

Health Law Webinar

AI and Big Data

February 9, 2022

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Agenda

- Introductions, housekeeping
- Overview: Uses of “Big Data” and AI in Healthcare
- Unique Intellectual Property Issues in Data and AI
- Health Care Regulatory Perspectives
- New Models for Addressing Privacy Concerns
- Evolving Standards for Ethical Approaches to Data and AI

Jargon and Terminology

- Artificial Intelligence (broad definition):
 - “A branch of computer science dealing with the *simulation of intelligent behavior in computers.*” - Meriam-Webster
 - “[T]he field of computer science dedicated to solving cognitive problems commonly associated with human intelligence, such as *learning, problem solving, and pattern recognition.*” - Amazon
- Software:
 - A set of *instructions, programs, algorithms* that enable a computer to perform a task.

Data: The Fuel that Drives AI

- Data is what powers AI
 - The AI can be only as good as the data it relies on
- Data is a critical corporate asset (and liability)
- Controls around data collection, acquisition, security, privacy, accuracy and ethical use are key

How are Big Data and AI Impacting Healthcare?

Big Data and AI are driving Digital Health.
“Digital health is the convergence of the digital and genomic revolutions with health, healthcare, living, and society.”

Source: <http://storyofdigitalhealth.com/>



Scope and Applications



Health Apps



Connected Devices / IoT



Automation and Robotics



Consumer apps and wearables



Clinical Research



Health IT / Services



Telemedicine

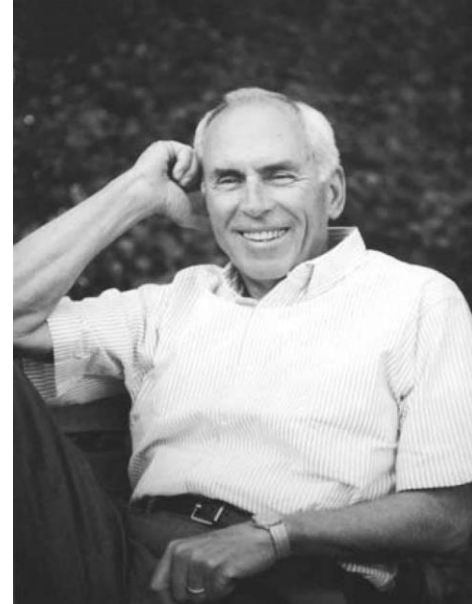


Medical Algorithms

Amara's Law

“We tend to overestimate the effect of a technology in the short run and underestimate the effect in the long run.”

- Roy Amara, Co-founder, Institute for the Future



Multiple Intersecting Issues

Technology and IP Rights Considerations

Regulatory Considerations

Life Sciences Considerations

Healthcare Considerations

Advertising Considerations

Ethical Considerations

Additional Considerations



Intellectual Property Issues in Big Data and AI

Key to understand ***IP rights*** (background and arising), ***who owns them, who can use them—many players and perspectives***

- ***Providers***
- ***Payors***
- ***Device/Pharma companies***
- ***Patient***
- ***Tech providers***
- ***Researchers/Academia***
- ***EMR vendors***

IP Implications of “Big Data” and AI

Not all aspects of data or an algorithm are treated the same

- Underlying data **elements**
- **Compilation** of the data
- Derived or **resulting** data
- **Insights**, other IP generated from access to the data (algorithms trained or improved, other insights/results)
- **Code**
- Machine learning **outputs**

Is Data or AI Protectable by Copyright, Patent or Trade Secret Status?

IP Implications of “Big Data”

Copyright – (“compilation” – *Feist Publications vs. Rural Telephone Service*)

- An original idea that is put to use (not the idea itself, but the physical use of the idea, e.g., the compilation of data, the written source code. Needs to be more than mere facts...)
- Copyright arises when work written (no need for registration)
- “Works for Hire” concepts
- Author/assignee has the exclusive rights to:
 - Reproduce the copyrighted work
 - Prepare derivative works based upon the work
 - Distribute copies of the work to the public
 - Perform the copyrighted work publicly
 - Display the copyrighted work publicly

IP Implications of “Big Data”

Patent – covering data (now), vs. database vs. code (maybe—systems and methods of arranging data)...

- What can be patented? Subject matter of the claimed invention must be:
 1. Patent eligible (data structure eligible subject matter?),
 2. Useful,
 3. New;
 4. Non-obvious; and
 5. Described with the particularity required so that people of skill in the relevant technology field or science can understand what the invention is, make the invention and use the invention without “undue experimentation.”
- As issued patent provides a government issued monopoly, e.g., the right to exclude others from:
 - Making (or having made) embodiments of the patented inventions
 - Using embodiments of the patented inventions
 - Selling embodiments of the patented inventions

IP Implications of “Big Data”

Trade secret protection (state versions of *Uniform State Secrets Act*)

- A trade secret is:
 - Information that has either actual or potential independent economic value by virtue of not being generally known,
 - Has value to others who cannot legitimately obtain the information, and
 - Is subject to reasonable efforts to maintain its secrecy.
- All three elements are required; if any element ceases to exist, then the trade secret will also cease to exist. Otherwise, there is no limit on the amount of time a trade secret is protected.
- The holder of a trade secret has the right to prevent disclosure, acquisition or use of information without consent
- Confidential Know How may be protected by contract even if not a “Trade Secret”

Can “AI” be an Inventor or Author?

Creative works (copyrights) generated by AI? Depends

- USA? No
- Other countries? Maybe



Patent protection for AI-generated inventions?

- » No (Dabus)

AI-Generated Portrait Sells for Over \$400K

Putting it all Together

Circle of invention and authorship-AI with Big Data

1. Choose/develop an algorithm
(or untrained model)
2. Collect and curate
“training data”
3. “Train” the algorithm to produce a trained model
4. Test and refine the model
5. Deploy the model
6. Develop insights from using the model (human involved?)
7. Continue improving the model (human involved?)
8. And so on...

Copyrights, Patents,
Trade Secrets
(Know How)

In the Face of Uncertainty in the Law, Make Sure Your Contracts Are Clear

- Data Considerations (Diligence & Contracting)
 - Who is providing the training and input data?
 - Do you have the right to provide the data
 - For training? For research? For other purposes?
 - De-identification requirements/data privacy and security considerations
 - Reps & Warranties – yours and theirs
 - License grants/limitations
 - Any use permitted outside of collaboration purposes?
 - How will you maintain control?

Be Clear

- Data (Contracting/allocation of effort)
 - What data preparation is required and who is responsible?
 - Do you get structured data back?
 - Ownership over processed data?
 - Data retention rights?
 - Who is responsible for security/data integrity?
 - Audits/inspections?

Be Clear

- AI (algorithms) (Contracting for use)
 - All the standard software licensing issues if will access the tools (whether for research, internal operations, clinical settings)
 - Even if are only contributing, not using:
 - Indemnification/insurance
 - IP allocation for suggestions/jointly developed works
 - Integration issues for data streams
 - Cyber security/support issues

Data Access/Sharing Arrangements-Quick Hit Checklist for IP and General Contract Provisions:

- Description of data elements
- Ownership rights – original data/compilation
- Scope of use, including access to third parties
- Derived data—allowed, who owns?
- Rights in other IP generated from access
- Delivery obligations (form/timing)
- Privacy/confidentiality/security obligations
- Applicable restrictions (including legal/reg.)
- Notices of ‘issues’ (integrity of data, breach of data)
- Payment terms
- Records/Reports and Audit Rights
- Confidentiality
- Representations and Warranties
- Limitations and Exclusions, Indemnification, and Insurance
- Term/Termination/Effect
- Impact of Bankruptcy- is it IP?
- Assignment and Change of Control
- Disputes (ADR or not, injunctive relief, waiver of jury trial)
- Export Control
- If technology onsite at HCP, or interacting, all the usual tech contracting issues
- General Clauses

Health Care Regulatory

Key Legal Issues

- FDA
- Reimbursement
- Fraud and Abuse
- Licensure and Corporate Practice of Medicine
- Information Blocking and Interoperability
- Liability Issues
- Privacy and Security



FDA

- FDA’s jurisdiction over “devices”
 - When should software be considered an FDA regulated “device”?
- FDA’s recent approach to regulating digital health
 - “Encourage innovation”

Reimbursement

- Payor reimbursement questions
- False Claims Act exposure?



Fraud and Abuse

Federal Laws

Anti-Kickback

Stark Self-Referral Prohibition

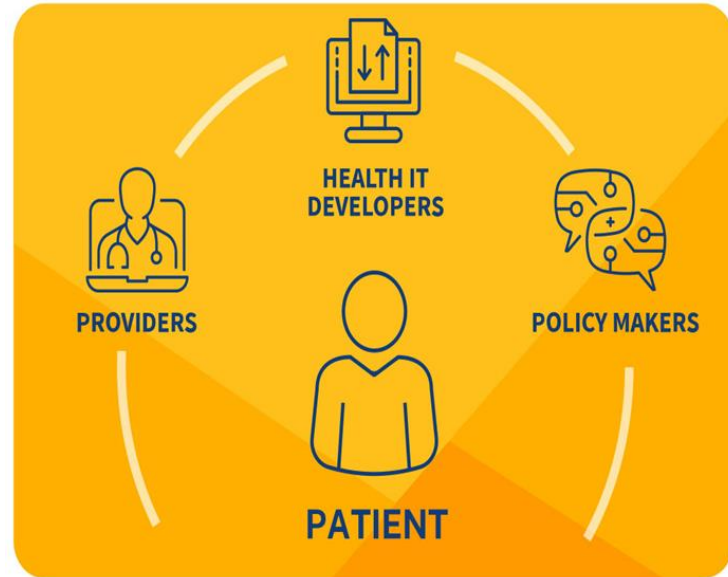
State Laws

State anti-kickback and self-referral prohibitions

Fee-splitting prohibitions

Information Blocking and Interoperability

Goal of seamless and secure access, exchange, and use of electronic health information



Liability Issues

- Providers
 - Malpractice Liability
 - When should providers override algorithms?
 - Informed Consent
 - What about AI-based, automated telemedicine?
 - Need for post-hoc explanations to fulfill duty to obtain informed consent?
- Developers
 - Learned intermediary doctrine

Liability Issues

- 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?

Miscellaneous Issues

Privacy and Security

- HIPAA
 - Privacy Rule Compliance
 - Security Rule Compliance
 - Business Associate Issues
 - Downstream vendors
- CCPA and Other State Laws
- FTC
- GDPR



Privacy and Security – Evolving Approaches

- Federated Learning-de-centralized machine learning. Data stays local.
- De-identified “data under the glass”- data is de-identified AND stays data stays local.

Ethical Use of AI

- Concerns:
 - Data Bias and Algorithmic Fairness
 - Reliability and Safety
 - Informed Consent
 - Accountability, Transparency, and Consent
 - Privacy

Ethical Use of AI

- Voluntary and involuntary regulation:
 - FTC Guidance, Blog Posts
 - Industry/Other Guidelines (World Health Organization, Assoc. of British Pharma Industry, AI Councils)
 - Regulations (EU)
 - Internal policies (AstraZeneca, Novartis, Sanofi)

Spotlight on FTC AI Guidance and Enforcement

- Background
 - Section 5 of FTC Act (prohibits unfair or deceptive practices- for instance, use of a racially biased algorithm...)
 - Fair Credit Reporting Act
 - Equal Credit Opp. Act.
- Guidance (April 2020)
 - Be transparent
 - Explain your decisions to the consumer
 - Ensure data and models are robust and empirically sound
 - Hold yourself accountable (compliance, ethics, fairness, nondiscrimination)

Spotlight on FTC AI Guidance and Enforcement

- Blog Post (April 2021)
 - Start with the right foundation
 - Watch out for discriminatory outcomes
 - Embrace transparency and independence
 - Don't exaggerate claims
 - Tell the truth about uses of data
 - Do more good than harm
 - Hold yourself accountable (“or be ready for the FTC to do it for you”)



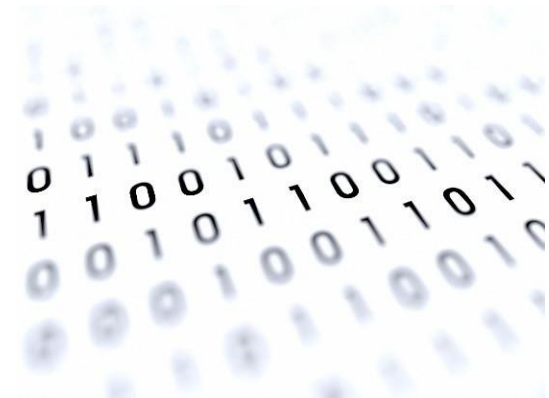
Spotlight on FTC AI Guidance and Enforcement

- Recent Enforcement Actions (Everalbum)
 - Used photos uploaded by app users to train facial recognition. Alleged misrepresentation about ability to delete from app.
 - Consequence:
 - B. Within ninety (90) days after the issuance of this Order, delete or destroy all Face Embeddings derived from Biometric Information Respondent collected from Users who have not, by that date, provided express affirmative consent for the creation of the Face Embeddings, and provide a written statement to the Commission, sworn under penalty of perjury, confirming that all such information has been deleted or destroyed; and
 - C. Within ninety (90) days after the issuance of this Order, delete or destroy any Affected Work Product, and provide a written statement to the Commission, sworn under penalty of perjury, confirming such deletion or destruction.

Mitigation – *Leadership, Resources, Policies*

Leadership

- Senior management and Board need to understand AI (and data):
 - Applications to business
 - Use by competitors, suppliers, customers and regulators
- Approve strategy, considering
 - AI implications; benefits, opportunities and risks
 - AI oversight challenges
 - AI role in long term value creation and social impact
 - Integrity, ethics and legal compliance



Mitigation – *Leadership, Resources, Policies*

Resources

- Privacy officer (consistency with ethical and legal approach to use of PHI, data subject rights, scope of consents)
- IT (how will 3rd party access data, technical architecture, what role will HCP play in de-identification and/or delivery, where will AI/Software tools reside, what interfaces)
- IT Security (technical reviews, ongoing assessments)
- Legal (contracting, legal and regulatory compliance, relationship to other existing contracts, risk allocation and mitigation)
- Compliance (health law matters, compliance with internal policies)
- Finance (understanding payment rights, accounting, reporting)
- De-identification expert?

Mitigation – *Leadership, Resources, Policies*

Policies (beyond your privacy policies...)

Example principals – Sanofi.

2. GUIDING PRINCIPLES	4
2.1. We aim for quality and conformance with good practice standards	4
2.2. We will assess the reliability of data	4
2.3. We will assess the robustness of our AI applications	4
2.4. We will strive to mitigate bias in our AI applications	4
2.5. We will be transparent and will strive to explain AI applications.....	5
2.6. We will aim to protect personal data	5
2.7. We will respect the self-determination of individuals	5
2.8. We will offer human intervention	5

Questions?



Ryan Johnson is a nationally-recognized lawyer for healthcare innovation.

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. He regularly counsels investors, senior executives, and corporate boards on the strategic threats and opportunities arising from emerging technologies and new laws and regulations, especially those affecting the healthcare industry.

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Ann Ladd has a special emphasis on working with companies in the technology and life sciences areas, including diagnostic, medical device, pharma, and health IT companies. Ann helps clients commercialize intellectual property and technology rights through a variety of transactions, including M&A, joint ventures, strategic alliances, collaboration and research agreements, material transfer agreements, development agreements, and technology and patent licenses.

Ann has been recognized repeatedly as one of the “IAM Patent 1000” for her informed view of the market and great judgement, which she capitalizes on in practical and problem-solving ways, and is a 2022 BTI “Client Service All Star.”

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