiPA)	Siemens Healthcare Diagnostics Inc.	Original PMA	Microbiology	03/14/17
Ipsogen JAK2 RGQ PCR Kit	Qiagen Inc.	Direct *de novo*	Molecular genetics	03/27/17
CINtech Histology (50 tests) CINtech Histology (250 tests)	Ventana Medical Systems Inc.	Direct *de novo*	Pathology	03/04/17

Medtech Insight Approvals Tracker

Q1 510(k) Clearances: Top Three Firms



Source: Medtech Insight Approvals Tracker

metal coronary stents, one from **Tryton Medical Inc.** (*Tryton Side-Branch*) and one from **CeloNova BioSciences Inc.** (*COBRA PzF NanoCoated*).

FOCUS ON HEP C AND 3D MAMMOGRAPHY

Also receiving repeat attention by FDA in the first quarter were novel *in vitro* diagnostics for the hepatitis C virus (HCV) and 3D digital mammography devices for breast-cancer screening.

On March 14, FDA approved an original PMAfor **Siemens AG**'s *Versant HCV Genotype 2.0 Assay*, a Siemens Healthineers assay intended to distinguish the genotype of a patient's HCV to guide anti-viral therapy. One month earlier, on Feb. 13, FDA had granted original-PMA approval to **Hologic Inc.**'s *Aptima HCV Quant DX Assay*, which is indicated for detecting and quantifying HCV RNA, and also to aid in the diagnosis of active HCV and to help manage anti-viral drug therapy.

In mammography, FDA approved an original PMA for **Fujifilm Medical Systems USA Inc.**'s *Aspire Cristalle Digital Breast Tomosynthesis Option* in January as a 3D mammography system to compete against systems from Hologic, Siemens and **GE Healthcare**. More recently, on March 24, FDA approved**iCAD Inc.**'s *PowerLook Tomo Detection Software,* a computer-aided detectiontool designed specifically to assess images concurrently with 3D tomosynthesis scans, rather than have to wait until after the scans are complete. PowerLook is designed to address radiologist complaints that 3D mammography reads take too long. *(Also see "iCAD Touts PMA-Approved Tool As Time-Saver For 3D Breast Assessment" - Medtech Insight, 28 Mar, 2017.)*

In total, FDA approved 11 original PMAs in Q1, including three in March. The Q1 number beats out first-quarter 2015 (9) and 2016 (8) numbers (2015, in full, was a user-fee-era record-setting year for original PMAs). There were four panel-track supplements approved in Q1 (including one in March), for significant indication and product changes requiring clinical data. That matches the Q1 2016 total, and 2016 was a user-fee era record year for panel-track supplements).

There were also 201 approvals in Q1 of all other types of PMA supplements (not including 30-day notifications), for less significant labeling changes, manufacturing updates and a range of other modifications.

MORE IVD *DE NOVOS*

Meanwhile, IVDs have dominated the *de novo* classification pathway, used for novel, moderate-risk devices, through Q1 2017. Six out of the seven *de novo* approvals this year have been for IVDs, and the final one also is diagnostic in nature – the *Companion* seizure-monitoring system.

In March, one de novo went to the *ipsogen* genetic test made by **Qiagen NV** for a biomarker (JAK2 V617F/G1849T mutation) to assess patients with suspected myeloproliferative neoplasm, a blood condition in which the bone marrow makes too many red blood cells, platelets, or certain white blood cells. The other last month when to the *CINtec Histology* assay from **Roche/Ventana Medical Systems Inc.**

The seven *de novos* in Q1 put FDA ahead of 2015 and 2016 so far, and at equal pace with the seven *de novos* cleared in Q1 2014. 2014 turned out to be a record year in volume of FDA *de novo* approvals.

CLICK
For sortable and searchable tables of all 2016 US and non-US approvals and clearances, check out our Approvals Tracker.

SIEMENS, MEDTRONIC LEAD IN 510(K)S

For 510(k) clearances, which make up the large majority of FDA go-aheads each month, the agency remains on a consistent pace. There were 275 clearances in March, and a total of 741 in Q1, on track with recent FDA performance in recent years.

Siemens AG is the leader in volume of 510(k) clearances through Q1, with 21. **Medtronic PLC** is close behind with 18 clearances.

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OUS APPROVALS:

Edwards And Trinity Lead Spring Surge

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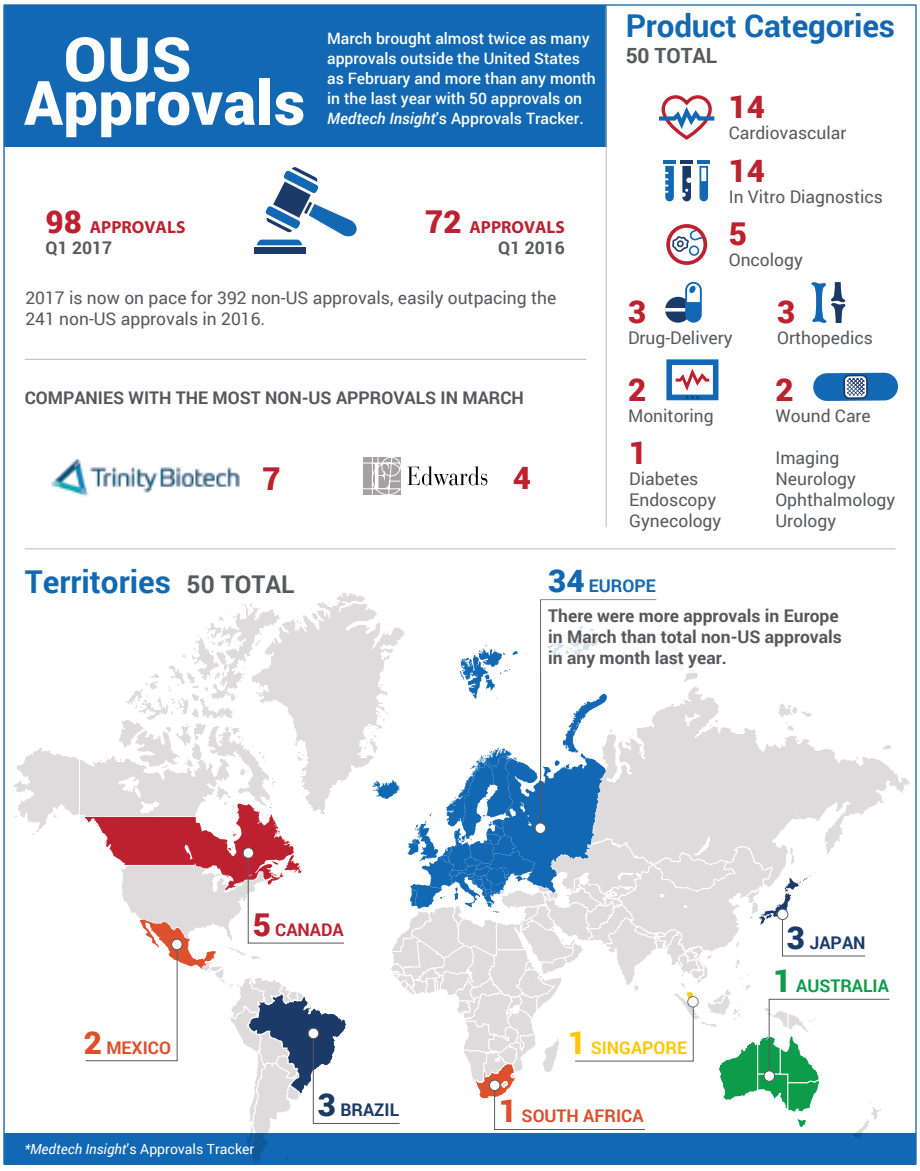
March 2017 was the biggest month in over a year for non-US medical device approvals on *Medtech Insight*'s Approvals Tracker, with 34 CE marks in Europe, and 16 approvals reported from other territories outside the US.

March's CE mark total alone is more than the total number of non-US approvals in any month of 2016 – the biggest month of 2016 was June, with 31 non-US approvals – and almost twice as many as February's total 28. With March's big haul, the first quarter of 2017 finished with 98 non-US approvals, a big jump from the 72 recorded on the Approvals Tracker in the first quarter of 2016. This puts 2017 on pace for 392 non-US approvals, compared to 241 medtech approvals from outside the US in 2016.

As usual, the two biggest product categories for non-US approvals during the month were cardiovascular devices and in-vitro diagnostics, with 14 each. The other 22 non-US approvals included products in 12 other categories, including oncology, drug-delivery, orthopedics, wound care, and patient monitoring. (See Figure 1).



TRINITY LEADS IVD LIST

Thirty different companies reported non-US approvals in March, and the companies with the most were **Trinity Biotech PLC** with seven and **Edwards Lifesciences Corp.** with four.

Trinity announced a series of European in-vitro diagnostics approvals under the *Uni-Gold* brand on March 23. Uni-Gold is Trinity Biotech's range of rapid point-of-care single-use immunoassays for HIV, sexually-transmitted diseases, respiratory diseases, and gastrointestinal diseases. The company touts Uni-Gold as fast and easy-to-use without any special instruments, with easy interpretation and built-in control in each test kit.

The new tests include the Uni-Gold glutamate dehydrogenase antigen test for *clostridium difficile*-associated diarrhea

PQ Bypass Detour procedure with Torus stent graft

Source: PQ Bypass

and infection, which has 97% sensitivity for screening and takes only 15 minutes to perform, according to the company. The Ireland-based company also announced the CE mark for the Uni-Gold test for the qualitative, simultaneous detection of *C.difficile* toxins A and B in human stool specimens to aid the diagnosis of *C. difficile* infections. The company says this 15 minute test has a 99% specificity for supplementary screening.

ANOTHER BIG MONTH FOR CARDIOVASCULAR TECH

Edwards' four March non-US approvals were all for *Fogarty* catheters, an embolectomy technology invented by Thomas Fogarty over 30 years ago for removing soft emboli and thrombi from peripheral arteries. The new approvals, announced Mar. 21, include the *Over-the-Wire Fogarty Thru-Lumen* embolectomy catheter. The company says this model can be used to remove fresh soft emboli and thrombi from vessels in the arterial system and for temporary occlusion of blood vessels, infusion of fluids, and blood sampling. The company claims it offers consistent balloon symmetry and uniform contact with vessel walls and is capable of helping guidewires cross occluded, tortuous, and stenotic arterial segments.

Also on Mar. 21, Edwards announced the CE mark for the Fogarty graft thrombectomy catheter, designed to remove tough thrombus from synthetic grafts, Fogarty arterial embolectomy catheter for simple and rapid removal of emboli and thrombi arteries, and the Fogarty adherent clot catheter, with a spiral-shaped, latex-covered steel cable for removing arterial plugs or clots too resistant to be removed with an elastomeric balloon.

Among the other cardiovascular approvals announced in March, **PQ Bypass Inc.** announced the CE mark for three devices that work together in a fully percutaneous femoropoliteal bypass procedure that the company is marketing as *Detour.*

The three CE marks for the Detour procedure, announced Mar. 13, include the *Torus* stent-graft system, an expanded polytetrafluoroethylene-covered self-expanding nitinol stent, indicated for improving blood-flow in patients with symptomatic peripheral artery disease in superficial femoral artery de novo and restenotic Trans Atlantic Inter-Societal Consensus II class C and class D lesions. In the Detour procedure, the interventionist uses fluoroscopy to deploy a series of Torus stents from the popliteal artery into the femoral vein, and from the femoral vein into the superficial femoral artery, to create a continuous, overlapping conduit with two independent anastomoses.

The Sunnyvale, California company also announced CE marks for the *PQ Snare* – indicated to retrieve and manipulate atraumatic foreign bodies in the distal peripheral vasculature – and the *PQ Crossing* – indicated for supporting the placement and positioning of guidewires in the peripheral vasculature.

PQ Bypass CEO Peter Wehrly told *Medtech Insight* that the current options for treating superficial femoral and popliteal artery disease only work well in short lesions. "The longer the lesions you have, the more likely it is not to work both in the short term and the longer term," he said. "Almost all of the technologies that have been approved, were based on studies looking at patients with lesions under 10 cm in length, which is great for them...but the average [femoropopliteal disease patient] has a 30 m long occlusion, so that doesn't work super well."

Open bypass surgery with a vein conduit leads to a wound infection in about 35% of patients. Polytetrafluoroethylene grafts from the femoral artery, but "that doesn't work quite as well, and if that gets infected, then most people end up losing their leg," Wehrly said. "So for the long-occlusions in these patients, which there is a huge number out there, having an option that's minimally invasive that will treat longer lesions is still a gap that no technology today treats."

The CE mark approval is based on results of the prospective, single-arm DETOUR I. In 60 patients with an average lesion length of 28.6 cm (96.7% of the lesions were chronic total occlusions) treated by Detour, the 30-day rate of major adverse events - including death, target-vessel revascularization, and target limb amputation – was 3.4%. The 84.7% six-month primary patency rate easily exceeded the prespecified performance goal of 70%. The technical success rate was 98.3% and 94.7% of patients improved by at least one category on the Rutherford Becker Clinical Category classification systems within six months, and 91.2% of patients improved at least two classes on that scale.

Two other devices for peripheral artery disease earned approval outside the US in March. On March 6, **WL Gore & Associates Inc.** announced that Health Canada approved its *Tigris* self-expanding peripheral stent. Tigris is made of single-wire nitinol stent with flexible fluoropolymer interconnections to make it both flexible and durable, and also features a heparin surface to prevent thrombosis. The US FDA approved Tigris in August based on clinical data showing a zero-percent one-year fracture rate. *(Also see "Gore Unleashes Tigris Peripheral Stent In The US" - Medtech Insight, 9 Aug, 2016.)*

And on Mar. 14, **Merit Medical Systems Inc.** announced the CE mark for *True Form*, a hyodrophillically coated, polymer-jacketed stainless steel steerable guidewire indicated for the placement of catheters in the peripheral vasculature.

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