IMDRF International Medical Device Regulators Forum

U.S. FDA Center for Devices and Radiological Health Update

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CDRH Strategic Priorities Update

The Center for Devices and Radiological Health (CDRH) issued its 2016 – 2017 Strategic Priorities in January 2016:

- Establish a National Evaluation System for Medical Devices;
- Partner with Patients; and
- Promote a Culture of Quality and Organizational Excellence.

http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf

ESTABLISH A NATIONAL EVALUATION SYSTEM FOR MEDICAL DEVICES

To successfully harness the diverse set of real-world evidence.

ESTABLISH A NATIONAL EVALUATION SYSTEM FOR MEDICAL DEVICES

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- To successfully generate and use robust real-world data in an efficient manner to quickly identify new safety problems for devices on the market and optimally and appropriately rely on real-world evidence to support product approvals, to shift some premarket data collection to the postmarket setting, or to meet postmarket data collection commitments, the U.S. must have the necessary infrastructure – a national evaluation system that leverages electronic health information generated in the clinical and home settings – in place.
- Through our priority *Establish a National Evaluation System for Medical Devices* we would establish the basic structure and operations for a national safety net to protect patients and for lower cost, faster evidence generation to incentivize innovation and promote timely patient access.

PARTNER WITH PATIENTS

We must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

PARTNER WITH PATIENTS

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- The role of patients has evolved over time- it's time to interact with patients as partners in advancing healthcare.
- Partner with Patients reflects and builds on our strong commitment to patients as our most important customer.
- CDRH will establish a foundation to facilitate the development of more patient-friendly information, promote more patient-centric trials, advance benefit-risk assessments that are informed by patient perspectives, promote the use of patient-reported outcome data, and foster access to new devices that meet patients' needs.

PROMOTE A CULTURE OF QUALITY AND ORGANIZATIONAL EXCELLENCE

Continually striving for high quality and excellence.

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- Quality and organizational excellence are about a culture that understands how its actions can improve product, service, performance, and decision-making quality and how its decisions affect the quality of life of U.S. patients.
- *Promote a Culture of Quality and Organizational Excellence* strives to improve medical device manufacturers' ability to design and make high-quality, safe and effective devices and CDRH's ability to provide the necessary oversight to give U.S. patients timely access to life-enhancing innovative medical devices while assuring that devices on the market are of high-quality, safe and effective.

PUBLIC NOTIFICATION OF EMERGING POSTMARKET MEDICAL DEVICE SIGNALS DRAFT GUIDANCE

- *Draft Guidance on Public Notification of Emerging Postmarket Medical Device Signals* issued December 31, 2015.
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm479248.pdf
- This document proposes a policy for how the FDA will notify the public about medical device "emerging signals."
- Because of the evolving nature of this information, FDA would be sharing it with the public at an earlier stage of the agency's assessment and evaluation of the signal.
- When finalized, the guidance document will be implemented by the CDRH Signal Management Program, and will serve to inform Signal Review Teams when an "Emerging Signals Communication" may be warranted.

Applying Human Factors and Usability Engineering to Medical Devices – Final Guidance

- *Applying Human Factors and Usability Engineering to Medical Devices – Final Guidance* issued February 2, 2016.
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259760.pdf
- This guidance will assist medical device developers in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses, and use environment."
- CDRH recommends that manufacturers include human factors data in their premarket submissions (i.e., PMA, 510(k)) if an analysis of risk for the device indicates that users performing tasks incorrectly or failing to perform tasks could result in serious harm.
- CDRH also issued the draft guidance List of *Highest Priority Devices for Human Factors Review* to make clear which device types are recommended to include human factors data in premarket submissions.

Postmarket Management of Cybersecurity in Medical Devices – Draft Guidance

- *Postmarket Management of Cybersecurity in Medical Devices Draft Guidance* issued January 22, 2016 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf

- To urge device makers to assess cybersecurity risks of medical devices in the postmarket setting, and outlines steps manufacturers should take to continually address cybersecurity risks with their devices.

- We believe it is critical that devices be continuously monitored and potential vulnerabilities be quickly addressed throughout a device's total product lifecycle.

SUNLAMP AND SUNLAMP PRODUCTS

- Exposure to ultraviolet (UV) radiation from indoor tanning is a preventable cause of skin cancer. FDA is protecting public health by, among other things, requiring that manufacturers inform consumers of the risks of using indoor tanning devices.

- In December 2015, FDA issued a proposed rule (a restriction) to prevent the use of sunlamp products (tanning beds) by minors and reduce the risks of using these devices on adults.

- The proposed restriction would require that manufacturers and tanning facilities take additional measures to help improve the overall safety of these devices.

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Recent Medical Device UpClassifications

- January 4, 2016 – FDA issued two final orders to manufacturers and the public to strengthen the data requirements for surgical mesh to repair pelvic organ prolapse (POP) transvaginally.
  - The Agency issued one order to reclassify these medical devices from Class II to Class III.
  - The Agency issued a second order that requires manufacturers to submit a Premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP.
    - These stronger clinical requirements will help to address the risks associated with surgical mesh for repair of pelvic organ prolapse.
    - The FDA intends to continue monitoring how women with this device are faring months and years after surgery through continued postmarket surveillance measures.

- February 18, 2016 – FDA issued a final order requiring manufacturers to submit a PMA application for two types of metal-on-metal (MoM) total hip replacement devices: the hip joint/metal/metal semi-constrained with a cemented acetabular component and the hip joint metal/metal semi-constrained with an uncemented acetabular component.
  - The FDA has determined that total metal-on-metal (MoM) hip replacement systems carry unique risks compared to other types of hip replacement systems.
  - The FDA's final order requiring PMA applications for total MoM hip replacement systems comes as a result of its review of independent scientific literature, international clinical reports, adverse event reports and device recall information.

THANK YOU