Artificial Intelligence: Regulatory and other Legal Issues. A primer for Clinical Laboratories

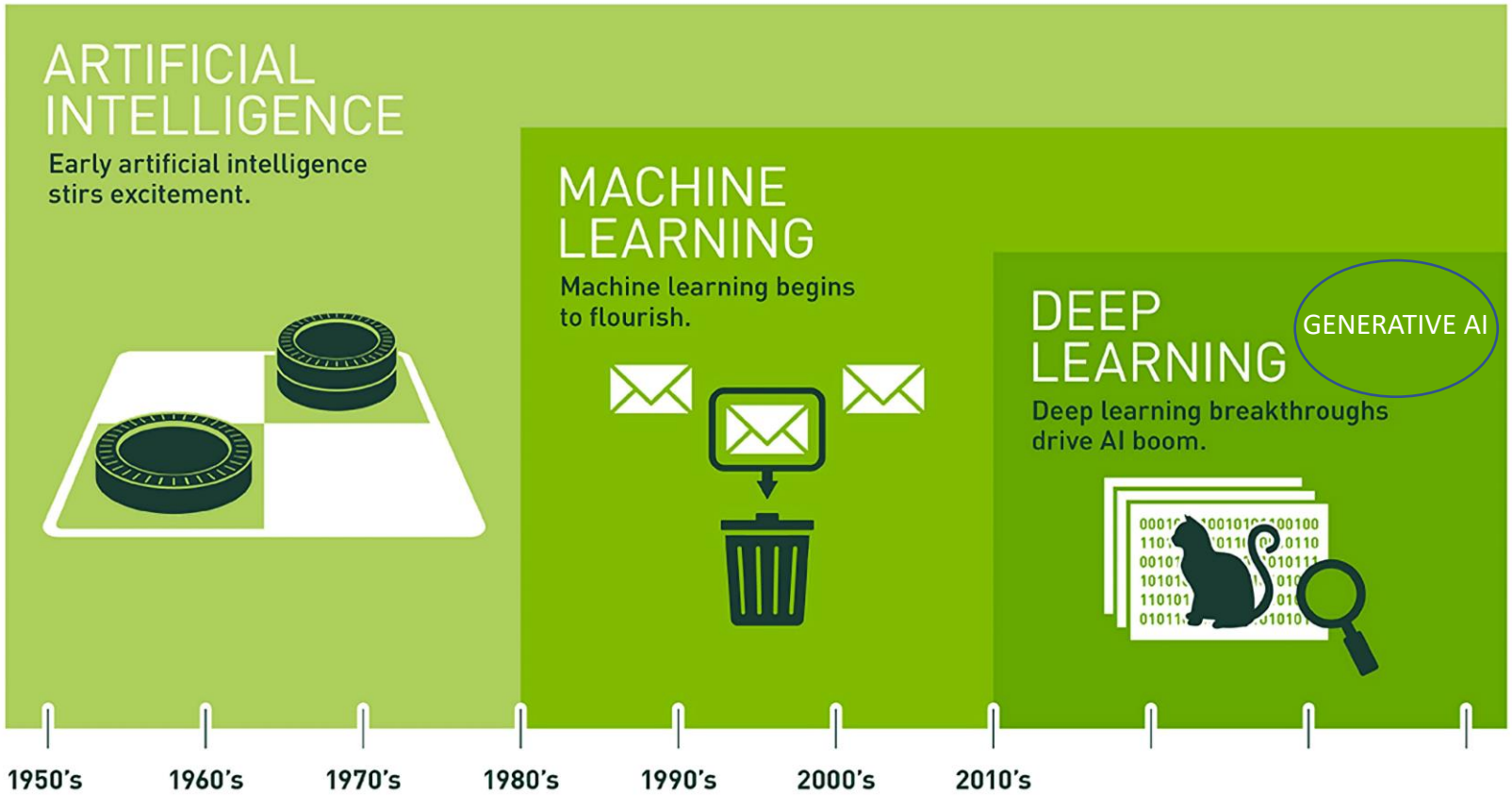
Roger D. Klein, MD JD
Executive War College
March 1, 2024

Introduction

- Definition of AI
- Categories of AI
- Differences from other software
- Legal and regulatory issues

What is artificial intelligence (AI)?

- “A branch of computer science that studies the properties of intelligence by synthesizing intelligence.” – Herbert Simon
- “[T]he science and engineering of making intelligent machines, especially intelligent computer programs.” - John McCarthy
- Computer technology that uses complex statistical algorithms and data analysis to solve human problems



Since an early flush of optimism in the 1950s, smaller subsets of artificial intelligence – first machine learning, then deep learning, a subset of machine learning – have created ever larger disruptions.

NVIDIA Developer, https://developer.nvidia.com/deep-learning

Written by
Bernard Marr

Bernard Marr is a world-renowned futurist, influencer and thought leader in the fields of business and technology, with a passion for using technology for the good of humanity. He is a best-selling author of 20 books, writes a regular column for Forbes and advises and coaches many of the world's best-known organisations. He has over 2 million social media followers, 1 million newsletter subscribers and was ranked by LinkedIn as one of the top 5 business influencers in the world and the No 1 influencer in the UK.

Bernard's latest book is 'Business Trends in Practice: The 25+ Trends That Are Redefining Organisations'

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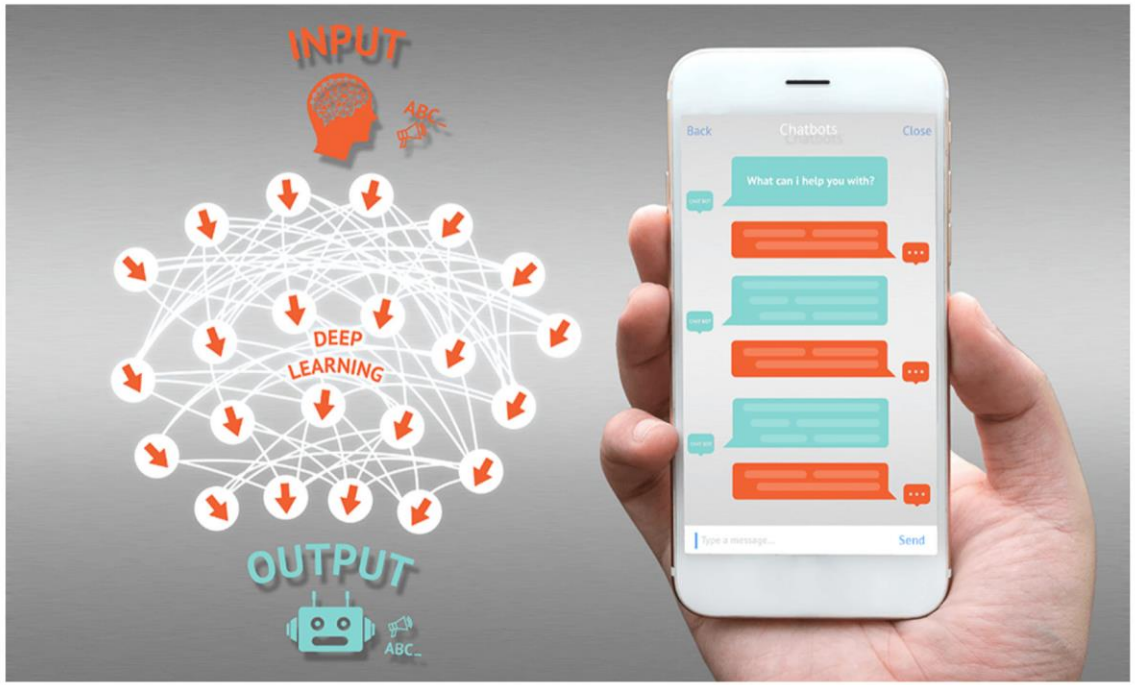
What Is The Difference Between Deep Learning, Machine Learning and AI?

Over the past few years, the term "deep learning" has firmly worked its way into business language when the conversation is about Artificial Intelligence (AI), Big Data and analytics. And with good reason – it is an approach to AI which is showing great promise when it comes to developing the autonomous, self-teaching systems which are revolutionising many industries.

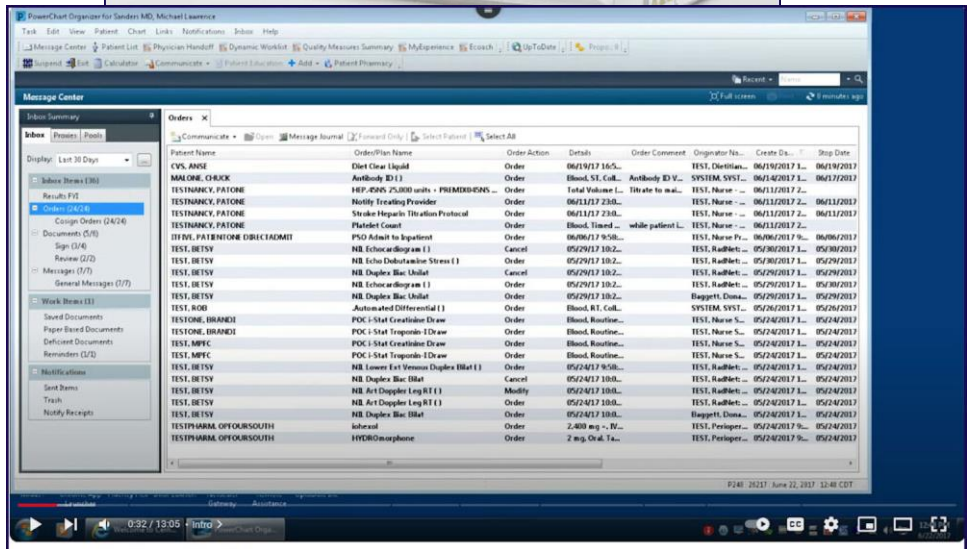


Deep Learning is used by Google in its voice and image recognition algorithms, by Netflix and Amazon to decide what you want to watch or buy next, and by researchers at MIT to predict the future. The ever-growing industry which has established itself to sell these tools is always keen to talk about how revolutionary this all is. But what exactly is it? And is it just another fad being used to push "old fashioned" AI on us, under a sexy new label?

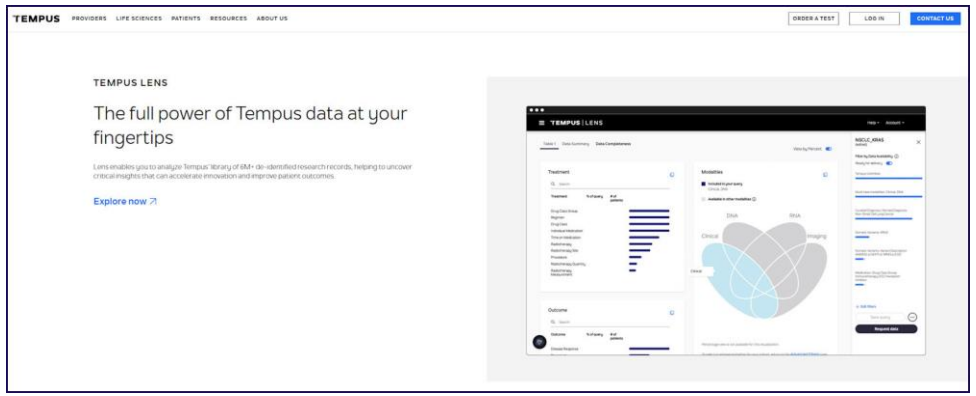
Differences from rules-based software

- Ability to learn
- Use of large, complex data sets
- Recognize patterns
- Reach conclusions
- Optimize practices
- Make informed judgments
- Predict future behavior

Current AI in clinical laboratories



Cerner Part 1 Creating a Patient List



Future AI uses

Clinical laboratory

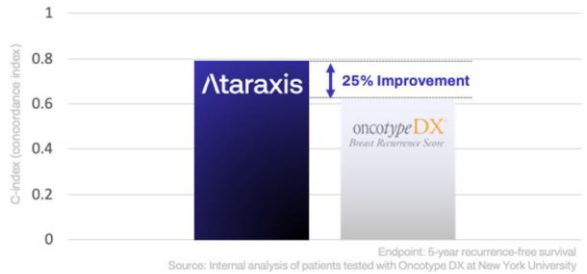
- Organization and laboratory levels
- Integrate with LIS
  - data analysis, predictive analytics, QC/QA
- Enhance accuracy, quality, efficiency, resource allocation, workflows, lower costs, allow smaller specimen quantities
- Advanced robots
- Genetic/genomic interpretation, precision medicine
- Test report generation and release
- Clinical decision support
  - ordering
  - interpretation
- External communication with clients
  - language translation
- Pathology image analysis
- Other algorithmic-based tests
- Mining EMR and lab data analysis for patterns and trends
  - clinical care and research

Business and administrative

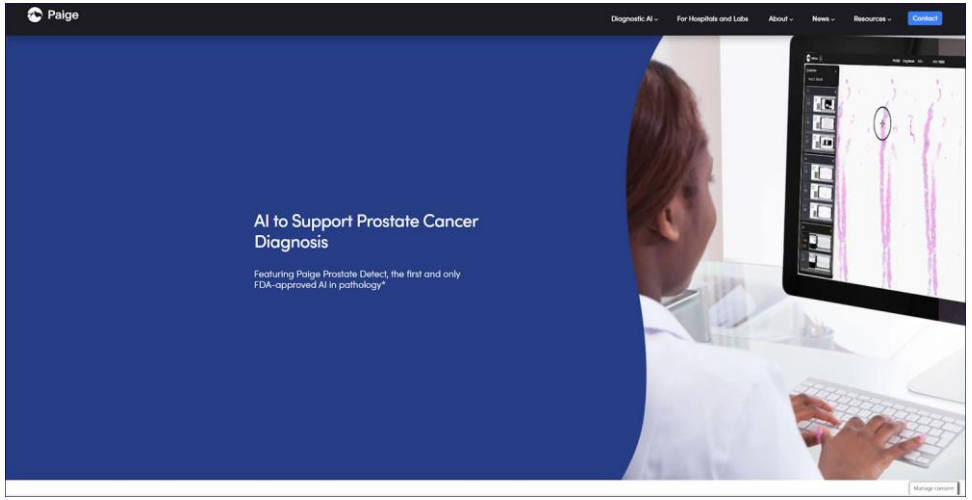
- Administrative and operational uses likely first applications
  - relative feasibility
  - lower risk
- Coding, billing, reimbursement
- Network and market insights
- Marketing and sales
- Finance
- Human resources, including recruiting, hiring, onboarding, evaluations, staffing, management, HR and IT questions, retirement planning
- Contracting
- External communications with clients and customers

AI tests

In retrospective analysis of NYU Langone patients, Ataraxis AI technology was 25% more accurate at predicting 5 year breast cancer recurrence than a common molecular test



Ataraxis
info@ataraxis.ai



Multivariable models, such as gene expression classifiers or artificial intelligence (AI)-derived digital histopathology biomarkers, can combine clinical, pathologic, and other biomarkers to further improve risk stratification.

Analytical Validation of a Clinical Grade Prognostic and Classification Artificial Intelligence Laboratory Test for Men with Prostate Cancer

Paul Gerrard,[1,*] Jingbin Zhang,[1] Rikiya Yamashita,[1] Huei-Chung Huang,[1] Sanghita Nag,[1] Sokha Nhek,[1] Joshua Kish,[1] Adam Cole,[2] Nathan Silberman,[1] Trevor J. Royce,[1] and Tim Showalter[1]

Abstract

Introduction: This is the first study of which we are aware to describe the analytical validation (AV) of clinical grade artificial intelligence (AI) algorithms for a commercially available prostate cancer test performed on hematoxylin and eosin stained specimens that is not dependent on *a priori* established molecules or *a priori* semantically meaningful morphology.

Methods: We adapted AV methods used in molecular diagnostics and clinical pathology to two AI biomarkers used in a clinical test for prostate cancer biopsy specimens. The two algorithms included one algorithm with prognostic performance and a second algorithm predictive for treatment benefit from short-term an-

renalytix™

FDA Grants De Novo Marketing Authorization for KidneyIntelX.dkd to Assess Risk of Progressive Kidney Function Decline in Adults with Diabetes and Early-Stage Kidney Disease

June 29, 2023

Simple Blood Test Aids Risk Assessment for Approximately 14 Million Eligible Patients in the United States

Diabetic Kidney Disease is the Leading Cause of End Stage Kidney Disease in the United States

LONDON and SALT LAKE CITY, June 29, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (LSE: RENX) (NASDAQ:RNLX) announces that the U.S. Food and Drug Administration (FDA) has granted De Novo marketing authorization for its KidneyIntelX.dkd ™ prognostic test. This affirms KidneyIntelX as a first-in-class, artificial intelligence enabled prognostic testing platform to guide care management for adults with type 2 diabetes and early-stage chronic (diabetic) kidney disease. Renalytix believes FDA authorization will lead to increasing test adoption, informing clinical guidelines, expanding insurance coverage, and pursuing additional international regulatory approvals.

"Meeting the rigorous safety, clinical and analytical validation, and scientific data requirements of an FDA review, from Breakthrough Device designation to De Novo marketing authorization, is a landmark event for health care providers and patients with diabetic kidney disease," said James McCullough, CEO of Renalytix. "With this approval a new class, Prognostic Test for Assessment of Chronic Kidney Disease Progression, has been established by the FDA, providing a roadmap for future expansion of KidneyIntelX into new indications and products."

KidneyIntelX.dkd accurately stratifies patients into three risk levels (low, moderate, and high). This result provides comprehensive information on patient risk for progressive decline in kidney function within five years, independently of the current standard of care measures. KidneyIntelX.dkd is the name used to differentiate tests to be provided under the De Novo marketing authorization by the FDA from those provided under the KidneyIntelX name as a Laboratory Developed Test.

Legal issues

- Responsibility, accountability, liability
  - treating physicians
  - pathologists/lab directors
  - companies/hospitals/institutions
  - software developers
- Contracts/Licenses
- Data
  - privacy
  - security
  - informed consent
- Intellectual property
- Torts
- Employment discrimination
- Regulation
- Antitrust

Contracting

- Develop, license, or combination
  - equipment
  - services
  - data
- Risk allocation
  - representation and warranties
- Indemnification
  - important to establish liability for AI's functionality in advance
- Limitations on liability
  - most important to vendor
- Insurance
  - provides assurance counterparty can meet obligations
  - must determine coverage that applies to situation
- Data
  - ownership and terms of use

Representations and warranties

- AI often introduced into critical functions
  - automating laboratory processes and services
  - streamlining supply chain and logistics
- Must address potential business impacts of system failure
  - if AI embedded in equipment, possible damages
- Non-infringement warranty of special importance
- Transparency, want to understand the training and working of algorithms, including representativeness

Non-infringement warranty

- Vendor typically represents that it owns or has sufficient rights to allow the customer to use or benefit from the software
- AI systems can produce infringing code when performing their functions
  - generative AI may create infringing content or its use may be infringing
  - the liability for such infringement is unclear and must be allocated

Data issues

- Negotiate ownership, use, and liability
- More data usually allows AI system to perform better
- Vendor may be allowed to aggregate customer data
  - potential for competitors to benefit from data
- Anonymization to prevents laboratory attribution
- Protection of confidentiality of laboratory data
- Personal data is subject to privacy laws and regulations
  - for PHI HIPAA and state privacy rules and regulations
  - other data protected by sectoral or state laws

Intellectual property

- Patents
  - must meet section 101 threshold (is it an abstract idea?)
  - takes several years during which time value may diminish
  - requires public disclosure
  - term 20 years (copyright 70 years, trade secret infinite)
- Copyright
  - source code and visual elements of AI program
  - protection does not include functional aspects, e.g. algorithms, formatting logic, or system design
  - limited to original expression
  - proof of infringement requires proof of copying
  - exceptions for fair use
  - incorporation of open source software may present ownership issues
  - must re-register every version
- Trade secret
  - protected under federal and state laws (Economic Espionage Act, Defend Trade Secrets Act, Uniform Trade Secrets Act)
  - applies to confidential business, financial, technical information of economic value
  - must continuously identify technology that needs protection
  - limit access to relevant servers, computer, media
  - mark relevant documents and physical media as confidential
  - take reasonable steps to protect, e.g. multi-factor authentication, mobile device management, data loss prevention software, written policies governing employee access and use, non-disclosure agreements, dedicating significant resources to protection
  - indefinite time frame
  - does not involve application, registration, or public disclosure

AI Intellectual property ownership

- Patents are owned by inventors
- Copyrights generally owned by authors
- Trade secrets belong to the entity protecting them
- Who owns AI created inventions, software, or data?
  - patents are only issued to people; AI inventions can be patented if the human contribution is sufficient to qualify for a patent
  - AI generated material is protected by copyright to extent there is sufficient human authorship to meet the standard for copyright protection, e.g., creatively selecting, arranging, or modifying the AI generated material
  - copyright applicants must disclose inclusion of AI-generated content and describe the human contribution to the work
  - trade secrets are owned by entity protecting the secret

Intellectual property infringement

- Who owns and has the right to enforce AI IP rights?
  - what if there are multiple users?
  - inducement or contributory infringement?
- If an AI system is infringes who is liable?
  - the developer?
  - one or more licensees?
- A "freedom to operate“ opinion provides risk assessment and demonstrates lack of willfulness if there is a lawsuit
- Include indemnification provisions in license agreements
- Use of copyrighted works including photographs, audio, or written materials to train AI systems may create infringement risks

Technology
AI

New York Times Sues Microsoft and OpenAI for Copyright Infringement

- Lawsuit says millions of Times articles trained AI tools
- Copyright case comes as OpenAI seeks $100 billion valuation

OpenAI has faced criticism for scraping text widely from the web to train its chatbots, and this is the first lawsuit by a media organization challenging the practice. *Photographer: Mario Tama/Getty Images*

By Mark Bergen

December 27, 2023 at 9:58 AM EST
Updated on December 27, 2023 at 4:56 PM EST

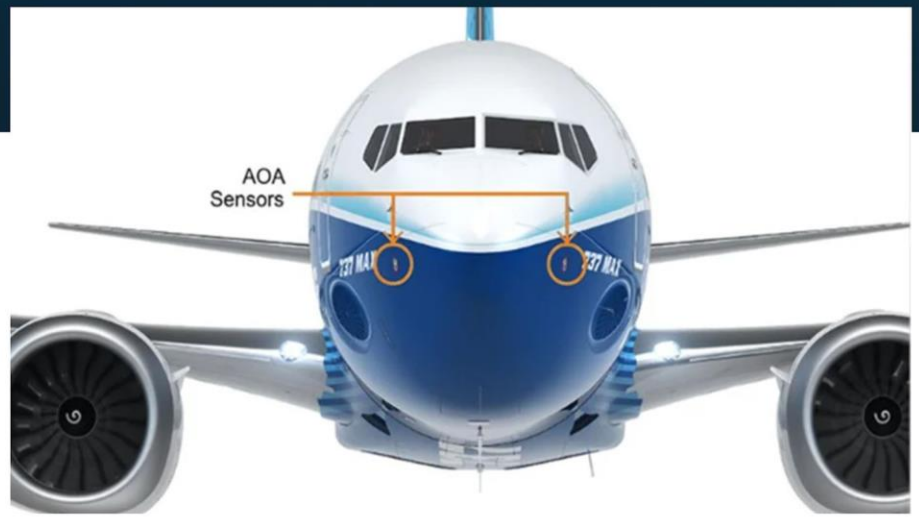
The New York Times Co. sued Microsoft Corp. and OpenAI Inc. for

ELECTRONICS

Killer software: 4 lessons from the deadly 737 MAX crashes

By **Matt Hamblen** • Mar 2, 2020 01:23pm

Acceleration/Vibration | Aerospace/Military | Sensor Applications | Software



Boeing 737 MAX planes are quipped with two angle of attack (AOA) sensors on either side of the fusilage nose, but a flight control software fix called MCAS was relying on data from just one of the sensors in the Lion Air crash in 2018, authorities said. (Boeing)

It's been widely reported that Boeing's decision to use a flight control software fix known as MCAS in its 737 MAX planes was one of the key factors

AI risks

- Automated processes malfunction
- Inaccuracy or non-representativeness of data
- Data exposure
- Unsupervised learning presents greater risk than supervised
  - less accurate
  - cannot measure results against truth offline
- “Hallucination” with generative AI

Product liability principles

- Negligence
  - imposes liability on defendant failing to meet standard of care that a reasonable actor should have exercised
  - plaintiff alleges negligent design or manufacture of product or inadequate warnings or instructions for use
- Breach of warranty
  - based on contract between purchaser and seller (usually rely on state law versions of UCC)
  - allege breach of express warranty, implied warranty of merchantability, or implied warranty of fitness for a particular purpose
- Strict liability
  - seller of defective product that is unreasonably dangerous liable for harm even if exercised all possible care in preparation and sale of product and consumer did not have a contractual relationship with seller

Product liability novel AI issues

- Holds “seller, manufacturer, distributor, or any party in the distribution chain” liable for physical injury or other damages caused by machines or tools, whether acting autonomously or assisted by a human
  - defective laboratory instrument that destroys precious specimens
  - defective software that publicly releases PHI
  - software hacked and placed under 3rd party control or theft of PHI or other private information
- Autonomous action raises novel issues, e.g., robots traditionally treated as other workplace tools
  - how to assign fault with learning and self-directed action
- Product evolution can change strengths and weaknesses
  - need for design without degradation in performance
  - need for warning
- In non-AI software regular updates improve and fix flaws, e.g. security.
  - AI greater potential for introduction of dangerous flaws not initially present as algorithms evolve
- Vendor may misrepresent nature or method of updates, e.g. causing slower improvement
- Because of complexity, unrecognized ‘defects’ in manufacturing, design, or instructions and warnings more likely present at time of sale or distribution

FDA

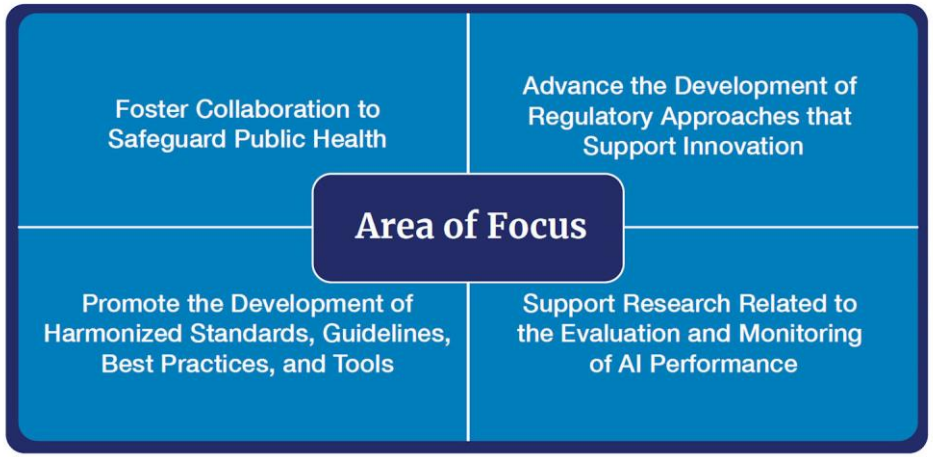
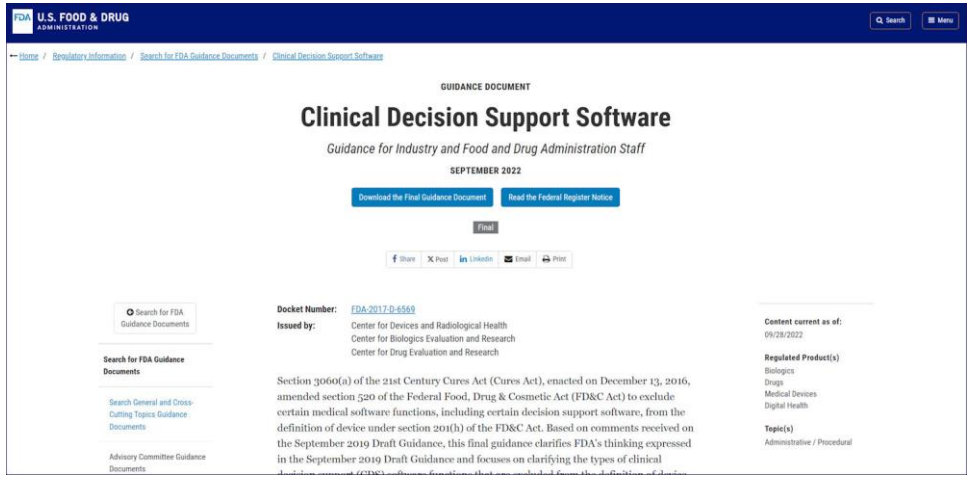


Figure 1. Four areas of focus regarding the development and use of AI across the medical product lifecycle.



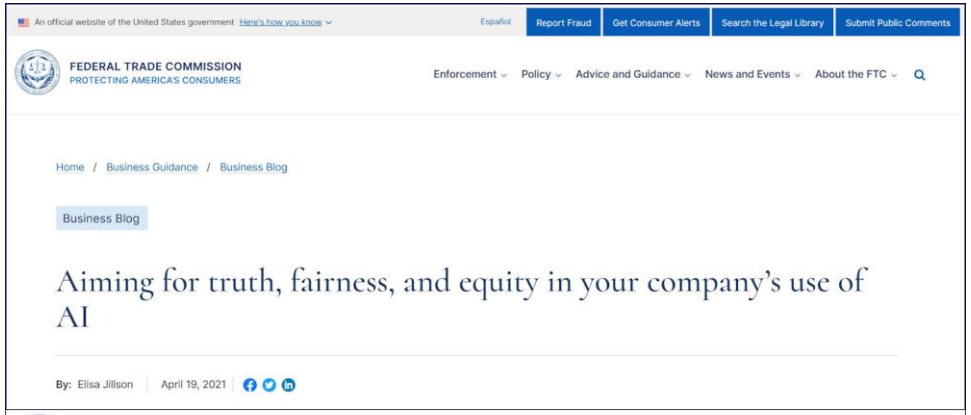
FDA AI regulation

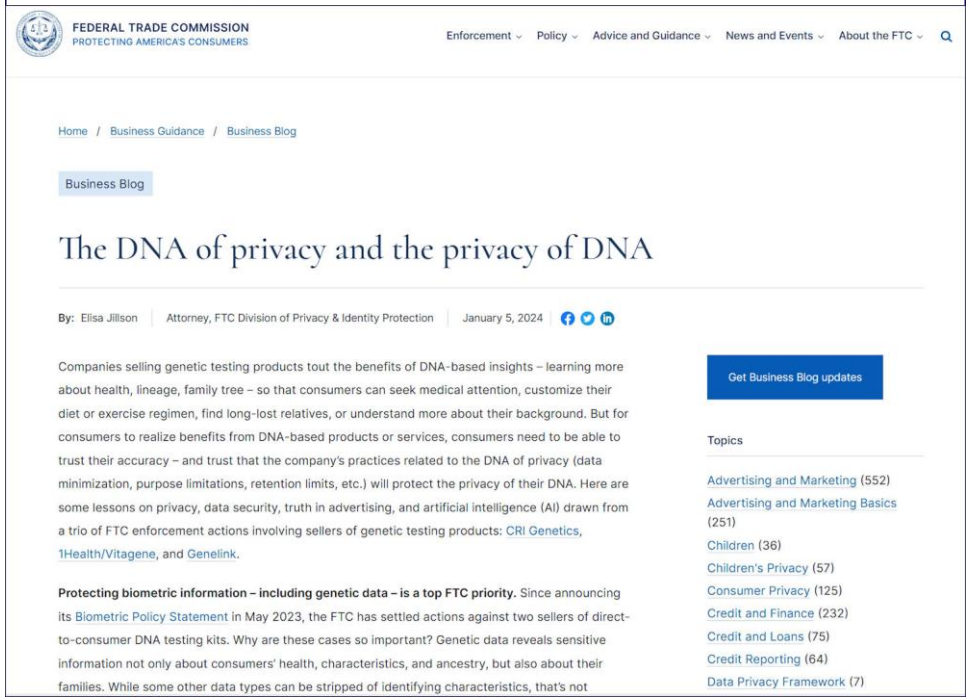
- Software as a medical device (SaMD)
  - International Medical Device Regulators Forum definition:
    "**software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device**."
- Software in a medical device
- Software used in manufacture and maintenance of a medical device

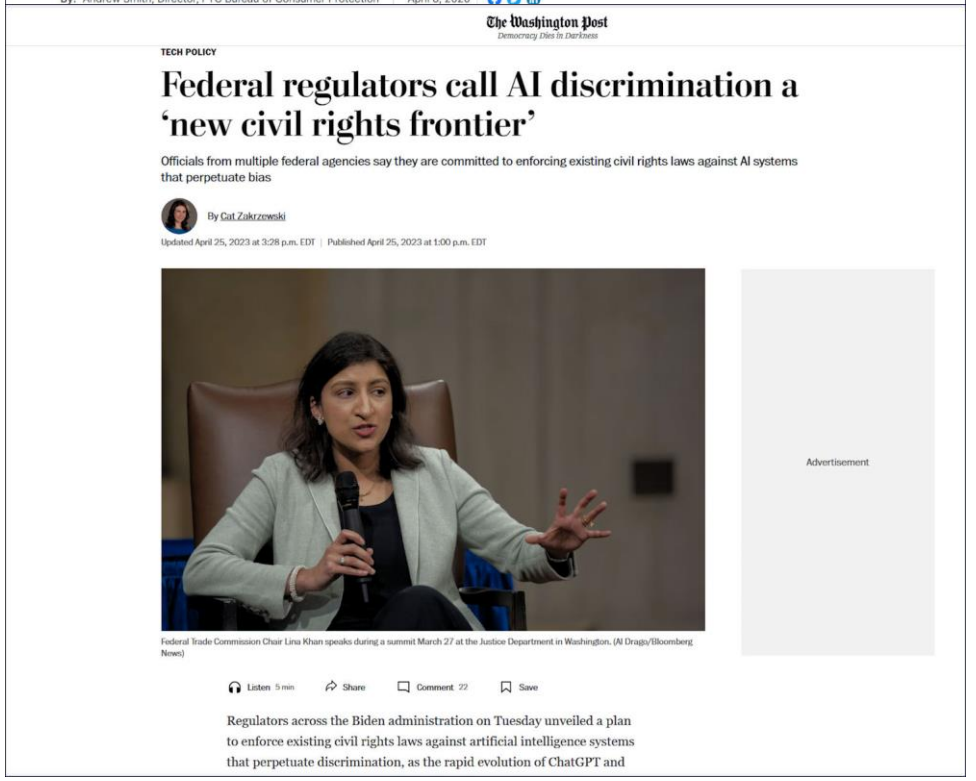
FDA AI regulatory activity

- Risk based framework that can be applied across products, tailored to relevant product
  - envisions product lifestyle based regulation
  - learn from real world experience
- Proposed “Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device” discussion paper on April 2, 2019
  - described the FDA’s foundation for a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications
- Published “Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan” in January, 2021
- Published “Good Machine Learning Practice of Medical Device Development: Guiding Principles in October 2021
- Released Draft Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions in April 2023
- Published “Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles” in October 2023
- Published “Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together” on March 15, 2024

Federal Trade Commission (FTC)



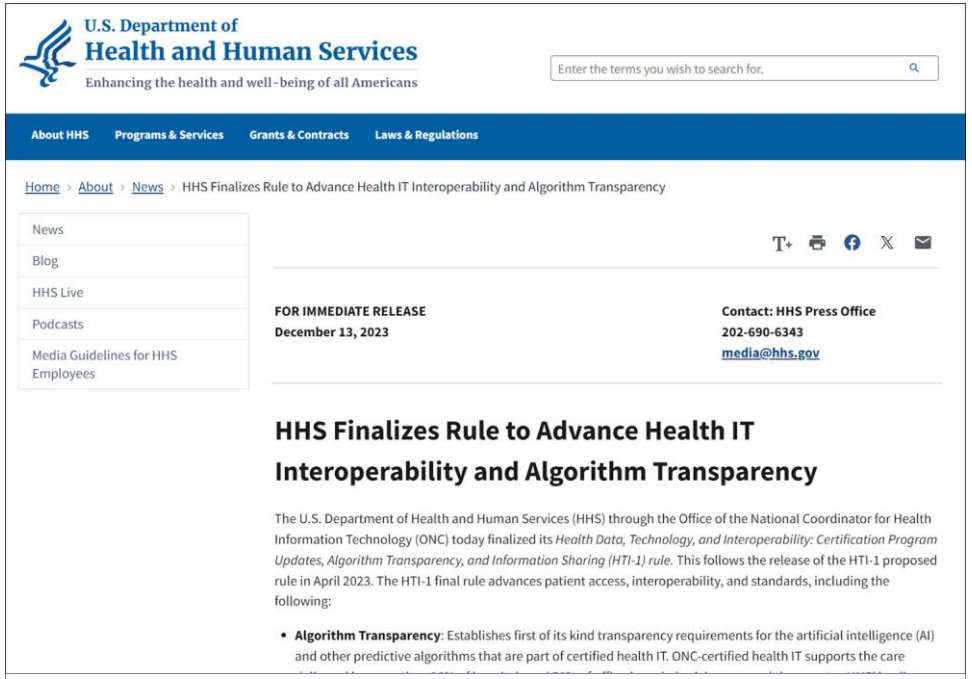




FTC

- Investigates and stops unfair or deceptive acts or practices affecting interstate commerce
  - seeks monetary damages
  - issues rules
  - makes reports and recommendations to Congress and the public
- April 2023 joint statement with Consumer Financial Protection Bureau, Department of Justice Civil Rights Division, and Equal Employment Opportunity Commission caution existing laws apply to AI and other automatic systems
- April 2020 guidance on managing AI consumer protection risks
- Joint Guidance with HHS addressing HIPAA and non-HIPAA consumer health information

Health and Human Services (HHS)



U.S. Department of Health and Human Services

Enhancing the health and well-being of all Americans

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Home › About › News › HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency

- News
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- HHS Live
- Podcasts
- Media Guidelines for HHS Employees

FOR IMMEDIATE RELEASE
December 13, 2023

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency

The U.S. Department of Health and Human Services (HHS) through the Office of the National Coordinator for Health Information Technology (ONC) today finalized its *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) rule.* This follows the release of the HTI-1 proposed rule in April 2023. The HTI-1 final rule advances patient access, interoperability, and standards, including the following:

- **Algorithm Transparency**: Establishes first of its kind transparency requirements for the artificial intelligence (AI) and other predictive algorithms that are part of certified health IT. ONC-certified health IT supports the care

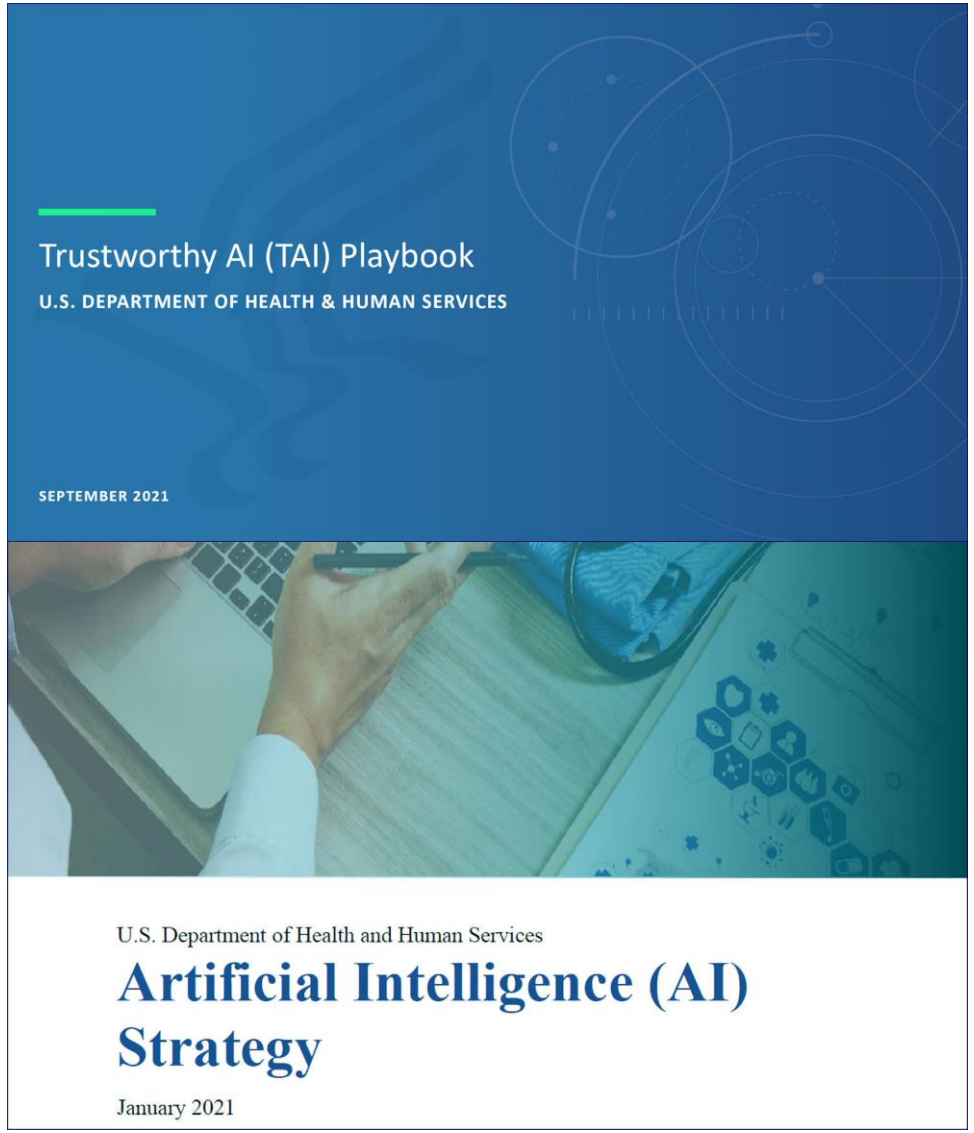
Department of Health and Human Services
OMB M-21-06 (Guidance for Regulation of Artificial Intelligence Applications)

This document constitutes the Department of Health and Human Services (HHS) response to OMB Memorandum 21-06 (Guidance for Regulation of Artificial Intelligence (AI) Applications). Consistent with the guidance provided in the memorandum, HHS's plan includes the five components outlined below:

1. Statutory authorities that directly authorize agencies to regulate AI applications in the private sector
2. Collections of information (approved by OMB under the Paperwork Reduction Act) related to AI applications in the private sector
3. AI applications in the private sector that are within an agency's regulatory authorities
4. Existing regulatory barriers to developing or commercializing AI applications
5. Any planned or considered regulatory actions on AI

As outlined in the memo, the content in this plan focuses on HHS's role as a regulator of the broader health and human services industry. As such, it does not include information on the many and various ways that HHS is already working to apply AI to its mission internally, from biomedical research to fraud detection in medical claims payment. Additionally, because AI is a rapidly evolving field where new technologies and applications are being developed almost daily, this plan represents a moment in time and will continue to evolve as HHS works with the broader industry to ensure that AI is applied in a manner that promotes the health and well-being of all Americans while preserving the public's trust in how data is collected, stored, and used.

Statutory Authorities Directing or Authorizing Agency Regulation of AI Applications.



Trustworthy AI (TAI) Playbook

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

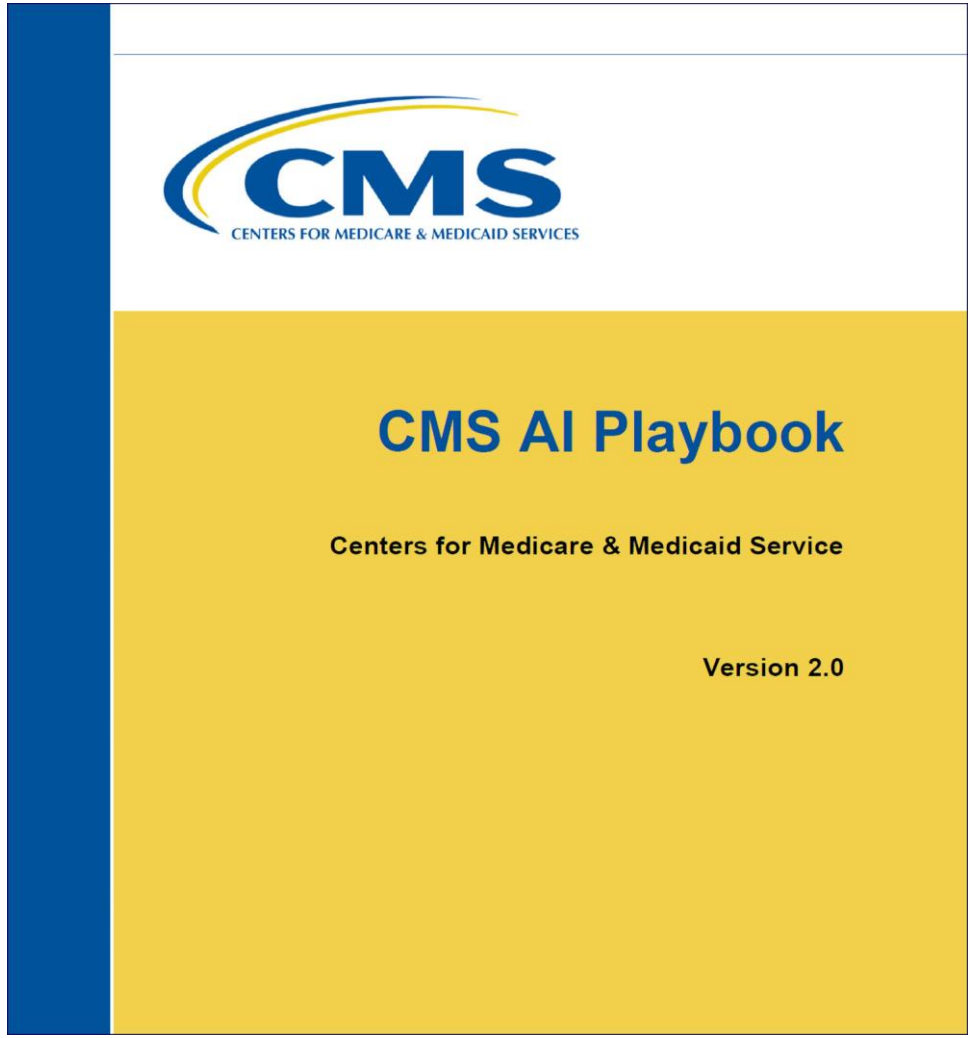
SEPTEMBER 2021

U.S. Department of Health and Human Services

Artificial Intelligence (AI) Strategy

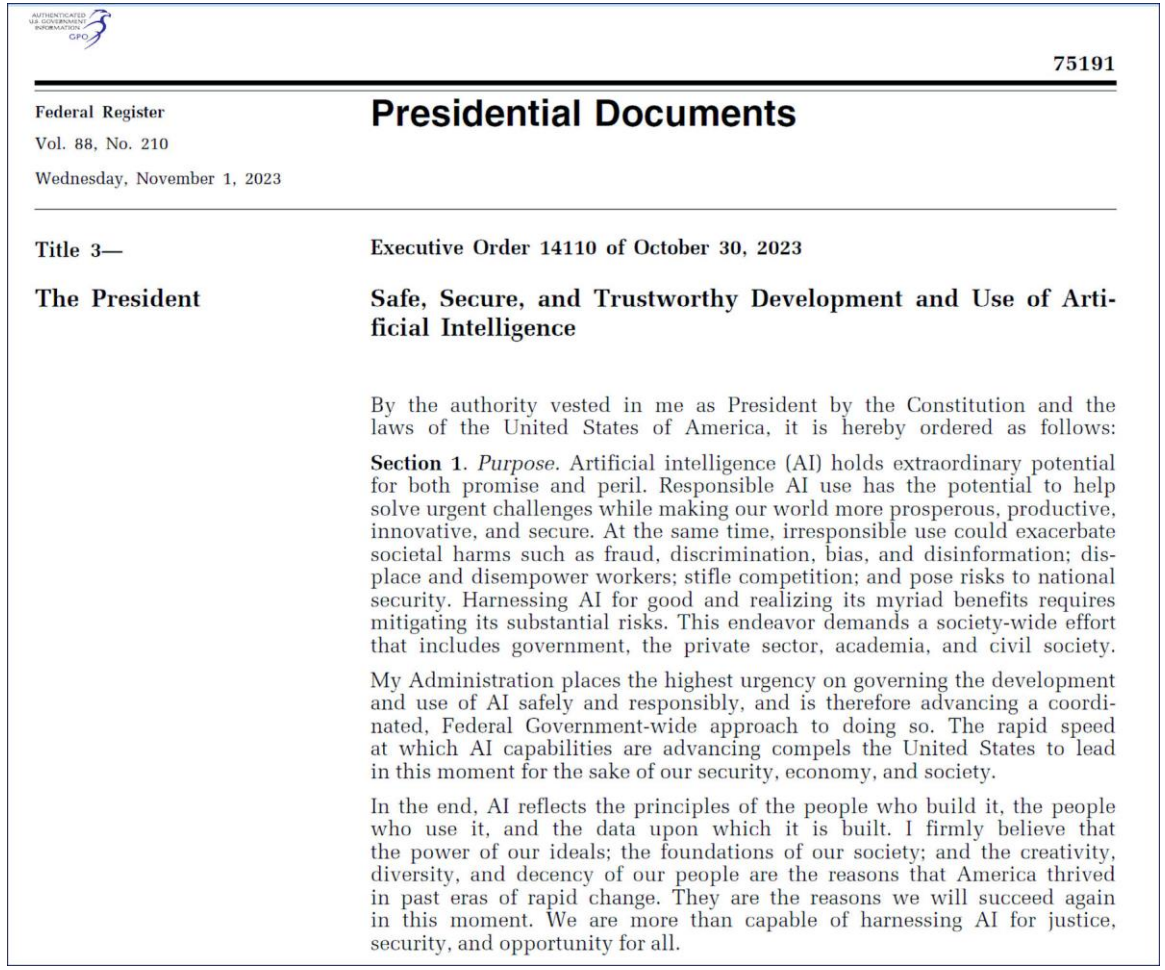
January 2021

Collaboration



CMS Medicare Advantage regulations

- Address Medicare Advantage plans' use of algorithms, software or AI for utilization review and medical necessity determinations
  - CMS commentary describes tools
  - use without complying with regulations is prohibited
- MA plans must provide same general coverage and benefits under traditional Medicare
- MA plans must make medical necessity decisions based on
  - coverage and benefit criteria in regulations
  - determination that providing the items and services is reasonably necessary
  - beneficiaries medical history, physician recommendations, and clinical notes
  - involvement of the plan's medical director
- MA plans must be making medical necessity determinations based on the specific individual's circumstances
  - algorithms or software must account for an individual's circumstances
  - denials is based on medical necessity must be reviewed by a physician or other provider with expertise in the field



75191

Federal Register
Vol. 88, No. 210
Wednesday, November 1, 2023

Presidential Documents

Title 3—
The President

Executive Order 14110 of October 30, 2023

Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* Artificial intelligence (AI) holds extraordinary potential for both promise and peril. Responsible AI use has the potential to help solve urgent challenges while making our world more prosperous, productive, innovative, and secure. At the same time, irresponsible use could exacerbate societal harms such as fraud, discrimination, bias, and disinformation; displace and disempower workers; stifle competition; and pose risks to national security. Harnessing AI for good and realizing its myriad benefits requires mitigating its substantial risks. This endeavor demands a society-wide effort that includes government, the private sector, academia, and civil society.

My Administration places the highest urgency on governing the development and use of AI safely and responsibly, and is therefore advancing a coordinated, Federal Government-wide approach to doing so. The rapid speed at which AI capabilities are advancing compels the United States to lead in this moment for the sake of our security, economy, and society.

In the end, AI reflects the principles of the people who build it, the people who use it, and the data upon which it is built. I firmly believe that the power of our ideals; the foundations of our society; and the creativity, diversity, and decency of our people are the reasons that America thrived in past eras of rapid change. They are the reasons we will succeed again in this moment. We are more than capable of harnessing AI for justice, security, and opportunity for all.

Directives to HHS Secretary

- Establish HHS AI task force
- Assess and address quality issues
- Address nondiscrimination compliance
- Establish an AI safety program
- Develop a strategy for use of AI in drug development
- Promote innovation

AI at work

- Use of AI in employee screening, recruiting, and hiring growing rapidly
  - creates risk of discrimination and bias
  - federal, state and local anti-discrimination laws apply, prohibit intentional discrimination against protected classes and facially neutral policies with disproportionate impacts
  - some AI tools access internet, social media, public databases containing applicant information employers could not legally request such as age, religion, race, sexual orientation, disability, and genetic information
- It may be impossible to know how or why AI reached a decision or made a prediction
  - more difficult to prove intentional discrimination, but harder for employers to satisfy burden of providing legitimate nondiscriminatory business reasons to rebut circumstantial, statistical evidence of discrimination
  - may identify statistical correlations lack causal relationships with inability to demonstrate practices sufficiently job-related or justified by business necessity
- Easier to allege class-wide discrimination with use of same AI tool on large pool of applicants
- Employers review and continue to monitor results as tools learn and adapt
- Some jurisdictions have enacted AI-specific laws for employment uses

Generative AI at work

- Employees are using with or without employers' knowledge or consent
  - analyzing data
  - conducting research
  - drafting emails, cover letters, memoranda, contracts, presentations, and other routine documents
  - responding to customer service inquiries
  - performing HR and employee management functions
- Unauthorized, unethical or otherwise improper use of exposes employers to business risks
  - bias in employment decisions and other violations of employment laws
  - intellectual property violations
  - breach of contract
  - inadvertent use or disclosure of confidential, proprietary, or personal information
  - creating or disseminating misinformation, which can lead to claims of fraud in advertising and marketing
  - errors and inaccuracies in work products
- Generative AI policies help ensure use is authorized, monitored, ethical, and compliant with federal, state, and local laws and regulations, and company policies and practices
  - AI ethics principles
  - AI use policies
  - Regular review updating of use and related policies

Privacy laws and enforcment

- AI use of large data sets has inherent privacy risks
- US without comprehensive federal law, relies on sector and state laws
  - transparency, consent, and fairness
- HIPAA applies to covered entities and business associated that handle PHI
  - can only be used for treatment, payment, and operations (TPO)
  - cannot sell PHI without valid authorization
  - consent can be a significant barrier for providing data for algorithm
  - deidentified information not PHI
- Genetic Information Nondiscrimination Act
  - prohibits discrimination in health coverage and employment based on genetic information
  - restricts employer's disclosure of genetic information
  - restricts employer's and health care plans or insurer's collection or use of genetic information
  - information collected and powering algorithms may include
- Substance abuse and Mental Health Services Administration (SAMSA) (part of HHS)
- State privacy laws

AI antitrust considerations

- AI allows faster response to market conditions, innovation, pricing, etc.
  - assimilate and instantly process significant amounts of information related to competitors' prices, demand, price and availability of substitutes, customer personal data
  - respond immediately to changes in market or competitor pricing
  - set prices to achieve a business objective consistently across all sales
- Use raises potential antitrust risks relating to unlawful, anticompetitive agreements
  - can facilitate price-fixing agreements among competitors
  - reach anticompetitive agreements with other AI systems
- Collusion under antitrust laws
  - agreements that unreasonably restrain trade
  - private right of action
  - price fixing or other agreements not to compete per se illegal
  - other agreements judged under rule of reason, weighs procompetitive benefits against anticompetitive harms
  - key to analysis is often establishing the existence of an agreement
- Aiding a traditional antitrust conspiracy (e.g., pricing algorithms used to fix prices)
- AI systems themselves may reach anticompetitive agreements or otherwise lessen competition independent from human interaction
  - develop sufficient learning capability to assimilate, test and understand market responses. AI could
  - on own or with other AI systems decide colluding with a competing AI system will to maximize profits
  - respond to competitor actions or movements in predictable manner that enables collusion
  - may be no communication between competitors or AI systems
  - unilateral conduct, or violate antitrust laws?
- Minimizing antitrust risk associated with AI
  - maintain up-to-date record of the AI's design and objectives
  - consider the impact of the AI competition

Conclusions

- Artificial intelligence utilizing machine learning will play broad and increasingly important roles in the clinical, research, and business operations and activities of diagnostic laboratories
- The implementation of machine learning and other advanced AI technologies presents new risks and raises novel legal and regulatory issues
- Legal and regulatory approaches will build on previous legal and regulatory experience addressing software with adaption and new or additional rules as needed
- Laboratories and laboratory businesses will need to the understand the legal and regulatory risks presented by the application of new AI technologies, potential mitigation strategies, and