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IN THIS ISSUE

Editor's Note: Due to summer breaks, *International Devices & Diagnostics Monitor* will not be published June 22. The next issue will be published June 29.

More Hospira Pumps Susceptible To Cyberattack, DHS Warns

The Department of Homeland Security issued an alert that more Hospira infusion systems may be susceptible to cyberattacks that could lead to over- or under-infusion of medications.

The latest memo from Homeland Security's Industrial Control Systems Cyber Emergency Response Team, released Wednesday, warns that a hacker with low skills could access the systems remotely and change the medication dosage.

The warning affects Hospira's Plum A+, Plum A+3 and Symbiq infusion systems.

ICS-CERT says the devicemaker is communicating with customers on steps to mitigate the vulnerability and is releasing its Plum 360

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Medtronic Adds 3 Partners For Diabetes Management

Medical device giant Medtronic is expanding its reach in diabetes management with three new partnerships.

On June 5, Medtronic and Ridgefield Park, N.J.-based Samsung Electronics announced plans to develop applications for use with Samsung's mobile devices that allow users to view data from insulin pump and continuous glucose monitors. The application will work with Medtronic's MiniMed Connect, which enables quick access to diabetes information and sends remote alerts. MiniMed Connect is set for U.S. launch in the next few months.

On June 8, Medtronic and BD Medical said they will introduce a new insulin pump infusion set. Under the deal, BD will manufacture the product and Medtronic will handle commercialization.

Also on June 8, Medtronic announced an agreement with Glooko to incorporate data from its insulin pumps and continuous glucose

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monitors into the Palo Alto, Calif., firm's secure mobile-based diabetes management platform.

The agreement will allow Medtronic to integrate other health and wellness data sources, such as food, medication, fitness and biometrics, with Glooko's CareLink platform. Glooko's software is FDA-cleared and HIPAA-compliant and syncs with more than 30 blood glucose trackers and health monitors across a range of manufacturers.

The partnerships are part of an ongoing effort to transition from an insulin pump and sensor manufacturer to a holistic diabetes management company, Medtronic spokeswoman Amanda Sheldon says. Diabetes care accounts for about 6 percent of Medtronic's total business, or $1.7 billion in annual revenue. — Elizabeth Orr

Philips Cautions Against Using ASV Therapy for Apnea, Heart Failure

Philips is advising clinicians not to use its adaptive servo-ventilation therapy devices to treat sleep apnea and chronic heart failure in light of recent safety risks that were revealed in a Phase 3 study.

In May, ResMed halted its Serve-HF clinical trial after finding that patients who received ASV treatment had a 2.5 percent higher risk of cardiovascular death than patients in the control group. The trial also didn't show any significant statistical difference in primary endpoints between the treatment and control groups.

The study was designed to assess whether treating moderate to severe predominant central sleep apnea with ASV therapy in addition to optimized medical care could reduce disease and death in patients with symptomatic chronic heart failure.

On Thursday, Philips said it is evaluating the ResMed study to determine the potential impact on patients using its BiPAP, autoSV/BiPAP and auto SV Advanced devices. Pending the outcome of that investigation, clinicians should not use ASV therapy in patients with symptomatic chronic heart failure and moderate to severe sleep apnea, the company said.

The devices displayed no performance issues during the trial, according to ResMed. They are indicated for noninvasive ventilatory support in adult patients with obstructive sleep apnea and respiratory insufficiencies caused by central and/or mixed apneas and periodic breathing. They are not labeled for the treatment of heart failure.

Philips' notice is available at www.fdanews.com/06-15-Philips.pdf. — John Bechtel

Wellness Apps, Other Products Could Save U.S. $50B by 2018

Devicemakers marketing mobile health solutions or other software that help patients manage chronic conditions may see big benefits in coming years, new research suggests.

Device software and mobile health applications saved $6 billion in 2014, according to a report from Accenture. Those savings were driven mainly by behavioral changes such as improved medication compliance and fewer emergency room visits. These savings could grow by as much as 53 percent annually over the next three years, the research says.

That means that by 2018, digital health solutions — many of which are devices — could cut $50 billion from annual U.S. healthcare costs. The projections are based on an assessment of FDA approvals between 2010 and 2014 and industry trends. Rapid growth in 510(k) clearance of digital health products, from 13 in 2010 to 26 in 2012 and 33 in 2014 could mean the number of clearances reaching 45 this year and 100 by 2018 if the rate continues.

Factors driving the uptick in digital health products include more clarity and consistency from the FDA and improved infrastructure that encourages caregivers to integrate devices with electronic health records and other clinical systems. — Elizabeth Orr

510(k) Turnaround Better in States With Strong Industry Presence

States with large pockets of medical device manufacturers appear to have an advantage at the FDA level, a recent study of 510(k) clearances suggests.

The study data set included 12,406 510(k) clearances from 45 states or U.S. territories, according to research released by LifeScience Alley. Seven states had filed at least 500 510(k)s each, 18 had filed 100 to 500, and 22 had filed fewer than 100. Minnesota, California and Massachusetts alone made up 36 percent of the cleared 510(k)s.

Devicemakers in Minnesota and Massachusetts fall under the national average in terms of the time it took to get 510(k) clearance, while California, Florida and Pennsylvania fall above the national average. The average 510(k) filed by a Minnesota-based company from 2010 to 2014 took 110 days to clear, while Massachusetts manufacturers took 133 days, both below the 145-day national average. California, Florida and Pennsylvania took 149 days or longer.

A potential factor benefiting Minnesota's device industry is that employees move fairly freely between large companies and smaller start-ups, taking expertise and training with them.

While California has a relatively high number of 510(k)s, the slow processing may be due to the larger geographic size of the state and the fact that the medtech industry isn't concentrated in one area of the state like the software industry in Silicon Valley.

The slowest states for 510(k) clearance were Hawaii at 260 days, Idaho at 236, New Mexico at 224, Oklahoma at 193 and Kentucky at184.

Experienced devicemakers — those with more than 10 510(k) clearances — saw an even faster turnaround at 103 days in industry-heavy states, versus 130 days nationally. — Elizabeth Orr

India Proposes National Authority To Oversee, Promote Medical Devices

The Indian government is creating a dedicated authority to oversee the regulation and production of medical devices, taking the first steps to separate the sector from the nation's pharmaceutical regulatory regime.

The plan is the latest attempt by the government to improve device quality in the absence of statutory regulations. Efforts to pass regulations in Parliament have failed repeatedly and registration of devices is limited to certain product categories under the country's drug laws.

India would also like to get a bigger slice of the global medtech pie. The government estimates its local industry contributes about $4.8 billion of the $220 billion worldwide market and most of its business is in disposables and medical supplies. About 65 percent of the country's medical devices, including nearly all implantable devices, are imported.

The government is considering offering incentives to the device industry, such as preferred purchasing of locally made devices, seed capital and viability gap funding, tariffs and revised tax and duty structures to attract new companies and have existing companies expand.

The National Medical Device Authority is to be headed by a cabinet-level secretary or joint secretary and housed within the Department of Pharmaceuticals.

Its responsibilities include setting up and managing medical device mega parks throughout the country, creating manufacturing benchmarks based on international best practices and partnering with industry to develop knowledge networks.

The government is seeking comment from industry groups through July 15.

View the draft policy at www.fdanews.com/06-15-15-india.pdf. — Elizabeth Orr

IRS: Consent Decree Payments May Be Tax-Deductible

Medical device companies under an FDA consent decree may be able to deduct some payments made as part of their settlement with the agency when they file their tax returns, according to an informal opinion by the Internal Revenue Service's chief counsel.

The opinion concerns a consent order with a company that makes active pharmaceutical ingredients and discusses the equitable disgorgement of profits — situations in which the FDA asks companies to pay it a share of the profits accrued while the company acted in violation of regulations.

U.S. tax law allows companies to deduct normal business expenses, but not fines. While the FDA has never clearly expressed an opinion on the tax status of consent decree payments, the agency's ambiguous statements seem to support the view that consent decree payments may be deducted, the IRS says. The IRS notes that the consent decree in question specifically states that payments made under it "are not a fine, penalty, forfeiture, or payment in lieu thereof."

"The legal theory behind disallowing a deduction for a fine or penalty is that allowing taxpayers to deduct fines or penalties would frustrate public policy," says Douglas Charnas, an attorney with McGuire Woods who blogged about the case.

While the ruling surprising, it's worth noting that the IRS took up the question at all, given the FDA's specific language that the payments are not a fine, Charnas says. "The takeaway from the [opinion] is that any settlement agreement should specifically state that the parties do not intend the payment to be a fine or penalty for all purposes, including federal income tax purposes," he says.

While consent decrees are relatively rare, the FDA has imposed them on several device-makers in recent years, including Medtronic and Maquet Holding.

The Jan. 26 opinion was posted online recently. View it at www.fdanews.com/06-15-15-IRS.pdf. — Elizabeth Orr

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infusion system, which is not vulnerable to the same cyberattacks.

Homeland Security is recommending that healthcare providers change a default password on the systems, monitor and log all network traffic attempting to access the systems, maintain layered security and isolate all medical devices from the internet and untrusted systems.

An independent researcher, Billy Rios, first identified the vulnerabilities in the LifeCare system in May 2014, according to the ICS-CERT advisory.

In May, ICS-CERT and the FDA issued warnings for Hospira's LifeCare PCA Infusion System.

At the time, Hospira said it had developed a new version that will not be susceptible to hackers and that the FDA is reviewing its 510(k) submission.

To read the ICS-CERT advisory, go to www.fdanews.com/06-15-Hospira.pdf. — John Bechtel

WARNING LETTERS

Filtration Systems Manufacturer Receives FDA Warning Letter

Failure to properly record complaint investigations and document evaluations of potential suppliers brought an FDA warning letter to a New Jersey manufacturer of filtration systems.

The May 27 letter say Nephros failed to include required information regarding complaint investigations involving two filters and a filtration system.

All complaints must include evaluation of the returned product or inventory samples, review of in-house device history records, review of shipping records, review of complaint trends, review of risk controls and/or review of product labeling, the FDA notes.

The FDA reviewed the company's response and concluded it was inadequate, as it included complaint numbers reviewed but didn't include actual customer complaint files.

The company's suppliers controls were also lacking, the FDA says. For example, the vendor list included suppliers that had not been adequately evaluated, including one used for sterilization of finished devices and suppliers of dialysis equipment.

The warning letter followed an Oct. 8 to 24, 2014, inspection of Nephros' River Edge, N.J., facility.

The company responded to a Form 483 on four occasions, but those responses weren't adequate, the agency says.

Nephros has 15 days to notify the FDA of its remediation plans.

The company could not be reached by press time.

View the warning letter at www.fdanews.com/06-12-15-nephroswarning.pdf. — John Bechtel

FDA Hands Warning Letters to Three Surgical Mesh Makers

Three medical devicemakers received FDA warning letters for marketing surgical mesh for off-label use in breast surgery.

In a June 1 letter to Allergan, the agency cites the company for promoting its SERI Surgical Scaffold for use in breast revision surgeries, breast lift procedures with or without augmentation, and breast reductions. The FDA cleared the scaffold for use as general soft tissue reinforcement, the letter notes.

A same day letter to Bridgewater, N.J.-based LifeCell letter accuses the company of promoting its Strattice Tissue Matrix for use in breast reconstructive surgery and breast augmentation, although it was cleared only for use as a soft tissue patch to reinforce weak soft tissue or repair damaged or ruptured soft tissue membranes. This is a major alteration to its intended use, the FDA says.

Similarly, TEI Biosciences' SurgiMend was cleared for plastic and reconstructive surgery, muscle flap reinforcement or hernia repair, but the firm marketed it as the superior biologic matrix for breast surgery patients, the May 29 warning letter says.

The agency wants all three companies to stop distributing the devices for use in breast surgery and submit remediation plans within 15 business days.

The companies couldn't be reached for comment by press time. View the warning letters at www.fdanews.com/06-06-15-allergan.pdf; www.fdanews.com/06-15-15-lifecell.pdf; and www.fdanews.com/06-06-15-TEI.pdf. — Elizabeth Orr

OraSure Nabs HHS Contract To Develop POC Ebola Test

HHS has awarded OraSure Technologies a $1.8 million contract to develop a point-of-care test for the Ebola virus.

The OraQuick rapid Ebola antigen test is the first POC device to get HHS support.

The goal is a test that will detect virus in a drop of blood or saliva on a test strip and provide results within 20 minutes, making it easy for use in doctor offices, hospitals, clinics or field settings.

HHS' Biomedical Advanced Research and Development Authority will oversee the development program. As part of the deal, OraSure will evaluate whether the test can be used to analyze oral fluids in people who have died of Ebola. A test that could determine disease status would aid in infection control and support the appropriate handling of remains infected with the virus, HHS says.

The contract could be extended for up to 39 months and $10.4 million.

BARDA is seeking additional proposals to develop drugs and devices to diagnose and treat Ebola and related illnesses. — John Bechtel

BRIEFS

FDA Names Chief Officer for Pediatrics

The FDA has named Vasum Peiris as chief medical officer for pediatrics and special populations in the agency's device center, effective Aug. 24. Peiris will report to the associate director for science and strategic partnerships, a role currently filled by Kathryn O'Callaghan. Peiris serves as chief of pediatric and adult congenital cardiology at the Texas Tech University School of Medicine. He has not yet announced his priorities for the role, FDA spokesman Eric Pahon tells *IDDM*.

FDA Approves Parkinson's Treatment

The FDA on Friday approved St. Jude Medical's Brio Neurostimulation System, an implantable deep brain stimulator device to help reduce symptoms of Parkinson's disease and essential tremor. The agency based its approval on two clinical trials that showed a majority of patients were able to control their symptoms without the need for medication. The system comprises a small rechargeable electrical pulse generator implanted in the upper chest with wire leads that attach electrodes to the brain. About 1 million people have Parkinson's disease and several million more suffer from essential tremor.

Linkage Gets CE Mark for PCR HLA Test

South San Francisco, Calif.-based Linkage Biosciences secured CE mark approval for its LinkSeq human leukocyte antigen test. The product is the first commercially available HLA testing platform compatible with real-time polymerase chain reaction technology, which enables identification of all classical HLA genes in one test, the company says. LinkSeq is indicated for organ and tissue evaluation for patients awaiting transplants.

FDA OKs Actavis' Breast Implants

Actavis' Naterelle Inspira breast implants have won FDA approval, the Parsippany, N.J., devicemaker says. The products are contraindicated for women with active infections, with existing cancer or precancer of their breast who have not received adequate treatment and for women who are pregnant or nursing. The devicemaker also warns that complications may result from breast implant surgery.

St. Jude Resumes Portico Trial

St. Jude Medical will resume its U.S. clinical trial of the Portico transcatheter aortic valve implantation system. The trial was launched in May 2014, but was paused in September after reports surfaced of reduced leaflet motion in study subjects. An FDA review determined that the leaflet motion was coming from the control arm of patients implanted with commercially available TAVR systems, the company says. The leaflet motion has occurred in TAVR and surgical valves throughout the industry and is not linked to adverse events, St. Jude says.

Outset Gets $91M for Dialysis System

Outset Medical has secured $91 million in equity and debt funding to further commercialize its Tablo

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dialysis system. The automated system received FDA clearance for acute and chronic care settings in May. The agency also approved a clinical trial to evaluate the system's efficacy. The San Jose, Calif., device-maker plans to use the money for a limited commercial launch this year and to pursue expanded FDA approval, which would allow patients to operate the device in their homes. Fidelity Research and Management Co., Warburg Pincus, The Vertical Group, Partner Fund Management LP, Perceptive Advisors and CRG were involved in the financing.

BSX Touts Precision Spinal Cord Stimulator

In a clinical trial, Boston Scientific's Precision Spectra demonstrated one-and-a-half times more overall pain relief and twice as much low back pain relief than an earlier spinal cord stimulation system, the devicemaker said Wednesday. The Precision Spectra features 32 contacts, and enables greater patient coverage of key pain areas.

Medtronic Launches GastriSail

Medtronic has launched its GastriSail gastric positioning system for bariatric surgery in the U.S., Europe and Middle East, the company said Tuesday. A worldwide launch is set for later this year. The product helps to promote more consistent sleeve creation and greater efficiency during sleeve gastrectomies. During the procedure, surgeons remove an estimated two-thirds of the stomach to create a smaller, sleeve-shaped pouch. The system allows surgeons to size and decompress the stomach pouch and test for leaks without having to use any additional devices, cutting down on the risk of irritating or injuring the esophagus. The FDA cleared GastriSail for marketing in February.

Gamma Knife System Gets CE Mark

Elekta's Leksell Gamma Knife Icon has won CE Mark approval, with University Hospital La Timone in Marseilles, France, being the first to install the device, the Swedish firm said Tuesday. The system, which features online Adaptive DoseControl technology for precise dose delivery and frameless treatment capability, can target almost any part of the brain. The hospital will treat the first patients using the system next month. FDA 510(k) clearance for the device is pending.

UMass Lowell Expands Incubator Programs

The University of Massachusetts at Lowell has opened a new incubator program for medical technologies and expanded an existing one. The Innovation Hub and the Massachusetts Medical Device Development Center, or M2D2, feature work and research space and mentoring for entrepreneurs and startups trying to break into the medtech industry. Tenants include Vantix Diagnostics, which is working to offer point-of-care medical diagnostic products, and NonSpec, a startup by UMass Lowell students who have created low-cost prosthetics for developing nations.

Spotlight Finalizes Memcine Acquisition

Spotlight Innovation announced that it has finalized its acquisition of Memcine Pharmaceuticals. The deal gives Spotlight access to Memcine's development-stage Immunoplex vaccine platform technology, which capitalizes on the body's natural targeting system when administering vaccine components to white blood cells. West Des Moines, Iowa-based Spotlight Innovation focuses on working with or acquiring early stage healthcare companies.

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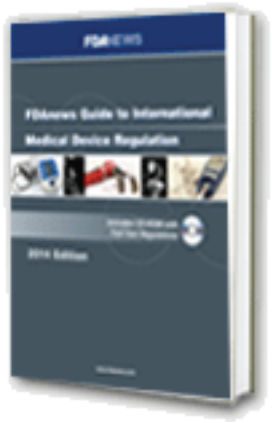

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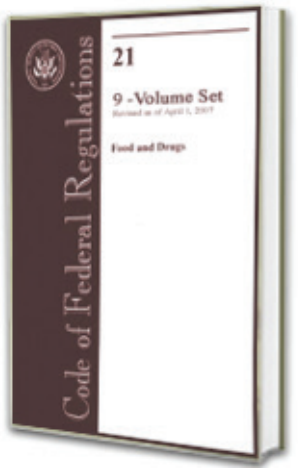

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