



# ***AI in Medicine: Legal and Ethical Issues***

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## *Disclosures*

- ◆ Will not be promoting unlabeled/unapproved uses of drugs, devices, products, protocols, or therapeutic strategies.
- ◆ Served as a bioethics consultant for Otsuka Pharmaceuticals on digital medicine portfolio and Dawnlight. Currently serves on ethics committees for Illumina and Bayer. Have participated sponsored by Philips with the Boston Globe and Washington Post. Have been retained for AI/Data Privacy expert witness testimony.

# *Ethics of Building + Implementing Predictive Analytics*



## **Phase 1: Acquiring Data**

- Consent
- Data Set Representativeness
- Governance

## **Phase 2: Building and Validating Model**

- Auditing
- Transparency
- Trade Secrecy

## **Phase 3: Testing Model in Real World Settings**

- Notice and Consent for Use on Patients?
- Liability
- Regulator Role





## **Phase 4: Broad Dissemination**

- Equitable Access

# Liability Regime for Each?



Figure.

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Scenario	AI recommendation	AI accuracy	Physician action	Patient outcome	Legal outcome (probable)
1	Standard of care	Correct	Follows	Good	No injury and no liability
2			Rejects	Bad	Injury and liability
3		Incorrect (standard of care is incorrect)	Follows	Bad	Injury but no liability
4			Rejects	Good	No injury and no liability
5	Nonstandard care	Correct (standard of care is incorrect)	Follows	Good	No injury and no liability
6			Rejects	Bad	Injury but no liability
7		Incorrect	Follows	Bad	Injury and liability
8			Rejects	Good	No injury and no liability

## Examples of Potential Legal Outcomes Related to AI Use in Clinical Practice

AI indicates artificial intelligence.

# Is There an AI in the House?/Informed Consent to AI Use

## Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?

I. GLENN COHEN\*

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Viewpoint | Adolescent Mental Health

ONLINE FIRST

October 16, 2023

## AI as a Mental Health Therapist for Adolescents

Douglas J. Opel, MD, MPH<sup>1,2</sup>; Brent M. Klous, MD, PhD<sup>3,4</sup>; I. Glenn Cohen, JD<sup>5</sup>

Author Affiliations

JAMA Pediatr. Published online October 16, 2023. doi:10.1001/jamapediatrics.2023.4215



IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

MATT DINERSTEIN, individually and on  
behalf of all others similarly situated,

*Plaintiff,*

v.

GOOGLE, LLC, a Delaware limited liability  
company, and THE UNIVERSITY OF  
CHICAGO MEDICAL CENTER, an Illinois  
not-for-profit corporation, THE  
UNIVERSITY OF CHICAGO, an Illinois  
not-for-profit corporation,

*Defendants.*

Case No.

**CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Matt Dinerstein brings this Class Action Complaint and Demand for Jury Trial against Defendants Google, LLC, The University of Chicago Medical Center, and The University of Chicago (collectively referred to as the "University" or "University of Chicago").

# Data Privacy + Consent

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## Viewpoint

August 9, 2019

# Big Data, Big Tech, and Protecting Patient Privacy

I. Glenn Cohen, JD<sup>1</sup>; Michelle M. Mello, JD, PhD<sup>2</sup>

» [Author Affiliations](#)

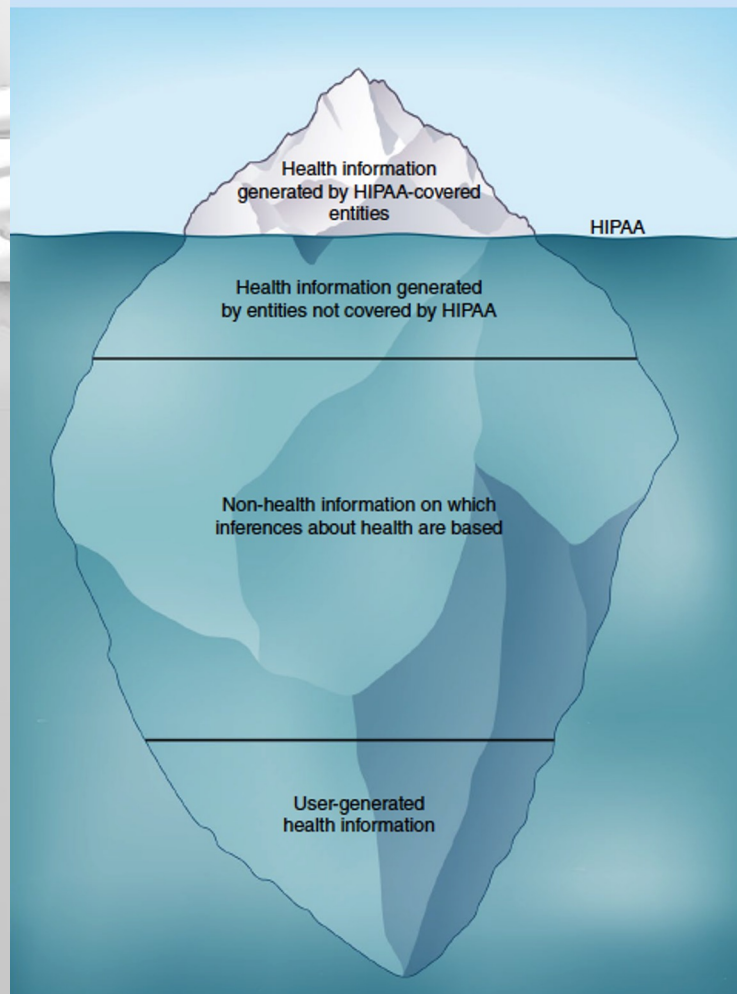
JAMA. 2019;322(12):1141-1142. doi:10.1001/jama.2019.11365



Full  
Text

The market for patient data has never been more active. Technology companies, from startups to giants, are eager to access electronic health record (EHR) data to build the next generation of health-focused products. Medical artificial intelligence (AI) is particularly data-hungry; large, representative data sets hold promise for advancing not only AI companies' growth, but also the health of patients.<sup>1</sup> Companies' overtures to major hospitals about data sharing have highlighted legal and ethical uncertainties as to whether and how to undertake these relationships.

# Types of Health Data



I. Glenn Cohen & W. Nicholson Price II  
*Privacy in the Age of Medical Big Data*, **Nature Medicine** (2019)

# AI and Bias: More Complex than Meets the Eye

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HOME > SCIENCE > VOL. 366, NO. 6464 > DISSECTING RACIAL BIAS IN AN ALGORITHM USED TO MANAGE THE HEALTH OF POPULATIONS

RESEARCH ARTICLE



## Dissecting racial bias in an algorithm used to manage the health of populations

ZIAD OBERMEYER , BRIAN POWERS, CHRISTINE VOGELI, AND SENDHIL MULLAINATHAN  [Authors Info & Affiliations](#)

SCIENCE • 25 Oct 2019 • Vol 366, Issue 6464 • pp.447-453 • DOI: [10.1126/science.aax2342](https://doi.org/10.1126/science.aax2342)

14,951 576



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### Racial bias in health algorithms

The U.S. health care system uses commercial algorithms to guide health decisions. Obermeyer *et al.* find evidence of racial bias in one widely used algorithm, such that Black patients assigned the same level of risk by the algorithm are sicker than White patients (see the Perspective by Benjamin). The authors estimated that this





# Premarket Review & the “Update Problem”

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Perspective | [Open Access](#) | [Published: 07 April 2020](#)

## The need for a system view to regulate artificial intelligence/machine learning-based software as medical device

Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen ✉

*npj Digital Medicine* **3**, Article number: 53 (2020) | [Cite this article](#)

5754 Accesses | 6 Citations | 45 Altmetric | [Metrics](#)

### Abstract

Artificial intelligence (AI) and Machine learning (ML) systems in medicine are poised to significantly improve health care, for example, by offering earlier diagnoses of diseases or recommending optimally individualized treatment plans. However, the emergence of AI/ML in medicine also creates challenges, which regulators must pay attention to. Which medical



### BIOMEDICAL TECHNOLOGY REGULATION

## Algorithms on regulatory lockdown in medicine

Prioritize risk monitoring to address the “update problem”

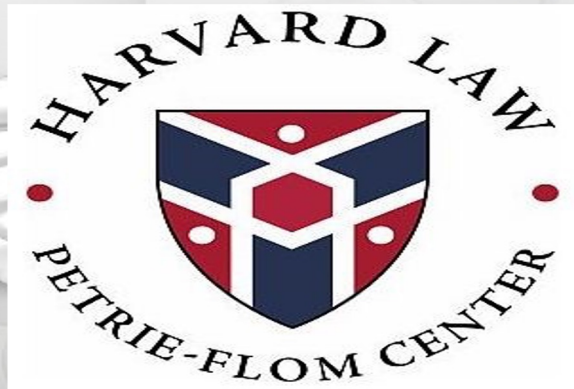
By [Boris Babic](#)<sup>1</sup>, [Sara Gerke](#)<sup>2</sup>,  
[Theodoros Evgeniou](#)<sup>1</sup>, [I. Glenn Cohen](#)<sup>3</sup>

**A**s use of artificial intelligence and machine learning (AI/ML) in medicine continues to grow, regulators face a fundamental problem: After evaluating a medical AI/ML technology and

similar patients similarly. We describe several features that are specific to and ubiquitous in AI/ML systems and are closely tied to their reliability. To manage the risks associated with these features, regulators should focus particularly on continuous monitoring and risk assessment, and less on articulating ex-ante plans for future algorithm changes.

tion. As the AI/ML system is used in clinical settings that include more African-American women, it becomes possible to more accurately estimate the parameters used to predict breast cancer in this subpopulation when making recommendations.

Although improvements in pre-specified testing of subgroups might provide some benefit in avoiding this problem, in some situations, relevant subpopulations may not be known ex-ante. For example, in conducting HIV vaccine studies, researchers did not (and perhaps could not) know ex-ante that in a particular trial, the vaccine might increase rather than reduce HIV infection risk for “uncircumcised men who both had sex with men (MSM) and had high titers of preexisting antibodies against Ad5” (5). Prespecified testing is unlikely to capture these kinds of



*Thank you!*



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# *Generative AI in Medicine: New-ish Issues*



- Prompt Privacy
- Right to Know an AI is involved
- Medical Deepfakes
- Oligopoly/Foundational Models
- Environmental Effects
- Patient Empowerment (?)