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IN THIS ISSUE

Congress Passes Two-Year Suspension On Medical Device Excise Tax, Again

The Affordable Care Act's widely unpopular medical device excise tax is off, again, for now.

Congress passed a stopgap bill for federal spending through Feb. 8 — after a 3-day government shutdown due to a lack of votes in support of the legislation — that includes the second two-year suspension on the 2.3 percent device excise tax.

The tax was enacted in 2013 as a mechanism to pay for other ACA provisions. It received its first temporary moratorium, with bipartisan support, under the Consolidated Appropriations Act of 2016 and came back into effect on Jan. 1.

The new two-year suspension had not been included in the original version of H.R. 195, which became law Jan. 22 — just a week before the first payments on the tax were going to be due.

The on-again, off-again device tax saga continued with industry voices getting louder, stressing to Congress that reenactment would not just hinder innovation efforts and job creation, but also impact access to medical technologies.

(See **Tax**, *Page 2)*

Czech Republic to Revamp Reimbursements, Launch EU Regulations Panel

The Czech Republic is revamping its medical device reimbursement system and preparing for implementation of the new European device regulations.

The country's system for reimbursing for the use of medical devices is failing in that it is based on codes provided by health insurance companies, the Ministry of Health said in a Jan. 22 announcement. It intends to introduce a new reimbursement system this year through an amendment to its Public Health Insurance Act of 1997, and have it come into full force by Jan. 1, 2019.

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Tax, *from Page 1*

Industry associations have applauded the recent efforts to at least provide more time for those required to begin making the semi-monthly payments. Prior to the enactment of the stopgap bill, the U.S. Internal Revenue Service notified devicemakers of a decision with the Department of Treasury not to enforce fines until the fourth quarter, due to the "short time frame between the end of the moratorium period and the due date of the first deposit" (*IDDM*, Jan. 22).

Now, the device tax is further suspended through 2020, though the real push has been for a full, permanent repeal of the tax.

Despite bipartisan support for a permanent repeal, industry has faced a continued struggle to get the issue on the list of priorities for Congressional leaders, Medical Alley Association President and CEO Shaye Mandle told *FDA*news.

The uphill battle was made harder by with having to adapt to a new administration, Mandle said, adding that while it is "huge to the industry, it is still small in the entire federal budget."

Political Uncertainty

"I know in the mix of everything else, people were forgetting our folks," Mandle said. "But a lot of members of Congress felt that this did need to be dealt with immediately."

Why provide another suspension, rather than a permanent repeal? Mandle believes a second suspension versus a permanent repeal, and two years versus something broader was "the least controversial way to solve an immediate problem."

The discussions for or against the device tax have not been about the merits of the tax, but rather how else the ACA is going to receive needed funding, Mandle added. According to CBO estimates, the device excise tax was worth $19.6 billion over ten years as of last September.

Still, devicemakers were making major decisions around the uncertainty of the fate of the tax that would have a substantial impact on their bottom lines. For example, one of the large, Medical Alley member companies froze internal hiring in anticipation of the tax's return.

Another mid-to-large company made plans to cut its R&D spending by 14 percent after this had been increased by more than 4 percent the year prior while under the assumption that the tax was not going to return.

These larger companies had the "quality infrastructure to pay the tax in the past," Mandle said, adding that smaller member companies were having to decide between hiring engineers to inch closer to profitability or tax administrators who would just be for compliance and not add value.

These were the stories shared with Congressional leaders as real-life examples of the tax's impact that ultimately helped get the second suspension, according to Mandle.

Renewed Push

Medical Alley anticipates that Congress will take up and resolve the tax by year's end. If not, addressing this would become the association's top priority for early 2019, though the goal would not be to have yet another suspension.

What's going to be different this time? Industry associations like AdvaMed, the Medical Device Manufacturers Association and Medical Alley, are going to increase their efforts, spending more time and resources getting the message across to those members of Congress "who don't have a Medtronic plant in their backyard and may not be thinking about this," Mandle said.

He believes the approach will be more consistent and engaged this time, targeted at every member of Congress. It will also focus on the people who would be impacted by constraints on medical technology.

Members of Congress need to understand that "this is truly a national issue, not just a jobs issue in a few places like Minnesota that really do have dependency on the industry," Mandle said. "It's an important part of the overall healthcare conversation. If we're trying to get to lower costs and better outcomes, medical technologies is an important part of that." — Ana Mulero

IMDRF Updates Device Safety and Performance Assessment Guidelines

The International Medical Device Regulators Forum released new guidance to help global regulators, conformity assessment bodies and industry assess whether a medical device conforms to regulations in each jurisdiction.

The updated guidelines on the essential principles of safety and performance of medical devices and in vitro diagnostics (IVDs) seek to harmonize documentation and procedures to support global regulatory convergence.

IMDRF said the guidance provides benefits in establishing an economic and effective approach to the control of medical devices in the interest of public health, while at the same time striking a balance between the responsibilities of regulatory authorities to safeguard public health and their obligation to avoid placing unnecessary burden on manufacturers.

The guidance describes fundamental design and manufacturing requirements that should be considered throughout the lifecycle of medical devices and IVDs. It lays out 14 essential principles that apply to all medical devices and IVDS, and it separates additional principles that apply to each category.

At the top of the list are general requirements that devices and IVDs perform as intended by the manufacturer and are suitable for their intended use. IMDRF considers quality system requirements and risk management principles as part of a continuous process of evaluation.

Clinical evaluation is not always required for devices, but when it is, that data should establish a favorable benefit-risk evaluation and follow good clinical practices in protecting human subjects, IMDRF said.

Devicemakers should pay particular attention to the choice of materials and substances used in terms of possible toxicity and the impact of manufacturing processes on material properties. They should conduct modeling research documenting mechanical properties of materials used, surface properties and confirm that the device meets chemical and physical specifications.

Sterility, packaging, and microbial contamination are covered at great length — and the guidance includes principles for packaging to avoid degradation and maintaining appropriate storage and environmental conditions.

If a device or IVD is to be used in combination with other devices or equipment, the entire combination, including the connection system, should be safe and not impair the performance. Any known restrictions on use need to be indicated on the label.

Particular attention should be paid to removing and reducing risk, including:

- Risk or injury to the users with respect to physical and ergonomic features;
- Risk of user error;
- Risks associated with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, radiation, pressure, humidity, temperature, etc.;
- Risks associated with using the device or IVD when it comes into contact with materials, liquids and substances, including gases;
- Risks associated with the possible negative interaction between software and the IT environment within which it operates;
- Environmental risks from unexpected egress of substances from the device or IVD;
- The risk of incorrect identification of specimens/samples/data and the risk of erroneous results; and
- The risk of interference with other medical devices or IVDs.

IMDRF also suggests risk mitigation strategies for particular situations and environments, including incorporating materials that are biologic in nature or combination drug/device products.

Finally, the document discusses the importance of labeling and instructions for use, including the formatting and required content of the label.

The proposed document from the IMDRF Good Regulatory Review Practices Working Group, is open for stakeholder comment through April 18, 2018.

Read the IMDRF document here: www.fdanews.com/01-24-18-IMDRF.pdf.

Brazil's ANVISA Nixes Medical Device Importation Requirements

Brazil is looking to simplify market entry for foreign manufacturers of medical devices by getting rid of certain import requirements, including mandatory inspections at entry points.

The country's National Agency for Sanitary Vigilance will no longer require inspections of medical devices and in vitro diagnostic devices (IVDs) at import locations after receiving product clearance, according to newly released guidelines.

Other notable changes to the ANVISA importation guidelines expected to streamline the process include: a 30-day deadline for responding to queries, and exemption from authentication and signature recognition for sponsors using electronic signing and petitioning.

The guidelines also list required information on imported IVD products, such as the expiration date, batch number, and date of manufacture.
— Ana Mulero

Panel, *from Page 1*

There will be a risk of the medical device reimbursement system collapsing, and a significant increase in the cost of the public health insurance system, if legislative action is not taken, the Ministry of Health said.

Securing reimbursement from public and private health insurers has been a longstanding industry struggle, and this will be tackled by a newly established standing committee for categorization and reimbursement of medical devices.

The new committee is comprised of the Ministry of Health, the State Institute for Drug Control, patient groups, and industry associations, among several others. It held its first hearing last December and scheduled another for this month, with the goal of accelerating the amendment's preparation.

Meanwhile, the European Commission is introducing new regulations on medical devices and in vitro diagnostics (IVDs) , and the overhaul has prompted regulatory bodies across the EU to craft their own, unique strategies to implement the regulations properly and on time.

For example, the UK's Medicines & Healthcare products Regulatory Agency recently launched an online service for medical device and IVD submissions to provide greater transparency throughout the process, allowing submission of multiple products in bulk with a single fee, among other benefits, to facilitate the new regulations. It remains to be seen how Brexit will impact the implementation of the EU regulations (*IDDM*, Jan. 22).

The Czech Republic's Ministry of Health is taking a different approach. It will to set up a Working Group on the Preparation of the EU Regulation on Medical Devices and IVD, consisting of notified bodies, the Ministry of Industry and Trade, the Ministry of Health, and the State Institute for Drug Control, among others.
— Ana Mulero

FDA Warns Oregon Device Firm Over Failing to Respond to Inspection Issues

Biomodeling Solutions drew an FDA warning letter after it failed to provide written responses to nonconformities identified in a Form 483.

An FDA inspection of the dental medical device manufacturer's facility in Beaverton, Oregon — conducted from Aug. 21 through Sept. 11, 2017 — revealed GMP and medical device reporting nonconformities that the agency considers significant violations.

The GMP violations include a lack of written procedures for design control, CAPA actions, and complaint handling. The firm provided a copy of each of these procedures, but the FDA responded to each one by stating "due to a lack of a written response to this observation after the inspection, we are unable to assess the adequacy of implementation of the procedure."

The last two GMP violations cited in the warning letter relate to failing to establish procedures for document control and for employee training. For example, the firm provided an unreviewed and unapproved document to dental laboratories for the manufacturing of its devices.

Biomodeling Solutions was also found to have violated the Medical Device Reporting regulation at the time of the inspection as it had not developed procedures that "provide for timely and effective identification, communication, and evaluations of events that may be subject to MOR requirements," the FDA said.

The agency also requested a meeting with the firm's president, Gurdev Dave Singh, to discuss other concerns, including promotional and advertising claims, as well as intended use and device modifications, regarding its Daytime Nighttime Appliance and its mandibular Repositioning Nighttime Appliance devices.

Read the Biomodeling Solutions warning letter here: www.fdanews.com/01-25-18-BioModelingSolutions.pdf. — Ana Mulero

Immunostics Draws 483 for Complaint Handling, Procedural Issues

The FDA cited Immunostics over CAPA procedure issues, inadequate complaint handling, calibration deficiencies and other problems at the firm's Eatontown, New Jersey facility.

During a November 2017 inspection, the FDA investigator found that numerous CAPA procedures were either not established or not followed adequately.

The agency official also found inadequate training in procedures to correct or prevent recurrences of nonconformities or quality system issues. Employees had been marked as properly retrained after committing a violation, but the retraining had not been documented.

The facility's medical device reporting and product recall procedures did not define the procedure for filing electronic reports, only including provisions for submitting hardcopy adverse event reports to the agency. In addition, product performance complaints the firm received had not been entered into its complaint handling system.

The facility also lacked adequate design change procedures. Specifically, it had not been requiring that design changes be validated.

Two instances of failure to routinely calibrate facility equipment were noted by the agency as well.

Read the Immunostics Form 483 here: www.fdanews.com/01-25-18-immunosticsinc483.pdf. — James Miessler

FDA Flags Validation, Complaints, DHRs at Japanese Device Facility

An FDA inspection at a medical device facility in Akita, Japan revealed nonconformities with process and software validation, as well as complaint handling and device history records.

The investigator who visited the Tanita Corporation of Akita facility last June found at least two processes had not been validated, one of which involved final device assembly. Another process lacked protocols for ensuring that it was validated with "a high degree of assurance" and "capable of producing consistent results," the investigator wrote in a Form 483.

In addition, the firm failed to provide any evidence of validating the intended use of the software it had been using for documenting and updating nonconformities, data analysis, supplier management, and training records. The software had not been validated to ensure it "can prevent unauthorized changes from being made to the data," the investigator said.

Customer complaint handling was also an issue. The reviewed complaints had not been processed in a timely manner, or evaluated to determine whether the events described should have been reported to the FDA.

For example, out of two complaint investigations that had been initiated in August 2014, one was not closed until May 2017 while the other had yet to be closed at the time of the FDA visit.

Several of the firm's devices in the U.S. had been replaced due to reasons such as "Failed load cell," "No calibration," and "Failed SW Membrane" — all of which "represent possible complaints, but were not reviewed, evaluated or investigated by the firm," the investigator said.

Inefficiencies with the firm's management of device history records were also flagged. The records were found to be incomplete, missing required information, such as primary identification labeling for each production unit and rework activities.

Read the Tanita Form 483 here: www.fdanews.com/01-25-18-tanitacorpakita483.pdf. — Ana Mulero

FDA Drops Biennial Inspection Requirement for Biologics

The FDA issued a direct final rule removing the biennial inspection requirement for biologics production facilities registered as medical device establishments and adopting a more flexible, risk-based approach to how often the agency will conduct inspections.

The rule will become effective 135 days after its Jan. 26 publication in the Federal Register, unless there are significant adverse comments from stakeholders.

The agency said the current biennial inspection requirement for biological product facilities is considered outdated, since the Food and Drug Administration Safety and Innovation Act in 2012 (FDASIA) established a risk-based inspection schedule.

The agency will also remove provisions regarding notices of inspection and timing of pre-licensure re-inspections of biological product facilities, as they are considered outdated and unnecessary.

The FDA issued the amendments in the form of a direct final rule because it believes the rule is non-controversial and will not attract significant adverse comments. Because the rule does not impose additional regulatory burdens, the agency expects no compliance costs and minimal economic impact.

The agency issued a companion proposed rule that would introduce the same changes, just in case the direct final rule hits a snag and has to be withdrawn.

Read the direct final rule here: www.fdanews.com/01-25-18-Biological.pdf.

Read the companion rule here: www.fdanews.com/01-25-18-Biological2.pdf. — James Miessler

APPROVALS

ZOLL Wins FDA Nod For Full Line of Defibrillators

ZOLL Medical received premarket approval from the FDA for its entire line of defibrillators, including the R Series and X Series monitor/defibrillators, as well as the AED Pro and AED Plus automated external defibrillators.

All of the devices feature the company's Rectilinear Biphasic waveform and Real CPR Help technology.

OrthoXel Apex Tibial Nailing System Achieves FDA Clearance and CE Mark

Orthopedic trauma devicemaker OrthoXel, achieved both FDA 510(k) clearance and a CE Mark for its Apex Tibial Nailing system.

The system has multiple locking modes, including the standard cross-locking and dynamization locking, to enable surgeons to tailor the fixation to patients' individual health needs.

The device "offers surgeons the greatest range of locking options of any intramedullary nail on the market, allowing tailored patient care with a simple and intuitive surgical procedure," the company said.

FDA Clears First-of-its-Kind Robotic Imaging System

Massachusetts devicemaker Medrobotics achieved 510(k) clearance for its Flex Robotic System.

The system includes two working channels to accept a wide variety of surgical and interventional instruments. It is the "world's first and only" flexible transabdominal and transthoracic robotic scope, the company said.

The system provides robot-assisted visual imagining during general, gynecological and thoracic surgical procedures, enabling minimally invasive treatments.

Viz.ai Gets CE Mark for Artificial Intelligence-Powered Stroke Care System

Viz.ai, a San Francisco-based developer of artificial intelligence imaging and workflow software, obtained a CE Mark for its ContaCT.

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The device conducts automatic analyses of brain CT scans using deep learning algorithms, and sends notifications to specialists of large vessel occlusions.

Early intervention is critical in stroke treatment, and ContaCT is the first AI-based "direct-to-intervention" system, the company said.

International Biophysics' Disposable Heart Pump Achieves FDA Clearance

The FDA cleared the FloPump 32 centrifugal disposable heart pump manufactured by International Biophysics.

The single use pump is intended for use with the company's Maquet RotaFlow console.

The product received a CE Mark in Europe and ANVISA clearance in Brazil last year.

Honda Snags CE Mark For Walking Assist Device

Tokyo-based Honda Motor received a CE Mark for its Honda Walking Assist Device.

The device is intended to use for walking training and rehabilitation.

The company worked with the Japan-based third-party ISO certification organization, Japan Quality Assurance Organization, and the German-based third-party certification organization, TÜV Nord Cert, to obtain the CE Mark.

FDA Clears Centric Medical Cannulated Screw System

The FDA issued 510(k) clearance to Life Spine's Centric Medical division for its Cannulated Screw Internal Fixation System.

The multi-component, titanium alloy system is intended for use in foot and ankle reconstruction procedures. It provides a variety of diameters and lengths with head and headless designs,

Entegrion Gets CE Mark for Portable Blood Coagulation Monitoring System

Entegrion received CE Marking for its portable blood coagulation monitoring system.

The system is indicated for use in clinical settings to obtain viscoelastic measurements of patients' whole blood coagulation and hemostasis.

It also "offers a near patient and fully automated whole blood result without the need for sample pre-treatment reagents or sample transfer to the clinical laboratory," the company said. "Within minutes, a clotting result will begin to be displayed at the patient's side."

Hologic Wins FDA Nod For Hepatitis B Assay

Hologic received PMA approval for its Aptima HBV Quant Assay for measuring hepatitis B viral load on its automated Panther system.

The assay joins two other Hologic viral load assays for use on the Panther system — one for human immunodeficiency virus and one for hepatitis C virus.

They assays all use the company's proprietary real-time transcription-mediated amplification technology and provide sample-to-result automation.

Mesa Biotech Snags CE Mark For 'Palm-Sized' Testing System

San Diego-based molecular diagnostic company Mesa Biotech received CE Marking for its Accula System.

The palm-sized, reusable dock with disposable test cassettes can provide test results in about 30 minutes using samples from nasal swabs.

Mesa Biotech plans on launch its Flu A/Flu B test first in the European market.

FDA Clears Diazyme Vitamin D Assay

The FDA cleared Diazyme Laboratories' EZ Vitamin D assay for marketing.

The assay is for use on validated clinical chemistry analyzers and provides fully automated results.

It also "enables clinical laboratories of almost any size to run Vitamin D tests in house without the need for expensive specialized instrumentation," said Chong Yuan, the company's managing director.

FDA Reports Underused Third Party Review Program for 510(k)s

Under the FDA's third party review program, there is only one accredited organization that has completed at least five 510(k) submissions, despite being launched nearly two decades ago.

Out of the seven organizations currently in the program, Regulatory Technology Services has been the most active so far, with a total of 11 510(k) submissions accepted by the FDA, according to a new CDRH report outlining performance metric results as of Q1 2018.

The other six — AAB, the Center for Measurement Standards of Industrial, the New York State Department of Health, the Nordic Institute of Dental Materials, the Third Party Review Group, and TUV SUD America — collaborated with agency staff in the review of another 7 510(k) submissions.

Under the latest reauthorization of MDUFA, the agency only committed to providing complete performance reports on organizations with at least five 510(k) submissions.

Third party submissions that received final MDUFA IV decisions, which can either be of substantial or non-substantial equivalence (SE or NSE) to an existing medical device, were all made within 30 days, as required by law.

The agency made a SE determination on 44 percent of submissions.

The average total time — from the date a third party submission is received to the final-decision-date — is 80 calendar days, according to the report. Data on all other performance metrics, such as third party hold time, are also included. These metrics are used throughout the four stages of a third party 510(k) submission process.

Only the manufacturers of eligible devices, which are listed on the FDA website, have the option of electing accredited third parties to review 510(k) submissions under the program — created by the FDA Modernization Act of 1997.

The program was launched in 1998 with the goal of improving the efficiency and timeliness of the 510(k) process.

Recent legislation, including MDUFA commitments in the FDA Reauthorization Act of 2017, has brought the agency increasingly under pressure to make better use of allocated resources.

In addition to providing quarterly updates on the program, MDUFA IV also included third party review commitments from the FDA to establish a plan for eliminating repetitive reviews and to issue draft guidance on the re-accreditation of third parties by the end of fiscal year 2018.

The FDA also intends to expand the scope of the program by seeking greater authority over how it is tailored.

An expansion would allow for the inclusion of "some product codes that require clinical data and to remove product codes from eligibility when appropriate," according to the 2016 report outlining MDUFA performance goal and procedures from FY 2018 through 2022 states.
— Ana Mulero

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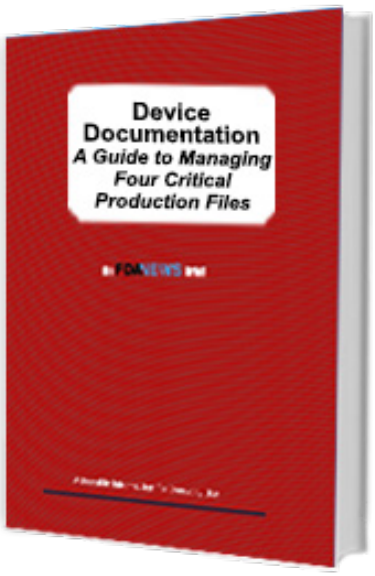

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