Will not be promoting unlabeled/unapproved uses of drugs, devices, products, protocols, or therapeutic strategies.

Serves as a bioethics consultant for Otsuka Pharmaceuticals on digital medicine portfolio.
Big Data, Predictive Analytics, Machine Learning: Promise and Peril

The Legal And Ethical Concerns That Arise From Using Complex Predictive Analytics In Health Care

Privacy in the age of medical big data

HIPAA and Protecting Health Information in the 21st Century

Machine learning in medicine: Addressing ethical challenges

Petrie-Flom Center launches Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)
Current and Near Future Applications

Nature
The International Weekly Journal of Science

Lesions Learnt
Artificial intelligence powers detection of skin cancer from images PAGES 38 & 115

ARTICLES
https://doi.org/10.1038/s41591-018-0107-6

Clinically applicable deep learning for diagnosis and referral in retinal disease
Jeffrey De Fauw\textsuperscript{1}, Joseph Nenad Tomasev\textsuperscript{1}, Samuel Daniel Visentin\textsuperscript{1}, George Faith Mackinder\textsuperscript{1}, Simon Karthikesalingam\textsuperscript{1}, Claire Catherine Egan\textsuperscript{2}, Adrian Trevor Back\textsuperscript{2}, Peng T. Kan\textsuperscript{3}, and Olaf Ronneberger\textsuperscript{3}

Arterys
Medical Imaging Cloud AI

Idx
Transforming healthcare through automation

Imagen

Orcam
## Two Possible Ways of Dividing the World

<table>
<thead>
<tr>
<th>Function</th>
<th>Purpose</th>
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</thead>
<tbody>
<tr>
<td>Imaging</td>
<td>Democratizing Expertise</td>
</tr>
<tr>
<td>Prognostics</td>
<td>Automating Drudgery</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>Optimizing Resources</td>
</tr>
<tr>
<td>Treatment</td>
<td>Pushing Frontiers</td>
</tr>
</tbody>
</table>

_Suggested by Nicholson Price, U Mich. Law School_
**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
Potential Liability for Physicians Using Artificial Intelligence

W. Nicholson Price II, JD, PhD; Sara Gerke, Dipl-Jur Univ; I. Glenn Cohen, JD

Author Affiliations Article Information

JAMA. Published online October 4, 2019. doi:10.1001/jama.2019.15064

<table>
<thead>
<tr>
<th>Scenario</th>
<th>AI recommendation</th>
<th>AI accuracy</th>
<th>Physician action</th>
<th>Patient outcome</th>
<th>Legal outcome (probable)</th>
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<tbody>
<tr>
<td>1</td>
<td>Standard of care</td>
<td>Correct</td>
<td>Follows</td>
<td>Good</td>
<td>No injury and no liability</td>
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<tr>
<td>2</td>
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<td></td>
<td>Rejects</td>
<td>Bad</td>
<td>Injury and liability</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Incorrect (standard of care is incorrect)</td>
<td>Follows</td>
<td>Bad</td>
<td>Injury but no liability</td>
</tr>
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<td>4</td>
<td></td>
<td></td>
<td>Rejects</td>
<td>Good</td>
<td>No injury and no liability</td>
</tr>
<tr>
<td>5</td>
<td>Nonstandard care</td>
<td>Correct (standard of care is incorrect)</td>
<td>Follows</td>
<td>Good</td>
<td>No injury and no liability</td>
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<td>6</td>
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<td>8</td>
<td>Incorrect</td>
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</tr>
</tbody>
</table>

Examples of Potential Legal Outcomes Related to AI Use in Clinical Practice
AI indicates artificial intelligence.
Privacy + Consent

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.

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”).

Viewpoint

August 9, 2019

Big Data, Big Tech, and Protecting Patient Privacy

I. Glenn Cohen, JD; Michelle M. Mello, JD, PhD

Author Affiliations


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. 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)
Thank you!