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Lawmaker Calls on Devicemakers To Combat Cybersecurity Vulnerabilities

Sen. Barbara Boxer (D-Calif.) is urging leading medical device manufacturers to take steps to address concerns that cybersecurity vulnerabilities are putting patients at risk.

Boxer raised the issue in a Feb. 5 letter sent to Johnson & Johnson, GE Healthcare, Siemens USA, Medtronic and Philips North America — five companies that jointly control more than one-quarter of the global device market.

"The actions your companies take to reduce medical device vulnerabilities exponentially reduce the global risk of medical device cyberattacks and send a powerful signal to the entire industry of the importance of good cybersecurity practices," Boxer says in the letter.

Last spring, an independent security researcher disclosed a vulnerability in certain drug infusion pumps used in hospitals all across the country, she points out. The weakness allowed the researcher to

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Senate HELP Committee Blesses 7 Biomedical Innovation Bills

The Senate HELP Committee unanimously approved seven bills last week as part of its biomedical innovation agenda, the upper chamber's piecemeal version of the House's 21st Century Cures Bill passed in July 2015.

The approval marks the first step toward creating a Senate counterpart to the House 21st Century Cures Act. However, the Senate version is introducing legislation in three different markup sessions rather than one measure.

Six of the bills passed by the committee affect devices and research: the FDA Device Accountability Act of 2015 (S. 1622), the Next Generation Researchers Act (S. 2014), the Enhancing the Stature and Visibility of Medical Rehabilitation Research at NIH Act (S. 800), the Advancing Research for Neurological Diseases Act of 2015

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infect the device software with malicious code and manipulate the pump's drug dosage levels (*IDDM*, Aug. 7, 2015).

"If this vulnerability had been discovered by a bad actor, thousands of patients could have been put at risk," Boxer says.

She emphasizes that conducting ongoing vulnerability testing on these devices is a critical component to ensuring patient safety, as there are currently no well-established standardized processes for identifying and remediating cybervulnerabilities in medical devices. An estimated 36 billion devices will be connected to the Internet by 2020, with many likely located in hospitals in the U.S.

The FDA highlighted this issue last month, releasing draft guidance for postmarket management of cybersecurity in medical devices (*IDDM*, Jan. 22).

Siemens complies with HHS security and privacy regulations to help customers meet their own IT obligations, says company spokesman Lance Longwell.

"Siemens is not aware of any safety incidents that have occurred as a consequence of security vulnerabilities in our medical devices. This does not lessen our commitment to maintain a strong focus on product security and help our customers protect their data," he tells *IDDM*.

Longwell says the company actively monitors reported potential vulnerabilities and incidents from sources — including customers, vendors, security researchers and government agencies — and cooperates with them when addressing reports.

GE agrees with Boxer that advanced cybersecurity protection is important to the healthcare industry, says spokesman Benjamin Fox. The company will continue to work with the FDA, industry and other stakeholders to support initiatives in the healthcare space to enhance cyber readiness, he tells *IDDM*.

GE intends to respond to Boxer's letter soon, Fox adds. J&J spokesman Mark Wolfe says the company is in the process of finalizing its response the letter. Medtronic and Philips could not be reached for comment by press time.

JC Scott, AdvaMed's senior executive vice president of government affairs, says manufacturers have numerous, rigorous safeguards and quality measures in place to ensure the security and integrity of their devices.

"We are actively working with FDA on their ongoing efforts to raise awareness about potential cybersecurity concerns," he tells *IDDM*.

Read the letter here: www.fdanews.com/02-16-BoxerLetter.pdf. — Jonathon Shacat

DHS Awards Adventium $2.2M For Device Cybersecurity Research

Minneapolis-based Adventium Enterprises has received $2.2 million from the Department of Homeland Security's Science and Technology Directorate to develop technology that can help defend medical devices from cyberattacks.

The project, titled "Intrinsically Secure, Open, and Safe Control of Essential LayErS," or ISOSCELES, aims to create and demonstrate an open source, reusable medical device architecture that could then be used by others as a starting point for building safe and secure networked medical devices, says Ken Hoyme, distinguished scientist with Adventium Labs.

"One aspect of significance is the recognition by DHS that there needs to be coordinated funding for work to improve our critical infrastructures — healthcare being one of the key areas identified in Presidential Policy Directive PPD-2 on Critical Infrastructure Security and Resilience," he tells *IDDM*.

Networked systems, including medical devices, need to be designed with security as an operational requirement, says Dan Massey, S&T Cyber Physical Systems Security program manager at DHS. "This project is critical to securing hospital systems and patient safety," he adds. — Jonathon Shacat

UK's NICE Wants More Research on Tests to Help Identify Sepsis Causes

The UK's healthcare costs regulator is recommending further research on three new tests that speed up the identification of bacteria and fungi in people with suspected bloodstream infections.

In final guidance released last week, National Institute for Health and Care Excellence says that although the tests show promise, there is not enough evidence to recommend their routine adoption in the NHS.

The guidance addresses Roche Diagnostics' LightCycler SeptiFast Test MGRADE, Molzym Molecular Diagnostics' SepsiTest and Abbott Laboratories' IRIDICA BAC BSI assay. The tests aim to identify the causes of infection more quickly than traditional microbiology techniques, which require blood samples to be incubated and cultured before pathogens can be identified.

The independent Diagnostics Advisory Committee determined that the tests may offer clinical benefit by providing results faster, but there was currently too much uncertainty in their accuracy for clinicians to use them to make treatment decisions, says Carole Longson, NICE's Health Technology Evaluation Centre director.

Abbott spokeswoman Rachael Jarnagin says IRIDICA is a significant diagnostic innovation compared with the current standard of care in identifying infection-causing pathogens, and the company is focused on generating clinical and health economic data to show the impacts of the platform through various clinical studies over the next several years.

"These studies will aim to demonstrate how IRIDICA may offer a better and faster way to detect and identify the broad range of the pathogens that can cause serious infections — including sepsis — and help clinicians in diagnosing and improving outcomes in the critically ill," she tells *IDDM*.

Molzym agrees with NICE that further studies are necessary under coordinated, strictly defined comparators to show the benefits of rapid molecular tests as regards clinical performance and cost effectiveness, says company spokesman Michael Lorenz.

Rapid molecular tests like Molzym's SepsiTest are used in clinical microbiology laboratories already, although they are operated as an ultima ratio option when cultures stay negative with patients under strong suspect of an infection, he tells *IDDM*.

"We regard the assessment of NICE a sound compilation and analysis of the current state of results obtained in clinical studies so far," Lorenz adds.

Roche could not be reached for comment by press time. Read the guidance here: www.fdanews.com/02-16-NICEGuidance.pdf.
— Jonathon Shacat

Defective Device in Study Does Not Impact Xarelto's Safety, EMA Says

The European Medicines Agency says a defect with Alere's INRatio blood testing device used in a study does not change the agency's conclusions on the overall safety or benefit-risk balance of Bayer's blood thinner Xarelto.

EMA started investigating the issue when Bayer reported the defect in September 2015.

The Rocket study evaluated Xarelto versus warfarin and was the main clinical trial underpinning the use of this anti-clotting medicine in patients with non-valvular atrial fibrillation, the EMA says. This decision means that Xarelto can continue to be used as before, in line with the current prescribing information.

Because of the defect, there were concerns that the device provided lower international normalized ratio values in some patients in the warfarin group. The lower values could have led investigators to give too high a dose, increasing the risk of bleeding and giving a false impression of the comparative safety of Xarelto.

The EMA says any incorrect measurements obtained with the defective device would have

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(S. 849), the Preventing Superbugs and Protecting Patients Act (S. 2503) and the Improving Health Information Technology Act (S. 2511).

S. 2503, introduced by Sen. Patty Murray (D-Wash.) earlier this month, would give the FDA additional tools to review and ensure the safety of medical devices, such as duodenoscopes (*IDDM*, Feb. 8).

Sen. Richard Burr (R-N.C.) introduced S. 1622. JC Scott, AdvaMed's senior executive vice president of government affairs, says the legislation includes reforms that aim to improve the agency's medical technology review process.

"Specifically, the bill will require additional training and oversight so FDA reviews are done efficiently and expeditiously; allow device clinical trial sponsors to use a central institutional review board to facilitate multi-center trials; and improve the CLIA-waiver process to accelerate the availability of point-of-care, rapid diagnostic information to physicians and patients," he says.

S. 2511, introduced by Sen. Lamar Alexander (R-Tenn.), improves federal requirements relating to the development and use of electronic health records.

The second of three markups is scheduled for March 9, when five more biomedical innovation bills will be considered. They include the Advancing Hope Act of 2015 (S. 1878), the Medical Electronic Data Technology Enhancement for Consumer's Health (MEDTECH) Act (S. 1101), the Medical Countermeasures Innovation Act of 2015 (S. 2055), the Combination Products Innovation Act of 2015 (S. 1767) and The Advancing Breakthrough Medical Devices for Patients Act of 2015 (S. 1077).

A third and final markup is slated for April 6 to complete the Senate's version of the measure. It is unclear whether the measure will come to the Senate floor as one bill or individual bills. — Michael Cipriano and Jonathon Shacat

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had only a marginal effect on the study results. In addition, data from other large studies confirmed the comparative safety of the medicine and showed similar rates of bleeding in their warfarin groups, the agency adds.

In December, advocacy group Public Citizen sent a letter to the EMA and FDA, saying its analysis of the FDA's Manufacturer and User Facility Device Experience database showed 9,469 malfunction reports and 1,445 injury reports from 2002 through November 2015 with INRatio devices (*IDDM*, Dec. 11, 2015).

In the letter, Public Citizen claimed that false readings by the device could have skewed clinical trial results in favor of Xarelto.

FDA spokeswoman Sandy Walsh tells *IDDM* that the agency is aware of the EMA's findings and is continuing to review relevant data regarding the INRatio device and its use in the Rocket-AF trial. — Jonathon Shacat

FDA Would Get $5.1B Under Obama Proposal

Republicans on the Hill already are blasting the White House's fiscal year 2017 budget, which would give the FDA about $5.1 billion, roughly $358 million more than what the agency received last year.

Of the $5.1 billion, the president is asking for $2.7 billion from Congress, with the remainder coming from user fees.

User fees for medical devices would increase from $138 million to $145 million. Under the budget proposal, the medical device program would receive $463 million, which would be an increase from $450 million.

The budget proposal includes $33.1 billion for the National Institutes of Health, or an increase of $825 million.

Some stakeholders — including AdvaMed — are concerned about this level of funding, which the group says should be more "robust," according to JC Scott, the organization's senior executive vice president of government affairs.

"In addition, we have concerns over the inclusion of proposals — such as expansion of the Medicare competitive bidding program — that could limit patient access to needed medical treatments," he says.

The budget also requests $755 million — consisting of $75 million for the FDA and $680 million for NIH — related to Vice President Joe Biden's Cancer Moonshot initiative, which will seek to address regulatory barriers to developing new cancer treatments (*IDDM*, Feb. 5).

"Targeted investments will advance research on new approaches to preventing and treating cancer, such as immunotherapy, enhanced early detection technologies, developing vaccines to prevent cancers caused by viruses, genomic analysis of tumor cells, and identifying common treatment opportunities for rare pediatric cancers through better collection and analysis of tumor specimens," the budget proposal says.
— Elizabeth Hollis and Jonathon Shacat

Sientra Returning All Products To U.S. Market Following Removal

Sientra is planning to return all of its medical devices — including breast implant products — to the U.S. market starting March 1.

The move follows completion of independent, third-party testing and analyses of its products in the U.S.

In a letter to physicians, the company says the testing shows its products are safe and do not represent a risk to patients in the U.S.

Under worst-case testing conditions, the products exhibit a high safety margin compared with numerous U.S. and international standards, the company says.

The company voluntarily removed its products from the U.S. market in October 2015 (*IDDM*, Oct. 12, 2015).

That move came after the UK's Medicines and Healthcare products Regulatory Agency, along with other European health regulators, suspended CE certification for all products made by Brazilian implant maker Silimed — which is used by Sientra as a contract manufacturer — after particle contamination was discovered during a facility inspection.

Margaret Kaczor and Scott Schaper of William Blair say that there are uncertainties for the company — including physician uptake and a lack of a reliable manufacturing facility. However, they believe Sientra will move forward.

"Sientra has an exclusive manufacturing contract with Silimed, which is due to expire in April 2017; given the time frame to qualify a new manufacturing facility (roughly 18 months), we would not be surprised if the company has been working on these alternative plans for some time," Kaczor and Schaper write. — Jonathon Shacat

Dräger Recalls Emergency Transport Ventilators

Dräger is recalling 117 emergency transport ventilators due to a system error that may lead to a halt in ventilation therapy.

The recall — designated by the FDA as Class 1 — involves the Oxylog 2000 plus, Oxylog 3000 and Oxylog 3000 Plus ventilators. They were distributed from April 1, 2007 to Dec. 12, 2015.

An electrical issue may cause the device to stop working if the control knobs are not regularly used, according to an FDA notice. If the device operator does not intervene, then the patient may not receive enough oxygen and could suffer serious adverse health consequences, including injury or death.

"As part of our product monitoring, we have become aware of situations where the error message 'Poti unplugged' was generated. In these cases, an acoustic and visual alarm is generated, the breathing system releases pressure, and the ventilation function stops operating," says company spokeswoman Marion Varec.

No injury was reported in any of these situations, she tells *IDDM*.

Dräger sent a letter to all customers with affected devices on Dec. 21, 2015, informing them of this issue and instructions on how to fix the situation.

Read the recall notice here: www.fdanews.com/02-16-DragerRecall.pdf. — Jonathon Shacat

Medicare Now Covering Boston Scientific's Watchman Device

The Centers for Medicare & Medicaid Services has decided to cover Boston Scientific's Watchman percutaneous left atrial appendage closure device under certain conditions.

Last week's decision, which took effect immediately, provides consistent and uniform access to the device as a non-pharmacological treatment option for stroke risk reduction, the company says.

CMS adopted the majority of physician and professional medical society feedback received during a 30-day public comment period, specifically as it relates to patient coverage criteria and future data collection requirements, Boston Scientific says.

The final decision appears to remove the two biggest issues in the proposed version, including replacing the contraindication to warfarin with: "A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation…" says Lawrence Biegelsen, a senior analyst with Wells Fargo Securities. This is consistent with the FDA label and should not be a barrier to adoption of Watchman. Also, he says, the final version removes the control arm from the registry, which will make implementation feasible.

Biegelsen says the decision is slightly more restrictive than the FDA label in terms of the patient population indicated for the device, but it is not expected to affect adoption.

While the label does not state a specific risk score in order to be eligible for the device, the decision states that a patient must have a CHADS2 score of 2 or greater or a CHADS2 VASc score of 3 or greater. Biegelsen points out the Prevail study only included patients with a CHADS2 score of 2 and above, so the device was not intended to be used in patients with a CHADS2 score below 2 because they are at a lower risk of bleeding.

Medicare beneficiaries account for the overwhelming majority of patients deemed candidates for the Watchman device. The remaining population is represented by private payers, Boston Scientific says. Prior to the CMS decision, a number of private payers, including several Blue Cross Blue Shield plans, have updated their policies to now cover the device.

The device — the first and only percutaneous LAAC therapy approved by the FDA — is indicated for patients with non-valvular atrial fibrillation who are at high stroke risk, suitable for warfarin and are seeking an alternative to long-term warfarin therapy. — Jonathon Shacat

BRIEFS

FDA Green Lights Medtronic's Defibrillators

Medtronic was blessed with FDA approval for the first and only magnetic resonance imaging conditional cardiac resynchronization therapy defibrillators, the company announced. The Amplia MRI Quad CRT-D SureScan and Compia MRI Quad CRT-D SureScan systems are approved for MRI scans on any part of the body without positioning restrictions. U.S. patients who receive these devices — which help treat their heart failure and reduce their risk of sudden cardiac arrest — now will have access to MRI scans if and when they need them. Both CRT-D systems will be commercially available in the coming months.

St. Jude Launches Optis in Europe, Japan

St. Jude Medical has launched its Optis mobile system in Japan and Europe. The diagnostic system is designed to couple optical coherence tomography and angiography co-registration with fractional flow reserve technology for hospitals with multiple catheterization labs. The latest Optis system offers physicians a way to optimize percutaneous coronary intervention procedures to treat vascular disease by combining diagnostic tools designed to improve patient outcomes into a portable device, the company said.

Resonetics Expands to Costa Rica

Resonetics plans to open a new production facility in the Coyol Free Zone Business Park in Alajuela, Costa Rica, the company announced. The new 18,000-square-foot plant will feature a large Class 8 cleanroom, state-of-the-art, ultrafast laser systems and 24/6 operations. The company anticipates that operations will commence in the fourth quarter of this year. "In response to our customers' need for improved logistics and lower costs, Resonetics is pleased to announce our first factory outside of the United States," said company CEO Tom Burns.

Jack Voorbrood Joins Qserve Group

Jack Voorbrood has joined global regulatory consultancy firm Qserve Group. He brings 18 years of professional experience as a test engineer of electro-medical equipment and systems. "Jack's addition emphasizes Qserve's role in complex regulatory and design engineering projects on active medical devices. We're excited to further enhance our capacities in this field," says Gert Bos, executive director and partner of Qserve.

ANVISA to Host IMDRF Meeting

On March 9, Brazil's ANVISA will play host to a steering committee meeting of the International Medical Device Regulators Forum. Representatives from the forum's eight members — as well as affiliated organizations and industry representatives — will discuss the regulation of health products industry.

Canada Gives Thumbs Up to AngioDynamics

Health Canada has blessed AngioDynamics' Celerity PICC tip confirmation system with navigation for the positioning of peripherally inserted central catheters in adult patients, the company announced. AngioDynamics anticipates having the product commercially available during the company's fiscal fourth quarter.

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Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Jonathon Shacat
(703) 538-7663
jshacat@fdanews.com

Ad Sales: Jim Desborough
(703) 538-7647
jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

Reporters: Michael Cipriano, Cameron Ayers
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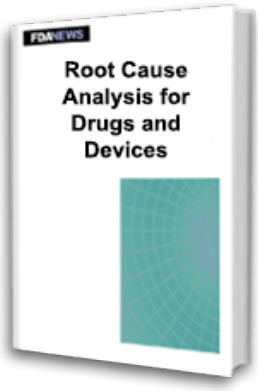

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