MEDTECH INSIGHT
CITELINE COMMERCIAL

07 Apr 2023 | **News**

News We're Watching: Abbott FreeStyle Libre Recall, Medtronic Partners With DaVita, Free SBOM Software

by Brian Bossetta

This week, Abbott announced a class I recall of several glucose management systems. Additionally, Medtronic announced partnerships with DaVita and Qure.Ai; Heartflow closed a funding round; and BiVacor readies for artificial heart trials.

Abbott Recalls Millions Of Glucose Monitoring Devices

Abbott is recalling its FreeStyle Libre, Libre 14 day, and Libre 2 Flash Glucose Management Systems because the lithium-ion batteries may get extremely hot, spark, or catch fire if they are not used with the Abbott-provided USB cable and power adapter. The units are not being physically recalled; instead, Abbott is instructing customers to visit a company *announcement* for instructions on the proper use and storage of all device components.

The recall does not affect any of the FreeStyle Libre family of sensors.

On 6 March, the US Food and Drug Administration *designated* the recall class I.

The recall, which Abbott initiated on 13 February, includes 4,210,785 devices distributed in the US from November 2017 through February. The company reports 206 incidents globally since 2014, including at least seven fires and one injury. No deaths have been linked to the issue, and the 206 incidents represent only about only 0.0017% of all units sold, Abbott says.

Medtronic And DaVita Introduce Mozarc Kidney Health Spin-Off

The new kidney health company created by *Medtronic plc* and *DaVita Labs* is called *Mozarc Medical*, the companies announced as part of the formal launch of the company on 1 April.

Medtronic announced plans to spin off its renal care solutions business into a new company equally co-owned by DaVita in May 2022. DaVita is one of the largest providers of dialysis and kidney-care services in the US. (Also see "*Medtronic Starts Planned Portfolio Simplification With DaVita Renal Care Spin Off*" - Medtech Insight, 27 May, 2022.)

Mozarc's CEO is Ven Manda, previously the head of Medtronic's renal care solutions business.

"At a time when patient preferences are evolving and in-home kidney care is on the rise, Mozarc Medical is uniquely positioned to better serve patients with kidney disease around the world," Manda said.

Through the first three quarters of Medtronic's fiscal year 2023, the renal care business recorded revenues of $64m, $63m, and $70m, respectively.

"The launch of Mozarc Medical holds tremendous promise to improve the lives of patients living with kidney disease as it seeks to revolutionize the approach to home dialysis by improving accessibility, ease of use, and clinical performance," said Mahesh Krishnan, the group vice president of research and development at DaVita.

Eracent Provides Free SBOM Software For Healthcare Orgs

Information technology company Eracent is offering free software to healthcare organizations to create software bills of materials (SBOMs).

The Consolidated Appropriations Act passed at the end of December amended the Food, Drug and Cosmetic Act with long-awaited cybersecurity amendments requiring pre-determined change control plans and SBOMs in medical device submissions. (Also see "*Expert: Cybersecurity Requirements In Omnibus Bill Will Provide Visibility For Industry*" - Medtech Insight, 10 Jan, 2023.)

But an SBOM on its own can be unhelp, explained Walt Szablowski, Founder and Executive Chairman of Eracent.

"There are two key aspects that every organization will have to address when using SBOMs. First, they must have a tool that can quickly read all of the details in an SBOM, match the results to known vulnerability data, and provide heads-up reporting. Second, they must be able to establish an automated, proactive process to stay on top of SBOM-related activity," Szablowski said in a *release*, and Eracent's software provides both of these.

"We are happy to get all healthcare sectors affected by the government's new medical device cybersecurity regulations on the road to compliance with the FDA's new SBOM mandates," he

said.

Currently, the agency is giving the industry a grace period to come into alignment with the new regulations. While the FDA will not issue refuse to accept (RTA) decisions based solely on the information covered in the cybersecurity amendments right now, it will begin enforcement on 1 October. (Also see "*'Refuse to Accept' Decisions For Cyber Devices To Begin In October*" - Medtech Insight, 29 Mar, 2023.)

Medtronic And Qure.ai Partner To Improve Stroke Detection In India

Medtronic subsidiary India Medtronic Private Ltd. will partner with Qure.ai to integrate artificial intelligence for advanced stroke management in India, the companies announced on 4 April.

Combining Medtronic's neuroscience expertise with Qure's artificial intelligence software, the collaboration will help comprehensive stroke centers and primary stroke centers in India establish a hub-and-spoke network to make stroke care more efficient and improve patient outcomes.

Qure has developed software specifically designed to help clinicians streamline the stroke care pathway for patients. The qER solution rapidly reads and interpretates computed tomography and delivers information to the Qure app where anybody in the care network can access it. The system has reduced the turnaround time of reading and diagnosing CT scans from about 65 minutes to 2 minutes, according to Qure.ai.

"Medtronic is working toward a future where stroke can be diagnosed quickly and treated efficiently to potentially save a patient's life," said Michael Blackwell, managing director of Medtronic India. "Introducing AI will personalize healthcare technology — in real time."

HeartFlow Closes $215m Series F Led By Bain Capital

HeartFlow, Inc. secured $215m to support the commercialization and development of its artificial intelligence-enabled, non-invasive system for predicting a patients' risk of a heart attack.

The series F round is led by Bain Capital with participation from Janus Henderson Investors and existing investors including Baillie Gifford, Capricorn Investment Group, Hayfin Capital Management, HealthCor, Martis Capital, USVP, and Wellington Management.

HeartFlow's RoadMap technology relies on fractional-flow reserve, computed tomography, and vascular plaque analyses to provide a comprehensive assessment of individual patient's coronary

artery disease.

"The oversubscription of our series F funding round, particularly in the current market backdrop, is a strong validation of our technology, our team, and the opportunity in front of us," said HeartFlow CEO John Farquhar. "We appreciate the support of our investors, both existing and new, who share HeartFlow's vision to build a new standard of care for people at risk of heart disease."

The new financing comes about a year after the HeartFlow abandoned a plan to go public through a reverse merger with Longview Acquisition Corp. II, a special purpose acquisition company (SPAC) sponsored by Glenview Capital Management LLC. (Also see "*Minute Insight: HeartFlow Drops SPAC Plan; Names New Leadership*" - Medtech Insight, 3 Mar, 2022.)

That merger proposal, first announced in July 2021, valued HeartFlow at about $2.4bn and would have provided the combined company with about $400m in cash.

BiVacor Raises $18m To Fund Trials Of Total Artificial Heart

BiVacor secured $18m to support a first-in-human trial of its continuous flow total artificial heart.

The funding, announced on 29 March, is led by Cormorant Asset Management and OneVentures.

BiVacor's total artificial heart is designed to be the first long-term therapy for people with severe biventricular heart failure. It has a magnetically levitated, double-sided centrifugal impeller that moves blood continuously.

Unlike most previous continuous circulatory assist devices, BiVacor's technology mimics the native heart's pulse by cycling the rotational speed of the impeller. And, unlike early artificial hearts that relied on volume displacement pumps, BiVacor's device is small enough to use in smaller women and some children. (Also see "*CMS Proposes Coverage With Evidence Development For Artificial Hearts*" - Medtech Insight, 11 Feb, 2008.)

BiVacor's total artificial heart is based on technology originally designed for a left-ventricular assist device. The company hopes to initially implant the system in people as a temporary bridge to a heart transplant, but hope that it may ultimately be an alternative to heart transplantation.

BiVacor is headquartered in Houston, but also has offices in southern California and Brisbane, Australia. It was founded in 2008 based on intellectual property developed by Daniel Timms, the company's chief technology officer. (Also see " *INTERVIEW: Carmat stays on the beat with*

potential 2016 artificial heart CE mark " - Medtech Insight, 20 Jan, 2015.)

Penumbra Works With VHA On VR-Enabled Rehab

Penumbra, Inc. is collaborating with the Veterans Health Administration's Office of Healthcare Innovation and Learning to test, co-develop and implement rehabilitative health care solutions through virtual reality (VR).

The collaboration will develop new rehabilitation tools based on Penumbra's Real System Y (REAL y) VR platform. (Also see "*HIMSS 2022: Penumbra Previews Expanded VR Rehabilitation System For Stroke With Planned Launch In April*" - Medtech Insight, 14 Mar, 2022.)

Penumbra touts REAL Y as the only hands-free, non-tethered, multi-disciplinary VR rehabilitation platform to address a wide variety of users, but the solutions created by this collaboration will specifically target neurorehabilitation and chronic condition management.

The agency also hopes to adopt and scale new technologies for remote therapeutic rehabilitation, remote therapeutic monitoring, and remote patient management.

The company previously donated VR systems to SoldierStrong, a non-profit organization that supports US military veterans and active military service members through their rehabilitation at more than 20 military and veteran US rehab centers.

"It is a great honor to work with the VHA on such an important initiative to not only maximize the key benefits of rehabilitation therapy with virtual reality, but to also broadly implement these tools so veterans, whether at a VA facility or in a remote location, will have access to these offerings," said Gita Barry, president of Penumbra's Immersive Healthcare business.

Proposed Bills Focus On AED Access, Cancer Screenings

Two bills aimed at putting life-saving devices in the hands of the public have recently been introduced in the US House of Representatives. The first, the *Access to AEDs Act*, aims to improve access to Automated External Defibrillators (AEDs) on school campuses to protect student athletes. It was inspired by Cincinnati Bengals' player Damar Hamlin's on-field medical emergency in January, in which Hamlin was quickly treated with an AED and CPR, and has drawn the support of the American Heart Association.

The bill directs the Secretary of Health and Human Services to award grants to elementary and secondary schools to support the development and implementation of programs that promote

access to defibrillators in schools, sponsor Rep. Brian Higgins, D-NY said. Grant money could also be used to purchase and maintain AEDs and train students, staff and volunteers on AEDs. Additionally, it can be used to develop Cardiac Emergency Response Plans and assist school athletic departments in creating heart screening programs for student athletes.

The other bill, the *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act*, is being sponsored by Reps. Jodey Arrington, R-TX, Terri Sewell, D-AL, Richard Hudson, R-NC, and Raul Ruiz, D-CA. It will create a benefit category for multi-cancer early detection tests that have FDA approval, allowing the Centers for Medicare and Medicaid Services (CMS) to pay for their use more easily. Support for the bill has been led by the Prevent Cancer Foundation.