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Timeline

The Future of FDA Regulation of HIT, including mHealth

By Bradley Merrill Thompson

- The law is not always clear
- March 19, 2013 House Energy And Commerce Committee Kicks Off Three Day Hearing Series On Potential Regulations and Taxes on Smartphones, Tablets, and Mobile Apps
    - In large official looking type, "After Multi-Day E&C Hearing Series Highlighting Uncertainty Created by Medical Device Taxes and Regulations, Obama Administration Finally Goes on Record with Pledge Not to Tax Consumers' Smartphones and Tablets"
- May 21, 2013-- FDA sends enforcement letter to Biosense
- September 5, 2013, the FDASIA advisory committee issues its report to HHS
- September 23 2013, FDA issues MMA guidance
- October 22, 2013, SOFTWARE Act introduced in House of Representatives
    - Medical software
    - Clinical software
    - Health software
- The government doesn't always get it right
- November 19, 2013 House Energy And Commerce holds hearings on the SOFTWARE Act
    - In large type "Examining Federal Regulation of Mobile Medical Apps and Other Health Software."
- December 18, 2013, IMDRF issues SaMD definitions
- The government doesn't know how to protect us – no warning signs
- February 10, 2014, PROTECT Act introduced in the Senate
- March 7, 2014, Gingrich Productions issues report "FDA Shouldn't Get to Veto Apps"
- March 19, UK/MHRA issues standalone software guidance including mobile apps
    - CDS: "software that applies some form of automated reasoning, such as a simple calculation, a decision-support algorithm or a more complex series of calculations, e.g. does calculations, symptom tracking, clinicians guidelines."
    - "Some decision support software may not be considered to be a medical device if it exists only to provide information to enable a healthcare professional to make a clinical decision as they ultimately rely on their knowledge."
    - Electronic health records generally are not regulated, unless they are complex.
    - The guidance also addresses the growing trend of trying to simply disclaim away regulatory obligations. The guidance bluntly says – it doesn't work.

- April 2, 2014, IMDRF issues SaMD classification guidance
    - Nature of the disease
        - Critical condition (including “serious disease”)
        - Serious condition
        - Non-serious condition
    - Role of the software
        - Sole determinant to treat
        - Sole determinant to diagnose
        - Drives clinical management
        - Informs clinical management
- The government sometimes misses the obvious – illiterate?
- April 3, 2014, FDA issues report to Congress under section 618 of FDASIA
    - Administrative Health IT Functionality
    - Health Management Health IT Functionality
    - Medical Device Health IT Functionality
- April 7, 2014 FR Notice soliciting comments on the ideas raised in the section 618 report
- April 10, 2014, AMDM Annual Meeting
    - insert slide from James on combination products
- May 13-15, 2014, FDA will host stakeholder meeting on congressional report
- May 31, 2014 IMDRF comment period closes on classification
    - planned CDS coalition comments
        - substantial user dependence
            - transparency
            - time to reflect
            - capability of user
    - planned MRC coalition comments
        - when is software classified as an accessory to a medical device
- June 30, 2014 FDA comment period closes on report to Congress
    - coalition comments will include submission of specific proposals for
        - the distinction between wellness and disease related claims
        - medical device accessories
        - medical device clinical decision support software
        - medical device software modules
- late summer, FDA issues draft guidances