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News We're Watching: Boston Sci Buys Silk Road Medical; EOFlow Injunction Blocked; LDT Compliance Dates Announced

by Brian Bossetta

This week, Boston Scientific agreed to pay $1B+ for stroke prevention device firm Silk Road Medical; the FDA asked for feedback on patient safety for non-device medical software; and a former medtech CEO was sentenced to six years for her part in a phony device scheme.

Boston Scientific To Pay Almost $1.2B For Silk Road Medical

Marlborough, MA-based *Boston Scientific Corporation* is acquiring device firm *Silk Road Medical, Inc.*, which makes products that use a minimally invasive procedure called transcarotid artery revascularization (TCAR) to help prevent stroke in patients with carotid artery disease. The agreement will see Boston Scientific pay $27.50 per share, or about $1.16 billion in total.

Carotid artery disease, which causes about one-third of all strokes, is usually treated through medical management or open surgery. During TCAR, a stent is placed in a narrowed carotid artery to reopen the vessel and discourage further plaque accumulation. Clinical trials have found that the procedure offers a lower rate of complications and greater success in preventing strokes than traditional open surgery.

Silk Road Medical's TCAR platform is the only FDA-cleared device utilizing the technique.

"The TCAR platform developed by Silk Road Medical is a notable advancement in the field of vascular medicine, which has revolutionized stroke prevention and the treatment of carotid artery disease," said Cat Jennings, president, Vascular, Peripheral Interventions, Boston Scientific. "We believe the addition of this clinically differentiated technology to our vascular portfolio demonstrates our continued commitment to provide meaningful innovation for physicians who care for patients with peripheral vascular disease."

FDA Asks For Best Practices On Non-Device Software Functions

Under the 21st Century Cures Act, some medical software functions – such as those related to hospital administrative support, encouraging a healthy lifestyle, or managing electronic health records – are not considered medical devices. But those functions remain of interest to the US Food and Drug Administration, which issued a *request for public comment* on 18 June.

The comment request is focused on patient safety. In particular, the agency wants to hear from stakeholders on "best practices to promote patient safety, education, and competency." Comments should be submitted by 18 July under docket number *FDA-2018-N-1910*.

The feedback received will be incorporated into an agency report on the risks and benefits to health of non-device software functions, which is due by the end of the year.

Medicare To Reimburse Ablation Procedure Targeting Epilepsy

The Centers for Medicare and Medicaid Services (CMS) has approved and granted a new procedure code for the OneRF Ablation System from NeuroOne, the Eden Prairie, MN, medical technology company recently announced.

The code, which takes effect in October, allows hospitals to be reimbursed for inpatient procedures that use the system to record electrical activity and ablate nervous tissue under temperature-controlled environments.

The FDA-cleared OneRF Ablation System is a thin-film Stereoelectroencephalography (sEEG)-guided tool used in neurosurgery to treat drug-resistant epilepsy.

NeuroOne says the code's approval helps facilitate broader market acceptance of the system's potential to "reduce hospital stays, numbers of surgeries, and adverse events, while offering enhanced patient safety."

The company further estimates the current brain ablation market to be at least $100M worldwide and growing rapidly, with the potential to grow multifold based on large addressable patient populations with unmet clinical needs.

Ex-Stimwave CEO Sentenced To 6 Years

Former Stimwave CEO Laura Perryman would serve six years in prison under a sentence handed down on 17 June by US District Judge Denise Cote of the Southern District of New York.

Perryman was convicted on health care fraud charges in March for her role in a scheme that saw phony device components implanted in patients. (Also see "*News We're Watching: LDT Survey Finds Concern, Abbott Recall, New Q-Sub Guidance*" - Medtech Insight, 15 Mar, 2024.)

Stimwave made a neurostimulator system for the treatment of chronic pain that included an external lead component containing electrodes as well as an implanted receiver component. When physicians informed the company that the receiver was too large to be implanted in some patients, Stimwave developed a smaller plastic "stylet" that could not receive signals and shipped these nonfunctioning stylets to unknowing physicians. Medicare and private insurers paid between $16,000 and $20,000 each for the faux devices.

"Laura Perryman callously created a dummy medical device component and told doctors to implant it into patients," US Attorney Damian Williams said. "She did this out of greed, so doctors could bill Medicare and private insurance companies approximately $18,000 for each implantation of that dummy component and so she could entice doctors to buy her device for many thousands of dollars. Perryman breached the trust of the doctors who bought her medical device, and more importantly, the patients who were implanted with that piece of plastic."

Stimwave previously paid $10M in a non-prosecution agreement.

Federal Circuit Overturns EOFlow Injunction

An injunction that blocked South Korean insulin pump firm EOFlow from selling products in the US has been overturned by the Federal Circuit Court of Appeals.

Insulet requested the injunction, which was granted last October, as part of a lawsuit claiming that EOFlow's insulin patch pump infringed on patents used in Insulet's Omnipod. The legal battle led Medtronic to withdraw an offer to buy EOFlow. (Also see "*Medtronic Is Not Going With The EOFlow – Deal Cancelled*" - Medtech Insight, 7 Dec, 2023.)

In a *17 June opinion*, the Federal Circuit said that the district court had not properly analyzed the chances Insulet's lawsuit would succeed, including such factors as whether the allegedly borrowed technology constituted a trade secret and whether the lawsuit might be blocked by the statute of limitations.

"In view of the failure to address the statute of limitations, the lack of a tailored analysis as to what specific information actually constituted a trade secret, as well as the finding that it was 'hard to tell' what subset of that information was likely to have been misappropriated by EOFlow, we find that the district court abused its discretion in granting the October 24, 2023 preliminary injunction," the opinion states.

FDA Updates LDT Enforcement Plan

The FDA has updated its *main website on lab-developed tests* to reflect the planned dates on which the agency will phase out enforcement discretion for the tests, thus putting into motion the agency's plan to begin regulating the products.

The dates are:

- Stage 1: LDT firms will need to comply with medical device reporting requirements, correction and removal reporting requirements, and quality system requirements regarding complaint files by 6 May 2025, which is one year after the publication date of the LDT final rule.
- Stage 2: FDA will esxpect compliance with requirements related to registration and listing, investigational use, and labeling by 6 May 2026.
- Stage 3: LDT developers will need to comply with all remaining quality system requirements by 6 May 2027.
- Stage 4: By 6 November 2027, high-risk IVDs that could be considered class III or are covered under section 351 of the Public Health Service Act will need to comply with premarket review requirements unless there is a premarket submission under review by the FDA. Products that are being reviewed will remain subject to enforcement discretion.
- Stage 5: Premarket review will be required for moderate- and low-risk LDTs as of 6 May 2028. As with higher-risk products, requirements will be waived while regulatory submissions are under FDA review.