MEDTECH INSIGHT
CITELINE COMMERCIAL

02 Apr 2021 | **Analysis**

FDA's Outgoing Abernethy: 'I Feel Very Strongly About Janet Woodcock'

US Regulatory Roundup, March 2021

by Shawn M. Schmitt

In an interview with *Medtech Insight*, Amy Abernethy, the US FDA's outgoing second-in-command, threw her weight behind Janet Woodcock to be the agency's next commissioner. News of Abernethy's impending departure from the FDA and other stories topped our list of most-read *Medtech Insight* articles in March.

Abernethy Endorses Woodcock For FDA Commissioner

Janet Woodcock is the "right person" for the role of US Food and Drug Administration commissioner, the agency's outgoing No. 2 official told *Medtech Insight* on 1 April.

"I feel very strongly about Janet Woodcock being the right person. I felt comfortable leaving my role because of the fact that Janet Woodcock is there," said Amy Abernethy, who will be leaving her job as FDA principal deputy commissioner later in April. More than two months into the Biden administration, it's still unclear who will be selected as the next agency commissioner. Woodcock has been filling the role on an acting basis since 20 January.

Abernethy at one time was considered to be the frontrunner for the commissioner job, but that never materialized, we explained in our *No. 1 story from last month*. She was recruited to the FDA from the private sector by former commissioner Scott Gottlieb in early 2019. He left the agency roughly a month later.

In our recent interview with Abernethy, she said it was obvious to her from the get-go that the FDA needed to modernize its technology systems. The agency was swamped with work, she said, because its various systems didn't talk to each other.

"It was clear to me that if we were going to scale the work of the agency, if we were going to be able to work more efficiently and faster, if we were going to be able to really leverage modern data sources, we were going to need to change the way that we use data and technology at the agency," Abernethy said.

As part of its ongoing technology efforts, the FDA will develop a Data Modernization Action Plan, or DMAP, that will allow the agency to make better regulatory decisions based on data. Woodcock and Abernethy announced DMAP in an early March blog post, we reported in *our No. 8 story*. The duo is confident the project will, among other things, help the FDA detect problems with approved products and better understand how products affect different populations.

Woodcock and Abernethy said DMAP complements the agency's Technology Modernization Action Plan. Launched in September 2019, TMAP was set up to help the agency modernize its technology infrastructure, develop technology products to support its mission and collaborate with stakeholders to drive technological progress. (*See our full interview with Abernethy in the sidebar story below.*)

FDA's Draft QSR Didn't Come In February

And speaking of the FDA, on 28 February it blew past its fifth internal deadline for releasing the draft of its new Quality System Regulation, which will be harmonized with international quality systems standard ISO 13485:2016. Our reporting on that was the *No. 3 story from last month*.

The agency hasn't selected a new target date yet for issuing its draft rule.

MCIT Rule Delay Creates Uncertainty For Industry

US lawmakers early last month pushed the Centers for Medicare and Medicaid Services (CMS) to enact the Medicare Coverage for Innovative Technologies final rule, as noted in our *No. 10 story from March*. Under MCIT, Medicare will cover a new breakthrough device or diagnostic as soon as the FDA approves it.

Exit Interview: Abernethy Tells Why She's Leaving FDA – But Staying On Her Own Path

By Ferdous Al-Faruque

06 Apr 2021

The FDA's outgoing second-in-command, Amy Abernethy, is confident she's leaving the agency in good hands but plans to continue to advocate for patients by focusing on areas such as trial design and use of real-world evidence. In this interview with *Medtech Insight*, Abernethy also talks about the work she put in to make sure there was a change in...

Read the full article here

But in the end it wasn't enough to keep the CMS from stopping the clock on the new regulation, as we explained in *our No. 4 story*. The rule was set to go into effect on 15 March, but has now been delayed until at least 15 May – creating more uncertainty in the medtech sector.

The CMS said it paused the final rule in line with the Biden administration's decision to take a closer look at so-called "midnight regulations" issued by the Trump administration in its waning days. The CMS said it postponed implementing the rule to address a number of concerns the agency and stakeholders have, including developing Current Procedural Terminology (CPT) codes and payment levels for devices that go through the MCIT program.

Based on its latest data, the CMS said roughly 400 devices could gain breakthrough designation under MCIT. While not all the devices will get that distinction, it's a much larger number of devices and workload than what the agency had anticipated.

"We recognize that not all of those devices will be market-authorized, and we cannot know the precise timing of those market authorizations," the CMS said. "Recent public data suggests a larger number of market-authorized breakthrough devices may be eligible for MCIT. The public may not have had an opportunity to consider this aspect of potential growth."

Spotlight On Adverse Events

The FDA late last month held a meeting of its General and Plastic Surgery Devices Panel, where a sharp increase in the number of adverse events related to dermal fillers was the subject of concern, as reported in our *No. 7 story from March*.

Fillers have become one of the most common cosmetic treatments in America in recent years, but the popularity has brought with it a rise in adverse events, including serious events that can occur when a filler is accidentally injected into a blood vessel. In fact, more than 5,000 serious injuries linked to fillers were reported to the FDA between 2015 and 2020.

"While the risk of intravascular injection has always been present for dermal fillers, the increased popularity of fillers and their use in a broad range of indications has highlighted this risk, with adverse events such as vision disturbances and even blindness and stroke being increasingly reported," said Cynthia Chang, director of the division of infection control and plastic surgery devices in the FDA's Office of Product Evaluation and Quality, within the agency's device center.

In other adverse event news, the FDA last month updated its electronic Medical Device Reporting (eMDR) system to accept adverse event codes devised by the International Medical Device Regulators Forum (IMDRF). It was the subject of *our No. 5 story*.

The change affects Secs. F10 and H6 of the FDA's MedWatch 3500A adverse event reporting form, "Adverse Event Problem." User facilities and importers report event codes under Sec. F10,

while device makers use Sec. H6 to report.

Reporters should refer to the FDA's updated adverse event *coding manual* when submitting MDRs. The agency also stressed that the eMDR system "still accepts the corresponding FDA and National Cancer Institute Thesaurus (NCIt) codes," and further explained that "no codes were retired as part of this maintenance update, so there is no risk of MDR rejection as a result."

Other Top Stories

These articles rounded out our Top 10 list in March:

- *No. 2 story*: The FDA says a review of 90 medical device and diagnostics submissions that used real-world evidence or real-world data shows that RWE/RWD can be a powerful tool to not only better understand how products work outside the clinical trial setting, but also get treatments to patients faster.

- *No. 6 story*: In late March the FDA affixed its highest risk designation, class I, to a recall of Medtronic PLC's Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir. The device is used on newborns, infants and small pediatric patients undergoing a cardiopulmonary bypass procedure.

- *No. 9 story*: A new standard on medical device irritation from the International Organization for Standardization (ISO) is nudging manufacturers away from testing on animals. Published in January, ISO 10993-23:2021 urges irritation testing on laboratory-grown skin – or *in vitro* reconstructed human epidermis (RhE) – instead.

The 10 most popular US regulation and policy stories in March, as determined by reader interest, are listed in the table below.

Rank	Story
1	*FDA's Second-In-Command, Amy Abernethy, Departing Agency*
2	*Top FDA Officials Tout Use Of Real-World Evidence Based On New Report*
3	*FDA Misses Fifth Target Date For Issuing Draft Harmonized Quality System Reg*
4	*CMS Pauses The Clock On Implementing Highly Anticipated Medical Device Reimbursement Rule*
5	*Adverse Event Codes From IMDRF Now Used By FDA's eMDR System*
6	*Dangerous Endotoxins Lead To Class I Recall For Medtronic Device Used On Pediatric Patients*
7	*US FDA Panel Grapples With Dermal Filler Adverse Events*
8	*FDA Launches Digital Modernization Plan To Complement Its Technology Modernization Plan*

9	*Q&A: New Standard For Device Irritation Nudges Industry Away From Animal Testing – And Toward Tests On Lab-Made Human Skin*
10	*Lawmakers Press CMS To Enact MCIT Breakthrough Device Coverage Rule*