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FDA's Position on Cybersecurity Needs More Teeth, ICIT Report Says

The Institute for Critical Infrastructure Technology says the FDA's cybersecurity guidelines should have more teeth, arguing that devicemakers and healthcare providers have the ability to disregard the agency's recommendations spelled out in draft guidance issued last month.

In a report issued last week, the nonpartisan think tank says that the FDA often seems to be making "subtle suggestions" to industry on cybersecurity, rather than enforcing strong standards. While some stakeholders have argued that strong standards could threaten innovation, the authors argue that a lack of "cybersecurity hygiene" can allow bad actors to access electronic health records and exploit vulnerabilities.

ICIT highlights draft guidance issued Jan. 15, in which the FDA outlines a voluntary framework organizations can use to ensure

(See **Cybersecurity**, *Page 4)*

Scott Whitaker Named President, CEO of AdvaMed

A familiar face in biotech circles soon will be joining AdvaMed as the organization's president and CEO.

Scott Whitaker, chief operating officer of the Biotechnology Innovation Organization, will come on board April 4.

Whitaker previously served in leadership roles at the Department of Health and Human Services, including as chief of staff and assistant secretary for legislation.

Among his top priorities, he plans to work with members of Congress and others on the need to fully repeal the device tax, Whitaker tells *IDDM*.

In December, President Obama signed a government funding bill that included a provision to suspend the 2.3 percent medical device excise tax for 2016 and 2017. Industry groups, including AdvaMed, have called the tax a "drag" on innovator devicemakers,

(See **AdvaMed**, *Page 2)*

India's Device Industry Pushes for Tariff Corrections, New Regulatory Regime

India's medical device industry is urging the government to implement several policy measures — including tariff corrections and a new regulatory regime — to ensure the financial viability of domestic device manufacturing parks in the country.

The Association of Indian Medical Device Industry is pushing for a separate Medical Device Regulatory Act and separate rules with the Indian Healthcare Products Regulatory Authority rather than proposed ongoing amendment to the Drug & Cosmetics Act with compliance audits by third party certification. The proposal calls for having a mandatory compliance and regulatory framework built on the soon-to-be launched Quality Council of India certification to ensure patient safety.

AIMED also seeks a department for medical devices — a separate ministry for healthcare products to act as a facilitator and regulator — and a coordinated plan between the central government and state governments to aid existing manufacturing clusters and new medical device parks.

In addition, the group wants continued tariff correction to enable business viability, and a maximum retail price based tax as a disincentive for high MRP to ensure consumer protection.

Other proposals call for the launch of a voluntary ICMED 13485 certification by QCI for enabling doctors and procurement agencies to have confidence in good quality medical devices, a 'Buy Indian' preferred market access policy for those manufacturers who have ICMED certification and a 15 percent preferential pricing online of World Bank and World Health Organization tenders to support domestic manufacturers and counter the 17 percent subsidy from China.

The recommendations come as three states — Andhra Pradesh, Maharashtra and Gujarat — work to establish exclusive world-class medical device manufacturing parks (*IDDM*, Nov. 13, 2015).

Rajiv Nath, forum coordinator of AIMED, presented the list to Shri Chandrababu Naidu, chief minister of Andhra Pradesh, during a recent meeting. Naidu is "gung ho" in ensuring success of this project, says Nath.

"He desired the Vizag Medical park to be among the top 3 medical device manufacturing hubs in the world instead of the top 5, as was being proposed by AIMED, and Andhra Pradesh to be the lowest cost and preferred healthcare treatment destination in the world and assured that his team and he would take steps to act on our suggestions to ensure this," says Nath. — Jonathon Shacat

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AdvaMed, *from Page 1*

saying it halted investment in R&D (*IDDM*, Dec. 18, 2015).

Whitaker says he also is focusing on the reauthorization of the Medical Device User Fee Act. He adds that his other goals include working with patient groups, medical societies, research advocates and others to improve access to medical technology, as well as educating policymakers on the importance of having a regulatory environment that encourages innovation.

"Given the many healthcare challenges throughout the world, it is critical that we work together to create a policy and regulatory environment that will allow this industry to continue to discover, develop and deliver innovative medical technologies to patients," he says.

As BIO's chief operating officer, Whitaker managed all aspects of the organization's day-to-day operations, including advocacy, policy, communications and non-dues revenue business. AdvaMed Board Chairman Vincent Forlenza says Whitaker has a proven track record as an association leader, and he believes he has the vision to set the course for the group's future.

"Medical technology companies are at the forefront of developing solutions that improve patient outcomes and enable the delivery of high-quality, cost-effective care. However, continued progress in these areas depends on ensuring a strong innovation ecosystem," he says. — Jonathon Shacat

Panel to Weigh In on Angel Medical's Implantable Cardiac Monitor System

Next month, an FDA advisory committee will consider Angel Medical Systems' PMA application for its implantable cardiac monitor that notifies patients about changes that could signal an oncoming heart attack.

The AngelMed Guardian system is designed to detect rapid changes in the heart's electrical signal caused by a coronary artery occlusion, the precursor to a heart attack.

If an occlusion is detected, the system alerts patients to seek medical care by delivering a series of vibratory, auditory and visual warnings, the company says.

At the meeting, scheduled for March 16, the Circulatory System Devices Panel will review data from a study of 907 high-risk subjects who had experienced a previous heart attack or acute coronary syndrome event (*IDDM*, Jan. 22).

All subjects were implanted with the AngelMed Guardian system and assigned to have the alerting feature of the device either turned on or off for a six-month period to assess whether the system alerts reduced the composite incidence of death, new Q-wave myocardial infarction or late presentation for thrombotic coronary occlusion events, Angel Medical says.

The company declined to release information to *IDDM* regarding the study's results and data prior to the advisory committee meeting.

The scheduling of the meeting triggered additional funding for Angel Medical, with the company receiving the final $10 million of a milestone-based $40 million convertible note financing that had its initial closing in 2012. — Jonathon Shacat

Stryker to Acquire Physio-Control for $1.3B

Acquisition-hungry Stryker has agreed to buy Physio-Control in an all-cash transaction worth almost $1.3 billion, in a deal that marks the second billion-dollar-plus acquisition in as many weeks.

The Kalamazoo, Mich.-based device giant will gobble up the company, which develops, manufactures and markets monitors and defibrillators, automated external defibrillators and CPR-assist devices.

Physio-Control, a portfolio company of Bain Capital Private Equity, had $503 million in sales last year, according to Stryker.

Word of the plans to acquire Physio-Control — announced Feb. 16 — came just days after Stryker announced that the company will buy Synergetics USA's neuro portfolio.

The portfolio includes the Malis generator, Spetzler Malis disposable forceps and Stryker's existing Sonopet tips and RF generator. The Synergetics' portfolio achieved sales in 2015 of roughly $31 million.

Terms of the Synergetics deal were not disclosed.

However, on Feb. 1, Stryker said it will acquire Sage Products for roughly $2.8 billion. Sage develops, manufactures and distributes a range of products, covering oral care, skin preparation and protection, patient cleaning and hygiene, turning and positioning devices and heel care boots (*IDDM*, Feb. 5).

Lawrence Biegelsen, a senior analyst with Wells Fargo Securities, says Stryker plans to stay active with acquisitions, despite $4 billion of deals in two weeks.

"Stryker believes that it still has sufficient capacity under its strong balance sheet to pursue other deals and is committed to maintaining its investment grade rating. While we think that Stryker could add several more billion in debt and maintain its investment grade rating, we would expect any near-term acquisitions to be smaller in size than Sage and Physio-Control," he says. — Elizabeth Hollis and Jonathon Shacat

Cybersecurity, *from Page 1*

that their cybersecurity strategies address risks (*IDDM*, Jan. 22). These recommendations build on NIST's 2014 "Framework for Improving Critical Infrastructure Cybersecurity," which resulted from an executive order calling for a standardized cybersecurity framework.

"The recommendations are not regulations," the report notes. "Regulatory frameworks are difficult to develop and enforce because different organizations operate under different constraints." Organizations can choose not to follow guidelines set out by the FDA.

Further, there is an antiquated notion among managers that reporting a vulnerability, exploit or breach will lead to a perception that the affected organization is weak or incompetent. "These decision makers fail to realize that the digital age has brought about a desire for transparency and an active information sharing community," the report states.

The draft guidance is a good start for the discussion of cybersecurity within the FDA and medical devices and health IT, but there is obviously a long way to go, says James Scott, a senior fellow at the ICIT.

"I hope the FDA puts some type of framework for actual regulations, so there is an actual standard in the industry," he tells *IDDM*.

The report urges stakeholders to petition the FDA in comments to the draft guidance to make the guidelines have regulatory teeth. Interested parties may comment on the draft document through April 21.

Read the report here: http://icitech.org/wp-content/uploads/2016/02/ICIT-Blog-FDA-Cyber-Security-Guidelines2.pdf. — Jonathon Shacat

NICE Recommends Medtronic's Glucose Monitoring System

The UK's healthcare costs regulator is recommending Medtronic's integrated automated glucose monitoring system for managing blood glucose levels in some people with Type 1 diabetes.

In final guidance, the National Institute for Health and Care Excellence says the MiniMed Paradigm Veo system is an option for people with Type 1 diabetes who experience frequent episodes of low blood glucose despite management with insulin pump therapy.

The system alerts users if glucose levels become too high or low, if levels are rapidly changing or if the system predicts levels will be too high or low in the near future. An automated low glucose suspend function operates independently of user action and stops insulin delivery for two hours if a user fails to respond to the alert.

Carole Longson, NICE's Health Technology Evaluation Centre director, says the independent diagnostics advisory committee considered evidence suggesting the MiniMed Paradigm Veo system may have benefit in reducing rates of severe hypoglycaemia, but the overall evidence base to support the best use of integrated sensor augmented pump therapy systems needs to be improved.

The guidance recommends that Medtronic makes arrangements to collect, analyze and publish data to demonstrate that using the system results in a sustained clinical impact on preventing or improving control of disabling hypoglycaemia.

The guidance also requires that the MiniMed Paradigm Veo system should be used under the supervision of a trained multidisciplinary team that is experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring if the person or the caregiver:

- Agrees to use the sensors for at least 70 percent of the time;
- Understands how to use it and is physically able to use the system; and
- Agrees to use the system while having a structured education program on diet and lifestyle, in addition to counseling.

The committee also evaluated a further integrated automated glucose monitoring system without a low glucose suspend function – the Vibe and G4 Platinum CGM system. The committee concluded the system shows promise, but there currently is insufficient evidence to support its routine adoption in the NHS, Longson says.

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

Pentax Issues Revised Reprocessing Instructions for Duodenoscopes

The FDA has signed off on reprocessing instructions for Pentax's ED-3490TK video duodenoscope that aim to prevent future of infections related to drug-resistant bacteria.

Pentax and two other companies that make duodenoscopes — Olympus and Fujifilm — have faced intense scrutiny after reports of antibiotic-resistant infections in Chicago, Pittsburgh, Seattle and Los Angeles. In early 2015, the FDA revealed that between January 2013 and December 2014, it had received 75 reports involving about 135 patients suffering from carbapenem-resistant Enterobacteriaceae transmissions linked to these devices.

All three companies received warning letters last year for a range of problems related to duondoscopes, including failure to inform the FDA in a timely manner about patient injuries (*IDDM*, Aug. 21, 2015).

For its part, Pentax has updated its instructions include a more rigorous protocol for precleaning, manual cleaning, manual high-level disinfection and liquid chemical sterilization procedures. In addition, updated instructions include additional text, figures, cautions and warnings intended to clarify the validated reprocessing procedure.

(See **Pentax**, *Page 6)*

Pentax, *from Page 5*

The key changes include additional detail for:

- Flushing the elevator mechanism with detergent during precleaning;
- Preparation and use of detergent solution during manual cleaning;
- Brushing the instrument channel inlet during manual cleaning;
- High-level disinfectant preparation and use during high-level disinfection; and
- Flushing the elevator mechanism during high level disinfection.

Other changes involve increased volumes of fluids for internal channels during cleaning and high-level disinfection, an increased number of endoscope rinses after detergent immersion, as well as the removal of ethylene oxide and addition of Steris System 1E as a liquid chemical sterilization method.

Pentax has sent a letter to healthcare facilities and other users of the ED-3490TK video duodenoscope outlining the updated, validated reprocessing instructions.

Pentax began modifying its reprocessing protocol in February 2015 and initiated testing three months later to validate its updated reprocessing instructions. Between July and September 2015, the company conducted additional testing to ensure its high-level disinfection protocols demonstrated an adequate safety margin. In October 2015, Pentax submitted cleaning, high-level disinfection and sterilization reports to the FDA (*IDDM*, Oct. 9, 2015).

The FDA reviewed the data and requested additional cleaning tests, which Pentax conducted. In January of this year, the company submitted additional test data, which the agency reviewed and found to be adequate.

The Senate HELP Committee unanimously approved seven bills earlier this month as part of its biomedical innovation agenda, including S. 2503, which would give the FDA additional tools to review and ensure the safety of medical devices, such as duodenoscopes (*IDDM*, Feb. 12).

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

Getting Up to Speed On the Direct De Novo Process

FDAnews held a webinar earlier this month in which three attorneys from Hogan Lovells, including partner Yarmela Pavlovic, explained the FDA's direct de novo process. The following is adapted from that event.

QUESTION: What are the procedures for a direct *de novo*?

PAVLOVIC: The principal way to talk to FDA about whether or not a company or a product is appropriate for a direct de novo is via the presubmission process. It allows for companies to submit a regular presubmission to talk to FDA not only about the data that may be relevant that may support clearance of the product but also about the regulatory pathway.

But there are other options. A company could opt to submit a 513(g) request instead of a full presubmission if, for example, a company were not yet ready to talk to FDA about the data that will support the product or about other aspects of the product development. There are, of course, strategic decisions that go into whether a 513(g) request or a presubmission is more appropriate.

For example, it's sometimes easier to argue to FDA that a product is appropriate for classification in Class II when the data that will support that clearance is available to FDA and is shared with FDA, or at least the plans to develop that data. When FDA can see how robust the data is going to be they may feel more comfortable with the product, more comfortable with it staying in Class II or even in Class I. But a 513(g) request is a possibility.

It is also possible for a company to submit a direct de novo request to FDA without previously talking to FDA, but it is strongly discouraged by the agency. We would typically advise clients that it is strongly discouraged, as well, because there is no opportunity then to get feedback from FDA prior to submission about what FDA wants to see in the submission package.

The presubmission does provide the opportunity to talk to FDA not only about the regulatory pathway but about the data that will support that pathway.

QUESTION: What types of clinical data are typically required for de novo applications?

PAVLOVIC: The nature of the required clinical data depends on the device type, the risks associated with that product and the concerns the FDA has about the product's performance. Data requirements can vary from small confirmatory studies to full randomized, controlled clinical trials.

However, it is not safe to assume that a safety-only study would be appropriate for establishing the performance of a product that's going to go through the de novo pathway. There might be circumstances where that's appropriate, but it's certainly not the default assumption.

The default assumption is that the study will show that the product is safe and effective for its intended use, so establishing both efficacy and safety. Whether that is done in a statistically significant manner depends on the particular product, but it is generally assessing both performance and safety.

QUESTION: How are special controls normally established for a de novo application? Is it based on the recommendation of the sponsor?

PAVLOVIC: In general, the special controls are derived from discussions between the sponsor and the FDA. During a presubmission meeting, sponsors should propose all of the appropriate validation testing, as well as mitigations for potential risks.

That could be things like specific labeling or adherence to certain standards. It could be specific testing that isn't in line with any particular standard but was developed by the sponsor. The sponsor then should get FDA feedback. There may be additional considerations and risks that the agency would like to see addressed.

BRIEFS

Brazil Grants Registration for Zika Test

ANVISA has granted registration for a test that the manufacturer says can detect Zika in 15 to 20 minutes. The test, manufactured by Canada's BioCAN Diagnostics, is the fourth product backed by ANVISA for the diagnosis of Zika and the third that can determine if the patient has had the disease. It detects IgM and IgG antibodies in blood samples, permitting post-infection diagnosis.

Abbott's FreeStyle Libre Gets Nod in Australia

The Therapeutic Goods Administration in Australia granted Abbott approval for its new glucose monitoring system, the FreeStyle Libre. The technology removes the inconvenience of finger pricks — instead glucose levels can be monitored through a round device worn on the back of the upper arm and secured by an adhesive pad. The "pain, inconvenience and indiscretion of finger pricking," are some of the main reasons people mismanage their diabetes, according to Jared Watkin, senior vice president at Abbott Diabetes Care. A reader is held over the sensor to deliver a result in real-time. The reader can hold up to three months of data.

Japanese, Thai Regulators Plan Joint Meeting

With an eye toward enhancing regulatory cooperation in the Asia-Pacific region, ThaiFDA and Japan's Pharmaceuticals and Medical Devices Agency have scheduled a symposium that will shine a light on recent changes in rules related to medical devices. Scheduled for March 24 at the Hotel Windsor Suites in Bangkok, the symposium will feature sessions on postmarket surveillance, QMS and expectations for industry in both countries. Additional information — including an agenda — is available at www.pmda.go.jp/english/symposia/0086.html.

Medtronic Snags FDA Approval for DBS

The FDA has granted an approval to Medtronic for its deep brain stimulation therapy for people with Parkinson's with recent onset of motor complications. "This decision by the FDA is significant in that Medtronic DBS Therapy may be considered before the symptoms and complications of disease becomes severe," according to Mahlon DeLong, the W.P. Timmie professor of neurology at Emory University School of Medicine, in a statement. As a result of the FDA's action, Medtronic DBS therapy may be used on patients who have had Parkinson's for at least four years, along with recent onset of motor complications, or motor complications of longer-standing duration that are not adequately controlled with medication.

FDA OK's St. Jude's Pacing Technology

The FDA gave St. Jude Medical its blessing with the approval of its first-moving Multi-Point pacing technology. The new technology may offer an additional option to patients who do not respond to other therapies. The new technology is featured on the Quadra Assura MP cardiac resynchronization therapy defibrillator, the Quadra Allure MP CRT-pacemaker and two new quadripolar Quartet LV leads. Multipoint is designed to improve CRT response and capture more ventricular tissue quickly, according to the company.

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— Michael Benedetto, Editorial Group Leader, FCB Health

"This is normally a dry topic, but with Dale it was anything but dry. Dale gave one of the best, most engaging presentations. Dale is highly knowledgeable and also very entertaining."

— Ellen Derrico, Global Head, Market Development - Life Sciences & Healthcare, QlikTech

"As a fellow regulatory professional, Dale is one of the most deeply knowledgeable experts I've heard on this complicated subject. As the pharmaceutical industry is experiencing, digital promotional tactics can trip up even experienced regulatory professionals, but Dale showed how basic principles can be applied to develop compliant promotional materials."

— Kathleen Koons, Sr Regulatory Affairs Manager, DJA Global Pharmaceuticals Inc.

Course Binder Materials:

Full slides from the PowerPoint presentations

Reference documents:

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- Help-Seeking Guidance
- DTC Broadcast Guidance & Q&A
- FDAAA Pre-Dissemination Review Requirements
- Product Name Guidance (All three versions from 1999, 2012, and 2013)
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Articles by Dale Cooke

- Developing Compliant Search Engine Marketing Campaigns (Publication Date of September 2014)!
- Industry Standards for Linking Disease Awareness Websites to Product Promotion!
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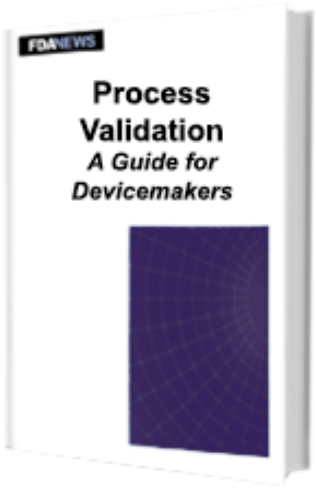

Process Validation
A Guide for Devicemakers

When must a process be validated? That is the first crucial question devicemakers must answer. But with no clear guidance from the CDRH, finding the answer can be difficult.

The new FDAnews management report — **Process Validation: *A Guide for Devicemakers*** provides you with the answers. This report will walk you through each point in the decision-making process, including how to determine if a product can be "fully verified," and how FDA inspectors define that term.

In it, you'll also find a valuable in-depth overview of all of the currently applicable regulatory guidelines that have an impact on process validation for devices, including those from three key sources: the FDA, the International Organization for Standardization (ISO) and the Global Harmonization Task Force (GHTF).

Process Validation: *A Guide for Devicemakers* teaches the proper application of the regulatory requirements that lead to successful process validation, and also offers advice on the practical issues confronting validation compliance by using real-life anecdotes and scenarios.

You also get invaluable extras, such as checklists for IQ, OQ and PQ — and hundreds of pages of appendices, including the invaluable *Medical Device Quality Systems Manual: A Small Entity Compliance Guide*, which is no longer available from the FDA.

But, most importantly, throughout the report, you'll find real-life examples that illustrate relevant concepts … show when processes need to be validated … identify the kinds of evidence you need to collect and maintain to demonstrate proper validation … and actual FDA warning letters to help you learn from others' mistakes.

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