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IN THIS ISSUE

Senate Panel Gives Blessing To FDA Appropriations Bill

The Senate Appropriations Committee has voted 28-2 to pass a bill that would grant the FDA $4.6 billion in total funding, an increase of $116 million over FY 2015.

Among the provisions is $134.5 million in medical device user fees, the same as provided for in the House version. It also provides for $424.6 million in appropriations — slightly more than what is included in the House version.

The $148.3 billion measure provides the agency with $2.6 billion in discretionary funds, $107 million less than what was sought in the President Barack Obama's budget request. The funding numbers are in line with what the House Appropriations Committee agreed to July 8.

The bill also includes a $3 million increase to combat antibiotic resistance — $12 million less than the budget request — as well as a $2 million increase for the Precision Medicine Initiative, which was $8 million less than requested.

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FDA Updates Thinking on MRDD Premarket Submissions

The FDA has revised its expectations on what information manufacturers should include in premarket submissions for magnetic resonance diagnostic devices.

In draft guidance issued July 14, the FDA says it is updating its recommendations on MRDD applications to reflect changes in standards and legislation since the 1998 release of guidance on the topic.

Equipment affected by the draft document includes nuclear magnetic resonance imaging systems, nuclear magnetic resonance spectroscopic systems and magnetic resonance specialty coils identified by product codes LNH, LNI and MOS, respectively.

The document provides manufacturers with a detailed overview of what they should include in their applications' device descriptions. Specifically, sponsors should describe and provide a diagram of how

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The White House introduced the PMI initiative earlier this year with the intent of accelerating biomedical discoveries. The initiative is designed to approach disease treatment and prevention by taking individual variability in genes, environment and lifestyle of each person into account.

While praising the committee's work and voting in favor of the measure, Sen. Barbara Mikulski (D-Md.), the top Democrat on the committee, said "the bill did fall short."

She highlighted the efforts of Sens. Jerry Moran (R-Kan.) and Jeff Merkley (D-Ore.), saying in a prepared statement that they "have done a good job with the spartan, sequester-based allocation. But the bill is $1.1 billion short of the president's request and $65 million below the fiscal year 2015 funding level."

In her statement, Mikulski stressed that the FDA needs more funding to remain "the gold standard for drug, medical device and food safety." Merkley agreed, and while he praised the committee's work, noting that "tough choices were necessary," he said more needed to be done.

He offered an amendment that, among other things, would have boosted FDA funding by $103 million. His amendment also included $12 million to combat antibiotic resistance and $8 million for the PMI. It failed in 14-16 in a vote that followed party lines.

The bill will now go on to the full Senate for consideration. The House version, H.R. 3049, was introduced in that chamber July 14. The bill, S. 1800, is available at www.fdanews.com/072015-senate-appropriations.pdf. — Elizabeth Hollis

MRDD, *from Page 1*

each principal component interconnects, to include the following: the magnet, gradient system, radio-frequency system, RF coils, specific absorption rate management and control system, imaging protocols, image processing modules and software.

Testing

Manufacturers may use agency-recognized standards to show substantial equivalence to a predicate device in their premarket submissions. Standards from the National Electrical Manufacturers Association, International Electrotechnical Commission, UL (Underwriters Laboratories), International Organization for Standardization, Association for the Advancement of Medical Instrumentation and American National Standards Institute may prove particularly useful in assessing safety and performance, the agency notes.

In terms of performance testing, submissions should document the following imaging quality metrics: signal-to-noise ratio, geometric distortion, image uniformity, slice thickness and spatial resolution. Although no standard test exists for spectroscopy performance, the FDA recommends that manufacturers assess spatial localization accuracy, spectral resolution, signal-to-noise ratio, solvent suppression, decoupling and spectral data processing.

When assessing safety, manufacturers should test the acoustic noise, gradient-induced electric fields, radio frequency energy deposition, and biocompatibility and flammability of patient-contacting materials.

The FDA also recommends that manufacturers provide sample clinical images for all of the coils, pulse sequences and imaging protocols described in the submission in a Digital Imaging and Communications in Medicine, or DICOM, format. "FDA requests that all images be accompanied by a description of the target anatomical site, scan parameters employed and total imaging time," the guidance says.

For the user or operator's manual, the FDA recommends the manufacturer address the contraindications, warnings, precautions and general risks associated with the device, and that it includes the following statement: "Caution: Federal law restricts this device to sale by or on order of a physician."

Interested parties may comment on the draft guidance until Oct. 13. To read the draft guidance, visit www.fdanews.com/072015-MRDD-draft-guidance.pdf. — Elizabeth Hollis

Devicemakers Forge Program To Accredit Global Suppliers

A group of devicemakers is developing a supplier accreditation program to get a better handle on their supply chains.

The FDA does not require suppliers to be qualified — that responsibility remains in the hands of devicemakers. However, as supply chains become more convoluted with outsourcing, that process has become more difficult to manage.

Called MedAccred, the program qualifies each of the critical processes in the supply chain that affect quality, says Joe Pinto, COO at the Performance Review Institute, a nonprofit trade group that administers and manages the accreditation program.

The program can be compared to the Rx360 program in the pharmaceutical space in its mission and scope. The consortium of drugmakers, suppliers and auditorscame together to develop global quality systems and processes to ensure product quality and authenticity throughout the supply chain. That group now has 25 manufacturers, including most multinational pharmaceutical companies.

Getting the Word Out

So far, only three device companies have subscribed to the MedAccred program. Subscribers are original equipment manufacturers and pay $90,000 to join. The price drops to $60,000 the second year and will drop more as other OEMs subscribe, Pinto says. Suppliers pay for the audit and accreditation.

These manufacturers all can benefit from the service, as they can learn about supply chain issues early. OEMs help set the industry standards via consensus and devise auditing checklists for each critical manufacturing process.

A group of 12 OEMs is involved with developing criteria for five critical areas initially: electronic circuits (PCBA), cables and harnesses, heat treating, sterilization and welding.

Audits are conducted by subject matter experts who have roughly 25 years of experience. PRI administers the program and handles nonconformances with suppliers to make sure CAPAs are conducted. If there are significant findings uncovered during an audit, all companies that use that supplier will be notified and appropriate action evaluated.

The MedAccred program was based on the Nadcap accreditation system for the aerospace industry, which is also administered by PRI, a nonprofit association.

The Federal Aviation Administration and NASA recognize Nadcap as an acceptable means for manufacturers to manage their supply chains, and the hope is that the FDA will support the MedAccred program once it gets going, Pinto says.

Companies Subscribe

Philips HealthTech was one of the first manufacturers to subscribe to the MedAccred program, along with Johnson & Johnson's Depuy and Stryker, says Ravi Nabar, Philips' senior director of supplier quality management. He has been active with the MedAccred program since its inception and served on the external subcommittee to present the program to stakeholders, including AdvaMed and the FDA.

"There has been discussion with FDA about inspecting firms less if they are MedAccred subscribers, but there have not been any assurances," Nabar tells *IDDM*.

He says Philips will ask its critical suppliers to become accredited. The thinking is that once the program gains a critical mass of subscribers, manufacturers will have more clout to demand accreditation of their suppliers. But that will take time.

"There are very few mandated technical standards in the medical device industry," Nabar says, "so this program helps at the process level

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to have agreement among industry stakeholders, and it provides clarity to suppliers."

Different suppliers will also have different checklists depending on the technology and type of commodity, and the critical control points will be different for each area.

Heat treater Solar Atmospheres was the first supplier to be accredited under the program. The company processes medical devices, including implantable joints, battery cases for pacemakers and other surgical tools. As a Nadcap supplier, the company already had much of the technical criteria in place before it was audited.

Ed Engelhard, corporate quality manager for Solar Atmospheres, works with about seven to eight devicemakers as well as aerospace manufacturers. He says the device industry is less transparent than aerospace.

"In the aerospace industry, I know exactly whose product I am working on at all times because everybody above me in the supply chain is required to pass that information along," Engelhard says.

"It's a very rigorous process under which the auditor may ask 500 to 1,000 questions," he explains, noting that International Organization for Standardization or quality system audits are more general in scope because they cover different facets of the business as they relate to processes and recordkeeping.

"The single biggest benefit to a supplier," Engelhard says, "is that in order to answer the audit criteria, you will have to establish very detailed and well thought out procedures so you know you will meet the requirements no matter when an auditor shows up." — Tamra Sami

FDA Starts MDUFA Cycle By Gathering Feedback

Top FDA officials last week listened to stakeholder feedback on what has worked well and what can be improved in the Medical Device User Fee Amendments.

"I do see clear signals that this program appears to have worked," said Acting FDA Commissioner Stephen Ostroff, adding "it's clear more can be done and should be done."

Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, pointed to some of the successes under MDUFA, including a 30 percent decrease in the number of pending 510(k) submissions since 2010 and a growing number of presubmission meetings with the agency to address potential problems and concerns early in the process. "It's clearly very popular with industry," he said.

Stakeholder Input

Held July 13 at the agency's White Oak campus in Silver Spring, Md., the meeting featured representatives from the agency, industry, academia, healthcare and patient and consumer groups and marks the first step in the development of MDUFA IV.

Participants identified improving FDA reviewer training and enhancing postmarket data collection as two key areas upon which CDRH should focus. Megan Hayes, director of regulatory standards strategy at the Medical Imaging & Technology Alliance, said "some troubling trends remain in the FDA review process," including the burdens created by answering reviewer requests for more information.

"The medical imaging industry is extremely important to healthcare," she said, emphasizing that many complex technologies come to market at a result of advancements in the field. It is essential to get new hires up to speed to prevent inconsistencies in reviews.

Emphasizing that she has seen significant progress — including improved interactions between industry and FDA staff and useful quarterly meetings with the agency — Janet Trunzo, trade group AdvaMed senior executive vice president, agreed that regulatory submission process was reviewer-dependent. While acknowledging that review times for applications have improved, she sees the assessment of combination products as one area in which progress is needed.

Looking to the Postmarket

Josh Rising, director of healthcare at the Pew Charitable Trusts, was among those who stressed the need for robust postmarket data collection. He pointed to the pharmaceutical industry, which uses its user fees on postmarket surveillance and patient-reported information.

Speaking on behalf of the American College of Cardiology, Frederic Resnic said postmarket surveillance is underdeveloped. He noted that CDRH faces an uphill battle retaining clinicians and other content experts to help in this regard. He offered the expertise of professional societies, such as ACC, to help make advancements in this area.

Greg Daniel, fellow and manager for evidence development and biomedical innovation at the Brookings Institution, highlighted areas in which progress can be made in conjunction with MDUFA IV to enhance postmarket data collection. These include interoperability, unique device identification and the collection of clinically meaningful data.

Timeline

The public meeting kicks off a 30-day review period during which stakeholders may offer their input to questions in a *Federal Register* notice on the MDUFA meeting, said Malcolm Bertoni, the associate commissioner for planning and director of the office of planning in the Office of the Commissioner. Starting in September and lasting one year, the agency will hold monthly meetings with members of industry with an eye toward developing a draft set of MDUFA recommendations.

The agency will publish the draft recommendations for stakeholder feedback, and follow that with another public meeting. Ultimately, the FDA

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aims to pass a finalized version by Jan. 15, 2017, so congressional committees may work on it and pass it before MDUFA III expires on Sept. 30, 2017.

Ostroff noted that while efforts to pass 21st Century Cures and the upcoming presidential election could make the atmosphere spirited, he has full confidence MDUFA IV will benefit industry. — Elizabeth Hollis

Lens Makers May Resume GUDID Submissions

The FDA is giving labelers of intraocular lenses the green light to restart submissions to the Global Unique Device Identification Database after extending the deadline by one year over data concerns.

To ensure that IOL information in the GUDID database is meaningful, the agency is asking labelers to include descriptive information about their lenses — such as cylinder power, optical diameter and diopter. Doing so, the FDA hopes, will ensure there is enough variation between the device identifiers to differentiate between versions and models. IOLs are used after the natural lens is removed, typically after cataract surgery.

The FDA's recommendation comes after the agency granted labelers an extension from the original Sept. 24, 2014, UDI deadline for certain Class III devices, citing worries over the sheer volume of device identifiers that would be loaded into the database. Industry also expressed concern that many of the submissions would be virtually indistinguishable from each other.

The FDA received more information from industry and determined the labeling strategy being employed would lead to only a "relatively small number" of submissions to the GUDID. The notice reminds companies to submit the DI records by the Sept. 24, 2015, deadline. — Elizabeth Hollis

Malaysian Authorities Grant Reprieve on Device Registration

Malaysia's Medical Device Authority has extended the application deadline for medical device manufacturers to register their products in that country.

In an announcement posted to its website, the regulator says manufacturers have until June 30, 2016, to register their devices. The original deadline, which was set by the 2012 Medical Device Act, was June 30. With this new announcement, manufacturers that submit their applications within the year timeframe may continue to import, export and market their products, pending a positive determination from the authority.

Prior to the MDA's announcement, manufacturers that failed to take advantage of fast-track registration by June 30 would have had their products blocked from importation (*IDDM*, March 27). This registration option was available for devices approved for marketing in the U.S., EU, Canada, Japan or Australia. Manufacturers would then have to identify a conformity assessment body by July 1, 2018, and obtain a conformity assessment by July 1, 2020.

"Many foreign device manufacturers have not yet taken advantage of the expedited registration offered during the transition period," explains Ames Gross, president of Pacific Bridge Medical. "Since the new regulations are still evolving, obtaining accurate information on what needs to be done has not been easy. Although the registration process itself is not overly daunting, the numerous regulatory adjustments announced in the past year and the lack of clarification on some of the guidelines might have made it difficult for device companies to follow through with their application."

Gross adds that international companies may not have felt the need to exhaust their resources to conduct a last-minute registration for Malaysia. Regulatory affairs professionals must register their products in multiple regions, and Malaysia is a smaller market. "When Singapore offered a similar expedited registration process during their transition to mandatory registration requirements for medical devices a few years ago, many companies failed to take advantage of the opportunity then as well," he says.

To see the MDA announcement, visit www.fdanews.com/072015-malaysian-registration-extension.pdf. —Elizabeth Hollis

FDA Cautions Surgeons on Off-Label Use of Suture Device

Following 45 reports of serious adverse events, the FDA is cautioning healthcare providers about using a SentreHeart device in a procedure intended to prevent strokes.

SentreHeart's Lariat suture delivery device is a tool used to aid in soft tissue closure during surgery. Some surgeons have used the Lariat system off-label — along with three cleared associated SentreHeart devices — for closing the left atrial appendage, a pouch-like region in the left atrium, in patients with atrial fibrillation who have had trouble taking blood thinners. The agency has not evaluated the device for this indication.

In a safety communication, the FDA says it has identified six deaths and other serious complications connected to using Lariat and associated devices in this procedure, including laceration or perforation of the heart, complete LAA detachment from the heart, bleeding, low blood pressure and fluid collection around the heart and lungs. About 34 cases resulted in the need to perform emergency surgery.

Healthcare providers are advised to report any adverse events to the FDA and the manufacturer.

The safety communication comes less than a month after the company reported that the FDA had signed off on the Amaze clinical trial intended to evaluate the Lariat device for closure of the LAA as an adjunct to ablation in patients with persistent or longstanding persistent atrial fibrillation (*IDDM*, July 13). Currently, only Boston Scientific's Watchman LAA closure device is approved as an alternative to warfarin for stroke prevention. — Elizabeth Hollis

Cavidi Gets Loan to Advance HIV Monitoring Device

The European Investment Bank has provided a US $11 million loan to Cavidi, a Swedish biotech company, to help develop a next-generation testing device for HIV viral load.

The loan, which Cavidi applied for, is the first transaction through the InnovFin Infectious Diseases financial tool to fund high-risk projects. The tool was launched last month.

The InnovFin program, a cooperative effort between the EIB and the European Commission, has made more than US $26.3 billion available to support research and innovation by companies of all sizes across a range of industries. It is part of a broader seven-year effort, dubbed Horizon 2020, intended to boost research and development in the EU.

"With this first InnovFin Infectious Diseases loan, we confirm our commitment to providing easier access to finance, especially for higher-risk projects, in the medical sector," says Jonathan Taylor, EIB vice president with responsibility for lending in Sweden. "This is crucial to bridging the gap from pure research and development to commercially viable enterprises in Europe."

Cavidi intends to launch its testing technology next year for less sophisticated laboratories, including those in low- to middle-income countries hit hardest by HIV. The device was tested in the EU-funded project HIVIND, which conducted a randomized trial of two approaches to influencing antiretroviral treatment adherence in 600 HIV-infected patients in India.

Currently, the company has products in roughly 40 countries, with customers primarily in Africa and Southeast Asia.
— Elizabeth Hollis

Two Companies Fined In Defective Syringe Case

The UK's Medicines and Healthcare products Regulatory Agency has successfully prosecuted two companies it says supplied defective prefilled syringes whose use resulted in a diabetic patient's death in 2010.

Calea UK and its wholesaler Fresenius will pay about US $80,000 and $790,000, respectively, after pleading guilty to violations of the Medicines Act of 1968. The fines come as a result of an investigation into the death of Neil Judge, 58, who experienced organ failure after being deprived of insulin for more than 13 hours. The syringe he was treated with at a UK hospital was found to contain no insulin.

Fresenius Kabi was convicted for its role in a "medicinal failure" that was a "major contributing factor" in Judge's death.

Ongoing Problems

During an inspection of the joint Calea-Fresenius site in Runcorn following Judge's death, MHRA inspectors determined the facility lacked an effective quality management system. The quality problems led to improperly labeled solutions used to compound insulin. As a result, the syringes were filled with extra saline, rather than insulin.

In a separate incident, Calea was found to have manufactured prefilled syringes containing tobramycin, which is used to treat infections, with three times the prescribed daily dose of the drug. No one died as a result, although one cystic fibrosis patient reported a fizzing sensation following treatment.

"Fresenius Kabi Ltd and Calea UK Ltd are equally responsible for the medicinal failure that was a major contributing factor in the tragic death of Neil Judge, who was deprived of the vital insulin his body needed because of a serious manufacturing error," says Alastair Jeffrey, MHRA head of enforcement. "I hope this case serves as a clear reminder to others, as MHRA will not hesitate to take enforcement action when serious failings occur."

MHRA inspectors noticed problems at the Runcorn site two years before Judge's death. During a November 2008 inspection, they determined these problems were "major" — meaning they could result in a product that does not comply with the marketing authorization or they are a result of a sizeable deviation from EU good manufacturing practices.

However, no "critical" deficiencies — those that could result in patient harm — were found. It wasn't until the inspection following Judge's death that critical deficiencies were identified, including the lack of an effective quality management system.

The facility still had not remedied this problem by the time MHRA conducted a follow-up inspection roughly six months later.

In September 2011, following the tobramycin incident, inspectors identified additional critical deficiencies. In particular, they cited an issue with unlabelled syringes used during the processing of mother bags and intermediates. The facility began to clean up its act, and by January 2013, no critical or major deficiencies were found.

"Although a number of critical and major concerns have been recorded over the years, the latest inspections showed that satisfactory improvements have been made to processes and procedures," an MHRA spokesman tells *IDDM*.

"We will continue with our inspection regime to ensure these improvements are maintained — as is the case with any premise we enforce."

The spokesman said no further enforcement action is planned against the companies at this stage. He added that regulatory penalties are separate from criminal sanctions. The convictions do not have immediate license implications. — Elizabeth Hollis

BRIEFS

Medtronic to Buy RF Surgical Systems

Medtronic has agreed to acquire Carlsbad, Calif.-based RF Surgical Systems in a deal valued at about $235 million. RF Surgical has developed a system intended as an adjunct to manual counting methods to help prevent surgical sponges, gauze or towels from being left inside patients during surgery. Further details about the deal were not disclosed. It is expected to close in August.

Smith & Nephew Scoops Up DeOst Unit

UK-based Smith & Nephew has bought the trauma and orthopedics business of DeOst group, which has distributed the S&N's products in Russia since 2009. "This investment, in-line with our strategy to build our platform in the emerging markets, significantly boosts our local presence and prospects and will enable us to take advantage of market dynamics and better serve Russian customers," S&N CEO Olivier Bohuon said. The companies did not disclose terms of the transaction.

Thoratec Snags CE Mark for HeartMate PHP

Thoratec is planning a staged launch of its HeartMate percutaneous heart pump after winning CE mark certification. Approval was based on data from a U.S. clinical trial evaluating the system for high-risk percutaneous coronary intervention procedures, the company says. It will make the study data available later this year. The device features a catheter that can generate an average blood flow of four to five liters per minute following administration through percutaneous insertion.

Zethon Recalls Forceps in UK

Citing sterility issues, Zethon is recalling certain batches of a bipolar forceps in the UK, Ireland's Health Products Regulatory Authority says. Healthcare professionals are being advised to identify affected products, quarantine them immediately and return them to the manufacturer. Zethon, formerly known as Ross Electro-Medical, issued the field safety notice July 3. No incidents related to the product's use have been reported.

iCAD Launches New Cervical Applicator

Nashua, N.H.-based iCAD has launched a new cervical applicator for its Xoft Axxent electronic brachytherapy cancer treatment system. The applicator works by administering a precise dose of radiation to targeted areas of the cervix while minimizing exposure to healthy tissue, the company says. The Xoft system is FDA-cleared and CE-marked for treatment anywhere in the body, including for nonmelanoma skin, early-stage breast and gynecological cancers.

France, Mexico Sign Device Pact

Mexico and France have signed a three-year cooperative agreement allowing the countries to exchange regulatory information and expand patient access to safe, effective and high-quality medical devices. The agreement — between Mexico's Federal Commission for Protection Against Health Risks and France's National Agency for Security of Medicines and Health Products — was reached July 11.

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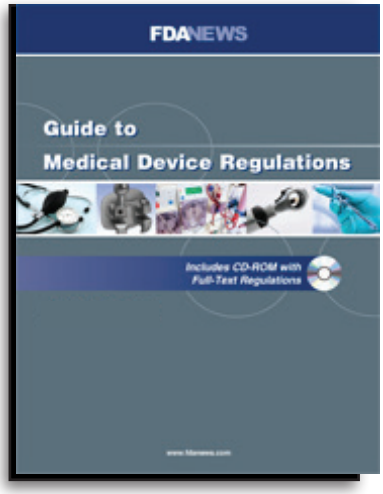

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