FDA Regulation of Glucose Monitoring

AACE/ACE Consensus Conference on Glucose Monitoring

September 28, 2014

Courtney H. Lias, Ph.D.
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration

Why "Regulate?"

What is regulation?

(hint – it isn't just premarket approval)

What is the value added of regulation?

Why should it be helpful?

What is the right balance?

Goal = Balance

Regulatory "bar" depends the purpose of the device and its risk

- Some devices are under FDA enforcement discretion – e.g., data storage/display software
  - are legally "devices" but FDA allows marketing without any regulatory requirements
- Some devices low risk – e.g., retrospective CGM analysis software
  - No premarket review
  - Design controls (for software), good manufacturing practices, adverse event reporting, etc. required
- Some devices are moderate risk – e.g., glucose meters, insulin pumps
  - Premarket review of 510(k) required
- Some devices are high risk – e.g., Artificial Pancreas devices
  - Premarket approval required (including premarket manufacturing inspection, change control)

Value Added

Premarket

- Premarket review
  - Independent assessment of analytical and clinical validity
  - does the device work for its intended purpose?
  - Does not require perfection – Benefit vs. Risks considered
- Design control
  - Focused process to ensure quality and safety
  - Device modifications deliberate and considered
- Good manufacturing practices – toward assuring consistency
- Labeling requirements: “truth in labeling” (per 21 CFR 809.10)

Value Added

Postmarket

- Assures accountability – Someone *is* responsible
- Enforcement / Compliance
  - Inspections, WLs, seizures, injunctions, civil money penalties
  - Recalls – multiple significant Class I recalls/yr for meters
  - Corrective actions – for cause actions to fix safety issues
- Manufacturing and Design
  - Design control
  - Corrective and Preventive Actions (CAPA)
  - Risk Assessment
- Independent analysis of adverse event trends and signals
  - 30,000 MDRs/yr. for meters
  - MDRs/yr for CGMs dramatically increasing – up to 30,000/yr
  - Under-reported

Ongoing Efforts

Premarket

- 2 draft guidances on Blood Glucose Meters (January 2014)
  - Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Draft Guidance
  - Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Draft Guidance
- Maintain (and enhance) access to glucose monitoring throughout the hospital
  - Outreach to HCPs
  - Nova clearance (September 24, 2014)
  - Hospital sensor Public Meeting (June 2012)
- Artificial Pancreas guidance
  - CGMs with added safety features (e.g., suspend, etc.)

Ongoing Efforts

Postmarket

- FDA is drafting new guidance for manufacturers on MDR reporting for glucose meters – aim to improve reporting consistency, data analysis
- FDA participated in Diabetes Technology Society's Error Grid project – potential new tool that may increase consistency in glucose meter event risk assessment
- DTS Surveillance program – FDA participating on steering committee
- Enforcement/Compliance Actions
  - Inspections, WLs, safety alerts, recalls
  - Not always public information

How can the public help?

Report Directly to FDA

- Patients, healthcare professionals and consumers who find a problem related to a medical device are encouraged to report medical device adverse events or product problems to FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Submit reports to FDA through the MedWatch program in one of the following ways:

  – Download the MedWatcher Mobile App - allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet

  – Complete the MedWatch Online Reporting Form - https://www.accessdata.fda.gov/scripts/medwatch/

Access

- We always encourage manufacturers to talk to payers early for novel technology – but it is rarely done
- Typically results in different study design (outcomes for CMS vs. “validity” for FDA)
- Opportunity to seek pathway for parallel FDA approval and CMS reimbursement

Thank you!

courtney.lias@fda.hhs.gov