MEDTECH INSIGHT
CITELINE COMMERCIAL

15 Sep 2023 | **News**

News We're Watching: New Branding For J&J, FDA Device Safety Report, LimFlow System Approval

by

J&J Drops Iconic Cursive Branding

Johnson & Johnson has declared itself to be entering a "new era." The company is moving on from its cursive script branding, which is based on writing samples from the company's co-founder, James Wood Johnson.

Source: Johnson & Johnson

The decision comes as the company moves further away from its shampoo and cosmetics roots – not only in response to historical issues surrounding its *potentially* asbestos-laden baby powder, but also as it leans into its drug and medical device businesses.

J&J CEO Joaquin Duato said of the decision, "Uniting our diverse businesses under an updated Johnson & Johnson brand reflects our unique ability to reimagine healthcare through transformative innovation, while staying true to Our Credo values and the level of care that patients and doctors expect of us."

In corporate fashion, J&J has declared new elements of its logo to mean *something.* Supposedly, its letter-wise pen-stroke design creates a "contrast that delivers both a sense of unexpectedness and humanity." Its new ampersand "captures a caring, human nature."

PR-speak aside, Johnson and Johnson's branding should start to make a bit more sense.

Kenvue, which took charge of J&J's consumer business in 2022, will continue to use the cursive logo on its products, which include bandages and painkillers, for the time being, but plans to

soon phase out its usage.

J&J's pharmaceutical business, which is currently called Janssen, will be named "Johnson & Johnson Innovative Medicine."

J&J's medical technology business, with its menagerie of current brands including Ethicon, Biosense Webster, and DePuy Synthes, will go on to be called Johnson & Johnson Medtech. It is uncertain whether its sub-brands will be changed.

FDA Issues Medical Device Safety Report To Congress

The US FDA's device center has issued a *report on device safety* to Congress, which it's required by law to do every other year.

According to the report, the Center for Devices and Radiological Health (CDRH) issued 45 safety-related communications in calendar 2022, including 30 medical device safety communications as well as 15 letters to health care providers.

Of the 45 safety-related communications issued in 2022, 23 provided new information about device safety, eight provided new information about device safety recalls that had resolved the problem, and 14 provided updated information about device safety to previous communications issued by CDRH. Of the 14, four added additional information to 2022 safety-related communications while 10 updated safety-related communications issued prior to 2022.

Along with reporting last year's safety communications, CDRH also noted in the report that it has issued nine device safety communications so far this year, including advisories on breast implants, N95 face masks, ultrasound devices, dental devices, devices for plastic and reconstructive surgery, joint replacement, and diagnostics.

FDA Updates Medical Device Shortage List

Earlier this week, the FDA updated its *medical device shortage list*.

Currently, the FDA says devices in the categories of anesthesiology; cardiovascular — circulatory support, structural and vascular devices; cardiac diagnostic and monitoring products; dialysis-related products; general hospital and plastic surgery devices; radiological devices, and certain ventilation-related products are in short supply.

The agency notes, however, that the presence of a device type on the list does not necessarily

indicate that patient care has been affected.

The FDA also added Oxygenator — circulatory support, structural and vascular devices (product codes: DTZ and BYS) to the list.

The agency's *Resilient Supply Chain Program (RSCP)* is responsible for managing CDRH's activities to anticipate and prevent disruptions to the supply chain for medical devices, including managing the medical device shortage list.

Along with listing devices in short supply, the agency also lists devices that have been discontinued, which include devices in clinical chemistry, general ICU products, infusion pumps and related accessories, orthopedic, personal protective equipment, peritoneal dialysis systems and accessories, sterilization products, testing supplies and equipment, ventilation-related products, and vital sign monitoring.

The FDA also provides an *FAQ* on medical device and supply shortages.

Class I Recall Of Valves From Irish Manufacturer

The US FDA has designated a *recall* from Mallinckrodt Manufacturing as class I, its most serious type.

The Dublin, Ireland-based company initiated the recall of several model numbers of its One-Way Valve, 22F x 22M, which is part of the INOmax Delivery System, in July.

In total, Mallinckrodt recalled 1,799 devices distributed in the US from January 2022 through July.

The INOmax Delivery System delivers nitric oxide gas into the tubes between the ventilator and patient airway. The One-Way Valve is used to prevent backward flow of nitric oxide gas into the INOmax DSIR injector module. If the valve is omitted, the patient may receive air high in nitric oxide.

The company recalled the valves for failing to open properly, which prevents or reduces the flow of ventilated air or oxygen. Use of the devices, according to the FDA, may cause serious adverse health consequences, including interruption in ventilation which may delay delivery of nitric oxide gas.

In neonatal or pediatric patients, this delay could lead to bradycardia. In other all patients it could lead to insufficient oxygen in the blood resulting in respiratory failure, and death.

There have been two complaints associated with this recall, but no reports of injuries or death.

However, if a One-Way Valve from an affected lot is currently in use and working as expected, the company advises not removing it from the circuit and continuing monitoring the patient's oxygen saturation levels.

FDA, CDC Investigating Tuberculosis Outbreak Linked To Bone Matrix Product

The US FDA recently *announced* that it is working with the Centers for Disease Control and Prevention (CDC) to investigate reports of an outbreak of tuberculosis (TB) caused by Mycobacterium tuberculosis (Mtb) associated with a bone matrix product.

The FDA said it issued the alert to increase awareness of the potential risk of "human cell, tissue and cellular and tissue-based products," or HCT/Ps, posing a risk for TB transmission.

Mtb transmission from transplantation of human bone, heart valves, and a dura mater allograft were reported in other countries, "decades ago," according to the FDA. Then, in 2021, there was a multi-state outbreak of Mtb in the US linked to bone allograft transplantations, which resulted in significant morbidity and mortality.

The FDA says the current outbreak appears similar.

Because Mtb transmission can occur from HCT/P donors with unrecognized and undiagnosed TB infection, the health officials warn these circumstances demand heightened awareness when screening potential donors.

The FDA says routine screening measures are in place for evaluating clinical evidence of infection in HCT/P donors and that the agency has provided recommendations in guidance to reduce the risk of transmission of infections, including due to sepsis, which may be caused by Mtb.

However, the FDA advises following a series of risk mitigation strategies outlined here.

FDA Approves LimFlow System For Chronic Limb-Threatening Ischemia

The US Food and Drug Administration has approved LimFlow's transcatheter deep-vein arterialization system for the treatment of chronic-limb ischemia, the company announced on 12 September.

The LimFlow system creates an arteriovenous fistula to shift blood from the tibial artery into the

tibial vein and revascularize the ischemic area of the lower leg. It is indicated for patients with severe peripheral artery disease with no other treatment options other than amputation.

The US Food and Drug Administration granted LimFlow its breakthrough designation in 2018 because these patients lack alternatives to amputation.

The approval is primarily based on the *results* of *PROMISE II*, a single-group study the LimFlow system in patients with nonhealing ulcers and no surgical or endovascular revascularization treatment options. Six-month results from 105 patients in the study were published in the *New England Journal of Medicine* in March. (Also see "*Cardiovascular Catch-Up: Philips New AI Finds AF Needle In ECG Haystack; LimFlow Moves Closer To US Approval*" - Medtech Insight, 11 Apr, 2022.)

After six months, 66.1% of the patients treated in the study survived without needing an above-ankle amputation. The prespecified performance goal was 54%. Also, a quarter of the patients who survived with their limb showed complete healing of their ulcer and 32 patients showed progress in healing. There were no unanticipated device-related adverse events.

“With LimFlow, we now have an option for the sickest patients who were previously consigned to limb loss and the downward spiral that accompanies it,” said PROMISE II primary investigator Daniel Clair, a vascular surgeon at Vanderbilt University Medical in Tennessee. “Using this new treatment, we have seen many patients whose limbs have been saved, whose pain has been reduced or resolved, whose chronic wounds are healed or healing, and who can now look forward to happier and more active lives.”

The LimFlow System is currently available commercially in Europe, but not Japan or Canada.

Google Announces AI Projects

Healthtech projects are among the 15 artificial intelligence projects Google selected to fund as part of its commitment to *sustainable development goals*.

Google selected these projects based on their prospective impact, scalability, sustainability, feasibility, and adherence to Google’s *AI principals and responsibility practices*.

Each project will receive up to $3m in cash, technical assistance, and Google Cloud credits. Some of the projects will also benefit from Google.org Fellowships; Google staff will work with organizations full-time for free for up to six months.

The selected projects include *RAD-AID*’s effort to develop AI diagnostic technology that can help low-resource hospitals triage and interpret X-rays and scans.

Another funded project is Makerere AI lab's effort to develop a 3D-printed adapter to connect mobile phones to microscopes so that AI can analyze images.

Google is also supporting IDInsight's maternal health project in South Africa. The company's Reach Digital Health program uses natural language processing to improve communication with expectant mothers in underserved communities.

MDIC Cybersecurity Benchmark Assessment Open

The Medical Device Innovation Consortium's second annual cybersecurity *benchmark assessment* is open for responses from medical device manufacturers.

The assessment is intended to measure the effect of the US's Healthcare and Public Health Coordinating Council's Joint Security Plan (JSP), which is a guide to best cyber practices for a medical device's entire life cycle.

Last year, 17 device manufacturers responded to the survey, culminating in what experts saw as an accurate assessment of where the industry stands in terms of cybersecurity preparedness. Almost two thirds of respondents reported that they did not use the JSP as a guide. Additionally, there was a lack of consideration for third party security in cybersecurity assessments. (Also see "*MDIC Cybersecurity Benchmarking Maturity Report: An 'Honest Reflection' Of The Industry*" - Medtech Insight, 24 Jan, 2023.)

"While cybersecurity maturity varies significantly between MDMs, the industry as a whole has a low level of cybersecurity maturity," the MDIC concluded in the report.

Reponses for the 2023 assessment can be submitted until 20 October.

ACLA Letter Urges MACs To Ensure Access For Genetic Testing For Cancer

A letter from the American Clinical Laboratory Association (ACLA) to Medicare Administrative Contractors (MACs) expressed concern about the exclusion of certain genetic tests for cancer in in a draft Local Coverage Determination (LCD).

The *letter*, co-signed by 44 other stakeholders addressed draft LCD, L39365 "*Genetic Testing for Oncology*." It was issued by Novatis and First Coast Service Options (FSCO) earlier this summer.

Under the current language, genetic tests for oncology would not be covered unless included "within at least one of three identified third-party 'knowledgebases,'" the ACLA wrote in a

release.

The approved knowledgebases are CliniGen from the National Institutes of Health, NCCN Compendium from the National Comprehensive Caner Network, and OncoKB from Memorial Sloan Kettering Cancer Center.

If a genetic test isn't included in one of the three databases, then a provider, organization, or Medicare beneficiary can submit a reconsideration request, but ACLA pointed out that those requests often take a while, and "all patients, especially those with cancer, require timely access to diagnostics that inform their treatment."

"We urge Novitas and FCSO not to finalize this LCD as drafted and instead work with stakeholders to address our significant concerns," ACLA president Susan Van Meter said.