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IN THIS ISSUE

Senate HELP Committee Approves 3 Medical Technology-Related Bills

Seven proposed 21st Century Cures Act bills sailed through the Senate HELP Committee last week, including three medical technology-related bills.

The three bills that will have an impact on the device industry are the Medical Electronic Data Technology Enhancement for Consumer's Health (MEDTECH) Act (S. 1101), the Combination Products Innovation Act of 2015 (S. 1767) and The Advancing Breakthrough Medical Devices for Patients Act of 2015 (S. 1077).

AdvaMed welcomed the efforts, saying they will improve the efficiency of the FDA's device review process. Specifically, S.1767 would provide greater clarity to the agency's process for reviewing combination products, ensuring more timely and predictable reviews of these novel products, says JC Scott, AdvaMed's senior executive vice president for government affairs.

(See **Senate***, Page 2)*

AAMI, BSI Meeting Aims To Clarify EU MDR Changes

Devicemakers face steep challenges due to a decline in the numbers of notified bodies, and industry is already seeing a culling of the weakest bodies.

Manufacturers already are feeling the squeeze, and some remaining notified bodies are deciding to not issue quotes for new clients, expert said.

In fact, 25 percent of notified bodies have stopped operations ahead of the upcoming regulations, and that number should only increase, Gert Bos, executive director and partner at Qserve Group told attendees of the recent Regulatory Affairs Professional Society Convergence Conference in Baltimore, Md., last year (*IDDM*, Nov. 6, 2015).

A big change will be the requirement for a certificate of all class 2b implants. That will "force us to be much busier than we currently

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are," said Suzanne Halliday, head of medical devices notified body, BSI.

Halliday presented BSI's approach to the looming changes when it comes to conformity assessments during her organization's joint meeting with the Association for the Advancement of Medical Instrumentation March 9 to 10. The group has taken a divide and conquer approach, bringing in people with different expertise to cover areas such as quality systems, microbiology, technical documentation and unannounced audits.

Bos and Erik Vollebregt, partner at Axon Lawyers, noted in an October 2015 BSI white paper that "manufacturers are facing problems due to decline in numbers of notified bodies as well as decisions from many remaining notified bodies to not, or only selectively, issue quotes for new clients, or even for new work under existing contracts."

EU and UDI

Another challenge facing device manufacturers supplying products in the EU is UDI. Lena Cordie, owner and consultant with Qualitas Professional Services, gave an overview of what industry might expect in this area in coming years. She cautioned that while device manufacturers with products on the U.S. market have had some guidance from the FDA, things will look different in the EU, and manufacturers should expect to do a lot of work.

"Don't look at this as just a project" that companies can wrap up — it's an ongoing process, she said.

Cordie highlighted some of the differences between the EU and U.S. For example, in the U.S., the labeler is responsible for establishing the UDI for devices, while in the EU, it's the manufacturer. Further, while the U.S. has established the Global Unique Device Identification Database, the EU has the nascent EUDAMED database.

Still, she said, those companies doing unique device identification in the U.S. should be able to comply with the EU regulations, with a few modifications. That is because the U.S. will require 62 data elements, whereas the EU will only want 33. For example, the FDA will want information on the sterilization method and packaging type and status, while EU officials will not.

For access to BSI white papers, visit www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/. — Elizabeth Hollis

Senate, *from Page 1*

He adds that S.1077 would build on initiatives under way within the FDA to create an accelerated, more predictable pathway for breakthrough medical technologies — those that offer the best hope for patients with life-threatening or irreversibly debilitating diseases or conditions who have no or limited alternative treatment options.

Finally, S.1101 would codify FDA's current regulatory paradigm for medical technologies using software and allow the agency to concentrate its resources on those products that have the greatest potential impact on public health, Scott adds.

The first markup occurred in February, with the committee passing seven bills, including six bills that 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 (S. 849), the Preventing Superbugs and Protecting Patients Act (S. 2503) and the Improving Health Information Technology Act (S. 2511) (*IDDM*, Feb. 12).

No changes were made to the bills during last week's markup. A third and final markup is scheduled for April 6 that will then go before a full Senate vote. An agenda has not yet been released. — Michael Cipriano and Jonathon Shacat

Repro-Med Dinged With Warning Letter For Quality System, MDR Violations

Chester, N.Y.-based Repro-Med, a manufacturer of infusion pumps and intravascular administration sets, has earned an FDA warning letter for failures involving quality systems and medical device reporting, as well as other violations.

The Feb. 26 warning letter, which follows a June 3 to 23, 2015 inspection, says the company failed to get FDA permission to change the specification ranges for pressure and flow rate for its Freedom 60 syringe infusion pump.

The warning letter also says Repro-Med is promoting its Freedom 60 syringe infusion pump for indications that fall outside the cleared intended use, such as the infusion of immunoglobulin G, antibiotics, Desferal, pain medication, chemotherapeutics and cardiac medications.

Further, the devicemaker is marketing its Freedom Edge syringe infusion systems, including the HigH-Flo subcutaneous safety needle sets, for subcutaneous immunoglobulin infusion, even though the company was unable to supply the agency with requested performance data.

In terms of quality systems, the warning letter says the company failed to complete verification activities to confirm that the design output meets the design input requirements, and failed to maintain plans that describe the design and development activities for the Freedom Edge syringe infusion pump.

The FDA says the company's response to the Form 483 was not adequate. For example, the response did not contain information regarding systemic corrective action, including a retrospective review of other products to ensure that design controls were documented and completed as required.

The warning letter also takes Repro-Med to task for failure to establish procedures to ensure

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Amarin Settlement in Promotion Case Will Affect Devicemakers

The FDA's decision to settle Amarin's First Amendment lawsuit will have broad implications affecting both the drug and device worlds.

Under the deal — which still requires court approval — the agency would be bound by the terms of an August 2015 injunction permitting Amarin to promote Vascepa, used to lower high levels of triglycerides, off-label using court-approved language to ensure that the information is truthful and not misleading.

There is no doubt that the Amarin case, in conjunction with the recent Vascular Solutions trial, changes the landscape regarding off-label promotion in certain ways, says John Fleder of the law firm Hyman, Phelps & McNamara.

"Both cases demonstrate that the government must consider the First Amendment when it is contemplating enforcement actions for both drugs and devices," he tells *IDDM*.

In the Vascular Solutions case, the company and its CEO Howard Root were acquitted last month of charges involving "off-label" promotion of its Vari-Lase Short Kit in a federal court in Texas (*IDDM*, March 4).

The settlement agreement, plus the VSI win and other recent government losses, puts pressure on the FDA to issue guidance on off-label speech for all medical products, says Lisa Dwyer of law firm King & Spalding.

Both industries are likely to be encouraged by Amarin's success. Further, the outcome of a declaratory judgment action brought by Pacira earlier this year could lead to more of these actions, she tells *IDDM*.

Moving forward, the settlement likely will increase the FDA's uphill battle in prosecuting off-label cases. Further, it puts pressure on the government to allege that the statements are false or misleading, which can be more resource intensive, says Dwyer. — Cameron Ayers and Jonathon Shacat

Dräger Expands Recall for Ventilator Power Supply Units

Dräger has expanded its recall to 2,501 units of its PS500 optional power supply units that were updated with new software.

The new software failed to correct the issue depleting the battery, so Dräger will now replace all affected PS500 power supply units, according to an FDA notice.

The optional battery power supply is sold for use with the Dräger Evita, designed for breathing support for children and adults, and Babylog ventilators, built for premature babies weighing at least 14 ounces.

"The ongoing PS500 power supply issue could cause the ventilator to shut down unexpectedly. If the ventilator shuts down, a patient may not receive necessary oxygen. This could cause patient injury or death," the FDA says.

Dräger became aware of cases in which the battery capacity of the optional PS500 power supply unit for the Evita Infinity V500, Evita V300 and Babylog VN500 was rapidly and unexpectedly reduced despite using the most recent power supply software (FW1.50) released in November 2015, says company spokeswoman Marion Varec.

"According to our findings, the new power supply firmware (FW1.50) doesn't represent an improvement. Therefore, the decision was made to cancel the distribution of the updated power supply software (FW1.50) and to downgrade devices on which this software version is already installed," she tells *IDDM*.

The amount of devices recalled reflects an increase from the 2,374 units reported in a December 2015 recall (*IDDM*, Jan. 8).

Affected products in the original recall were distributed from June 1, 2011 through Oct. 30, 2015. The expanded recall extends the distribution date to Jan. 31 of this year.

Read the notice here: www.fdanews.com/03-16-DragerRecall.pdf. — Jonathon Shacat

FDA Spells Out Data to Support IDE Applications for Neurological Devices

The FDA is aiming to clarify the types of data it would like sponsors to submit to support an IDE for clinical trials involving devices targeting neurological disease progression.

In draft guidance dated March 7, the agency acknowledges that sponsors of devices that treat conditions such as Alzheimer's disease face unique challenges, as many in the clinical community are more familiar with pharmaceutical options.

However, the agency sees potential for devices to control progression of these diseases and would like stakeholder input on the risks and benefits of using these devices.

"This draft guidance is intended to leverage advances in the state of science, and facilitate faster, more efficient device development, regulatory evaluation, and ultimately approval/clearance of innovative devices," the document states.

To that end, the agency advises sponsors to include the complete investigational plan in their IDE applications. In addition, sponsors should describe all phases of the clinical investigation, detailing any anticipated study and explaining any plans to pool data from more than one phase.

Further, for each planned clinical study, sponsors should include the following:

- The proposed indications for use, which should include the target population;
- The study type (e.g., pivotal, expansion or feasibility trial);
- The design of the study, including objectives, any masking, randomization, and controls;
- The total time planned for subject follow-up;
- The sample size;
- The number of investigational sites, both inside and outside the U.S.;
- The subject inclusion and exclusion criteria;
- Primary safety and effectiveness endpoints described as specific objective clinical targets;
- A study plan detailing tests and testing methodologies;
- A schedule/time table of all clinical tests to be performed for pre- and post-operative evaluation of the subjects; and
- The participating investigators, if known.

The agency also recommends using a benefit-risk framework to support "a comprehensive, balanced decision-making approach." It adds that it may disapprove an IDE application if there is reason to believe that the risks outweigh the anticipated benefits to the subjects.

Comments are due by June 5. Read the draft guidance, *Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes*, here: www.fdanews.com/03-16-FDAIDE.pdf. — Jonathon Shacat

Industry, FDA Still Far Apart In MDUFA Negotiations

Industry and the FDA appear to be far from reaching an agreement on the fourth iteration of the Medical Device User Fee Act, based on newly released meeting minutes posted last week.

On Feb. 18, industry representatives presented a proposal package on presubmission improvements, performance goals for *de novo* requests, upgrades for the clinical laboratory improvements amendments waiver process and third party 510(k) reviews.

They also proposed providing $6 million to continue the independent assessment of the premarket review process and $4.5 million to develop the myDevices Portal and eSubmitter/Tracker.

However, industry representatives failed to include elements proposed by FDA officials during a Jan. 27 meeting, according to the agency.

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Senators Urge CMS to Incorporate UDIs on Insurance Claim Forms

In a bipartisan push, two lawmakers are pushing for the Centers for Medicare & Medicaid Services to work with the FDA to incorporate unique device identifiers into insurance claims forms, saying it would improve postmarket surveillance and curb waste.

According to Sens. Chuck Grassley (R-Iowa) and Elizabeth Warren (D-Mass.), including UDI in claims would allow for faster identification and recall of poorly performing devices and ensure proper reimbursements for hospitals, device manufacturers and CMS, the senators say in a March 8 letter to HHS Secretary Sylvia Burwell, CMS Acting Administrator Andy Slavitt and FDA Commissioner Robert Califf.

The senators point to a Sept. 1, 2015 letter that they received from HHS Inspector General Daniel Levinson that said recalls of defective products have likely resulted in millions of claims for monitoring services and device replacement-related procedures and services.

Time is of the essence, say Grassley and Warren, adding that the next claims form will be implemented in 2021, but "the window to make changes is rapidly closing."

Read the letter from Grassley and Warren here: www.fdanews.com/03-16-SenateLetter.pdf.

The letter from the inspector general is here: www.fdanews.com/03-16-OIGLetter.pdf.
— Jonathon Shacat

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that equipment is routinely calibrated, inspected, checked and maintained, and failure to maintain procedures for retesting and revaluation of nonconforming product after rework, for implementing corrective and preventive action, and for acceptance activities.

The FDA acknowledges that Repro-Med's response indicates the company will develop a calibration manual and master validation plan, has revised the corrective action process, and will be revising its tubing and needle set flow test procedure. However, the agency was unable to provide an evaluation on the response because the company didn't provide details.

Finally, the FDA says Repro-Med failed to adequately develop, maintain and implement written medical device reporting procedures. For example, its MDR procedure does not establish internal systems, such as specify who makes decisions for reporting events to the agency, or describe how it will address documentation and record-keeping requirements.

Repro-Med could not be reached for comment by press time. Read the warning letter here: www.fdanews.com/03-16-RMSLetter.pdf.
— Jonathon Shacat

MDUFA, *from Page 5*

Specifically, the FDA highlighted what it called high-priority areas, such as using real-world evidence for premarket decision-making and having agency staff ensure consistency across a device's entire regulatory lifespan.

FDA officials also were concerned about the lack of a mechanism to address workload uncertainty. Industry representatives expressed a willingness to consider this proposal, and agency officials agreed to provide more details.

That said, industry representatives indicated that several of the FDA's proposed initiatives were not priorities for user fee negotiations, and could be pursued in other ways.

Previous meeting minutes revealed that the agency was eyeing a $500 million deal to implement additional resources for several programs under MDUFA IV (*IDDM*, Feb. 28).

Another meeting was scheduled for March 4, but the minutes from that event have not been released.

Read the Feb. 18 minutes here: www.fdanews.com/03-16-MDUFAminutes.pdf. — Jonathon Shacat

CDSCO Launches Portal for Import Licenses, Registration Certificates

India's Central Drugs Standard Control Organization has opened up an online portal to multinational companies seeking registration certificates or import licenses for medical devices and diagnostics.

The site, known as SUGAM, allows sponsors to submit and track the status of applications, respond to queries and upload documents.

The portal, which was launched for pharmaceuticals Nov. 14, 2015, was expanded to devices and diagnostics on March 4, according to a notice issued by CDSCO.

Rajiv Nath, forum coordinator of the Association of Indian Medical Device Industry, tells *IDDM* that his organization has asked the government to consider similar electronic online registration for Indian manufacturers.

Applicants should register on the portal by March 15. Hard copies will be accepted after March 15 from applicants who have pre-registered in the portal. Starting on April 1, online applications only will be accepted, CDSCO's notice says.

Read the notice here: www.fdanews.com/03-16-CDSCONotice.pdf. More information on SUGAM is here: www.cdscoonline.gov.in.
— Jonathon Shacat

Malaysia's MDA Unveils Guidance on Conformity Declaration Requirements

Malaysia's Medical Device Authority has revamped the conformity declaration requirements for registering medical devices in the country.

As part of the requirements, manufacturers must attest that their devices comply with the essential principles for safety and performance. Devicemakers also must submit a declaration of conformity, which will be reviewed and confirmed by an assessment body, according to guidance issued last month.

The DoC should contain basic information, such as the manufacturer's name and address, the device's name, model, country of origin and risk-based classification, and the name, position and signature of the person who is authorized to complete the document.

The guidance also explains who should sign the DoC. For local manufacturers, the signatory is top management or the responsible person, such as proprietor, president, vice president, director, CEO, managing director or general manager. For foreign manufacturers, it is "any person in the top management category."

Late last year, the MDA issued draft guidance on conformity assessment procedure for devices that have been approved by recognized foreign regulatory authorities or notified bodies. It explains the requirements to perform a verification process and how the MDA approves conformity assessment certificates (*IDDM*, Nov. 25, 2015).

The guidance on declaration of conformity follows the release of a document earlier this year on good refurbishment practices for medical devices.

The document names the steps to take when considering refurbishing a medical device, such as its type, configuration, condition, age, upgradeability and phase in its life cycle. The document provides a description of the activities needed to select what medical devices should be refurbished, as well as the information and resources involved in each step.

In addition, the document details the activities and resources needed for dismantling, packaging and transporting these medical devices.

The document notes that some countries have banned the import of used medical equipment, because a number of devices have not been maintained per the requirements of the OEM. "These bans usually fail to distinguish between high-quality refurbishment to the original manufacturer's specifications and second-hand equipment of undefined quality, with the effect that patients may be denied access to the safe and economical medical device they need," according to the document.

Read the good refurbishment practice guidance here www.fdanews.com/03-16-MDBGRPMD.pdf and the declaration of conformity guidance here: www.fdanews.com/03-16-MDBDOC.pdf.
— Elizabeth Hollis and Jonathon Shacat

BRIEFS

FDA Warns of Device Interference Risks

The FDA is warning of reports that breast tissue expanders with magnetic ports may interfere with implantable cardioverter-defibrillators or pacemakers. The interference causes the ICD or pacemaker to enter "magnet mode." ICDs in magnet mode will not deliver life-saving shocks or anti-tachycardia pacing therapy, which can be life-threatening to the patient if a dangerous abnormal heart rhythm were to occur. When a pacemaker enters magnet mode, the device continuously paces without sensing the patient's own heart rhythm, which can result in symptoms such as irregular heartbeats, abnormal heart rhythms, or rarely, more serious patient harm. The agency says there is a very small population at risk, as it is generally uncommon for patients with an ICD or pacemaker to have breast reconstruction. Read the letter here: www.fdanews.com/03-16-FDAWarning.pdf.

Australia's TGA Issues EpiPen Alert

Australia's Therapeutic Goods Administration is warning of discrepancies on batch numbers and expiration dates for some EpiPen adrenaline autoinjectors produced by Alphapharm. TGA is urging users of the product to check that the expiry date on each EpiPen device is the same as that on the carton, following reports from pharmacies in a small area of Victoria. Read the alert here: www.fdanews.com/03-16-TGAAlert.pdf.

Work Starts on Varian's Brazilian Facility

Executives, government officials, clinicians and partners gathered for a groundbreaking ceremony celebrating Varian Medical System's proposed 50,600-square-foot facility in Jundiai, Brazil. The facility — which is expected to be completed in the second half of 2017 — will include a radiotherapy training center, demonstration rooms, manufacturing, warehousing and radiotherapy equipment servicing, the company says. The new facility is part of a partnership between Varian and the Brazil Ministry of Health to improve access to radiotherapy treatment in Brazil and across Latin America.

Roche Wins CFDA Approval for Test

Switzerland-based Roche has gained approval from the China FDA for its CINtec PLUS Cytology test, intended to enhance the detection of human papillomavirus. The approval was based on a study that demonstrated "greater overall performance of combined sensitivity and specificity" of the CINtec PLUS Cytology test in determining which women are more susceptible to developing cervical cancer versus pap cytology, according to the company. The test is now available in China, Europe, Asia, Latin America and Canada.

Hitachi, Redlen to Develop System

Hitachi Medical Corporation has entered into a partnership with Canadian devicemaker Redlen Technologies to jointly develop a direct conversion semiconductor x-ray detector module necessary for new photon counting computed tomography systems, the companies announced. The companies will collaborate to create a multi-energy PCCT semiconductor detector module, with Hitachi exploring diagnostic applications. Redlen manufactures high resolution cadmium zinc telluride semiconductor radiation detectors.

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Cybersecurity, Privacy and Security Guidance for Medical Device Manufacturers

With electronic medical devices capable of logging and storing more and more data on device use and patient health, cybersecurity risks from medical devices are growing. Even the FBI recently warned the industry that this will create a rich environment for cybercriminals to exploit.

Cyberattacks on medical devices can compromise not only the safety of patients, but also the security of hospitals and healthcare networks.

What can you do now to prepare? Order **Cybersecurity, Privacy and Security Guidance for Medical Device Manufacturers** from FDAnews. It'll give you what you need to deal with cybersecurity risks and HIPAA/HITECH compliance, including:

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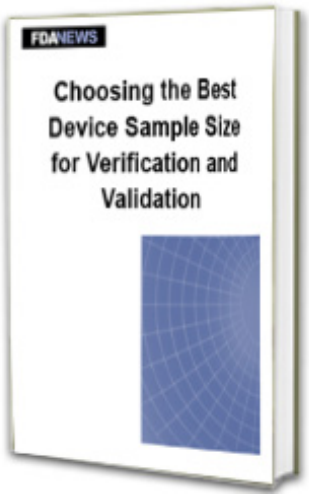

Choosing the Best Device Sample Size for Verification and Validation

If you're like many manufacturers, you understand the essence of the *21 CFR 820.30* requirement: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. And, like many manufacturers, you've probably had trouble for years determining exactly how many units of a product you should test to satisfy the FDA.

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