
# Regulation and Implementation of Health AI in the US

Sponsored by IHE CATALYST

Chris Carr - RSNA/IHE International

# Overview

- Review aspects of current and prospective AI regulation in the US relevant to health IT including:
- FDA pre-market approval and clearance of AI SAMD
- Predetermined Change Control Plans
- White House Executive Order on AI
- HHS and AI Assurance Policy
- ONC HTI-1
- AI Assurance Labs

# FDA AI SAMD Approach

- FDA has treated AI-based systems similarly to other SAMD
- Has issued draft guidance for monitoring post-market performance of AI systems

# FDA Clearance/Approval Pathways

- Premarket Notification 510(k): new device safe and effective because “substantially equivalent” to already approved device
- De Novo Classification Request: no legally marketed predicate device; must meet risk-based assessment criteria under General Controls (Class I - lowest risk) or Special Controls (Class II - moderate risk)
- Premarket Approval: Class III - highest risk devices that “support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury”

# Development and Change in AI Models - FDA Guidance

- Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan (Jan. 2021)
- Good Machine Learning Practice for Medical Device Development: Guiding Principles (Oct. 2021) [with UK MHRA and Health Canada]
- Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (April 2023)
- Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles (Oct. 2023) [with UK MHRA and Health Canada]

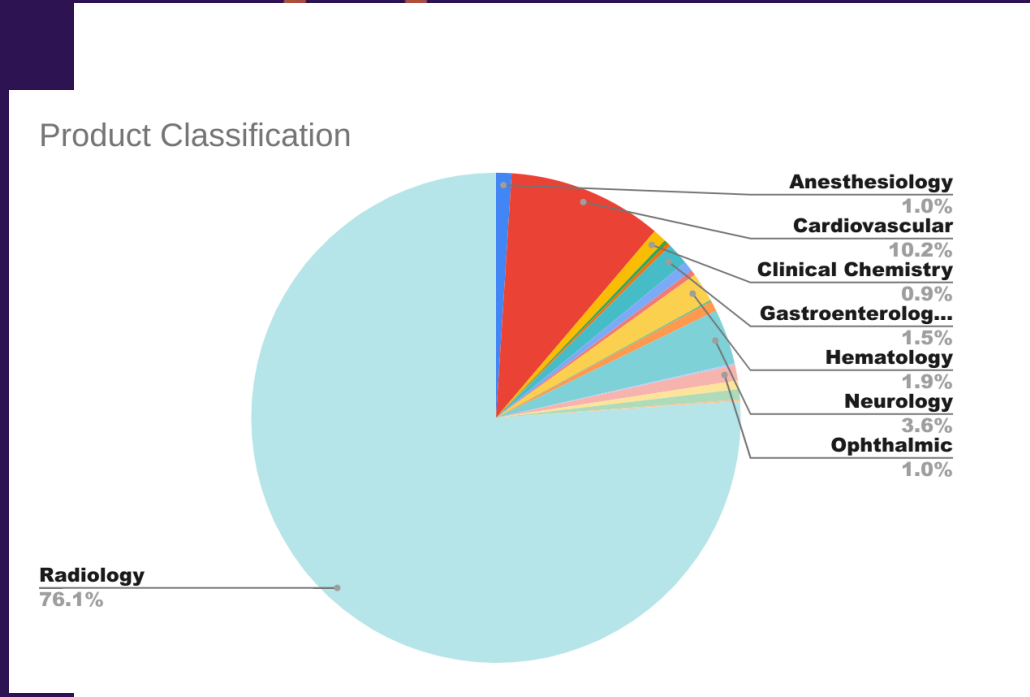
# Five Principles of a Predetermined Change Control Plan

1. Focused and bounded change
2. Risk-based plan for change
3. Evidence-based evaluation of change
4. Transparency of changes to users and stakeholders
5. Total Product Lifecycle (TPLC) perspective

*Entirely advisory and voluntary, no current regulatory impact.*

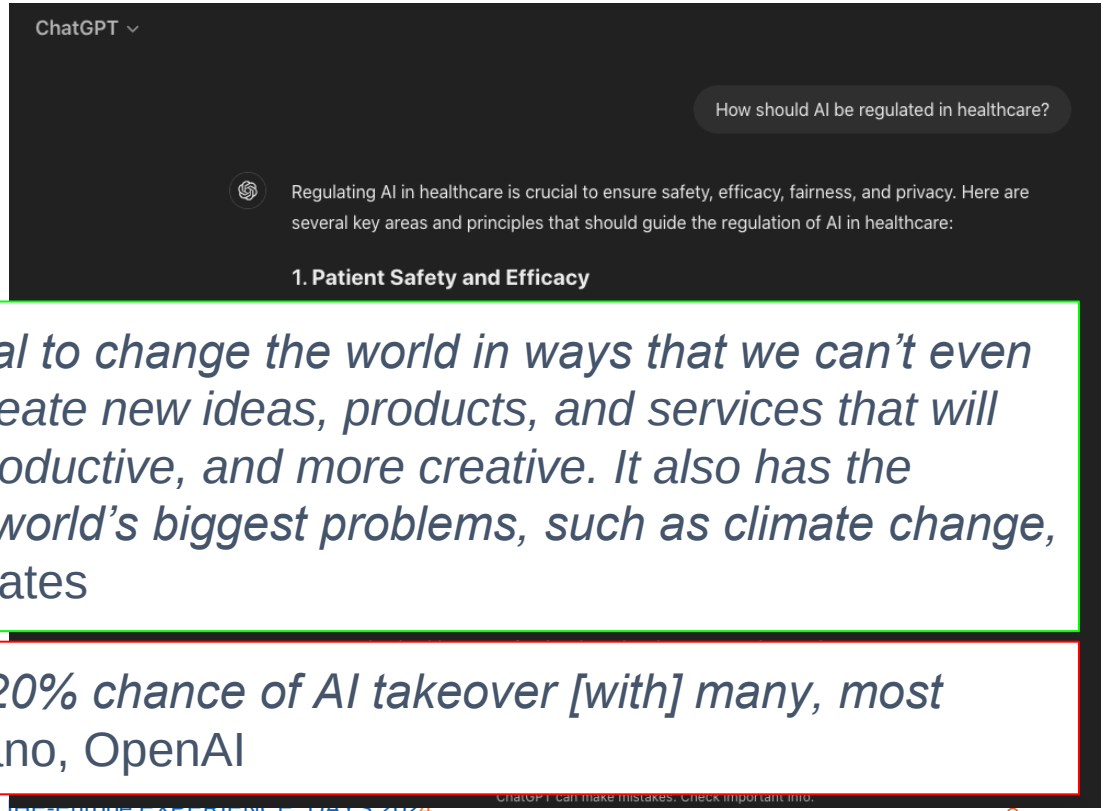
# FDA-cleared AI Devices by Product Classification

- 882 AI-based devices approved to date
- 191 new devices added May 13, 2024
- 151 submitted since Aug. 30, 2023 plus 40 earlier submissions added through “refinement of methods”
- Medical imaging accounts for substantial majority
- Predictive AI trained on retrospective data



# Generative AI and New Regulatory Scrutiny

- Nov. 2022 - Chat GPT introduced
- First broad awareness of foundation models




*"Generative AI has the potential to change the world in ways that we can't even imagine. It has the power to create new ideas, products, and services that will make our lives easier, more productive, and more creative. It also has the potential to solve some of the world's biggest problems, such as climate change, poverty, and disease."* -- Bill Gates

*"I think maybe there's a 10 to 20% chance of AI takeover [with] many, most humans dead."* -- Paul Christiano, OpenAI

# Government Response

Oct. 2023 - Biden Admin issues “Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence”

- Eight principles:
  a. Develop policies, institutions, and mechanisms to test, understand, and mitigate risks to ensure AI is safe and secure
  b. Promote responsible AI innovation, competition and collaboration
  c. Protect workers
  d. Advance equity and civil rights
  e. Protect interests of users
  f. Protect privacy and civil liberties
  g. Increase government capacity to regulate, govern, and support responsible use of AI
  h. Federal Government to provide leadership

- Attempts to balance promotion of US AI leadership with protection against potential harms

# Executive Order AI Directives Pertaining to Health IT

- "HHS [shall] develop a strategy, in consultation with relevant agencies, to determine whether AI-enabled technologies in the health and human services sector maintain appropriate levels of quality, including . . . the development of AI assurance policy — to evaluate important aspects of the performance of AI-enabled healthcare tools — and infrastructure needs for enabling pre-market assessment and post-market oversight of AI-enabled healthcare-technology algorithmic system performance against real-world data."
  - Safety and efficacy
  - Non-discrimination and bias
  - Tracking "incidents that cause harm, including through bias or discrimination"

# ONC Contribution to AI Assurance Infrastructure

- Developers and regulators need data to provide transparency and assess efficacy, safety and fairness of AI systems
- Office of the National Coordinator for Health IT (ONC) oversees certification programs for health IT products (EHRs) and health information exchanges covering care delivered by more than 96% of hospitals and 78% of office-based physicians around the US
- In Dec. 2023, ONC published Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)
  - Establishes rules for data supporting transparency of AI models
  - Expands data elements required to be shared by EHRs and networks, US Core Data for Interoperability (USCDI)

# Algorithm Transparency and Expanded USCDI

- HTI-1 requires EHRs to support 31 source attributes across nine categories to be made available directly to end users:
  - (1) Details and output of the intervention
  - (*2*) Purpose of the intervention
  - (*3*) Cautioned out-of-scope use of the intervention
  - (*4*) Intervention development details and input features
  - (5) Process used to ensure fairness in development of the intervention
  - (6) External validation process
  - (7) Quantitative measures of performance
  - (8) Ongoing maintenance of intervention implementation and use
  - (9) Update and continued validation or fairness assessment schedule
- Applies to Predictive AI Decision Support Interventions provided by certified health IT

# Public-Private Collaboration

- Executive order gives HHS the mandate to develop AI assurance policy
  - That responsibility not vested in any specific agency
  - Emphasis on collaborative approach with industry and AI users
- Coalition for Health AI (CHAI) formed in 2023 publishes Blueprint for Trustworthy AI (Apr 2023) and JAMA editorial (Dec. 2023)
  - Broad range of stakeholders including major research institutions and care centers, industry and US government agencies

# CHAI - AI Assurance Labs

- JAMA editorial, “A Nationwide Network of Health AI Assurance Laboratories” (Dec. 2023) identifies needs for
  a. development of standards, guidelines, and best practices to harness the capabilities of using AI guidance, while minimizing risk associated with it;
  b. concrete guidance on procedures to ensure that the use of AI, including genAI, in health care is fair, appropriate, valid, effective, and safe (FAVES);
  c. a place—an assurance lab—where standards and validation procedures can be applied to produce reports on model performance that can be widely shared; and
  d. processes for managing the lifecycle of AI models to ensure they maintain their performance over time, populations, and sites.
- Method of implementation sketched as federated structure guided by clear central guidance

# Conclusions

- Practical regulatory structure for AI-based decision support systems has not changed
  - FDA has issued voluntary guidance for submission and monitoring specific to AI
- Generative AI has raised scrutiny of AI and discussion of regulation
- Approach toward expanded regulation has been cautious and collaborative
- ONC has implemented some new interoperability requirements to support AI transparency
- Public-private collaboration toward defining methods for evaluating and monitoring AI systems has taken early steps

# Resources

- FDA: Artificial Intelligence and Machine Learning in Software as a Medical Device
- Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence
- ONC HTI-1 Final Rule Overview
- US Core Data for Interoperability (USCDI)
- CHAI: Blueprint for Trustworthy AI
- JAMA Editorial: A Nationwide Network of Health AI Assurance Laboratories

# Questions?