MEDTECH INSIGHT
CITELINE COMMERCIAL

15 Mar 2024 | **News**

News We're Watching: LDT Survey Finds Concern, Abbott Recall, New Q-Sub Guidance

by Brian Bossetta

This week, the US Congress advanced legislation that would support better cardiac emergency preparedness in schools; the former CEO of device company Stimwave was convicted on two counts of fraud; and the FDA issued a draft guidance document on the thermal affects of medical devices.

Industry Survey Shows High Concern On LDT Proposal

The clinical lab industry stands largely opposed to the FDA's proposed approach to regulating lab-developed tests, a *recent survey* conducted by ARUP Laboratories found.

ARUP Laboratories is a nonprofit laboratory based at the University of Utah. The survey, which was sent to ARUP clients, drew 503 respondents who identified themselves as lab employees or management, medical directors, physicians, clinicians, or PhD scientists.

Of the group, only 8.2% supported the proposed rule, with 71.6% in opposition and the rest undecided. About two-thirds of respondents said they worked for labs that performed LDTs; of those, 83.9% believed the proposed rule would be bad for their labs, and 60.9% said they believed they would need to offer fewer tests if the rule is implemented as written. The cost of FDA submissions was a particular source of concern, with only 3% saying they were sure they could afford to get their tests cleared for market.

"This survey shows there is profound concern within the clinical laboratory community about the proposed rule and its negative impact on patient care," said Jonathan Genzen, ARUP's chief medical officer and senior director of governmental affairs. "If labs cannot afford to comply with the proposed regulations, they will have to discontinue essential tests, and that harms patients."

Legislation Calls For Better Cardiac Arrest Resources In Schools

The US House Energy and Commerce Subcommittee on Health has approved the Cardiomyopathy Health Education, Awareness, Research and Training in Schools (HEARTS) Act, legislation that could potentially save lives by ensuring that students and staff are prepared for a cardiac emergency.

The American Heart Association issued a *statement* applauding the bill and urging the full committee to pass and move it forward.

“When someone experiences a cardiac arrest at school, their chance of survival should not depend on whether an automatic external defibrillator (AED) is close by or if someone can perform Hands-Only CPR until emergency responders arrive. In schools with proper equipment and cardiac emergency response plans (CERPs), students and staff know what to do immediately to save a life,” the statement said in part.

“The American Heart Association is pleased with the bipartisan support for the HEARTS Act, which would require the Department of Health and Human Services, in partnership with other agencies and stakeholders, to develop and distribute educational resources on cardiomyopathy, a leading cause of disability and sudden cardiac death among young people. The bill also calls for guidelines regarding the placement of AEDs in schools and childcare centers, the establishment of CERPs and information on CPR training.”

Former Stimwave CEO Convicted On Fraud Charges

Laura Perryman, who once served as CEO of neurostimulation device firm Stimwave, has been convicted on two fraud charges after an 11-day jury trial, the US Attorney’s Office for the Southern District of New York announced recently.

Stimwave made a neurostimulator system for the treatment of chronic pain known as the StimQ PNS System. The system included an external lead component containing electrodes as well as an implanted receiver component. When physicians complained that the receiver was too large to be implanted in some patients, Stimwave developed a smaller plastic “stylet” that could not receive signals and shipped these nonfunctioning stylets to unknowing physicians for use in patients. Medicare and private insurers paid between $16,000 and $20,000 each for the faux devices. (Also see "*Pain Device Firm’s Undoing Over $16K ‘Piece of Plastic’*" - Medtech Insight, 14 Mar, 2023.)

Perryman now faces up to 10 years in prison on one count of health care fraud and an additional

20 years on one count of conspiracy to commit health care fraud and wire fraud. Stimwave has already paid $10m to resolve potential charges against the company.

FDA Updates Draft Guidance For Interacting With The Agency On Device Submissions

The FDA has issued an updated draft guidance, "R*equests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program*." The document provides an overview of how submitters can request interactions with the agency related to medical device submissions.

The Q-sub program, initiated in 2018 under a MDUFA IV requirement, is a process that companies can use to get feedback from the FDA before submitting their device for regulatory approval.

When finalized, the draft guidance will supersede the document issued on 2 June 2023, and provide clarification and additional information on the scope of Q-submission, or Q-sub, types, as well as offer better delineation of how sponsors can obtain feedback from the FDA for different types of questions, such as informal communication versus pre-submission or other Q-sub types, and improved examples.

The updated draft guidance provides additional information on the scope of Q-sub types, as well as clarifications to existing policies and procedures; content from "Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies — for Use by CDRH and Industry," with no changes to existing policies and procedures for PMA Day-100 meetings, and revised examples of common review topics and questions.

A PMA Day-100 meeting is a meeting with the FDA that fulfills the agency's obligation to meet with the applicant, upon written request, no later than days after the receipt of an original PMA application that has been filed.

The draft also provides updates on informal meetings, which are requests to share information with the FDA without the sponsor expecting feedback; study risk determinations, which are requests for an FDA determination for whether a planned medical device clinical investigation is significant risk (SR), nonsignificant risk (NSR), or exempt; and various other Q-sub types.

Comments on the guidance can be submitted at *Regulations.gov*.

Class I Recall For Abbott HeartMate Touch System

Abott initiated a *recall* in January of more than 1,500 HeartMate Touch Systems due to the risk of the device's pump unexpectedly stopping or starting.

The FDA has classified the recall as class I.

The HeartMate Touch is a communication system that monitors patients who have an implantable HeartMate 3 Left Ventricular Assist Device. The system works with the HeartMate System Controller and includes a tablet, wireless adapter, flash drive, power adapter, and USB. The system is used only by clinicians in hospitals or clinics to provide a detailed, large-scale display of a patient's cardiovascular status.

Issues with the system may occur if it is disconnected from a patient's HeartMate Controller while a "pump stop" command is running. When the system is reconnected to the same or a new controller, the pump will either stop or start, depending on the status of the pump at connection.

If the pump was stopped at reconnection, the pump will restart. If the pump is running at reconnection, a pump stop will occur. There are no alarms or indications that warn the user that the "pump stop" command is still in the command queue.

This issue may cause serious adverse health consequences, including lightheadedness, sudden change in blood flow, loss of consciousness, and death.

The FDA said there have been 8 reported injuries, and no reports of death.

FDA Issues Draft Guidance On Evaluation Of Thermal Effects Of Medical Devices

The US FDA has published draft guidance on relevant information that should be included in submissions of medical devices that produce local, regional, and/or systemic changes in body tissue temperature.

The document, "*Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling*," covers the evaluation of thermal effects of devices that produce temperature changes — heating and/or cooling — "either as an intended or unintended result" of the device use.

Examples of devices that produce thermal effects include those that deliver radiofrequency, microwave, light, or other forms of electromagnetic energy; devices that deliver ultrasound, electroporation devices, devices that produce temperature change — such as hyperthermia, high temperature ablation, hypothermia, cryoablation by contact; and devices where electrical

components — such as batteries, generators, chargers, leads, and electrode contacts — can potentially heat surrounding tissue during use.

When a change in tissue temperature happens because of device-induced heating or cooling, there is potential for adverse health consequences, according to the FDA, such as tissue damage and/or a negative impact on physiological functions.

The FDA says assessing thermal effects of devices is an important aspect of its premarket review process.

An evaluation of thermal effects, the guidance states, should include verification of device parameters and an assessment of tissue effects — thermal damage, tissue appearance, tissue/organ function — and related spread of thermal energy.

The FDA says submitters can perform an assessment of tissue effects and thermal energy spread experimentally, such as using phantoms, ex vivo animal tissue models, and/or in vivo animal testing, either computationally, and/or clinically.

The document provides more information on how such evaluations should be conducted and presented in premarket submissions, including verification of device parameters; experimental assessment of tissue effects and thermal energy spread — including various types of animal testing; tissue testing methodology; computational evaluation of tissue effects and thermal energy spread; clinical evaluation of tissue effects and thermal energy spread; and labeling.

Comments may be submitted at *Regulations.gov* through 14 May.

ASCA Public Workshop Planned

The FDA plans to discuss strategies for expanding the Accreditation Scheme for Conformity Assessment (ASCA) program in a 17 April *virtual public workshop*.

The program, which was launched in 2020, allows manufacturers to outsource some product testing to accredited labs as a way to streamline conformity assessment aspects of medical device review. Right now, standards from the basic safety and essential performance and biocompatibility series are eligible for ASCA review. (Also see "*FDA's 5 Steps To A Successful ASCA Pilot Submission*" - Medtech Insight, 14 Apr, 2021.)

The April event will discuss lessons from the program's pilot phase; potential approaches to expansion, including leveraging existing conformity assessment schemes and adding new standards or test methods; and new technical areas that could be added to the ASCA program.

Eric Franca, a lead device reviewer and engineering consultant for the FDA, will lead the session.

Registration is open through 16 April.