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FDA Regulatory Environment for Wearables, Implantables, and Other Digital Health Devices

June 7, 2016

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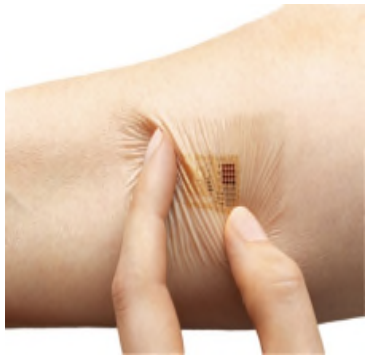
What is digital health?

- Hardware, software and mobile connectivity coming together to create new ways to manage health and treat disease
  - Wearables are an example of digital health technology
- From an FDA regulatory standpoint, we want to consider:
  - What is regulated? What is unregulated? What is subject to enforcement discretion?



How does FDA define a "medical device?"

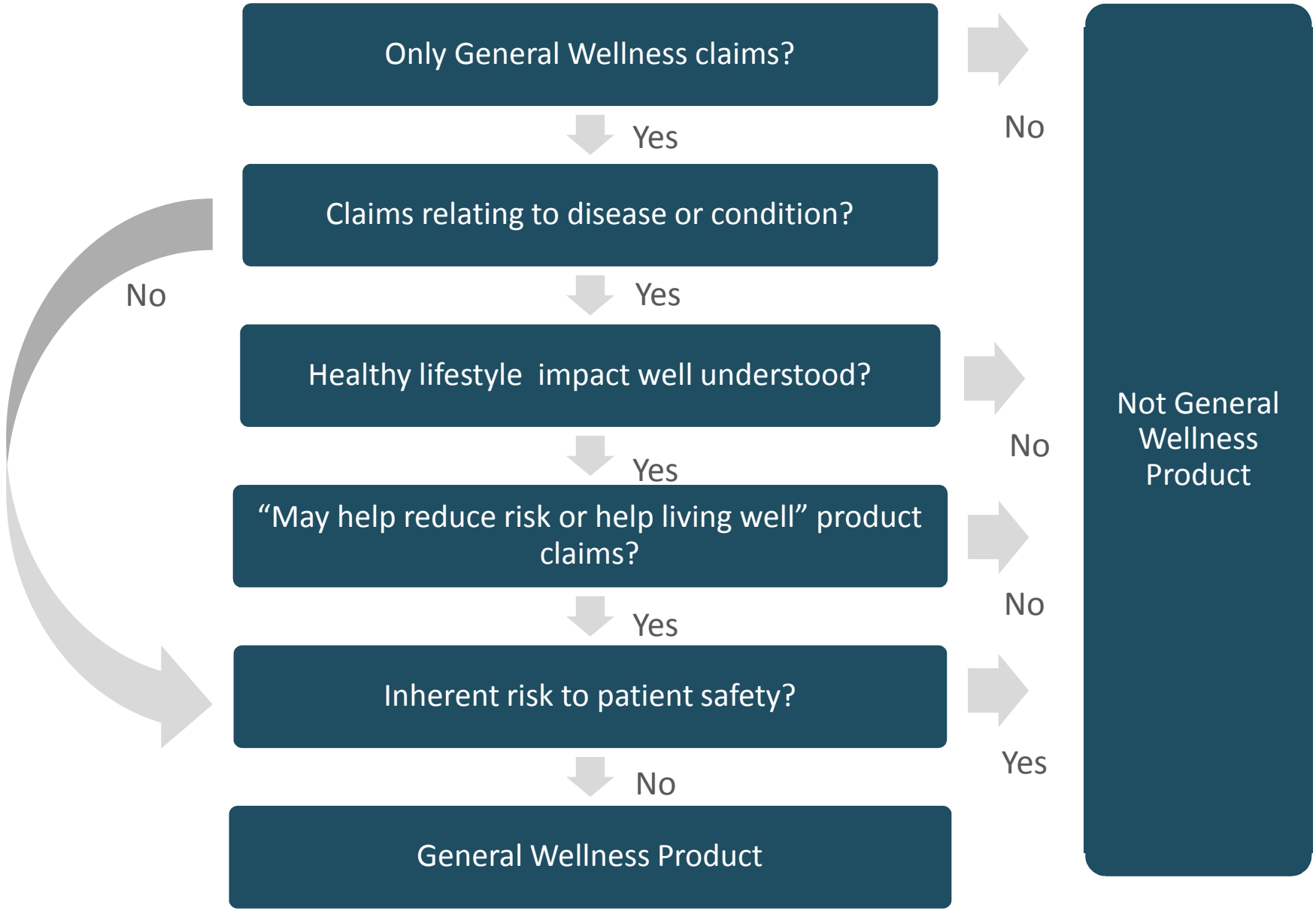
- Section 201(h) of the FD&C Act defines a "device" to include an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man…or
  - intended to affect the structure or any function of the body of man...and

  [that does not achieve its principal intended purposes by chemical action or by being metabolized (i.e., is not a drug or biologic)]."
- Whether something is a medical device turns on whether the manufacturer **intends** it to be used for a medical purpose

FDA Guidance Recap

- Mobile Medical App Final Guidance
- Medical Device Data System (MDDS) Final Guidance
- Accessory Draft Guidance
- Wellness Draft Guidance
  - FDA will not regulate "general wellness products" that are (1) intended only for general wellness use and (2) present a very low patient safety risk
  - A "general wellness product" either has an intended use:
    - Related to maintaining a general state of health or encouraging a health activity (e.g., weight or sleep management, fitness, etc.) or
    - That associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions (and it is well accepted that a healthy lifestyle may play a key role in health outcomes for that disease/condition)
  - Fitbits and other popular wearable exercise trackers would fall under this category

General Wellness Product Decision Tree



What Gets Regulated?

Unregulated

- General purpose IT
- Educational tools, medical textbooks
- Apps that facilitate patient access to information
- Administrative products
- Health Management Health IT
- Health and Wellness

Enforcement Discretion

- Electronic Health Records
- Patient Portals
- Trending, tracking and sharing data with healthcare providers
- Coaching apps – support change in daily environment
- Health tracking apps
- Medication Reminders
- Certain Telemedicine products
- Medical Device Data Systems

Regulated

- Meets definition of medical device under FD&C Act
- Accessories to a medical device
- Apps that connect to an existing device to control its operation/function
- Apps that analyze patient-specific medical device data
- Apps that transform a mobile platform into a regulated medical device

Questions?

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Upcoming Webinars

Wearables Crash Course Series

- **Digital Health Devices and Clinical Trials**
  June 14, 2016 at 2:00 – 2:15 p.m. ET
  Daniel G. Gottlieb

- **FDA Cybersecurity Recommendations to Comply with NIST: A Best Practice for All Wearables?**
  June 21, 2016 at 2:00 – 2:15 p.m. ET
  Kim Tyrrell-Knott

- **Privacy and Wearables**
  June 28, 2016 at 2:00 – 2:15 p.m. ET
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Thank you.