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# Industry Advocacy Group Goes Global After Device Tax Repeal

by Ferdous Al-Faruque

After an eleventh-hour win last year that saw Congress repeal the medical device excise tax, AdvaMed is going more global. CEO Scott Whitaker sat down with *Medtech Insight* for a lengthy chat about what the lobby group will focus on in 2020, including reimbursement challenges, the upcoming medical device user-fee negotiations, and negotiations with governments that are key to the industry ecosystem.

AdvaMed may have won a seven-year fight to repeal the 2.3% medical device excise tax, but the largest medtech advocacy group is not resting on its laurels just yet. CEO Scott Whitaker says the next battlegrounds include reimbursement certainty for industry, access to international markets, ensuring realistic ethylene oxide (EtO) sterilization regulations, and more.

> ***"I was excited to get device tax off the plate because I didn't want to be defined as a device tax trade association or a device tax industry." – Scott Whitaker***

Whitaker recently sat down with Medtech Insight at his office in Washington, DC, for a podcast interview covering a broad range of topics, including the strategy the industry group took to repeal the device tax and what's on the agenda for 2020. (See sidebar Q&A.)

## Device Tax Repeal

On 23 December, President Trump signed into law a repeal of the medical device tax that has been the focus of AdvaMed's lobbying for the past seven years. While the tax was intended to

raise $30bn over ten years, it was only in effect for three of the past seven years, as medtech lobby groups were able to pass a couple of temporary moratoriums, essentially kicking the can down the road until they could get a full repeal. (Also see "*Trump Signs Bill Bolstering US FDA Device Center Funding By 2% To $8M*" - Medtech Insight, 23 Dec, 2019.)

Despite the bipartisan and bicameral support for repealing the tax in the US Congress, it faced political and procedural hurdles. In the past year, AdvaMed said it realistically only expected another moratorium for a year or two, despite pushing for a full repeal. (Also see "*AdvaMed Chair: Another Device Tax Moratorium More Likely Than A Full Repeal*" - Medtech Insight, 24 Sep, 2019.)

***Q&A: AdvaMed CEO Discusses 2020 Priorities In Broad-Ranging Interview***

By Ferdous Al-Faruque

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Following closely on the heels of a medical device tax repeal win, AdvaMed CEO Scott Whitaker sat down with *Medtech Insight* to discuss how the industry advocacy group ended the Obamacare excise tax and what it has in store for 2020.

*Read the full article here*

Even until the last moments, Whitaker said the lobby group was contemplating a temporary moratorium that would last a few months until Congress could reconvene and look to pass another long-term moratorium or a full repeal. But then, just days before Congress passed a last-minute omnibus bill, AdvaMed realized it may actually win a full repeal after all.

“There were times when I thought, ‘Hey, if we can get one month just to carry us over into the next year, [for] two months, to give us a little more time to make our case, maybe we'll be in a better position,’” Whitaker said. “A week or so before the end of the year, before the deal was struck, I started to feel better … because I knew members were weighing in, and weighing in very aggressively on it.”

The Trump administration had already thrown its support behind repealing the tax, but it needed to get to the president’s desk first. Whitaker said he implemented a so-called “four-corner strategy” to win over the four key Republican and Democratic leaders from both chambers of Congress: Sens. Mitch McConnell, R-KY, and Chuck Schumer, D-NY; and Reps. Nancy Pelosi, D-CA, and Kevin McCarthy, R-CA.

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> *we could shift Pelosi to being either supportive or not opposing for repeal of the tax, and at the end of the day that was the key." – Scott Whitaker*

While AdvaMed already had support from the White House, it also knew it had the backing of all three lawmakers except for Pelosi.

At the eleventh hour, labor groups teamed up with the medical device lobby groups to support repealing the medical device tax as long as they also got backing to support repealing the Affordable Care Act's Cadillac Tax: a 40% excise tax on high-cost employer-sponsored health plans. That led to Pelosi to support fully repealing the device tax, which tipped the balance in favor of the medtech industry.

Whitaker, however, says that didn't happen till a day or two before passage of the omnibus bill.

"I think the big challenge for us was trying to understand whether we could shift Pelosi to being either supportive or not opposing for repeal of the tax, and at the end of the day that was the key," he said. "At the end of the day, she came around and I think was willing to cut a deal, and part of that deal was full repeal of the tax."

## Gearing Up For 2020

Now that the tax has been repealed, Whitaker said he feels more liberated because AdvaMed can spend more resources to focus on other areas important to the medtech industry.

"I was excited to get device tax off the plate because I didn't want to be defined as a device tax trade association or a device tax industry," he said. "There's so much about this industry that's amazing and wonderful, and now we can begin to tell that story without this threat of a looming bad tax hanging over the industry."

Over the past decade, the US Food and Drug Administration has made significant changes to its review process that has led to faster and more consistent product application decisions that have received industry praise. While groups like AdvaMed agree there is still room for improvement, their focus in terms of agency reform over the past few years have started to shift to the US Centers for Medicare and Medicaid Services (CMS), which is the largest public insurer in the country. It's responsible for deciding what treatments are reimbursed and for how much.

Industry groups have complained of the lag time between when the FDA greenlights medical

devices for the US market and when the CMS makes a decision on reimbursing those products, which they've dubbed "the valley of death." (Also see "*Crossing The 'Valley Of Death': Breakthrough Devices Rule Could Lead To Slew Of New Products*" - Medtech Insight, 24 Apr, 2019.)

Over the coming year, AdvaMed says it will be on the offensive to push for legislative changes for diagnostic regulation reform.

Beyond regulatory certainty another major issue for industry stakeholders has been for diagnostic tests to get faster and more consistent reimbursement decisions from the CMS. (Also see "*Medtech Industry Groups Spend Millions In 2019 Lobbying For Device-Tax Repeal – And Much More*" - Medtech Insight, 2 Oct, 2019.)

Similarly, Whitaker says the lobby group will keep pushing for breakthrough device legislation regulations that will ensure products made for unmet needs are automatically reimbursed by the Medicare agency as soon as they pass FDA review. CMS has already indicated it is working on a new rule that is expected any day now that would do just that. (Also see "*CMS Clarifies Criterion To Evaluate New Tech Add-On Payments In Inpatient Rule*" - Medtech Insight, 8 Aug, 2019.)

"But we're also going to continue our work on the Hill to make sure that if it's not done right from a regulatory standpoint that there's a legislative package that directs," Whitaker added.

AdvaMed also expects to lobby Congress on the issue of so-called "surprise billing," wherein patients are caught off guard because the actual costs of their treatments are not disclosed up front when they are treated at hospitals. Lawmakers have been advocating to require more transparency for patients before they are billed. (Also see "*US Senate Sponsors Push Back Vote On Balanced Billing Legislation To Autumn*" - Medtech Insight, 25 Jul, 2019.)

"There's an issue of surprise billing that's coming through Congress at some point in the first half of this year, maybe the first quarter of this year, so we'll be tracking that, making sure that that's right, making sure that there are not things in there that have unintended consequences," Whitaker said.

Another key area AdvaMed is keeping its eye on is the issue of EtO sterilization. Half of medical devices sterilized in the US are cleaned using EtO, but recent concerns about the risk of cancer to people who live near sterilization plants has gotten the attention of state officials and lawmakers.

While some states around the country have closed plants that sterilize medical devices using EtO, AdvaMed – and even the FDA – has cautioned that ending EtO sterilization could lead to a medical device shortage. (Also see "*US FDA Experts Caution Against Banning EtO, Encourage More Duodenoscope Training*" - Medtech Insight, 8 Nov, 2019.)

## MDUFA V Is Coming

Another major issue on the table is the negotiations between FDA and medtech industry groups that happen every five years under the Medical Device User Fee Act of 2002. The agreement to set certain metrics for FDA reviews and develop new programs under MDUFA IV in 2017 but that deal is set to expire in fiscal year 2022.Negotiations for the next iteration of user fees under MDUFA V are set to begin in the first half of 2020. (Also see "*US FDA Toying With Idea Of 'Regulatory Legos' In MDUFA V*" - Medtech Insight, 1 Oct, 2019.)

While Whitaker declined to discuss what issues are important to AdvaMed in the upcoming negotiations, he said that on a very high level the group is looking for more clarity, transparency and predictability in the FDA review pathways.

> *"You've heard a lot of talk about real-world evidence. What does that actually mean, and how is that going to be implemented, going forward?" – Scott Whitaker*

One major area of contention in the last user-fee talks was over the collection and use of real-word data. While the FDA proposed to continue its work shifting to a new review paradigm where medical devices under review could be approved and cleared for the market with less premarket data, and be contingent on more postmarket data, industry pushed back, arguing there was insufficient evidence that real-world evidence will bring significant improvement for their members and patients. (Also see "*Real-World Evidence User-Fee Funding Praised At FDA Meeting*" - Medtech Insight, 2 Nov, 2016.)

A cornerstone of that discussion was over the development of the National Evaluation System for health Technology, or NEST. The system, which was finally agreed on and is being developed with the help of the Medical Device Innovation Consortium (MDIC), is meant to gather medical device RWE that can inform the FDA about the long-term safety and efficacy of a medical device. (Also see "*MDIC Snags $3m For FDA Real-World Evidence Coordinating Center*" - Medtech Insight, 13 Sep, 2016.)

"You've heard a lot of talk about real-world evidence. What does that actually mean, and how is that going to be implemented, going forward?" Whitaker said. "That will likely be part of the conversation, as well."

And if the industry groups are unable to pass diagnostics regulatory reform legislatively, it may

become a part of the MDUFA negotiations, he noted.

## Going Global

Over the past few years, AdvaMed has also taken a more international approach to its lobbying by directly engaging key stakeholder governments such as China and India, where there is significant medical device manufacturing, and opening regional offices to directly address issues on the ground.

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Whitaker noted that the lobby group has been in discussions with the Office of the US Trade Representative and the governments of India and China.

The Trump administration has been in a trade war with China that includes tariffs on medical devices, and the trade group has been trying to lobby the administration and the government of China to try to minimize blowback on the industry. (Also see "*US Trade Representative Removes Host Of Devices, Parts From China Tariff List*" - Medtech Insight, 11 Jul, 2019.)

AdvaMed has also been discussing the issue of medical device reimbursements with the governments of China, India and Japan to ensure what it says is a fair playing field for medtech companies to profit and innovate. (Also see "*FDI In India's Medical Devices Sector Plunges, Experts Blame Price Controls*" - Medtech Insight, 22 May, 2019.)

Whitaker also said the group is keeping an eye on emerging regions where medtech is starting to take a strong foothold, such as South America.

"There's a lot of work going on in Brazil right now from a trade standpoint, a lot of companies operating down there, so we're doing a lot of work in Brazil," he said. "So we're all over the globe now, as the industry is all over the globe. With device tax behind us, it frees us up to spend more of our time making sure the entire ecosystem is as strong as it could be for these products to get to patients."

*Editor's Note: This article was updated on 30 January to correct the fact AdvaMed CEO Scott*

*Whitaker was talking about lobbying for diagnostic regulatory reform during the interview rather than diagnostic payment reform which is also an issue the industry has an interest in.*