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IN THIS ISSUE

FDA Rejects New Device Regulation For Third-Party Servicers

The FDA rejected a push to impose additional regulations on third-party servicers of medical devices, saying there is insufficient evidence to justify imposing new regulatory requirements.

In a report released May 15, the agency calls for developing voluntary standards rather than mandating specific regulations.

This "reflects the agency's belief that the current processes in place at servicing facilities support continued quality, safety, and effectiveness of medical devices that undergo servicing," FDA spokesperson Deborah Kotz told *FDAnews*.

Reactions to the report were mixed. AdvaMed called it "disappointing" and urged Congress to step in to "require third-party servicers to follow FDA quality systems, adverse event reporting, and registration regulations."

(See **Regulation**, *Page 2)*

Brazil Mulls Changes To Notification Pathway For Low-Risk Devices

Brazil's National Surveillance Agency is considering replacing its current registration process for low-risk medical devices with a notification pathway that would no longer require premarket reviews.

"It is our understanding that ANVISA plans to replace 'Cadastro' registration requirements for Class I medical devices and in vitro diagnostics with a notification-only registration system," BMI Research analyst Karen Simpkins told *FDAnews*.

"However, to the best of our knowledge ANVISA has yet to launch a public consultation on this which would be the normal route prior to enacting a regulatory change. Such a move would be in line with the regulator's policy of freeing up stretched resources to focus on higher risk devices and align with recommendations from the International Medical Device Regulators Forum."

(See **Brazil**, *Page 6)*

Regulation, *from Page 1*

The limited actions proposed in the FDA report, "while welcome, do not go far enough to effectively address the scope of the problem," said J.C. Scott, AdvaMed's chief advocacy officer.

However, Jeff Fall, president of Oxford Instruments Healthcare, said he believes it was the right decision. "When the FDA analyzed the objective data of adverse events that are attributable to third parties, the problems were so minimal that it doesn't rise to the level of requiring new regulation," he told *FDAnews.*

Fall noted that "the report gets at the requirement for manufacturers to provide adequate information about installation, calibration and servicing of their products," saying he would "like to see the FDA be more aggressive in their enforcement of this. It has been and will continue to be a problem as the [original equipment manufacturers] try to hide this data from consumers and third parties."

Four Actions

Fall said that the push by OEMs to cut third parties out of the market while they continue to service one another's equipment "looks like a blatant commercial grab for market share by the OEMs."

Although the report found that formal regulatory action is unwarranted at this time, the FDA intends to pursue four specific actions based on the report's findings.

First, the agency intends to "promote the adoption of quality management principles" by working with entities that perform medical device servicing to develop a voluntary framework for ensuring quality servicing.

The FDA also intends to clarify the difference between servicing and remanufacturing. The agency defines a remanufacturer as "any person who processes, conditions, renovates, repackages, restores or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use," while servicing does not significantly change the performance, safety specifications or intended use of the device.

Many of the reported adverse events actually related to remanufacturing rather than servicing, and the FDA already "regulates remanufacturers as device manufacturers and expects them to follow the same reporting, registering and quality system regulations," Kotz said.

The report also proposes to "strengthen cybersecurity practices associated with servicing of medical devices." Many OEMs, healthcare establishments and third-party servicers lack cybersecurity expertise, policies and practices necessary to ensure device security, according to the report. The FDA proposes to develop standards and best practices for all entities responsible for servicing medical devices.

Underreporting

Lastly, the FDA intends to "foster evidence development to assess the quality, safety and effectiveness of medical device servicing." Persistent underreporting of patient safety events and device malfunctions, along with poor documentation of device service history, currently impedes the FDA's ability to reach conclusions about the existence or severity of problems associated with servicing devices. The FDA intends to create a multi-stakeholder data collection and analysis effort.

The report concludes with a recommendation to create a public-private "Collaborative Community" to address challenges inherent in safely and effectively servicing medical devices if there is "sufficient interest and willingness to participate by all stakeholder groups."

Rob Kerwin, general counsel for the International Association of Medical Equipment Remarketers and Servicers said his organization is pleased that the FDA said they will establish a collaborative community. "Manufacturers aren't always providing the equipment information

(See **Regulation***, Page 6)*

Industry Urges Congress to Update Laboratory Diagnostics Legislation

Industry leaders are calling on Congress to modernize legislation covering clinical laboratory diagnostics to bring it into the 21st Century.

A May 9 letter sent to Sen. Lamar Alexander (R-Tenn.), Sen. Patty Murray (D-Wash.), Rep. Greg Walden (R-Ore.) and Rep. Frank Pallone (D-N.J.) urges them to move quickly on comprehensive legislative reform to ensure patients have access to innovative and high quality clinical laboratory diagnostics.

Signed by organizations representing patient advocates, providers, laboratories and diagnostics manufacturers, the letter says there is an urgent need to reform regulations covering laboratory developed tests (LDTs) and in vitro diagnostics (IVDs). Currently, the FDA regulates IVDs but does not actively regulate LDTs.

"FDA Commissioner Scott Gottlieb has made repeated public comments that comprehensive legislative reform of clinical laboratory diagnostics is timely and appropriate," the letter says.

New Pathway In The Works

Gottlieb told the World Economic Forum in Davos, Switzerland, earlier this year that the FDA would be looking for new authority to regulate diagnostics.

"I think it's time that the agency needs to work with Congress and stakeholders to develop very specific targeted legislation that would give us a unique set of authorities to regulate diagnostics properly," Gottlieb said.

"My view is that the old 510(k), PMA pathway…the traditional pathway for approving medical devices, doesn't really fit well with modern diagnostics, and we need very well-fashioned authorities when it comes to diagnostics" (*IDDM*, Feb. 5).

Last year, Representatives Larry Buchson (R-Ind.) and Diana DeGette (D-Colo.) circulated a discussion draft called the Diagnostic Accuracy and Innovation Act (DAIA) that would create a new regulatory structure for in vitro clinical tests (IVCTs) that would comprise both IVDs and LDTs and would be regulated separately from devices, drugs, and biologics.

The discussion draft would establish FDA jurisdiction over IVCT development and manufacturing while maintaining Centers for Medicare and Medicaid Services' (CMS) oversight of laboratory operations. It also would establish a regulatory structure for IVCTs that addresses risk classification, premarket requirements, modifications, quality, post-market monitoring, and innovation (*IDDM*, April 3, 2017).

Bucshon and DeGette invited comments on the draft and were to formally introduce legislation after reviewing the comments, a spokesman for Bucshon told *FDAnews*.

'Bad Policy'

They said the proposal would bring "much needed certainty" to the diagnostic industry by applying the same regulatory principles to the same activity regardless of where a test is developed.

AdvaMed said in its comments on the DAIA draft that the association has long supported FDA oversight of all diagnostics, including LDTs. "Maintaining two very different oversight mechanisms for tests based only on who develops them is bad public policy," the association said, because it leads to clinical use of tests without sufficient clinical data and stifles innovation of high quality diagnostics.

The association said it supported the proposed legislation in principle, although it was concerned about some of the timelines proposed.

In January, instead of finalizing draft LDT guidance, the FDA released a discussion paper outlining a possible approach that would focus on new and significantly modified high- and moderate-risk LDT (*IDDM*, Jan. 16, 2017).

"Stakeholders have never been more aligned on the need for diagnostics reform than we are now," the letter says. "We believe the goal of a new statutory framework is within reach."

Read the letter here: www.fdanews.com/05-15-18-Letter.pdf.

FDA Proposes to Drop 2nd Appeals For Medical Product Classifications

A process for second appeals of FDA designations for medical product classifications would be eliminated under a new FDA proposed rule.

Part 3 of CFR 21 directs the FDA to assign products that are some combination of a drug, a device and/or a biologic based on the product's primary mode of action, while non-combination biological products, devices and drugs are assigned within the agency based on their classification.

Under current regulations, sponsors can appeal their classification and make a second appeal if they disagree with the decision, in a process that has been "confusing to sponsors and inefficient for sponsors and agency staff," the FDA said.

The initial consideration is based on so much data — with no new information allowed to be introduced during appeals — that very few second appeals result in a new classification.

The proposed rule also would clarify that Part 3 procedures apply to those products whose classification is in dispute. Sponsors are often uncertain whether they must ask for a classification or assignment determination before making a premarket submission for the product if the classification is clear. The proposed rule would clarify that the Part 3 procedures are unnecessary in such cases.

The rule also outlines steps to bring Part 3 more in line with legislative and regulatory actions adopted since it was implemented in 1991. In 2005, the FDA clarified the meaning of "proposed mode of action" for assignment of combination products. In 2009, the Biologics Price Competition and Innovation Act amended the definition of "biological product mode of action."

Read the proposed rule here: www.fdanews.com/05-14-18-Rule.pdf. — Zack Budryk

FDA Seeks to Improve Development Of Medical Devices for Women

Clinical trial sponsors must step up their efforts to address underrepresentation of women among subjects in clinical trials, including for medical devices, said FDA Commissioner Scott Gottlieb during a meeting to commemorate National Women's Health Week.

Gottlieb said that the agency is making moves to improve the development of safe, women-oriented medical devices. He noted the agency's initiative to form a registry network, part of the Device Safety Action Plan, which will focus on health technologies that provide more data in women-specific clinical areas like uterine fibroids and pelvic floor disorders.

He also noted the FDA's initiative to gather real world evidence of device performance, the Women's Health Technologies Strategically Coordinated Registry Network. Improving analysis and data collection will require the development of common data elements for sex and gender, to be included in some prominent medical device registries, he said.

Complaint Handling, Process Controls Lacking at Battery Maker Alpha Source

The FDA uncovered serious complaint handling and CAPA deficiencies during an inspection of Alpha Source's Milwaukee, Wisconsin facility from Jan. 17 to Feb. 2 and handed the firm an eight-item Form 483 at the close of the inspection.

The manufacturer, which makes battery packs for medical devices including defibrillators, patient monitoring equipment and ventilators, failed to adequately investigate complaints of battery failures. For example, six of nine complaints were processed as alleging no failure of the device, labeling or packaging, although this was contrary to customer complaints that the devices failed.

All nine complaint records lacked adequate investigations that documented whether the device failed to meet specifications, whether the device was being used for treatment or diagnosis, the relationship of the device to reported complaints, and the root cause or corrective actions taken.

All of the complaints were evaluated as not being reportable, the 483 said, but there was no information in the complaint records to support how the determination was made. Seven of nine complaint records related to an infusion pump or ventilator battery holding a charge, but the firm did not identify this as a trend in its CAPA reports.

(See **483***, Page 6)*

Four Steps to Medical Device Reporting

One of the most frequent stumbling blocks companies face regarding MDR reporting is lack of procedures for the following activities:

- Screening all complaints to determine whether they should be reported;
- Training individuals in the complaint handling unit to identify potential reportable complaints;
- Defining an escalation procedure to quickly identify and review safety issues; and
- Developing a formal documented process for assessing complaints for reporting.

The FDA has multiple reporting time frames. A five-day report is required when an event is the result of a malfunction that requires remedial action to prevent unreasonable risk for substantial harm to public health.

Alternately, there is the 30-day report. This report is tied to death or serious injury, as well as malfunctions or user errors that could result in death or serious injury should they recur.

But how do you identify reportable events? Ask: Did the event relate to a product distributed by the company? If the answer is yes, move to the next step, remedial action requirements.

Was the event the result of a malfunction that requires remedial action to prevent an unreasonable risk of substantial harm to the public? If remedial action is required, you must submit a report on form 3500A to the FDA within five days. If it is not necessary, move on to the next step.

Ask: Did the event result in a serious injury or death? Is it life threatening or does it result in permanent impairment or require medical or surgical intervention to prevent permanent impairment of a body structure? If you answered yes to any of these questions, you must submit a report to the FDA within 30 days.

Assuming the answer was yes; identify the cause of the event. Was it a malfunction? If so, ask:

Could the malfunction cause death or serious injury if it recurred? Work with the assumption that the malfunction will recur. If not, then no report is necessary. Make sure you document your rationale as to why the event was not deemed a safety issue.

Was the event caused by a user error? If so, you must ask: Could a repeat of this error cause death or serious injury? If yes, report to the FDA within 30 days. If no, you will need to document why the error is not a safety issue.

Excerpted from the *FDAnews* management report: *Troubleshooting Your Quality System: A Guide to Five Devicemaker Quality Compliance Traps*.

483, *from Page 5*

There was no evidence of risk assessment activities being performed nor was there evidence to support re-training of personnel as part of CAPA procedures, the agency said.

The firm's process control procedures were found to be inadequate because lot numbers and expiration dates were not recorded as part of the manufacturing record, and there was no value recorded for the number of samples tested to meet specifications. Acceptance criteria were also found lacking in that the product acceptance status didn't indicate whether a product conformed to specifications.

Read the Alpha Source Form 483 here: www.fdanews.com/05-08-18-alphasourceinc483.pdf.

Brazil, *from Page 1*

Under a notification system, a manufacturer's Brazilian registration holder would electronically submit a minimal amount of information to the agency, with no technical analysis performed, Simpkins said. "It would considerably reduce the burden of compliance for manufacturers of lower risk devices, although they would still need to maintain technical dossiers and comply with INMETRO certifications and related requirements where appropriate."

"Cadastro registrations (Class I and Class II devices) accounted for around 40% of premarket applications submitted to ANVISA for review in 2016," she said.

The proposed move would align with recent changes at ANVISA to streamline operations. Marcelo do Ó, managing director and partner at L.E.K. Consulting, in São Paulo, Brazil, told *FDAnews* that Anvisa is working on reducing bureaucracy and streamlining internal processes.

"We should continue to see progress as ANVISA addresses the inefficiencies. ANVISA was considering at one point granting registration, or temporary registration, if a product was approved by a major recognized regulatory authority, such as the FDA or EMA," he said.

In a similar move to reduce bureaucracy, ANVISA recently extended its renewal period for medical devices from five years to 10 years (*IDDM*, Feb. 12).

Regulation, *from Page 2*

that independents need to calibrate and repair equipment. By regulation for radiation emitting devices, you're supposed to give [assembly, installation, adjustment and testing] information, and it's not being done in a consistent way. A better solution for patients and the industry is to work collaboratively."

The FDA is accepting comments on the report until Nov. 12.

Read the full report here: www.fdanews.com/05-18-18-FDARA.pdf.
— Donna Scaramastra Gorman

TGA Reports More Cases Of Implant-Associated Lymphoma

Australia's Therapeutic Goods Administration reported that more cases of anaplastic large cell lymphoma have been associated with breast implants. The regulator reported 72 confirmed cases of ALCL.

Breast implant-associated ALCL is a rare type of lymphoma that develops near breast implants. Most cases of breast implant-associated ALCL are cured by the removal of the implant and the capsule surrounding the implant, the agency said. However, a small number of cases have been more aggressive.

The Medical Journal of Australia published a journal article in September 2017 about the connection between ALCL and breast implants, and it advocated for strategies to strengthen the Australian Breast Device Registry.

FDA Exempts Some Respirators From Premarket Notification

The FDA issued an order exempting certain surgical apparel from premarket notification requirements.

The exemption is for single-use, disposable respiratory protective devices (RPD) worn by healthcare personnel during procedures to protect the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.

Commonly referred to as N95 filtering respirators and surgical N95 respirators, the devices are currently regulated by FDA under product code MSH.

All other Class II devices under FDA's surgical apparel classification continue to be subject to premarket notification requirements, the agency said.

APPROVALS

PeraHealth Receives Clearance For Clinical Surveillance Technology

The FDA granted PeraHealth 510(k) clearance for PeraTrend, its clinical surveillance technology.

The real-time, predictive technology utilizes the Rothman Index to leverage data within a hospital's electronic records to quantify and visualize patient risks, improvements and deterioration.

The index it utilizes uses a range of physiological measures, such as labs, vital signs and nursing assessments, to continuously measure a patient's condition.

Nextremity Solutions Cleared For Lapidus Procedure System

The FDA granted clearance for Nextremity Solutions to market its InCore Lapidus system.

The device is used to stabilize and correct multi-planar deformities while giving visibility for the surgeon's preferred joint preparation during Lapidus procedures.

It is indicated as a three-part construct meant for internal fixation for First Metatarsocuneiform Arthrodesis (Lapidus or Tarsometatarsal Fusion), and has an application pending for a CE Mark.

BrainsWay Granted Clearance For Deep TMS Stimulator

The FDA awarded BrainsWay 510(k) clearance for its new stimulator, which will be integrated into the BrainsWay deep transcranial magnetic stimulation system for treating major depressive disorder.

The device is designed for use with the company's proprietary H-Coil helmet in treating MDD. It includes new features that increase physician ease of use and improve energy efficiency.

The stimulator also provides a patient management system with a depression treatment protocol and a tool for motor threshold detection.

(See **Approvals***, Page 8)*

Approvals, *from Page 7*

Stryker Wins Expanded CE Mark for Stent Retriever

Stryker won an expanded CE Mark for its Trevo stent retriever, a thrombectomy device used as a front-line treatment for acute ischemic stroke.

The expanded indication increases the previously cleared treatment window by 18 hours to 24 hours, following a similar action by the FDA in February.

Clinical trial data showed that patients treated with the Trevo Retriever in the six- to 24-hour window were almost four times as likely to be functionally independent at 90 days post stroke.

CardioFocus Gains Approval For Excalibur Balloon

The FDA granted CardioFocus' HeartLight Excalibur balloon approval for treating paroxysmal atrial fibrillation.

The device optimizes the magnitude and speed of target tissue contact during pulmonary vein isolation procedures. It also allows users to make real-time adjustments to the balloon's size.

FDA Clears OrthoPediatrics' Pediatric Nailing Platform

OrthoPediatrics' received 510(k) clearance for its pediatric nailing platform, its 25th surgical system cleared by the FDA.

OrthoPediatrics markets systems for pediatric trauma and deformity, scoliosis and sports medicine, among other orthopedic procedures.

The new platform will allow surgeons to treat a wider range of pathologies, the company said.

BacterioScan Cleared for UTI Infection Detection System

The FDA granted 510(k) clearance for BacterioScan's rapid infection detection system, an automated diagnostic system approved for detecting urinary tract infections.

Current UTI testing is a manual culturing process that can require 2 days or more for results. BacterioScan's system can detect UTIs in a matter of hours with a laser sensor that reduces lab turnaround time.

CurveBeam Wins 510(k) Clearance For Weight Bearing CT System

CurveBeam received FDA 510(k) marketing clearance for its LineUP multi-extremity weight bearing CT system.

The system allows radiologists and orthopedic specialists to visualize three-dimensional bone detail of the lower extremities while the patient is standing so they can assess the anatomy in the weight-bearing position. The LineUP can perform bilateral scans of legs from below the heel to above the knee and accessories enable scanning of hands, wrists and elbows.

Caliber Imaging & Diagnostics Gets 510(k) Clearance for Improved VIVASCOPE

Caliber Imaging & Diagnostics won 510(k) clearance from the FDA for modifications to its VIVASCOPE imaging system, a microscopy tool that allows dermatologists to non-invasively visualize cellular structures in the skin.

The system uses a low-powered laser to provide high-resolution images of the epidermis in thin, optical slices.

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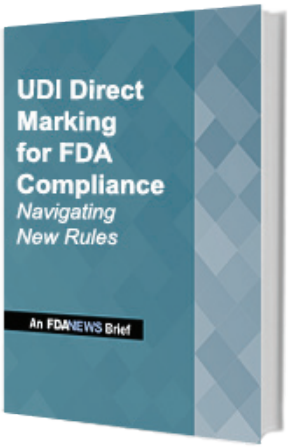

UDI Direct Marking for FDA Compliance: *Navigating New Rules*

Confused by the FDA's UDI direct marking regulations? What information should go on the label and the device itself? What methods of marking are acceptable? What's the difference between a device identifier and a production identifier? What additional requirements are placed on reprocessed devices?

The FDA's final guidance on UDI (unique device identification) raises as many questions as it answers. With full compliance for Class I, II and unclassified devices looming, lawyers are hard at work parsing the FDA's language.

Jay Crowley was the architect of UDI while at the FDA. Now a consultant advising devicemakers, he remains the go-to expert on UDI compliance. In the FDAnewsBrief, **UDI Direct Marking for FDA Compliance**, Crowley lays out a path to compliance. He explains:

- The technology necessary for creating and verifying bar codes
- The difference between direct marking and direct part marking
- How the rules apply to device components and accessories
- Exceptions to the direct marking requirements
- Record-keeping requirements
- Testing to make sure any direct mark doesn't affect the safety or performance of the device
- UDI requirements in the premarket submission stage.

Order your copy of the **UDI Direct Marking for FDA Compliance: *Navigating New Rules*** and receive guidance from the man who wrote the FDA's Unique Device Identification rules.

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Hack-Proofing Medical Devices: *Ensuring Product Safety through Cybersecurity*

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- Types of cybersecurity threats, including ransomware and device piggybacking
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