PennState
Dickinson Law

# Ethical & Legal Considerations for Biomedical AI

BMI 702 – May 8


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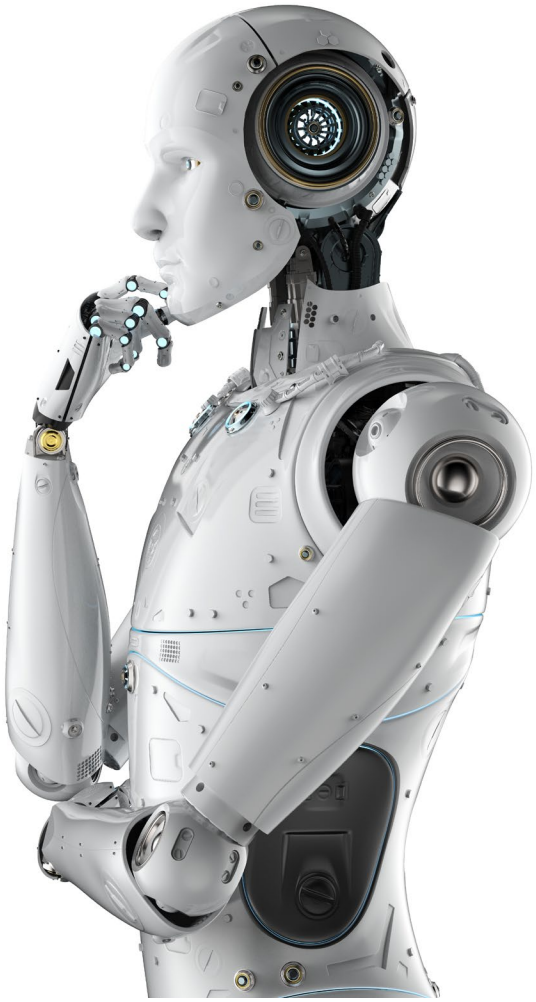
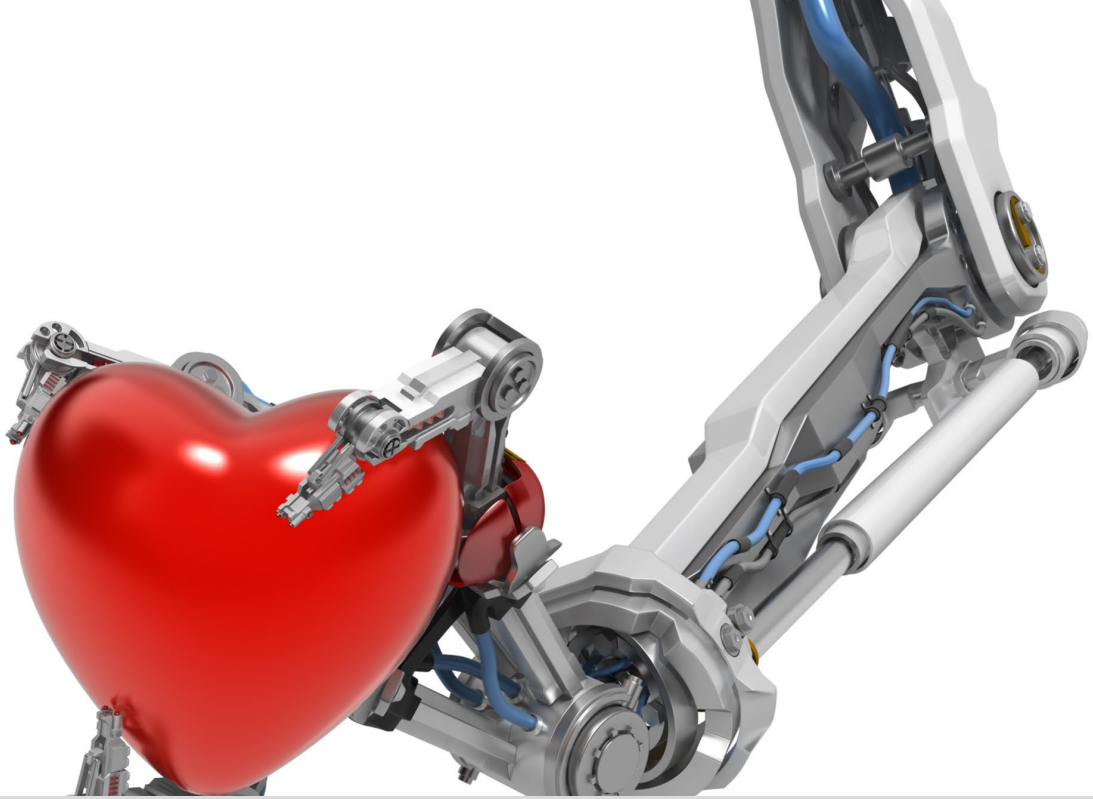
# Outline

- Ethical Frameworks
- Data Privacy
- Regulation of AI/ML
- Liability



# Ethical Frameworks



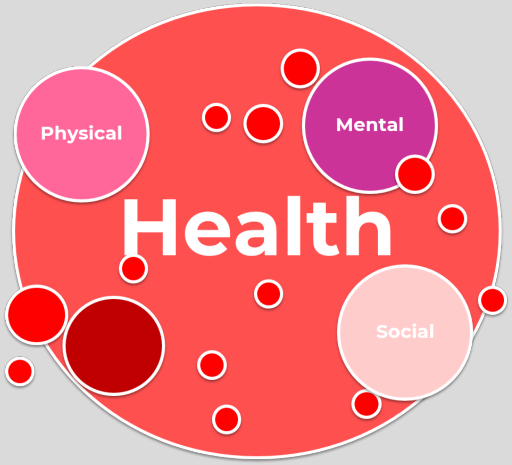
# 1.

# What Is Health AI Ethics?

# Health AI Ethics

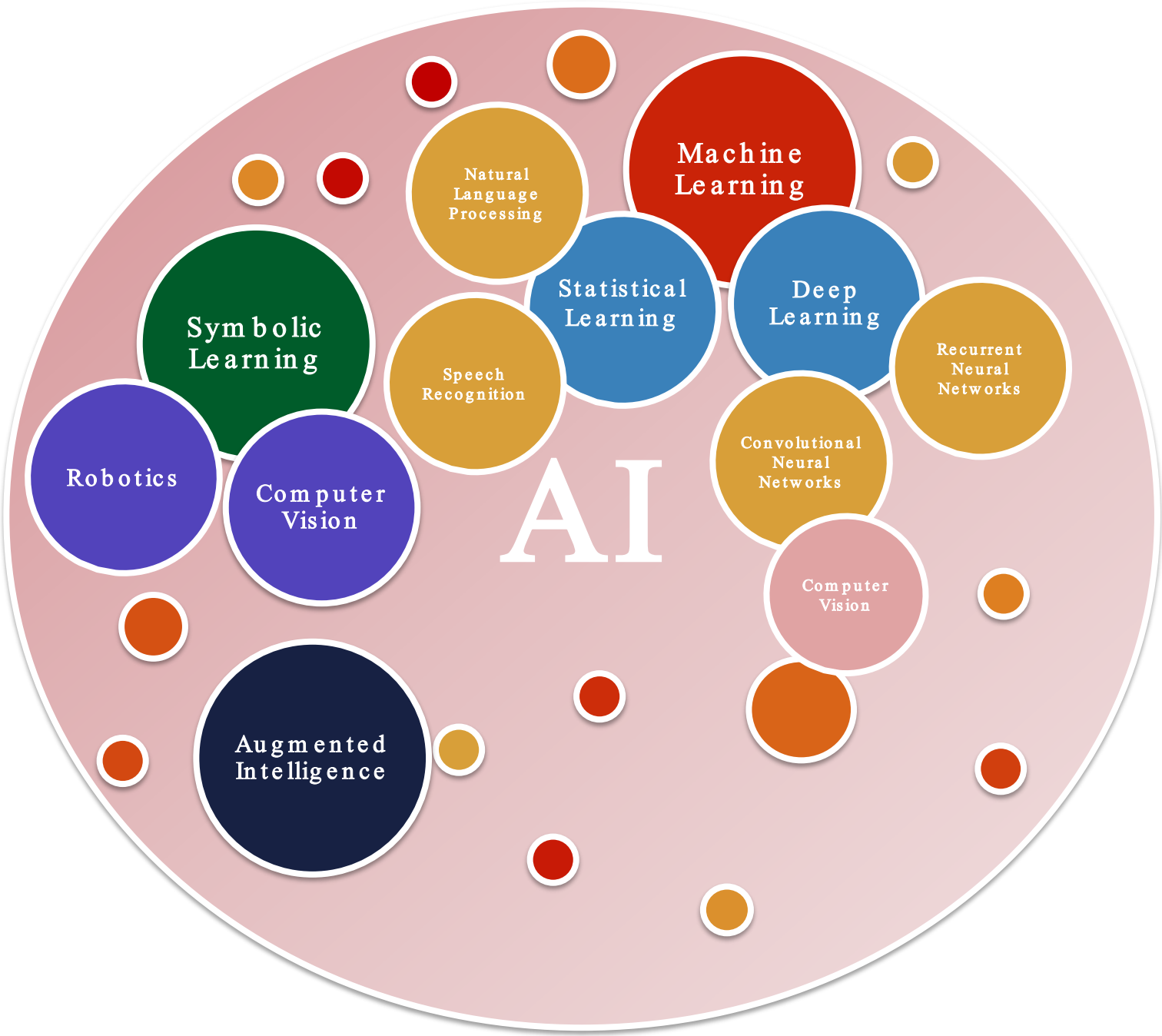
**Application and analysis of ethics to contexts in health in which AI is involved**

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).




*A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*

World Health Organization. Constitution. https://www.who.int/about/governance/constitution.


AI
Machine Learning
Natural Language Processing
Statistical Learning
Deep Learning
Symbolic Learning
Speech Recognition
Recurrent Neural Networks
Convolutional Neural Networks
Robotics
Computer Vision
Computer Vision
Augmented Intelligence

# Ethics

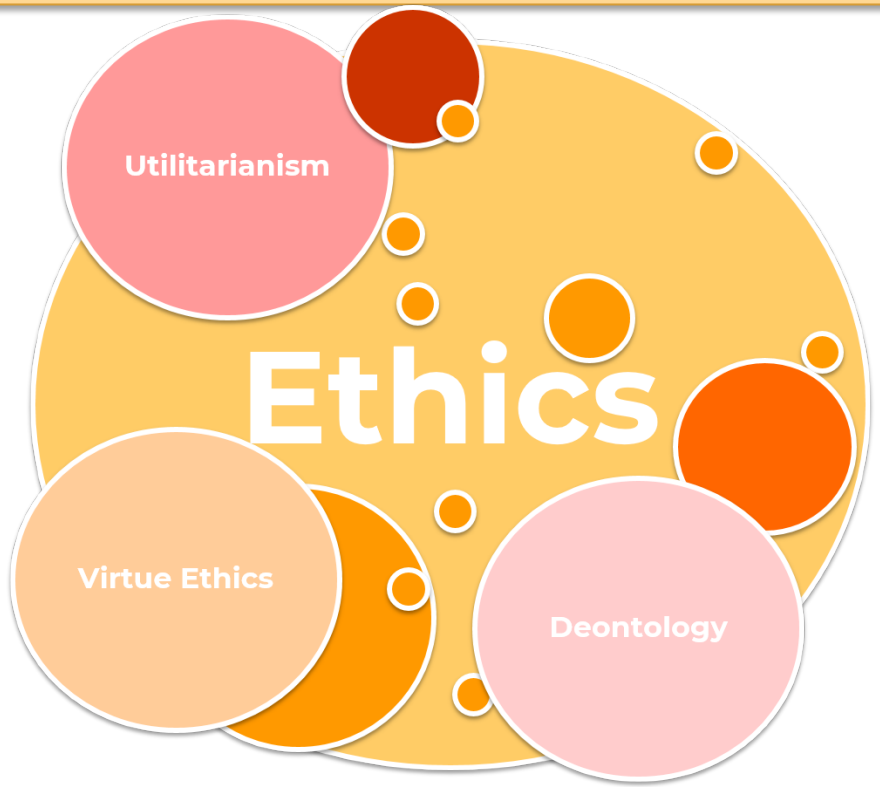
Normative Ethics

Metaethics

Applied Ethics

# Normative Ethics

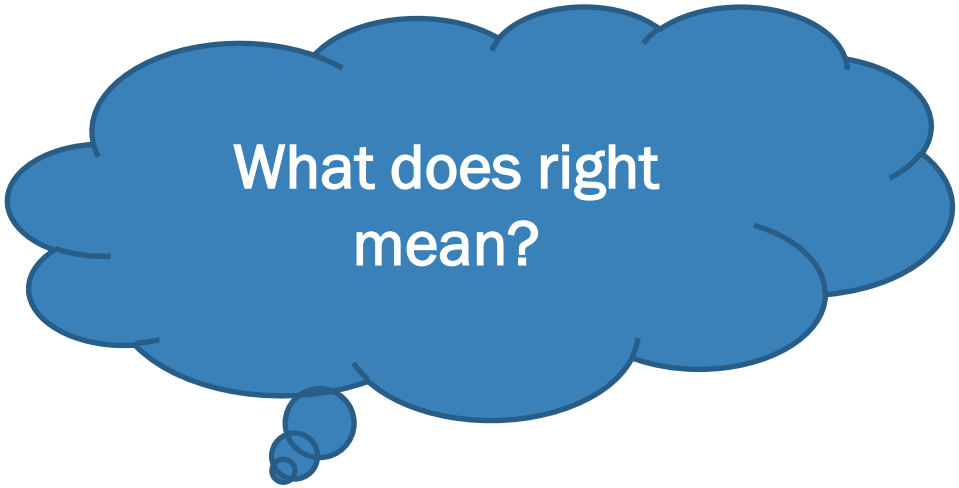
- Tries to answer questions about the right way to act.




Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

# Metaethics

- Addresses questions about the nature of right and wrong



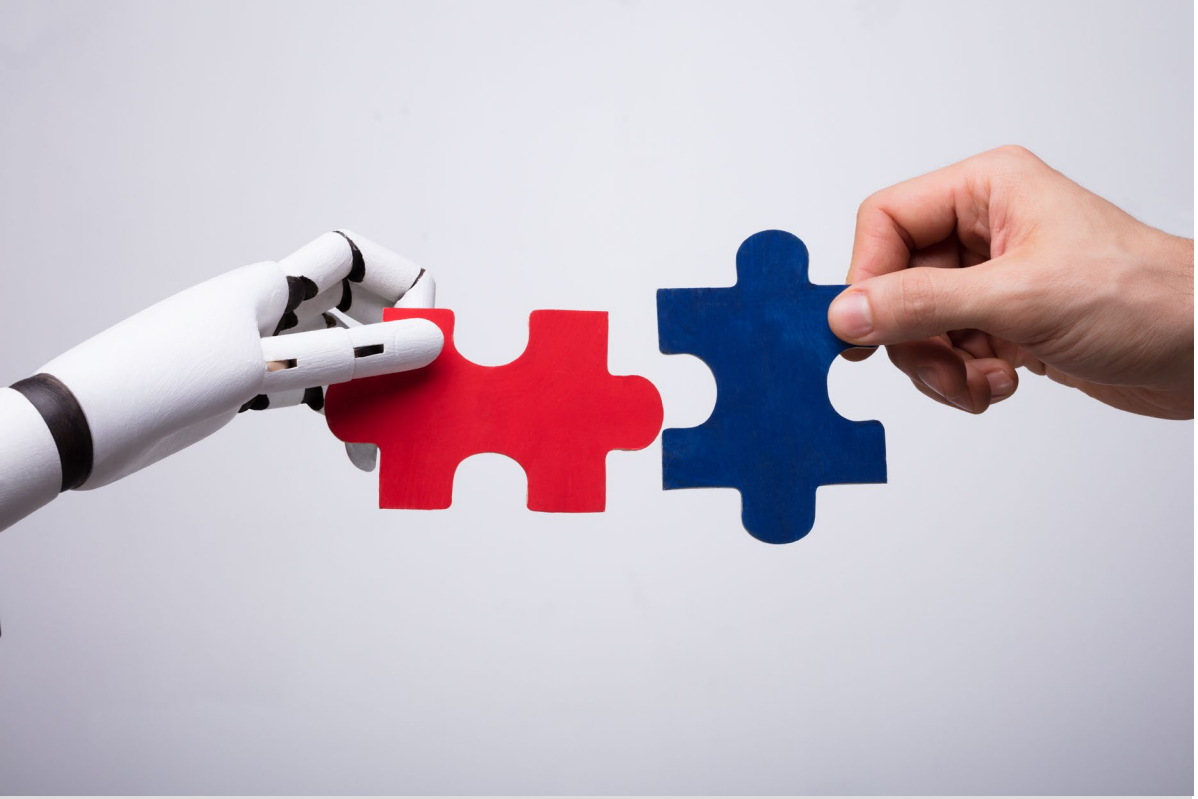

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

# Applied Ethics

- Deals with applying ethical theories or principles to specific, real-life issues

Principles of Biomedical Ethics by James F. Childress and Tom L. Beauchamp

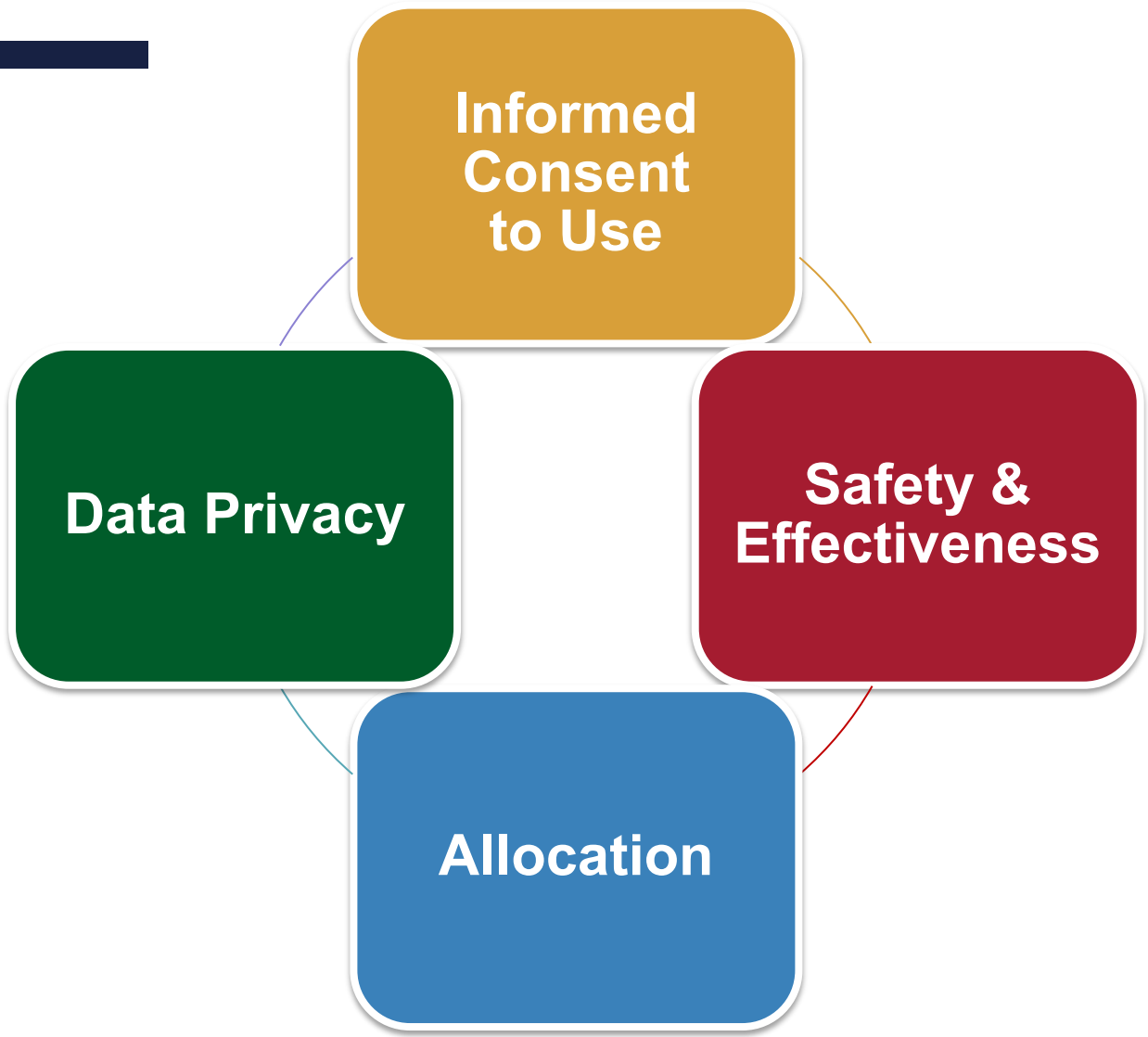

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).



# 2.

# Ethical Issues

# Ethical Issues



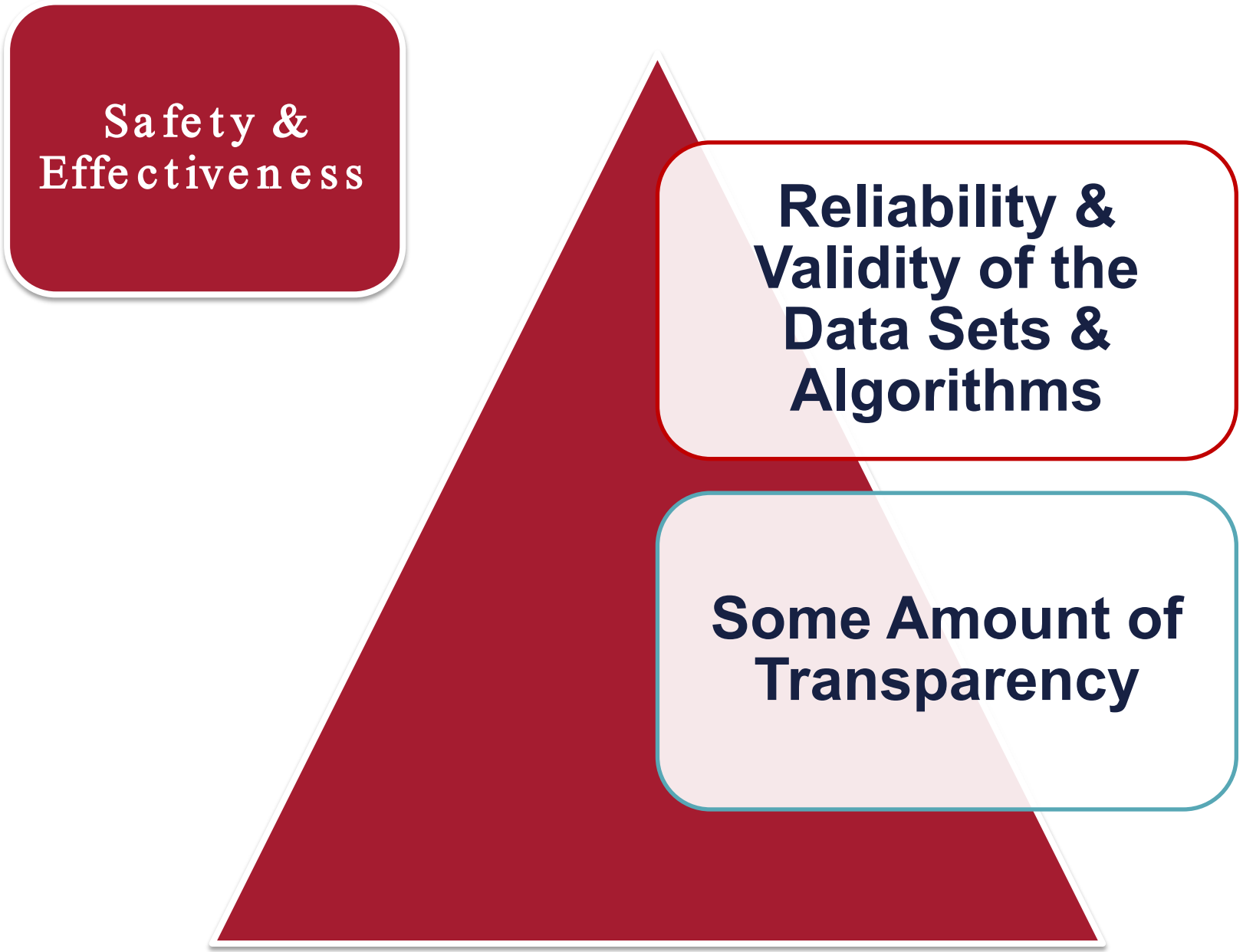
# Informed Consent to Use


Need to examine under what circumstances (if at all) the **principles of informed consent** should be deployed in the clinical AI space.

Especially challenging to answer in cases where the AI operates using **"black-box" algorithms**.


Health AI apps & chatbots raise questions about **user agreements** & their relationship to informed consent.

Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).




Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

Safety & Effectiveness

Reliability & Validity of the Data Sets & Algorithms

Training Data

Algorithmic

Contextual

Unconscious


Ethics by Design

Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

Timo Minssen, Sara Gerke, Mateo Aboy, Nicholson Price & I. Glenn Cohen, Regulatory Responses to Medical Machine Learning, J. L. BIOSCI. lsaa002 (2020).

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

Sara Gerke, Timo Minssen, Helen Yu & I. Glenn Cohen, *Ethical and Legal Issues of Ingestible Electronic Sensors*, 2 NATURE ELECTRON. 329 (2019).

Safety & Effectiveness

Some Amount of Transparency

E.g., shortcomings of the software


Trust


Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

# Allocation

SCIENCE

## WHAT HAPPENS WHEN AN ALGORITHM CUTS YOUR HEALTH CARE

By Colin Lecher | @colinlecher | Mar 21, 2018, 9:00am EDT

*Illustrations by William Joel; Photography by Amelia Holowaty Krales*

SHARE

For most of her life, Tammy Dobbs, who has cerebral palsy, relied on her family in Missouri for care. But in 2008, she moved to Arkansas,

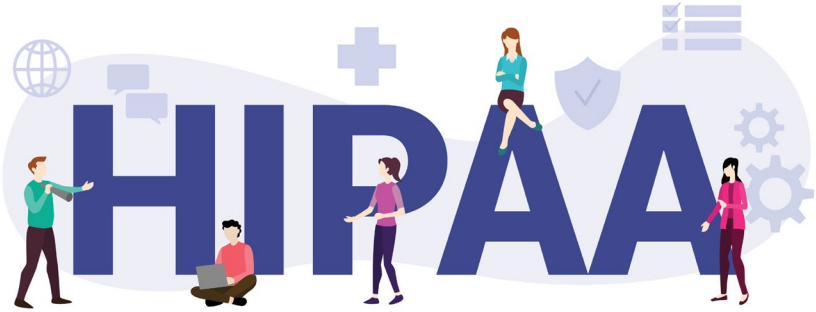
Photo Credit: https://www.theverge.com/2018/3/21/17144260/healthcare-medicaid-algorithm-arkansas-cerebral-palsy

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

# Case Problem

## The Patient With Diabetes

# Data Privacy




Health Insurance Portability and Accountability Act

**Data Triangulation**

**Protected Health Information (PHI)**

generated by

**Covered Entities**

or their

**Business Associates**

**Individually identifiable health information**

- **Health Plans**
- **Health Care Clearinghouses**
- **Health Care Providers**

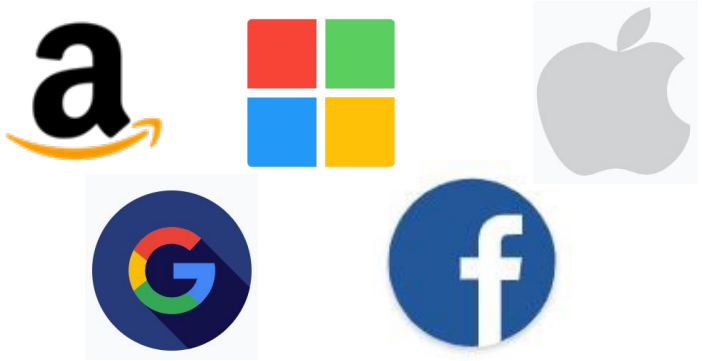
**Person or entity that performs certain functions or activities on behalf of, or provides services to, a covered entity that involve the use or disclosure of PHI**

share

BAA

**De-Identified Health Information e.g., removal of 18 identifiers**

**Health Information Generated by Entities Not Covered by HIPAA**



Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

# Data Privacy

## New Legal Developments to Protect Privacy


- Has been applied since **25 May 2018 in all EU Member States**
- **Protects fundamental rights and freedoms of natural persons** and in particular their **right to the protection of personal data** (Art. 1(2))
- **Broad material & territorial scope** (Arts. 2, 3)
  - **Impact on U.S. entities** (e.g., processing activities are related to the offering of goods or services to data subjects in the EU)

# Data Privacy

## New Legal Developments to Protect Privacy in the U.S.

Photo Credit: https://redcloveradvisors.com

Became effective on **January 1, 2020**

**Grants various rights to California residents** with regard to **personal information that is held by businesses**

Sara Gerke & Delaram Rezaeikhonakdar, *Privacy Aspects of Direct-To-Consumer Artificial Intelligence/Machine Learning Health Apps*, Intelligence-Based Medicine 6 (2022) 100061

## Case Problem

# The Patient With Diabetes – Part 2

# Regulation of AI/ML

Regulation of AI/ML

# Medical Device Definition, FDCA Section 201(h)(1)

(…) an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

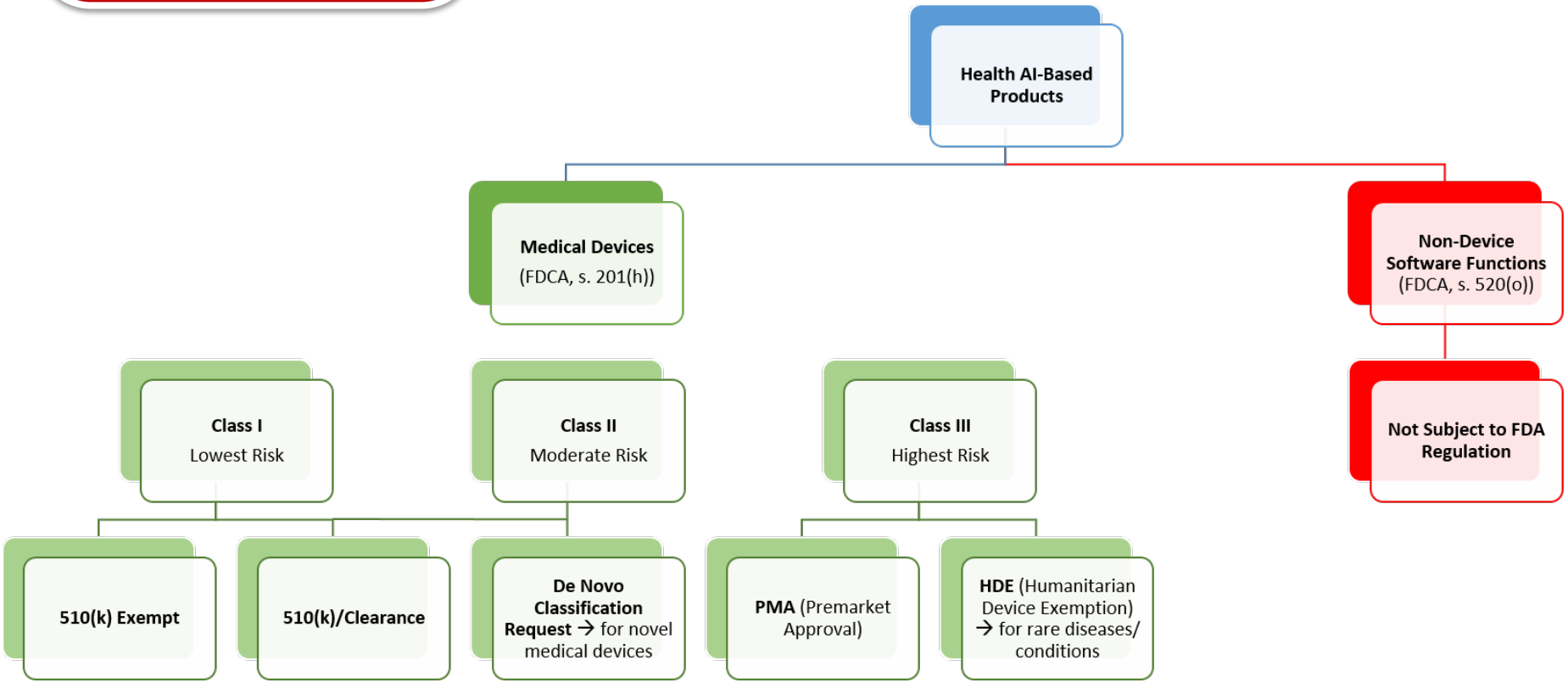
(B) **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man** or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

**which does not achieve its primary intended purposes through chemical action within or on the body of man** or other animals **and which is not dependent upon being metabolized for the achievement of its primary intended purposes**. The term "device" does not include software functions excluded pursuant to section 520(o).

Regulation of AI/ML

# Regulatory Pathways




Adapted from Sara Gerke et al., *Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19*, 26 NATURE MED. 1176 (2020).

Regulation of AI/ML

# Non-Device Software Functions, FDCA Section 520(o)

1. For administrative support of a health care facility

2. For maintaining or encouraging a healthy lifestyle

3. To serve as electronic patient records

4. For transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results

5. To support certain clinical decisions

# Regulation of AI/ML

Update Problem

## AI/ML-Based SaMD

(**A**rtificial **I**ntelligence/**M**achine **L**earning-**B**ased **S**oftware **a**s a **M**edical **D**evice)


IMDRF/SaMD WG/N10FINAL:2013

IMDRF International Medical Device Regulators Forum

**Final Document**

| | |
|---|---|
| **Title:** | Software as a Medical Device (SaMD): Key Definitions |
| **Authoring Group:** | IMDRF SaMD Working Group |
| **Date:** | 9 December 2013 |

Software intended to be used for **one or more medical purposes** that perform these purposes **without being part of a hardware medical device**.

Those purposes that are **intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions.**

FDA

FDA (2019) Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD), https://www.fda.gov/media/122535/download.

# Regulation of AI/ML

Update Problem

**"Locked" Algorithm**

**"Adaptive" Algorithm**

FDA

An algorithm that provides **the same result** each time **the same input is applied to it** and **does not change with use**.

An algorithm that **may change** as it is **applied to new data**.

FDA (2019) Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD), https://www.fda.gov/media/122535/download.

# Regulation of AI/ML

Update Problem


Photo Credit: https://www.fda.gov/media/122535/download

**Total Product Lifecycle (TPLC) Regulatory Approach**

**Predetermined Change Control Plan**

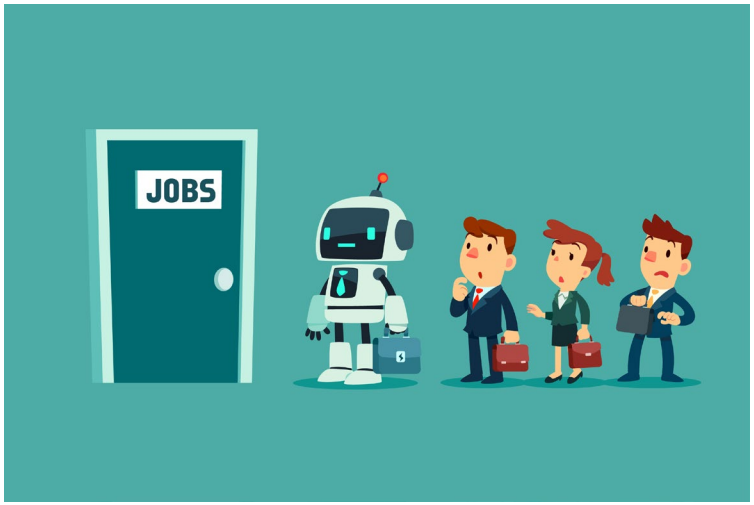
**Continuous Risk Monitoring**

**Focus on new risks due to AI/ML characteristics.**

Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Algorithms on Regulatory Lockdown in Medicine: Prioritize Risk Monitoring to Address the "Update Problem"*, 366 SCIENCE 1202 (2019).

**Regulation of AI/ML** ⇨ **System View**

- Regulators like the FDA need to **widen their scope** from evaluating medical AI/ML-based products to **assessing systems**.




Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen, *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device*, 3 NPJ DIGIT. MED. Article number: 53 (2020).

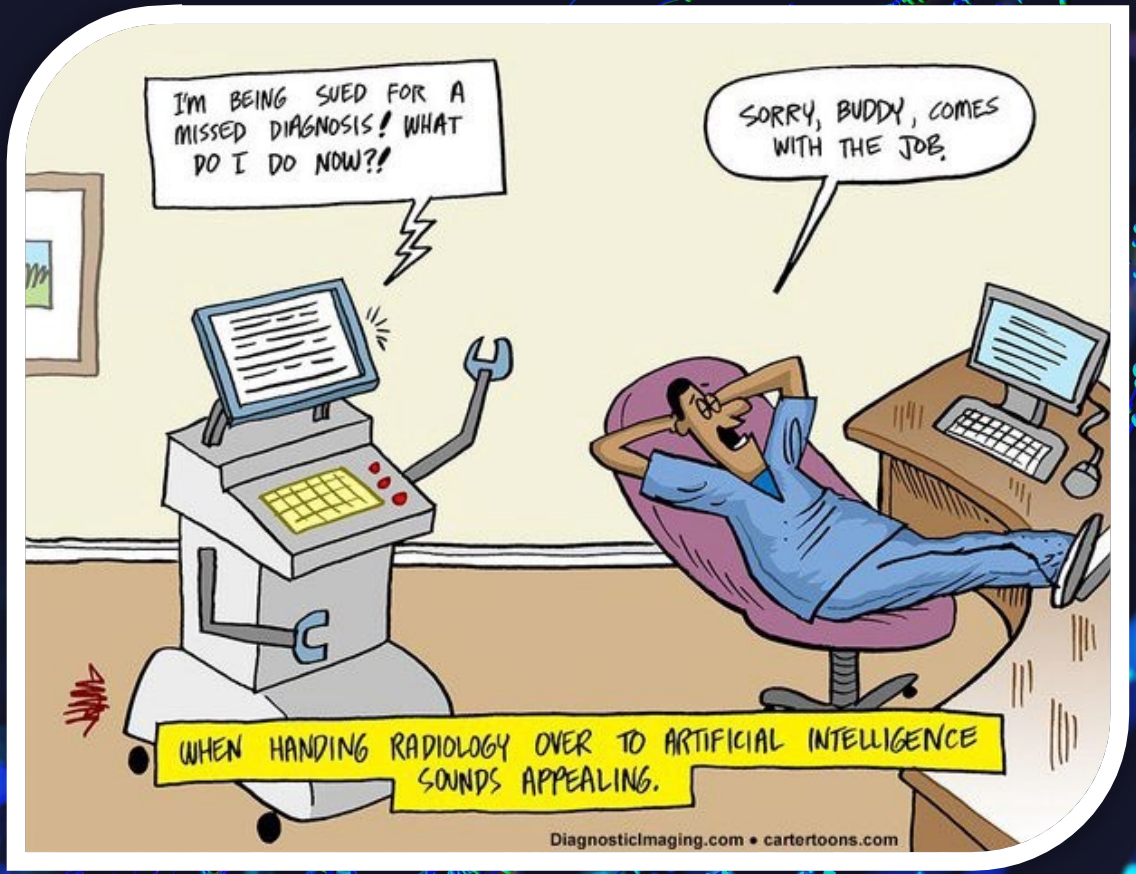
Regulation of AI/ML

# The FDA's New Action Plan


- **Further developing the proposed regulatory framework**, including issuing draft guidance on a predetermined change control plan
- Supporting the development of **good machine learning practices** to evaluate and improve machine learning algorithms
- Fostering a **patient-centered approach**, including device transparency to users
- Developing methods to **evaluate and improve machine learning algorithms**; and
- Advancing **real-world performance monitoring** pilots.

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

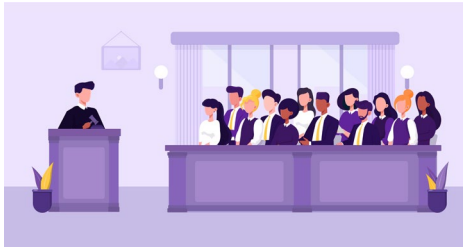
# Liability


I'm BEING SUED FOR A MISSED DIAGNOSIS! WHAT DO I DO NOW?!
SORRY, BUDDY, COMES WITH THE JOB.
WHEN HANDING RADIOLOGY OVER TO ARTIFICIAL INTELLIGENCE SOUNDS APPEALING.
DiagnosticImaging.com • cartertoons.com

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

| 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 |

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).



W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *How Much Can Potential Jurors Tell Us about Liability for Medical Artificial Intelligence?*, 62 THE JOURNAL OF NUCLEAR MEDICINE 15 (2021).

# Ecosystem of Liability


- Physicians
- Hospital Systems
- AI Makers
- Payers

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).

# Thanks!

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