Key Developments in the Regulation of Software and Digital Health:
New Guidance, Initiatives, and Enforcement

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Marian J. Lee
202.887.3732
MJLee@gibsondunn.com

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Beijing • Brussels • Century City • Dallas • Denver • Dubai • Hong Kong • London • Los Angeles • Munich
New York • Orange County • Palo Alto • Paris • San Francisco • São Paulo • Singapore • Washington, D.C.

The Digital Health Opportunity

Market Growth
- Targeted for more than 20% in next 5 years
- $60 billion market by 2018

Benefits
- Patient engagement in own care
- Real-time data and feedback
- Continuous monitoring
- Rich source of data
- Enhanced remote care choices

Drivers
- Rapid adoption of mobile devices
- Rise of chronic diseases
- Aging population
- Efficiency and savings
- EHR adoption

Challenges
- Regulatory flexibility vs. regulatory clarity
- Convergence of multiple regulators
- Big data responsibilities, privacy, and cybersecurity

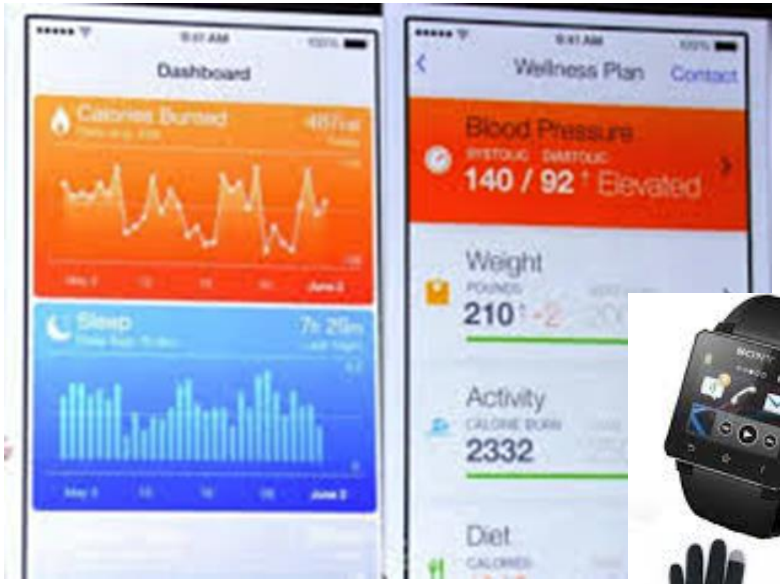
Dexcom Share Glucose Monitoring App

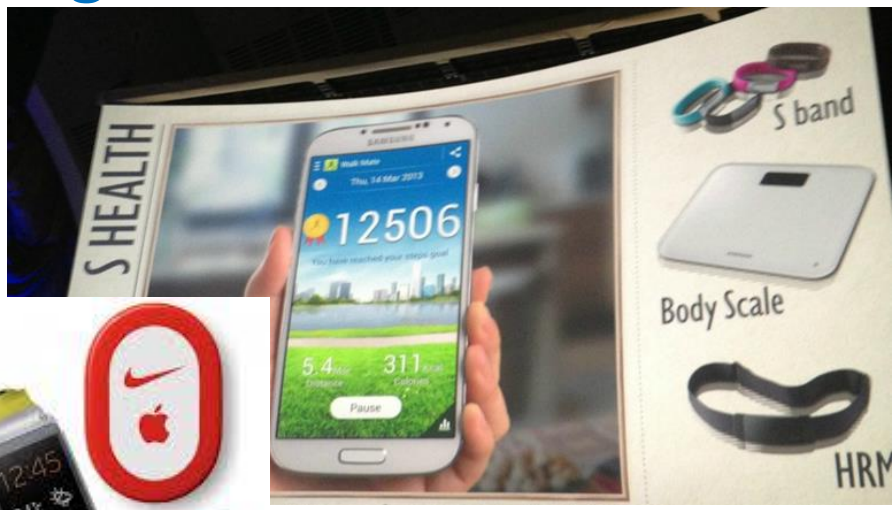
- January 2015 – 1st FDA-reviewed app that allows continuous glucose monitoring (CGM) and sharing of data with other people
- Software displays data from CGM system via apps on patient's device and followers' devices
- De novo classification → Class II, 510(k)-exempt

myVisionTrack

- Enables patients with retinal diseases to monitor their vision function between medical visits
- Device stores test results, tracks disease progression, and automatically alerts a health care provider if detects significant deterioration of visual function
- Product code HPT: Ophthalmic; perimeter, automatic, ac-powered
- Class II, prescription device
- Cleared February 2013

Explosion of Consumer Digital Health Products





Key Developments

1. **New FDA Guidance Documents**
   - Guidance on Mobile Medical Apps
   - Draft Guidance on Medical Device Accessories
   - Draft Guidance on General Wellness Products
   - Guidance on Medical Device Data Systems (MDDS)
2. **FTC Scrutiny and Enforcement**
3. **21st Century Cures Act**

FDA's Comments on the Regulation of Software

- "There is no definitive list"
- "The product spectrum is highly diverse and complex"
- "Decision requires a detailed review of the information available"
- **"Can be confusing very quickly"**

(Source: John F. Murray Jr., FDA/CDRH Software Compliance Expert, March 2010 Presentation)

FDA Guidance: *Mobile Medical Apps (2013, revised 2015)*

- FDA intends to apply its regulatory oversight to:
  - Mobile apps that are medical devices *and*
  - Whose functionality could pose a risk to patient's safety if the mobile app were to not function as intended
    - Used as accessory to regulated device, or
    - Transforms mobile platform into regulated device
- For all manufacturers of mobile apps that are devices, FDA "strongly recommends" --
  - Follow QSR (21 C.F.R. Part 820) during design and development; and
  - Initiate prompt corrections

Regulated Mobile Medical Apps

- Apps that are an extension of a medical device by connecting to the device for the purpose of controlling the device
  - e.g., apps that calibrate or change settings in a cochlear implant
- Apps that transform the mobile platform into a regulated device by using the platform's built-in features, attachments, display screens, or sensors, or by including functionalities similar to those of currently regulated medical devices
  - e.g., apps that attach a blood glucose strip reader to a mobile platform to act as blood glucose meter
- Apps that perform "patient-specific analysis" and provide "patient-specific diagnosis, or treatment recommendations"
  - e.g., apps that creation radiation therapy dosage plan
  - "sophisticated analysis"

FDA's Enforcement Discretion Over Mobile Apps

- Apps that help patients self-manage their disease/condition without providing specific treatment or treatment suggestions
- Apps that meet the definition of medical device data systems (MDDS)
- Apps that enable patients or providers to interact with PHR/EHR
- Apps that prompt a user to enter a drug they would like to take and provide information about drug-to-drug interactions reported in the literature
- Apps that use GPS information to alert asthmatics of environmental conditions that may trigger symptoms
- Apps that use patient age, sex, and behavioral risk factors to provide patient-specific screening and preventive recommendations based on well-known and established sources

FDA Draft Guidance: *Medical Device Accessories* (January 2015)

Is it an accessory?

1. **Intended for use with one or more parent devices**
   - Examine labeling and promotional materials for the accessory
   - Generally would not include mobile phones used as general platform for mobile medical apps

Medical Device Accessories (cont'd)

2. **Intended to "support," "supplement," and/or "augment" the performance of one or more parent devices**
   - Support = enable or facilitate the parent
   - Supplement = add new function or new way of using parent, without changing the intended use of the parent
   - Augment = enable parent to perform intended use more safely or effectively

Medical Device Accessories (cont'd)

- Historically, FDA classified accessories by either --
  - Grouping them with the parent device, or
  - Creating unique, separate classification

→ *Regulate device accessories* ***based on the risks presented when they are used with parent devices***
  - *Will not impute all parent risks to the accessory*

→ *Encourage use of* ***de novo classification*** *for lower-risk accessories of a new type (FDCA § 513(f)(2))*

FDA Draft Guidance:
General Wellness Products (January 2015)

1. **Intended Use**
   - Maintaining/encouraging a general state of health or healthy activity – no reference to disease/condition
   - Associates role of healthy lifestyle with helping reduce the risk or impact of certain chronic diseases/conditions
2. **Present "very low risk" to user safety**
   - Invasive?
   - Pose risk to user's safety if device controls are not applied?
   - Novel questions of usability?
   - Biocompatibility?

→ ***Does not intend to examine whether these products are devices, or, if they are devices, whether they comply with FDA requirements***

FDA Guidance:
Medical Device Data Systems (February 2015)

- MDDS include hardware and software that permit the transfer, storage, conversion of formats, and display of medical data
- MDDS do not modify data or control the functions of any other medical device
- MDDS are not intended for use in active patient monitoring

→ *"Low risk" products that have an "important" role "in advancing digital health"*

→ *Will exercise enforcement discretion --*

- *MDDS (21 CFR 880.6310),*
- *Medical image storage devices (21 CFR 892.2010)*
- *Medical image communications devices (21 CFR 892.2020)*

FDA Enforcement: *uChek Urine Analyzer App*

1

Dip stick in sample for

2 seconds

2

Insert stick in the mat

Use white paper as background

3

Enclose mat in Cuboid

Place phone in place so that camera and flash peep through

uChek™app

4

Click "Begin" and in the next 30 seconds,

Centre the ColorMat in camera overlay screen.

Wait while the app is processing...

5

View results

Email | Save | Trend

FDA Enforcement: *uChek Urine Analyzer App*

- FDA's "It Has Come to Our Attention Letter" (May 2013)
  - Urinalysis dipsticks are FDA cleared, but only when interpreted by direct visual reading
  - "Since your app allows a mobile phone to analyze the dipsticks, the phone and device as a whole functions as an automated strip reader. When these dipsticks are read by an automated strip reader, the dipsticks require new clearance as part of the test system. Therefore, any company intending to promote their device for use in analyzing, reading, and/or interpreting these dipsticks need to obtain clearance for the entire urinalysis test system…."

FTC Scrutiny and Enforcement

FTC's Broad Reach

- Power to prohibit "unfair or deceptive acts or practices in or affecting commerce" - FTC Act, Section 5
- Advertising for non-restricted medical devices
- Heightened focus on health-related privacy and data security in mobile and software technologies
  - "Mobile Privacy Disclosures: Building Trust Through Transparency: A Federal Trade Commission Staff Report"
  - "Medical Identity Theft: FAQs"
  - Health Breach Notification Rule
  - FTC Staff Report, "Internet of Things" (January 2015)
  - FTC Workshop on cross-device tracking (November 2015)

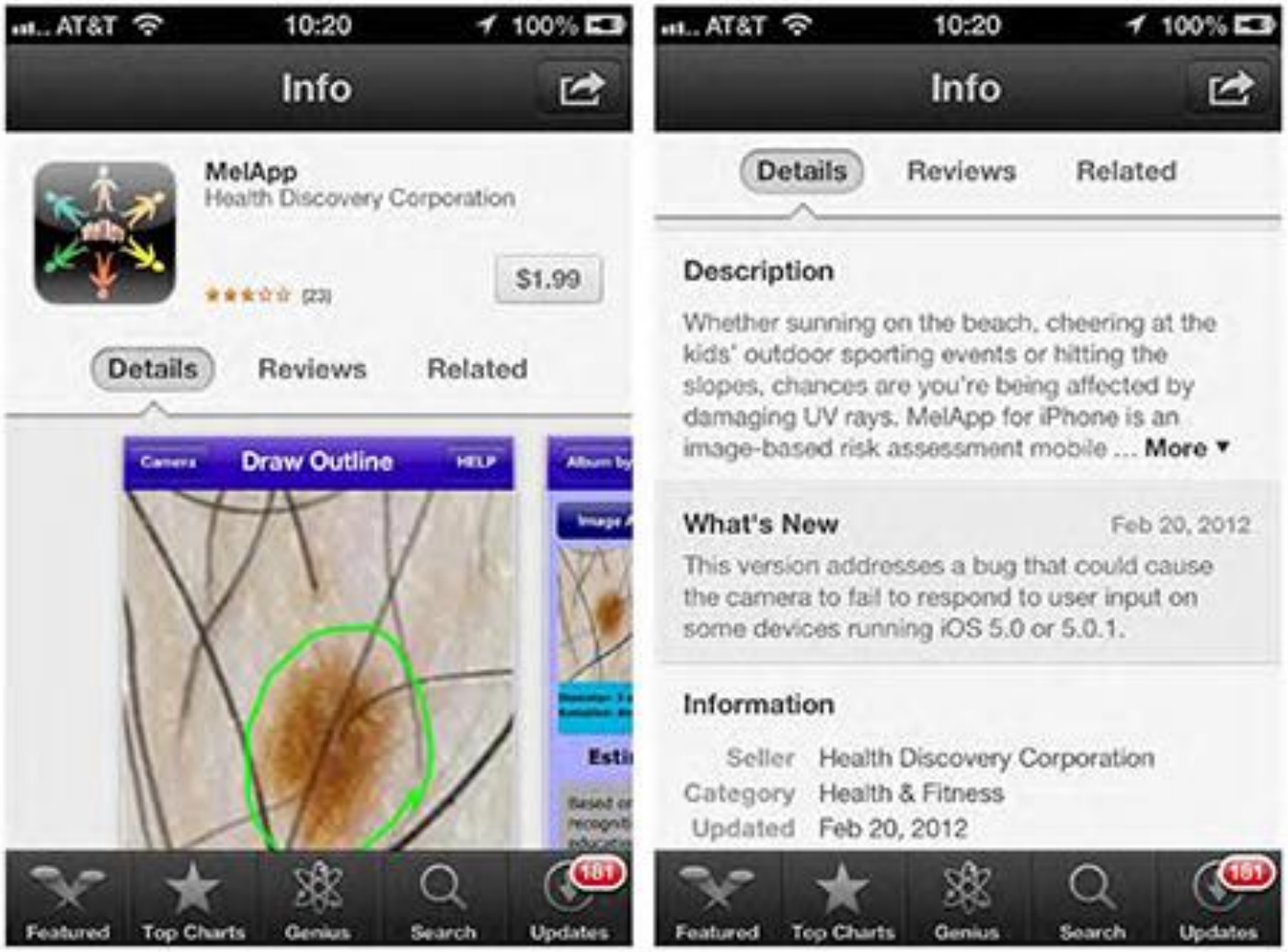
FTC Enforcement: *Acne Apps*

- September 2011 FTC settlement with manufacturers of two apps that claimed to treat acne with colored lights emitted from smartphones
- FTC charged that promotional claims were unsubstantiated
- $16,000 fine

"Smartphones make our lives easier in countless ways, but unfortunately when it comes to curing acne, there's no app for that."

- FTC Chairman, Jon Leibowitz

FTC Enforcement: "MelApp" and "Mole Detective"



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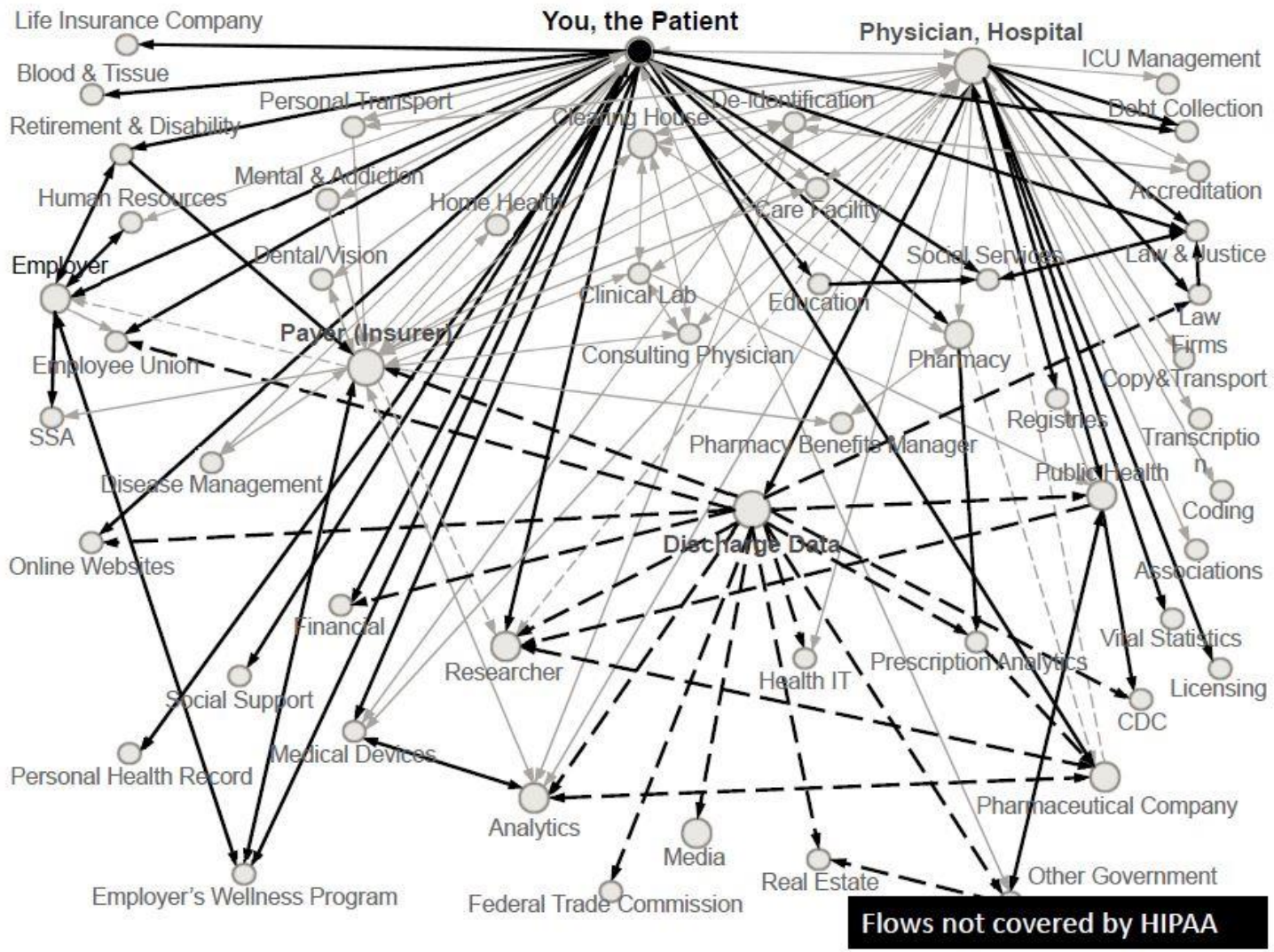
"MelApp" and "Mole Detective" (cont'd)

- Users submitted pictures and information about suspect moles and apps analyzed risk of melanoma (low, medium, high)
- Product claims
  - "patent protected state-of-the-art mathematical algorithms and image-based pattern recognition technology to analyze the uploaded image"
  - "first and only app to calculate symptoms of melanoma right on the phone"
  - "analyzes your mole using the dermatologist ABCDE method and gives you a risk factor based on the symptoms your mole may or may not be showing"
  - "increase the chance of detecting skin cancer in early stages"
  - "saves lives through the early detection of potentially fatal melanoma" using "shape recognition software"

"MelApp" and "Mole Detective" (cont'd)

- FTC's allegation: Deceptive claims that app accurately analyzed melanoma risk and could assess such risk in early stages, and that its accuracy was scientifically proven
- Final consent orders (April 2015)
  - Prohibit making claims that device can detect or diagnose melanoma, unless the representation is truthful, not misleading, and supported by competent and reliable scientific evidence in the form of human clinical testing of the device
  - Prohibit making any other deceptive claims about a device's health benefits or efficacy, or about the scientific support for any product or service
- Companies to pay over $20,000 total as part of settlements



FTC, Consumer Generated and Controlled Health Data, May 2014

FTC Meeting (2014): Digital Health Privacy Studies

- **2014 FTC study of 12 health and fitness apps and 2 wearables**
  - Focus on app traffic
  - Apps transmitted personal and identifying information to 76 different 3rd parties
- **2013 study of 43 free and paid health and fitness apps**
  - Focus on app traffic and privacy policies
  - 26% free apps and 40% paid apps had no privacy policy
  - 39% free apps and 30% paid apps sent data to someone not disclosed by developer
  - 13% free apps and 10% paid apps encrypted all data connections between apps and developer's website

FTC Enforcement: *LabMD*

- FTC complaint against LabMD, alleging that the medical testing lab failed to reasonably protect the security of the personal data (including medical information) of approximately 10,000 consumers
  - Billing information (SSN, dates of birth, health insurance providers, medical treatment codes) for over 9,000 consumers was found on a P2P file-sharing network
  - Documents containing sensitive personal information (SSN, bank accounts) of at least 500 consumers were in the possession of identity thieves
- FTC proposed order
  - Creation of comprehensive information security program
  - Evaluation of program every 2 years for next 20 years by independent expert
  - Require company to notify consumers whose information was or could have been accessible to unauthorized persons

FTC's Perspective

- "LabMD and other companies may well be obligated to ensure their data security practices comply with both HIPAA and the FTC Act. But so long as the requirements of those statutes do not conflict with one another, a party cannot plausibly assert that, because it complies with one of these laws, it is free to violate the other."
- "There are significant privacy implications where health routines, dietary habits, and symptom searches are capable of being aggregated using identifiers unique to that consumer."
- "Although the Commission currently has authority to take action against some IoT [Internet of Things] related practices, it cannot mandate certain basic privacy protections such as privacy disclosures or consumer choice absent a specific showing of deception or unfairness. Commission staff thus again recommends that Congress enact broad based (as opposed to IoT specific) privacy legislation…. In the meantime, we will continue to use our existing tools to ensure that IoT companies continue to consider security and privacy issues as they develop new devices."

21st Century Cures Act

21st Century Cures Act

- Passed by House Energy & Commerce Committee on May 21, 2015; full House of Representatives to consider in July
- Builds off of SOFTWARE Act
- Would focus FDA regulation on health software that poses "a significant risk to patient safety"
  - Fate of clinical decision support software remains unclear
- Would require FDA to classify device accessories according to the accessory's intended use, "independently of any classification of parent device with which it is used'
- Would require FDA to gather stakeholder input within 18 months of enactment before issuing any reg or guidance

Thank You