MEDTECH INSIGHT
CITELINE COMMERCIAL

06 Sep 2019 | **News**

US Regulatory Roundup, August 2019: Safety And Compliance Take A Front Seat

by Shawn M. Schmitt

Concerns about paclitaxel-coated balloons and stents, as well as recalls linked to two large device manufacturers, captured the attention of many of our online readers last month, as did compliance-focused features that offered tips and advice from US FDA officials. Here are August's 10 most popular US regulation and policy stories from *Medtech Insight*.

An early August update from the US Food and Drug Administration that says more long-term clinical trials are needed to investigate a possible mortality risk tied to paclitaxel-coated balloons and stents was of most interest to *Medtech Insight*'s online readers last month.

Paclitaxel coatings have been the subject of ongoing FDA scrutiny since a meta-analysis of randomized trials found that peripheral arterial disease (PAD) patients who received devices coated with the drug posed a more than 50% greater risk of death within five years. The agency told physicians in March to avoid use of the drug-coated devices in most PAD patients.

The update, reported on in our *No. 1 story from August*, incorporates recommendations based on current FDA research and the conclusions of a June meeting of the agency's Circulatory Devices Advisory Panel. The update says the FDA will take additional steps to address safety signals based on the new information; specifically, the agency is working with firms to add language addressing the mortality risk to device labeling and clinical trial patient consent forms.

The paclitaxel-coated balloons and stents update from the FDA wasn't the only drug-device combination product news that garnered significant attention from readers last month. Our *No. 6 story* detailed how long-delayed changes to the agency's approach to postmarket safety reporting for combo products are finally set to come into effect in 2020. The agency released a 44-page final guidance document on the topic in late July.

Meanwhile, a pair of *Compliance Corner* stories captured the No. 2 and No. 7 positions on our top

10 list. *In the first*, FDA investigator and medical device expert Phil Pontikos explained how device-makers can avoid running afoul of the agency's rules and expectations for sterilization activities, while *in the second*, FDA Compliance Branch directors Gina Brackett and Melissa Michurski shined a light on the agency's use of regulatory meetings.

Also of high interest to readers in August was an *in-depth profile* of Amy Abernethy, the FDA's principal deputy commissioner. That landed at No. 4 on our list, while a *separate story* that detailed Abernethy's skepticism about the use of wearable technologies for clinical needs was the third most-popular article last month.

Safety was also on the minds of *Medtech Insight* readers. Our *article on a high-risk class I recall* of Edwards Lifesciences' Sapien 3 Ultra Heart Valve delivery system was No. 5 on our top stories list; the problematic device has been linked to 17 injuries and one death. And in our *No. 9 story*, the FDA notified the public about a recall of certain Abbott Ellipse implantable cardioverter defibrillators, which are prone to electrical shorting because of a manufacturing flaw.

Other articles of interest included *an announcement of a white paper* by the Medical Device Innovation Consortium (MDIC) that lists what information is needed to ensure that patients understand the risks and benefits of their treatments, and news that manufacturers will see *significant user-fee increases* in fiscal year 2020.

The 10 most popular US regulation and policy stories in August are listed in the table below.

Rank	Title
1	*FDA Announces More Actions On Drug-Coated Devices*
2	*Compliance Corner: FDA Investigator Sees These 4 Common Sterilization Problems When Inspecting Facilities*
3	*Top FDAer Skeptical Of Wearable Devices, Says Agency Is Working To Improve Standards And Technology*
4	*MTI Profile: US FDA's Second-In-Command Has Her Eye On A Tech-Forward Future*
5	*Class I Recall On Edwards Sapien 3 Ultra Valve System*
6	*Combination Product Reporting Rule Set For 2020 Enforcement*
7	*Compliance Corner: 2 FDA Compliance Branch Heads Talk Regulatory Meetings – And What You Can Expect*
8	*MDIC Weighs In On Best Way To Inform Patients Of Risks And Benefits*
9	*New Heartache For Abbott Implantable Cardiac Devices After Manufacturing Flaw Discovered*
10	*Medtech Firms To See Significant User Fee Increases In FY 2020*