

Digital Health in a Digital World



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SOA Antitrust Compliance Guidelines

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The United States antitrust laws aim to protect consumers by preserving the free economy and prohibiting anti-competitive business practices; they promote competition. There are both state and federal antitrust laws, although state antitrust laws closely follow federal law. The Sherman Act, is the primary U.S. antitrust law pertaining to association activities. The Sherman Act prohibits every contract, combination or conspiracy that places an unreasonable restraint on trade. There are, however, some activities that are illegal under all circumstances, such as price fixing, market allocation and collusive bidding.

There is no safe harbor under the antitrust law for professional association activities. Therefore, association meeting participants should refrain from discussing any activity that could potentially be construed as having an anti-competitive effect. Discussions relating to product or service pricing, market allocations, membership restrictions, product standardization or other conditions on trade could arguably be perceived as a restraint on trade and may expose the SOA and its members to antitrust enforcement procedures.

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- **-Do not** discuss what you or other entities plan to do in a particular geographic or product markets or with particular customers.
- **-Do not** speak on behalf of the SOA or any of its committees unless specifically authorized to do so.
- **-Do** leave a meeting where any anticompetitive pricing or market allocation discussion occurs.
- **-Do** alert SOA staff and/or legal counsel to any concerning discussions
- **-Do** consult with legal counsel before raising any matter or making a statement that may involve competitively sensitive information.

Adherence to these guidelines involves not only avoidance of antitrust violations, but avoidance of behavior which might be so construed. These guidelines only provide an overview of prohibited activities. SOA legal counsel reviews meeting agenda and materials as deemed appropriate and any discussion that departs from the formal agenda should be scrutinized carefully. Antitrust compliance is everyone's responsibility; however, please seek legal counsel if you have any questions or concerns.

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INTRODUCTION



What is Digital Health?

- Coming together of digital technologies with health, healthcare, living and society to enhance the efficiency of healthcare delivery
- Hardware and Software solutions, technologies and services
- Multidisciplinary domain - clinicians, researchers, scientists with expertise in healthcare, engineering, social sciences, public health, health economics and data management
- Counts for 32% of health care deals as pharma accounts for growing proportion of deal share

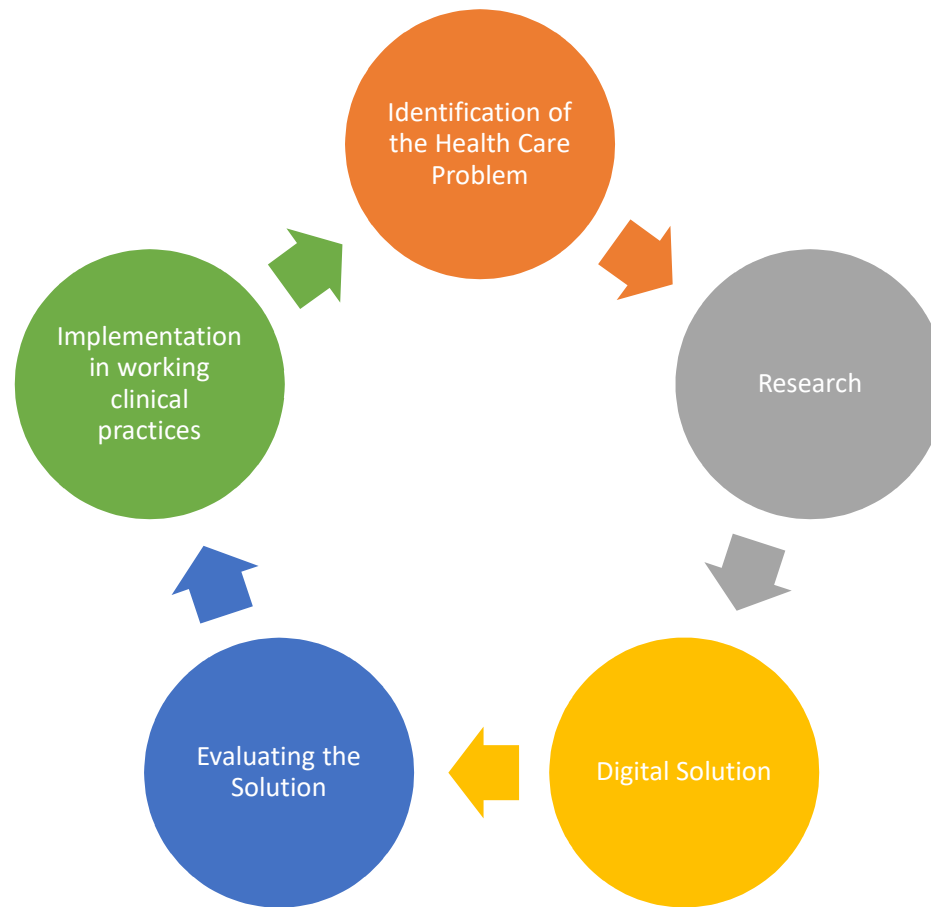
Polling Questions

- How many of you have a Fit Bit?
- How many of you have an Apple Watch?
- How many of you have an App to track your steps or your physical fitness levels?
- How many of you have an App to track your mood or happiness levels or weight?
- How many of you have had a telehealth appointment within the past 6 months?
- Have you used 23 and Me or another company similar to this one?

How we might be familiar with Digital Health

- Wearable devices – Fitbit, Apple Watch
- E-health – delivers health information and services to enable data transmission, storage and retrieval for clinical, educational and administrative purposes
- Mobile Health – practice of medicine and public health supported by mobile devices
- TelADoc, Livongo, Retrofit, Noom

The Innovation Cycle



Livongo

- Glen Tullman's son diagnosed with diabetes at age 10; asked Dad to find a cure
- Focuses on Diabetes
- Sells an FDA cleared two-way, interactive glucometer, unlimited supplies for monitoring, cloud-based analytics, and real-time monitoring and support to customers
- Personalized Insights – prompt members to take action when it is most likely to have clinical impact; health coaching
- Measurable Outcome is to reduce HbA1c – 1% reduction in HbA1c leads to a 21% reduction death from diabetes; 14% reduction in Heart Attacks and 43% reduction in Peripheral Vascular Disease
- Owns Retrofit – weight loss digital health company
- Measures success using Net Promoter Score as well as ROI
- Dean Foods saved \$70 per participant per month on costs for Livongo Members (from website)

ZEST HEALTH

Since Livongo, Glen Tullman has created ZEST HEALTH, which is telemedicine where ever you are

- Smart phone app

- Upload insurance card into Zest app

- Concierge can answer questions about coverage

- Can schedule in-network care – via email, call, chat in app

- Can tell you about price for the procedure

- Billing issues – will help file an appeal

Digital Health Areas - Apps

■ Clinical Trials –

- companies working to improve operations in drug research and development, study design, patient recruitment and adherence and compliance
- Fitabase
 - Uses mobile health tools to measure, track and engage research participants
- Trialbee
 - Help clinical trials find the right patients and help to retain them in the studies

■ Women's Health

- Focuses on fertility solutions, period-tracking apps, pregnancy and nursing care, menopause
- CLUE – app to track the ovulation cycle and in-depth information to learn about your body

Digital Health Areas – Apps + Regulation

- Cannabis
 - Resolve
 - Leading provider of standardized medical cannabis for cancer patients
 - A smart flower inhaler designated for health and the research market
- Mental Health and Wellness
 - Over 10,000 apps available
 - Focus on boosting your mood, increasing your sleep, and even help to manage addictions
 - Any app that is intended to diagnose, prevent or treat a mental illness must undergo efficacy and safety studies to gain pre-market clearance from the FDA
 - Lack of efficacy
 - Non-existent or inaccurate suicide Crisis helpline phone numbers
- Genomics
 - Lead to quicker diagnosis and tailored treatments
 - Helix purchased HumanCode
 - Takes on sample collection, sequencing, and data storage, enabling third party developers to take care of DNA insights for projects related to health, ancestry and more

Digital Health Areas- Regulated

- Digital Therapeutics

- Independent category of evidence-based products within broader digital health arena
- Out of hospital solutions
- Deliver software-generated therapeutic interventions directly
 - to address a medical condition
 - to manage or prevent a medical disorder or disease,
 - to optimize medication
 - to treat a medical disease or disorder

- AI

- Prime focus is radiology and pathology
- SigTuple – hardware and software products to digitize pathology results for hospitals and clinic
- Lifetrack Medical Systems – easy to interpret radiology readings for medical diagnosis by pairing a resident with an experienced radiologist who helps evaluate medical images and send the reports

Digital Health Regulation

- Digital Health Innovation Action Plan
- FDA in 2019 created Digital Health Program
- Continually improve safety and effectiveness of medical devices
- Frequent updates and modifications
- Challenges of cybersecurity and interoperability
- Consumer technology transcending international boundaries

Digital Health Program

- Focuses oversight on mobile medical apps to only those that present higher risk to patients
- NOT focus on technologies that receive, transmit store or display data from medical devices
- NOT focus on products that only promote general wellness
- DOES provide clarity on expectations pertaining to cybersecurity
- 510(k) – submit when there is a software change to an existing device 90 days prior to offering device for sale

Financing of Digital Health Startups

- Private Equity and Venture Capital financing of over \$3B in Q1 2020
- Venture Capitalists
 - > First Round
 - > Jumpstart
 - > Chiratac
 - > Civilization Ventures
 - > Perceptive Advisors
 - > **Echo Health Ventures**
 - > F-Prime
 - > Illumina
 - > Khosla

42 Health Unicorns Valued at almost \$100 Billion Globally

North American Digital Health	
Samumed	Butterfly Network
Intarcia Therapeutics	Calm.com
Outcome Health	Human Longevity
Oscar Health	HeartFlow
GRAIL	Proteus Digital Health
Tempus Labs	Adaptive Biotechnologies
Clover Health	Ginkgo BioWorks
Devoted Health	GoodRx
ZocDoc	Health Catalyst
23andMe	

European Digital Health	
Benevolent AI	Ottobock
Roivant Sciences	Doctolib
Nanopore	CureVac
Mindmaze	

Asia Digital Health	
United Imaging	WeDoctor
JD Health	Medlinker
Tencent Doctorwork	iCarbonX
Henlius	LinkDoc





Expectations from Public and Private Payors

- Deliver clinical, service efficiency, and health economic benefits
- Achieve commercial scale through partnerships between digital health companies and industry partners
- Demonstrate improved clinical health and economic outcomes at patient and population levels
- Receive coverage similar to existing medicine and therapies

Lines of Business

- Needs to be a primary payor
 - Commercial
 - ASO plans
 - Medicare Advantage
- How to Measure Success
 - ROI – savings over amount paid
 - Net Promoter Score – subjective
- Is the feature needed to be market competitive?
- If it is a device, for example, to monitor the heart, how does it get covered by insurance?

COVID19 and Digital Health

- Telehealth and Mental Health arena are the 2 big categories of funding
- Contact Tracing, testing and surveillance
- Just recently Northwestern University has come out with a throat patch which can adhere to a person's throat and can monitor a person's cough, breathing patterns, heart rate and body temperature
- Focus on Seniors

Discussion

- What ideas do you have for a digital health opportunity?
- What would you say would make a digital health opportunity to be a good partner with a health plan?
- What opportunities do you think an actuary could have within a digital health company?

References

- <https://www.weforum.org/agenda/2020/04/high-anxiety-calls-for-innovation-in-digital-mental-health-6b7b4e7044>
- <https://www.idigitalhealth.com/news/genomics-startup-helix-acquires-humancode-grows-leadership-team>
- https://dtxalliance.org/wp-content/uploads/2018/09/DTA-Report_DTx-Industry-Foundations.pdf
- CB_Insights_Healthcare-Report-Q2 2019.pdf
- CB_Insights_Healthcare-Report-Q1-2020.pdf
- <https://www.fda.gov/medical-devices/digital-health>

