US FDA Regulation of Standalone Software: 2014 update

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Software in a medical device

- FDA has a long history of regulating software in a medical device
- Regulatory considerations are well understood
- Premarket considerations
  - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

  Quality System considerations
  - General Principles of Software validation

Software in a medical device: Recent Changes

- FDA expects more than ever that submitters will carefully follow the 2005 Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Different FDA reviewers can interpret the guidance in very different ways, even within the same review branch
- Biggest challenge for my clients: Getting the right level of detail for software requirements, and being able to trace requirements through design and testing.

Software in a medical device: Recent Changes

- FDA has been routinely asking about "Static Analysis"

  Please provide information about whether you performed any static analysis. If so, please provide the test results and actions taken accordingly. If you did not use any static analysis tool for your implementation and testing, we recommend that you use one to ensure the integrity and quality of your code.

- If you are not routinely using such a tool to test you code, you may wish to consider it

Software in a medical device: Recent Changes

- The premarket software guidance states that you should provide a list of “unresolved anomalies” (e.g., bugs)
- FDA is asking more questions about these, including:
  - Detailed description of the anomaly
  - Root cause
  - Risk analysis
  - Timeframe for addressing

Software as a medical device

- FDA has historically regulated a few types of stand-alone software:
  - Picture archiving and communication systems
  - Radiation treatment planning software
  - Drug Dose calculators
- FDA has generally classified other types of stand-alone software as an accessory to a classified medical device
  - Interpretive ECG
  - BIS (bispectral index) for depth of anesthesia
- But what about Health IT? And Mobile Apps?

Mobile Medical Apps

- FDA issued its final guidance on Mobile Medical Apps on September 25, 2013
- FDA will only regulate mobile apps that are intended:
  - to be used as an accessory to a regulated medical device; or
  - to transform a mobile platform into a regulated medical device.
- FDA will NOT regulate manufacturers of general purpose mobile phone platforms or owners of “App Stores”.

Mobile Apps that are NOT medical devices

- Electronic copies of books
- Educational or training tools for healthcare providers
- Apps for general patient education
- Tools to automate general office functions
- General purpose products with medical uses

Mobile Apps subject to "Enforcement Discretion"

These are Apps that meet the strict definition of a device, but that FDA will not regulate

1. Apps that supplement professional clinical care by coaching patients with specific diseases or identifiable health conditions in their daily environment.

A few clarifications:

- These apps cannot provide a diagnosis
- They also cannot be intended to replace professional clinical care
- They CAN target patients with a specific disease, but you need to be careful about making any claims about improving patient outcomes.
- The apps are intended to help a patient MANAGE a disease or condition, not to TREAT it.

Mobile Apps subject to "Enforcement Discretion"

2. Medication reminders intended to be used for pre-determined dosing schedules
3. Tools to help patients organize or track health information
4. Videoconference portals for medical use
5. Apps that perform simple calculations routinely used in clinical practice
   - The calculation needs to be based on an "authoritative medical source".

Mobile Apps that will be regulated

- Mobile apps that perform the functions of a regulated device:
  - Remote display of bedside data
  - Patient monitoring
- Mobile apps that transform a mobile platform into a regulated device using attachments such as:
  - Glucose strip reader
  - ECG electrodes
  - Blood pressure cuff

Recent 510(k) clearances

- DANA mobile-based cognitive assessment software tool

- Alivecor heart monitor with Atrial Fibrillation diagnostic

- KinetiGraph automated reporting of a Parkinson's disease patient's movements for treatment optimization

Cybersecurity

- On October 12, 2014, FDA finalized its “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”
- FDA expects that manufacturers will develop cybersecurity controls to assure medical device cybersecurity and maintain medical device functionality and safety.
- This needs to occur during the device design phase, as part of defining design inputs.

Cybersecurity

- The guidance describes the documentation that should be provided in a premarket submission:
  - Hazard analysis
    - What risks did you consider?
    - How did you mitigate them?
  - Traceability from risks to controls
  - Summary of the plan to provide validated updates
  - Summary of controls to assure software integrity until it leaves control of the manufacturer
  - Labeling regarding appropriate cybersecurity controls for user

Wireless

- If your device incorporates wireless technology, you need to address the issues identified in FDA's guidance "Radio Frequency Wireless Technology in Medical Devices (August 14, 2013)"
- FDA is particularly interested in:
  - Detailed description of the wireless technology and function, including potential risks and how they are mitigated
  - The required wireless Quality of Service required by the intended use and use environment of the device.
  - Wireless coexistence testing demonstrating that your device can safety and effectively operate in an environment where there are other wireless products
  - Labeling should provide detailed information about wireless technology, testing, and mitigations

Regulatory Framework for Health IT

- FDA, the Office of the National Coordinator for Health IT, and the FCC released a June 2014 report on the future of a nationwide health infrastructure.
- Key conclusions were:
  - We believe a limited, narrowly-tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities is prudent.
  - We also recommend that no new or additional areas of FDA oversight are needed
  - We believe a better approach is to foster the development of a culture of safety and quality; leverage standards and best practices; employ industry-led testing and certification; and selectively use tools such as voluntary listing, reporting, and training

http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm390588.htm

What does this mean for the medical device industry?

- Consistent with the Mobile Medical Apps guidance, where health IT enters into "traditional medical device" space, FDA will likely regulate it as a medical device
- This would include:
  - New types of imaging analysis software (e.g., 3-D tomosynthesis)
  - Phone-based controllers for devices such as infusion pumps, glucose meters, and physiological monitors
  - Extending the range of and data provided by remote monitoring systems

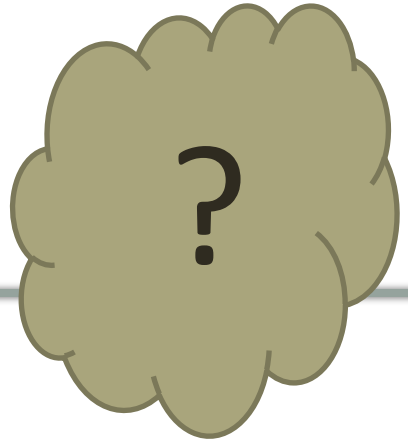
Medical Device Data Systems

- FDA has previously classified Medical Device Data Systems (MDDS) as Class I (exempt)
- On June 14, 2014, FDA issued a guidance stating that it would exercise enforcement discretion over the following Class I standalone software devices:
  - MDDS
  - Medical Image Storage Devices
  - Medical Image Communication Devices

What is not so clear: Clinical Decision Support

FDA has been promising further guidance on this topic, but it has yet to appear

At one end is electronic copies of clinical practice guidelines and simple calculations



At the other end are sophisticates algorithms based on statistical analysis of large datasets, potentially incorporating machine learning, that make predictions about the likelihood of a particular disease or outcome

These are clearly not medical devices.

These sound like medical devices.

What should you do if your product is in the grey area?

- Consider the published FDA guidance documents
- Look for precedent – 510(k) data base or *mobilehealthnews* feed.
- If you are in the grey area, you can move forward with your device presuming that FDA will tell you if you are doing something wrong (?risk)
- You can ask FDA how your device is classified by submitting a 513g
- You can work with a knowledgeable consultant

Useful References

- Mobile Medical App Guidance
  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf
- Guidance on software in premarket submissions
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf
- Cybersecurity Guidance
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf
- Wireless Guidance
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf

Thank you!

You can only find truth with logic if you have already found truth without it. G.K. Chesterton

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