International Devices & Diagnostics Monitor

Vol. 4, No. 37
Sept. 17, 2018

IN THIS ISSUE

FDA Gives Feedback to Congress On New Diagnostics Standards

FDA Commissioner Scott Gottlieb said the agency has advised Congress to take a three-pronged approach to modernizing diagnostics standards.

The agency has proposed a regulatory framework based on a few key principles, Gottlieb said in remarks at the Friends of Cancer Research's 7th Annual Blueprint for Breakthrough Forum in Washington, D.C.

First, he said, regulatory agencies and policymakers should take a consistent approach for all in vitro clinical tests regardless of whether they are developed by a traditional manufacturer or a clinical laboratory.

Second, the FDA's premarket review process should focus on the analytical and clinical validity of novel or high-risk tests, and any approach reallocating the agency's premarket review resources

(See **Diagnostics**, *Page 2)*

Health Canada to Offer Preclinical Meetings to Devicemakers

Health Canada is launching a pilot program to offer preclinical advice to devicemakers on their investigational testing protocols.

The agency hopes the new program — under Health Canada's Regulatory Review of Drugs and Devices Initiative — will improve the quality of submissions and provide "more timely regulatory decisions."

Device manufacturers will be able to contribute to the design of the pre-clinical meetings and guidance material, the agency said.

Health Canada said industry stakeholders had complained that the criteria for requesting meetings was not clear. By launching the pilot project, the agency hopes to improve communications and develop processes that improve the quality of submissions and provide "more timely regulatory decisions."

The pilot program will run from November 2018 to March 2019. The "Device Advice: Pre-Clinical Meetings" will offer device

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manufacturers recommendations on their investigational testing protocols.

The agency recommends that device manufacturers that are planning to submit an Investigational Testing Authorization application for a Class II or Class IV device, or a Class II device that could be considered a novel or disruptive technology, consider participating in the pilot program.

Interested parties should submit expressions of interest by Sept. 21.

The initiative is part of a broader plan to overhaul Canada's regulatory system to make it more efficient and to support more timely access to therapies.

For manufacturers, the overhaul will include an expanded priority review process to reduce review times for products, as well as renewal of the special access program for products not approved in Canada. The agency said it also plans to expedite applications for digital health technologies for home use.

As part of the digital health effort, Health Canada will expand its capacity for digital reviewing health technologies, especially emerging innovations such as artificial intelligence and telerobotics. To do this, it plans on engaging more with "counterpart regulatory agencies and health technology assessment organizations to increase alignment in review approaches."

Health Canada is also establishing a new division within its Therapeutic Products Directorate's Medical Devices Bureau that will allow for a more targeted pre-market review of digital health technologies to respond to faster innovation cycles.

The new Digital Health Review Division will increase expert review capacity and help integrate digital health technologies into the wider healthcare system. Key areas will include: wireless medical devices, mobile medical apps, telemedicine, software as a medical device, artificial intelligence, cybersecurity and medical device interoperability.

Read the Health Canada notice here: www.fdanews.com/09-13-18-HealthCanadaNotice.pdf.

Diagnostics, *from Page 1*

should also include "robust post-market authorities" to shield patients from potential risk.

Third, he said, the approach must avoid redundancy by leveraging the current framework rather than simply replicating it.

The FDA's proposed approach would grandfather in most laboratory-developed diagnostic tests, Gottlieb said, putting all in vitro clinical tests under a single set of requirements.

The agency has also proposed a precertification pathway to Congress, which would allow eligible sponsors to submit a single test for review. Taking these steps, Gottlieb said, "would enable the FDA to take a risk-based approach that would focus our resources and expertise on the individual premarket review of certain categories of tests where it's most needed, including tests that are higher-risk and novel, and many companion diagnostics and home-use tests."

"In pursuing a new framework for the appropriate regulation of diagnostics, there will be difficult policy decisions to make and tradeoffs on any path to legislation," Gottlieb said. "We know that the FDA must be flexible and open minded to new approaches that best meet the needs of patients so that patients can have confidence in the results and the treatment that comes from it. That's the spirit of our proposed reforms." — Zack Budryk

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NHS Drafts Code of Conduct For AI, Data-Driven Technologies

England's National Health Service rolled out a voluntary code of practice for data-driven technology such as artificial intelligence and other data-driven applications and clinical support tools.

The code spells out what the agency expects from suppliers and manufacturers and it also includes commitments the government will make to ensure that the healthcare system is ready to adapt new technology.

The voluntary code will also provide the basis for digital technology suppliers to enter into commercial arrangements with technology companies and healthcare providers.

The NHS guidance on the code lays out 10 principles manufacturers should follow for digital innovations, recommending they should:

- Define the user by understanding and showing who your product is for, what problem you are trying to solve and what benefits they should expect;
- Define the value proposition by showing why the technology was developed;
- Be fair, transparent and accountable about what data you are using. Show you have used privacy-by-design principles with data-sharing agreements, data flow maps and data protection impact assessments;
- Use data that is proportionate to the identified user;
- Make use of open standards;
- Be transparent on the limitations of the data used and algorithms deployed;
- Make security integral to the design;
- Define the commercial strategy;
- Show evidence of effectiveness for the intended use; and
- Show what type of algorithm you are building, the evidence base for choosing that algorithm, how you plan to monitor its performance on an ongoing basis and how you are validating performance of the algorithm.

The code also highlights commitments the government will make to ensure that the healthcare system is ready to adapt new technology. These including simplifying the regulatory and funding landscape, creating an environment that enables experimentation, encouraging the system to adopt innovation, improving interoperability and openness, and listening to users.

The NHS invited feedback from industry on the draft and said it expects to republish the code in December.

Read the guidance here. www.fdanews.com/09-12-18-NewGuidance.pdf.

India's CDSCO Wants J&J's DePuy to Compensate Patients for Hip Implants

India's Central Drugs Standard Control Organization is calling on Johnson & Johnson to compensate patients who suffered serious adverse events linked to the company's ASR hip implants.

CDSCO is recommending compensation of 2 million rupees (roughly US$28,000) per patient who underwent revision surgery with the ASR XL acetabular hip system and ASR hip resurfacing system. The ASR implants were globally recalled in 2010 due to defects. About 4,700 patients in India received the hip implants.

The Aug. 30 order is based on the degree of disability and monetary losses patients suffered. The recommendation followed an investigation by the Ministry of Health & Family Welfare. The ministry's expert committee released a report in January reviewing actions taken by J&J to replace the faulty ASR implants and to judge the adequacy of the firm's response.

"Many patients in India and across various countries have suffered due to the ASR and have been forced to live a compromised life to the [the] faulty implant," the expert committee concluded. It said an "opportunity should be given to make the claim for 'just and adequate' compensation to each

(See **India***, Page 4)*

FDA Proposed Rule Would Simplify Premarket Device Submissions Process

The FDA released a proposed rule that would simplify the process for electronic premarket device submissions.

Under the proposal, the agency would require a single submission in electronic format for the device premarket submissions, removing paper and multiple copies from the equation.

If implemented, the proposal would cut the number of copies required in electronic format and streamline the premarket submission program.

It would further amend all device regulations that reference the specific form of a submission to require an electronic submission, thereby generating savings for sponsors without imposing increased regulations, according to the FDA.

The agency also proposes to replace mailing addresses with a website for eSubmissions, eliminating the need for new amendments to current regulations every time the FDA updates addresses.

Read the proposed rule here: www.fdanews.com/09-13-18-Device.pdf. — Zack Budryk

FDA Issues Two Guidances On Voluntary Consensus Standards

The FDA issued two draft guidances on the use of voluntary consensus standards for medical devices.

The first guidance deals with the recognition and withdrawal of voluntary consensus standards. In developing the standards, the guidance states, recognized bodies must be open to all interested parties and must ensure that no single interest dominates the decision-making.

They must also ensure due process that includes documented and publicly-available policies and procedures and adequate notice of meetings, an impartial appeals process and consensus, the agency said.

The second draft guidance deals with the use of voluntary consensus standards in premarket submissions for devices and will replace guidance issued in 2007. There are two appropriate uses of consensus standards in the premarket process, according to the FDA.

The first is a declaration of conformity in keeping with the FD&C Act, which certifies that the device is in compliance with a consensus standard recognized by the FDA, after which the agency will determine in its review whether the submission complies with applicable premarket requirements.

The second is general use, where a submitter chooses to comply with a consensus standard but does not submit a declaration of conformity. The reasons for this may include the manufacturer making changes to the consensus standard methodology or the manufacturer choosing to use a consensus standard without a recognition number.

Read the draft guidances here: www.fdanews.com/09-13-18-Guidance.pdf. — Zack Budryk

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India, *from Page 3*

and every patient who had undergone revision surgery to mitigate some of their pain and sufferings."

The report says that J&J "has been found to be evasive in providing the information desired by the committee regarding the design of the ASR [and] patient details" and that it failed to provide the exact number of patients who had undergone surgeries/re-surgeries with ASR.

The expert committee also recommended that J&J provide medical management to all affected patients both with and without symptoms.

It also urged the government to strengthen its device oversight program and to establish an independent registry for tracking high-risk medical devices.

Numerous lawsuits over metal-on-metal Pinnacle Acetabular Cup System hip implant devices are working their way through U.S. courts. J&J stopped selling the devices in 2013. The most recent verdict came from a Dallas federal court in November 2017 that ordered J&J to pay $247 million to six patients (*IDDM*, Nov. 27, 2017).

J&J's DePuy did not respond to a request for comment by deadline.

FDA Says Medtronic Needs Followup Inspections to Confirm Corrections

The FDA hit two Medtronic device facilities with warning letters last week, citing faulty device history records and CAPA procedures.

In one warning letter following up on an April-May inspection of a Medtronic facility in Juncos, Puerto Rico, the agency noted the company failed to validate production processes for its Blackwell implantable cardiac defibrillators, leading to a recall. Medtronic promised to update its process validation and its change control process.

The inspection also found a failure to document certain activities in the device history records for the cardiac defibrillators. In response, the company committed to updating product identification and traceability procedures, as well as its training of new hired and manufacturing personnel. Medtronic further promised to implement tighter procedure controls for the defibrillators and assess manufacturing areas to identity similar problems elsewhere.

In the second warning letter to Medtronic concerning its cardiac rhythm and heart failure (CHRF) facility in Mounds View, Minnesota, the agency noted that an April/May inspection of the facility found design transfer was approved for the defibrillators prior to qualification of certain processes and the processes were implemented at the Juncos manufacturing facility even though a classification was never conducted.

In response to the findings, Medtronic committed to reviewing all manufacturing processes, and assessing any of the processes at issue for current implantable therapy and diagnostic devices to evaluate the validation status of all processes that were not fully verified.

The inspection also found the Juncos facility made a change to a manufacturing process without the approval of Medtronic CHRF as required

(See **Warning**, *Page 6)*

Overused and Typically Inappropriate Corrective Actions

An auditor or inspector can quickly get a sense of the quality of an investigation by looking at the number of events where “training” was the corrective action. Training is often the default solution because “human error” was the designated root cause.

Training, as important as it is in developing knowledge and skills, should be the last option considered in your corrective actions. Why? It is the most unreliable and often most expensive solution because in and of itself, training rarely solves the underlying problem, meaning there will most likely be a recurrence.

One other over-used corrective action is “changing the procedure,” which usually involves adding something to the SOP. Rarely does the investigation team simplify the procedure or redesign the task. James Reason, a noted professor of psychology who has studied human error, says that since the most common failure when using a procedure is to skip a step, it doesn’t make much sense to add something to a procedure — making it longer — and giving the user more things that can be potentially skipped. Einstein said that anyone can make something complicated; it takes a real genius to make it simple. Preventing recurrence of deviations requires that we do our creative best when coming up with a solution.

There can be some confusion about the terms correction, corrective action and preventive action. According to definitions in ISO 9000-2005, a correction is the action used to eliminate a detected nonconformity while a corrective action is an action to eliminate the cause of a detected nonconformity. For example, if a labeling machine is putting crooked labels on bottles, the immediate action would be stopping the labeler; the correction would be removing the misplaced labels (if possible or scrapping the bottles altogether) and re-labeling them — you are fixing the thing that was affected. The corrective action would be fixing the labeler so it doesn’t put crooked labels on the bottles. A true preventive action might be looking at other labeling equipment at other sites (where the problem has not yet been seen) to identify if that same fix is appropriate.

Preventive actions are those taken to eliminate the cause of a potential nonconformity.

Excerpted from the FDAnews management report: *Quality Management Essentials – Expert Advice on Building a Compliant System*.

Czech Republic Launches New Portal to Track Medical Devices

The Czech Republic's Ministry of Health is launching a new web portal to track medical devices in the country.

The portal includes information on roughly 14,587 devices in 206 healthcare providers that have given their consent to release the information.

The move will provide greater transparency and give patients access to innovative devices, said Minister of Health Adam Vojtech.

Patients will be able to locate devices by provider, device category and region. Access the portal here: https://ztnemocnice.uzis.cz/.

Health Canada to Modify List Of Recognized Standards for Devices

Health Canada has called for comment on a draft guidance that updates its list of recognized medical device standards.

The consultation period is from Sept. 11 to Nov. 9, giving stakeholders two months to provide feedback on the proposed changes.

The standards cover a broad range of areas, such as sterilization of health products, basic safety and essential performance of various devices, transplantation of specimens and verification and validation of assays.

The draft guidance adds 15 standards, including standards for implantable defibrillators, a standard test method for the seal strength of flexible barrier materials and medical electrical equipment.

It eliminates various standards from the list, such as for cardiac valve prostheses, general requirements for basic safety and essential performance of medical electrical equipment.

It also updates certain standards, such as for implantable devices, risk management of medical devices and safety requirements for electrical equipment for measurement, control and laboratory use.

The agency noted that it is replacing recognition of the IEC 60601-1-2:2007 — ED 3.0 technical standard for performance of medical electrical equipment, with recognition of the standard's 4th edition. The agency will continue to allow conformity to the 3rd edition for premarket submissions until December 31, 2018.

Read the proposed changes to the list here: www.fdanews.com/09-13-18-RecognizedStandards.pdf. — James Miessler

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by company procedures. In response, the facility promised to review CAPAs for the past year relating to CHRD products in the field and determine whether they were appropriately escalated to CRHF for review.

The FDA wrote in both warning letters that Medtronic's responses to the issues appeared to be adequate, but that follow-up inspections will be necessary to confirm compliance.

Read the two letters here: www.fdanews.com/09-13-18-MedtronicWL.pdf. — Zack Budryk

13th Annual FDA Inspections Summit

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So much has changed since last year's Inspections Summit that it sometimes feels difficult to keep up. The FDA is focused on any number of new topics: more generics, lower prices, opioids, internal restructuring, and much more. But one thing that hasn't changed is that they are still doing inspections….and the regulated community is still making mistakes.

The FDA will always — **always** — do inspections, and Commissioner Scott Gottlieb and the FDA have certainly not provided any hint that they are going to stop doing them any time soon. You can't afford to be caught off guard. Warning letters, 483 citations, and hits to your reputation can cost you time, energy and money!

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OIG: FDA Needs to Better Integrate Cybersecurity Into Device Reviews

The FDA needs to do more to ensure the cybersecurity of networked medical devices, according to a new report from the HHS Office of Inspector General.

The OIG acknowledged the FDA has been working to address cybersecurity threats, noting the agency currently considers known cybersecurity risks when reviewing devices and requests cybersecurity documents from manufacturers. But the OIG determined that cybersecurity checks are missing from two key tools in the premarket review process.

The agency's "Refuse-to-Accept" checklists don't include checks for cybersecurity, and the "Smart" template the agency uses to guide submission reviews — at the time of the OIG's study — didn't include any cybersecurity questions. The template also lacked a dedicated section for recording cybersecurity review results.

The "Refuse-to-Accept" checklists were developed in 1994 and the Smart template in 2013 —before the increase in networked submissions and the accompanying risk of cybersecurity threats, OIG noted.

Networked medical devices — such as infusion pumps, diagnostic imaging equipment and pacemakers — are susceptible to ransomware and unauthorized remote access if they lack adequate security controls. This could "adversely affect device functionality, disrupt the delivery of health services and lead to patient harm," the OIG reported.

In 2015, the FDA urged healthcare providers to stop using an infusion pump after its manufacturer confirmed it could be remotely accessed and controlled by an unauthorized user. And in 2017, 465,000 implantable pacemakers were recalled due to the risk of unauthorized access (*IDDM*, Oct. 9, 2017).

Along with updating the "Refuse-to-Accept" checklists and the Smart template, the OIG recommended the FDA promote the use of its presubmission meetings to address cybersecurity-related questions. The presubmission program allows manufacturers to voluntarily obtain formal, targeted feedback for their device before submission, including steps they need to take to mitigate cybersecurity threats.

FDA staff noted in the OIG report that more manufacturers need to take advantage of the presubmission meetings. Manufacturers who request meetings "rarely ask questions related to cybersecurity" resulting in initial submissions that

(See **OIG***, Page 8)*

FDA Highlights Mobile App Innovation, Cites De Novo Reviews

FDA Commissioner Scott Gottlieb and CDRH Director Jeff Shuren hailed the "reimagination" of health care delivery through mobile medical apps and cited steps the agency is taking to encourage innovations in the rapidly developing market.

The agency has granted Apple de novo status for two mobile medical apps that will be featured in the latest incarnation of the Apple Watch. One app creates an electrocardiogram to detect atrial fibrillation and regular heart rhythm, while the other analyzes pulse rate data to notify users of irregular heart rhythms.

The agency worked closely with Apple throughout the development and testing, Gottlieb and Shuren noted in a joint statement. They also cited other actions the agency has taken to promote digital health innovation, such as the launch of the Digital Health Innovation Action Plan last summer, which laid out a blueprint for issuing medical software guidance, revamping digital health product oversight and increasing agency expertise in digital health.

The agency is also trying out a precertification pilot program to help determine how it should regulate digital health products (*IDDM*, June 25). — James Miessler

APPROVALS

AMDT's FixSix System Cleared by FDA

The FDA granted 510(k) clearance to AMDT's FixSix software and instrumentation, used to analyze and correct limb deformities.

Intended for use with the Smith and & Nephew Taylor spatial frame, the system reduces the time and effort needed for inputting measurements.

After inputting the measurement data, the system generates a prescription defining incremental adjustments to be made to the spatial frame's strut that will correct the deformity.

FDA Clears PhysIQ's Atrial Fibrillation Analytic

The FDA granted 510(k) clearance for PhysIQ's atrial fibrillation analytic designed to generate clinical insight from wearable biosensors.

The clinical insight the analytic generates can help clinicians reduce re-hospitalization rates and move towards personalized precision medicine for atrial fibrillation.

The analytic is intended to support both health systems and payers in addition to pharmaceutical and medical device companies that use wearable biosensors in their clinical trials.

Medtronic's Sheathed Bipolar Sealer Granted 510(k) Clearance

The FDA handed 510(k) clearance to Minneapolis devicemaker Medtronic's Aquamantys sheathed bipolar sealer, a device used for hemostatic sealing during spinal cases.

The device enables surgeons to stop bleeding from cut muscle and epidural veins using a combination of radiofrequency energy and saline in order to reduce blood loss and increase visualization during spinal procedures.

The device's ability to reduce blood loss has been linked to faster surgery times and reduced rates of blood transfusions.

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"insufficiently cover cybersecurity," they said. The resulting back-and-forth increases the amount of time the FDA needs to review a submission.

The FDA concurred with the OIG's recommendations and said they had already taken some of the steps outlined in the report. The agency updated the Smart template in September 2016 "to include a specific section on cybersecurity," said the FDA's Deputy Associate Commissioner for Public Health, Lisa Rovin. They will continue to update the template "to keep pace" with evolving cybersecurity developments.

AdvaMed agrees with the OIG's recommendations and believes the process improvements will add "more transparency and predictability to the premarket review process," said Janet Trunzo, AdvaMed's senior executive vice president of technology and regulatory affairs.

"Cybersecurity is a shared responsibility among all health care stakeholders. Providers have to do their part. Medtech companies are doing our part, and we look forward to continuing to partner with FDA," said Trunzo.

Read the OIG's full report here: www.fdanews.com/09-11-18-Cybersecurity.pdf. — Tiffany Winters

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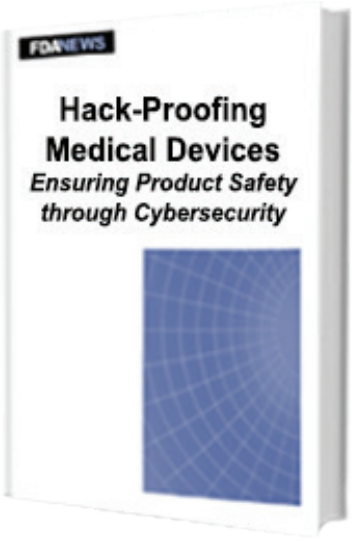

Hack-Proofing Medical Devices: *Ensuring Product Safety through Cybersecurity*

How does the FDA expect you to fight cyber incursions?

With the recent release of the final guidance on postmarket management of cybersecurity, you now have advice from the agency.

The key is awareness — of product vulnerabilities, current threats, developments in cybersecurity protection, how to defend your company from disastrous liability litigation… and the list goes on.

Hack-Proofing Medical Devices will show you how to get — and keep — control of your devices' networked operations. The management report covers:

- Six environmental stressors that contribute to cybersecurity problems
- The overwhelming magnitude of the problem — 68,000 medical devices were found to be freely accessible through the Internet in 2015
- How the FDA and international regulators are handling issues involving software as a medical device (SaMD)
- Types of cybersecurity threats, including ransomware and device piggybacking
- And much more!

BONUS — the report also provides a variety of tools including:

- A checklist for verifying a device's cybersecurity controls status
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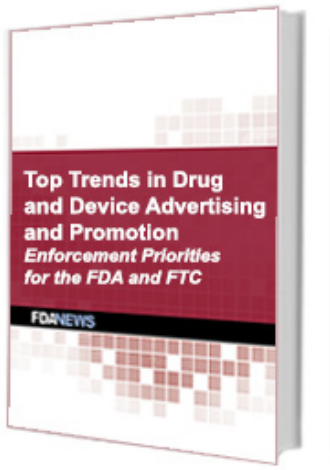

Top Trends in Drug and Device Advertising and Promotion: *Enforcement Priorities for the FDA and FTC*

As drug and device companies develop new and innovative ways of promoting their products — such as targeting new markets, influencer marketing and using social media and reality television — it's important to understand the regulatory priorities of the FDA and the FTC to avoid running afoul of those agencies.

Top Trends in Drug and Device Advertising and Promotion takes a deep dive into six areas regulators give the most attention:

1. **Consistent Communication:** Three factors that ensure communications are consistent with a product's approved labeling
2. **Direct-to-Consumer Advertising:** Use of distracting visuals, competing superimposed images and lively music that can minimize the required presentation of risk information
3. **Risk Disclosure:** How much information needs to be presented and how
4. **Payer Communications:** Disseminating healthcare economic information, or HCEI, to payers postapproval
5. **Preapproval Promotion:** A new safe harbor for communicating information about investigational products to payers
6. **Transparency:** Making it clear that a communication is sponsored advertising

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