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News We're Watching: More Class I Recalls, FDA Expands TAP, Guardant Appeals Patent Verdict, And More

by Brian Bossetta

This week, the US FDA labelled several recalls class I, approved an at-home diagnostic for chlamydia and gonorrhea, and announced the expansion of its TAP pilot program. Guardant Health also announced it would appeal a verdict in a patent suit against the company and AdvaMed voiced its continued support for pending breakthrough device legislation.

Cardinal Health Branding Error Results In Class I Recall

Cardinal Health initiated a recall in September of some Cardinal Health Monoject syringes because they differ from the previously branded Covidien Monoject devices and have different dimensions.

In total, the company recalled more than 32 million syringes which are used to inject fluid into the body or withdraw fluid. When used with syringe pumps, the Monoject disposable syringes are loaded with fluid or medication and placed into the pump.

The US Food and Drug Administration *said* the affected Cardinal Health Monoject syringes should not be used with syringe pumps because the dimensional differences may result in pump performance issues such as overdose, underdose, delay in therapy, and delays in occlusion alarms.

The FDA has identified the recall as class I recall, meaning use of these devices may cause serious injuries or death.

Cardinal Health has received 15 reports of delayed therapy due to syringe infusion pumps not

recognizing syringes, and 13 reports of inaccurate volume/rate dispensing, including some injuries, according to the FDA. However, there have been no reported deaths.

The FDA further noted the recall is a correction, not a product removal.

Class I Recall For Baxter's Novum IQ Syringe Pump

Baxter Healthcare is recalling some 2,000 Novum IQ Syringe Pumps for potential underdosing. The pumps may indicate an infusion is complete when it is not.

The FDA has *identified* the recall as class I.

The problem with the devices, the FDA said, has been traced to a software error that may miscalculate volume after the pump detects a blockage.

Patients treated with the affected pumps might not get the necessary fluids needed, or time-sensitive treatment could be delayed, both of which could lead to serious adverse health consequences, especially for people receiving life-sustaining medications. In high-risk populations, insufficient fluid delivery could lead to death.

There have been no reports of serious injury or death associated with the software problem.

Fresenius Medical Gets Class I For Recall Of Single Use Syringes

Fresenius initiated a *recall* of 12,477,300 units of Sanxin Single Use Sterile Syringes due to blood or heparin leaking back or from the syringe.

The syringes, which are used during hemodialysis treatment, draw heparin, a blood thinning medicine, used to prevent blood clots.

The company recalled the devices due to blood or heparin leaking back or from the syringe. There have also been reports of an unknown black material inside the syringe.

Use of the affected syringes may cause serious adverse health consequences, including sepsis, or blood loss due to leakage. Other risks include the wrong heparin dosage, leading to blood clotting, embolism, and death.

The FDA has designated the recall class I.

There have been 37 reported incidents and no reported injuries or deaths.

FDA Announces TAP Pilot Expansion, Enrollment Of Additional Devices

The US FDA recently *announced* it has increased the number of devices enrolled in its Total Product Lifecycle Advisory Program (TAP). The voluntary program, which the agency rolled out in January, is aimed at speeding up the development of innovative medical devices.

The program's first phase began with the FDA announcing it would enroll up to 15 cardiovascular devices regulated by the Office of Health Technology 2 (OHT2): Office of Cardiovascular Device.

As of 2 October, the FDA announced it was continuing to accept enrollment requests for OHT2 as well as the Office of Neurological and Physical Medicine Devices (OHT5).

As of 14 November, the FDA said it has enrolled 16 devices in TAP with plans to continue the program's expansion in the coming years.

The FDA said the long-term vision for the program is to spur more rapid development of medical devices as well as more rapid and widespread patient access to those devices.

Guardant Health To Appeal Federal Court Verdict, Says CEO

Guardant Health co-CEO Helmy Eltoukhy *said* the company will appeal the verdict of a federal patent case ordering Guardant to pay $83.4m in damages to the University of Washington and TwinStrand Biosciences for patent rights violations.

On 14 November, the jury in the US District Court for the District of Delaware found that the Guardant 360 CDx cancer liquid biopsy test infringes on the University of Washington's duplex sequencing patents which are exclusively licensed to TwinStrand Biosciences.

The patented technology in question, according to TwinStrand, enables the detection of ultra-low frequency DNA mutations with a resolution 10,000 times greater than conventional next-generation sequencing diagnostics currently on the market. (Also see "*Guardant Health Launches New Firsts: Blood Test To Track Patient's Response To Immunotherapy, Tissue-Based Test*" - Medtech Insight, 23 Jun, 2021.)

Eltoukhy said he is confident Guardant Health did not infringe the patents.

"We strongly disagree with this decision and will vigorously appeal for its overturn," said

Eltoukhy. “We believe the ruling ignores the strengths and merits of our R&D and intellectual property, which we painstakingly developed for over a decade.”

FDA Grants Marketing Authorization To First At-Home Chlamydia And Gonorrhea Test

The US FDA has *granted* marketing authorization to LetsGetChecked for the Simple 2 Test, making it the first FDA-authorized diagnostic test for chlamydia and gonorrhea with at-home sample collection.

Prior to the agency’s authorization on 15 November, the only cleared tests for either condition were used with samples collected at the point of care, such as a doctor’s office.

The Simple 2 Test is available over-the-counter and is the first FDA-authorized test with at-home sample collection for any sexually-transmitted disease other than HIV.

As the FDA noted, the authorization opens the 510(k) pathway for other tests for chlamydia and gonorrhea with at-home sample collection.

The test is intended for patients 18 years and older.

“The authorization marks an important public health milestone, giving patients more information about their health from the privacy of their own home,” said Jeff Shuren, director of the FDA’s Center for Devices and Radiological Health.

According to the US Centers for Disease Control, chlamydia and gonorrhea are the first and second most common bacterial sexually transmitted infections in the US, with 1.6 million cases of chlamydia in 2021 and more than 700,000 cases of gonorrhea.

AdvaMed Lauds House Progress On Breakthrough Device Legislation

Following a markup session by a US House subcommittee on pending legislation that would ensure temporary Medicare coverage of FDA-designated breakthrough technologies, AdvaMed released a *statement* praising the subcommittee’s work and expressing its support for the legislation.

The bipartisan Ensuring Patient Access to Critical Breakthrough Products Act, which was introduced in March by representatives Brad Wenstrup (R-OH), Suzan DelBene (D-WA), Gus

Bilirakis (R-FL), Tony Cárdenas (D-CA), Blake Moore (R-UT), Terri Sewell (D-AL), Brett Guthrie (R-KY) and Anna Eshoo (D-CA), would guarantee Medicare cover breakthrough devices for four years following regulatory approval and mandate the agency make permanent coverage determinations on those devices during that time.

AdvaMed argued that the bill would ensure safe and effective care is available to millions of patients while addressing temporary coverage for breakthrough devices that did not exist when Medicare was created.

After the House Energy & Commerce Subcommittee on Health's markup session on 15 November, AdvaMed CEO Scott Whitaker said the legislation ensures seniors on Medicare have access to life-saving technologies.

"Because there currently is no pathway for Medicare coverage of these breakthrough treatments, millions of patients are missing out on the latest innovations that could extend, improve, and even save their lives," Whitaker said. "It is critical that Congress and the administration move these polices forward."

Some observers believe the legislation would strip Medicare of its discretion to deny coverage, which is sometimes necessary.

In an opinion piece in *Nature*, researchers from the Brigham and Women's Hospital and Harvard Medical School argue that breakthrough devices are often approved on weak evidence, such as changes to unvalidated surrogate measures. (Also see "*Bill Covering Breakthrough Products 'Step In The Wrong Direction,' Researchers Say*" - Medtech Insight, 27 Sep, 2023.)

They further argue the legislation essentially reinstates Medicare Coverage of Innovative Technologies (MCIT), a Trump-era Medicare rule the Biden administration "wisely" repealed in 2021.