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US Regulatory Roundup, 2018: 5 Core Issues That Help Explain The Year In Medtech Policy

by David Filmore

Global harmonization, regulatory innovation, rising safety scrutiny, medtech reimbursement hopes and global trade threats were key underlying concepts for the medtech regulatory and policy environment in 2018. Here's a spotlight on those issues and the top 30 articles from last year.

Although 2018 ended with a government shutdown, for most of the year, new proposals and programs flowed out of Scott Gottlieb's US FDA at a mile-a-minute. It remains to be seen what elements of the agenda will end up as lasting components of US device regulation, but there is no question that the past year has been a period of regulatory innovation, with multiple pilots picking up speed, major reforms announced, and *restructurings* pursued.

Much of FDA's recent reform plans have been framed as paths to streamlining regulations and supporting the US as a *go-to market for medtech*. But as the year progressed, FDA and industry faced increasingly public pushback from consumer advocates, documentarians and reporters casting doubt that current oversight of devices and planned reforms are sufficient to protect patient safety.

Meanwhile, many in industry will say that issues outside of FDA's jurisdiction were, in fact, the source of most US public-policy anxiety for the sector in 2018. Most significantly, reimbursement remains laden with uncertainty for device companies. And trade policy has been thrust into hard-to-predict realms by the protectionist policies of the Trump administration.

Here is a look at the five most important US regulatory and policy themes for the medtech sector from 2018, based in part on what *Medtech Insight* online readers paid most attention to. The 30 most popular US policy stories that ran last year are also spotlighted. (See table below.)

1. Global Harmony?

Efforts to support long-term harmonization were a significant underlying force driving FDA activities in 2018. It certainly is a theme that *Medtech Insight* readers picked up on, in particular, with regard to FDA's plans to harmonize its Quality System Regulation with international quality systems standard ISO 13485. Our coverage of those plans and implications accounted for multiple spots on our top 30 list – and it's no wonder, as *it's a major change* that will impact how every single company in industry approaches its manufacturing and design operations. Kim Trautman, who authored the QSR in the 1990s, dished about the challenges of bringing the US regulation together with the ISO standard and what to expect in an August *interview with Medtech Insight* that was the most popular regulatory story of 2018.

Another important 2018 development that fell in the harmonization bucket is the advancement of the Medical Device Single Audit Program, which allows device manufacturers to undergo a single audit to satisfy the quality requirements of the US, Australia, Brazil, Canada, and Japan in lieu of facing many inspections from different regulators. 2018 was an important transition year for the program – as of Jan. 1, 2019, companies must have undergone an MDSAP audit to *continue selling product in Canada*. Further, FDA *is consider*ing whether MDSAP audit results can take the place of a pre-approval inspection.

FDA also took steps to shore up its use of standards and is pushing for an alternative 510(k) pathway that would put more emphasis on consensus standards instead of predicate device comparisons. The agency *has referenced harmonization* as one key driver for these policies.

2. Spotlighting Maturity And Excellence

A central theme to 2018 regulatory innovation is FDA's development of new approaches to evaluating company

Medtech's Next Top Maturity Model

One coverage highlight for the year was *Medtech Insight*'s four-part series on the new paradigm FDA is developing for the appraisal of manufacturing capability and maturity in the medical device industry:

- *Chasing Quality Isn't Easy. But An FDA Pilot Aims To Boost Quality By Appraising The Capability Of Manufacturing Sites*
- *Device-Makers Like Baxter Are Lining Up To Let CMMI Evaluate Their Manufacturing Site Capabilities. Here's What To Expect If You're Appraised*
- *Boston Scientific, Edwards Lifesciences, Baxter Used CMMI To Measure Their Manufacturing Capability. Here's What They Said About The Experience*
- *Assessing A Device-Maker's Manufacturing Capability Is Serious Business For These 2 Longtime CMMI Appraisers. Here's Their Story*

operations by assessing things like manufacturing maturity and operational excellence.

The approach puts more emphasis on incentivizing companies to pursue quality instead of reacting to a more compliance/enforcement mindset, and on FDA establishing trust in engaged firms to streamline or outright remove the need for individual submission reviews and inspections.

One great example of this approach that took off in 2018 is the agency's Voluntary Medical Device Manufacturing and Product Quality Pilot Program, which applies a medtech industry-tailored "maturity model" framework to measure a company's capability and maturity. *Medtech Insight*'s multi-part *feature series* on the effort proved popular with readers in 2018, perhaps one sign that the approach has legs as FDA looks to stand it up beyond the pilot phase in 2019.

The goal of the program is to empower companies to holistically measure quality and improvement needs, and to incentivize firms to stay on a path of continuous improvement. Participating companies benefit from streamlined options for 30-day notices, site-transfer changes and pre-market submissions. Eighteen firms, including heavy-hitters like *Boston Scientific, Medtronic and Edwards Lifesciences*, were assessed under the pilot, which closed on Dec. 31. (Also see "*FDA's Maisel Updates Industry On Maturity Model Pilot, Facility Inspections, MDSAP*" - Medtech Insight, 18 Dec, 2018.)

A similar theme underlies FDA's drive over the past year to leverage a regulatory approach it calls "pre-certification." The concept puts attention on company operations and particularly its demonstration of "excellence" in how it designs, develops and ensures the safety of its products. Companies that prove such excellence can be pre-certified, and minimize or outright avoid product-by-product FDA reviews.

FDA has been *busy developing* this approach for software devices in a pilot it hopes to launch into a full-fledged program this year. The agency is also *championing* the concept for the regulation of lab tests as part of reforms under consideration in Congress. And it is *applying the approach already* for direct-to-consumer genetic health risk testing services, where it will exempt DTC test-makers (starting with 23andMe) from pre-market review after each individual developer comes to the agency for a one-time review to ensure it meets FDA requirements.

FDA's focus on pre-certification, and related approaches that put more emphasis on companies' holistic operations, seem likely to expand in 2019.

3. Scrutiny Escalates

Even as FDA has put significant emphasis on supporting device innovation, companies should not get too comfortable. Several serious safety issues that cropped up with particular devices in recent years are driving an *increasingly vocal community of patient and consumer advocates*. They

are demanding stricter safety oversight of devices, including more pre-market data requirements. *Medtech Insight* has documented those increasingly prominent demands, and the issue captured significant reader attention in 2018.

The message found a home earlier in the year in a documentary called "The Bleeding Edge," which was picked up by Netflix. It attracted public attention and was *strongly criticized* by some in industry as misleading. More recently, the International Consortium of Investigative journalists launched the *"Implant Files,"* an investigation of the industry that paints a picture of unsafe products and unchecked companies putting profits over safety. (Also see "*Device Sector Braces For Investigative Stories Critical Of Industry*" - Medtech Insight, 21 Nov, 2018.)

The Apps Have It

Even beyond FDA's focus on pre-certification, digital health was a major emphasis for the agency in 2018. Artificial intelligence technology moved squarely into the clinic in 2018 with multiple FDA approvals and clearances throughout the year. In addition, the agency approved its first high-profile consumer mobile apps this year, with the *Apple Watch ECG app* and Natural Cycles Nordic's *contraceptive app*. The developments parallel the tech industry's increasing movements into the medtech space – a trend that is cause for some trepidation by device firms. And there *have been concerns* raised by some in industry that FDA is giving big-tech companies like Apple special treatment.

FDA is certainly feeling some pressure. In the weeks before the ICIJ investigation was made public (but when FDA was being asked for input by ICIJ reports), the agency released multiple announcements highlighting its focus on device safety and *catching problems early*.

On Nov. 26, the day after the first Implant Files story came out, FDA released a series of pre-planned proposals to reform the 510(k) pathway, by which most products and product updates reach the US market. Primarily, the agency says it plans to encourage less use of older predicate devices. It made a point in the *announcement* to stress that 510(k) submissions have gotten longer and have been subjected to more scrutiny in recent years.

The announcements appear to represent a tone switch by FDA away from a more prominent focus in public statements on streamlining the path of new innovations to market. Where the agency's balance between encouraging innovation and ensuring safety settles when it comes to policy development will be a key variable to monitor in 2019.

4. Impending Progress With Medicare

But, for now, at least, the sense is FDA has become a more welcoming place for getting innovative products to market. Meanwhile, FDA's sister agency, the Centers for Medicare and

Medicaid Services, has been the source of greater sector anxieties. As companies face quicker FDA market approvals, they often also face an unclear path to the coverage and payment necessary to support market adoption. Nadim Yared, CEO of CVRx and outgoing chairman of AdvaMed, *calls this period* between approval and coverage the "valley of death" for industry.

But in reimbursement policy in 2018, there were positive signs for industry, if not clear-cut advancements. White House and CMS officials *made clear* in multiple public statements throughout the year that the administration is prioritizing improving the reimbursement process for innovative devices and diagnostics.

That promise was formalized somewhat when CMS put a breakthrough device reimbursement pathway on its latest regulatory agenda, with a proposal expected by March. The plan, supported by US industry, would establish automatic, but temporary, Medicare coverage for devices designated as "breakthrough" by FDA while manufacturers collect real-world data for the new technology, and it would also establish a similar approach that can be tapped by devices even if they have not been formally designated as breakthrough.

5. Trade Troubles

As the Trump administration puts out positive signals for industry regarding reimbursement, trade policy is a different matter. The administration escalated trade tensions around the world by implementing tariffs on aluminum and steel from many places around the world and a broader set of tariffs specifically on products made in China.

The device industry was impacted indirectly by the former, and more directly by the China tariffs, which are charged to *more than two-dozen device products*. While that is an improvement from what was originally proposed by the White House, tariffs and related challenges to device companies acting on a global stage will remain an important headwind for the year ahead.

Rank	Headline
1.	*QSR Author Kim Trautman Predicts What A Mash-Up Of FDA's Quality System Regulation And ISO 13485 Might Look Like*
2.	*Top Medtech Lobbyist Doubts Legislative Repercussions Of New Netflix Documentary*
3.	*US FDA Commissioner: Agency Will Propose New Rule That Blends Quality System Regulation, ISO 13485*
4.	*Bye-Bye QSR? FDA May Swap Its Quality System Regulation For ISO 13485 'In The Coming Years, Official Says*
5.	*Investigator Horror Stories 3: Boozing On The Job? Yup, That Happened – As Have These Other Shocking Tales Of Irregular FDA Inspections*
6.	*Chasing Quality Isn't Easy. But An FDA Pilot Aims To Boost Quality By*

	Appraising The Capability Of Manufacturing Sites
7.	FDA's Speedy Apple Watch De Novos Raise Questions For Industry
8.	CMS Actively Looking For New Reimbursement Pathway For Innovative Devices
9.	Proposed FDA Guidance Would Provide Alternate Route For 510(k) Applications
10.	Medtronic Slapped With 2 FDA Warning Letters For Problems At Minnesota, Puerto Rico Sites
11.	Device Sector Braces For Investigative Stories Critical Of Industry
12.	Device-Makers Like Baxter Are Lining Up To Let CMMI Evaluate Their Manufacturing Site Capabilities. Here's What To Expect If You're Appraised
13.	CDRH's New Post-Market Paradigm: Why The Public Should Be Worried
14.	Patient Group Pushes FDA For LASIK Ban
15.	FDA: Apple De Novo Approvals Signal Innovation To Digital Health Firms
16.	Gottlieb Unveils Next Steps In Digital Health Plan
17.	FDA Looks To Expand Special 510(k) Program
18.	US FDA Tweaks Direct Marking Rules In UDI Enforcement Delay
19.	Compliance Corner: FDA Investigator Lists 7 Common Human Factors Problems, Says Usability Is 'Overlooked'
20.	'We Survived MDSAP': Cynosure Aces Single-Audit Program Twice; Tells How Your Firm Can, Too
21.	US Trade Rep Cuts 22 China-Made Devices From Tariffs List, But Retains 27
22.	FDA's Alternative 510(k) Proposal Falls Flat With Industry
23.	New Safety Framework Mixes Current Efforts, New Investments At US FDA
24.	NSF's Trautman Talks MDSAP, Swapping FDA's QSR For ISO 13485, Regulatory Convergence, EU's MDR & IVDR, And More
25.	With New Initiatives, Case For Quality Embarks On Mission To Create 'Safe Space,' Engage CEOs, #makeCAPAcool
26.	MDSAP Auditors Aren't Applying A Consistent Auditing Approach, Medtech Group DITTA Claims In Letter To FDA
27.	US FDA Device Funding Would Leap By 26% In 2019 Under Trump Budget Proposal
28.	FDA Sends Record-Low Warning Letters To Device-Makers In 2017 As Agency Takes More Personalized Compliance, Enforcement Tack
29.	US FDA Finds Ongoing CAPA Issues In Zimmer Plant Reinspection

30.	*FDA's US-First Strategy: Device Center Sets Three-Year Goals*