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News We're Watching: Edwards Scoops Up Cardio Firms, BD And Quest Partner, Admera Settles Kickback Case

by Brian Bossetta

This week, Edwards announced that it has purchased JenaValve and Endotronix; a New Jersey lab has agreed to pay the government $5m for violating anti-kickback law; eCential Robotics' spine platform made its debut for human use; and more.

Edwards Purchases Two Cardiac Device Firms

Edwards LifeSciences announced on 25 July that it is expanding its structural heart portfolio with the purchase of two firms in the space, JenaValve and Endotronix. While Edwards opted not to disclose what it spent on each of the purchased firms, the company said the total outlay for both was $1.2bn.

JenaValve's focus is on the transcatheter treatment of aortic regurgitation, a common and serious condition for which there is currently no treatment. The JenaValve Trilogy Heart Valve System is currently in its pivotal trial, and Edwards anticipates it will win US Food and Drug Administration approval by the end of 2025.

"As the pioneer in valve innovation for more than 60 years, Edwards believes it is uniquely positioned to lead this next frontier of aortic valve disease treatment," Edwards explained.

Edwards is also exercising a purchase option on heart failure firm Endotronix that it has held since 2016, the announcement states. The heart failure firm recently received FDA authorization on Cordella, an implantable pulmonary artery pressure sensor that allows for early, targeted therapeutic intervention. A Medicare coverage determination for Cordella is expected in 2025.

"These acquisitions expand our opportunities to address the unmet needs of aortic regurgitation

and heart failure patients around the world," said Bernard Zovighian, Edwards' CEO. "We are pleased to enter these structural heart therapeutic areas with innovation, world-class science and clinical evidence to provide access to life-saving technologies for patients around the world."

BD Enters Collaboration With Quest Diagnostics

Becton Dickinson and Quest Diagnostics struck a collaboration agreement to develop, manufacture and commercialize flow cytometry-based companion diagnostics for cancer treatments and other diseases. Flow cytometry technology is used to analyze patients' cells to match them with the best treatment available.

"Our collaboration with Quest underscores a shared commitment to advance personalized medicine by leveraging this technology in the development of companion diagnostics to be used alongside therapeutic options for patients," said Steve Conly, worldwide president of Biosciences at BD. (Also see "*BD's CTO Beth McCombs Discusses Key Initiatives – AI/Gen AI; DE&I Strategy; Succession Planning*" - Medtech Insight, 20 Mar, 2024.)

Using companion diagnostics to help select the first-line therapy for cancer patients can be critical to ensuring the best outcomes and cost savings, the companies said.

In 2022, BD teamed up with Labcorp in a similar deal to develop new companion diagnostics using flow cytometry to help physicians select optimal treatment for cancer patients.

Clinical Lab To Pay $5M To Resolve Kickback Claims

New Jersey-based Admera Health has agreed to pay $5.4 million to the US and an additional $147,851 to the states to resolve allegations that it violated the False Claims Act by paying commissions to third-party marketers, the US Department of Justice announced on 24 July.

The company offers biopharmaceutical research services to health care facilities. Until 2021, it also provided pharmacogenic testing that analyzed which patients might be good candidates for specific drugs based on their genetic traits. The settlement resolves allegations that between 2014 and 2021, Admera paid commissions to marketing firms in exchange for referrals or orders for the company's genetic testing services, which were then reimbursed by insurers including Medicare and Medicaid.

The DOJ also noted that Admera kept the commissions scheme in place even after being informed that it violated anti-kickback law. The whistleblower suit was brought by two former

employees of a marketing firm hired by Admera.

“The law prohibits health care providers, including those that provide laboratory services, from paying kickbacks in the form of commissions to third parties as an inducement to generate business,” said Brian Boynton, head of the Justice Department’s Civil Division. “The department is committed to holding accountable those who engage in kickback arrangements that undermine the integrity of federal healthcare programs.”

FDA Updates Flu Tests Webpage

The US FDA recently announced an update to its *Influenza Diagnostic Tests webpage*, indicating that lab-developed tests (LDTs) for highly pathogenic avian influenza (HPAI) — commonly known as avian or bird flu — offered by clinical labs certified under Clinical Laboratory Improvement Amendments (CLIA) and qualified to perform high-complexity testing currently fall under the FDA’s general enforcement discretion approach for LDTs.

The FDA said it generally does not expect CLIA-certified labs that perform high-complexity testing to request marketing authorization from the FDA for their LDTs for HPAI prior to offering them, nor would the agency issue emergency use authorizations for such tests given that there is no relevant statute to do so.

HPAI is highly contagious and often deadly in poultry, caused by highly pathogenic avian flu viruses, which can be transmitted by wild birds to domestic poultry and other bird and animal species. Although bird flu viruses do not normally infect humans, sporadic human infections have occurred, the agency said.

First Robotic Spinal Surgery Using eCential Robotics’ Spine Open Platform

The first robotic spinal surgery using eCential Robotics’ spine open platform has been successfully performed by US Providence St. Joseph Hospital. The eCential surgical platform was used to implant Spineart’s PERLA minimally invasive screw fixation system.

The French and US-based company eCential Robotics has developed a scalable 2D/3D imaging, navigation, and robotic platform to assist with bone surgery. eCential reported that the surgeries performed at California-based Providence St. Joseph Hospital mark the first in-human use of the eCential robotic technology and the start of eCential operations in the US.

eCential received FDA clearance for its surgical robotic platform for spine surgery However, “the goal is to increase the indications of the robot to help with the implantation of other spinal and

musculoskeletal devices," said eCential.

The company said compatibility with other medical devices is achieved through different digital applications developed by partners on the eCential Robotic OPEN platform. "The eCential Robotic OPEN platform can support multiple applications and augment its compatibility with medical devices/implants."

Earlier this week, eCential announced US Food and Drug Administration (FDA) 510(k) clearance for its spine navigation and robotic-assistance device on July 22. The robot, separate from the eCential Robotic OPEN Platform, was developed in collaboration with DePuy Synthes, Johnson & Johnson's orthopedics arm. However, eCential stated, "We will not play any role in the sale of the robot."