Digital Therapeutics: The Third Phase of Medicine?

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TREEHOUSE HEALTH

Fredrikson & BYRON, P.A.

Presenters

J.D. Blank
Managing Director
TreeHouse Health
612.486.5932
jd@treehouse-health.com

Ryan Johnson
Shareholder
Fredrikson & Byron, P.A.
612.492.7160
rjohnson@fredlaw.com

Jeff Steinle
Counsel
Fredrikson & Byron, P.A.
612.492.7205
jsteinle@fredlaw.com

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Rising Cost of Healthcare

- Healthcare is not getting less expensive
  - CMS projects 5-6% growth in spending over the next decade (up from 4.2% growth from 2009-2016)
- Consumers are not immune
  - CMS projects Out-of-Pocket expenditures to increase from an average growth rate of 2.7% from 2010-2016 to 4.65% from 2017-2026

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

Rising Cost of Healthcare

- Healthcare expenditures in the U.S. exceed all other industrialized nations, but outcomes are not much better
  - Need to control costs by reducing waste and inefficiencies

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

Access and Utilization

- Despite an increase in health insurance enrollment, as many as 28% of all insured adults are classified as “underinsured”
- One-third of U.S. adults go with out recommended care because of access to affordable healthcare
- Patients and their caregivers often lack the tools to better self-manage care

http://www.commonwealthfund.org/publications/in-the-literature/2016/nov/2016-international-health-policy-survey-of-adults

Consumerism

- With more “skin in the game,” consumers are more likely to be engaged in their health and are more sensitive to price
- Widespread adoption of HCIT by incumbent players makes consumer oriented digital health solutions possible

https://www.accenture.com/us-en/insight-new-2018-consumer-survey-digital-health

Consumerism

- Consumers are using technology to manage their health
  - 75% of U.S. consumers acknowledge that technology is important to managing their health
- Consumers are demanding convenience and access
  - 90% of patients use convenience and access as a proxy for quality

https://www.accenture.com/us-en/insight-new-2018-consumer-survey-digital-health

The Role of Digital Health

- Cost
  - Reduce inefficiencies inside a clinical setting
    - CDS
    - Personalized medicine
    - Process improvement
  - Reduce inefficiencies outside of a clinical setting
    - Telemedicine
    - mHealth solutions
    - Wearables

The Role of Digital Health

- Access
  - Ability to reach more people and break through cost and geographic barriers
- Consumerism
  - Provide a better consumer/member experience
  - Use data to reach and engage consumers in new ways

What are digital therapeutics?

- Intervention based on software
- Examples:
  - Pear Therapeutics
    - Software-only substance abuse therapy
  - Proteus Digital Health
    - Sensor-equipped pill with companion app
  - Akili Interactive Labs
    - Video game-based pediatric ADHD treatment

How do digital therapeutics fit into the digital health ecosystem?

Digital Health Broadly

Health Apps

Health IT / Services

Telemedicine

Automation and Robotics

Consumer apps and wearables

Clinical Research

Connected Devices / IoT

Medical Algorithms

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Digital Therapeutics

Health Apps

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Medical Algorithms

What are the regulatory challenges for digital therapeutics companies?

- FDA approach to regulating digital health
  - “Encourage innovation"
  - “Bring efficiency and modernization" to digital health regulation
- FDA’s jurisdiction over “devices”
  - When should software be consider an FDA regulated “device”?

21st Century Cures Act

- Clarifies FDA jurisdiction over digital health products
  - Excludes certain types of software from definition of “medical device”
  - Clinical-decision support software

"Clinical and Patient Decision Support Software" Draft Guidance

- Intended to "make clear what types of CDS would no longer be defined as a medical device, and thus would not be regulated by" FDA
- Provides that FDA will "continue to enforce oversight of software programs that are intended to process or analyze medical images, signals from in vitro diagnostic devices or patterns acquired from a processor like an electrocardiogram that use analytical functionalities to make treatment recommendations, as these remain medical devices under the Cures Act"

“Section 3060 Guidance”

- Outlines types of software FDA no longer considers medical devices (e.g. lifestyle or wellness apps)
- Proposes changes to FDA's earlier General Wellness products and Mobile Medical Applications and other guidance to “be consistent with the Cures Act and reflective of the agency's new, more modern approach to digital health products”

“Section 3060 Guidance”

- Not “devices”
  - Software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition

“Software as Medical Device (SaMD): Clinical Evaluation”

- Goal: create common understanding of clinical evaluation and principles for demonstrating the safety, effectiveness and performance of SaMD
- Three key principles
  - valid clinical association
  - analytical validation
  - clinical validation

“Software as Medical Device (SaMD): Clinical Evaluation”

- If foregoing not established, manufacturer must revise the SaMD’s intended use consistent with available evidence, modify the target clinical association and/or make changes to the software

Digital Health Innovation Action Plan

- FDA's attempt to “reimagine the FDA's approach to ensuring all Americans have timely access to high-quality, safe and effective digital health products”
- Digital Health Software Precertification Program
- Digital Health Entrepreneur-In-Residence Program

Final Thoughts on FDA . . . (for now)

- FDA focused on “encourag[ing] innovation in the ever-changing field of digital health" by providing "more clarity on and innovative changes to [FDA's] risk-based approach to digital health products”
- Cures Act amended the FDCA to exclude certain types of medical software from the definition of “device”

Final Thoughts on FDA… (for now)

- Certain AI-based health products excluded if, among other things, the software allows independent review of clinical recommendations by health care professional(s)
- FDA working with industry and other stakeholders to develop a new, more efficient regulatory paradigm

Consumer Product Safety Commission

- Digital health products may be considered consumer products under CPSC jurisdiction
- CPSC responsible for consumer product safety (not privacy)

Federal Advertising Laws

- Federal Trade Commission
  - FTC consumer protection law prohibits unfair or deceptive trade practices
    - Applies to all mobile apps
- Enforcement actions
  - Cheerios Letter
  - Acne Case

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What areas of medicine are best positioned for digital therapeutics?

- Chronic diseases/behavioral
  - Shortage of providers compared to needed patient contact
  - Family members supplementing care
- High data / multi-factoral diagnoses
- Closed loop devices

What are some of the evolving business models for digital therapeutics?

- Direct to consumer/patient?
- Should employers or payors cover the services?
- Focus on value-based healthcare
- Reimbursement model better suited for gain-sharing rather than traditional fee for service/products

What are some of the evolving business models for digital therapeutics?

- Risk shift to providers from payers
- Potential for application in new cost-focused markets (i.e. private pay hospitals in emerging markets)
- Mix of capital equipment, licensing, white label, subscription based and freemium models

What are some practical strategies for protecting intellectual property?

- Trade secrets vs. patents
  - *Alice Corp. v. CLS Bank International*
  - Rapid technology turns
  - May be difficult to reverse engineer
- *Data* as the new IP
  - Track data ownership; consolidate rights
- *People* as the new IP
  - Limited number of people with AI skills

How should digital therapeutics companies prepare for an exit?

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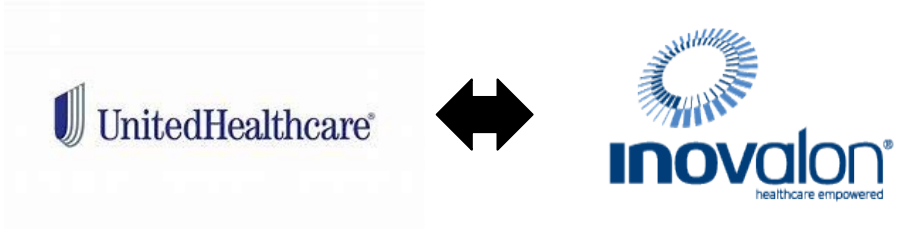
The Players

- Traditional med tech:
  - Medtronic
  - Abbott
  - Boston Scientific
  - Johnson & Johnson
- Tech companies:
  - Google
  - Apple
  - Amazon
  - Samsung

- Spin-outs/divisions/JVs:
  - Verily
  - Verb
  - Galvani
- Payers:
  - Optum
  - BCBS
  - Aetna
- Healthcare Orgs:
  - Mayo
  - TMC
  - Cleveland Clinic
- Smaller, purpose-driven new companies

Types of Strategic Deals

- Heightened need for collaboration
- Data gatherers, aggregators/processors, users
- Data sharing arrangements, joint ventures, licensing
- Roll-up of smaller players earlier in company life cycle



What other challenges do digital therapeutics companies face?

- Legal:
  - Cybersecurity
  - Privacy
  - Product liability
  - Malpractice
- Non-Legal:
  - Funders
  - Personnel
  - Standing out, while plugging into existing ecosystem

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