Clinical facilities, doctors and engineers are crucial resources for any surgical medical device start-up pursuing disruptive innovation, and cardiothoracic surgeon and serial entrepreneur William E. “Billy” Cohn says he has them in multitudes in his new gig.

Admittedly, Cohn, who has invented the technology behind six venture-backed startups, is not in a typical start-up situation. In 2016, he was hired by Johnson & Johnson to start and run the Center for Device Innovation (CDI) out of the Texas Medical Center in his hometown of Houston. The idea is to have a start-up-like operation within the confines of Johnson & Johnson’s business.

CDI “has the incredible resources of Johnson & Johnson on its speed dial, and all the materials scientists, marketing folks and connection to the businesses, so we think we know what the customers want, and what the business needs,” Cohn said in an interview.

The center was founded out of Johnson & Johnson Innovation LLC, a subsidiary that is intended to act as an incubator for high-impact (and perhaps higher investment risk) life science innovations. CDI officially got off the ground last November, hired its first engineer in February and now has about dozen members on its team.

The Innovation business also launched the company’s JLABS several years ago to provide incubator space and collaborative opportunities for external entrepreneurs that may, or may not, end up having a long-term business relationship with the company.

JLABS “is an incredible accelerator for companies to come in and run their play,” Cohn said, but CDI is different. While the center agreed to house a few start-ups with aligned interests, the focus of the effort is to hire a diverse range of experts internally to Johnson & Johnson, with the end goal of producing disruptive technologies that the company will take to the market. (Also see "Interview: J&J Goes Big In Texas" - Medtech Insight, 24 Oct, 2016.)

On the one hand, the steady funding source from Johnson & Johnson makes this a decidedly more stable operation than a standard early-stage start-up, and, as part of that, CDI staffers must keep the fundamental business direction of the company in mind – they are not going to target clinical areas where Johnson & Johnson doesn’t compete and has no plans to compete. On the other hand, according to Cohn, his group has a lot of freedom and flexibility to pursue potentially transformational ideas that might be too experimental to get funding and attention within the conventional structures of Johnson & Johnson’s medical device businesses.

The type of pushback that Cohn says he wants to hear from a Johnson & Johnson business leader is “that won’t work because of this, this and this.” And I’ll say, ‘OK, look, here are 20 reasons why it might not work, and those three you named aren’t in the top 10. But if we can get it to work, would that be interesting?’ Because if you look at all the disruptive medi-

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MTI 100 Rankings
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FDA sees Alzheimer’s “breakthroughs”
Multiple technologies seeking to address Alzheimer’s disease have been selected for US FDA’s Breakthrough Device program this year, including, most recently, a three-biomarker assay to help distinguish patients with Alzheimer’s.

Implant cards in Australia
New Australian requirements are due to kick in on Dec. 1 for manufacturers of new permanently implantable devices to provide patient implant cards and consumer leaflets with their products.

Device Week
In the latest episode of our weekly podcast, Medtech Insight journalists discuss digital health innovations in cardiology, and they spotlight companies that are employing marine bioresources to innovate in medtech.

Cover / Exec Chat: Billy Cohn Talks About His J&J Play In Texas
– The surgeon and serial device inventor has been getting Johnson & Johnson’s Center for Device Innovation off the ground this year on the vast Texas Medical Center complex, and he says it’s like nothing he has ever experienced.

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8 Lots of Oversight But Little Legislation Expected If Dems Take House – Medtech and political experts agree the Democrats will likely take control of the US House after the upcoming election but, if they do, very little legislation will be able to get passed because of GOP dominance in the Senate and White House. But there will be plenty of oversight hearings.

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Temple Hopes To Be Center Of New Medtech Boom In Texas

REED MILLER reed.miller@informa.com

The Temple Health and Bioscience Economic Development District (THDB) is one recent example of a local government looking to the medtech sector to build local investment and start-up activity. THDB is based in Temple, Texas, a city with a population of about 73,000 about halfway between San Antonio and Dallas, 70 miles north of Austin.

"Our hope is to make this a medtech triangle. There are a lot of people working very hard to make that happen," THBD's executive director Tami Annable told Medtech Insight.

Annable said THBD’s three-year-old 5,000 square-foot facility in Temple is currently about 75% occupied. Its current tenants include: Advanced Scanners, a developer of custom 3D scanners for medical and scientific applications; NeuroFront Technology, which is developing a non-invasive stroke monitoring device; WashSense, which specializes in infection control devices and software; and SiMMo3D, which is creating 3D-printed training and simulation tools for medical education and device development.

"We’re small – we’re just a 5,000 square foot facility, [but] in my mind we’re a 'proof-of-concept,'" Annable said. "My job is to fill it and then go back to the board of directors and say ‘build me more.’"

In 2003, legislation passed at the state and local level allowed the city of Temple to create the THBD, the first such district to be created in Texas. It was founded as a collaboration of the city with several local hospitals, health systems and educational institutions, including Baylor Scott & White Medical Center, Texas A&M Health Science Center College of Medicine, Temple College, the Veterans Healthcare System of Central Texas, and Texas A&M’s Blackland Research and Extension Center.

"We bring these companies in, nurture them, and help them grow," Annable said. "They start to hire Temple employees … We’re going to make them love it so that when they outgrow our facility, hopefully, they will establish in Temple, and continue their business."

Temple also may be attractive for established companies looking for a relatively inexpensive place to expand. Texas has no state income tax and the cost of living is much lower in Temple than in Austin or Dallas. "You can come to Temple Texas and do business cheaper," Annable said.

The availability of public funding means THBD can offer start-ups very affordable rents – companies can rent office space in the THBD facility for as little as $500 – as well as seed-funding and equipment, if necessary. The facility has a common laboratory space with a state-of-the-art 3D printer, laser microdissection microscope, linear-torsion material testing system, an advanced nucleic-acid analysis system, and other tools that would otherwise be prohibitively expensive for most start-ups and researchers.

"The main thing that brought us [to THBD], as a start-up, is the cost of rent," Ryan Quinn, the CEO and co-founder of Simmo3D, told Medtech Insight. "Right now, we get an office and lab space for probably a tenth of the cost of what we’d be paying in Austin. It gives us a lot more runway and lead-time, plus the availability of all the equipment, the large-scale 3D printers, the mechanical testing machines - everything a start-up dreams about - all in one location." His company has especially taken advantage of THBD’s Stratasys Objet 350 Connex3 3D printer, which can print models with malleable materials that mimic human organs.

"We wouldn’t even be a company anymore if we didn’t have the THBD," he said. "We would probably have set up shop in Austin and probably be broke."

The proximity to so many physicians and researchers, some of whom also use the equipment in THBD, is one of the selling-points of Temple as a place to start a medtech company. "We’re as central Texas as you can get, which is fantastic … we’re surrounded by health care." THBD also sponsors webinars, symposiums, and other events to bring together medtech entrepreneurs, potential investors and the wider community.

Quinn said it still is not always easy to find people with the specific skills his company needs in Temple, so he has to bring them in from Austin. But "there are a lot of really good people in the area and we’ve been able to work with tons of the physicians through our product development."
cal devices that have come out in the past couple of decades, nobody thought any of them were going to work."

LOCATION, LOCATION, LOCATION
But Cohn says the most unique and advantageous aspect of the CDI is location. Specifically, he says, it’s the extreme efficiency in iterative design that is made possible by being housed at the TMC Innovation Institute, on the campus of Texas Medical Center, which bills itself as the largest medical complex in the world. Cohn, who has spent a lot of tinkering with new surgical heart devices and then moving them toward the clinic, sounds like a person truly in his element when describing the resources now at his disposal within a mile of what Johnson & Johnson is calling the CDI@TMC.

In particular, he emphasizes how fast his team has been able to move from the prototyping face to conducting animal experiments to clinical studies. "We can go and watch surgery, we can have the surgeons come into the pre-clinical lab with us. We can have them come over to the prototyping facility and weigh in on design features and functionality," he says. His team can also take the device prototypes to TMC operating rooms to have surgeons handle them and perform bench top, pre-clinical and animal experiments with them," he said.

"We can get a bunch of doctors together and have them argue about which prototype they like best. Then refine that and take it into them. All without buying a plane ticket."

Once the collaborators decide a prototype is ready for pre-clinical testing, Cohn said, "We can make a phone call, and schedule it three to four days from then," rather than having to fly multiple doctors in and make arrangement with an outside lab, which can take weeks to months.

"We are taking shots on goal on a weekly basis. Kicking ideas to the curb that don’t work. Doubling down on those that do," he said. "I have never been involved in an effort that combined the resources of a large health tech organization like JNJ, the sense of urgency and speed of a med-tech start up, and the unparalleled resources of the TMC."

A DIGITAL ‘EUREKA’ SOUGHT
CDI currently has five projects going that it says have shown early promise to have a big potential impact in health care and have some buy-in from a Johnson & Johnson device business division.

The focus of the projects is under wraps. While surgical and implantable devices are clearly a passion and specialty for Cohn, there is at least one of the five projects that is "pure digital," he said. He didn’t provide more details than that on the focus of the project.

The company says it is generally looking for digital-based solutions to enhancing pre-op, OR and after-procedure care. It has been adding digital tools to its portfolio that are intended to complement its devices employed in the OR. In April, it acquired C-SATS, which developed a cloud-based system that provides feedback to surgeons to improve their skills, leveraging cameras in the OR, expert reviews and artificial intelligence. (Also see "DePuy Synthes’ Measured Path To Building A Digital Surgery Capability" - In Vivo, 23 Jul, 2018.)

And, last November, it acquired Surgical Process Institute, which markets a digital surgical workflow system that attempts to standardize procedures with step-by-step checklists. (Also see "The Tailor Will See You Now – J&J’s EMEA VP Explains Total Care Partnership For Hospital Systems" - In Vivo, 19 Feb, 2018.)

There are a lot of digital-focused efforts in health care right now, and many of those may not transform patient care. But Cohn is clearly excited about the prospect of finding a way to employ digital tools to truly change how clinicians and patients engage with the system. He cites the highest profile Silicon Valley industry disruptors as models that he seeks to emulate.

"Somebody sitting down with a notebook and a pen came up with Uber, or Airbnb, leveraging something that everybody had in their hand, and disrupting a business," he said. "Right now, everybody is trying to see what that looks like in medicine. And everybody’s saying, ‘I know, we will put a chip in this and it will tell you that.’

‘And it is like, yea, you can do that, but it is not Uber. But there are medical Ubers out there that no one has had the ‘eureka’ about yet. If we are thinking about them all the time, maybe it will be us.”

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Device Industry Champion Erik Paulsen In Tough Election Fight To Retain House Seat

SUE DARCEY sue.darcey@informa.com

Device excise tax repeal sponsor Erik Paulsen, R-Minn., may be facing the political challenge of his life in the race for his District 3 House seat against businessman Dean Phillips, according to pollsters. *Cook Political Report* shows Democrat Phillips running ahead of Paulsen.

Paulsen is a five-term incumbent representing a well-to-do suburban area west of Minneapolis/St. Paul, a hot-spot region for the global medical device industry. Paulsen has garnered tremendous support from the industry for his attempts to permanently end the excise tax and promote more favorable reimbursement policies for medtech products, among other issues.

The congressman sits on the House Ways and Means Committee, and this year sponsored H.R. 184, a device tax repeal bill, which passed the House on July 24 by a 283-132 vote that included 57 Democrats. (Permanent repeal hasn’t passed the Senate, but the tax is suspended until 2020.) He also sponsored a provision of the Opioids Crisis Response Act originating as the PROPER Act requiring education for Medicare beneficiaries on device pain control alternatives; that bill was passed by Congress earlier this month, and President Trump said he will soon sign it. *(Also see “Sunshine Provision Retained In Opioids Bill Compromise” - Medtech Insight, 26 Sep, 2018.)*

Paulsen’s challenger, Phillips, inherited and managed his family’s distilling company, and co-founded the gelato company, Talenti. Phillips has been touting his opposition to a Republican tax reform bill that Paulsen helped write. It was signed into law in 2017 and lowered corporate taxes. Phillips argues it has not been as helpful for the middle-class families in the district he represents.

Paulsen is one of the few Republican House members who have been talking publicly about the benefits of the tax reform law, mentioning it in 37% of his campaign ads, according to data from the *Wall Street Journal*.

**POLLING GROUPS PLACE PHILLIPS AHEAD OF PAULSEN**

The *Cook Political Report*, as of Oct. 4, had placed Phillips ahead of Rep. Paulsen in the suburban twin cities district where the two are running. The Cook group listed Phillips as running one point ahead of Paulsen, and the race as “leaning Democratic.” Also, an earlier *New York Times*/Siena poll showed Phillips in front of Paulsen, with Phillips being favored by the district’s voters by 51% compared to Paulsen’s 42% favorable rating, according to an analysis by Cook’s David Wasserman.

Meanwhile, both politicians have been running, in some cases amusing, attack ads against each other, with Paulsen saying that Phillips did not purchase health insurance for his coffee-shop workers. Phillips has defended himself during local news programs by pointing out the workers at his shop were all part-time employees.

In the pro-Phillips ads, the businessman states that Paulsen is closely aligned with President Donald Trump’s positions on taxes, and against the interests of women. Another Phillips ad features a “Big Foot” character searching for Paulsen on the job, a character who claims that the congressman is always “missing” and can’t be sighted – except when you look for him at big pharmaceutical companies.

**FUNDRAISING NUMBERS SOMEWHAT SIMILAR**

Both Paulsen and Phillips have managed to raise millions to spend on their election campaigns. Paulsen, the incumbent, has raised a total of $3.82m and spent $1.49m for the 2018 campaign as of July 25, according to the Open Secrets website that uses data from the Federal Election Commission. Meanwhile, during the same period, Phillips raised $2.46m and spent $1.62m, Open Secrets reports.

Data drawn from the same website the week of Oct. 7th, shows that device companies contributed $72,400 to Paulsen’s campaign via political action committees and from individuals within device firms. Paulsen also received $212,150 from pharmaceutical manufacturers – the sixth highest amount received by any candidates for the House or Senate in the 2018 election cycle from drug companies.
Lots of Oversight But Little Legislation Expected If Dems Take House

FERDOUS AL-FARUQUE danny.al-faruque@informa.com

Democrats are likely to win a slim margin in the US House come Nov. 6 but will unlikely be able to push through significant legislation due to Republican opposition, according to a panel of experts at the recent MedTech Conference in Philadelphia. Among policies Democratic lawmakers historically would be expected to favor are tighter US FDA oversight of the device industry. In the absence of legislative pathways, they are likely to focus on oversight investigations of US FDA and other agencies, and on the implementation of the Affordable Care Act.

The lobby group AdvaMed brought together top federal government and industry experts to discuss how the upcoming midterms are likely to shake out and what the medtech industry can expect in the new Congress.

The panel was moderated by Greg Crist, AdvaMed’s incoming chief advocacy officer and included Charlie Dent, a former Republican congressman from Pennsylvania; Walt Rosebrough, CEO of Steris; Elizabeth Pika Sharp, AdvaMed’s managing director for government affairs; and Jennifer Nieto, VP of federal affairs at the California Life Sciences Association.

**NUMBERS FAVOR DEMOCRATS**

Currently, both chambers of Congress and the White House are controlled by Republicans, but the midterm elections are expected to change that. The GOP has a 23-seat majority in the House of Representatives and 51 seats are up for grabs come the first Tuesday of November. According to the latest numbers from the Cook Report, Democrats have 182 safe seats against the GOP’s 145 safe seats. There are 44 GOP seats that are considered toss ups or worse and of those at least 13 are at a serious risk of going Democrat. Democrats only need 23 seats to pick up the House.

According to FiveThirtyEight.com, there is a 78% chance Democrats will take control of the House and about 80% chance they will gain between 16 and 56 seats.

Dent says it’s clear that the GOP is at considerable risk of losing the legislative body and added historically the party in power on average tends to lose 32 seats during midterms.

“So, the Republicans are completely on defense in the House, the Democrats are only defending at best 13 seat and I would say of those only three are truly competitive maybe up to five,” Dent said.

By contrast, however, the Senate, where the GOP has a slight majority, is likely to stay in Republican hands. Only one-third of the upper house is up for elections or 33 seats. Of those, Dent says Democrats are unlikely to take the chamber unless they are able to flip Texas and Tennessee, but the polling numbers are not in their favor right now.

But not everyone on the panel is as sure about what the future will bring. While Rosebrough doesn’t disagree with Dent, he says recent political prognostication have failed so miserably that he isn’t as sure about how the midterms will play out.

“…”No matter what we think is happening, lately it seems to go a different way so … God only knows what’s really going to happen,” he said.

AdvaMed’s Sharp also didn’t want to venture a guess which way the political winds are going to blow come election day.

“I totally agree [with Rosebrough], I think we’ve come to expect the unex-
peceted,” she said while adding that what is already a contentious election is expected to only get more contentious.

**PEERING INTO THE CRYSTAL BALL**

If Democrats do take the House, and the Senate stays in GOP hands, Dent says the first bill proposed by the Democrats will likely be one protecting Robert Mueller from getting fired by President Trump as the Justice Department investigator continues to probe potential links of collusion between his campaign and the Russian government in the 2016 elections.

However, after that, Dent says Democrats will likely propose a bill to stabilize the health-care market, which would require providers, insurers and potentially pharmaceutical companies to pay for managing rising health care costs. The third and fourth bills he argues are likely to be focused on immigration reform and an anti-harassment bill as a response to the #metoo movement.

Sharp says the only bill she would add to Dent’s list is one that would deal with ensuring insurance coverage for preexisting conditions that could be rolled up into a market stabilization bill. Republicans have been trying to end a provision in the Affordable Care Act that mandates insurers accept customers with preexisting conditions.

Dent said that if Democrats take the House they are likely to push for incremental changes to the US health-care system, knowing they don’t have the ability to make major changes such as "Medicare for all" or a single-payer system.

"A lot of people like to talk about health care, but I don’t think anybody wants to do anything really big," he said.

He also expects there will be a lot of hearings on why cost of health care is rising which will create strife within the health care industry.

"They’re going to try pit you against each other in a very public way so just get ready for that," Dent added. "There’s going to be a lot of internal messy warfare among some of your friends and allies."

**FOCUS ON OVERSIGHT**

Dent says if Democrats take the House, there is likely to be a lot of oversight investigation into the government’s handling of the Affordable Care Act as well as various government agencies such as FDA. However, those regulatory oversight hearings are not necessarily going to result in a lot of legislation, since Republicans are still likely to control the Senate and would need the president to sign off on bills.

Though oversight sometimes does lead to legislation, Sharp agrees Democrats are not likely to be able to do oversight as well as push out legislation that has a chance of becoming law because of the political climate. In health care, a big focus for Democratic legislators will be how the ACA has been implemented. Another area she says will directly affect the medtech industry is hearings on the oversight of FDA, which Sharp notes happens all the time regardless of who’s in power.

"I’m not predicting that a lot of bills are going to get done in the new Congress," Dent added. "I think oversight will be the order of the day, they’ll be pounding their shoes and then in 2020 depending on who wins the presidency, that’s when it gets really interesting in terms of legislation that actually crosses the finish line and gets signed into law, but I wouldn’t expect a lot signed into law in the new Congress."

Outside of medtech, Dent also said Democrats are likely to take a stab at Medicare Part D pricing with legislation challenging the non-interference clause in the Medicare Modernization Act. He predicts they will try to move to a more government-set pricing system, rather than let the pricing be negotiated between the insurance plans and the pharmaceutical industry.

"I think they’re going to go after health care costs generally and they’re going to put everybody on the barrel," he added. "There are going to be subpoenas flying in every direction, it’s going to be really messy for a lot of folks in health care I think."

Rosebrough says that health care is typically a non-partisan issue but the climate in Washington has changed, making it a very partisan topic.

If the GOP were to maintain control of the House, Dent says they would likely to try make permanent many of the provisions in the recent tax law and at least extend the device tax moratorium and tie it in with other tax issues. In addition, he said, they would likely go "hog wild" on fighting the opioid crisis.

**BACK TO THE DEVICE TAX**

CLSA’s Nieto notes the Republican and Democratic leaders in the House are from California where health-care accessibility and affordability has been a priority for both parties regardless of who is in control after the dust settles in November. She said the California Life Sciences Association has been working with its 55 members of congress to push their priorities.

"Hopefully, we can make them champions [for medtech] on the first day when they are sworn in," she added.

One issue that has been looming is the 2.3% medical device excise tax, which was intended to raise $20bn over a decade to help fund the Affordable Care Act. Lobby groups such as AdvaMed have been trying to repeal the tax for several years but have only been able to get moratoriums so far temporarily delaying its implementation.

"I’m not complaining about the fact we got an extension, it’s better to have an extension rather than not have an extension," said Rosebrough, while lamenting that the tax has not been repealed yet. He said unlike bigger compa-
nies like Steris and Johnson & Johnson that are financially well-established, smaller companies in the medical device ecosystem are unlikely to fare as well if the tax returns. Lobby groups have argued the tax disproportionately hurts smaller medtech companies that are critical to helping bring new innovations to the market.

Rosebrough echoed that sentiment by stating bigger companies rely on much of their innovation and argued the tax has already made venture capitalists warier of investing in smaller companies. For larger companies, he argues the tax is still harmful as it factors into whether they decide to make long-term investments in areas such as new factories and R&D.

Dent said during the most recent fight in congress to repeal the device tax, he was disappointed that the tax was decoupled from the Cadillac tax; an ACA excise tax on high-cost employer-sponsored health plans. While the Cadillac tax is on hiatus until 2022, the device tax is only on hold till 2020.

Since Democrats were strongly against implementing the Cadillac, tax which is intended to raise $170bn over a decade, Dent said that if there is no full repeal of the medical device tax, it is likely to get recoupled with the Cadillac tax to extend the moratorium.

"It's going to be all right because we're going to end up tying these two back together again at some point when we have to revisit the tax extenders," he said.

When asked about the potential for new legislation that impacts the medtech sector during the "lame duck" session (the period after the election and before the new Congress is sworn in), Sharp said lame ducks are always hard to predict. However, she is optimistic that Democrats and Republicans are aligned on certain issues, such as the device tax repeal, that Congress may be able to address before the new lawmakers take their seats.

Regardless of who wins, Nieto says legislators will need to work together because of the narrow advantage that any party will have.

"Hopefully we can work with Democrats and Republicans, because whether Democrats or Republicans are in charge, it's going to be a narrow majority, so they're really going to need to hopefully be bipartisan," she said. "And we would really want to make sure that if there's an effort to stabilize the markets and make things more accessible and affordable, that they're doing it without dismantling the intellectual property system or [with] price controls."

"The UK leads 20% of the centralized authorizations including a lot of the most difficult ones," says Jonathan Mogford, MHRA.

"What hasn't moved on is the fundamental question that has been asked for quite some years now, which is what do we actually want to happen. There isn't a discussion going on at the moment about... how to get a positive outcome out of what is a rather disappointing thing that is happening in my view."

"I think there are some pretty big things that need now to be negotiated and probably fast. It is perhaps disappointing that there really hasn’t been a discussion on anything other than no deal and [the UK ending up as a] third country."

Mogford reiterated that the primary objective for the UK government, the MHRA and also the pharmaceutical and medical device industries, is that after Brexit there should be an ongoing close regulatory partnership with the EU in which the UK continues to play an active role.
role. “Patients in the EU27 and the UK have been well served over the last 30 years by a regulatory regime which has brought everybody together,” he noted.

**DISPROPORTIONATE CONTRIBUTION**

Mogford reminded delegates at the symposium of the disproportionately large contribution the UK makes to the EU health-care products regulatory regime.

For drugs in the EU “we lead 20% of the centralized authorizations including a lot of the most difficult ones,” he said. “We lead approaching half of the nationally led decentralized work” and “we’ve got one of the strongest if not the strongest signal systems in Europe with the yellow card, 40 years of it.”

The MHRA policy director added that UK regulators had “corporate knowledge of 30 years of products, because if you lead the decentralized process you then become the lifetime lead regulator for about 3,500 products on the EU market.”

It doesn’t stop there. The UK produces “90% of the world’s international biological standards,” and it has “the single largest inspection force,” Mogford said.

Regarding medtech, Mogford said that “five of the active notified bodies in the EU are regulated by the UK, and we reckon… about 50% or 60% of CE-markings for the highest-risk medical devices are from UK notified bodies.”

**BIG UNCERTAINTIES**

There are still “some big uncertainties” about the outcome of the Brexit negotiations against the primary negotiating objective that the government set out in July 2017, Mogford said.

He noted that the work going on in the UK basically comprises three blocks of activity.

Firstly, there are preparations for the UK’s withdrawal from the EU and a no-deal situation that will result in the UK operating as a third country.

Secondly, there is preparation for an implementation period, which if ratified will result in the UK remaining in the EU system but essentially on an observer basis.

Thirdly, work is ongoing around the future relationship and the preferred outcome. “But obviously also there are fall backs if the EU doesn’t want that preferred outcome,” Mogford noted.

“In terms of how this is going to pan out I have absolutely no idea,” the MHRA policy director conceded, but the next few weeks would be critical.

One of the things the UK has been wanting to do is to encourage those who are interested in a continued close regulatory partnership to “make sure that you are making that voice heard and that there is focus given to that in a space where actually pretty much all the attention is on ‘no-deal’ contingency preparations,” Mogford declared. “It’s really important that that discussion about the positive potential of regulatory frameworks also happens.”

In the meantime, the MHRA policy director said the UK would continue to make sure that “practically we’re ready for the two practical scenarios” for March 29, 2019, when the UK leaves the EU. These are either an implementation period operation or a no-deal scenario.

Regarding an implementation period, Mogford said that “in process terms” this would be “relatively straightforward and relatively simple to prepare for.”

As for a no-deal Brexit, he noted that the government had recently published technical notices on how such a scenario would need to be handled. “There will be an entirely pragmatic sense which makes sure that products, both pharmaceuticals and devices, continue to flow to the health systems and to the patients,” he said.

“We simply do not see that you can say to patients in the UK that products that were in good regulatory standing on Brexit day minus one suddenly… becomes bad regulatory standing on Brexit plus one.”

“Clearly, we have a public health job to do as a national regulator, but the guiding principle is to make sure that patients get the products that they need.”

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Since the early days of Brexit, Phil Brown, director of technical and regulatory activities at the Association of British HealthTech Industries (ABHI), has been resolute in his assertion that the political situation may well produce opportunities for the sector. However, the prospect of the “no-deal” scenario has tempered this optimism – at least in the short to medium term, he says.

**THREAT OF REGULATORY DIVERGENCE**

The prospect of no formal agreement between the UK and the EU raises the chances of early regulatory divergence, Brown warns in an interview with Medtech Insight. “The minimum burden and disruption for the industry is better served by alignment with EU regulation; a view mirrored repeatedly by our members. Any divergence will add to the burden and disruption,” Brown said.

To this end, the UK, European and indeed, the global medical device industry, have sought clarity on the regulatory platforms that will be operated by the MHRA from day 1 of Brexit in 2019.

While a recent consultation preamble and Technical Note from MHRA clearly identify the Medical Device and IVD Regulations as the initial route to placing products on the UK marketplace, a no-deal outcome would immediately bring into question how amendments, implementing and delegated acts, guidance documents and other resources would be managed, Brown said.

The potential and consequential regulatory divergence from the Medical Device Regulation would be a real worry to industry, unless suitable mutual recognition agreements are forged with Europe, or if the MHRA introduces appropriate mechanisms for “revision control.”

**EU STANDS TO LOSE OUT TOO**

The current influence of the UK’s MHRA in the application of European regulations should not be underestimated, Brown argues. The pragmatism that the UK authority brings to the overall regulatory debate is well recognized. UK officials have been major players in the creation of both the Medical Device Regulation and its forebear, the Medical Device Directive. Furthermore, the UK’s input into the development of the Competent Authorities for Medical Devices group and the Medical Devices Coordination Group to support the new regulatory platforms has been critical in the adoption and implementation phases so far. The potential for the UK to be outside of this process in the future will have negative implications for both the UK and Europe, Brown said.

**RISKS TO EUROPEAN HEALTH?**

It is not only the UK legislative process that may be disadvantaged in the event of a no-deal, he noted. The Medical Device Regulation places great emphasis on the provision of robust post-market surveillance practices through the EUDAMED database and overall transparency of data.

Of course, manufacturers intending to place CE marks on products will have to follow the EU regulations in any event – or the UK statutory instrument implementing them, which is set to change. But will the UK be obliged to input device information into EUDAMED? Will the MHRA have visibility of European vigilance issues as a result? And how will communication and transparency of potential health issues across Europe be maintained? These questions have yet to be answered. It is no secret that the UK is a major contributor to the overall European vigilance and post-marketing surveillance effort. Any lessening of this activity has the possibility of restricting the ability to get early warnings of device failures and patient safety issues for the UK and EU 27.

Brown suggests that maximum effort should be made to ensure the MHRA has continued input into these systems, which have been the driving force for the development of the new regulation, to enhance patient safety rather than diminish it.

**FUTURE MHRA**

As a standalone regulator, under a no-deal Brexit, MHRA would likely need additional resources to cope with the workload normally shared with other EU institutions, Brown argues.

He goes on to say that this comes at a time when industry is struggling to find appropriately qualified experts to manage their own regulatory compliance commitments. He also questions whether the agency risks being overwhelmed with work as a result of a no-deal, or whether it will have to re-think the way it manages its role. Any dilution of its current role will no doubt lessen the world-renowned credibility the MHRA presently enjoys, unless it plays a wider, more global game, Brown asserts. But this is a longer-term aspiration that will come at a high cost of resources.

**ABHI EFFORTS**

Although the UK Government is stressing that a no-deal is the least likely outcome of the current negotiations, ABHI has been busy trying to attract European support for its Brexit message, Brown explains. Discussions with European trade association partners in France, Germany, Spain, Italy and Ireland are at an advanced stage, with the aim of preparing joint statements on regulatory and trading alignment.

He is also keen to stress that the ABHI has been working closely with MHRA and other government departments to ensure that the UK medtech industry is not disadvantaged by Brexit – no-deal or deal – and continues to do so. While hurdles and difficult questions remain, he said, opportunities are always being sought.
Industry Still Not Sufficiently Ready Or Engaged With EU MDR, Survey Shows

AMANDA MAXWELL amanda.maxwell@informa.com

In total, 29% of European respondents and 45% of North American companies who took part in the most recently publicized survey on preparedness for the new EU medical device requirements were "not very confident" about being able to meet the regulatory deadline for the EU’s Medical Devices Regulation (MDR).

These figures emerged in a survey, “The Race to EU MDR Compliance,” conducted by professional services firm KPMG and the Regulatory Affairs Professional Society (RAPS). The survey also found that companies with higher revenues are more likely to feel they understand the regulations and will be able to meet the 2020 deadline.

The survey collected data in June 2018 from 220 regulatory affairs or quality assurance professionals from a variety of medical device organizations, split evenly between small, medium-sized and large organizations. The approximate geographic distribution of the respondents is: 45% from North America, 45% from Europe, 6% from Asia, 2% from Oceania and 1% from the Middle East.

When asked "how well does your organization understand the MDR regulation and timeline for implementation?” 8% confessed to having not yet even read the MDR. Another 33% said they understood the regulation at a basic level. (See Figure 1.)

These statistics come at a time when EU decision-makers at the European Commission and the competent authorities are mulling over calls from the EU industry that the deadlines and conditions for implementation of the MDR and IVDR need to be amended to give industry sufficient time to meet the new requirements.

The new survey results suggest that many companies have barely reached the first stage of preparing for compliance. When it comes to the vital step of conducting a gap analysis between their current regulatory status and the upcoming requirements, the survey found:

- A total of 43% of respondents have not yet started a gap analysis
- 53% of smaller organizations have either not arranged the time/resources for the gap analysis or have just created a plan for doing one
- Only about 7% of larger firms have still to conduct a gap analysis
- 65% of European organizations surveyed have started a gap analysis versus 51% of North American firms, and 36% of Asian companies.

FIGURE 1
How well does your organization understand the MDR regulation and timeline for implementation?

<table>
<thead>
<tr>
<th>Percentage Of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>My organization has not read the MDR at this point in time</td>
</tr>
<tr>
<td>My organization understands the regulation at a basic level, cross-functionally</td>
</tr>
<tr>
<td>My organization understands the regulation at a moderate level, cross-functionally</td>
</tr>
<tr>
<td>My organization has a deep understanding of the regulation and has prepared a strategy for addressing its impact on our business</td>
</tr>
</tbody>
</table>

Source: KPMG/RAPS

CLINICAL DATA HIGHLIGHTED AS MOST CHALLENGING ASPECT

In all, 58% of respondents described clinical data as a "significantly more challenging" aspect of the new regulations. This compared with just 8% of respondents that reported "understanding reclassification criteria" as the most significantly challenging element. The other elements of the regulations assessed were manag-
FIGURE 2

Compared to current MDD requirements, how challenging do you anticipate the following areas will be under the new regulations?

Clinical Data

Managing Legacy Devices

Understanding Re-classification Criteria

Managing Potentially Hazardous (e.g., CMT) Materials

Working With Notified Bodies To Agree To The Requirements

In all, 18% of respondents to the survey indicated that they would be retiring more than 10% of legacy products, while at the other end of the scale, 35% of respondents indicated they would not be withdrawing any at all. (See Figure 3, next page.)

These figures reflect the findings of a previous survey conducted in the US, the outcome of which was publicized over the summer, where 35% of the 169 respondents said they would not be withdrawing any legacy products. In that survey, 17% of respondents said they would be retiring over 10% of legacy products.

Additional figures that emerge in the KPMG/RAPS survey are:

- 78% of medical device companies do not have a sufficient understanding of EU MDR.
- 58% percent of all respondents said they had no strategy in place to remediate gaps in their clinical data or processes for collecting data and 17% were unaware of the upgraded and more stringent requirements as prescribed by the EU MDR.
- Only 25% were actively collecting clinical data and felt confident to be able to address this requirement.
- 41% of companies have not evaluated long-term maintenance to maintain EU MDR compliance.
- 9% of respondents were unaware of the need to have a person responsible for regulatory compliance. Only 21% had identified and documented the role – with larger companies more likely than smaller to have identified individuals, and companies in North America behind those in Europe in preparing to fulfill this requirement.
- The greatest barriers to MDR compliance were found to be the understanding of the regulation itself,
followed by the number of designated notified bodies.

RECLASSIFICATION
When it comes to whether organizations have assessed their product family and determined their reclassification plan, 27% of respondents said they have not performed a gap analysis on product risk classifications, but 26% said they have performed the analysis and "have a robust plan in place to manage reclassification." (See Figure 4.)

KPMG and RAPS suggest in the report that medical device makers should evaluate their products’ clinical evidence right away to see if there are any gaps and develop a remediation plan; address changes that need to be made in the recertification process for existing products; and build cross functional teams from quality assurance, supply chain management and regulatory compliance.

The authors note that establishing proactive systematic and sustainable processes for collecting information from both a pre- and post-market standpoint are critical for maintaining compliance with the MDR.

When it comes to the revamped EU medical device database that is being developed, RAPS and KPMG warn that the database may not go live until after the May 2020 EU MDR deadline. If this is the case, the authors remind the industry that manufacturers will not have a reprieve from collecting required data, but instead will have six months from the go-live date to submit the backlog of data.

In particular, they advise that to meet the EU MDR deadline, companies should accelerate strategic decision-making on issues with long lead times such as headcount, staffing, labeling, product roll-outs, clinical guidelines and documentation.

Companies should also simultaneously evaluate their technical file structures for consolidation opportunities, as more frequent updates and maintenance of technical documentation will be required post-2020, the survey report says. This will help reduce maintenance costs and efforts for maintaining not only technical files but also associated clinical and safety documents.

Further, firms should evaluate their overall product portfolios to ensure that the return on investment for new and existing products can be justified vis-à-vis the costs of the EU MDR implementation and life-cycle maintenance.

The survey has also looked at the percentage of companies surveyed that have achieved certification to the medical device quality system standard, ISO 13485: 2016.

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US Senators Question FDA's Pre-Cert Program Authority, Concerned About Safety

FERDOUS AL-FARUQUE danny.al-faruque@informa.com

Three top Democratic Senators on the US Senate Health, Energy, Labor and Pensions Committee (HELP) want answers on US FDA's planned pre-certification program; they've sent Commissioner Gottlieb an extensive list of questions on the subject. The lawmakers are concerned the agency may be moving forward without proper statutory authority and are concerned the program may not provide the oversight needed to ensure medical software products meet the agency's level of safety and efficacy.

The agency has been developing the program, which remains in a pilot phase, for about the past two years. The concept was for FDA to let software developers bring SaMDs to market based on how much FDA trusted them to produce "excellent" products rather than having to review each individual piece of software or software update that a company puts out.

Since then, the regulatory agency has moved swiftly to put together a pilot program with nine participants including major multi-national corporations such as Apple Inc., Samsung Electronics Co. Ltd., Johnson & Johnson and Roche. The evolving working model for the program would have FDA vet the software design and quality processes at companies as a basis for pre-certifying the firms. Depending on the pre-certified company's track record and the risk level of the software, products from the firm would qualify for some level of reduced, or potentially eliminated, pre-market requirements.

SHOW ME THE STATUTES

In response to prior questions raised by industry stakeholders about FDA's statutory authority to get the program launched, FDA has stated it is focused on developing the program in a manner that will comport with its current authorities. (Also see "US FDA’s Software Pre-Cert Program: Is The Authority On The Books?" - Medtech Insight, 31 Jul, 2018.) Murray, Warren and Smith said they understand FDA's attempt to develop a more agile regulatory paradigm for software as a medical device (SaMD) but are "unclear" on the statutory basis for developing the pre-cert program.

The lawmakers say that while FDA says it plans to launch the testing phase of the pilot program by 2019, based on the agency's most recent working model, they are not sure what specific statutory and regulatory authorities the agency is using to justify the pre-cert program or if the agency thinks it will need new authorities beyond the pilot.

While FDA has moved quickly with the ambitious plan and generally received praise from industry, some questions have been raised about whether the program can fit within FDA's current statutory authority. Now, it's attracted the attention of lawmakers on the Hill who are questioning the agency's authority to move forward with the program. Senators are also scrutinizing the funding required to get it off the ground, how third-party reviewers will be used to evaluate companies in the program and the agency's authority to let those third-party reviewers do what is supposed to be FDA's job.

In a letter to Gottlieb dated Oct. 10, Rep. Patty Murray, D-Wash., ranking member of the HELP committee, along with Reps. Elizabeth Warren, D-Mass., and Tina Smith, D-Minn., who are also on the committee, say that while they support FDA's ongoing work to accommodate digital health products, they want to ensure any changes to the agency's regulatory framework is in compliance with statutes and does not compromise public safety.

"The agency should be focused on ensuring it has the tools and capacity to guarantee that software products that perform medical device functions are safe and effective and to hold companies that skirt the rules accountable," the legislators wrote. "Instead, the Pre-Cert Pilot focuses heavily on the potential of standards for design, validation, and maintenance of software and the ability to capture post-market data to reduce premarket review time or eliminate the need for premarket review all together."

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DEFINING EXCELLENCE
They also wrote they are particularly concerned about use of "phased market authorization." That’s a topic the agency has asked stakeholders for feedback on where some elements of the SaMDs should be reviewed pre-market, while others are reviewed post-market to support full market authorization. The idea aligns with FDA’s ongoing work to create a more robust real-world information network, with the nascent National Evaluation System for Health Technology (NEST), to allow more flexibility where some data requirements would to be shifted to the post-market realm.

"It is again unclear what statutory authorities FDA would rely on to establish a 'phased market authorization' program that allows SaMDs to be legally marketed without sufficient evidence to support full market approval," said the lawmakers.

The premise of the pre-cert program is FDA would accept that a company meets a certain level of "excellence" that would give the agency confidence to allow the manufacturer to get their product to market without the agency having to fully review each of its products. However, defining what constitutes excellence is something the agency has been grappling with from the beginning.

FDA held a public workshop at the National Institutes of Health headquarters in Maryland and has sought feedback from stakeholders at various conferences, including the most recent MedTech Conference in Philadelphia, to help define the elements that prove a company meets the necessary threshold for organizational excellence. It has also stated the elements need to be flexible over time as the agency tries to better understand what metrics are most valuable. (Also see "Coming Together On Pre-Cert: Digital Health World Engages With FDA To Hash Out Regulatory Future" , 6 Feb, 2018.)

The lawmaker say they are concerned that whatever requirements the agency develops may still not be enough to ensure products getting to market meet the necessary level of safety and effectiveness to protect the public.

"FDA states a belief ‘that there should be flexibility in the specific mechanisms by which excellence can be demonstrated,’ write the congresswomen. "While it is entirely appropriate for FDA to solicit this feedback, we are concerned that the standards of excellence the agency is considering and the process for assessing this excellence may not establish sufficiently rigorous criteria for qualifying for a streamlined review.”

PASSING THE BUCK?
Another part of the proposed pre-cert program that lawmakers take issue with include what they say is an expansion of companies and products that may be eligible for the program. They note the agency initially said back in April that it would look at its past experience with a manufacturer as a metric for demonstrating organizational excellence. (Also see "FDA Readies Digital Health Pre-Cert Program For Lift Off" - Medtech Insight, 26 Apr, 2018.)

But that seems to have broadened with the working model in June, where the agency said "any organization" could be eligible for the program, and even moderate and high-risk devices could get to market through it. FDA’s proposed use of third-party reviewers in its working model is also a concern for the lawmakers. (Also see "Size Doesn’t Matter: US FDA Refines Dig-Health Pre-Cert Model!" - Medtech Insight, 19 Jun, 2018.)

"The use of third-party review to qualify companies for participation in the pre-certification program could mean that SaMDs could be legally marketed without FDA ever reviewing either the medical device software developed by a company or the company itself,” they write. "FDA has not yet articulated the statutory authorities it would rely on to utilize third party review in this manner or identified circumstances where such review may be inappropriate.”

Murray, Warren and Smith specifically are asking for clarification on how third-party reviewers will be accredited, how the agency intends to audit the reviewers and what statutory authority the agency is citing. They also are concerned the agency in effect may be setting up a "self-policing" review system where it will be hard for FDA to ensure companies are complying with the goals and requirements of the pre-cert program.

Finally, another major concern raised by the lawmakers is where FDA intends to get the funding to launch the pre-cert program, noting there is no such funding specific to the program. They worry it could reduce funding FDA has for other initiatives or require new user fees specifically for digital health products.

They are asking Gottlieb to respond to their extensive list of questions by Nov. 9.

FDA spokeswoman Stephanie Caccomo said the agency will directly respond to the Senators’ questions but noted the agency is still working with various stakeholders to design the pre-cert pilot while at the same time trying to execute it within the agency’s existing statutory authority.

"We have been transparent about our proposed working model for the program, including seeking public feedback, and will be publishing the next iteration in December," she added. "We will continue to solicit public feedback as we continue developing the pre-cert program throughout 2019.”

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What Should You Be Earning?
Salary Benchmarks And Hiring Trends In Regulatory Affairs

AMANDA MAXWELL amanda.maxwell@informa.com

Nearly as many companies initiated a hiring freeze on regulatory staff or were downsizing their regulatory staff in 2017 as were increasing their regulatory staff, according to a recent survey from the Regulatory Affairs Professionals Society.

Among the 2,305 respondents, about 17% reported a regulatory hiring freeze last year and another 12% said regulatory staff was downsized, while about 32% said regulatory staffing was increased in 2017, RAPS reports in its biennial report on the work and compensation of regulatory professionals in the health-care products sectors.

But almost half (48%) expect their employers were at least somewhat likely to hire additional regulatory staff in 2018 and 2019, and 64% said downsizing of regulatory staff was not at all or not very likely over these two years. About half of survey respondents worked primarily in the device or IVD sectors, while about 27% said they worked in the drug industry, and another 14% said they worked in biotechnology. Almost three-quarters of respondents are based in US, while 11% come from Europe and about 7% from Asia. Overall, individuals from 64 countries are represented in the “Compensation & Scope of Practice Survey,” which RAPS claims is the largest, most comprehensive study of regulatory professionals, featuring original data and findings.

SALARY RANGES
A large section starting in the second half of the report looks at compensation by job title, separated out for the US, EU and Canada, and offers a comprehensive benchmark for anyone in the sector to see how their pay measures up.

For the US, where most of the respondents are based, the analysis presents salary breakdowns into further specific criteria, such as numbers of years of regulatory experience, where regulators are based, numbers of global employees at the organization and the highest level of education completed.

At the top end, total compensation is close to the $400,000 mark (€346,000), whereas in the EU (where there were 61 respondents to the salary questions and fewer breakdowns are given), top end salaries are close to the €215,000 mark ($248,695). Salary figures in Canada are more aligned, overall, with EU amounts than US amounts.

Other salary stats include:
- The average base salary increase between 2016 and 2017 was 4.7%
- US respondents who have the Regulatory Affairs Certification (RAC), which is administered by RAPS, earn 17.6% more than those without it, on average.
- The level of education does not appear to be the biggest factor in predicting salaries in the US or EU.

WORKFORCE FACTS AND FIGURES

Gender Breakdown
- Two-thirds of the survey respondents were female.
- Job titles with the highest percentage of females included project manager (76%), associate (69%) and specialist (69%).
- Job titles with the highest percentage of males included vice president (44%) and CEO/president (42%).

Hours Worked:
Post-Approval Hogs The Most
- The average number of hours worked per week by respondents ranged from 39.1 hours for a consultant to 50.4 hours for a VP of a company.
- In a typical week, regulatory professional respondents spend most of their time (30%) on post-approval functions. Other common functions include regulatory intelligence and strategy (22%); pre-approval/approval (18%); and general/full product lifecycle efforts (17%).

Why Work There?
- Location was the most important factor influencing regulatory employees’ decision to accept a position with their current employer. Work environment and the person who would be their supervisor were the next two most important factors.
- The relationship with the supervisor was the most important factor encouraging employees to stay with their current employers.
- Just over 70% of respondents believe their senior management and executives are somewhat or very aware of their value to their organizations. Another 19% believe they are not aware, and 10% are neutral.
- More than 80% of respondents help shape their organizations’ key strategic decisions, business decisions or both.

Experience And Education
- On average, professionals based in North America and Europe reported more regulatory experience than their counterparts in Asia and other parts of the world. In many regions, including Asia and Latin America, this may be due to the relatively recent development of the regulatory profession and regulatory job functions there.
- Regulatory professionals are a highly educated group. Nearly two-thirds (63%) of respondents have a post-graduate degree, including 20% with a doctorate. Common areas of concentration include life/natural sciences (47%), engineering (17%), business/finance/economics (15%), regulatory affairs (14%) and clinical science (13%).

Scope Of Practice
- More than half of the respondents indicate they spend 100% of their time with a single type of product (listed within the report).
- On average, they spend 86% of their time on their primary product type.
Regulatory Professionals Can Now Seek Device-Or Drug-Specific Certifications

SHAWN M. SCHMITT shawn.schmitt@informa.com

Device and drug regulatory professionals have fresh avenues to pursue post-academic credentials in their respective areas thanks to two new RACs offered by the Regulatory Affairs Professionals Society (RAPS).

RAPS is now accepting spring 2019 exam applications for its novel device- and drug-related RACs, or Regulatory Affairs Certifications. They’re the first industry-specific RACs offered by RAPS; they join the organization’s suite of four regional RAC exams (US, EU, Canada and Global).

The RAC (Devices) exam will test knowledge of product development and life-cycle requirements for devices and in vitro diagnostics under US and EU regulations and guidances, RAPS says. The exam will also cover applicable global regulatory practices.

The RAC (Drugs) exam offers an equivalent scope for those working in the pharmaceutical space.

RAPS Executive Director Paul Brooks said in a release that the new sector-specific exams were requested by regulatory professionals in both fields.“Over the past year, the RAC Board explored the demand for, and feasibility of, these exams and confirmed there was a need that RAPS could and should meet,” he said.

Brooks further explained why the separate device/drug certifications were created: “The regional RAC exams, such as for the US or EU, require extensive regulatory knowledge for products that are quite different, and they are regulated differently. And while many regulatory professionals work across different product types, many are specialists working predominantly in a primary product sector.”

FDA Hasn't Publicly Released A Device-Related Close-Out Letter For 5 Months, Defeating Purpose Of Program

SHAWN M. SCHMITT shawn.schmitt@informa.com

Are you a regulatory w0rk who scour US FDA's website for up-to-date warning letter close-outs? Well, good luck finding any.

The agency has not released a device-related close-out letter for more than five months – the first time it has stopped posting such missives since FDA began handing them out in 2010.

FDA's close-out program publicly indicates when a manufacturer has addressed agency concerns outlined in a warning letter. The last device-related close-out posted online was sent to Ropack Inc. on April 23, 2018. It was added to the agency's close-out webpage in May. (Also see "Warning Letter Close-Outs – May 2018" - Medtech Insight, 1 Jun, 2018.)

Since then there's been radio silence when it comes to close-outs – a potentially sticky wicket for industry given that device-makers work hard to close out warning letters and want public recognition for doing so.

On Sept. 6, Medtech Insight reached out to FDA to find out why close-outs aren't being published. More than a month later, on Oct. 11, we received this email response from agency spokeswoman Deborah Kotz: "There has been no change to our policy or process for issuing warning letter close-out letters. Close-out letters have been consistently issued over the past six months at the same rate as they were issued for the six months prior to that. We are aware that the warning letter close-out webpage is not up-to-date, and we are working to resolve the issue."

Kotz noted that 10 device-makers were issued close-out letters during that six-month timeframe.

But a firm being "issued" a close-out letter isn’t the same as having FDA publicly announce it online for the world to see – which, one could argue, is the whole reason behind the close-out program in the first place.

When pressed to further explain what happened – why the close-outs aren’t being posted – Kotz followed up with another email: "Don’t know the details. I know these letters need to go through [the] FOIA office to get redacted before they’re posted." (FOIA is the Freedom of Information Act.)

Medtech Insight has been tracking close-out letters since the very first one was publicly posted eight years ago. (See box)

So far this year, FDA has posted only six close-outs. When added to the 10 that have yet to be added online, the agency has sent a total of 16 close-out letters to firms in 2018 to date.
Despite Media Report, Alex Azar Likely To Stay At HHS

FERDOUS AL-FARUQUE danny.al-faruque@informa.com

The medical device industry doesn’t have to worry about US Department of Health and Human Services Secretary Alex Azar stepping down from his post any time soon, according to a close confidant and top medtech lobbyist.

On Oct. 11, the Wall Street Journal published a story reporting President Trump was again considering firing Attorney General Jeff Sessions. On the list of top candidates to take his spot, according to WSJ, is Azar.

The president has periodically expressed disappointment with Sessions for recusing himself from the Robert Mueller investigation into whether the Trump campaign colluded with the Russian government in the 2016 US election. While Azar has an impressive legal background, Scott Whitaker, CEO of AdvaMed, assures Medtech Insight that Azar would turn down any offer to head the Department of Justice.

“I think the president is considering it, but I don’t think Alex wants to do that,” said Whitaker. “I think he views himself as a health-care leader, not a lawyer, and loves the role he’s in right now.”

A graduate of Yale Law School, Azar has served as a law clerk for several prominent judges, including former Supreme Court Justice Antonin Scalia. He was also an associate independent counsel working for Kenneth Star during the Whitewater scandal investigating allegations of improper real estate dealings by Bill and Hillary Clinton in the 1990s.

While Trump has taken jabs at those in his own cabinet and inner circle before, Whitaker says the president thinks very highly of Azar and, if other high-level positions open up, he would likely be in consideration for those jobs too. But for the time-being, Whitaker is confident that if asked to step up to the AG spot, Azar would turn down the job.

“I think stability at HHS and the agencies is important to us from the medtech perspective,” he said. “The president thinks very highly of Alex but he’s not going anywhere and that’s good for us.”

Whitaker and Azar worked together at HHS when Azar was general counsel and Whitaker was assistant secretary chief of staff. Whitaker also advised Azar during his HHS secretary confirmation hearings at the Senate. (Also see “AdvaMed CEO: Less Optimistic On Full Device Tax Repeal By Deadline” - Medtech Insight, 17 Nov, 2017.)

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CMS Solicits Input On Coverage Of Ambulatory Blood Pressure Monitoring

REED MILLER reed.miller@informa.com

The US Centers for Medicare and Medicaid Services has agreed to reconsider the Medicare coverage policy on ambulatory blood pressure monitoring (ABPM) in response to a request from physician groups, the agency announced Oct. 9.

The national coverage review was initiated by a request from the American Heart Association/American Stroke Association and American Medical Association for Medicare coverage of ambulatory blood pressure monitoring to align with the 2017 recommendation of the US Preventive Services Task Force (USPSTF) that ABPM be used as the reference standard for confirming the diagnosis of hypertension.

CMS’ current coverage policy for ABPM, determined in 2001, states that ABPM should only be covered for those patients with suspected “white coat hypertension,” the phenomenon of patients’ blood pressure spiking during office visits because of stress. The current coverage policy provides three criteria for suspected white-coat hypertension: office-blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; at least two documented blood pressure measurements taken outside the office which are <140/90 mm Hg; and no evidence of end-organ damage. ABPM is not covered for any other patients. (Also see "Medicare makes ambulatory BP (blood pressure) coverage decision" - Medtech Insight, 22 Oct, 2001.)

"Improving the diagnosis and control of high blood pressure is an organizational priority for both of our organizations," AHA/ASA and AMA explain in their request letter. The associations launched the Target: BP education program in 2016 to reduce heart attacks and strokes by urging medical practices, health service organizations, and patients to prioritize blood pressure control. "Target: BP aims to..."
increase awareness, engagement and action of health care provid-
erers and patients by educating them on steps they can take to help
improve blood pressure control and, in turn, prevent the progression
to serious or sometimes deadly co-morbid conditions, with a shared
commitment to increase the national blood pressure control rate to
70 percent or higher.

"A large body of evidence amassed since CMS last reviewed this
benefit supports ambulatory blood pressure monitoring (ABPM) as
an effective diagnostic tool to correctly diagnose HBP/hypertension," the
societies explain in their request letter. The AHA and American
College of Cardiology released new guidelines in 2017 outlining the
current expert-consensus on prevention, detection, evaluation, and
management of high blood pressure in adults.

The request letter also points out that the USPSTF commissioned
an evidence review on ABPM from the Kaiser Permanente Research
Affiliates Evidence-based Practice Center in 2015 and released a re-
commendation supporting screening for adults for high blood pres-
sure and obtaining blood-pressure measurements outside the clin-
cal setting for diagnostic confirmation before treatment.

USPSTF’s "A" rating for "high certainty that the net benefit is sub-
stantial" were based on "convincing evidence that ABPM is the best
method for diagnosing hypertension," the task force concludes in
the final recommendation statement released in September 2017.

"Although the criteria for establishing hypertension varied across
studies, there was significant discordance between the office diag-
nosis of hypertension and 12-and 24-hour average blood pressures
using ABPM, with significantly fewer patients requiring treatment
based on ABPM Elevated ambulatory systolic blood pressure was
consistently and significantly associated with increased risk for fatal
and nonfatal stroke and cardiovascular events, independent of office
blood pressure," USPSTF explained.

CMS is soliciting public comment on the request from AHA/ASA
and AMA through Nov. 8 and expects to release a proposed decision
memo on it by April 9, 2019.

Manufacturers of ABPM devices include Welch Allyn, Meditech
Diagnostic Systems, and SunTech Medical, among others.

Robert Ford Steps Up
At Abbott Labs

DAVID FILMORE david.filmore@informa.com

Robert Ford has been tapped as Abbott Laboratories Inc.’s
president and chief operating officer to oversee all the com-
pany’s operating divisions.

In the new role, Ford will retain his current responsibilities as ex-
ceutive VP of medical devices, which is Abbott’s largest business,
but he will also now assume responsibility for the firm’s diagnos-
tics, established pharmaceuticals and nutritional divisions.

Ford already has significant experiences in several of Abbott’s
businesses. He has worked for the company for more than 20 years.
He led the diabetes business (part of the device portfolio) during
the launch of the firm’s Freestyle Libre flash glucose monitoring
system, and he has also worked in the company’s nutritional and
diagnostics divisions. Ford took over the device division in 2015,
and during his tenure he led the integration of Abbott’s $25bn ac-
quision of St. Jude Medical.

"This news represents good talent development and succession
planning in our view," Wells Fargo analyst Larry Biegelsen noted
in an Oct. 15 research report, pointing out that Ford might eventually be a good replacement for current CEO Miles White. "Given Robert’s
strong track record to date, we believe he is now in line to eventually succeed Miles if he continues to execute well in his new role."

In Post-Alice Patent World,
Diagnostics Turn To Trade
Secrets Protection

ELIZABETH ORR elizabeth.orr@informa.com

D iagnostic developers may face a narrowing path to get
patent protection in the wake of court determinations
that “fundamental laws of nature” aren’t patentable.
Some legal observers advocate carefully deploying trade se-
crets to bridge the gap.

In 2017, the Federal Circuit Court of Appeals rejected two
patents held by the Cleveland Clinic on methods for diagnos-
ing heart disease because they didn’t go beyond measuring a
natural phenomenon. The ruling expanded on a landmark 2014
decision from the Supreme Court in a case called Alice Corp. v.
CLS Bank International, which determined that abstract ideas
could only be patented under certain specific conditions. [Also
see “Alice’ In Patent Land: Finding Patentable Digital Health Inno-
vations Is No Easy Task” - Medtech Insight, 23 Feb, 2018.]

“There’s a tension right now in patent law as to whether or
not a diagnostic is a patentable invention under Section 101 of
the patent act,” which defines the conditions under which tech-
nology can be patented, said attorney Joshua Stowell, partner,
Knobbe Martens. “Since the Supreme Court’s decision in 2014 in
Alice, there’s been a real focus on this 101 case law, and there’s
a real dilemma being faced by a lot of industries on whether to
seek patent protection and risk a 101 rejection, or whether to try
to keep an invention as a trade secret.” Section 101 is the part of US federal statutes addressing patentable inventions.

The Cleveland Clinic decision, he said, offered further discouragement for diagnostics developers hoping to patent-protect their inventions. Many of his clients are now looking to the trade secrets route as a patent alternative – but that approach carries its own significant risks.

**PLAN AHEAD**

Any confidential business information that provides a company with a competitive advantage may be considered a trade secret. They are protected indefinitely without any specific registration.

Medical device companies may need to plan ahead to make the most of a trade secrets approach, Stowell said. For example, getting FDA approval may involve turning over data that includes some trade secrets, and FDA’s view of what qualifies for trade secret protection may not match a diagnostic developer’s. So before applying for FDA clearance, companies should review all materials to determine what may be sensitive and document evidence supporting those decisions. That may make it easier to make a case to FDA as to why specific data is a trade secret, Stowell said.

“Ultimately the burden will be on the company to explain to FDA why the information shouldn’t be turned over and why it is a trade secret,” he explained.

Additionally, companies protecting sensitive information as trade secrets need to ensure their non-disclosure agreements (NDAs) with staff and vendors are well-crafted and well-enforced, Stowell said. For example, Stowell has noticed that sometimes companies don’t follow through on policies to protect information given to third-party vendors, such as documenting conversations about trade secrets in memos and ensuring all trade secrets are always marked confidential. That documentation can be crucial to protecting diagnostic technology.

It’s also useful to limit the absolute number of people who have access to trade secret information, he said. “Obviously the more people you disclose to, the larger chance there is of some form of inadvertent public disclosure,” he said. “And I think when you’re considering trade secrets you should think about how disastrous it would be if the information were disclosed, even quickly.”

Diagnostics developers may also be able to protect their ideas by crafting patents that center specific methodologies or types of equipment, which are patentable. “What I think a lot of skilled patent drafters will do is try to incorporate concrete pieces of equipment and procedures so that it’s not merely abstract,” Stowell said.

Stowell further notes that cases related to diagnostic patents and the Alice test continue to percolate through the court system, and that US Patent & Trademark Office officials have also indicated a desire to clarify and narrow the scope of the law. “I would expect additional changes to continue to happen in this area, and I would expect a narrowing in rejections at the patent office,” he said, though he noted that a specific impact on medical diagnostics is difficult to gauge.

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**Utah Court Case Could Protect Devices From Some Liability**

ELIZABETH ORR elizabeth.orr@informa.com

A case before the Utah Supreme Court could give device companies more protection from product liability suits filed within the state.

The case, *Burningham v. Wright Medical*, involves a patient who says she was injured by a metal-on-metal hip manufactured by Wright Medical Group NV. The company is asking for the case to be dismissed on the theory strict product liability should not apply to implantable medical devices.

Some products have long been legally exempted from product liability cases because they are “unavoidably unsafe.” In 1991, Utah courts determined that the exemption applied to FDA-approved prescription drugs. Wright is now asking the Utah court to apply the principle to all implanted medical devices, whether they reached market via the 510(k) or the PMA approval process.

Wright’s argument has drawn supportive *amicus curiae* briefs from the Washington Legal Foundation and a coalition including device trade group AdvaMed. Both groups say a ruling favoring Wright would help protect high-tech products from unfair and excessive liability claims.

WLF says that holding implantable device manufacturers responsible for defective design under strict liability standards allows courts and juries to overrule FDA analysis as to product safety. States, including Washington, California and Ohio, have already ruled that all medical devices are protected by the “unavoidably unsafe” standard, the group said in its brief.

Additionally, WLF argued that liability findings could lead a manufacturer to raise the price of a product or even stop making it.

“The public has a substantial interest in the availability and affordability of potentially life-altering medical devices.
Allowing courts to decide the fate of devices that pose inherent, unavoidable risks will harm manufacturers and consumers alike,” WLF attorney Marc Robertson said in a statement. AdvaMed, meanwhile, said the Utah court’s ruling protecting prescription drugs was highly relevant to 510(k) products. The 1991 ruling cited product affordability and timely availability as key reasons why prescription drugs needed to be protected from liability suits. Because the 510(k) process is usually less expensive and faster than the PMA process, protecting products cleared via that route “advances the important Utah public policy goal of promptly providing consumers with affordable health care,” the brief states.

Other members of AdvaMed’s coalition supporting Wright include the American Tort Reform Association, the National Association of Manufacturers, the US Chamber of Commerce, PhRMA and BioUtah.

Most PMA products are already protected from many product liability claims by federal preemption, which often blocks patients from suing manufacturers of FDA-approved products. (Also see “In Victory For Device Industry, Supreme Court Favors PMA Pre-emption” - Medtech Insight, 25 Feb, 2008.) But the courts have not support preemption protections for 510(k)-cleared devices. The case now before the Utah court would offer some protection to 510(k) products.

Myriad Genetics Signs Marketing Plans With Pfizer For BRACAnalysis CDx Test

MARION WEBB marion.webb@informa.com

Myriad Genetics Inc. inked a deal with pharmaceutical giant Pfizer Inc. to promote Myriad’s BRACAnalysis CDx test to identify breast cancer patients that would benefit from treatment with talazoparib, Pfizer’s investigational poly-ADP ribose polymerase inhibitor drug.

Under the agreement, both companies will remain responsible for marketing their own products, but will collaborate on certain activities to support BRACAnalysis CDx as a companion diagnostic for talazoparib, Myriad announced Oct. 9.

Both talazoparib and BRACAnalysis CDx are still under US FDA review. Myriad expects a decision from US regulators by December. Talazoparib has priority review status from the FDA and both companies have submitted data to US regulators from the 431-patient EMBRACA trial which evaluated talazoparib versus physician’s choice chemotherapy in patients with germline (inherited) BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer.

Data from EMBRACA released at the 2017 San Antonio Breast Cancer Symposium last December showed that talazoparib-treated patients had a median progression-free survival of 8.6 months vs. 5.6 months for the physician’s choice-treated control group. The overall response rate was 62.6% for patients in the talazoparib arm versus 27.2% for those in the physician’s control group. Results from the trial published in the Annals of Oncology in September showed patients who received talazoparib had significant overall improvements and significant delay in time to definitive clinically meaningful deterioration in multiple cancer-related and breast cancer-specific symptoms, functions, and global health status and quality of life.

About one in eight patients are diagnosed with breast cancer in the US and one-third are diagnosed with or will progress to the metastatic stage of the disease, Myriad pointed out in a press release. (Also see "Liquid Biopsy In Oncology: An Increasingly Crowded Landscape” - Medtech Insight, 6 Sep, 2016.)

Myriad and Pfizer will remain responsible for marketing their own products, but will collaborate on certain activities to support BRACAnalysis CDx as a companion diagnostic for talazoparib.
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