SFIA THOUGHT LEADERSHIP WEBINAR

September 17, 2019

Racing Ahead & Keeping Pace in Wearable Technology:
Evolution of the Industry and its Legal Risks

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IF YOU WOULD LIKE TO ATTEND, PLEASE CONTACT ALEX KERMAN, AKERMAN@SFIA.ORG
Racing Ahead and Keeping Pace in Wearable Technology

Dr. Scott McLean and Michelle Gilboe, Esq.
September 17, 2019
Michelle Gilboe, Managing Partner, Lewis Brisbois

- Experienced trial attorney representing sports and fitness companies, consumer products and medical device manufacturers, and health and wellness products
- National counsel defending clients across the country in product liability, mass tort and multi-district litigation, class actions and toxic tort claims
- Focus on science and medicine to support and defend clients
- Client advisor on risk management before, during and after product launch, regulatory compliance and recall and reporting issues
- SFIA Legal Task Force Member
Scott McLean, Ph.D.

- Sports and Recreation Injuries
- Exercise equipment
- Wearable Technologies
- Virtual Clinical Trials
- Tech Accuracy / Quality Standards
- Wearable Data Regulation and Compliance
Tech-Driven Experience and Expertise
Wearable tech continues to rapidly expand what we can measure and how and when we can measure it. Everyone is a athlete whose performance can be quantified, optimized and maintained.
Wearable Tech By the Numbers

56 Million Adults Will Use Wearables During 2019

Global Market Value Projected to reach USD 75 Billion by 2023
Wearable Tech – The Great, Good and Not so Good

- Provides unique insights into personal activity, health and wellness
- Proliferates and drives daily life and function
- New ways of quantifying and sharing who we are
- New and evolving tech continues to WOW the consumer, the athlete, the coach and and clinician
- WOW factor masks growing challenges, pitfalls and concerns
Evolving Use of Wearable Technology Creates New Legal Risks

- Wearable Tech in Court
  - Provides evidence – but how reliable is it?
  - Regulatory compliance issues – who regulates?
  - New crop of civil lawsuits against manufacturers, users and data gatherers of wearable technology
    - Inaccuracy – risk to health; employment opportunities; monetary loss
    - Data breach/Cyber Security
    - False advertising
    - Misrepresentation
    - Ownership of data and duty
Areas of Concern - Opportunity and Growth

- Data Quality / Accuracy
- Data Insights / Interpretation
- Data Ownership / Discovery
- Regulatory Compliance
“Any technology is only as viable as the data that it generates”
Data Quality and Accuracy

Tech hardware/algorithms developed, tuned and validated against homogeneous populations under constrained test conditions – often do not represent broader user base
Data Quality and Accuracy

Limited Product Accuracy Standards Exist Within the Wearable Tech Space

Immediate Need for Standards that are Technically and Legally Viable
Consumer Wearable Tech Proliferation Risks

Consumer Grade Wearable Tech Accuracy Challenges and Limitations Within High-Performance and High-Risk Environments
Wearable Tech And The Patient

Increased prevalence of non-HIPPA Compliant and non-FDA Approved / Regulated Wearables in the Clinical and Rehabilitation Sectors

Massive Data Accuracy, Application and Privacy Concerns
Wearable Tech And The Athlete

Data inaccuracies may directly impact long-term employment, performance incentives, and earning opportunities.
Data Quality and Accuracy

“Best in Class” Accuracy Claims – What Does This Mean for Litigation?

Adverse Impacts of Data Accuracy Mismatches in Review of Forensic Injury Risk
Proliferation of Legal Risk – Anticipate & Protect

• New frontier – New technology and use of known technology in new ways generates new exposure to lawsuits and regulatory oversight

• Lack of applicable standards for consumer products creates broad range of quality of product and affects consumer expectations

• No industry standards strips manufacturers of defense that they did what the industry said they should when hit with claims, lawsuits and regulatory oversight
Potential Claims – Use Your Imagination

• Individual claims for personal injury due to data inaccuracy or interpretation
• Class action lawsuits – Beyond those you have heard of about skin reactions or sleep monitoring
• False Advertising – Marketing claims about accuracy, function, and use opens door to claims of misrepresentation, inducement to buy, detrimental reliance resulting in economic loss
• Regulatory oversight and potential for fines – FDA, CPSC…
• And more
Legal Risk in Medical Application of Wearable Tech

• Broad use: High benefits and high risk
• Wearable technology used in medical settings
  – Outpatient monitoring (heart rate, blood sugar), dispensing of medication
  – Virtual clinical trials – Accuracy of data paramount to validate a new device, pharmaceutical and projected scope of use
  – Testing and gathering of data to diagnose and treat conditions on individuals
  – Using big data in studies to validate potential treatments
Legal Risks of Inaccurate or Misinterpreted Wearable Tech Data

• Medical professional relies upon inaccurate data for treatment give rise to lawsuits:
  – claims of negligence, strict liability, breach of warranty, false advertising and foreseeable misuse against manufacturer or owner of data used

• Users suffer injury and blame wearable tech for reliance on incorrect data
  – Claims for personal injury
  – Claims of economic loss from lost employment opportunities, contracts even loss of benefits

• Users relying on wearable technology to help diagnose or treat conditions and apps or people who interpret the data
  – Everyone in the chain is at risk – manufacturers, data collectors and manipulators, apps, interpreters, users
Data Inaccuracy & Legal Risk

• Contractual and employment implications
  – Anticipate lawsuits alleging lost business opportunities, lost job opportunities
When is Wearable Tech Subject to FDA Regulation

- Wearable tech creates a blurred line between consumer product and medical device
- Primary considerations are efficacy, functionality and safety
- Device used for general wellness and presents a low risk to safety of users and others - No FDA oversight.
- FDA will regulate wearable technology that if the intent is to diagnose, treat or prevent. FDA looks at whether:
  - (1) is intended to be used as an accessory to a medical device; or
  - (2) transforms a mobile platform into a regulated device

Assess compliance issues before launch or change in marketing

1 See, FDA guidance: General Wellness: Policy for Low Risk Devices, July 2016)
What Can / Should We Do?

- Early Stage Risk Assessment and Mitigation Strategies
- Generate Regulatory Paper Trail
- Strategic Partnerships
- Product Introduction and Integration

Integrated Technical/Legal Support, Guidance and Regulation From the Ground Up
Legal Risk Assessment – Early and Often

• LRA should be a “built-in” step in your product or idea development

• “An ounce of prevention is worth a pound of cure”

• The old adage is equally applicable in today’s fast changing world of wearable tech
What is an LRA?

• An investigation, conducted prior to litigation, and ideally during early stages of product or idea development, that seeks to identify potential issues that may give rise to legal liability and creates an action plan to address those issues.

• If your product or idea is beyond the initial development stage- it’s not too late.

• An LRA can and should be a valuable tool throughout your product’s lifespan.
Potential Areas to Assess Risk

• Many Facets of Wearable Tech that Would Benefit from an LRA
  – Data Considerations:
    – Ownership, Privacy & Discovery
    – Data Sharing, Application & Monetization
  – Product Use Considerations:
    – General Product Liability Concerns
    – Specific Regulatory Hurdles
    – FDA, etc.
Data Ownership, Privacy and Discovery

Strava suggests military users 'opt out' of heatmap as row deepens

Fitness-tracking company suggests secret army base locations were made public by users, while militaries around world weigh up ban

A Strava heatmap showing the centre of Pyongyang, North Korea. Photograph: Strava heatmap

Fitness-tracking company Strava has defended its publication of heatmaps that accidentally reveal sensitive military positions, arguing that the information was already made public by the users who uploaded it.

Polar fitness app broadcasted sensitive data of intelligence and military personnel

July 10, 2018 By Pierluigi Paganini

The mobile fitness app Polar has suspended its location tracking feature due to the leakage of sensitive data on military and intelligence personnel.

A new privacy incident involved a fitness application and military, this time the mobile fitness app Polar has suspended its location tracking feature due to the leakage of sensitive data on military and intelligence personnel from 59 countries.

This is the second incident in a few months, in January experts discovered that military worldwide have publicly shared online their exercise routes recorded through the fitness tracker Strava revealing the fitness sessions conducted inside or near military bases.

During the weekend, Dutch security experts revealed they were able to find data on some 6,000 individuals including military personnel from dozens of countries and FBI and National Security Agency personnel.

A High Profile Wearable Tech Issue of National (Security) Importance
Data Ownership, Privacy and Discovery

3:52 PM on Monday, June 3, 2019

Public profile sharing
FlyBys
Who’s Watching / Looking ?
Employment / Safety Consequences

Data Privacy/Discovery Issues at the Consumer Level
Data Ownership, Privacy and Discovery

Users typically sign their data rights over to wearable tech companies at device adoption. Limited knowledge of how these expansive personal datasets are stored, used, and/or shared.

Limited Legal Regulation

Healthcare and / or Big Data Companies

New Product Development
Data Sharing Across The IoT

Numerous Unconsidered Consequences

Increased Sharing and Application of Integrated Personalized Data
Data Sharing, Application and Monetization

- Work Performance Incentives
- Activity-Driven Health Insurance
- Premium Adjustments
- Sports Gambling and Athlete Biometrics
Data Sharing, Application and Monetization

**Two major health insurance companies now offer wellness programs featuring free Apple Watches**

Aetna and UnitedHealthcare jump on the smart watch wellness bandwagon

Bailey King

If you put in a little bit of effort, you'll find that most health have your benefit when it comes to healthy living. Some even have gym memberships and weight management programs as part of their plans.

Now some are even offering free Apple Watches as part of their programs.

**Fitbit Charge 3 Now Integrated With UnitedHealthcare Motion Walking Program; Fitbit Inspire HR to be Added to the Wearable Device Program Later This Year**

May 14, 2019

SAN FRANCISCO--(BUSINESS WIRE)--May 14, 2019--

Fitbit (NYSE:FIT) today announced the next phase of its integration with UnitedHealthcare® Motion™ by offering Fitbit Charge 3™, the No. 1-selling health and fitness tracker in the U.S., as a buy-up option to eligible program participants.

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**Continued Wearable Proliferation and Adoption Within Activity-Based Health Plans**
Data Sharing, Application and Monetization

Incentivized Outcome (Bonus, Insurance Premiums)

- Non-Standardized Activity Targets
- Illness
- Injury
- Disability
- Data Fraud

Daily / Monthly Activity “Counts”

Immediate Standardization and Regulation Required
Data Sharing, Application and Monetization

New Tech Integration Brings New Legal Challenges and Concerns
Data Sharing, Application and Monetization

Expert warns over wearable tech data security

Personal data security is being put at risk as companies race to create wearable device-optimised versions of their apps, according to one expert.

“Potential data compromise threats range from people’s activity metrics, such as their walking paths or running speeds, to access to their location, contacts, camera and personal data - age, height, weight, and gender - and potential access to financial information if a consumer is using an unprotected wearable device to make payments,” he stated, adding: “Such behaviour is precisely why organisations must make security at the device-level a top concern.”

Increased Wearable Utility Brings New and Critical Data Protection Challenges
LRA Can Help Identify and Protect

• Proactive Not Reactive
  – Identify Issues, Promote Strengths, Minimize Weaknesses
• Work With Internal and External Experts
• Ensure Your Documents and Product Story are Consistent with Your Goals
• Early Development of Mitigation Strategies
• Knowledgeable Counsel/Informed Client = Long Term Cost Savings
Data Sharing, Application and Monetization

Real-Time Player Biometrics

Feeding New Gambling Ops and Issues

Sports Betting and Gambling and the Evolving Wearable Data Dilemma

What Constitutes Viable Presentable Data?
Primary Considerations Moving Forward

Drive early stage tech development and implementation pertaining to product and data accuracy, application and regulation

Regulation of tech-driven data privacy, sharing and discovery practices, from high profile sports through to individualized consumer sectors

Optimal Success Through Integrated Technical – Legal Support Framework
Early Stage Involvement, Advisement and Representation is Key
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Thank You
Thank you to all of our participants!