# Digital Health: Emerging Legal, Regulatory and Ethical Issues

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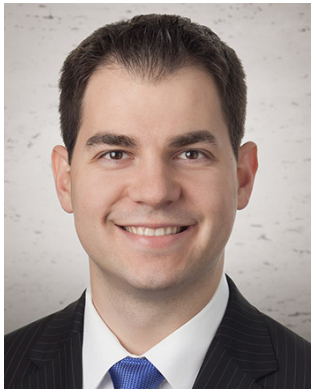
# Presenters

Ryan is a digital health and corporate attorney in Fredrikson & Byron's Health Care and Innovation Groups. Ryan helps his clients develop and launch innovative business models designed to improve healthcare quality, accessibility, and affordability. He serves as outside general counsel for digital health companies and healthcare providers who are transforming healthcare through innovation and cutting-edge science and technology.



Nick is an IP attorney in Fredrikson & Byron's Intellectual Property and Artificial Intelligence Groups. Nick leverages his computer science background to advise clients in efficiently and successfully resolving complex IP issues. He represents clients in federal courts throughout the United States and in *inter partes* review proceedings before the Patent Trial and Appeal Board.

# Today's Agenda

- Overview of Digital Health Ecosystem
- Common Legal Issues for Digital Health Companies
  - Data: Privacy and Security; Intellectual Property
  - Liability: Negligence, Contracts (indemnification/risk allocation)
  - Reimbursement
  - Fraud and Abuse
  - Regulatory: FDA and FTC
- Q&A

# Digital Health Broadly

Health Apps

Health IT / Services

Telemedicine


Automation and Robotics

Consumer apps and wearables


Clinical Research

Connected Devices / IoT

Medical Algorithms

# The Role of Digital Health

- Reduce Costs
- Improve Access and Quality
- Engage and Empower Consumers

# Data as an Asset

- Big-Data Revolution
- Value of Data

# Digital Health: Barriers to Adoption

- Legal and Regulatory Landscape
- Reimbursement
- Lack of Data Strategy and Management

# ARTIFICIAL INTELLIGENCE

# Artificial Intelligence/Machine Learning

- What is AI?
- What is machine learning?

# AI in Healthcare

- AI in medicine
  - Clinical Care
  - Medical Research
  - Efficiency
  - Other Applications

- “Black-box” concerns

# AI: Legal and Ethical Issues

- Privacy and Security
- Liability
  - negligence/malpractice
- Regulatory Landscape (FDA)
- Fraud and Abuse
- Intellectual Property

# Privacy and Security

- HIPAA's Applicability
  - Covered Entities
  - Business Associates
- Protected Health Information
- Treatment, Payment and Healthcare Operations
  - authorization not required
  - do definitions work for AI
- De-identification
  - risk of re-identification

# Feeding the Machine

- Accessing data to train algorithms
  - Does data contain PII?
  - Publicly available data?
  - Terms of license?
  - Source of data?

# Tort

- Liability of developers?
- Liability of healthcare professionals/ providers?

# Liability of Developers

- Courts generally reluctant to hold software developers liable
  - rulings made before advanced AI
  - clinicians made final decisions

# Liability of Healthcare Professionals/Providers

- Duty of care
- Reliance on AI?
  - Duty to evaluate and confirm quality, accuracy and reliability of “black box” algorithms?
  - Risks of second-guessing/rejecting AI recommendations?

# Regulatory Landscape: FDA Overview

# What are the regulatory challenges for digital health 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 (“CDS”)

# "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

- 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

# FDA and AI

- Certain AI-based health products excluded if, among other things, the software allows independent review of clinical recommendations by health care professional(s)
- FDA supports innovation in areas with evolving regulatory standards, including AI.
  - performance benchmarks, data collection (imaging datasets, wearable device data, patient-reported outcomes), clinical trials

# Final Thoughts

- 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."
- 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

# Fraud and Abuse

- Anti-Kickback Statute
  - illegal to offer, solicit, make or receive any remuneration intended to influence referrals under a federal health care program
- Self Referral Prohibition (Stark)
  - physician may not make a referral to an entity for the furnishing of designated health services if the physician (or an immediate family member) has a financial relationship with the entity
- State Laws
  - AKS, self-referral, fee-splitting

# AI Components with IP Considerations

- Hardware/Technological Components
  - What is AI incorporated into?
- Software/Algorithm
  - Complex and becoming even more complex (sophisticated)
  - The core of AI
- Data
  - This is what drives AI
  - Must be generated/acquired, organized, and analyzed

# IP Considerations for AI Components

- Protection
  - Can the IP/Data remain yours? Can you restrict others' use?
- Inventorship/Authorship
  - Who is the inventor/author of the invention/artistic work?
- Ownership/Accessibility
  - Are you the sole owner of the IP/Data? Can you use/receive Data?
- Marketability
  - Can you sell the product with any necessary restrictions/obligations on use?

# IP Protection

- **Patent**
  - Protects functionality – suited for complex systems or processes
  - Requires disclosure
  - Requires application and time until issuance
  - Geographic limitations
  - Powerful right to exclude for limited term
- **Trade Secret**
  - Protects functionality
  - Requires secrecy
  - Immediate protection
  - Can be lost instantly through public disclosure or independent invention
- **Copyright**
  - Protects original works
  - Limited to specific expression, not functionality or utility
  - Immediate protection

# IP Protection – Patent

- Requires:
  - Eligible subject matter (35 U.S.C. § 101)
    - Recent case law has significantly impacted the opportunity for software/AI inventions
    - Excludes “abstract ideas”
  - Novelty (35 U.S.C. § 102)
    - Your invention must be “new”
  - Non-obviousness (35 U.S.C. § 103)
    - Your invention must not be “obvious” from existing “prior art”
- “Prosecution” process through U.S. Patent and Trademark Office
- Application timing is key
- European Patent Office recent guidelines on AI patentability

# IP Protection – Trade Secret

- Requires:
  - Eligibility
    - “information, including a formula, pattern, compilation, program, device, method, technique, or process”
  - Derives independent economic value from not being generally known
  - Reasonable efforts to maintain secrecy
- Strengthened by enactment of Defend Trade Secrets Act
- No guarantee for protection against independent discovery or public disclosure

# IP Protection – Copyright

- Requires:
  - Eligibility: “original works of authorship,” which includes computer programs, graphics, appearance, word choice, and compilations of data
- Protection exists when work is fixed in “tangible medium of expression”
  - Registration of a copyright offers several benefits
- “In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery….” 17 U.S.C. § 102
- Consider including encryption or anti-circumvention technology

# How to Best Protect AI

- Consider the following:
  - Can the invention be reverse engineered?
  - Likely to be independently discovered?
  - Likely to sell or cross-license?
  - Do purchasers/users need to understand internal process to have confidence in result?
  - Where do you need protection?
  - How long do you need protection?
  - What is the expected value/importance of the innovation?
  - How much cost can you invest?

- Context matters!
  - Consult with an IP attorney to discuss best course of action

# Inventorship/Authorship of IP

- **AI-Generated Patents**
  - With limited exceptions, a patent application must be made or authorized by inventor
  - Is AI likely to be considered an inventor in the eyes of the law?
  - Without an inventor, IP could enter public domain
  - Important to address delivery, use, or direction of AI systems through assignment agreements

- **AI-Generated Copyrights**
  - Guidance from the Copyright office:
  - "[t]o qualify as a work of 'authorship' a work must be created by a human being." Compendium of U.S. Copyright Office Practices § 313.2.
  - Copyright Office will "not register works produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or invention from a human author."

# Ownership and Accessibility

- Ownership and right to use are generally governed by contract/licenses

- Considerations:
  - Where is data acquired from?
  - Does it need to be periodically updated?
  - Who owns the data?
  - Are there restrictions for using the data?
  - Sharing with other parties?
  - Do you have any responsibility/liability for data?
  - Privacy concerns?
    - HIPAA
    - GDPR
    - California Consumer Privacy Act of 2018

# Takeaways for AI Innovations

- Consider what drives the value for AI
- Consider how to best protect the value of any innovation
- Consider what data may be necessary to allow AI to work
- Consider what competitors are doing with respect to AI

# Closing Thoughts on AI

- Remember duties to patients
- Evaluate AI software capabilities
  - due diligence; continual process
- Contractual protections
  - representations/warranties, indemnification, insurance, etc.
- Pay attention to legal/regulatory developments
- The future of AI in clinical-decision making?

# Digital Therapeutics

# What are digital therapeutics?

- Interventions 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



# Legal/Regulatory challenges for digital therapeutics companies?

- Privacy and Security
- FDA
- Federal Trade Commission
  - Direct-to-Consumer
    - advertising must be truthful and non-deceptive
    - advertisers must have evidence to back up claims
    - advertisements cannot be unfair
- Consumer Product Safety Commission
- Americans with Disabilities Act

# 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


# Consumer Product Safety Commission

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

# Americans with Disabilities Act

- Anti-discrimination provisions covering disabled persons
  - covers technologies such as websites and apps
  - plaintiff law firms are very active
- Actions to reduce risks
  - adopt Accessibility Policy
  - require vendors to provide “accessible” work product and services
  - obtain Cyber Liability Insurance with coverage for ADA and Rehabilitation act claims
  - do not throw out or ignore a demand letter

# 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

# IP Considerations for Digital Therapeutics

- Same components to consider as AI
  - Hardware
  - Software
  - Data
- Same considerations for the components
  - Protection
  - Ownership/Accessibility
  - Marketability
- Also consider
  - Brand or source protection through trademark law

# IoT: Legal Issues

- Privacy and Security
- Service Levels
- FDA
- Consumer Terms

# Precision Medicine/Genomics

- What is precision medicine/genomics?
- Legal Issues and Considerations
  - Discrimination
  - Privacy concerns
  - Liability: variances of unknown significance
  - Reimbursement
  - Direct-to-Consumer Issues
  - FDA

# What is Blockchain?

- Blockchains
  - technology behind cryptocurrencies
- Blockchains are Distributed Ledgers
  - ledgers:  historically centralized and private
  - Blockchains are decentralized or distributed

# Types of Blockchains

- Permissioned vs. Permissionless Blockchains
  - Centralized
    - usually “private”
  - Decentralized
    - usually “permissioned”
  - Distributed
    - usually “permissionless”

# How Blockchain Works

- Chronological Ledger
  - transactions are
    - “pseudo-anonymous”
    - grouped together in “blocks”
    - logged and stamped with information about the time, amount, and participants as if a notary is present at every transaction
- Blockchain is not centralized, but there are strict rules about how it is maintained

# How Blockchain Works: Maintaining the Ledger

- "miners" approve transactions by:
  - bundling transactions into a block
  - verifying the transactions are valid
  - select a header of the previous block and insert it into the header of the new block as a "Hash" combined with an incremental number called a "Nonce"

# How Blockchain Works: Amending the Ledger

- When miners agree on problem solution, the block is added to the chain and is visible to the entire network
- Hash is like a digital version of a wax seal
- The unbroken Hash (seal) confirms that the block, and therefore every block before it, is legitimate

# Smart Contracts

- self-automated computer programs that can carry out the terms of any contract

- mostly based on objective conditions precedent
  - "If, then" criteria

# Healthcare: Blockchain Potential Applications

- Audit and Compliance
- Financial and Contract Management
- Internet of Things (IoT)
- Data Liquidity
- Cyber Security

# Some Examples

- Sunshine Act Compliance
- Payment and Reimbursement
  - pre-authorization
- Supply Chain Management
  - pharmaceuticals

# Legal Issues

- Privacy and Security
  - HIPAA and Business Associates
- Governance
  - Decentralized
- Fraud and Abuse

# IP Considerations for Blockchain

- Same components to consider as AI
  - Hardware
  - Software
  - Data
- Same considerations for the components
  - Protection
  - Ownership/Accessibility
  - Marketability
- Also consider
  - Restrictions from any open source software

# Closing

- Summary
- Key Take-Aways
- Q&A

# Presenters

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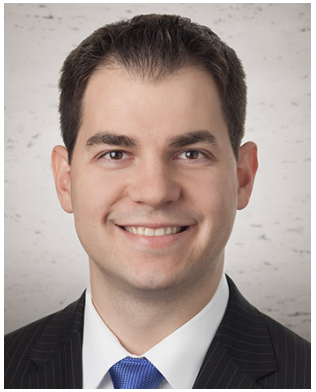

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