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FDA Ready to Oversee LDTs, Plans To Issue Final Guidance in 2016

The FDA plans to issue final guidance next year on how it will enforce the regulation of laboratory developed tests, Center for Devices and Radiological Health Director Jeffrey Shuren told a House subcommittee last week during a hearing that focused on proposed legislation for diagnostic regulatory reform.

Rep. Marsha Blackburn (R-Tenn.) criticized the FDA for taking so long to release the final guidance. Shuren clarified that he does not actually have the authority to decide when to issue the document, and the agency hopes to finalize the guidance earlier in 2016, rather than later in the year.

News of the guidance's arrival may not be welcomed by a number of groups that promised to fight the agency on its proposals last year, including the American Clinical Laboratory Association.

(See **LDTs**, *Page 2)*

Inspector General: Networked Devices Pose Security Threat

The HHS Office of Inspector General plans to review whether the FDA's oversight of hospitals' networked medical devices is doing enough to safeguard electronic protected health information.

That strategy was unveiled earlier this month in the OIG's Fiscal 2016 Work Plan. It is one of six FDA priorities the office aims to undertake in FY2016, only one of which is device-specific.

"Computerized medical devices, such as dialysis machines, radiology systems and medication dispensing systems that are integrated with electronic medical records and the larger health network, pose a growing threat to the security and privacy of personal health information," the OIG's Fiscal 2016 Work Plan says.

Devices are being increasingly used in networked environments and are expected to communicate with one another securely

(See **OIG**, *Page 4)*

LDTs, *from Page 1*

The proposed guidance to regulate LDTs would be highly disruptive to laboratory services and compromise patient care, the group says in a statement issued last week.

The ACLA was among more than 50 organizations that wrote a November 2014 letter to the FDA asking the agency to withdraw the draft guidance because it conflicts with existing regulations and would impose substantial new requirements.

However, now several proposals from the lab community are acknowledging that LDTs must demonstrate they are analytically and clinically valid, that they should be subject to premarket review in moderate and high-risk tests, and that certain problems need to be reported to the government, Shuren said.

"None of those are currently enforced on them today. They all exist under an FDA framework," he said.

Increasing Complexity

LDTs have increased in complexity and availability and are now frequently used to diagnose common, serious medical conditions, including cancer and heart disease, Peter Lurie, FDA's associate commissioner for public health strategy and analysis, said in a statement. Yet, LDTs are still under a general policy of enforcement discretion, which means they rarely undergo FDA review to determine whether they are accurate, reliable and provide clinically meaningful results, he added.

The agency issued a report last week listing 20 case studies that shows how a lack of LDT oversight may cause significant harm to patients.

However, when questioned last week by Rep. Michael Burgess (R-Texas) during the hearing before the Energy and Commerce Committee's subcommittee on health, Shuren said that there are more than 11,000 laboratory developed tests. Burgess pointed out that the rate of detecting problems is far less than one percent. In response, Shuren said, "There is no reporting system on LDTs. We are not monitoring for problems, and so you can't say what the rate is, quite frankly."

In response to a white paper the committee circulated last year, a number of labs and pathologists said the FDA should only have limited role in regulating a set of tests as medical devices, while the rest should be overseen by the Centers for Medicare & Medicaid Services through an updated Clinical Laboratory Improvement Amendments program.

A legislation discussion draft the committee circulated last month clarified FDA and CMS responsibilities on LDTs. FDA would regulate test development in risk-based manner. CMS would regulate lab operations. However, some alternative proposals would divide regulatory and oversight between the FDA and CMS, depending on the type of test.

Shuren told the House subcommittee that such a system would lead to inefficiencies, leading to inconsistent standards treating the same test differently depending upon who makes the test. "If we are going to assure that tests work, we need one unified system," he said.

"On the other hand, CMS does not have scientific staff capable of determining whether a test is difficult to successfully carry out or likely to prove detrimental to a patient if carried out improperly. This expertise resides within the FDA, which assesses clinical validity in the context of premarket reviews," said Patrick Conway, acting principal deputy administrator for the agency.

In a statement last week, AdvaMedDx said creating a new regulatory system at CMS dedicated solely to LDTs would duplicate resources and perpetuate disparate treatment of similar tests.

"FDA oversight of all diagnostic tests — under a risk-based framework — is crucial to ensuring patient safety, and FDA is the only agency with the current regulatory appropriate expertise and resources to provide effective oversight of this rapidly evolving area of healthcare," said Andrew Fish, executive director of AdvaMedDx.

Read the FDA's report here: www.fdanews.com/11-15-FDA-LDT.pdf. Here is the House draft: www.fdanews.com/11-15-House-Draft.pdf. — Jonathon Shacat

FDA Orders Custom Ultrasonics to Recall Endoscope Reprocessors

Citing continued violations of a 2007 consent decree, the FDA has ordered Custom Ultrasonics to recall all 2,800 automated endoscope reprocessors in hospitals and outpatient clinics in the U.S.

The move, which comes after reports of inadequately reprocessed duodenoscopes were linked to infection transmission in hospitals across the country, follows an April agency inspection that found a number of violations, including the inability to validate that the AERs can adequately wash and disinfect endoscopes to mitigate the risk of patient infection.

Despite an agency request to fix the violations and provide additional validation data, the FDA has determined that the company has not adequately addressed the problems. To lessen the risk of infection transmission, the agency is recommending that healthcare facilities currently using Custom Ultrasonics AERs adopt alternative methods to reprocess flexible endoscopes as soon as possible.

Ongoing Problems

This is not the first time Custom Ultrasonics has fallen under FDA scrutiny after entering the consent decree. In 2012, the agency ordered the company to stop manufacturing and distributing all AER device models and components, and ordered their recall after the company failed to obtain clearance following a significant change to the software operating system for one of the reprocessors.

Custom Ultrasonics subsequently obtained clearance, and the products were permitted to remain on the market.

Since that time, the company has not been authorized to manufacture or distribute AERs, but it has continued to service them.

Endoscopes pose potential risks if they are not cleaned properly. The instruments recently topped the ECRI Institute's 2016 list of health technology hazards (*IDDM*, Nov. 16).

Earlier this year, the FDA strengthened controls on reprocessing of certain products, including AERs, in response to the infections linked to the duodenoscopes. In final guidance, the FDA required manufacturers of the products to include data validating the effectiveness of their reprocessing methods as part of their 510(k) submissions (*IDDM*, March 13).

Custom Ultrasonics did not respond to a request for comment by press time. — Jonathon Shacat

FDA Cancels TransMedics' Donor Heart Care System Meeting

The FDA cancelled an advisory committee meeting scheduled last Wednesday to consider the premarket approval application for a TransMedics donor heart care system.

The Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee was slated to discuss, make recommendations and vote on information regarding the TransMedics Organ Care System Heart. The system is intended to preserve a donor heart in a beating state from retrieval until transplantation.

FDA spokeswoman Deborah Kotz declined to elaborate on the reason for the cancellation, except to say that the agency determined that the meeting was no longer needed.

Company spokeswoman Marienne Sanders says TransMedics is communicating with the FDA, but she could not comment further.

The FDA also postponed an advisory committee meeting that was scheduled for last Thursday to discuss the classification of the product codes LKX and associated name "Device, Thermal, Hemorrhoids;" LRL and associated name "Cushion, Hemorrhoid;" and LKN and associated name "Separator, automated, blood cell and plasma, therapeutic."

A future meeting date has not been set. — Jonathon Shacat

OIG, *from Page 1*

and accurately, the FDA says. Medical device cybersecurity was listed among the top 10 regulatory science priorities by CDRH last month in its Fiscal 2016 report.

Research is needed to enhance performance and security of medical devices and interoperability, and to understand the impact of software modifications on device performance, the CDRH report says (*IDDM*, Oct. 23).

The OIG also plans to review Medicare costs resulting from additional use of medical services associated with defective medical devices.

The fiscal 2015 version of the Work Plan included examining the sufficiency of Centers for Medicare & Medicaid Services' oversight of security controls over networked devices at hospitals, but that specific item is not listed in the fiscal 2016 Work Plan.

Read the work plan here: www.fdanews.com/11-15-OIG-WorkPlan.pdf. — Jonathon Shacat

Class 1 Recall Issued for Hamilton's G5 Ventilator

Hamilton Medical has recalled its G5 Ventilator, following one report of device malfunction due to ventilation and alarm failure, the FDA says in a recall alert issued last week.

The Class 1 recall involved roughly 1,000 of the V2.00 and V2.31, with distribution dates of March 2007 to March 2014. The recall was initiated in April 2014. No injuries or deaths were reported.

"We have notified all affected customers, and this recall has been closed," Hamilton spokesman Bret Everett tells *IDDM*.

According to the recall alert, the ventilator may stop working without sounding an alarm when the device operator presses the oxygen enrichment key to attach the ventilator mask to the patient. If the operator does not intervene, the patient may not receive enough oxygen and could suffer injury or death.

Read the recall alert here: www.fdanews.com/11-15-G5-Recall.pdf. — Jonathon Shacat

FDA's Approval Rate for PMAs Hits Record High in FY2015

CDRH approved 98 percent of the premarket approval applications that it received for medical devices in fiscal 2015, marking an all-time high since the start of the Medical Device User Fee Amendments.

It's the FDA's highest rate since 2001, soaring since the all-time low of 59 percent in 2010 and well above the second-highest rate of 90 percent in 2005, according to a quarterly update on performance goals for MDUFA III.

The 98 percent approval rate is only reflective of those submissions that have received a final MDUFA decision, points out FDA spokesman Jeff Ventura.

"There are still a number of submissions from FY2015 that haven't yet reached a final MDUFA decision, so that number will likely change once we have closed out the entire cohort," he tells *IDDM*.

Still, the FDA believes higher approval rates are the result of an increase in the amount of interactive reviews that are helping the agency resolve issues during the review process, says Ventura.

PMAs also are getting approved more expeditiously, with CDRH cutting the average decision time significantly from 432 days in 2013 to 262 days in 2014, according to the report.

In recent years, the FDA has implemented several changes to its policies and the PMA program itself meant to help expedite device reviews.

These changes include streamlining the clinical trials program, facilitating and encouraging the use of innovative clinical trial designs and incorporating a patient-centric benefit-risk framework into PMA device reviews, says Ventura.

The agency also has been working with manufacturers through the pre-submission process to facilitate the development of a quality premarket submission and help industry avoid regulatory hurdles during the review process, he adds.

Read the MDUFA III performance report here: www.fdanews.com/11-15-FDA-MDUFA.pdf. — Jonathon Shacat

FTC Order Settles Anti-Competitive Charges for Wright-Tornier Merger

The Federal Trade Commission approved a final order last week settling charges that a $3.3 billion merger between Wright Medical and Tornier would lead to unfair methods of competition.

The companies were required to sell Tornier's U.S. rights and assets to its total ankle replacement products and total silastic toe joint replacement products to Integra Lifesciences.

The sale includes intellectual property, manufacturing technology and existing inventory.

Wright and Tornier also are required to supply Integra with total ankle replacements for up to three years and total silastic toe joint replacements for up to a year, while Integra transitions to become an independent competitor.

Integra's acquisition of these assets closed Oct. 2

Wright, headquartered in Memphis, Tenn., and Amsterdam-based Tornier, entered into the merger agreement in an all-stock transaction in October 2014.

The FTC subsequently filed a complaint claiming that the merger would violate federal antitrust laws by substantially lessening competition in the U.S. markets.

Last month, the FTC issued a consent agreement to resolve accusations that the merger would lead to unfair methods of competition. The comment period ended Oct. 30 (*IDDM*, Oct. 9).

The merger, which joins two global orthopedic device companies, closed Oct. 1, says company spokeswoman Julie Tracy. — Jonathon Shacat

AdvaMed Reaches Strategic Cooperation Deal in China

AdvaMed has signed a strategic cooperation agreement with the government of Xining municipality in Qinghai province in China, in a deal designed to encourage scientific research, cooperation and exchanges.

Cooperation under the agreement focuses on Qinghai, but AdvaMed hopes to expand it into the region more broadly, says Ralph Ives, the organization's executive vice president of global strategy and analysis.

China is one of the world's fastest growing markets for medical technology. Many of AdvaMed's members have made significant investments there, establishing R&D centers and manufacturing bases that contribute to the country's growth.

Of the 31 Chinese provinces, Qinghai's healthcare spending is the third lowest. It is only 0.5 percent of China's total, or one-eighth of those in Shanghai, for example, says Helen Chen, head of L.E.K. Consulting's China life sciences practice.

One challenge for the MNC medtech companies in China is the uneven economic development and healthcare infrastructure, Chen tells *IDDM*. So, while the top hospitals in Beijing and Shanghai are using the latest technology and clinical practices, it takes a long time for such advancements to make it to inland and poorer locales like Xining — if they ever do at all.

"It's admirable for AdvaMed to launch such an initiative in a place like Xining. If this is purely about commercial impact for their members, they could have selected a much wealthier and accessible city. If they are successful in this collaboration, it would be a great demonstration that the innovative medical technologies can help patients in the remote areas of China, and not only in the urban centers," she says.

Last year, AdvaMed opened an office in Shanghai, where many of the organization's members have their Chinese headquarters. That move substantially enhanced AdvaMed's ability to partner with Chinese authorities and other stakeholders, and provided members expanded opportunities to engage on important policy issues. — Jonathon Shacat

FDA Commissioner Nominee Fends Off Questions on Industry Ties

Facing members of the Senate's Committee on Health, Education, Labor and Pensions last week, Robert Califf, President Barack Obama's choice to head the FDA, defended his record, emphasizing he would not lower standards for device approvals.

Many Committee members had great praise for Califf. HELP Committee Chairman Sen. Lamar Alexander (R-Tenn.) called his qualifications "impressive," and Sen. Patty Murray (D-Wash.) said he is a "strong nominee" with an impressive resume and a longstanding commitment to transparency. She encouraged her colleagues to vote for him.

However, not all members were impressed, with the sharpest criticism coming from Democratic presidential nominee Sen. Bernie Sanders (I-Vt.).

The senator already has said he does not support Califf because of his cozy relationship with industry and prefaced his line of questioning with a statement of disapproval.

Sen. Elizabeth Warren (D-Mass.) also had some tough questions for Califf — particularly over whether he would lower the standards for approval of drugs and devices.

Califf maintained that he is "not a proponent of lowering standards for anything." This answer did not seem to satisfy Warren, who promised that she would not vote on his nomination until she read all of Duke University's contracts with industry during his time there overseeing clinical trials.

Califf also claimed that he donated any money he received as a consultant to nonprofit charities.

He also told the committee that he is working closely with CDER head Janet Woodcock to create a template across the FDA to make sure that medical device and drug standards are similar.

Sen. Sheldon Whitehouse (D-R.I.) asked Califf if greater FDA oversight was needed for medical apps. Califf said that the agency fully intends to regulate apps, depending on their risk.

A health-related app that counts calories or steps likely wouldn't be regulated, he said, as the agency doesn't want to waste its time. However, an app that connects to a defibrillator or a glucose monitor, for example, needs to be looked into.

"Apps will need to be regulated," he said, and that even something as simple as a heart rate monitoring app may be used differently by a heart failure patient, and it could have a greater effect on him or her.

Finally, Califf opined that another regulatory pathway is needed for combination products, adding that within the next year, the FDA hopes it can present its opinions and work with Congress to develop the "right balance" for potential regulations. — Kellen Owings

TGA Updating Guidance For In Vitro Diagnostics

Australia's Therapeutic Goods Administration is updating guidance materials on in vitro diagnostic medical devices, following new amendments to the regulatory framework.

The TGA also is updating forms as a result of changes to the electronic application process for Class 4 in-house IVDs and the notification process for Class 1 to 3 in-house IVDs.

Laboratories with Class 4 in-house IVDs before July 1, 2016, will have until July 1, 2017, to apply for inclusion in the Australian Register of Therapeutic Goods.

New Class 4 in-house IVDs introduced after June 30, 2016, must be included in the ARTG before they can be used by the laboratory to issue patient results.

Notifications for Class 1 to 3 in-house IVDs must be submitted by July 1, 2017.

More information is here: www.fdanews.com/11-19-15-TGA-IVDs.pdf.
— Jonathon Shacat

BRIEFS

ConMed to Acquire SurgiQuest for $265M

Surgical device provider ConMed will acquire SurgiQuest for $265 million. SurgiQuest markets the AirSeal system, an integrated access management technology for use in laparoscopic and robotic procedures that consists of a valve-free trocar. It also provides continuous pressure sensing and an integrated insufflator and smoke evacuator. According to ConMed, clinical data show that AirSeal leads to shorter procedure times and reduced postoperative pain. The transaction is expected to close in the first quarter of 2016.

Alphaeon to Acquire Lensar for $59M

Alphaeon will acquire medical device company Lensar in a transaction valued up to $59 million. Lensar is a manufacturer of the Femtosecond lasers systems for cataract treatment. Its Lensar system is designed for patients seeking an enhanced vision outcome following the removal of their crystalline lens. The transaction is subject to the completion of certain closing conditions on or before December 31.

FDA Clears INOmax DSIR Plus MRI Device

Specialty biopharmaceutical company Mallinckrodt has received FDA clearance for its INOmax DSIR Plus MRI device for the delivery of nitric oxide for inhalation during MRI procedures. The system provides a constant concentration of nitric oxide to the patient and is indicated for use only with magnetic resonance-conditional ventilators validated to be compatible. Clearance is based on the determination of substantial equivalence to the INOmax DSIR. The new device includes hardware modifications to the cart, as well as a software update with an MRI set-up wizard and modified labeling. The company plans to commercialize the device this month.

CDRH Holds Experiential Learning Training

Medical device industry, academia and healthcare facilities are invited to participate in the 2015 Experiential Learning Program General Training Program, which is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices and challenges faced in broader disciplines that affect the device development life cycle. Requests to participate must be submitted either electronically or in writing by Dec. 16. Read the notice here: www.fdanews.com/11-15-FDA-ELP.pdf.

ElMindA Raises $28M for BNA System

Neuroscience-based technology company ElMindA has raised $28 million in Series C financing to continue advancing its proprietary Brain Network Activation system, which uses multi-channel EEG-ERP electrophysiology technology to provide a more accurate, objective assessment of brain functionality over time. ElMindA also will use the funds for commercial and clinical adoption following BNA's 2014 FDA clearance in the U.S., and CE Mark approval in Europe for brain function assessment. The investors include Shanda Group, New England Patriots owner – The Kraft Group, Wexford Capital, WR Hambrecht & Co, Palisade Capital Management, OurCrowd and Healthcrest AG.

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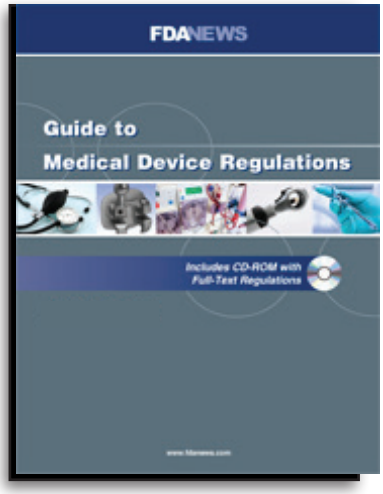

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