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THE TRUMP CONUNDRUM:

Republicans Will Run US Government, But Incoming President Is A Wildcard

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With a Republican in the White House and the same party controlling both chambers of Congress, convention would say the medtech industry's push to further reduce regulatory burdens and permanently repeal the device tax has hit the fast track. But the one hard-to-answer question is: What will Donald Trump do?

Trump was elected to the presidency in a surprise result Nov. 8, delivering a decisive Electoral College victory over the favored Hillary Clinton (despite the fact that Clinton is expected to win the popular vote). In parallel, the Republican party retained its control of the House and Senate.

But an underlying question is how well a President Trump will work with lawmakers in his own party, many whom did not see eye to eye with the candidate at the top of their ticket during the campaign. There is also more uncertainty than usual about anticipated cabinet and agency appointments under the Trump administration.

It is highly likely that there will be new leadership at FDA and CMS. But, "It is harder than usual to predict who these leaders would be, how much latitude they would have to set policy, and what their priorities would be," Wells Fargo medtech analyst Larry Biegelsen stated in a Nov. 9 research note. "First, since Trump has never held office before, there is no legislative or executive branch record of past positions, nor is there a network of current and former staffers from which a president-elect would be expected to draw upon to staff key positions."

It also remains unclear at this point, observers say, how many "establishment" health-care and regulatory experts from business and government would be willing to serve or would be accepted by the Trump administration.

WORKING WITH CONGRESS

Meanwhile, Republican leaders of Congress who retained their seats are on record as supporting legislative provisions that would streamline device and drug FDA regulations, add more R&D funding, and permanently repeal the device excise tax.

Trump himself did not speak about FDA regulatory issues during the campaign nor the device tax, although industry-favored positions on those points were included in the Republican party platform. Trump did, of course, promise to quickly dismantle the Affordable Care Act, under which the device tax was enacted.

But market and policy experts question how easy or straightforward that will be,

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FROM THE EDITORS OF: **THE GRAY SHEET, CLINICA, START-UP** AND **MEDTECH INSIGHT NEWSLETTER**

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Medtech insight

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TRUMP'S TRIUMPH:

Markets React, But 'Wait-And-See' Approach Advised For Medtech

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When life deals a blow, it's usually the big and strong that can withstand the impact better than the small and weak. This seems to be the case for health-care stocks and the reaction of the markets on Nov. 9, the day after the US voted for its next president and Donald Trump emerged as the surprise victor.

"The initial reaction [to the US election result] is one of a 'risk-off' attitude," said Nick Keher, director, health-care equity research, at RBC Capital in London. In the European health-care market, he told *Medtech Insight*, the big profitable names have reacted positively to the news while smaller names that have yet to reach profitability or are still in heavy R&D mode – hence a riskier investment proposition – have underperformed.

There is also a discrepancy in terms of how medtech stocks have performed compared to pharma stocks. Pharma companies have seen their share prices go up, as investors react favorably to Hillary Clinton's failure to become the next chief executive of the US. Clinton's plan to lower drug prices did not sit well with pharmaceutical companies and with her out of the way, this risk is now diminished. "Before this year, we've seen medtech outperform biotech due to uncertainty in this pricing issue … but now they're starting to rotate back and we're seeing a revision from medtech into pharma," said Keher.

Mick Cooper, analyst at boutique research house Trinity Delta, noted the divergence between biotech stocks – which went up – and medtech stocks – which went down – immediately after the presidential election result, but he remained cautious as to whether drug pricing control as an issue has been swept under the carpet.

"There have been so many contradictory comments from Trump; nobody really knows what his policies are. That's why I'm surprised there has been so much movement in the market," he told *Medtech Insight*. While Clinton may have been *persona non grata* to the pharma industry, Cooper said Trump has indicated that he may encourage Medicare to negotiate with pharma companies to bring down the cost of drugs after all. "Trump has only just been elected and he has said so many different things; it's a case of wait and see what he actually does and what he's allowed to do."

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The impact of repealing Obamacare is mixed. While getting rid of Obamacare altogether would also rid medtech companies of paying the medical device tax, this would also mean they lose market volume.

Two issues that would have a knock-on impact on medtech companies if Trump does see them through is related to the repeal of Obamacare – the Affordable Care Act and the medical device tax that goes with it – and the repatriation of overseas capital into the US.

The impact of repealing Obamacare is mixed. While getting rid of Obamacare altogether would also rid medtech companies of paying the medical device tax, which they have long contested and which is now under a two-year suspension, this would also mean they lose market volume. "Twenty-to-thirty million Americans who have medical insurance because of the Affordable Care Act might lose it. Volume will be down materially and this will have a knock-on impact on the medtech world more than anything," said Keher of RBC Capital. Unlike pharma companies that could offset this with price increases, medtech companies are under constant pricing pressure and unlikely able to mitigate volume shortfall through price hikes.

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With regards to repatriation, if Trump does manage to cut a deal so that the estimated $1.5 trillion of assets and capital which companies have outside the US can bring it back into the country without being penalized too heavily, this could be a boost – for US health-care stocks that would be on the receiving end of this repatriated money.

"US companies don't want to repatriate their cash because if they do, they have to pay 35 percent tax on it. So they've been using this cash to buy overseas assets which has been giving a boost to European valuations, especially those that are big-dollar earners, said Keher. "That could be a long-term negative on the [European health-care] sector if a deal is cut – they'd repatriate their cash and spend it on US names instead. So our US desk is talking about how it could be a boost for US biotech evaluations as companies look to buy talent from US grounds instead."

Cooper of Trinity Delta added that another negative of a Trump win is the issue of tariffs for non-US companies. "Trump has indicated he will be increasing tariffs to 'stop US jobs going overseas,' as he puts it. If that's the case, that would be negative without a doubt for non-US companies looking to export into the US."

While Trump has emerged the clear winner in the US presidential election, a blanket of uncertainty continues to shroud his policies and the potential scenarios that could play out over the next four years. "We need to know more about what is going to happen. Trump made some conciliatory remarks during his acceptance speech that he might not be as extreme in his actions as some people fear, but we don't know until he starts making policies," said Cooper.

While Trump has emerged the clear winner in the US presidential election, a blanket of uncertainty continues to shroud his policies and the potential scenarios that could play out over the next four years.

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even with a Republican-controlled federal government.

"My own prediction is that it would be a terrible idea and it would fail when push came to shove," because there is not enough of a plan to replace the coverage currently provided to millions of individuals, James Capretta, who is a fellow at the conservative American Enterprise Institute, said at a US Chamber of Commerce conference right before the election.

Wells Fargo analyst Biegelsen noted that "even though a Republican-controlled Congress has previously passed legislation to repeal the ACA, it was done with the certainty that President Obama would veto the repeal effort." He pointed out, with guidance from in-house health-care policy experts, "With the expectation that President Trump would sign legislation modifying or eliminating much of the ACA, congressional Republicans will have to proceed with caution lest they cause substantial disruption to individuals and businesses who are several years into living with the current system."

Also at issue: There is not full agreement among Republican lawmakers about how to address health-care coverage issues and about what, if any, elements of the current ACA to retain.

Ultimately, Republicans will only have a slim majority in the Senate, so to push through big repeal legislation they will need to employ the "budget reconciliation" process, which allows bills to pass on a simple majority, but is procedurally complex. That will require close coordination between the House, the Senate and the White House, which is likely to take time.

"Full repeal of the device tax may have to wait until the larger issues around the ACA, the tax code and infrastructure spending can be negotiated," Biegelsen said in his note.

While the device industry favored congressional Republicans with campaign contributions during the 2016 race, the industry significantly favored Hillary Clinton over Trump in its donations. That aligns with donation trends from other industries, and might reflect deep-seated questions the private sector has with Trump's capability to effectively manage the economy, how his policy priorities will play out, and his opposition to trade deals such as the industry-favored Trans Pacific Partnership.

Those questions were also reflected in the massive initial after-hours stock plunge that followed Trump's declared victory. Since then, the market reaction has been more nuanced.

Overall, though, uncertainty about what's to come in the days and months ahead is higher than during standard post-election periods. The approach taken by Trump's transition team, and who is appointed to oversee key areas of policy, will determine how long that outsized uncertainty reigns.

With regard to FDA and CMS agency heads, "It is harder than usual to predict who these leaders would be, how much latitude they would have to set policy, and what their priorities would be," Wells Fargo analysis Larry Biegelsen says.

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FDA, CMS Heads Press For 'Single Front Door' For Real-World Evidence

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The heads of FDA and CMS are outlining a vision for collaboration on development of real-world evidence ahead of the transition to a new presidential administration.

FDA Commissioner Robert Califf, Deputy Commissioner for Medical Products Rachel Sherman, and Acting CMS Administrator Andy Slavitt published a "viewpoint" piece entitled, "Knowing When and How to Use Medical Products: A Shared Responsibility for the FDA and CMS," in the *Journal of the American Medical Association* on Nov. 7.

The article notes the historical and public health reasons why FDA and CMS have different standards for evidence and play different roles in the health-care system, but cites an important, shared opportunity: "Changes in the organization of health care and in the larger information ecosystem should allow the FDA and CMS to move increasingly toward use of shared sources of evidence while still applying the most appropriate criteria to their decision-making."

The publication came on the eve of the presidential election, and a few days after Slavitt and Califf talked about real-world evidence development as a priority during the Prevision Policy/Friends of Cancer Research Biopharma Congress. Slavitt, in particular, highlighted his work with sister agencies as an important and satisfying area of focus as acting administrator of the Medicare and Medicaid agency during his Nov. 3 remarks.

Slavitt noted that he, Califf and National Institutes of Health Director Francis Collins "have established tri-lateral leadership discussions among our agencies." He jokingly referred to the monthly discussion as "a sleeper group," but declared a broad goal: The three agencies "hope to establish critical ties that can eventually create a single front door to research safety, efficacy, coverage and pricing – with appropriate firewalls and safeguards," Slavitt declared.

"Together we're making it a priority to figure out how to coordinate in ways that advance product development," he said. He noted CMS' decision to transition its parallel review program with FDA for medical devices from pilot project to permanent status.

Within FDA, device-center Director Jeffrey Shuren has been particularly vocal and active in championing FDA and CMS collaboration, including floating ideas for other ways in which FDA processes can be used to fill in some of the resource gaps at the Medicare agency.

The emphasis on real-world evidence also dovetails with the nascent National Evaluation System for health Technology (NEST), which is being launched to establish a robust network of device data from registries, electronic patients records and other sources to inform health-care and regulatory decisions. FDA officials, including Califf and Shuren, have been particularly vocal in championing NEST, but CMS officials are also directly involved.

With both Califf and Slavitt likely to leave office in January, the *JAMA* article amounts to a shared vision statement and a public call for continued collaboration on real-world evidence by the next group of health-agency leaders in the US.

The article outlines three areas of focus:

1. **Clinical trial demographics.** FDA and CMS are "clarifying the need for including diverse populations and measuring relevant clinical outcomes within the sphere of trials conducted for regulatory approval and to inform labeling.
2. **Analyzing electronic health data.** "FDA and CMS are collaborating with other federal agencies to build functional links across a range of systems developed to capitalize on existing digital information collected in the course of health-care delivery, including electronic health records, insurance claims, and data housed in clinical registries."
3. **Collaborating with the public and private sector.** "The Patient-Centered Outcomes Research Institute, which is overseen by a board representing key stakeholders (including the medical products industry), is one example of an entity designed to develop this knowledge."

"For too long, physicians, patients, regulators, policy-makers, and payers have depended on suboptimal data to guide decision making because of constraints, perceived or real, about what was affordable, practicable, or desirable," the article concludes. "But now, thanks to rapidly accelerating scientific knowledge and new perspectives, the FDA and CMS are poised to change this approach for the better and improve outcomes for patients."

A RECURRING THEME FOR CMS' SLAVITT

In his appearance at the Biopharma Congress, Slavitt returned to the collaboration theme in two different contexts during Q&A.

First, regarding the appropriate regulation of and reimbursement for diagnostics used in personalized medicine, he acknowledged that it is a difficult question. "It is something that Rob and Francis and I do talk about," he said. As a core principle, he stressed, the "way to structure and construct this is not to slow down but actually to speed up." That said, the right approach to reimbursement "is a new area that requires some statutory work to create a new regime." It will also require a deepening of the expertise within CMS, Slavitt said.

Specifically, he raised collaboration in real-world evidence in response to a question about how pharmaceutical companies can develop strong cost-effectiveness arguments. **"**One of the priorities I put on our team is to enable health economics and outcomes research using our data," Slavitt said. As a result, we have more data out there for people to use and test, and do health economics and outcomes research on other sorts of real-world evidence."

Slavitt also noted the importance of FDA's policies on health economic promotion as an important topic. "The other piece of it is probably has to do with labeling because …if it's not on the label, then the concern is then they can't claim it, and if they can't claim it, then we can't create a value-based model on it to say you've reduced hospital bed days by X amount of dollars, and therefore you'd offset that."

ELECTION IMPACT:
Key Senate Committees

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Senate Finance Committee

Sen. Toomey is the Health Subcommittee chairman; Sen. Stabenow is the top ranking Democrat on the subcommittee.

REPUBLICANS	DEMOCRATS
Orrin Hatch, Utah, Chairman	**Ron Wyden**, Ore., Ranking Member (retained seat)
Chuck Grassley, Iowa (retained seat)	**Chuck Schumer,** N.Y. (retained seat)
Mike Crapo, Idaho (retained seat)	*Debbie Stabenow*, Mich.
Pat Roberts, Kan.	*Maria Cantwell*, Wash.
Mike Enzi, Wyo.	Bill Nelson, Fla.
John Cornyn, Texas	*Bob Menendez*, N.J.
John Thune, S.D. (retained seat)	Tom Carper, Del.
Richard Burr, N.C. (retained seat)	*Ben Cardin*, Md.
Johnny Isakson, Ga. (retained seat)	*Sherrod Brown*, Ohio
Rob Portman, Ohio (retained seat)	**Michael Bennet**, Colo. (retained seat)
Pat Toomey, Pa. (retained seat)	Bob Casey, Pa.
~~***Dan Coats***~~, Ind. (retiring)	*Mark Warner*, Va.
Dean Heller, Nev.	
Tim Scott, S.C. (retained seat)	

Bold = Up for re-election in 2016; ~~Strike through~~ = Defeated in election, retired, or sought a different office; *Italics* = Health Subcommittee member

Senate HELP Committee

Sen. Enzi is chairman of the primary health subcommittee, which has jurisdiction over devices and diagnostics; Sen. Sanders holds the ranking Democratic slot on that subcommittee. Though identified as an Independent, Sanders caucuses with the Democrats.

REPUBLICANS	DEMOCRATS
Lamar Alexander, Tenn., Chair	**Patty Murray**, Wash. Ranking Member (retained seat)
Mike Enzi, Wyo.	~~***Barbara Mikulski***~~, Md. (retiring)
Richard Burr, N.C. (retained seat)	*Bernie Sanders* [I], Vt.
Johnny Isakson, Ga. (retained seat)	Bob Casey, Jr., Pa.
Rand Paul, Ky. (retained seat)	Al Franken, Minn.
Susan Collins, Maine	***Michael Bennet***, Colo. (retained seat)
Lisa Murkowski, Ark. (retained seat)	*Sheldon Whitehouse*, R.I.
~~***Mark Kirk***~~, Ill. (lost election)	*Tammy Baldwin*, Wis.
Tim Scott, S.C. (retained seat)	*Chris Murphy*, Conn.
Orrin Hatch, Utah	*Elizabeth Warren*, Mass.
Pat Roberts, Kan.	
Bill Cassidy, La.	

Bold = up for reelection in 2016; ~~Strike-through~~ = lost election, retired or ran for a different office; *Italics* = member of the Subcommittee on Primary Health and Retirement Security.

Key House Committees

House Ways and Means Committee

Rep. Tiberi chaired the Health Subcommittee and Rep. McDermott was the top ranking Democrat of the subcommittee.

REPUBLICANS	DEMOCRATS
Kevin Brady, Texas, Chairman	Sander M. Levin, Mich.
Sam Johnson, Texas	~~Charles B. Rangel~~, N.Y. (retiring)
Devin Nunes, Calif.	~~*Jim McDermott*~~, Wash. (retiring)
Pat Tiberi, Ohio	*John Lewis*, Ga.
Dave Reichert, Wash.	Richard Neal, Mass.
~~Charles Boustany~~, La. (unsuccessfully ran for Senate)	Xavier Becerra, Calif.
Peter Roskam, Ill.	Lloyd Doggett, Texas
Tom Price, Ga.	*Mike Thompson*, Calif.
Vern Buchanan, Fla.	John B. Larson, Conn.
Adrian Smith, Neb.	*Earl Blumenauer*, Ore
~~Robert Dold~~, Ill. (lost to Democrat Brad Schneider)	*Ron Kind*, Wis.
Lynn Jenkins, Kan.	*Bill Pascrell*, N.J.
Erik Paulsen, Minn.	Joseph Crowley, N.Y.
Kenny Marchant, Texas	*Danny K. Davis*, Ill.
Diane Black, Tenn.	Linda Sánchez, Calif.
Tom Reed, N.Y.	
~~Todd Young~~, Ind. (won US Senate race)	
Mike Kelly, Pa.	
Jim Renacci, Ohio	
Pat Meehan, Pa.	
Kristi Noem, S.D.	
George Holding, N.C.	
Jason T. Smith, Mo.	
Tom Rice, S.C.	

Note: All House members are up for reelection, unless they retire or seek another office. A strike through designates members who lost or relinquished their seat, followed by an explanation in parentheses. Italics designate members of the Health Subcommittee.

House Energy and Commerce Committee

Rep. Pitts had chaired the Health Subcommittee and Rep. Green is the ranking Democrat. Reps. Upton and Pallone are ex officio members. Rep. Ed Whitfield, R-KY, resigned from Congress in September.

REPUBLICANS	DEMOCRATS
Fred Upton, Mich., Chairman	Frank Pallone, N.J., Ranking Member
Joe Barton, Texas, Chair Emeritus	Bobby Rush, Ill.
John Shimkus, Ill.	Anna Eshoo, Calif.
~~*Joseph R. Pitts,*~~ Pa. (retiring)	*Eliot Engel,* N.Y.
Greg Walden, Ore.	*Gene Green*, Texas
Tim Murphy, Pa.	Diana DeGette, Colo.
Michael C. Burgess, Texas	~~*Lois Capps*~~, Calif. (retiring)
Marsha Blackburn, Tenn., Vice Chairman	Michael F. Doyle, Pa.
Steve Scalise, La.	*Jan Schakowsky*, Ill.
Bob Latta, Ohio	*G. K. Butterfield*, N.C.
Cathy McMorris Rodgers, Wash.	*Doris Matsui*, Calif.
Gregg Harper, Miss.	*Kathy Castor*, Fla.
Leonard Lance, N.J.	*John Sarbanes*, Md.
Brett Guthrie, Ky.	Jerry McNerney, Calif.
Pete Olson, Texas	Peter Welch, Vt.
David McKinley, W.V.	*Ben R. Luján*, N.M.
Mike Pompeo, Kan.	Paul Tonko, N.Y.
Adam Kinzinger, Ill.	John Yarmuth, Ky.
Morgan Griffith, Va.	Yvette Clarke, N.Y.
Gus Bilirakis, Fla.	Dave Loebsack, Iowa
Bill Johnson, Ohio	*Kurt Schrader,* Ore.
Billy Long, Mo.	*Joseph Kennedy III*, Mass.
~~*Renee Ellmers*~~, N.C. (lost in primary)	Tony Cárdenas, Calif.
Larry Bucshon, Ind.	
Bill Flores, Texas	
Susan Brooks, Ind.	
Markwayne Mullin, Okla.	
Richard Hudson, N.C.	
Chris Collins, N.Y.	
Kevin Cramer, N.D.	

Note: All House members are up for election, unless they retire or seek another office. A strike-through designates members who lost or relinquished their seat, followed by an explanation in parentheses. An italics members of the Subcommittee on Health.

Medical Innovation Bills On Fast Track In Congress, But Some Barriers Remain

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The election of Donald Trump as the next US president and a secure Republican-led Congress for the 2017-2018 session has provided the device industry with fresh hope that its legislative wish-list will become a reality, trade groups and industry attorneys say.

Campaign results in tight Senate and House races have left most device-friendly legislators still sitting on key committees. And with Democratic President Barack Obama winding up his term of office next month, and a new Republican president on deck, some anticipated vetoes of any legislation aimed at repealing major portions of the Affordable Care Act, including the device excise tax and Independent Payment Advisory Board, have been erased.

"AdvaMed congratulates Donald J. Trump on being elected the 45th President of the United States," said the group's president and CEO Scott Whitaker. "In the coming year, policy-makers will be dealing with … authorization of the Medical Device User Fee agreement, repeal of the medical device tax, and ensuring that the coverage process allows patients access to the latest innovations. The medical technology community stands ready to work with President Trump, his administration and the new Congress on pro-innovation polity solutions."

As an example of the legislative agenda to come, industry groups and congressional committees have been working behind the scenes of the 2016 presidential and congressional elections to put together a package of House 21st Century Cures Act (approved by that chamber in July 2015) and Senate medical innovation bills, which include multiple provisions to streamline the path to market for devices, for passage during the lame-duck session that started Nov. 14. Nonetheless, continued controversies over of price-gouging by the drug industry could slow progress, at least one attorney predicted.

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"Hopefully, [Congress] can get the Cures bill out of this lame-duck [after] they come back next week," MITA Executive Director Patrick Hope says.

"There are two priorities for me for the lame-duck," said Senate Majority Leader Mitch McConnell, R-Kent., on Nov. 9. "How you are going to fund the government, and second, the 21st Century Cures bill. The president is interested in the Precision Medicine part of that, the vice president is interested in the "cancer moonshot" of it, and I'm interested in the regenerative medicine part of it," McConnell added.

Congress approved a short-term funding bill in late September to keep the government running until Dec. 9, but it must pass an appropriations bill to last through the entire 2017 fiscal year before then.

As to a Cures package, executive director of the Medical Imaging and Technology Alliance (MITA) Patrick Hope affirmed that "both Republicans and Democrats have been working behind the scenes, during the recess period, to roll the Cures and medical innovation bills up into one package," and to "get it passed during the lame-duck. … Hopefully they can get it out of this lame-duck session when they come back next week."

However, while the stars are aligning for swift passage of a Cures/medical innovation bills package – which would reform FDA standards to make it easier for manufacturers to provide adequate evidence for product clearances and approvals – some obstacles remain, said Latham & Watkins partner John Manthei in a Nov. 9 post-election briefing.

"A broad issue that may come up in consideration of Cures is that there were 13 groups that signed a letter [in late October,] including the Center for American Progress, the AFL-CIO and others, saying there shouldn't be any action on Cures until US drug pricing issues are addressed," Manthei noted.

The Oct. 26 letter, addressed to key Democratic leaders in the House and Senate, advised that the members "not move forward with the 21st Century Cures Act during the lame-duck session" until the legislation

had been improved "to rein in the cost of prescription drugs." It pointed to "a series of incidences of price gouging by pharmaceutical corporations," including **Mylan Pharmaceuticals Inc.**'s pricing of *EpiPen*, an epinephrine delivery device used to treat allergies, which costs $600 per for the name-brand product, and $300 for a generic.

In addition to the Center for American Progress, the letter was signed by public health organizations including Consumers Union, Doctors for America and Public Citizen, as well as several unions representing private and federal government employees. The Center for American Progress was closely linked to Hillary Clinton's campaign for president, so its influence will likely be severely diminished once Trump enters the White House.

2017 USER FEE BILL: HOT TOPICS INCLUDE OFF-LABEL, RWE

If the Cures package does not pass during the lame-duck session, it is likely to become part of user-fee reauthorization legislation, a "must-do" before the most recent medical device user fee authorization (MDUFA) bill and other pieces of user-fee legislation expire on Oct. 1, 2017, Manthei noted.

FDA and device industry groups recently reached agreement on user-fee payments and FDA performance commitments for the next iteration of MDUFA, but in addition to that, Congress is likely to add on more.

"MDUFA, PDUFA and GDUFA … are always the engines for additional legislative reform at FDA," he noted. The 2017 MDUFA bill, he predicted, would produce many regulatory reforms for the device industry – especially for emerging device companies.

Other topics likely to be taken up in Congress during next year's user fee authorization debates will be FDA's off-label communications policies, as well as agency efforts to deal with big data and real-world evidence generation, Manthei predicted.

As part of the MDUFA talks, he said, "There is going to be continued pressure on the FDA to address its regulation of off label communications. Recently, FDA leadership has been touting the benefits of real-world evidence and asking industry to pay for FDA initiatives to develop it for regulatory decision-making. It's hard for FDA to talk about its benefits, and then restrict companies from using it. Combine this with courts imposing the First Amendment on FDA, and all of this will soon be coming to a head."

COMMITTEE POSTS

As for leadership of key congressional committees next year, Manthei says he anticipates that Sen. Lamar Alexander, R-Tenn., and Sen. Patty Murray, D-Wash., will stick with their current roles as chair and ranking member, respectively, of the Senate Health, Education, Labor, and Pensions Committee. However, there have also been rumors that Murray will take over retiring Sen. Barbara Mikulski, D-Md.'s seat as ranking member of the powerful Appropriations Committee.

> Rep. John Shimkus, R-Ill., who saw to it that industry-favored device reform provisions got into the 21st Century Cures bill, will likely take over chairmanship of the House Energy and Commerce Committee.

In the House, Rep. John Shimkus, R-Ill. – who sponsored a number of important device reform provisions in the Cures bill – is expected to take over the House Energy and Commerce Committee gavel from retiring chairman Fred Upton, R-Mich.

Manthei also predicted that Rep. Frank Pallone, Jr., D-N.J., will stay on as the ranking member of the House E&C, and that the current vice chairman of the Energy & Commerce Health Subcommittee, Rep. Brett Guthrie, R-Kent., will take over the chairmanship of that subpanel from the retiring Rep. Joe Pitts, R-Pa. Rep. Diana DeGette, D-Colo., is expected to remain as the ranking member of the health subpanel, Manthei indicated.

TRUMP'S ELECTION CREATES 'URGENT' CLIMATE FOR DEVICE TAX REPEAL

An even higher priority for device-makers and the advanced imaging industry with a Republican in the White House, MITA's Hope said, is permanent repeal of the medical device tax. The tax is currently under a two-year suspension, but industry says full abolishment is crucial. "As to what's changed, the election has created this urgency we've been looking for, to repeal the device tax, and it would appear that things are now lining up for that to occur," he told *Medtech Insight*.

Hope pointed out that Trump had promised several times on the campaign trail to repeal ACA (which includes the device tax). Hope added that while an anticipated effort by Republican leaders to abolish the law is expected to be contentious, "it's important to note, that repealing the medical device tax, has *not* been contentious; it's always been bipartisan." Hope may have been referencing several votes in the House by both Democrats and Republicans to repeal the tax in recent years, as well as bipartisan non-binding votes in the Senate.

"It's important for Democrats and Republicans to see that, at least this component, could be an improvement to the law," he added.

MDMA president and CEO Mark Leahey also said he welcomed the incoming president as a partner to achieving many of the device industry's goals.

"We look forward to working with President-elect Trump, the new Congress and all policy-makers to confront the obstacles standing in the way of innovation. We have had a strong tradition of broad, bipartisan support to advance issues important to the medtech community such as suspension of the device tax, reauthorization of MDUFA, protecting intellectual property rights and more, and we hope this will continue," Leahey stated Nov. 9.

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EU Member States Tread Carefully In Scrutinizing Final Regulation Changes, Preparing For Challenges Ahead

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Fourteen pages have been added to the EU Medical Device Regulation text since political agreement was reached on the new framework in May, according to Adrian Bartlett, EU policy manager at the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

EU member states are now in the middle of scrutinizing the updated document, which includes "a lot of very minor technical legal changes, but a couple of more substantial things," Bartlett said during the European Symposium on The New Agreed Draft Regulations on Medical Devices in Prague. He spoke via link from the UK to the meeting organized by the European Association of Authorized Representatives.

The latest version of the MDR under review runs 369 pages, up from the 355 in the document agreed in May. Either way, it's a major jump from the 60 pages that entail the full current Medical Devices Directive (MDD). The MDD only had 20 articles, compared to 97 for the MDR.

Bartlett suggest that the texts, including the MDR and the parallel IVD Regulation, might not be adopted until April next year, slightly later than the first quarter predictions that had been made by others.

The good news is that updates made since May are mainly focused on finding practical solutions to some current inconsistencies in the original document. But member states need to tread carefully in reviewing the proposed legal review changes, Bartlett suggested.

"It is not clear if the changes will find their way into the final version of the texts, because we are at the stage where if one single member state objects, then we can't proceed because it is too risky to reopen negotiations again. But we are working very hard to rectify the small legal nuances that we have," he said.

More significant changes that are being proposed to the IVD Regulation text include amendments to address a couple of important anomalies impacting class B, C and D devices (all but the lowest risk IVDs). Specifically, there are revisions addressing the fact that the conformity assessment of class B and C IVDs would currently require an identical amount of effort, burden and time – whereas requirements for class B devices should be less onerous than requirements for class C products.

There is also attention on the originally included requirement for reference laboratories to be designated 4.5 years into the IVD transition period, i.e., probably in the final quarter of 2021. This is considered too late given that the IVDR fully applies in spring 2022. On this point, it appears that the European Commission will propose bringing forward that date or including some transitional provision. The transitional provision, Bartlett explained, is likely to state that if you comply during the transition period with all other requirements for a class D IVD but a reference laboratory does not exist in the EU, then you would not need the opinion of a reference laboratory before putting the product on the market.

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> "Updates made to the MDR in the past six months include "a lot of very minor technical legal changes, but a couple of more substantial things," says Adrian Bartlett, UK MHRA.

CHALLENGES AHEAD

Starting from six months after the regulations take effect – i.e., likely from October 2017 – devices can, in theory, be placed on the market under the new regulations, Bartlett noted. In reality, however, it will only be possible to put some class I medical devices onto the market and class A IVDs, as notified bodies will not have been designated by that point and these are the only products that can reach the market without the involvement of a notified body.

EU MDR/IVDR implementation challenges and steps to address

IMPLEMENTATION CHALLENGES	KEY DETAILS OR STEPS TO ADDRESS
Re-designation of notified bodies	The EU member state competent authorities are working with the commission to identify the most pragmatic solution. The commission has said, for example, that if a notified body has recently undergone a joint assessment with no major nonconformities, that it would not see merit in repeating a lot of that work a year, or a year and a half later, but instead building on the results of that assessment against the slightly more expansive MDR requirements.
Further documents still to draft	Some documents need to be in place by the date of application (early 2020 for the MDR and early 2022 for the IVDR) and some even earlier to provide clarification for the system to show what the regulations actually mean and how they will take effect. These include some "implementing and delegated acts," as well as some common specifications and guidance.
Implementing acts	Only 14 of the implementing and delegated acts of the 80 or so in the new regulations are "compulsory" and need to be completed by the date of application. The competent authorities are currently working on these. The commission taking the lead, but the national authorities are having "quite a significant say in the content of them," Bartlett said. The rest of the implementing and delegating acts are intended to aid future enhancements and clarifications of the legislation.
Guidances	Member states will not be at liberty to draft their own guidance documents any more. It is the responsibility of the commission to issue single consolidated guidance on an issue for the whole EU. The competent authorities will be heavily supporting the commission to identify what guidance needs to happen when, draft it and reach agreement with other competent authorities. The role UK MHRA could play in the process following the carry-through of the country's exit from the EU remains to be seen.
EU-wide collaboration	To address all the challenges, the Competent Authorities for Medical Devices (CAMD) group has set up a task force whose goal is to collaborate on implementation issues, both for the sake of consistency and to prevent authorities limited resources around Europe from being wasted in duplicating efforts across member states. This group is defining key priorities with the intention of sharing the load.
National derogations	There will be a lot of activity at the national level because of potential derogations, for example, for in-house manufacturing and reprocessing, where member states are free to make some choices at the national level.
Brexit	Bartlett emphasized that as far as the MHRA is concerned, the UK remains a full EU member state until it actually leaves the EU. And the MHRA is working on the assumption that even at that juncture in time "the UK will follow the EU's MDR and IVD requirements the same way as the rest of the EU will. Whether this will be within a different regulatory framework or system, I don't know, but I am finding it hard to think of a scenario where we follow different requirements," Bartlett said.
Eudamed medical device database	The commission is leading on this, another major implementation challenge. The ball is in its court and the commission has provided reassurances that Eudamed will be ready in time, Bartlett said, although some are not convinced this will be the case. The UK is leading the Eudamed Working Group.

He also noted:

- Re-designation of notified bodies can start to happen beginning six months after texts take effect;
- The Medical Device Coordination Group will also be established from six months after the texts take effect, and the commission plans providing more information on that in due course;
- By the end of the transition period for the MDR, around April 2020, there will need to be common specifications for new products that are considered "aesthetic devices without a medical purpose," which are addressed in Annex XV of the MDR document posted in May, but is "Annex XVI in the latest version," says Bartlett; and
- The new Eudamed database will need to be operational as soon as possible, but if it is not fully operational, there is a provision for the Eudamed requirements related to be delayed until the commission declares the database operational.

Bartlett described the re-designation of notified bodies as "probably the biggest challenge in our whole implementation program." He said it is creating a "massive" amount of work that is vital to the success of implementing the regulations. Another particularly tough hurdle is having the new European medical device database, Eudamed, ready on time.

See the table below for details on the approach being taken on these matters, and several others, according to Bartlett.

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Notified Bodies Can Concurrently Audit Under New And Old EU Rules, UK Official Confirms

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When the European Commission redesignates a notified body under the new Medical Devices Regulation (MDR) from the established Medical Devices Directive (MDD), that notified body will still be able to issue certificates under the MDD, as well under the MDR, during the three-year transition period until MDR is fully applied, likely in the first half of 2020. The Commission recently clarified that point, according to Adrian Bartlett, EU policy manager for medical devices at the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

Bartlett disclosed that update during the Nov. 7-8 European Symposium on The Agreed Draft Regulations on Medical Devices, organized by the European Association of Authorized Representatives (EAAR) in Prague, Czech Republic.

"It is not as if on the day that the notified body is redesignated it loses its designation under the MDD," Bartlett, asserted during a Q&A session at the symposium. This wording is not in the new Regulation, he said, but "it is the position of the Commission," he said.

> "It is not as if on the day that the notified body is redesignated it loses its designation under the MDD," UK MHRA's Bartlett says.

His statement follows many contradictory opinions voiced at recent meetings on the notified body's eligibility to continue testing against the MDD once redesignated under the new regulation.

The notified bodies are communicating that they want as long as possible to manage the transition phase, Bartlett told the Prague meeting. The organizations may have clients with hundreds of products and need to phase in auditing under the new regulations over the transition period.

Bartlett provided interesting and revealing answers to a range of questions put forward by those active within the EAAR, especially on the subjects of the continuation of the Medical Device Experts Group; the possibility for companies to rely on using historic clinical data; and whether delays in the new MDR/IVDR system could bring the provision of health care in the EU to a grinding halt.

A snapshot of some of the questions and answers during the session are provided below.

Mika Reinikainen, managing director Abnovo (UK): At the moment we have a good system for collecting stakeholder opinion with Medical Device Experts Group (MDEG) and the various working groups. Do you see that continuing? Or are we moving into a system within the Medical Devices Coordination Group (MDCG) where member states appoint experts and other stakeholders do have not access anymore?

Bartlett: I understand that the MDCG and its open plenary sessions will replace the MDEG and I can't see any reason why the Commission would exclude stakeholders and not seek their views on a regular basis, although I can't speak for how it would model it. The Commission hasn't set out in detail what the MDCG structure will look like and how often it will meet. But it has said that resources are limited, so they are not overselling how often it will meet.

Sarah Sorrel, president, MedPass (France): We deal with a lot of novel high-class devices and we are very preoccupied with clinical evaluations. You talked about the competent authority task force. Are all the competent authorities you mentioned active in all areas of the task force? Or who is on the task force for clinical?

Bartlett: All of the task force countries work together on the task force as a whole. We have assigned one or two people to lead on each cluster. [**Editors' note:** *There are 7 clusters*.] The HPRA in Ireland has taken the lead on clinical. But it is collaborative and we need to get all the task forces to buy into the plan. It is not an exclusive task force. It is open to any member states who want to get involved.

Sorrell: One big multinational company at a meeting explained that it was, disturbingly, going to have to retire some devices that had been on the market for a long time because of the new clinical evaluation requirements that will apply to devices. Are you planning any grandfathering for devices that have been on the market for a long time in the view of the work there would be to redo all these clinical evaluation reports under the new requirements?

Bartlett: The latest version of the regulations will allow for clinical data gathered under real-market use to be used for

proving the safety of your device in the future - as long as you are not making substantial changes to it and the previous data is still relevant.

You should be able to use data already gathered for existing devices. But where the change is substantial, then you may need more clinical evidence. But these are the high-risk, class III devices.

Sorrel: With emerging technologies and the scrutiny procedure, when we are developing something that is novel and high-risk, it is important to have some sort of strategic or scientific advice. Since the system is changing and these products may undergo a scrutiny procedure later, what is the status of appointing the expert panels? What sort of panels will be available at EU level - by technology or by therapeutic area? Who will be on these panels? And when will these panels be available?

Bartlett: The Commission has not determined this yet. There will be a pool of experts available to the Commission through its Joint Research Centre and manufactures would write to the JRC at the Commission if they wanted an earlier/ facultative consultation. The commission would then assemble an appropriate expert panel. It is not as if the panels already exist now; the commission will determine how to create the panels on a case-by-case basis

The panels will all be clinically focused and made up of practicing clinicians with real world usability perspective and I am sure between now and then there will be more clarity on what the commission will do in the future.

> "The latest version of the regulations will allow for clinical data gathered under real-market use to be used for proving the safety of your device in the future - as long as you are not making substantial changes to it and the previous data is still relevant," Bartlett says.

Ronald Boumans, senior global regulatory consultant at Emergo (Netherlands): There are many reasons why devices will lose market access during the transition period – increased clinical evidence requirements, notified bodies ceasing, for example. Have the authorities assessed how many devices can randomly exit before the health-care system breaks down?

Bartlett: No. we have not done that analysis concerning products that can't be brought into conformity with the regulations.

But when it comes to certificate validity and extension of that validity under the Medical Devices Regulation for class IIa, IIb and III products, [Editors' note: All of which need the involvement of a notified body], there will be the option to continue to place them on the market up to four years after the end of transition period under the certificate issued under the Directives. IVDs will have just two years after this point, but there is a longer transition period [of five years].

That was negotiated to allow for more time for manufacturers to get up to speed. The hard line from the [EU] Council, Commission and Parliament is that if companies can't get their products into line with the new regulations within seven years, then they shouldn't be on European market.

Boumans: Companies are already having problems getting certificates renewed and extended. Notified bodies are going out of business. I asked this question to a hospital manager in Netherlands and he said that if between 1% and 2% of devices are randomly cut out of the system, hospitals will have to cease working.

Bartlett: One of the key problems is the notified body issue and that is probably our number one concern and focus throughout this. This is why we need clear communication with hospitals and patients about what we are doing and why. But it is our hope that as we raise standards, more innovative products will appear and the quality will be raised.

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New EU Competent Authority MDR/IVDR Task Force Formed

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Given the huge challenges for competent authorities associated with implementation of the EU's new Medical Device and IVD Regulations, the European Commission's Competent Authorities for Medical Devices group (CAMD; made up of member state authorities) has set up a task force to explore opportunities for collaboration.

The task force, which met last month in Bratislava, Slovakia, is being led by the UK, with Ireland, Germany Switzerland, Sweden and the commission involved, Adrian Bartlett, EU policy manager at the UK's Medicines and Healthcare products Regulatory Agency (MHRA), revealed for the first time publicly in Prague this week. The Dutch have recently said they would like to join the task force as well.

Bartlett explained that the measures are being proposed to optimize the implementation throughout the European Economic Area. "We are tackling the big issues together and supporting each other with the output, as this will be a big resource issue for all of us," he told the European Symposium on the New Agreed Draft Regulations on Medical Devices in Prague. The meeting was organized by the European Association of Authorized Representatives and Bartlett spoke via a link from the UK.

The task force aims to draft a clear plan of action – which it is well on the way to doing, Bartlett said. At the meeting in Bratislava, it identified key problems and what steps to take. The group is taking a bite-sized approach, the MHRA policy manager said. It is all about collaboration between member states and establishing a consistent message, he emphasized.

The task force has broken down the regulations into seven manageable priority clusters:

- Notified bodies, including how to get them redesignated and capacity issues;
- Clinical issues, including drafting common specifications and more clarity on clinical evaluations and equivalence issues;
- Issues surrounding classification and scope, including the reclassifying some devices from MDD to MDR; the new rule on software and aesthetic devices;
- Registration, including UDI, looking at how the supply chain deals with the single registration number, and implant cards;
- Market surveillance, including looking how to coordinate liability;
- Vigilance, including looking at periodic safety update reports, how the Eudamed medical device database can be integrated, and how data can be used for improving patient safety and oversight of the system; and
- IVD-specific issues, with companion diagnostics being seen as a particular unique challenge.

Bartlett explained that this work is going to be split up across Europe, and that all member states – not just from the EU, but also other countries in the European Economic Area – are engaged in cooperating.

The task force is at the stage of analyzing feedback on its proposals and the next step "will be to compile it all into a higher level action plan with these priorities."

He added that CAMD will be engaging widely with stakeholders in early 2017 and planning workshops –possibly in Brussels and the UK.

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UK Extols NHS Asset In The 'No Plan B' Post-Brexit World

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The UK medical technology industry is subject to a constant barrage of challenges.

It suffers under the wider funding peculiarities that the national provider, the National Health Service (NHS), endures; and it has its own battles with policies relating to the adoption and reimbursement of cost-saving innovations. The challenges come in waves, and the wave looming offshore right now might be the biggest one yet.

The size of the task ahead was quantified at the UK industry association's (ABHI) recent markets conference.

Slowly, the UK health-care landscape is changing, with a gradual shift to accountable-care organization (ACO)-style health-care delivery based around the new model-of-care Vanguard sites, and Sustainability and Transformation Plans (STPs). But medtech small-to-medium enterprises are continuing to face difficulties accessing the national market, due partly to "hostile behavior in the procurement arena," ABHI chairman Phil Kennedy observed.

This is making companies turn their backs on the NHS, he said. "Week by week, more and more companies are exiting the NHS procurement market – it's an intolerable situation," Kennedy told delegates at the **Simmons & Simmons**-hosted conference. It's a missed opportunity when these companies should be viewing the NHS as a platform to build their local, and then, export positions.

Consultant and former NHS senior manager Mike Farrar agreed. 99.5% of the UK population is registered to the NHS. It should be a market of choice for medtech developers. "If you can demonstrate proof-of-concept here, it's the best shop window for the rest of the world."

Farrar did not downplay the financial woes of the NHS, with £22bn ($27bn) of the projected £30bn funding gap in 2020 needing to be filled from internal productivity gains, according to an assessment by NHS chief executive Simon Stevens.

But NHS has not responded to the overwhelming financial challenges by innovating and digitizing. ABHI chief executive Peter Ellingworth complained that the medtech industry has had to face "constant change in the way it goes to the market with the NHS."

Nonetheless, there were encouraging words from parliamentary Under-Secretary of State for Health Lord Prior of Brampton on the financial and delivery challenge during the meeting. "In the past we've seen the medtech industry as part of the problem, but I see it as part of the solution," he said, adding that access to the biggest single-payer system in the world could and should be a massive incubator and engine for the industry.

The Accelerated Access Review (AAR), belatedly published this month, is a good start, he said. Lord Prior said that in the next three to four months he will be drawing up a life-science strategy to file as a Green Paper by the end of March 2017. He will push for longer-term private capital to play a greater role in UK health care, bearing in mind that venture capital funding is short term as a rule.

Accelerated access to the NHS is a potential trump card for the UK now and as it leaves the EU, he believes. "Brexit is a catalyst – a wake-up call. We do want sustained access to the EU market, but 'business as usual' is no longer an option," he said. "In fact, it means failure." In his view, there is an attractive narrative that could come from being outside of Europe.

TRANSFORMATION HAMPERED BY CAPITAL ISSUES

The problem as Nuffield Trust chief executive Nigel Edwards described it is that the NHS has little transformation capital – its budgets have been "raided," and the economics of change for hospitals are financially challenging. Compounding the situation, the social-care sector has flat funding and the concept of standardization of procurement has been promised before. Getting to the heart of patient flows and lengths of stay will require new services and workflow models.

The NHS Improvement (NHSI) body was set up in April 2016 from the merger of Monitor, the NHS Trust Development Authority (TDA) and four other groups to provide a better oversight function for NHS providers. NHSI wants to work with industry on specific programs such as the "digital outpatient." It also wants providers to contribute to the STPs, and to promote the spread and adoption of innovation via the Academic Health Science Networks (AHSNs).

> "Week by week, more and more companies are exiting the NHS procurement market – it's an intolerable situation," ABHI's Kennedy says.

EXPLICIT REIMBURSEMENT ROUTES

At the NHS, Stevens has been laying out pathways for more rapid reimbursement of proven innovations. At the NHS Confederation annual meeting in June 2016, he set out three new routes of a so-called New Innovation and Technology Tariff. This, he says, presents for the first time a clear path to market for innovations identified in three new "real-world" assessment programs:

- The NHS Innovation Accelerator (NIA) program, which was actually launched in 2015 to introduce high-impact, tried and tested innovations into the NHS. By fall 2015, 68 more organizations were using NIA innovations than at the start of the program;
- The NHS test-beds program (launched at the World Economic Forum in January 2016), which was set up in January 2016 to evaluate new technologies that offer better care at the same, or lower, overall cost. The test beds are due to produce evidence of the impact and cost effectiveness of their innovations in 2018; and
- A Commissioning through Evaluation (CTE) program, which will enable a limited number of patients to access treatments that are promising but not yet funded by the NHS, while new clinical and patient experience data are collected within a formal evaluation program.

The NIA initiative kicked off the three-pronged plan in 2016-2017. The other two routes will follow in 2017-2018. These explicit national reimbursement routes should accelerate the uptake of new medtech devices and apps for patients with diabetes, asthma, sleep disorders, heart conditions other chronic health conditions, common mental health disorders, infertility and pregnancy issues, and those needing obesity reduction/weight management care.

Lord Prior also wants the UK medtech industry ecosystem to be ready to adopt best-practice methods in R&D and innovation integration that are used in selected overseas life sciences development hubs, in, say, Minneapolis, the Bay Area and Boston. This will be all the more necessary as UK allocation of GDP to public health care is projected to dip from 7.5% to 6.5% by 2020-2021.

CLOUD OF BREXIT NEVER FAR AWAY

Meanwhile, with regards to Brexit, what trading relationship with the EU27 that the UK government selects will not be known for several months. And its choice may be restricted by the UK Parliament, based on recent successful legal challenge (that is being appealed) to the UK government's assumption that it may decide these matters independently. There are further concerns over the UK's diminishing access to the EU's Horizon 2020 research program, and, after that, its FP9 program.

As an economic theme, Brexit is ever-present and will be all-encompassing, but it is just one of the elements driving the necessary changes in UK health care. Lord Prior is adamant: "I've never known a time when the NHS has been more ready for change."

Change is imperative, and in fact there is no "Plan B" to the course the government has set for the NHS, he warned. "We are fully committed to the STP process, and to taking care into people's homes from hospitals." And as to the industry's role, as expected, it will require a "huge input" from companies in terms of new technologies.

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UK Looks To Model New Medtech Strategy On US Successes

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The UK is now drawing up a new life-sciences strategy, the medtech elements of which will seek to emulate the activities and programs run out of Minneapolis, the Bay Area and Boston in the US. It is also looking at a small handful of other global hubs in Germany, Shanghai, Ireland, Singapore and Israel, as models.

Junior UK health minister Lord Prior of Brampton described the attributes of these US and other hubs that he wants the UK life-sciences sector – worth £61bn ($76bn) and employing 222,000 people – to absorb. Speaking at the UK Association of British Healthcare Industries (ABHI) market conference on Nov. 2 in London, he said it was vital to reach out and learn from proven success stories.

Part of the backstory is that he wants the UK to remain open to talent post-Brexit, and, indeed, to know how to poach it. "Fifty percent of UK research involves foreign collaborations, and the UK has to stay open to talent for the EU and rest of the world," he told ABHI delegates. He itemized the reasons to look at the US hubs for inspiration:

- Minneapolis' historic basis in cardiothoracic implantables, from the Mayo Clinic and University of Minnesota, makes it worth of study, even though the industry is having to operate under new, stricter FDA regulations which is disproportionally affecting complex implantables.
- The Bay Area of San Francisco has an entrepreneurial culture and talent base, including venture capital funding activities at the Stanford School of Medicine and the University of California, San Francisco, and it is also a region where major venture capitalists drive extensive through-cycle funding.
- Boston has a "square mile of talent, skills, and funding" – at Kimble Square – and fosters the organic growth of start-ups and corporates around Harvard Medical School and the Massachusetts Institute of Technology. And it has a rich of basic science expertise, including in the CRISPR genome editing system.

But Europe – including the UK – is "way off the pace" vis-à-vis technology developed in the US, Lord Prior said. In the US, a different mind-set prevails – one where «competition drives innovation.» Lord Prior wants the UK to work more collaboratively with US FDA on regulation. He suggested that, post-Brexit, «We can do something quite special in this country on regulation,» while having no firm ideas to reveal just yet.

As part of his brief, Lord Prior has been visiting global medtech industry capitals to takeaway best practices. In Minneapolis last month, he also visited the AdvaMed 2016 conference, where he was hosted by the ABHI, and spoke to UK-based companies that are looking to increase their US exposure and business. He also canvassed the industry's views on national issues, such as the Health Services Medical Supplies (Costs) Bill, the UK Apprenticeship Levy, and proposed charges from the UK MHRA and National Institute for Health and Care Excellence (NICE).

The new realities of what it takes for global business success were the pervading themes at the AdvaMed conference. The key takeaways for the UK delegation were the consensus about the move away from payments based on volume activity and move toward an outcomes-based systems of payments fed by real-time data collection using analytical technologies such as the **IBM Watson**.

The ABHI says it plans a major UK initiative launch at AdvaMed 2017 (to be held in San Jose, Calif.).

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How Open Science Is Keeping Allergan's R&D Pipeline Strong

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Innovation is a key pillar in the growth strategy of any life-sciences company, but according to David Nicholson, chief research and development officer of specialty pharmaceutical firm **Allergan PLC**, it is also the biggest challenge.

"You need to focus, you need to interact with the external world and make sure the pipeline is full of innovative products," he told *Medtech Insight*. The days where one can come onto the market with me-too products are long gone, said Nicholson, and the products in a healthy R&D pipeline today need to be truly disruptive. "And there is so much R&D that can be done outside of one's company walls than done within, which is why excellence in partnership, excellence in collaboration and excellence in open science is essential."

This concept of "open science" is the basis of Allergan's R&D model, and to which the company attributes the strength of its pipeline. Indeed, speaking at the Credit Suisse Health Care Conference on Nov. 8, Allergan CEO Brent Saunders described the firm's R&D pipeline as its "best-kept secret," housing several "really innovative opportunities" to change diseases in seven therapeutic areas it is focused on: dermatology (including medical aesthetics), ophthalmology, central nervous system, gastrointestinal disorders, urology, women's health and anti-infectives.

Many of these products are already in late-stage clinical trials, and the company is expecting eight new product launches in 2017. "We're in a very strong innovation cycle and the opportunity for new product launches at Allergan has never been greater," Saunders told delegates at the Credit Suisse conference.

So what does following an open science R&D model entail?

"Our open-science model is about having an open attitude to the outside world. It means we build our pipeline primarily through partnerships, acquisitions, collaborations and in-licensing with academia, biotech and other pharma companies," explained Nicholson. In addition to acquiring and in-licensing, Allergan also has an internal R&D group which partners with the company's collaborators. "This group's expertise is to finalize and complete development of the products that are in-licensed, get them approved by regulatory authorities and keep them on the market."

David Nicholson, chief R&D officer, Allergan

Photo credit: Allergan

> "There is so much R&D that can be done outside of one's company walls than done within, which is why excellence in partnership, excellence in collaboration and excellence in open science is essential."

Allergan is by no means a pure-play medtech, with a large part of its portfolio made up of pharmaceuticals. Prior to its milestone merger with **Actavis** in March 2015, **Allergan Inc.**'s medical device assets – mainly breast implants and fillers for aesthetic medicine – accounted for roughly 14% of sales, and there was speculation that devices might be put on the auction block once Allergan's $66bn acquisition by the generics giant was completed.

However, this has not been the case. Not only have medical devices stayed put, the new bulked-up Allergan PLC has made a number of interesting device acquisitions to expand its pipeline.

These acquisitions have mainly been in eye care and include: **Oculeve Inc.**, acquired in August 2015, **AqueSys Inc.**, acquired in October 2015, and its most recent purchase, **ForSight Vision5 Inc.**

Stanford University spin-out Oculeve brought Allergan an intranasal neurostimulation device – to be marketed as *True Tear* – designed to alleviate dry eye by stimulating the trigeminal nerve that innervates the lacrimal gland and thus induce production of natural tears. "In the clinical studies that were performed [on True Tear], many of the patients who utilized the device didn't want to give it back; they wanted to keep it," said Nicholson. That is a bit anecdotal but speaks to the efficacy and usefulness of the device for dry-eye patients." While Allergan already markets *Restasis* (cyclosporine) – a

drug and one of the company's top sellers – for dry eye, Nicholson believes that there is more than enough room in the market for a device-based therapy.

"Dry eye is relatively underdiagnosed and it's certainly undertreated. It's our belief that the awareness of dry eye is going to grow. The number of patients treated for it will increase and there will be more demand for an alternative treatment regimen. We do believe a good proportion of dry-eye patient will like or even prefer True Tear," he said. "What we've seen in clinical studies is really impressive efficacy, which was maintained over time without any drop-offs. So we really do believe there is a substantial place in the market for this novel device."

True Tear is CE-marked and currently under review for *de novo* approval by US FDA; the device will hopefully be among the batch of new product launches planned for next year.

Also under review by the US agency, for a 510(k) clearance, is AqueSys' *Xen45* gel stent for reducing intraocular pressure in glaucoma patients. The product is already CE-marked and while it will likely be initially used in patients with more severe forms of glaucoma and greater elevation of intraocular pressure, Nicholson believes that over time, XEN45 could move toward more mild to moderate grades of glaucoma. "It is very easy to implant and as people get more used to it, then we'll see greater use of the stent in glaucoma then we're going to see initially."

With drugs featured heavily in its portfolio, finding innovative drug-device combinations for better delivery of therapeutic agents is also high on Allergan's R&D priority list.

The ForSight Vision 5 acquisition has brought to Allergan a noninvasive periocular ring designed to be inserted into the eye, resting under the eyelid, while it releases a therapeutic agent over several months. The first indication for the ring is glaucoma and it has been developed to release bimatoprost, although it can be applicable to different indications and drug combinations.

Allergan's pipeline also includes its own drug-device combinations, such as bimatoprost SR, a tiny implantable rod that releases the agent over time. Outside of glaucoma, the company is already marketing globally Ozurdex, an dexamethoasone intravitreal implant for treating diabetic macular edema. The advent of these and other less invasive, more efficient devices and drug-device combinations will, to some extent, tip the balance in the drugs-dominated eye-care market, Nicholson predicts.

Within aesthetics and dermatology, the other key therapeutic area where Allergan's main device offerings are based, the company has also been shopping and acquired in October last year Northwood Medical Innovation, developer of *earFold*, a medical device for the correction of prominent ears.

Allergan is also looking at advances in hyaluronic acid, high- and low-molecular weight combinations, for different parts of the face. "We want to develop fillers that more closely mimic the rheological properties and viscosity of the natural tissue in different parts of the face. We're working on that and we're already rolling out some of those fillers. We are also looking at duration of effect of the fillers and are finding out, in consultation with dermatologists, how long the patients would like to see fillers work after single administration," said Nicholson.

The chief R&D officer acknowledges that Allergan's device offerings are largely in medical aesthetics and eye care, rather than in the company's other five therapeutic focus areas. But he added: "Devices at the moment are somewhat more applicable in some therapeutic areas than others, but if there were devices which are going to be useful in the treatment of psychiatric disorders, for example, then we would be absolutely interested in that."

He asserted that Allergan's overriding interest is "in providing things that bring benefits to our customers and to our patients, and to meet that unmet need. So whether we're dealing with pharmaceuticals or devices, we're agnostic to that."

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Siemens Teases With Healthineers-Go-Public Message

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Siemens announced it plans to publicly list its health-care unit after more than two years' speculation about whether or not an IPO is really on the cards for the €16bn-plus business. However, details are lacking about when the listing is taking place and how big the shares float will be.

Siemens first said in May 2014 that it was legally carving out its health-care business – which took on the new brand name Siemens Healthineers earlier this year – and managing it separately as "a company within a company." The move was part of the group's wider Vision 2020 initiative to streamline and reorganize its different businesses for long-term growth potential. The separation of health care aimed to restructure the business in a way to meet the specific requirements of the health-care market, rather than to conform to Siemens' organizational matrix. At that time, Siemens said that the realignment will give its health-care business "greater flexibility on the medical technologies market, which is characterized by fundamental changes and paradigm shifts."

While Siemens has since regularly given updates on its progress on the carve-out, the group has never officially confirmed that its ultimate intention was to float Siemens Healthineers – until now.

The confirmation came as Siemens reported its fourth-quarter and full-year figures for fiscal year 2016, which ended Sept. 30. The German group described the fiscal year was "one of the strongest in the history of the company." Healthineers reported Q4 revenue of €3.70bn (+2%) and full-year revenue of €13.53bn (+5%), while its double-digit, high-teens profit margins were the highest of all Siemens' businesses. Healthineers was a key growth driver – together with Power and Gas, Energy Management and Wind Power and Renewables – that helped offset declines in weaker units like Process Industries and Drives.

In a Nov. 10 conference call with investors, Josef Kaeser, Siemens president and CEO, said there was clear revenue growth in the diagnostic imaging segment and called Siemens Healthineers the "undisputed innovation leader with best-in-class market shares in diagnostic imaging and an installed base of around 600,000 systems in the field." In lab diagnostics, he said the company is expecting to catch up with competition after the rollout of a new platform, Atellica. "[This product division is] continuing to invest in innovation and we're investing in go-to-market to enhance our already very strong technology position."

"As you can see, there's a lot of progress which we have made… and we have delivered on what we promised according to our Vision 2020," he told investors. With the legal carve-out of Siemens Healthineers nearly completed, a public listing is "the best option and a logical next step to provide flexible access to the capital markets and further strengthen the Healthineers business in the future," said Kaeser.

When pushed for more details about its IPO plan, Kaeser demurred. "The market should take as a message [from this announcement] that 'we do what we say and that we are preparing the next step.' That's the message. Sometimes it helps to reassure stakeholders by doing what we said we would do. There's nothing more and nothing less," the CEO said.

The company indicated its commitment "to remain a long-term majority shareholder of the Healthineers business." Kaeser maintained, "We are convinced that we can easily further extend our leading position."

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Sphere Medical Gears Up For EU Expansion With Proxima 4

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Blood-monitoring specialist **Sphere Medical** is set to expand its commercial footprint in Europe in the coming months, after CE-marking its newest generation *Proxima 4* device in September.

Proxima 4 is a patient-connected blood gas analzyer that measures blood gases and electrolytes over a 72-hour period using a disposable transducer that sits within a patient's arterial line. When an arterial blood gas analysis is required, blood is collected from the patient into the Proxima sensor in a closed system and a panel of analytes is used to measure results. The blood is then returned to the patient and results are displayed on a bedside monitor.

The system is designed to be used on patients across a wide therapeutic range, enabling "faster clinical decision-making and improved patient outcomes." It also aims to overcome some of the challenges associated with frequent measurements, such as blood and infection risk.

CEO Wolfgang Rencken told *Medtech Insight:* "The current solutions on the market are not very supportive of frequent measurements, so with Proxima 4 we tried to develop a system that addresses these issues. As our device is a closed system it can deal with infection risk, and by returning all the blood to the patient it avoids bloods loss." He added that as the device is patient-connected and collects data from the bedside it delivers closer monitoring than standard BGE solutions, resulting in a reduced workload for nurses.

Rencken explained that an additional benefit of the device was its capacity for multiple usage, compared to competitors that charged clinicians per test. "You can do as many tests as you want within 72 hours, and we have a fixed price for the de-

“There’s no similar system out there on the market to us so we are pretty unique, and we’re considered the new kid on the block who is going to shake up the tree. However, our competition is more inertia – getting people to change their medical practice. That’s our biggest barrier,” Sphere Medical CEO Wolfgang Rencken says.

vice which is irrespective of the number of tests [that are performed]. So the more you test, the value proposition increases and the cheaper the technology becomes,” he said.

The company conducted a study at University Hospital Southampton cardiac intensive care unit in early 2016 to examine the workflow impact of Proxima in hospitals. The study recruited 20 patients – 10 on Proxima and 10 using standard blood-gas analyzers – and took an average of 10 measurements from each patient over 24 hours. Results showed that Proxima delivered a significant reduction (>20%) in total time per sample, and a >50% reduction in delay to start of testing. It also reduced the mean time nurses spent away from the bedside.

Proxima 4 aims to be an improved update of the company’s earlier prototype, *Proxima 3*, which was launched in 2014 in the UK and is currently sold in Europe via a small salesforce operating in the UK, Germany, the Netherlands and Belgium. Rencken said whilst Proxima 3 had not been earmarked for “big commercial traction,” it had shown early promise with increasing interest from the market. “For Proxima 3, it was all about getting the product out there and getting feedback. However, progressing to a commercial sale in each territory was important in showing that it’s not a UK-specific or German-specific product. We’ve shown that every single country (if you start selling in that country) will adopt the product after some time.”

The device was upgraded based on feedback received from clinical staff using Proxima 3 that identified a number of improvements. New functions in the latest-generation system include glucose and sodium analysis, and increased connectivity with hospital IT systems. The device will also be suitable for use with patients aged three and above for the first time. Feedback also showed that nurses wanted a more automated process – a request the company intends to develop for future upgrades.

Currently, Sphere Medical has plans to roll out Proxima 4 across Europe by lining up distribution partners. The company recently appointed Burke & Burke as its Italian distributor and expect additional partnerships to be lined up during the coming year. While the US and Japan have also been identified as major markets, Rencken said they were still in the stages of evaluating strategy for approval.

He admitted that the major challenge with Proxima 4 was convincing clinicians to change clinical practice. “There’s no similar system out there on the market to us, so we are pretty unique, and we’re considered the new kid on the block who is going to shake up the tree. However, our competition is more inertia – getting people to change their medical practice. That’s our biggest barrier.”

Additional updates have also been identified by the company in the hope to expand its market reach even more with a Proxima 4+ update in the next year and a half. Rencken said: “We’ve learned that by bringing on lactate to the system we can target sepsis patient groups as sepsis requires patients to be monitored very frequently. So by adding lactate to the system we can tackle an even larger unmet need and increase the number of patients [using the device] further.”

The company is currently backed by fund managers Woodford Investment Management, Arthurian Life Sciences and LSP. Analysts from Trinity Delta have forecast Sphere to record sales of £0.7m ($0.87m) in 2017 – up from an estimated £0.1m for 2016 – with Proxima 4 giving the topline a significant boost.

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Biocompatibles Settles Charges Of Illegally Selling Device As Drug-Delivery Combo

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Biocompatibles Inc.'s recent $36m settlement with the federal government stemmed from allegations that the **BTG Plc.** subsidiary sold its *LC Bead* device as a combination product without proper approval, according to US Department of Justice. The arrangement included a guilty plea to a misdemeanor misbranding charge.

LC Bead is used to treat liver cancer, among other conditions. US FDA cleared it as an embolization device that could be placed in blood vessels to block or reduce blood flow to tumors or arteriovenous malformations. But DoJ says Biocompatibles also marketed the product as a drug-device combination or "drug-delivery" bead, an indication that had not been approved by FDA.

In fact, FDA in 2004 specifically sought and obtained the company's agreement not to market the device for drug delivery. But two years later, Biocompatibles' US sales and distribution company began to do exactly that, according to DoJ. The sales company reportedly told its sales reps that LC Bead was a drug delivery device and encouraged them to "aggressively penetrate the chemoembolization market," DoJ says. The government claims the company's sales reps made unsupported claims including that the device increased the level of chemotherapy delivered to a liver tumor and resulted in "better tumor response rates."

DoJ claims Biocompatibles intended to market the LC Bead as a combination product from the time the product entered the US market in 2005. The company submitted the drug-delivery indication for FDA clearance in 2009, but was told there wasn't sufficient clinical evidence.

The $36m payout includes an $8.75m criminal fine for the misbranding and a $2.25m forfeiture. Additionally, Biocompatibles is to pay $25m to resolve civil violations of the False Claims Act by causing false claims to be submitted to government health-care programs. When used as a drug-delivery device, LC Bead became a combination product that had never been approved by FDA or assigned payment by Medicare.

The alleged violations took place between 2003 and 2011; BTG bought Biocompatibles in 2011. The investigation was first announced in 2014.

The civil settlement, which did not include an admission of guilt, also resolves a whistleblower suit filed by former LC Bead marketer Ryan Bliss. Bliss stands to get about $5.1m as a result of the settlement.

Biocompatibles could not be reached for comment. The company previously announced the settlement in October without disclosing details of the alleged wrongdoing; at that time, BTG CEO Louise Makin said she was pleased to resolve the legacy issue.

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