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US Regulatory Roundup, September 2021: Product Safety, Pediatric Devices, EUAs Revoked, And More

by Shawn M. Schmitt

With news of high-risk medical device recalls and troubles with COVID-19 diagnostics, product safety was of paramount concern to *Medtech Insight* readers in September. Also topping the most-read list were articles focused on pediatric patients, the revocation of emergency use authorizations for products to treat and diagnose COVID-19, and more.

Product Safety At The Fore

With news of high-risk medical device recalls and troubles with COVID-19 diagnostics, product safety was of paramount concern to *Medtech Insight* readers in September, with three safety-related articles landing on our Top 10 list of most-read stories.

In our *No. 1 story* from last month, we explained how Alinity m SARS-CoV-2 AMP and Alinity m Resp-4-Plex AMP Kits made by *Abbott Molecular Inc.* may falsely diagnose patients as having the SARS-CoV-2 virus when they don't. The US Food and Drug Administration said the tests could give false-positive results because samples in reagent trays can be contaminated by other neighboring samples.

The FDA urged clinical labs that use the Alinity tests to reach out to people who tested positive since June and let them know they might've been misdiagnosed. The agency granted Abbott emergency use authorization (EUA) for the Alinity m SARS-CoV-2 AMP test in May 2020 and for the Alinity m Resp-4-Plex AMP test in March 2021.

Meanwhile, high-profile, high-risk recalls were also of high interest to readers in September. In our *No. 3 story*, the FDA said two deaths were linked to a class I recall of *Medtronic PLC* stents.

The Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology are used to treat brain aneurysms that bulge or balloon out the sides of the blood vessel.

A guidewire delivery system is used to implant the devices. Medtronic initiated the recall in July because there's "a risk of the delivery system's wire and tubes fracturing and breaking off when the system is being used to place, retrieve or move the stent inside a patient," the FDA said.

The stent recall is Medtronic's ninth to be categorized as high-risk class I this year.

In other September recall news, *Royal Philips* began the unenviable task of repairing and replacing millions of recalled bi-level positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), and other mechanical ventilator devices. The company's effort will take one full year, our *No. 9 story* from last month explained.

More than 2 million of the devices were recalled in June because sound abatement foam can break down over time, posing a risk to patients. The FDA gave the recall a class I designation in July.

Most of the recalled products – of which more than half are in the US – are part of Philips' first-generation family of DreamStation devices. The manufacturer will rework some devices by replacing the foam, while others will be switched out with new DreamStation 2 CPAPs.

"The company intends to complete the repair and replacement programs within approximately 12 months," Philips said, noting that it "remains in dialogue with the FDA with respect to other aspects of the recall notification and mitigation plan in the US."

The fallout from Philips' recall has been unrelenting on the company. Patients in at least two countries have sued in the wake of the recall, including class-action suits filed in Massachusetts and Toronto.

FDA Revokes Slew Of EUAs

And in a sign that the pandemic is more manageable now, the FDA in September revoked a slew of EUAs for a range of products used in the treatment and diagnosis of COVID-19, including Curative Inc.'s Curative-Korva SARS-Cov-2 Assay.

Our *No. 2 story* from last month explained that the EUA for Curative's test was revoked because the company asked for the FDA to do so. The company stopped using the Curative-Korva test in July; Curative told the agency it's now using a different test.

Aside from that particular diagnostic, the FDA revoked 12 EUAs for decontamination systems for

personal protective equipment (PPE) and one EUA for a bioburden reduction system for PPE, and two umbrella authorizations for certain imported disposable respirators that weren't approved by NIOSH, the National Institute of Occupational Safety and Health.

Pediatric Devices In Spotlight

A pair of pediatric-related articles were on our Top 10 list, including our *No. 7 story*, which detailed concerns by the FDA's top doctor for pediatric devices that more products aren't being designed with patients 22 and younger in mind.

"One of the fundamental issues that we're dealing with from a public health standpoint is a dearth of medical devices that truly are designed, evaluated, approved [and] labeled for pediatric patients," said Vasum Peiris, chief medical officer for pediatrics and special populations within the FDA's Center for Devices and Radiological Health (CDRH).

His comments came on 21 September at a NEST RWE² meeting hosted by the Medical Device Innovation Consortium (MDIC) and the National Evaluation System for health Technology Coordinating Center Collaborative Community, or NESTcc. NESTcc is an ongoing project that attempts to link device data from different sources, including clinical registries, billing claims and electronic health records, to improve the quality of real-world evidence.

"When we look at our data over the last 13 years or so at CDRH with respect to PMAs [premarket approvals] and HDEs [humanitarian device exemptions] that have been approved, we see increasing numbers generally year-to-year, which is a great harbinger of innovation for the US public," Peiris said. "However, when we normalize that data toward pediatric approvals or pediatric labeling, you'll see about [only] 23% to 25% over that entire 13-year period" were for PMAs and HDEs for pediatric patients.

Further, only roughly 10% of the devices represented in the FDA's data address a patient population under 18 years old – and it's only 2% to 3% for neonatal patients, Peiris said – but he's hoping that the use of real-world data can help solve that problem.

Meanwhile, our *No. 8 story* focused on an interview with Sharief Taraman, chief medical officer for *Cognoa Inc.* He told *Medtech Insight* that he has high hopes for using artificial intelligence and machine learning (AI/ML) to change the world of pediatric medicine – but he's also wary that many of the disparities in the health care system today could be amplified in the medical software of tomorrow if developers aren't careful.

The FDA authorized in June Cognoa's de novo for its Canvas Dx software to help diagnose autism in children. The software as a medical device (SaMD) was expedited to market as a breakthrough device.

Taraman said AI/ML has the greatest potential to help in areas in health care where there are significant physician shortages, such as for neurodevelopmental disorders. But while AI/ML can help in these areas, he also believes developers need to understand the potentials and limitations of what the technology offers.

That's why, he said, it's important that developers of SaMD products are aware of the inherent racial, ethnic and gender disparities that already exist in the health care system and are likely to be magnified by AI/ML software based on the current available data.

"Like any technology this is a tool in the doctor's bag; this is not a replacement for physicians. We have to be very thoughtful about how we apply tools," Taraman said.

Other Top Stories

These four articles rounded out our Top 10 list in September:

- *No. 4 story*: The lead author of the FDA's Quality System Regulation predicted that device makers won't need as much time as the agency to adapt to a new QSR that's harmonized with international quality systems standard ISO 13485:2016.

- *No. 5 story*: Device makers presented with an affidavit by the FDA during a facility inspection should walk away as quickly as possible, King & Spalding partner Jessica Ringel advised in this *Compliance Corner* feature article.

- *No. 6 story*: A proposed change to Medicare billing that would go into effect on 1 January could give one maker of implantable stents for glaucoma an edge over its competitor.

- *No. 10 story*: A study published in the *Journal of the American Medical Association* (*JAMA*) reviewed trends in US premarket review pathways for medtech products from 1976 to 2020, and concluded that the regulatory process has become complex and the path to market for some devices tricky.

The 10 most popular US regulation and policy stories in September, as determined by reader interest, are listed in the table below.

Rank	Story
1	*Overflow Issue With Abbott COVID Tests Could Result In False Positives*
2	*FDA Revokes EUA For Curative Test, Slew Of Other COVID-19 Products*
3	*2 Dead In Class I Recall Of Medtronic Stents*
4	*QSR Author Says FDA – Not Industry – Will Need Most Time To Adapt To New Quality System Reg*