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Trade Expert: New TPP Deal A Missed Opportunity For US

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A new version of the Trans-Pacific Partnership trade deal that is being worked out by the remaining 11 members of the negotiations seems to be a major missed opportunity for the US and American manufacturers, a trade expert says.

Earlier this month the remaining members of the TPP deal announced they had come to an agreement on the core positions of the deal, which is now called the Comprehensive and Progressive Agreement for Trans-Pacific Partnership. The members include Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.

The new deal, however, does not include key parts that the Obama administration was trying to negotiate to improve intellectual property rights – specifically, an annex that was geared toward helping drug- and device-makers.

The original TPP was intended to be a high-standard agreement that would outline trade rules for almost half the global population; the largest of its kind. It was also meant to be an opportunity for the US to introduce strong rules and tariff-cutting measures intended to help American companies get a better footing in international markets.

"With the US not being part of that trade agreement, the challenge is that we've lost that opportunity to help set some of those rules that are so important, particularly for our innovative companies, including in the medical innovation industry," said Gina Vetere, an international trade attorney at the law firm Covington and Burling.

She said the rules include multi-lateral obligations related to regulatory approval processes, intellectual property, and commitments intended to provide due process and procedural fairness with respect to reimbursement procedures for medical products.

"For the medical innovation industry, robust intellectual property rules were critical in TPP, as TPP provided an opportunity to enhance global IP rules – such as the [World Trade Organization's] Trade-Related Aspects of Intellectual Property Rights," or TRIPS, Vetere said.

While TRIPS still covers a lot of ground for the medical industry, TPP was an important opportunity for US medical manufacturers to introduce rules that ensured that their products were being properly valued across borders. Vetere says this is an important part of the deal what would have given more incentives to develop new medicines and technologies, and prevent other countries from "free-riding on US innovation."

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EU Industry Tells Authorities To Get Their Act Together As Pressure Builds

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MedTech Europe, the EU's largest association representing medical device and IVD manufacturers, has issued several position papers calling for swift action from national and EU authorities to implement the new Medical Device and IVD Regulations (MDR and IVDR) within the foreseen timeframes.

Their appeal to the authorities to ensure the necessary foundations are in place comes less than two weeks after the publication of the EU's long-awaited roadmap to the implementation of the regulations. The roadmap, published on Nov. 10, was drafted by the Competent Authorities for Medical Devices (CAMD) group alongside the European Commission and the biggest surprise to industry was that the document was more about creating a roadmap to implementation, rather than detailing what work is needed to comply with the regulations. *(Also see "EU Roadmap: Catalyst For More Work, And A Long Way To Go" - Medtech Insight, 13 Nov, 2017.)*.

It was even necessary to latterly introduce a new work item (8.1) to the roadmap to deal with issues that urgently need tackling most urgently. *(Also see "New 'Transitional Measures' Taskforce To Answer EU's Most Critical Questions" - Medtech Insight, 8 Nov, 2017.)*.

Against this background, MedTech Europe has issued three position papers focusing on what it believes to be particularly critical areas of implementation. It is calling on the European Commission and member states in each of the respective position papers to:

1. Ensure the capacity and availability of notified bodies early in the transition periods.
2. Invest additional resources needed to successfully implement the new regulations and clarify the new governance system under which guidance and secondary legislation will be developed.
3. Ensure that all actors have a consistent interpretation and respect for the transition periods of the new regulations.

THE THREE PAPERS AND THE CRUSADE

Oliver Bisazza, director of regulations and industrial policy at MedTech Europe, told *MedTech Insight*: "These are high level papers that spell out our concerns at 'headline' level. We will continue to seek hard data/statistics from our members about the number of products planned for future CE marking under the IVDR and MDR, so that the exact size of the problem can be better qualified."

The plan is for the association to use that data and the position papers to raise awareness within the European Commission.

Moreover, Medtech Europe intends to work with its national member associations to build awareness within the national Ministries of Health that supervise the competent authorities and designating authorities and to seek additional funding necessary to create the structures so urgently needed as soon as possible.

> "We've been told that much of Q1 2018 will be spent simply reviewing the [paper] applications notified bodies start submitting, with onsite assessments only starting in Q2 2018. We would like to see more ambitious timelines attempted," says Oliver Bisazza, director of regulations and industrial policy at MedTech Europe.

Bisazza also explained that while many issues raised in its three position papers can be addressed by equipping member state competent authorities (and designating authorities) with more resources, some of the extra resources, typically, can only come from the political leadership within Ministries of Health.

In several member states, however, IVD and medical devices regulators report into medicines agencies. So, an alternative to 'finding more resources' externally could be for the leadership of national medicines agencies to allocate more internal resources to IVDs and medical devices.

Areas where complementary support from senior leadership in ministries and/or heads of medicines agencies is needed include on the larger and more structural issues. This is the case for notified body designation, or contingency planning for a scenario where transition arrangements might prove unattainable.

NOTIFIED BODIES: A MATTER OF URGENCY

In the position paper on notified bodies, arguably the area that is currently drawing the most attention at the moment because of the critical and pivotal role these organizations play in auditing products, MedTech Europe "urgently calls" on the European Commission and member states to ensure the availability of notified bodies "early in the transition period".

"We feel the timing will really depend on the amount of ambition and resources that are thrown at the challenge," Bisazza told *Medtech Insight*. "For instance, the more national experts that the member states nominate to conduct the joint assessments, the greater the 'bandwidth' that will exist in the system to review candidate NBs quickly and simultaneously," he said. "We know these experts are starting to be nominated, but we do not yet know

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Exec Chat: How B Braun Is Staying Ahead Of The APAC Game

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Photo credit: B Braun Medical

Anna Maria Braun, President, APAC, B Braun Medical

"Whether it's China or Sri Lanka, all markets are crucial for us," B Braun's Anna Maria Braun says.

Parents have always been warned against playing favorites with their children. This lesson, it seems, could also be applied to nurturing your business across the many and varied markets in Asia-Pacific.

"I don't believe in setting priority markets," Anna Maria Braun, president of **B Braun Medical**'s APAC operations told *Medtech Insight* unequivocally, when asked to point out specific country markets that stood out more than others for growth opportunities. "Whether it's China or Sri Lanka, all markets are crucial for us. We have very good development in the somewhat smaller markets and we value them as much as we value the big markets like China, Australia, Japan, India. This is also part of our success – we don't prioritize markets. We have a very strong base in ASEAN [Association of Southeast Asian Nations] and within that group, you have many small countries that show excellent growth and there are opportunities there. Our strength is to encourage any market – we don't say we will focus on the top 3 or 4 only, while the rest can develop how they see fit."

Evidence that this strategy works is reflected in the firm's financial reports. The German multinational, whose portfolio encompasses more than 5,000 products across 18 therapy fields, reported total sales of €6.47bn in 2016, up 5% from the previous year. A big driver of this growth was sales from Asia-Pacific, which grew 11% constant currency (8% reported) year-over-year to €1.16bn. This makes the region the third largest contributor to group revenue after Europe (including Germany) and the US.

In an interview with *Medtech Insight* at the recent Asia-Pacific Medtech Forum in Singapore, Braun said she did not see this upward trajectory flattening out any time soon. "[B Braun's APAC growth] is definitely not stabilizing. The region, for us and also for many other companies, have been a key growth driver for the group and this is how we see the future to be. We don't see stabilization, but [instead] for APAC to continue delivering double-digit growth."

She acknowledged, though, that there are differences in growth rates from country to country; markets like Japan and Taiwan are more mature and will grow at a slower pace than Indonesia, for example. But there are still insights to be gained from more mature markets; the opportunities there lie in taking a "system partnership" approach, Braun said.

In the Q&A below, Braun explains this approach in more detail, and also discusses the critical role of innovation in keeping the company ahead of the competition; where the opportunities for innovation lie in commoditized products; the regions' regulatory and market access challenges; and dealing with local low-cost competitors.

Medtech Insight: What exactly do these system partnerships entail?

Anna Maria Braun: it's one of key strategic initiatives to engage with the customer and take a more holistic approach to finding out what they need. Not just sell a single product or service but really look into their entire system and discuss with them the whole patient pathway – from the patient entering the hospital, being diagnosed, treated and then being discharged – and we analyze with the customer where are the gaps, how we can support and make this process better while improving outcomes.

There are cases where we do look at single therapies and discuss with them how we can address their specific needs and achieve benefits in certain therapies. Or additional adjacent processes, for example, sterilization or patient discharge management, how we can support that and help our customers gain efficiencies. For that you need the customer on the other side who are aware where their cost challenges or their problems lie and you need to build their trust to address these problems. That's the way we want to approach the customers in future across the APAC countries.

The theme of this year's Asia-Pacific Medtech Forum is innovation and the critical role it plays in sustaining companies' growth in the region. What initiatives does B Braun have in place to ensure there is a constant flow of innovation into its extensive portfolio?

Braun: Innovation is one of our core values. Without innovation, our company wouldn't have lasted as long as it has. You

pointed out how huge our product portfolio is, and it takes a lot of effort to maintain that, the incremental innovation. Apart from working with our teams within the group, we also put more emphasis on looking at what's happening around us externally but there is no one-fix solution to handle it. So we've created an innovation hub to centralize all our links to external innovation. We have different models where we either invest on our own in start-ups at different phases – seeding or later stage – or we invest in funds specific to the medtech industry that look at technologies or start-ups. We've partnered with Trendlines, an Israeli incubator. We have one fund in Israel but also one now in Singapore where we are a partners and it gives us a window to see what is happening in the markets and we decide what we want to engage in.

So while we are pushing our own internal innovation, we also have different means of seeing what's happening outside.

A significant proportion of your products are the more commoditized products. Where do you see the innovation coming from with those devices?

Braun: Those products still have opportunity for innovation. For example, having certain sensors in them to provide more information so you can make these commoditized products smart. Then there is the manufacturing process, which is crucial. Every aspect we work on is to help realize this so-called Industry 4.0 – that's the term we often use in Germany. Because these products are commoditized, the level of automation in their manufacturing is already very high but it's about taking the next step up to the 'connected factory'. So when a customer complaint comes in, it analyzes what is the root cause – is it the product, or the handling or another challenge – a feedback loop can be created directly to the production floor and give us a lot of knowledge and opportunity for improvements without losing too much time. The same with the supply chain – how do we revolutionize the supply chain so that as soon as the nurse of doctor uses a product, this is triggered back and go right into the production planning for the facilities. These elements of innovation are very interesting to look at for commoditized products.

The commoditized products that you are offering tend to be vulnerable to competition from local low-cost manufacturers. How big a threat do you view these potential rivals to be?

Braun: I don't see competition as threat. In Germany, we have a saying, "Competition enhances the business." Of course, local players that develop good products will challenge us and that is good. The danger is to become too complacent but in the end, especially for commodities, it is a question of scale; to be able to produce a significant volume of IV catheters, for example. and to have the benefits from production costs, you really need to have scale [that B Braun has] and not be present in just one market. So, I don't see local competitors as a threat. I know you have to watch them and be challenged by them. That will keep us on our toes and that will be beneficial for everyone because we need to develop better products.

Regulation and market access are two big challenges that are often brought up by medtech companies operating in APAC. From your perspective as leader of an APAC business, just what is the magnitude of these challenges?

Braun: They are very big challenges and it's about the increased complexity. It creates a lot of tensions and our job is to figure out how to live with or resolve these tensions. But the complexity comes in when the country comes with their own individual approach. We can't start producing a different product for every country or have a specific study done in the country for all the portfolio products. There needs to be some harmonization, in APAC and in the world. But that's the task for [a regional medtech trade association] like APACMed to engage with the governments and work on a sensible solution. We have to live with this and resolve them eventually. So it's about constantly engaging with all the stakeholders and increasing transparency on how to solve these issues.

B Braun is on the board of APACMed and was pivotal in establishing the association three years ago with other key global medtech players. What were the catalysts for setting up an organization like APACMed at this particular juncture in time?

Braun: All the founding members of APACMed felt the need to have a platform in the region where we can address the challenges in APAC. It is a very diverse market and more than half of the global population resides in this part of the world – APAC is the world on a smaller scale because any problem you have in the global health-care arena you can find in APAC. We didn't want an association that only represented European or US companies, but one that represent medical device companies that operate in APAC. This is what we want to move forward with and find new ways of cooperation. The needs are so big, not one single company or one single government can address all these challenges which is why we wanted to establish APACMed and drive new solutions and new cooperation models to address these needs.

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Shopping Spree Not Over For Philips, Bags Data Analytics Start-Up

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Philips Healthcare is expanding its data analytics capabilities for enhancing radiology workflow and operational performance with the acquisition of **Analytical Informatics Inc.**, a US company spun out of the University of Maryland in Baltimore.

The start-up specializes in vendor-agnostic software that provide performance data trend and analysis to hospitals so they can improve the radiology departments' clinical and operational efficiency. Its core technology, *AI Bridge*, is a data aggregation and electronic medical record middleware platform that powers suites of software tools and Philips plans to integrate these capabilities into its *PerformanceBridge Practice*, one of the offerings in the Philips *PerformanceBridge* portfolio.

PerformanceBridge Practice is designed to help imaging departments simplify and unify various levels of data and unlock actionable information to enhance operational and clinical decision-making. Integrating Analytical Informatics' software will allow further customization of Philips' intelligence tooling and data analytics, said the Dutch group.

In addition to acquiring external capabilities, Philips said it plans to release from its own pipeline other products to expand the PerformanceBridge portfolio. This includes: *PerformanceBridge Utilization Services*, which delivers cross-modality utilization indicators including utilization rate, volume, and average change over time. In addition to Philips' CT, MR and interventional X-ray systems, this application is intended to also directly collect data from Philips' ultrasound and general X-ray systems, as well as CT, MR and interventional X-ray systems from other vendors; and *PerformanceBridge Protocol Manager*, which is designed to identify opportunities for MR imaging protocol optimization, standardization and efficiency improvements.

The acquisition of Analytical Informatics, of which financial details were not disclosed, marks Philips' eighth acquisition this year to date.

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Medtech Sales Not Fully Reaping Rewards Of Digitalization, Industry Survey Reveals

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The medtech sector may be playing catch-up to other industries when it comes to embracing the digital revolution, but many medtech companies are now engaging and investing in digitalization initiatives. These efforts are not just targeted at improving product portfolios, but also at enhancing sales processes to boost top-line revenue. But a new survey suggests that only a small proportion of companies are reaping the benefits from efforts to digitalize sales organizations.

That was a key finding from this year's cross-industry Global Pricing & Sales Survey, conducted by strategy and marketing consultants Simon-Kucher & Partners, in collaboration with the Center for Pricing at Simon Business School, University of Rochester and Z. John Zhang, professor of marketing at The Wharton School.

Senior executives from more than 20 industries, including medical technology, and in more than 40 countries took part in the survey that was conducted between July and August – 1,925 responses informed the results analysis.

Among the survey's medtech respondents, 79% say they do expect digitalization to improve sales force effectiveness and 71% say they have made investments in digital initiatives in the past three years with the goal of increasing their top-line and reducing sales costs.

> "In sales, buying or implementing the software is not a hurdle," Simon-Kucher's Joerg Kruetten says. "What's really lacking is the change of behavior of the sales rep."

These initiatives fall largely into two areas, explained Joerg Kruetten, senior partner and head of global health care and life sciences activities at Simon-Kucher & Partners. "One bucket of activity is around customer-relationship management. With the new digital tools, it is much easier to store and capture customer intelligence and that data can be used to prioritize sales activities, promotional campaigns and help steer sales strategy.

"Another important area of digitalization in sales is the use of online channels, either for enhancing or replacing engagement with the customers. So, the traditional personal customer interaction can be partly replaced by using these online channels to provide information to the customer or as a platform for selling products to smaller accounts. This allows you to segment the customer base and separate the big key accounts from the long tail of small accounts; it may not be worth sending a sales rep to these much smaller customers and an online platform will allow them to order products as well as obtain any relevant information they need."

But while medtech companies are investing in digital sales tools, only 21% of respondents say they've have made a visible impact on the top-line – the remainder either say these initiatives have not made any impact whatsoever (25%) or that the impact is only just starting to become noticeable (54%). (See Figure 1.)

Kruetten told *Medtech Insight* that for the lack of success might have more to do with the users' attitudes rather than the tools themselves. "In sales, buying or implementing the software is not a hurdle. Many big companies have taken that step and they have the prerequisites to do a lot with that. What's really lacking is the change of behavior of the sales rep."

The typical medtech sales rep, Kruetten explained, is very adept at managing personal relations with the physician customers; much of their sales success boils down to these customer interactions. "People own this personal relationship and it is natural they would hesitate to share all kinds of intelligence around the relationship that they own. Also, sales reps in medtech are typically entrepreneurial, they have the autonomy to steer and do what they think is best to hit their numbers. They are not used to being told by a software tool that they need to spend X amount of time with this account and so on, especially if they have been successful doing things their own way. This is where two different worlds clash in a way."

This dynamic will likely change as time brings in a new generation of sales reps who are more willing and open to embracing digital tools, said Kruetten.

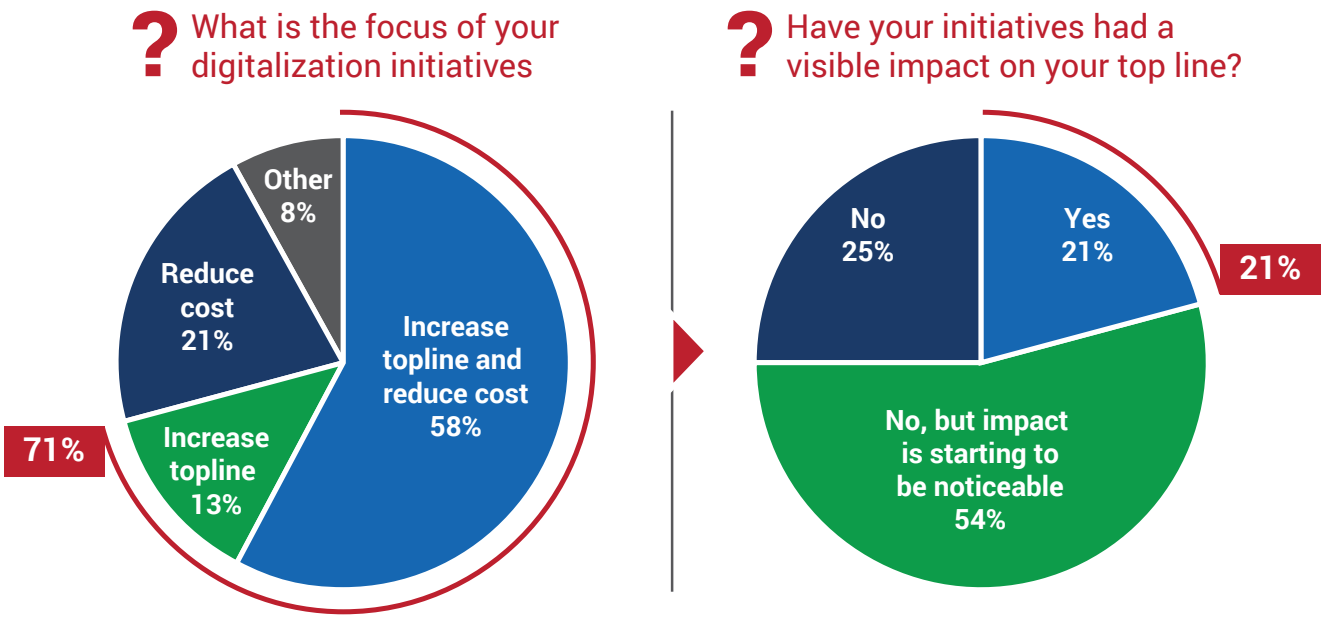
MONETIZING DIGITAL SERVICES

Changing the mindset of the traditional medtech sales rep might be one element to help realize the benefits of digital tools, but it is also important to make your money in the right areas and with the right objectives r to allow for adequate returns.

The survey found that improving customer-relationship management and improving channel management were two areas in which respondents have made some of the biggest investments. But the visible impact that these initiatives have had on companies' revenues was very low. On the other hand, initiatives to optimize and monetize digital services and those to optimize prices using big data received the least attention from companies; yet those who did invest in these two areas were most likely to see the benefits of the investment in their top line. (See Figure 2.)

FIGURE 1

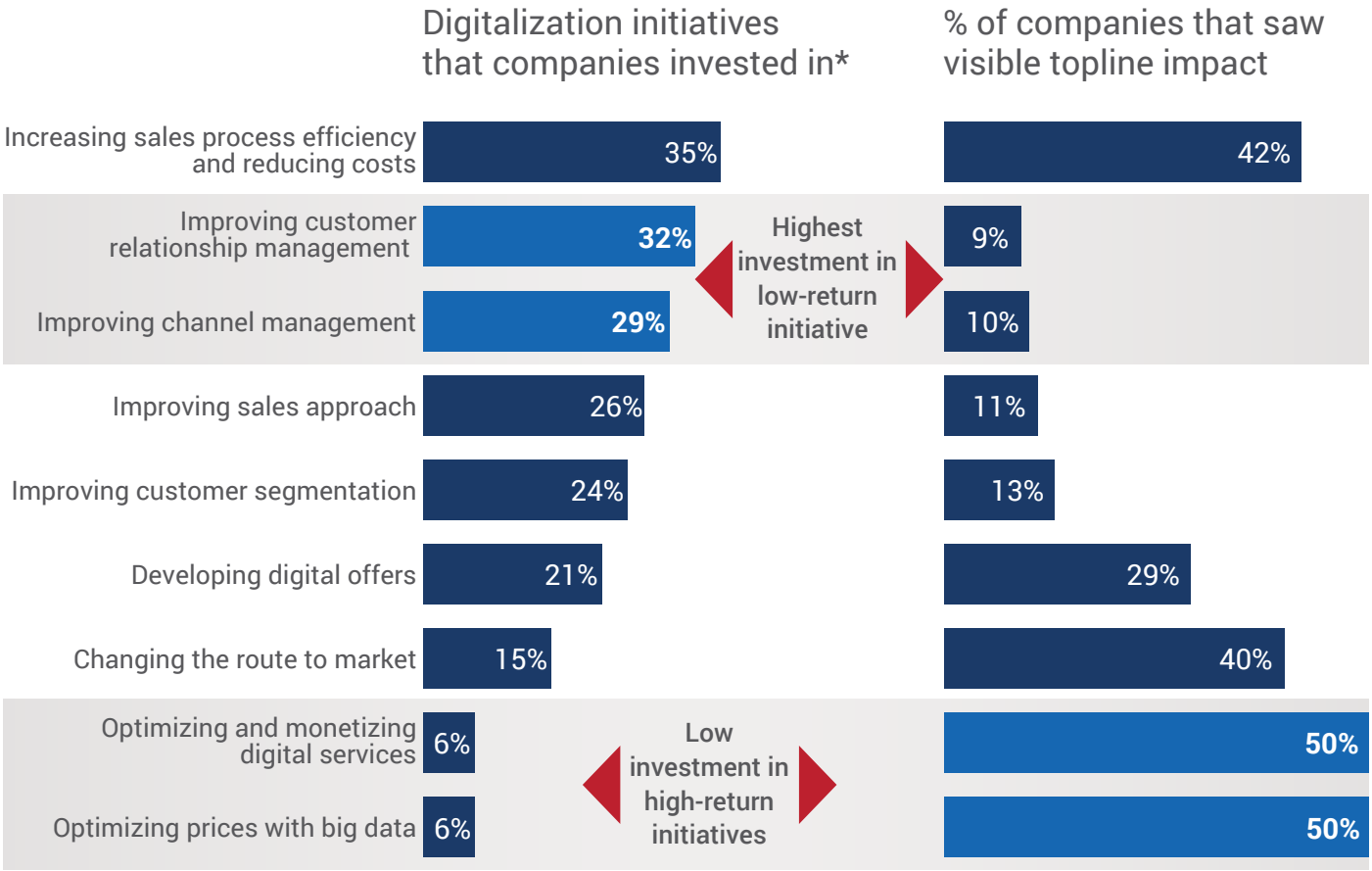
71% Of Digitalization Efforts Focused On Increasing The Top Line, But Only 21% Of Medtech Firms Saw A Top-Line Impact



Source: Simon-Kucher & Partners

FIGURE 2

Most Medtech Companies Focus Digitalization Investments On Initiatives With Limited Top-Line Impact



Source: Simon-Kucher & Partners

These latter two digitalization initiatives – monetizing digital services and optimizing prices – are not a primary driver for medtech companies, according to Kruetten.

"In other industries, you see a lot more of companies saying, 'I know so much about a client and I have benchmarking data from other companies and I can use that to generate incremental revenue.' So, in addition to selling a product to hospitals, medtech companies can say to customers, for example, 'If you buy this product, I can also provide you with good access to this benchmarking database so you can benchmark your [operating room] processes with best-in-class companies and this is something I [can] give you at an attractive price.'"

Again, Kruetten believes that a younger generation of sales people will help accelerate the changes needed for medtech companies to fully capitalize on digital-sales initiatives. "They see having more data and more intelligence as a value rather than a threat," she said.

But it will also be useful for organizations to showcase the benefits of performing these types of sales, advised Kruetten.

"If you haven't seen the benefits, you see it as a threat," he explained. "So, you can create a pilot project: take a certain number of accounts in a country, have a group of people implement these steps and track customer experience and customer satisfaction. Then you can showcase this to the rest of the organization and show the results and then try to scale this up. This is an important element to try and generate buy-in in any organization. You have to do it this way, you cannot drive these things top down otherwise you risk losing a lot of people that you need."

Another way of getting buy-in from the sales force for digital initiatives is to involve them in the design of the activities. "The [digital] systems that you buy can ask a lot from you in terms of data, but not every piece of information is necessary or valuable. If you take some experienced sales people to set up the logic and strategy around how to use it, that will help generate buy-in but also help you avoid unnecessary work."

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[**Editors' note:** *For more information on the Global Pricing & Sales Study 2017, contact Angela Ott of Simon-Kucher & Partners (angela.ott@simon-kucher.com, www.simon-kucher.com)*]

Successful Selling: Adapting The Distributor Sales Model For A Changing Marketplace

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Is the traditional distributor sales model dead?

Distributor sales models exist for varied and valid reasons. Manufacturers often opt to leverage this independent sales channel when they have small product portfolios. In smaller markets, companies use them primarily to gain economies of scale as the distributor can combine portfolios of multiple companies to create a critical mass opportunity. Larger industries, like orthopedics, have often leveraged the distributor model as a means for getting capital investment, similar to franchise models, as well as fostering closer local relationships. Others choose this channel for better and faster access to existing "feet on the street" for rapid expansion or access to markets that might otherwise be blocked or difficult.

Regardless of the reasons, the distributor model is still common and has been successful in many markets for a long time, but does its future look as rosy? Is it a model that can persist amid rapid and significant marketplace changes? Is it flexible enough to survive? Or, perhaps due to its independent nature, does it provide a more flexible structure that can course-correct faster than larger company-driven sales structures? Correctly managed, can a distributor model do as well or perhaps better than direct models?

In today's health-care environment, especially in the US, most medtech firms are evolving and upgrading their sales models to address changing customer needs. These sales channel changes help companies support new sales and marketing tactics like value and clinical-based messaging, and selling to value analysis committees. More sophisticated companies with broader portfolios are also implementing new commercial strategies to better handle increasingly sophisticated centralized purchasing at integrated delivery networks (IDNs), government tenders and other integrated buyers, as well as supporting complicated integrated offerings and services to meet the needs of new market forces like accountable care organizations. Not surprisingly, much of this evolution is led by large manufacturers with diverse portfolios and direct sales models. Many smaller firms are also adapting to the new marketplace, while companies both small and large with distributor-based sales forces are evolving at a much slower pace.

This discrepancy, in large part, is driven by the fact that distributor-based sales teams can be harder to influence and often have a diverse go-to-market structure across many different independent distributor owners. Much of the issue comes from the "independent" nature of the distributors, who by definition aren't employees but instead act as independent agents. This model has served many industries well, especially to support growth, but leaving it unchanged in a rapidly changing marketplace can be a recipe for disaster.

WHICH ROUTE TO SUCCESSFUL CHANGE?

But this change isn't easy. There are far more examples of failure than success. There are cases where distributors were penalized by the manufacturer for not growing or were pushed too hard to adopt new sales structures and, instead of complying, decided to switch to a competitor brand and take the customers with them, leaving "scorched earth" for the original manufacturer. There are also cases where distributors attempted to make changes but lacked the appropriate people, processes or tools to do so successfully, or were too slow to implement the changes and lost most of the opportunity to competitors. In other cases, companies have tried to take distributors direct, either by buying out the distributor or firing the distributor and trying to substitute a new direct sales force to cover their existing customers. Although this has worked for some, especially in the long run, there are more cases where the strategy backfired and the manufacturer has had to try to either reestablish relationships with the original distributor or pursue new distributor relationships, all while hemorrhaging sales for many months or years.

There are also significant risks from doing nothing. There are many examples of established distributors who refuse

to make any change. They're often resistant to change or refuse to invest in the channel because they're already paid well for the business they built and have little incentive to pursue growth or new strategies. In these cases, however, doing nothing allows more nimble competitors to take advantage of the situation to grow and take share.

Is there a solution? Is there a way to evolve the distributor model more effectively? Or is the distributor model dead or dying?

Actually, there's hope, and there are some relatively easy things to be done to help turn the situation around.

Firstly, recognize that the distributors are just as interested in long-term success as you are. You both need each other and should be able to find mutually beneficial ways to course-correct together. The exact approach you should take will depend on your specific needs and situation with the distributor, but at least some of these approaches should apply to almost any situation where you are trying to help change your sales strategy through an indirect distributor sales channel.

One of the simplest approaches may be to **add one or more overlay sales roles to help support the specific strategies that you desire.** This could include adding a key account management (KAM) role to help with centralized decision makers (for example, C-suite negotiations at IDNs), or specialized reps to support more complicated products or sales processes. This will be easiest to implement if it's funded by the manufacturer, but it's more likely that you may need to negotiate a way to help fund this role by either reducing payments (such as commission rates) to the distributor or separating out the sales that relate to that support from any commission-like payment that you might make to the distributor. Since this additional role will add costs but will also increase sales, it should be relatively easy to find ways to make it fund itself, at a minimum.

It's also worth exploring opportunities to **improve the support provided to the distributor**, which might not be simple to implement but could potentially have a higher ROI. This can come in many forms, but one of the more common options is providing some type of commercial operations support to the distributor. This can include licensing software like Salesforce.com, providing access to better market data (such as account-level procedure volume data from a third party), conducting sales force effectiveness analysis that identifies opportunities to improve sales force performance, providing insightful reports on historical performance as well as opportunities to grow sales, administering the distributor's incentive compensation plans, or providing any other desired data, tools or process support that the distributor can't afford to support at its smaller scale. This type of support should obviously be focused to support your desired new strategy, and if it's done well and is focused on the most impactful opportunities, it can easily have a 10 times or higher ROI.

Many companies have some type of distributor manager, an employee of the manufacturer who helps train and coach the distributor reps. Distributor managers should be key leaders in shaping changes in sales strategy, although this role is insufficient when it comes to supporting larger-scale strategy changes, as they often lack the skills, tools and scale that's needed.

To help ensure that the new strategies have strong results, it's important to **make sure that you have appropriate contracts, incentive plans and metrics in place**. It's impossible to cover all potential contracting issues within one article, but you want to at least be sure that appropriate non-compete and non-disclosure agreements are in place. You also should ensure that contracts can be cancelled or renegotiated within a reasonably short time frame so that new strategies can easily be re-discussed and you have some leverage to encourage successful implementation of strategies.

Since many distributor pay contracts are simple and pay a commission rate based on sales from the first dollar of sales, this may need to be adjusted to implement strategies that desire differentiated focus on specific products or strategies. For example, if you want the distributor to focus less on maintaining current sales and start focusing more on sales growth, you may want to pay a low commission rate up to prior-year sales, and pay a much higher rate for each dollar of growth. Metrics should also be put in place at the beginning of any change so that you have a baseline and can make sure that the data needed for measurement is collected and stored, and is available for periodic metric calculations in the future. This could be as simple as measuring the growth of a product line that's the focus of a new strategy, or it could be more complicated, like trying to track the performance of hospitals covered by IDN contracts versus those without a contract.

Clearly, the use of a distributor sales model can make new sales strategies more complex to implement, but that doesn't mean that the model can't survive marketplace change. With a clear understanding of how the channel may need to change to support a new strategy, a plan to implement that change based on a goal to make the change mutually beneficial, and the development of metrics to monitor success and identify needs for minor course corrections, most any strategy can be achievable and successful. An adaptable, robust distributor sales model can still be very powerful in the US. and in many global markets.

As long as management leverages good planning and execution, and perhaps a bit of creativity, there's no need to worry about the death of the distributor sales model.

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[**Editor's note:***Views expressed by guest columnists do not necessarily reflect those of* Medtech Insight.]

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US FDA Approves Device To Aid Cataract Patients

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Patients suffering from cataracts now have a new option for treating their condition after US FDA approved a device from RxSight Inc. that will allow them to see better when they're not wearing eyeglasses. Approved on Nov. 22, the firm's Light Adjustable Lens and Light Delivery Device makes small adjustments to the artificial lens' power after cataract surgery.

During surgery for cataracts – a common eye condition where the natural lens becomes clouded and impairs vision – the cloudy eye lens is removed and replaced with an intraocular lens (IOL). After surgery, many patients have minor residual refractive error requiring the use of glasses or contact lenses. Refractive error, caused when the artificial lens does not focus properly, causes blurred vision.

RxSight's IOL is made of a unique material that reacts to UV light, which is delivered by the Light Delivery Device 17 to 21 days after surgery. Patients receive three or four light treatments over a period of one or two weeks, each lasting about 40 to 150 seconds, depending on the amount of adjustment needed. The patient must wear special eyeglasses for UV protection from the time of the cataract surgery to the end of the light treatments to protect the new lens from UV light in the environment.

The device is intended for patients who have astigmatism before surgery and do not have macular diseases.

Malvina Eydelman, director of the Division of Ophthalmic, and Ear, Nose and Throat within FDA's Center for Devices and Radiological Health, touted the device's effectiveness. "Until now, refractive errors that are common following cataract surgery could only be corrected with glasses, contact lenses or refractive surgery," she said. "This system provides a new option for certain patients that allows the physician to make small adjustments to the implanted lens during several in-office procedures after the initial surgery to improve visual acuity without glasses."

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Clearblue Connects Peak Fertility Data To Smartphone App

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The *Clearblue* Connected Ovulation Test System pairs pregnancy-detection with a wireless application to facilitate getting pregnant, **Procter & Gamble Co.** says.

Rolling out to mass-market stores now, the test tracks a user's hormone profile and, via *Bluetooth* technology, sends data to a smartphone, which alerts users to the four or more best days to get pregnant. The product provides a window into fertility two days longer than any ovulation testing brand on the market, the firm says.

In a study of 87 women, four or more fertile days were identified in 80% of cycles using actual cycle length, the firm says. It contends that other OTC fertility apps predict the best days for conception 9% of the time.

Clearblue Connected comes with a battery-powered, digitized holder and 25 disposable urine testing sticks.

The device detects the amount of estrogen and luteinizing hormone in the user's urine stream every morning and communicates results to the smartphone app. Peak fertility is relayed with a smiley face that stays on the display for 48 hours.

The app can also be used to track a woman's menstrual cycle and sexual intercourse so she can compare information from previous cycles to better understand her personal fertility information, P&G says.

The Clearblue Connected app is compatible with most *iPhone* and *Android* phones that are equipped with Bluetooth 4.0/BLE. It is available at retailers and online for around $54.99.

Ovulation and pregnancy kit competitor **Church & Dwight Co. Inc.**in early 2016 launched an ovulation app for smartphones with its Bluetooth-enabled *Pregnancy Pro* line extension of its *First Response* pregnancy test kit. *(Also see "Church & Dwight Adds Minions To Vitamins, Bluetooth To Pregnancy Test" - Medtech Insight, 4 Feb, 2016.)*

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Researchers Call For More FDA Credit In Device Studies

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The role of US FDA in designing pivotal trials of new medical devices too often goes unacknowledged, two researchers said in a paper recently published in the *Journal of the American Medical Association* (JAMA) *Cardiology*.

The Viewpoint column argues that the Center for Devices and Radiological Health plays a key role in shaping device pivotal trials via the investigational device exemption (IDE) process. To ensure data collected during the pivotal trial can support device approval, FDA normally guides sponsors toward a study protocol that includes "appropriate" design, trial end points and duration, and is adequately statistically powered for agency purposes.

And study sponsors conducting research for an FDA approval usually follow recommendations requiring a sophisticated trial infrastructure, including monitoring, audits, core laboratory review, patient safety monitoring and statistical analysis. As a result, the column states, they're often more complex in design than other device studies.

"Pivotal studies are supported by highly trained staff members from within the sponsor company and from contract research organizations," authors Aaron Kaplan and Ariel Stern wrote. "Device studies that are performed outside the context of FDA/CDRH approval typically lack many of these features."

But FDA's role is rarely acknowledged in published trial data, Kaplan and Stern say. They think more researchers should explain how FDA contributed for several reasons, including consistency with standard scientific practices around attribution; highlighting that a trial met regulatory standards; and giving readers a more nuanced understanding of the context of the research.

Aaron Kaplan, director of clinical research at the Geisel School of Medicine at Dartmouth University, told *Medtech Insight* that the paper grew out of his dual roles as a research cardiologist and a medical device developer. He often saw products reach the market when he believed the trial had been highly influenced by FDA.

> "If we see a study that gets published based off a pivotal trial that was done to a standard that would be sufficient for PMA approval, we know that's actually a higher quality trial, perhaps, than one that isn't done in pursuit of meeting the standards that CDRH has set," Harvard's Ariel Stern says.

"But you go to these studies, and you often can't find that FDA was even a part of it," he said. "The premise of the paper was, how can that be?"

Additionally, he believes that more acknowledgement of FDA would build public understanding of FDA's process. "There's a big dialogue going on whether FDA standards are appropriate or inappropriate, and reminding people that these are trials that were for FDA approval helps with keeping that in people's consciousness."

His coauthor, Ariel Stern, is a health economist at Harvard Business School who researches the way the regulatory approval process creates different incentives for different types of products. She says adding discussion of the FDA's role to published research could serve as a kind of seal of quality.

"One takeaway is that informing consumers about the regulatory science side of this gives understanding that trials that are done in pursuit of FDA approval are done often with extremely high standards that will help practitioners actually interpret the studies that get published," she said. "So if we see a study that gets published based off a pivotal trial that was done to a standard that would be sufficient for PMA approval, we know that's actually a higher quality trial, perhaps, than one that isn't done in pursuit of meeting the standards that CDRH has set."

Stern and Kaplan have submitted some data supporting the journal column to a major cardiology conference, and hope to present early in 2018.

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A HELPING HAND:

'MedTech Color' Aims To Move Minorities From Shop Floor To Executive Suite

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Kwame Ulmer

When Kwame Ulmer has visited various medical device companies over the years, he couldn't help but notice that people in top positions at those firms typically didn't look like him.

However, "when I'd go to manufacturing facilities, I would consistently see people of color on the shop floor," said Ulmer, an industry expert, and African-American, who has worked for both device-makers and US FDA.

"Now, when I say 'the shop floor,' I mean the people who are actually making the devices – so, generally, the lowest-paid people are black and brown people," he told *Medtech Insight*. "But when I would meet with the executives, they would look much different. They'd be middle-aged, Caucasian men.

"That always struck a chord with me – and not in a good way – because I thought there would be more diversity up and down the ranks, but there isn't," Ulmer added. "This has been consistent over my 15-year career in medtech."

After spending 12 years in FDA's Office of Device Evaluation (he left in 2014), Ulmer was a regulatory affairs director for Danaher Corp. and a quality/regulatory executive at dental implant-maker Implant Direct before striking out on his own, making angel investments in early-stage medtech companies.

Because of those disparities, Ulmer created "MedTech Color," a group whose aim is to move more minorities from the shop floor to the executive suite. MedTech Color held its first in-person meeting at AdvaMed's Medtech Conference in San Jose, Calif., in August.

"The first step for us as a group was to get together at a luncheon during the AdvaMed meeting to talk about how we could move the needle, but that luncheon went on for so long that it turned into a dinner," Ulmer said. "We got sponsorship from Danaher and [recruiting firm] Korn Ferry for the meeting; those firms really facilitated the 15 executives coming together."

During the dinner, Ulmer discovered that others had similar experiences with racial disparity at device firms.

"We went around the dinner table, and everyone had different stories, but they were consistent in noticing issues like lack of representation" for minorities, he said. "People opened up in really amazing ways and were very candid."

But MedTech Color isn't only looking to move people of color up the corporate ladder. It also wants to increase the number of minorities that serve on the board of directors at device firms, as well as push more people of color to found medtech companies.

The group has three core objectives. "The first is to build community, to build out this network of people of color who are in medtech," Ulmer said. "The second is to add value to the ecosystem – how do we support each other so we're actually giving talks on pertinent issues in medtech? And the third objective is increasing the number of people of color who enter and stay in medtech."

MedTech Color has devised some potential short-term goals, including "publishing a list of executives of color in medtech to gain better visibility of who is in this community," Ulmer said. Another idea is to "create a speakers bureau where people could easily access thought leaders who happen to be thought leaders of color."

The group also wants to build formal partnerships with device manufacturers and industry advocate organizations such as AdvaMed, which Ulmer said has expressed interest in working with MedTech Color.

Thanks to its Women's Executive Network (WEN), which aims to put more women in executive roles, "AdvaMed already has a great track record of supporting gender diversity," Ulmer said, and he's hoping that AdvaMed's involvement will do the same for people of color. "It's a little early, but over the coming months I think we'll get more traction with AdvaMed."

As for building relationships with device-makers, MedTech Color is well on its way. "Johnson & Johnson has the largest number of executives in MedTech Color's planning group," Ulmer said. "J&J is really interested in this topic." Executives from Medtronic and 3M also were part of the August dinner meeting.

What MedTech Color won't be doing, though, is creating training programs for device-makers looking to help people of color rise through the ranks.

"But what we may develop is some sort of virtual network of peers who can serve as sponsors across companies, so if someone is stuck at a particular company, they have an outlet. They're visible and can be sponsored, provided that they're sponsor-ready, in a more accelerated fashion," Ulmer said.

"Another big, bold idea we're discussing is leveraging a virtual platform so we can form an angel network to fund companies that have founders of color," he said. "So, I would say we're thinking less tactical and more strategic. "

For the foreseeable future, MedTech Color will hold a series of virtual planning meetings. Its next in-person gettogether will probably be at AdvaMed's next annual conference in September 2018.

To join the group, visit MedTech Color on LinkedIn or send an email to Ulmer at Kwame.Ulmer@MedTechColor.com.

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US FDA Is Dedicating A 'Patient Affairs' Staff Without A Formal Reorg

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US FDA's new patient affairs office will not be an actual "office" in the official sense of the word, but will remain a group working to help patients and advocates find their way around the agency.

In part because of the bureaucratic moves that would be necessary to make such a change, the agency is instead creating a patient affairs group, said Principal Deputy Commissioner Rachel Sherman.

The clarification comes after agency officials in documents and public appearances have called it a patient affairs office.

"It's not an office because that requires a reorg," Sherman said Nov. 14 during the Biopharma Congress, sponsored by Prevision Policy and the Friends of Cancer Research. "But we are standing up a patient engagement staff in what is currently the Office of Medical Products and Tobacco."

That likely means that there will not be another bubble added to the OMPT organizational chart designating a patient affairs group. It now includes the Offices of Special Medical Programs and Oncology Center of Excellence, as well as the centers for drug evaluation and research, biologics evaluation and research, devices and radiological health, and tobacco products.

Indeed, the requirements for adding another office to the FDA organization chart are substantial and time-consuming. It not only requires substantial paperwork, but also congressional approval. FDA's Center for Devices and Radiological Health is currently setting up its own super office, combining device review, compliance and surveillance functions. *(Also see "'Super Office' To The Rescue: FDA's Device Center Is About To Undergo A 'Total Product Life Cycle' Makeover" - Medtech Insight, 29 Sep, 2017.)*

CENTRAL POINT OF CONTACT

The patient affairs group is intended to be a central point of contact for patients, advocates and other stakeholders looking to interact with FDA and are unsure where to go.

Sherman reiterated during the conference that those who already have developed relationships within FDA will not lose them when the new group is up and running. "We wanted a very visible single point of entry to help guide them," she said.

Rachel Sherman

Commissioner Scott Gottlieb also said the group will help set agency-wide policy. *(Also see "US FDA's Centralized Patient Affairs Office Aims For No Disruption" - Medtech Insight, 13 Sep, 2017.)*

FDA floated the idea in March and it initially gained support from patient groups. *(Also see "US FDA Patient Affairs Office Could Accelerate Involvement With 'Central Entry Point'" - Medtech Insight, 14 Mar, 2017.)* Several met with Sherman and other FDA officials in August to make sure the patient affairs office idea remained a priority. *(Also see "Patient Advocates Continue To Push US FDA For Central Office" - Medtech Insight, 5 Sep, 2017.)*

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BREXIT:

Vital Strategies For Keeping Devices On EU And UK Markets

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It is nearly 18 months since the UK voted to leave the EU, yet month after month goes by without any more certainty about the broad political framework for Brexit and, more specifically, what the regulatory solution will be for the medical devices sector.

With a Brexit date fixed for March 29, 2019, less than 18 months from now, medtech stakeholders who have yet to act are realizing that they must make tough decisions now to be prepared in time for a very possible "hard Brexit" scenario, or similar arrangements where the regulatory regime in the UK is not subject to mutual recognition (MR). In this version of events, the UK will be fully cleaved from the EU.

Many UK notified bodies have already started to make preparations for this scenario, with BSI and LRQA among those who

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Alison Dennis' Breakdown Of Brexit Options

STATUS OF PRODUCT	IF UK NB CURRENTLY	IF EU NB CURRENTLY	FACTORS IN DECISION-MAKING
New products seeking compliance against MDR/IVDR	Key question: UK NB with ability to recognize their work in the other region (EU27 or UK)?	Can use the current NB, but be aware in the event of no EU-UK mutual recognition, firm will need a separate certification for UK sales	Where is the launch market?
Current NB in EU27 – continued compliance against MDD/AIMDD/IVDD between March 29, 2019, and date of full application of MDR/IVDR, or date by which current certificates become invalid (which could be four-five years after date of full application)	Transfer to UK NB based in EU27 if UK market is the most important	Continue with this NB if UK market is not as important as EU27 – can apply for UK NB if no mutual recognition is established	If UK market is important, perhaps prepare by transferring to a related entity of a UK NB based in EU 27 now, with a hope to "flip" into UK in the event of a hard Brexit
Current NB in UK – and seeking to have devices certified under MDR/IVDR	Option to transfer certificates to EU subsidiary of notified UK body	Second certificate for UK at March 29	The transfer process could take up to 14 months. It is not possible to apply at same time for certificate in UK, so this would mean that urgent action is needed to transfer to EU NB
Current NB in EU27 and not seeking MDR/IVDR	If selling in the EU27, should transfer to EU27-based NB	If UK market is important, approach a UK-based NB now for a separate UK authorization following "hard Brexit."	Still need to continue to sell products post-Brexit under the medical device directives – decide which market is the most important: UK vs EU27

have announced that they have, or are, relocating their main offices from the UK to a country that will remain in the EU. *(Also see "Contradictory Messages Over Medtech and Brexit: MDR? No MDR?" - Medtech Insight, 10 Oct, 2017.)*

But what are the options for medtech manufacturers? There are several alternatives for companies if the UK goes it alone, according to Alison Dennis, partner and head of at Fieldfisher's Life Sciences and Healthcare team.

Dennis says that it is best to prepare for the worst-case scenario, in particular, that "a hard Brexit on 29 March 2019 will necessitate having a notified body in the EU27 and a separate notified body in the UK."

She recommends in a just-published blog the following options, depending where a company's products fall in the regulatory cycle, and the location of current notified bodies:

1. **Companies seeking to have new products certified under the Medical Device Regulation**: Medical device companies looking to obtain notified body certification for a new product under MDR might consider using a UK notified body, but via a subsidiary based in the EU27. The hope would be, in the hard-Brexit scenario, that the UK parent company would then recognize the certification work for UK purposes – although there would be a risk of additional fees.
2. **Companies seeking to have devices certified under the MDR or IVD Regulation and that currently retain a notified body that is not in the UK:** This is not a straightforward decision: Is it better to follow the route 1, above, for new products, and lose the experience the current notified body based in the EU27 has with a firm's products? The decision to take that approach or switch to a notified body that does include a UK presence will most likely depend on how important it is to be able to sell into the UK market immediately after Brexit, against the importance of selling in the EU27.
3. **Companies seeking to have devices certified under the MDR and IVDR, and whose current certifications under one of the legacy EU Directives are with a UK notified body**: There is the option of transferring these certificates to one of the EU27 subsidiaries of that notified body. Companies will need to consider the timing for obtaining a transfer (which could take as much as 14 months in practice), plus a second certification for the UK beginning March 29, 2019. The goal is to have as little interruption as possible for product availability in the two markets.
4. **Companies with current certifications with notified bodies based in the EU27 and who will not be seeking a recertification under the MDR or IVDR**: If the UK market is important, then an opening discussion with a UK notified body, in particular, around timelines for a separate UK notification, should be pursued so that preparations can be made in advance of March 29, 2019.

Dennis warns that under both the current Medical Devices Directives and the MDR it is not permitted for companies to undertake parallel negotiations with two notified bodies for the same certification.

In strictly legal terms, this means that discussions concerning a second certification for the UK or EU27 (as applicable) will need to be speculative only, and on the basis that it will not be the same certification as that already held in the other regulatory jurisdiction, she advises.

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UK To Offset Brexit, Spur Global Growth With Life-Science Sector Deal And Industrial Strategy

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Good news management by the UK government, or just good news? Probably both, but a government suffering Brexit blows daily, and being criticized by all and sundry over the mishandled and stalling EU withdrawal negotiations, would naturally relish a bit of respite.

That arrived today, with the publication of the government's Industrial Strategy white paper, a document planned in the wake of the 2016 Brexit vote by the newly-installed May cabinet, accompanied by the four "sector deals," including one for life sciences. *(Also see "UK Medtech Upscales International Plans Ahead of Brexit" - Medtech Insight, 21 Jun, 2017.)*

The findings and recommendations of the Life Sciences strategy, issued on Aug. 30, were used to secure the sector deal for life sciences, which the Department for Business, Innovation and Skills (BEIS) describes as a multi-billion-pound deal designed to keep the UK at the forefront of medtech and pharma innovation. *(Also see "Moonshot Projects In Life Sciences Strategy Can Lift UK Over Brexit Hurdle" - Medtech Insight, 30 Aug, 2017.)*

BEIS secretary of state Greg Clark said the Industrial Strategy white paper among other things describes how the UK will meet the challenges of: integrating artificial intelligence (AI) and big data; helping older people lead more independent lives, supported by smart home technologies, wearable devices and tech-enabled health and care; and promoting both "clean growth"; and future transport/mobility concepts.

Work towards the solutions to these challenges will be supported by funding from the Industrial Strategy Challenge Fund, matched by commercial investment.

Prompted by Brexit, the UK is broaching a new era of free trade with increased numbers of global partners, while hoping to retain close business links with the EU. Given the anticipated disruption in EU-UK affairs in the short and mid-term, the UK is currently hoping to agree on an implementation period of around two years to allow UK and EU businesses time to adapt to the new arrangements.

In terms of the challenges, the Industrial Strategy white paper's recommendations and actions seek to make the UK a global center for artificial intelligence and data-driven innovation. There are plans to invest in a £210m ($280m) "data to early diagnostics and precision medicine" program, to maximize the potential of health data to diagnose life-changing diseases early and develop precision treatments.

AI is directly addressed in one of the four sector deals. The Life Sciences strategy, too, makes AI a major area of attention, pressing for more focus on machine learning to transform pathology and imaging. Oxford Professor John Bell, author of the life sciences document, asserts the need for readiness to co-develop

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themes where life science and wider industrial strategy elements overlap, for instance in the field of AI.

The UK is home to major pharma companies, such as GSK and AstraZeneca, and has a strong SME sector as well as major health charities, such as the Wellcome Trust and Cancer Research UK. In announcing the Industrial Strategy today, the UK was able to play up some big-picture successes, listed in the document, such as Novo Nordisk's £115m investment in a diabetes research innovation center in Oxford; MSD's commitment to life sciences discovery research facility in the UK; and Qiagen's partnering with Health Innovation Manchester to develop a genomics and diagnostics campus.

Such announcements are a major fillip to UK efforts to keep the ship steady in anticipation of stern Brexit headwinds. But there are other UK life sciences projects planned that are not necessarily tinged with the Brexit brush, such as developing the Oxford-Milton Keynes-Cambridge corridor and the Northern Health Science Alliance, both expected in further phases of the deal.

More immediately, the UK has the massive potential of the NHS to exploit. Closer industry collaboration with NHS is widely seen as a crucial element in the success of the sector deal. In the short term, it is hoped that the Industrial Strategy white paper ideas should lead, over the coming months, to more sector deals, and to partnerships with industry, universities, researchers and civil society in tackling the four challenges outlined.

The UK medtech industry association, the ABHI, which is also looking increasingly beyond UK and EU borders to guarantee more business penetration for UK device companies, said it is ready to work with all stakeholders to ensure the vision of sustained NHS collaboration is achieved.

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how many exist so far, and how much in earnest authorities are working to make as many experts available as possible."

While there are "many possible sources of delay", the main thing authorities can do is to nominate as many (full time) experts as possible for the joint assessment teams which audit the notified bodies, Bisazza added, "and to commit to an aggressive schedule of joint assessments as early in 2018 as possible"

"We've been told that much of Q1 2018 will be spent simply reviewing the (paper) applications notified bodies start submitting, with onsite assessments only starting in Q2 2018. We would like to see more ambitious timelines attempted," he said.

MedTech Europe is concerned that based on the current investment of resources, notified bodies will not be available and be able to certify the vast number of products early enough.

One critical element to unlock the bottlenecks is to ensure that there is a sufficient number of available auditors at the authority level for the joint assessment of notified bodies, the notified body position paper states.

It is also important to guarantee that there is a necessary number of experts within the notified bodies staff that can complete the certification procedures on time, the association says.

The timely availability, the expertise and the sufficient capacity of notified bodies is absolutely critical for the medical technology industry" said Serge Bernasconi, CEO at MedTech Europe. "We are stressing to the European Commission and Member States that they need to put the necessary resources to successfully complete the many joint assessments on-time."

TOO LATE?

It seems this plea has come late, *Medtech Insight* notes, since it is now six months into the three-year transition of the MDR and the five-year transition period of the IVDR.

With most experts acknowledging it is going to be 12-18 months before the first notified bodies are designated under the new regulations, this could mean there would be only a further 12-18 months left before the regulations fully apply.

What is more, the actual number of notified bodies that are auditing medtech companies under the new regulations is likely to be significantly lower even at the end of the transition period than the current number – so far, only 24 notified bodies – all members of the EU trade association, TEAM-NB – have declared their interest under the MDR, and 12 of these under the IVDR also.

When asked about how many notified bodies, realistically, might be appointed by May 26 2019, two years after the regulations came into effect, Bisazza answered: "We really cannot estimate this with much confidence, and that's a big part of the problem. If we had more confidence in how to answer this, it would mean better business certainty for manufacturers"

He added that if the paper drafted by the Notified Bodies Operations Group (NBOG) is right, "mid-2019 (i.e., November 2017 + 18 months) is when only the first trickle of notified bodies might start becoming available for IVDR/MDR certifications".

MedTech Europe would certainly like to see this happen much earlier, for as many Notified Bodies as possible, and for both regulations, Bisazza stressed.

Of course, there is then an extension of up to four to five years for some companies, *Medtech Insight* notes, but just how many will be able to make use of it is a big question. Certainly any product that needs notified body involvement for this first time – and this includes IVDs - and any product that is being upclassified will not be able to make use of the extension. Moreover, no product where there is significant change will be able to make use of the extension – instead it will need re-auditing under the MDR/IVDR.

"We really cannot estimate with much confidence [how many notified bodies will be appointed by May 26, 2019], and that's a big part of the problem. If we had more confidence in how to answer this, it would mean better business certainty for manufacturers," Oliver Bisazza says.

NOTIFIED BODIES: TIME, CAPACITY AND EXPERTISE

Industry needs, above all, much greater clarity from authorities on the notified body designation process. An action plan with prioritization, clear deadlines, and training plans for auditors is required, MedTech Europe says.

It is only through this that product certification can start in time and finish by the end of the transition periods. The ultimate goal is to prevent any disruption to the availability of needed medical technologies to patients and health-care systems in times of regulatory transition.

But it is concerned that this may not be achieved in time. The trade association says that its notified body concerns are threefold:

1. The additional expertise and capacity that notified bodies need to invest to sufficiently address the new requirements of the two regulations,
2. The time and capacity needed at authority level to designate new and existing notified bodies under the regulations, and
3. The time and capacity needed for notified bodies to complete all necessary certifications of:

a. Products having notified body oversight for the first time, e.g. most IVDs;
b. Products already on the market today needing recertification to the new rules; and
c. New and innovative products in the pipeline to be certified for the first time.

IVD NOTIFIED BODIES NEEDED URGENTLY

All too often, the IVD sector seems to fall into the shadow of the bigger medical devices sector. But Medtech Europe makes a special plea for what is needed in the IVD field. "The designation of notified bodies under the IVD Regulation must happen simultaneously to the designation of notified bodies under the MD Regulation and should not be postponed due to the IVD Regulation's later date of application," it says.

This is because not only will more IVDs be in the scope of the new regulation, but also there are also many new and strengthened requirements to be met. Some 85% of all IVDs will require notified body oversight for the first time.

"IVDs … need to be worked on as equal priority to medical devices," MedTech Europe stresses.

RESOURCES AND GOVERNANCE POSITION PAPER

In light of the "substantial workload on the near horizon", industry is seeking reassurance that the European Commission and the authorities will allocate the necessary resources to implement the Regulations smoothly and on-time.

The association also urges clarity concerning the new governance system under which guidance and secondary legislation will be developed, including to ensure the early and meaningful involvement of stakeholders

Stakeholder involvement should not only be when approving the final draft guidance and secondary legislation, "but also when conceiving and drafting these documents," it says.

RESOURCES

Authorities will need to invest in both the mechanical aspect, e.g. IT systems etc., and in having sufficient number of in-house staff with the necessary expertise to understand and apply both regulations. This in-house expertise is essential to drafting appropriate secondary legislation and technical guidance - in collaboration with stakeholders, it notes.

With respect to the IVD Regulation in particular, MedTech Europe encourages member states to invest in experts who are sufficiently familiar with IVD products and processes and who are empowered to appropriately implement the specific IVD regulatory framework. This would prevent the risk that principles or content is developed first for the Medical Device Regulation "and then inappropriately mirrored to the IVD Regulation."

CONSISTENT INTERPRETATION: CLARITY NEEDED OVER TRANSITION PERIODS

The medtech industry is concerned that there is currently a lack of clarity between authorities, notified bodies and industry regarding the "complex transitional provisions and timelines" of each of the new regulations and there needs a "strong explanation and communication effort" from the Commission.

It is important to stress that until the end of the transition periods, namely May 26, 2020 for medical devices and May 26, 2022 for IVDs, the EU medical devices directives will remain valid and fully applicable, MedTech Europe says.

This means that products can be placed on the market, following the rules of the current Directives up until that point.

Additionally, it stresses the need to make it clear that, in certain cases, the certificates issued under the Directives can continue to be valid beyond those transition periods:

- **Medical devices** may continue to be placed on the market up until May 26, 2024, subject to conditions and depending on the type of certificate issued (note: Class I MDs without certificates only have until May 26, 2020 and devices certified via the EC verification route only have until May 26, 2022); and
- **IVDs** may continue to be placed on the market up until May 26, 2024, again subject to conditions (note: this provision is applicable only to a small percentage of higher risk and self-tests IVDs).

The association also points out that markets from both within and outside the EU need to understand these rules and continue to accept products complying with the current Directives until the new regulations become fully applicable in May 2020 for medical devices and in May 2022 for IVDs.

LACK OF READINESS MEANS TIMES IS ALREADY EBBING AWAY

But even with those extended periods for compliance, time is already starting to narrow. MedTech Europe points out that only once all players have fully applied the new system – for example, for designating notified bodies, harmonizing standards to the regulations, and setting up the EU database (Eudamed – can manufacturers plan and implement (re)certification of their existing and new product portfolios.

"Most diagnostics and devices cannot comply yet with the new regulations," it says. Secondary legislation, containing important implementation details, still needs to be prepared, agreed upon and then published by the European Commission.

This secondary legislation is needed to specify how key provisions of the new EU Regulations will work, such as how the new Eudamed will function.

Moreover, new governance and oversight structures need to be set up, such as the Medical Devices Coordination Group, notified bodies, expert panels and reference laboratories that will support certification of certain high-risk devices.

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Labeling And QMS Addressed In Updated EU Harmonized Standards Lists

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A revised standard on the requirements relating to use of symbols on device and IVD labels in Europe to convey information on a product's safety and effectiveness is among the new entries in the European Commission's updated lists of harmonized standards.

EN ISO 15223-1:2016, on the use of these symbols in the labeling of and information supplied with products, will supersede its predecessor, EN 980:2008, on Dec. 31, according to the Nov. 17 edition of the *Official Journal of the European Union*.

The *OJ* contains three updated lists of harmonized standards. One list relates to products covered by the Medical Devices Directive (93/42/EEC). Another list relates to products governed by the Active Implantable Medical Devices Directive (90/385/ EEC). The third list covers products that fall under the IVD Directive (98/79/EC). While some of the new entries in the lists relate to a particular directive, others, like EN ISO 15223-1:2016, are applicable to products covered by all three directives.

Other changes to the lists include EN ISO 13485:2016 on quality management system requirements for regulatory purposes. This standard, which appears in all three lists, will supersede EN ISO 13485:2012 on March 31, 2019.

EN ISO 11137-1:2015 (part 1), which updates the requirements for the development, validation and routine control of a radiation sterilization process, has been published in the list covering IVDs for the first time, the *OJ* notes.

Revised standard EN 60601-2-33:2010, which addresses requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis, will replace its predecessor on Dec. 31, according to the list covering MDD harmonized standards.

Also in the list relating to the MDD standards are two new harmonized standards covering prosthetics. EN ISO 10328:2016 on the requirements relating to structural testing of lower limb prostheses is to replace EN ISO 10328:2006 on June 30, 2018, according to the *OJ*. EN ISO 22675:2016 on testing ankle-foot devices and foot units will also replace its predecessor, EN ISO 22675:2006, on June 30, 2018.

The use of harmonized standards is voluntary, and manufacturers,

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other economic operators and conformity assessment bodies are free to choose another technical solution to demonstrate compliance with the mandatory legal requirements, the commission says.

THE NEW MEDTECH REGULATIONS

Europe's new regulations governing medical devices (2017/745) and IVDs (2017/746), which entered into force in May, will replace the three medtech directives when they start to apply after a transitional period – in spring 2020 for medical devices and spring 2022 for IVDs.

The Commission has recognized the need to develop a prioritization process to guide its work on reassessing whether and how European harmonized standards should help industry meet the requirements of the new regulations. At a seminar in September, the Commission proposed that it should draft a streamlined standardization request based on a priority list of standards that should be harmonized and cited under the new regulations. Under this process, some standards would be recognized as harmonized before others under the new regulations. *(Also see "Which Medtech Standards Will Be Live, And When, Under EU Regulations?" - Medtech Insight, 26 Sep, 2017.)*

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MISSING PROVISIONS BAD FOR MEDTECH

In the original TPP deal, the US was also pursuing solutions to tackle non-tariff barriers including a chapter that dealt with intellectual property, and a pharmaceuticals and medical devices annex that could have been beneficial to US medical device companies. Fundamentally the aim was to ensure that the trading system between the member countries did not discriminate against products that were made abroad, and in effect required regulatory approval processes for domestic products to apply the same rules to foreign products as they would for domestic ones.

The fact that the US is no longer a part of the TPP "does not mean that US intellectual property will receive less protection than the IP of other TPP members," said Vetere. "Everybody is still subject to the foundational IP protections in TRIPS. What's disappointing for US companies is that this is a lost opportunity to enhance or clarify certain rules that would have made sure that US intellectual property and regulatory data receive the highest level of protection from the members of the TPP."

She noted that 11 of the 20 provisions suspended by the latest version of the deal were on IP rules that the US was keenly interest in, most of which were related to patents or regulatory data protections. Further, the annex relating to pharmaceuticals and medical devices was also suspended, which would have been beneficial to those US industries.

Vetere said the suspended annex was similarly worded to how the US had negotiated deals in the past with individual countries, including Australia and South Korea. It was aimed at providing greater procedural fairness and transparency in the regulatory system for pricing and reimbursement, which was a priority for the medical device industry.

"Another goal for the US industry was to lock in greater procedural fairness and transparency protections in other countries to ensure that US medical innovations were treated fairly overseas," added Vetere. "The suspension of this annex sends a disappointing message about the priority other countries place on providing such due process and related protections."

"We now have an agreement where the US is no longer at the table setting the standards and rules that promote an innovative economy. The countries remaining at the table sent a message that they don't value the same rules US innovators do, and I think it's unfortunate we missed that opportunity," attorney Gina Vetere says. says.

While the US can still negotiate individually with countries in the TPP, which is something President Donald Trump says he prefers, American companies won't be able to benefit from the tariff-cutting provisions in the new deal. Vetere says this missed opportunity is another reason why the absence of the US from the trade deal is another major disappointment. And while it has trade agreements with a number of the countries that are part of the new TPP, the US could have achieved more if it was at the negotiating table.

That said, the US is still one of the most open markets in the world but the deal would have improved its access to other countries, according to Vetere. In particular, she noted that pharmaceutical and medical device companies see robust IP protections and transparency in health-care systems as important factors in providing certainty that their innovations will be protected.

"TPP would have helped increase that certainty for the US medical innovation industry," she added.

PUBLIC PUSHBACK ON MULTILATERAL TRADE DEALS

During the 2016 presidential election, Democratic primary candidate Bernie Sanders and then-candidate Trump vowed to pull out of the TPP deal, statements that were later echoed by Democratic general election candidate Hillary Clinton. While Trump's decision to leave the negotiating table was a campaign promise fulfilled, Vetere says the reason behind it seems to be that there was a groundswell push by the American public to take a new approach to global trade.

"Those of us who believe in free trade need to do a better job explaining [to the public] why our trade agreements are so important," said Vetere. "We now have an agreement where the US is no longer at the table setting the standards and rules that promote an innovative economy. The countries remaining at the table sent a message that they don't value the same rules US innovators do, and I think it's unfortunate we missed that opportunity."

In general, Vetere said free-trade proponents such as herself and those in various industries need to step up and find ways to better educate the public about the importance of being at the table helping to develop the rules of trade. She says hopefully that's a lesson they will keep in mind as the US looks to renegotiate the North American Free Trade Agreement (NAFTA) and other international trade deals.

Vetere pointed out that there seems to be a perception by the American public that trade agreements benefit foreign governments at the expense of the US, when in reality such deals tend to have more benefits for the US economy.

"The election definitely represented a groundswell of discontent about what many perceived as the fault of trade agreements," she said. "Job dislocation, job losses or other economic discontent can be attributed to a number of other factors, but trade agreements seem to be an easy scapegoat."

Asked whether the US may join TPP later, Vetere said it will depend on where the new TPP deal ends up. The US will have to see what the rules in TPP are and whether another trade deal ends up superseding it.

She emphasized, however, that the Trump administration has made clear that they are not interested in multilateral deals.

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Anthem Joins Other Large Insurers In 'Artificial Pancreas' Coverage

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Health insurance company Anthem Inc. announced Nov. 17 that it will cover hybrid closed-loop insulin pump/continuous glucose monitor (CGM) systems used to treat type 1 diabetes. The move means the US' 25 largest private insurers have all agreed to pay for the system, just 14 months after **Medtronic PLC** 's *Minimed 670G* became the first such device, which some call an artificial pancreas, to gain FDA approval. *(Also see "US FDA Approves First 'Artificial Pancreas' In Medtronic's MiniMed 670G" - Medtech Insight, 28 Sep, 2016.)*

Artificial pancreas systems consist of an insulin pump that is linked to a CGM that can automatically determine when and how much insulin a user might need. The device continuously delivers insulin to maximize the time the glucose levels are within the target range. The systems are expected to drive diabetic management device growth over the next several years. *(Also see "Advent Of Artificial Pancreas Tech To Galvanize Fast-Growing Diabetes Market" - Medtech Insight, 26 Apr, 2017.)*

Anthem, which is the second-largest insurer in the country, by number of members, had said in August that it considered the MiniMed 670G an "investigational" device and wouldn't cover it. The company reversed its decision after speaking with experts and reviewing additional information on the success of the system that was presented at scientific meetings over the summer, Medtronic spokeswoman Janet Kim says.

"Overall, the reception by payers has been positive towards our system with many major payers confirming coverage under existing insurance policies," Kim said. "We're pleased Anthem reversed their coverage policy after evaluating additional information presented at recent scientific meetings, additional feedback from diabetes specialists and information provided by Medtronic."

The Juvenile Diabetes Research Foundation (JDRF), which has helped to fund and promote artificial pancreas research over the past decade, also helped push Anthem and other insurers to cover the technology via the group's Coverage-2Control campaign. The foundation briefed insurers' health experts on the benefits of artificial pancreas technology, and also gathered more than 50,000 signatures on a petition advocating coverage, says Cynthia Rice, JDRF senior vice president for policy.

"When the first system was approved last fall, we swung into action and started planning to reach out to the companies to talk about the importance of the device and why it mattered to people with type I diabetes," Rice said. "To have the 25 largest plans by number of beneficiaries all covering it within months of market launch has been quite remarkable."

Federal health-care programs like Medicare and Medicaid don't yet cover artificial pancreas systems. Rice says JDRF has been "talking" to Medicare about coverage for CGM technology in general, but hasn't yet focused on the artificial pancreas itself.

"To have the 25 largest plans by number of beneficiaries all covering [the artificial pancreas] within months of market launch has been quite remarkable," says Cynthia Rice, JDRF

ANTHEM, OTHERS MEET BROADER DIABETES CARE GOALS

Anthem also adopted other reforms advocated by the JDRF campaign. For example, the company's list of preventive medicines now includes insulin, which helps cut out-of-pocket costs for diabetic treatment. Additionally, the company doesn't have exclusive contracts with medical device providers, which means members can choose where to buy supplies, Rice says.

Other insurers with diabetes care programs meeting JDRF's Coverage2Control criteria include Aetna; Blue Cross and Blue Shield plans of Alabama, Florida, Massachusetts, Minnesota, North Carolina and Tennessee; Health Care Service Corporation; Humana; Kaiser Permanente and Medica Health Plans, the foundation says.

In June, Medtronic entered into an agreement with Aetna in which reimbursement amounts are based on outcomes in patients with self-adjusting insulin pump systems. *(Also see "Medtronic Enters New Outcomes-Based Insulin Pump Deal With Aetna" - Medtech Insight, 26 Jun, 2017.)*

While the only artificial pancreas now available is Medtronic's MiniMed 670G, Rice says that's just a starting point. "Our goal is widespread access to the artificial pancreas system," she said. "We want to have multiple systems on the market. We want to have multiple generations of systems that are getting better and better and help people achieve better glucose control."

Additionally, Rice hopes to have artificial pancreas technology available for a wider range of people with diabetes. Only about a third of adult diabetics meet FDA's indications for use, she says.

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