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U.S. Calls for Multistakeholder Group To Oversee Device Surveillance

The U.S. FDA is proposing a new multistakeholder entity to ratchet up device postmarket surveillance.

The National Medical Device Postmarket Surveillance System, or MDS, would oversee all device postmarket activities in the U.S. and allow the FDA to quickly identify poorly performing devices, facilitate device clearance, reduce postmarket data collection requirements for manufacturers and help healthcare providers and patients make better-informed decisions, according to a report released Feb. 23.

Total costs of running the program for the first five years would be between $200 million and $250 million, the report says. While some of the money could be generated by user fees and other private contributions, Congress would need to authorize additional FDA funds to put the plan into practice.

'21st Century Solution'

Under the proposal, devicemakers and other stakeholders would get access to postmarket information gathered from a variety of sources, including insurance claims, patient-generated reports, electronic health records, and device-specific and clinical care registries. Government proposals mandating device software interoperability would ease the data sharing, as would implementation of the unique device identification system. MDS would serve as a central contact point and manage data governance policies.

MDS "is a 21st century solution to an age-old problem," says CDRH Director Jeffrey Shuren, in announcing the plan.

The changes described in the report won't take place overnight. During the first two years, stakeholders would focus on developing a five-year implementation plan through fact-finding and pilot programs. Years three through seven would focus on strategic priorities, sustaining broad stakeholder participation and establishing system performance measures.

AdvaMed is still reviewing the report but supports the effort to improve postmarket oversight and the central role of UDI in

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establishing an effective MDS, says Janet Trunzo, senior executive vice president of technology and regulatory affairs.

The FDA organized the planning board and commissioned the report in 2012 as part of a five-point plan to improve device postmarket surveillance. Other key steps include establishing UDI, promoting the development of registries, modernizing adverse event reporting and developing new methods for evidence generation, synthesis and appraisal.

A multistakeholder planning board organized by the FDA's device center developed the proposal. The report, which was issued by the Brookings Institution's Engelberg Center for Health Care Reform, is available at www.fdanews.com/03-02-15-surveillance.pdf.
— Elizabeth Orr

Indian Devicemakers Worry Bill Will Legitimize Pseudo-Manufacturers

In an effort to protect local industry, Indian devicemakers are urging the government to tighten the definition of "manufacturer" in this year's Drugs & Cosmetics Amendments Bill to ensure that importers and multinationals don't misappropriate the term.

The draft bill, released by the health ministry on Dec. 31 (*IDDM*, Jan. 9), defines a manufacturer as "a person who himself or through any other person on his behalf manufactures" the product.

That language is ambiguous and misleading, says Rajiv Nath, forum coordinator for the Association of Indian Medical Device Industry, who fears importers and MNCs will use the loophole to label their products "Made in India."

The group suggests changing the definition to "the person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name."

Not modifying the definition would defeat the purpose of Prime Minister Narendra Modi's "Make in India" vision, since importers could simply claim to be manufacturers by changing the labeling and packaging requirements, Nath argues in comments on the bill.

AIMED calls for more precise definitions for a number of other concepts as well. For example, a "new medical device" should mean one not approved by India's central licensing authority or any other international regulatory, the group says. Other definitions that need clarification include "accessories," "clinical evaluation," "custom-made device," "quality management system" and "notified body," AIMED says

The group also suggests renaming the bill the Medical Devices & Patient Safety Bill 2015, and calls for a new Indian Healthcare Products Regulatory Authority with distinct divisions for devices, drugs and cosmetics.

Threat of Prosecution

Meanwhile, a provision in the bill would give the Central Drugs Standard Control Organization discretion in prosecuting clinical investigators — a bad idea, according to Mark Barnes, a partner at law firm Ropes & Gray.

The threat of criminal prosecution will only make skilled physicians in India more reluctant to conduct clinical trials, thus denying Indian patients access to cutting edge experimental therapies and further damaging this sector of the national economy, he tells *IDDM*.

Nath calls the measures — which include arrest and imprisonment for procedural errors and manufacturing defects — draconian and says they also won't help the "Make in India" vision.

Criminal action should be reserved for nonlicensed manufacturing or, in rare cases, licensed manufacturers who willfully and knowingly flout multiple rules for safeguarding the interests and safety of consumers, he says.
— Jonathon Shacat

Device-Linked Superbug Outbreak Sparks Call for U.S. Hearings

A U.S. lawmaker is demanding hearings on the FDA's failure to address the risk that reused endoscopes could spread antibiotic-resistant "superbugs."

The call stems from a Feb. 19 FDA safety communication urging healthcare providers to be sure that they follow manufacturer reprocessing instructions carefully take care in reprocessing and reusing duodenoscopes — flexible, lighted endoscope tubes used to drain fluids from blocked pancreatic and biliary ducts. The specific design of the duodenoscope, which includes moving parts with microscopic crevices, makes it particularly hard to clean, the agency said.

The agency received reports of 135 cases of suspected superbug transmission related to duodenoscopes between January 2013 and December 2014, and said it was possible there were other cases that were not reported. Seven patients have already died in an ongoing superbug outbreak at UCLA Ronald Reagan Medical Center in Los Angeles.

Rep. Ted Lieu (D-Calif.) asked the Committee on Oversight and Government Reform to hold hearings, citing similar outbreaks in recent years in states like Pennsylvania, Illinois and Washington. He said the FDA has known of the connection for at least two years, and manufacturers were aware of the design concerns.

Meanwhile, the FDA is encouraging hospitals to adhere to manufacturer cleaning instructions on duodenoscopes and implement quality control programs for reprocessing the devices. The agency is also working with the Centers for Disease Control and Prevention on ways to reduce the duodenoscope infection risk.

Pentax, Fujifilm and Olympus market duodenoscopes in the U.S.

View the safety notice at www.fdanews.com/03-02-15-endoscopes.pdf. — Elizabeth Orr

U.S. Lowers Regulatory Bar For DTC Genetic Tests

The FDA cleared 23andMe's direct-to-consumer screening test for Bloom disease via the de novo process and said similar tests to determine if a person carries a specific gene will be exempt from 510(k)s.

A notice and comment period on the decision is forthcoming.

The de novo was based on two accuracy tests across four labs, one involving 123 samples and a second with 105 samples. In addition, 23andMe did a usability study of 295 people not familiar with its saliva collection device and 302 individuals to show that the instructions and results were easy to follow and understand. More than 90 percent of test participants understood the results, according to the FDA.

The clearance and announcement of Class II status represent a serious effort on FDA's part to lower regulatory barriers for genetic testing, says attorney Bradley Merrill Thompson of Epstein, Becker, Green. "A few years ago, I would never have dreamed FDA would take this action, but the agency genuinely seems to be getting out of the way of quality genetic testing."

Manufacturers of gene carrier tests will need to follow certain guidelines to ensure consumer safety. For example, labeling must include an explanation of what the results may mean, and companies must provide information on how to contact a board-certified medical professional for pre- and post-test counseling. The approach is similar to that the FDA has used for home pregnancy, cholesterol and HIV tests.

23andMe says it will wait to launch the Bloom disease test until it has additional clearances and can market a more comprehensive product set. The company suspended sales of all health-related tests in early 2014, after it was warned by the FDA for selling unapproved tests.

Bloom disease, which affects about 150,000 people worldwide, causes increased cancer risk, short stature, sun sensitivity and other health-related problems. — Elizabeth Orr

China, Switzerland to Cooperate On Range of Regulatory Activities

Swiss and Chinese regulators plan to harmonize their regulations on market authorization and postmarket surveillance, with the aim of speeding access to new products in both markets.

The bilateral agreement, signed late last month, calls for cooperation on a broad range of regulatory activities — from good manufacturing and good laboratory practices, to inspections, registration and postmarket surveillance. It will also facilitate acceptance of reports, certifications and authorizations issued by conformity assessment bodies in each country.

Yet another goal, according to the pact, is to develop and implement risk-management principles for product monitoring, safety, compliance and enforcement.

The agreement is a good start, but still very preliminary, says Jack Wong, director of regulatory affairs for Asia Pacific in TerumoBCT's Singapore branch. Its key value at this point is establishing a platform to enable mutual understanding.

A steering committee comprised of staff from Swissmedic and the China Food and Drug Administration will meet this spring to begin implementing the agreement, says Swissmedic spokesman Peter Balzli. Product-specific working groups may also be created to address mutually agreed issues.

The agreement builds on a 2005 memorandum of understanding on health cooperation and a July 2013 free trade agreement between the countries.

The European Union has a similar collaboration with China through the EU-China Regulatory dialogue, although it is less detailed on operational aspects. It aims to promote information exchange, mutual understanding and cooperation on devices and related administrative, regulatory or scientific matters, says Aikaterini Apostola, spokeswoman for the European Commission.

View the bilateral agreement at www.fdanews.com/02-15-China-Switzerland.pdf. — Jonathon Shacat

FDA Reclassifies Powered Exoskeletons as Class II

Manufacturers of powered exoskeletons must verify the devices' software and manual override controls and ensure biocompatibility of elements that touch the patient, according to an FDA final order placing the products in Class II.

The reclassification order also requires companies to test their products for durability and flame-retardant. The special controls are intended to reduce common risks associated with powered exoskeletons, such as falls, soft tissue injury, burns or electrical shock and malfunction.

Powered exoskeletons were originally placed in Class III along with other preamendment devices. Worn externally, they help limb movement when mobility has been impaired by weakness or paralysis.

The reclassification follows a June 2013 request by Argo Medical Technologies (now ReWalk Robotics) to classify its ReWalk Personal Exoskeleton as Class II. The FDA approved the request last summer.

In addition to the manufacturing controls, companies must provide training for the clinician, user and the user's companion.

The reclassification order takes March 26. View it at www.fdanews.com/02-23-15-Exoskeleton.pdf. — Charlotte Astor

Indian Regulator Demands Information on Stent Pricing

Indian authorities are asking manufacturers of cardiac and drug-eluting stents to explain why they haven't provided the government with information on pricing and availability of their products, as requested in early December.

Officials of the National Pharmaceutical Pricing Authority met with the companies — including Medtronic, Abbott, Boston Scientific, Edwards Lifesciences and Johnson & Johnson — on

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Wednesday, after two follow-up letters in early and mid-February failed to solicit the information.

NPPA already requires this information for nonscheduled drugs under the Drug Price Control Order of 2013. Manufacturers and importers must provide price lists to distributors, the state drugs controller and the union government. Notified devices, which include stents, are currently regulated under the drug law.

Steven Kelly, a spokesman for Abbott's vascular business, says the company responded to NPPA's initial query last year and addressed a request for further details at the Feb. 25 meeting

Last December, NPPA sent letters to 10 companies requesting descriptions, current price lists and pricing revisions for cardiac and drug-eluting stents, orthopedic implants and other notified products from the previous two years.

A Maharashtra FDA study, released in September, alleged that foreign devicemakers were selling drug-eluting stents to hospitals at triple the imported price. The study implicated Medtronic, Abbott and J&J in the profiteering scheme.

Boston Scientific, Edwards, J&J and Medtronic could not be reached for comment by press time.

Read NPPA's notice at www.fdanews.com/02-15-NPPA-Letter.pdf. — Jonathon Shacat

India Plans Central Testing Labs For Implants, Electrical Devices

The Indian government has taken the first steps in establishing central testing laboratories for medical devices, issuing reports that outline basic requirements for testing medical implants and electrical and electronic devices.

One of the labs being proposed would focus on biomaterials and biocompatibility testing, while the other would test products for electromagnetic compatibility and interference.

The Commerce Department has offered to finance the projects, which will give Indian devicemakers access to low-cost testing, says Rajiv Nath, forum coordinator for the Association of Indian Medical Device Industry. The states of Haryana and Gujarat, as well as government-owned corporations, have offered land for the labs.

The reports are timely and encouraging, given the "Make in India" campaign launched by Prime Minister Narendra Modi, says Sanjiv Kumar, executive director of the health ministry's National Health System Resource Center.

Manufacturers in India are required to conduct tests for safety, efficiency and accuracy of equipment and implants, but infrastructure is inadequate and only a limited number of private and semi-private labs that perform these services, he says.

The reports were prepared by the NHSRC, in collaboration with the World Health Organization and U.S.-based Underwriter Laboratories.

India's device industry has huge untapped potential and can be a potent force globally if regulated and pushed in the right direction, says Brooke Higginbotham, a spokeswoman for UL.

For the industry to achieve a $25 billion target, there needs to be greater emphasis on developing industry standards and amending the Drug and Cosmetics Act, she tells *IDDM*. There's also an urgent need to provide affordable and quality healthcare and promote awareness of medical standards and device safety among caregivers, Higginbotham says.

The reports are available at www.fdanews.com/02-15-India-Report1.pdf and www.fdanews.com/02-15-India-Report2.pdf. — Jonathon Shacat

FTC Cracks Down on Mole Check Apps, Bars Sales of Two Products

With U.S. FDA plans to use discretion in enforcing most medical app claims, the job of policing the fast-growing industry has fallen to the Federal Trade Commission.

Their latest target: firms that make and market mobile apps to diagnose skin cancer.

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The FTC on Feb. 23 announced settlements with New Consumer Solutions, developer of the Mole Detective, and Health Discovery, which markets MelApp, both of which purport to check moles for melanoma symptoms. Users are asked to photograph the mole and input other information about it, and the apps categorize the mole as low, medium or high risk for melanoma.

The problem, the FTC says, is that there's no scientific data to back the claims up. The settlements bar the companies from distributing the products. Health Discovery will also pay $17,963 in penalties.

The FTC also filed a district court complaint against Mole Detective marketer L Health, which declined to settle. If convicted, the company could pay up to $16,000 per violation.

Commissioner Maureen Ohlhausen split from the five-member panel, warning the regulatory crackdown could have a chilling effect on other medical app makers. "These matters are another example of the Commission using an unduly expansive interpretation of advertising claims to justify imposing an inappropriately high substantiation requirement on a relatively safe product," she said.

In January, the FTC settled with a software company that claimed its products help children with attention deficit hyperactivity disorder (*IDDM*, Feb. 2).

View the Mole Detective settlement and administrative order at www.fdanews.com/ext/resources/files/03-15/03-02-15-lasarow.pdf, or the MelApp settlement at www.fdanews.com/ext/resources/files/03-15/03-02-15-healthdiscovery.pdf. — Elizabeth Orr

Appeals Court Allows 22-Year-Old Breast Implant Case to Continue

A federal appeals court remanded a 22-year-old product liability suit against Dow Corning to the U.S. district court in North Carolina, saying the lower court was wrong in ruling that the silicone breast implant injury case was beyond the statute of limitations.

The lawsuit was filed in North Carolina in 1993 by a Virginia woman who believed her silicone breast implants were responsible for a variety of serious medical problems. It was later transferred to Michigan district court when Dow Corning filed for bankruptcy there.

In 2012, 24 years after the plaintiff first got the implants, the Michigan court concluded that the claim was null due to the statute of limitations and granted summary judgment to Dow Corning.

On Feb. 20, the U.S. Court of Appeals for the Sixth Circuit ruled that the case should have been decided under North Carolina law.

The plaintiff's case was initially included in a class action suit settled in Alabama in 1994, but she opted out of the settlement at the time. A series of appeals determining jurisdiction followed. In 2009, after new settlement negotiations failed, Dow Corning moved to certify the case

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for trial. The district court agreed, and woman filed a new complaint in January 2010.

Dow Corning asked for summary judgment on grounds that the suit was beyond Michigan's statute of limitations, which grants patients three years to file a product liability lawsuit after first experiencing symptoms. The district court agreed, leading to the latest appeal.

In the majority opinion, Judges Jane Brantetter Stanch and Gilbert Merritt agreed that there was "a genuine dispute of material fact" as to when the plaintiff knew the implants were making her sick, because she got a variety of diagnoses between 1988 and 1992. However, claims should be viewed "in the light most favorable to the plaintiff," and North Carolina has a more generous timeline, they said.

The three-judge panel was not unanimous. Judge Jeffrey Sutton dissented, saying the woman should have known the implants were the cause of her symptoms by early 1989 — outside the statute of limitations for the 1993 filing for any of the courts involved. Therefore, the Michigan court's decision to dismiss in Dow Corning's favor should have been allowed to stand, Sutton said.

Dow Corning did not respond to a request for comment by press time. — Elizabeth Orr

Device Deal Volume Drops, But Value Increases in Q4

Deal activity in the medical device sector was "robust" last year, with overall volume increasing 37.5 percent and value up 4.1 percent over 2013, PricewaterhouseCoopers reports.

The number of deals dropped off in the fourth quarter — to nine deals from 13 in the third quarter, but the value of those deals grew 2.1 percent from $3.7 billion to $4.9 billion.

In the diagnostics sector, the volume of deals also dropped in the fourth quarter, from four in the third quarter to a single deal. This is still an increase from zero deals in the fourth quarter of 2013. Deal value declined 98 percent from the third quarter, from $820 million to $16 million.

No diagnostics deals were announced in the fourth quarter, but six device deals — valued at $14.7 billion — were announced, including Becton Dickinson's proposed acquisition of CareFusion for $12 billion.

Overall, 2014 was "a very significant year in deal activity across the life sciences, and med tech was no exception," James Woods, director of PwC's deals practice, tells *IDDM*. In particular, there was a large volume of midsize and bolt-on type transactions in the orthopedic and medical/surgical arenas, he says.

Divestitures Expected

Looking to 2015, PwC predicts more buyer agility, divestitures, globalization and consolidation. For example, several mergers and acquisitions have involved companies swapping assets to refocus their business. A variety of companies also divested assets to focus on core areas. Other companies may reevaluate their portfolios this year and look for areas to divest, the report says.

Recent limits on corporate inversions may have caused companies to reevaluate their foreign transactions, but shouldn't cause a major change in the volume or size of deals in the device space, Woods says.

Last year's pace in the device sector should continue as payer and provider groups consolidate, forcing companies to hang onto their negotiating power through broader product offerings and new business models, the report says.

Further, the 2.3 percent medical device excise tax has prompted an overall uptick in deals by companies trying to find new ways to deliver value and improve outcomes, says Woods. "This is something we can expect to see continue as players in the industry aim to be both broader and deeper."

Meanwhile, the continuing maturation of personalized medicine may lead to more consolidation in the diagnostics sector, Woods adds.
— April Hollis

U.S. FDA Fixes eMDR Rule To Protect UDI Regulations

The FDA has fixed an editorial glitch that would have removed several requirements of the unique device identification system from the Code of Federal Regulations.

According to Friday's *Federal Register*, the UDI requirements were unintentionally omitted from the final electronic medical device reporting regulations when they were published in February 2014. The problem occurred because both UDI and eMDR regulations require amendments to 21 CFR 803. The eMDR final rule, which was released a few months before the UDI final rule came out in September 2014, did not account for the changes that would be made by the UDI rule and would have unintentionally erased the UDI requirements when it took effect.

To ensure UDI remains law, the FDA is updating the eMDR regulations. A table below shows the changes.

The corrected eMDR final rule takes effect Aug. 14. View the notice at www.fdanews.com/03-02-15-eMDR.pdf. — Elizabeth Orr

Provision	Original UDI Citation	Updated Citation
Amendment of 803.3	Listed alphabetically within 803.3	803.3(aa) and 803.3(bb)
Amendment of section 803.32	803.32(c)(6)	803.32(c)(4)
Amendment of section 803.33	803.33(a)(7)(iv)	803.33(b)(7)(iv)
Amendment of section 803.42	803.42(c)(6)	803.42(c)(4)
Amendment of section 803.52	803.52(c)(6)	803.52(c)(4)

South Korea Clarifies Clinical Documents Needed for Approval

Sponsors of substantially equivalent devices won't need to submit clinical trial documents to register their products in South Korea, under proposed changes to the medical device regulations.

The proposal — seen as positive by industry — specifies 63 life-sustaining products, such as cardiac devices, that require clinical trials.

The proposal, released for comment by the Ministry of Food and Drug Safety, clarifies the trial documents that should be included in supportive documents for device approval and review. It also eliminates redundancies and simplifies methods for product specifications necessary to compose the summary technical document.

Still other revisions clarify and streamline the scope of performance data required for approval of devices with built-in or standalone software, expand the scope of documents accepted for sterilization testing for sterilized devices and eliminate the need for reprocessed Class I devices to show a certificate of inspection.

AdvaMed spokesman Jon Dobson says the changes "will eliminate some burdensome requirements, refine and speed product approvals … and improve transparency."

Comments are due April 3. The proposal, which takes effect Jan. 1, 2016, is available in Korean at www.fdanews.com/02-15-KoreaRegulation.pdf. — Jonathon Shacat

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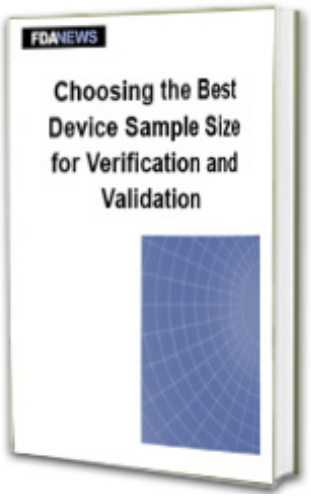

Choosing the Best Device Sample Size for Verification and Validation

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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