MEDTECH INSIGHT
CITELINE COMMERCIAL

24 May 2024 | **News**

News We're Watching: Panel Backs Guardant Shield, EU Adopts AI Act, Magellan Settles Lead Test Claims

by Brian Bossetta

This week, an FDA advisory panel recommended approval of the Guardant Shield blood test for colon and rectal cancers; the EU Council signed off on the world's first AI law; and the FDA challenged innovators to develop AI/ML technologies to detect gait freezing in individuals with Parkinson's disease

FDA Panel Strongly Recommends Approval Of Colon Cancer Blood Test

The *Guardant Health, Inc.* Shield, which screens the blood for markers of colon and rectal cancers, got the thumbs up from a US Food and Drug Administration advisory panel on 23 May.

Most of the 150,000 people in the US who develop colon cancer each year are diagnosed through a colonoscopy or a fecal test. The Shield test offers several advantages over those methods: For example, it wouldn't require the fasting or other preparation needed for a colonoscopy or the mess that comes with collecting a fecal sample. Guardant Health believes that many patients who currently opt out of colon cancer screenings would be open to a simple blood test that can be performed during a routine office visit.

In its pivotal trial, the Shield test demonstrated 83% sensitivity for the detection of colon and rectal cancers, with 90% specificity for advanced neoplasia. However, it was only 13% sensitive for detection of advanced adenoma.

Fecal swab tests currently on the market range from 69%-92% accurate, Guardant said.

The Shield's proposed indication for use is as a primary colon cancer screening tool in people aged 45 and up at average risk of colon cancer. For that use, panelists voted 8 to 1 that there is reasonable assurance Shield is safe, 6 to 3 that there is reasonable assurance Shield is effective, and 7 to 2 that its benefits outweigh its risks.

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“The advisory committee’s strong support for the approval of Shield reinforces the crucial role that a blood test option can have in improving CRC screening rates for those at average risk,” said AmirAli Talasaz, co-CEO of Guardant Health. “Despite the importance of detecting colorectal cancer early, there are notable barriers that can deter average-risk Americans from completing existing screening methods. Shield effectively detects cancer at an early stage when it is most treatable. Providing people with this blood test alongside other non-invasive stool tests can increase the rate of colorectal screening and potentially reduce preventable CRC deaths.”

EU Gives Final Nod To First AI Law

The European Union Council announced on 21 May that it has signed off on its AI Act, which now becomes the first major piece of regulation in the world to specifically target artificial intelligence.

The act uses a risk-based framework to set guidelines around uses of AI. It bans some uses that the union considers too risky, such as “social scoring” programs that rank citizens based on aggregated data. Medical devices are considered high-risk by the act and will be evaluated on the risks they pose to the health, safety and fundamental rights of individuals.

The EU Parliament adopted the act in plenary in March. Medtech industry experts believe its success is now in the hands of the EU’s new AI Office, which will be in charge of monitoring AI products and enforcing the act. (Also see "*European Parliament Adopts AI Act, But Success Hangs On The AI Office*" - Medtech Insight, 14 Mar, 2024.)

Magellan Pays $42M In Lead Test Settlement

Magellan Diagnostics Inc. has pleaded guilty to criminal charges related to malfunctioning tests for blood lead levels, the US Department of Justice announced on 21 May.

In addition to pleading guilty to violating the Food, Drug and Cosmetics Act, Magellan also agreed to pay a $21.8m fine, $10.9m in forfeiture and $9.3m to compensate patients. The company also signed a deferred prosecution agreement to resolve felony and conspiracy fraud charges against the company.

The company’s LeadCare Ultra, LeadCare II and LeadCare Plus tests were used to detect blood lead levels and lead poisoning in both children and adults. In 2013, Magellan learned that the tests often gave incorrect low readings when used with venous blood samples. However, the company did not notify the FDA until it was acquired by *Meridian Health* in 2016, and falsely told

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the agency that it had only learned of the problem in late 2014. The tests were removed from the market in 2021. (Also see "*Recall Of Magellan Lead Tests Just Keeps Getting Bigger And Bigger*" - Medtech Insight, 28 Sep, 2021.)

FDA Announces AI Gait Freezing Detection Development Challenge

The US Food and Drug Administration's Digital Health Center of Excellence (DHCoE) launched a challenge to develop AI/ML technologies to *detect gait freezing*.

Gait freezing occurs in individuals with Parkinson's disease. It's a debilitating symptom that causes an individual's legs to lock up and freeze while they're walking, which can cause falls and psychological distress.

The DHCoE's challenge is intended to "better understand the ability of DHTs to provide digitally-derived endpoints," which are measurable outcomes that come from digital health technologies.

The first phase of the challenge launches 28 May, and participants will use publicly available datasets to create AI models to predict endpoints for gait freezing detection.

The top challenge performers will be announced on 28 August, and those models will be given access to curated datasets from the FDA for validation, which will take place from September through November.

Preregistration for the challenge opens on 20 May.

Hologic BioZorb Marker Recalled After 71 Injuries

The BioZorb Marker from *Hologic, Inc.* is being recalled due to reports of pain, infection and other adverse events, the FDA *announced* on 22 May.

The agency has designated the recall as class I, the most serious level.

The device is an implantable radiographic marker used to mark soft tissue (such as breast tissue) for future medical procedures, such as radiation. It has two components: A permanent titanium implant, and a component made of plastic that resorbs over the time. It is meant for one-time use.

Patients implanted with the device reported complications including pain, infection, rash, device migration, device erosion, fluid build-up, discomfort, or the need for additional treatment to

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remove the device. A total of 71 injuries have been reported, but no deaths.

The recall notice instructs people implanted with the BioZorb Marker to contact their physicians about treatment options including device removal. Additionally, health care providers are being asked to discuss the potential risks of the device. Complications can be reported to breasthealth.support@hologic.com as well as the FDA's adverse event reporting program.

Second Version Of Sonio AI Prenatal Ultrasound Gets 510(k) Clearance

The US FDA has cleared Sonio Detect AI, which the femtech company said will improve clinical outcomes for expecting mothers and their babies by providing high-quality exams, automatically detecting views, anatomical structures, and verifying quality criteria of ultrasound images.

New capabilities of this latest version of Sonio Detect include a reliable ability to recognize fetal ultrasound views and automatic extraction of complex views (heart/brain) from clips.

Additionally, it implements the latest IT infrastructure technologies and adheres to stringent security standards, such as HIPAA compliance and encryption protocols, to safeguard sensitive medical information and mitigate the risk of data breaches. It also enables clinicians to review images and reports remotely.

"By harnessing the power of advanced imaging technology and intuitive software solutions, OB/GYN professionals can enhance diagnostic accuracy, optimize practice efficiency, and deliver exceptional patient care, ensuring a brighter and healthier future for women's health," Sonio said.

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