MEDTECH INSIGHT
CITELINE COMMERCIAL

27 Oct 2023 | **News**

# News We're Watching: Apple Watch Imports Blocked, Fresenius Recall, Groups Ask For Longer LDT Comment Period

by Brian Bossetta

This week, the International Trade Commission ruled in favor of Masimo and blocked the import of some Apple Watches; Fresenius faced a recall; City of Hope announced a pancreatic cancer grant; and organizations asked for a longer comment period on the US FDA's proposed rule on lab-developed tests.

## Apple Watches Hit With Limited Exclusion Order; Cease And Desist

The International Trade Commission has upheld a preliminary decision that Apple Inc violated two of Masimo Inc's pulse oximeter patents and has issued a limited exclusion order that will block the import of Apple Watches with the technology. It also issued a cease-and-desist order against the tech giant.

The 26 October decision was delayed from a 10 October deadline, which had originally been set for 17 July. (Also see "*News We're Watching: FDA Announces Meetings On Ortho Safety And Radiology; News Orgs Sue FDA For Philips Docs, ITC Delays Apple Watch Case; And More*" - Medtech Insight, 6 Oct, 2023.)

Now, President Biden has a 60-day period to veto the LEO, but there have only been two vetoes of this kind in the past 30 years. If Biden takes no action, the LEO will take effect.

Since the 60-day timeframe will end close to the holiday season in the US in December, there is a chance the decision timeline could be delayed, Washington Analysis noted in an earlier report. (Also see "*News We're Watching: FDA Announces Meetings On Ortho Safety And Radiology; News Orgs Sue FDA For Philips Docs, ITC Delays Apple Watch Case; And More*" - Medtech Insight, 6 Oct,

2023.)

Apple now has the option appeal to the court of appeals for the federal circuit, but if the LEO is not vetoed by the Biden Administration, it will be in effect during the appeals process.

Another option to bypass the LEO is for Apple to remove the patent-infringing pulse oximeter from its watches to allow import of the product into the US.

## Class I Recall For Fresenius Medical Care Hemodialysis Machines

The US Food and Drug Administration has designated a recall of some 200 hemodialysis machines from *Fresenius Medical Care* as class I, the agency's most serious level.

The German healthcare company initiated the recall of the 2008 Series last November because of the potential for exposure to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) that leach from some peroxide-cured silicone tubing used as part of the hydraulics in the machine and dialysate lines.

The company, according to the FDA, is updating affected machines manufactured between 21 August 2008 and 6 June that contain chlorinated peroxide cured silicone tubing and have been used for less than 486 total hours.

The machines serve as an artificial kidney and are used for hemodialysis, which is a treatment to pump blood from the patient's body to remove toxins and excess water to mimic the function of a healthy kidney. Hemodialysis also helps to control blood pressure and balance important minerals in the blood, such as potassium, sodium, and calcium.

Use of the affected machines, the FDA said, may cause serious adverse health consequences months to years after exposure, including endocrine dysfunction, liver issues, neurobehavioral changes, skin problems, and male infertility.

Fresenius notified customers in September to contact the company if they have an affected machine, which the company will update to platinum-cured silicone tubing for free. However, machines purchased after October 2022 are not included in the recall and were manufactured with platinum tubing.

In May 2022, the FDA warned healthcare providers of the company's machines potentially emitting harmful toxins. (Also see "*Toxins In Silicone Tubing Leads To FDA Warning About Hemodialysis Machines Made By Fresenius*" - Medtech Insight, 9 May, 2022.)

## City Of Hope Granted $4.5M For Pancreatic Cancer Screening Research

The National Cancer Institute has awarded a $4.5m grant to cancer clinic network City of Hope and its its Translational Genomics Research Institute (TGen). The money will go towards an international project to validate a blood-based liquid biopsy test for the early detection of pancreatic cancer.

The diagnostic was developed by the National Cancer Institute's Pancreatic Cancer Detection Consortium and analyzes exosomal microRNAs associated with pancreatic cancer. TGen says that it has shown promise in identifying abnormal cell growth in early trials. With the new grant,researchers plan to enroll pancreatic cancer patients from at least 10 sites, including two that primarily serve African-American or Asian patients.

"We desperately need tools for very early detection of pancreatic cancer at stages where it can be treated effectively. Our preliminary data are promising, and this grant will help solidify just how reliable this test will be," TGen distinguished professor Daniel Von Hoff, the effort's co-principal investigator, said in a statement.

## Medical Groups Ask For Extended Comment Period On LDT Proposed Rule

Five medical groups have asked the US Food and Drug Administration to extend the comment period on its proposed rule on the regulation of lab-developed tests. The comment period for the 3 October regulation is currently set to end on 4 December. (Also see "*Proposed Rule Would Apply FDA's Diagnostic Rules To LDTs*" - Medtech Insight, 29 Sep, 2023.)

But the American Red Cross, the Coalition for Innovative Laboratory Testing, the Association for the Advancement of Blood and Biotherapies, the American Society for Microbiology and the American College of Medical Genetics and Genomics have asked the agency to give stakeholders a further 60 days, which would push the comment deadline into February 2024. The organizations say that 60 days is not enough time to gather input and data and provide a detailed response.

"The proposed rule is complex and requires numerous stakeholders across our organization to review, evaluate, and write a detailed response," Red Cross executive director J. Scott Webber wrote in *one representative request*. "Given the implications this proposed rule will have on our laboratories, we are asking for additional time to fully complete the evaluation and provide a response, with appropriate data, to ensure that patients have access to reliable, accurate, and safe LDTs."

The FDA had already received 972 comments regarding the proposed rule as of 27 October, *regulations.gov* shows.

## US Copyright Office Wants To Renew Medical Device Repair Exemption

The US Copyright Office would like to renew an exemption that allows those working to maintain or repair a medical device to access copyrighted computer programs, a 19 October *Federal Register* notice shows.

The exemption, first issued in 2021, permits access to "computer programs that are contained in and control the functioning of medical devices or systems, and related data files, for diagnosis, maintenance or repair." It is issued under the Digital Millennium Copyright Act and must be renewed by the Library of Congress every three years. The library typically follows recommendations from the Copyright Office.

The exemption has been controversial, with some device industry advocates claiming it undermines FDA standards and could reduce device safety. However, supporters of the exemption say it's necessary to allow for outside services to perform device repair and maintenance.

AdvaMed and other trade groups have filed a lawsuit against the exemption. The suit, which was dismissed by the US District Court for the District of Columbia in March, is currently being appealed. (Also see "*Trade Groups Appeal Dismissal Of Device 'Right To Repair' Case*" - Medtech Insight, 13 Jun, 2023.)

## Vektor Medical's Arrythmia Analysis Tech Receives New CPT Code

Vektor Medical's vMap technology for arrythmia analysis has received a new Category III CPT code from the American Medical Association.

vMap is a non-invasive tool that can identify the location of premature ventricular complexes based on computational simulations.

According to Vektor Medical CEO Rob Krummen, the most successful treatment of atrial fibrillation, which causes arrhythmia, is ablation and only about 2% of sufferers received the treatment. Additionally, many ablations are only 50-60% successful, which is where mapping comes in. (Also see "*Cardio Conversations: Vektor Addresses 'Global Health Crisis' With Arrythmia Mapping*" - Medtech Insight, 14 Apr, 2023.)

vMap can help doctors find the locations of the “faulty circuitry” to better guide ablation treatments.

The code will be published 1 January 2024 and will go into effect on 1 July 2024.