



November 8, 2023

Chairman Ed Markey
Ranking Member Roger Marshall
U.S. Senate Committee on Health, Education, Labor & Pensions
Subcommittee on Primary Health and Retirement Security
428 Senate Dirksen Office Building, Washington, D.C., 20510

Re: CAIDP Statement for the Record: “Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence in Health Care”

Dear Chairman Markey and Ranking Member Marshall,

We write to you regarding the hearing, “Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence in Health Care.”¹ As Merve Hickok, CAIDP President, stated in her testimony before the House Oversight Committee: “AI systems determine people’s opportunities in life.”² We appreciate the significance of this hearing, and we commend the Committee’s timely consideration of the implications of AI in healthcare.

Our recommendations to this Committee in brief are:

1. Consider the risks to privacy and bias in unregulated deployment of AI systems
2. Create guardrails through federal legislation. We support the Blumenthal-Hawley Bipartisan framework for US AI Act as first step towards comprehensive legislation

About CAIDP

The Center for AI and Digital Policy (CAIDP) is an independent research organization based in Washington, D.C. We advise national governments and international organizations regarding artificial intelligence and digital policy.³ CAIDP currently serves as an advisor on AI

¹ Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence in Health Care, U.S. Senate Committee on Health, Labor, Education, and Pensions, Subcommittee on Primary Health and Retirement Security, <https://www.help.senate.gov/hearings/avoiding-a-cautionary-tale-policy-considerations-for-artificial-intelligence-in-health-care>

² Testimony and statement for the record of CAIDP President Merve Hickok, *Advances in AI: Are We Ready For a Tech Revolution?*, House Committee on Oversight and Accountability: Subcommittee on Cybersecurity, Information Technology, and Government Innovation (Mar. 8, 2023), https://oversight.house.gov/wp-content/uploads/2023/03/MerveHickok_testimony_March-8th-2023.pdf.

³ CAIDP, *CAIDP Statements*, <https://www.caidp.org/statements/>.



policy to the OECD, the Global Partnership on AI, the European Union, the Council of Europe, UNESCO, and other national and international organizations. In April 2023, we released the third edition of our Artificial Intelligence and Democratic Values Index,⁴ providing a comprehensive review of AI policies and practices in 75 countries.

1. Consider the risks to privacy and bias in unregulated deployment of AI systems

The Food and Drug Administration has allowed the use of medical algorithms since 1995, the vast majority of which are related to medical imaging.⁵ Numerous companies and researchers have been developing and testing AI technologies for use in health care—for example, to improve the drug development process by increasing efficiency and decreasing time and cost, to detect diseases earlier, and to more consistently analyze medical data.⁶

As companies race to offer AI systems for non-clinical or diagnostic healthcare services, a Wired report documents the extensive bias and discrimination produced by predictive systems deployed in mental and physical healthcare. “Racially biased medical devices, for example, caused delayed treatment for darker-skinned patients during the Covid-19 pandemic because pulse oximeters overestimated blood oxygen levels in minorities. Similarly, lung and skin cancer detection technologies are known to be less accurate for darker-skinned people, meaning they more frequently fail to flag cancers in patients people, meaning they more frequently fail to flag cancers in patients, delaying access to life-saving care. Patient triage systems regularly underestimate the need for care in minority ethnic patients. One such system, for example, was shown to regularly underestimate the severity of illness in Black patients because it used health care costs as a proxy for illness while failing to account for unequal access to care, and thus unequal costs, across the population. The same bias can also be observed along gender lines. Female patients are disproportionately misdiagnosed for heart disease, and receive insufficient or incorrect treatment.”⁷

⁴ CAIDP, *Artificial Intelligence and Democratic Values* (2023), <https://www.caidp.org/reports/aidv-2022/>.

⁵ HealthExec, *FDA has now cleared more than 500 healthcare AI algorithms*, (Feb. 6, 2023), <https://healthexec.com/topics/artificial-intelligence/fda-has-now-cleared-more-500-healthcare-ai-algorithms> [“HealthExec Report”]

⁶ Congressional Research Service, *Artificial Intelligence: Overview, Recent Advances, and Considerations for the 118th Congress*, (Aug. 4, 2023), pg. 4, <https://crsreports.congress.gov/product/pdf/R/R47644> [“CRS Report: 118th Congress”]

⁷ Wired, *Health Care Bias Is Dangerous. But So Are ‘Fairness’ Algorithms*, (Feb. 8, 2023), <https://www.wired.com/story/bias-statistics-artificial-intelligence-healthcare/>



Another study⁸ done by researchers from Berkeley, Chicago and Boston published in *Science* found that, “Health systems rely on commercial prediction algorithms to identify and help patients with complex health needs. We show that a widely used algorithm, typical of this industry-wide approach and affecting millions of patients, exhibits significant racial bias: At a given risk score, Black patients are considerably sicker than White patients, as evidenced by signs of uncontrolled illnesses. Remedying this disparity would increase the percentage of Black patients receiving additional help from 17.7 to 46.5%. The bias arises because the algorithm predicts health care costs rather than illness, but unequal access to care means that we spend less money caring for Black patients than for White patients.”

Apart from the specific applications to diagnostic or clinical procedures, the application of AI/ML systems in generating consumer reports and insurance scoring decisions pose particular risks for ensuring fair and equitable access to healthcare for Americans.

CAIDP President, Merve Hickok led a study on “*The Distilling of a Biased Algorithmic Decision System through a Business Lens*.”⁹ In that study the researchers noted that the “healthcare sector sits on a mine of data, making it one of the most lucrative fields for big data-based analytics...making it paramount for all stakeholders to develop, deploy, and implement the algorithmic tools safely and ethically. Otherwise, these systems can have detrimental effects on the life, well-being, and safety of patients.”

The Federal Trade Commission has also highlighted the risks of AI systems in its business guidance. The FTC states “The use of AI technology – machines and algorithms – to make predictions, recommendations, or decisions has enormous potential to improve welfare and productivity. But it also presents risks, such as the potential for unfair or discriminatory outcomes or the perpetuation of existing socioeconomic disparities. Health AI offers a prime example of this tension. Research recently published in *Science* revealed that an algorithm used with good intentions – to target medical interventions to the sickest patients – ended up funneling resources to a healthier, white population, to the detriment of sicker, black patients.”¹⁰

⁸ Ziad Obermeyer et al., *Dissecting racial bias in an algorithm used to manage the health of populations*, *Science*, 366,447-453 (2019), DOI:10.1126/science.aax2342, <https://www.science.org/doi/10.1126/science.aax2342>

⁹ Merve Hickok, Colleen Dorsey, Tim O'Brien, Dorothea Baur, Katrina Ingram, Chhavi Chauhan, Attlee M. Gamundani, *Case Study: The Distilling of a Biased Algorithmic Decision System through a Business Lens*, DOI: 10.31235/osf.io/t5dhu; <https://osf.io/preprints/socarxiv/t5dhu/>

¹⁰ Federal Trade Commission (FTC), *Using Artificial Intelligence and Algorithms*, Business Blog, (Apr. 8, 2020), <https://www.ftc.gov/business-guidance/blog/2020/04/using-artificial-intelligence-and-algorithms>



Senators Booker and Wyden previously sent letters to the [Federal Trade Commission](#), [Centers for Medicare and Medicaid Services](#), and to health companies Blue Cross Blue Shield, Cigna Corporation, Humana, Aetna, and UnitedHealth Group. The senators asked FTC to investigate whether decision-making algorithms discriminate against marginalized communities. Senators also demanded these organizations to explain how companies explain what safeguards the companies have put in place to prevent bias.¹¹

The Congressional Research Service Report on AI Considerations for the 118th Congress states, “Researchers and clinicians have raised questions about the accuracy, security, and privacy of these technologies; the availability of sufficient health data on which to train systems; medical liability in the event of adverse outcomes; the adequacy of current user consent processes; and patient access and receptivity. These questions reflect the potential risks from using AI systems. For example, a poorly designed system might lead to misdiagnosis; systems trained on biased data can reflect or amplify those biases in their outputs; and if a flawed AI system is adopted widely, it might result in widespread injury to patients.”¹²

2. Create guardrails through federal legislation

The Pew Research Center report which explored public views on AI in healthcare and medicine found that, **60% of Americans would be uncomfortable with provider relying on AI** in their own health care.¹³ “Six-in-ten U.S. adults say they would feel uncomfortable if their own health care provider relied on artificial intelligence to do things like diagnose disease and recommend treatments... The security of health records is also a source of some concern for Americans: 37% think using AI in health and medicine would make the security of patients’ records worse, compared with 22% who think it would improve security.”¹⁴

AI/ML systems developed and provided by Big Tech companies are integrated into various consumer facing services including healthcare services. “Consumers in this machine learning as a service (MLaaS) market know very little about the nature or quality of the services they are purchasing. Whereas consumers of ordinary products like laptops, cars, or refrigerators

¹¹ News Release from the Office of Sen. Cory Booker, *Booker, Wyden Demand Answers on Biased Health Care Algorithms*, (Dec. 03, 2019), <https://www.booker.senate.gov/news/press/booker-wyden-demand-answers-on-biased-health-care-algorithms>; Wired, *Senators Protest a Health Algorithm Biased Against Black People*, (Dec. 3, 2019), <https://www.wired.com/story/senators-protest-health-algorithm-biased-against-black-people/>

¹² CRS Report: 118th Congress, pg. 5

¹³ Pew Research Center, *60% of Americans Would Be Uncomfortable With Provider Relying on AI in Their Own Health Care*, Report, (Feb. 22, 2023), <https://www.pewresearch.org/science/2023/02/22/60-of-americans-would-be-uncomfortable-with-provider-relying-on-ai-in-their-own-health-care/> [“Pew Report: AI in Healthcare”]

¹⁴ Pew Report: AI in Healthcare



can turn to *Consumer Reports* or *Wirecutter* to help them evaluate a product’s quality, there are no such resources for MLaaS consumers. For example, MLaaS consumers don’t know what data was used to train any given ML API, how accurate any given service’s predictions will be for their own data, or if paying more will yield better predictions.”¹⁵

There are also privacy and security concerns of unregulated AI systems in healthcare. A report published by the National Library of Medicine also cautions “Because health records are important and vulnerable, hackers often target them during data breaches. The absence of standard guidelines for the moral use of AI and ML in healthcare has only served to worsen the situation. There is debate about how far artificial intelligence (AI) may be utilized ethically in healthcare settings since there are no universal guidelines for its use. Therefore, maintaining the confidentiality of medical records is crucial.”¹⁶

Europe is already progressing on regulating AI systems in healthcare through provisions in the EU AI Act while steadily trying to reconcile conformity assessments between sectoral legislation and the AI Act. “Under the proposed AI Act, medical or in vitro diagnostic medical devices that are themselves an AI system or use an AI system as a safety component, would be subject to the MDR/IVDR and the AI Act. The Act will determine how and if new AI-enabled medical technologies will be placed on the market and reach hospitals and patients.”¹⁷

President Biden’s Executive Order on “Safe, Secure, and Trustworthy Artificial Intelligence” sets out steps to be taken by the Department of Health and Human Services to ensure the safe, responsible deployment and use of AI in the healthcare and public health sectors.”¹⁸ Section 8 pertaining to protecting consumers, patients, passengers, and students, the Executive Order directs federal agencies to use the full range of their authorities to “to protect American consumers from fraud, discrimination, and threats to privacy” through measures “including clarifying the responsibility of regulated entities to conduct due diligence on and monitor any third-party AI services they use, and emphasizing or clarifying requirements and

¹⁵ Stanford University, Human Centered Artificial Intelligence, *A Consumer Reports for AI Services*, (Jan. 9, 2023), <https://hai.stanford.edu/news/consumer-reports-ai-services>

¹⁶ Bangul Khan, Hajira Fatima, Ayatullah Quereshi, Sanjay Kumar, Abdul Hannan, Jawad Hussain, Saad Abdullah, *Drawbacks of Artificial Intelligence and Their Potential Solutions in the Healthcare Sector*, Biomed Mater Devices, (2023 Feb 8:1-8), <https://doi.org/10.1007%2Fs44174-023-00063-2>

¹⁷ Euractiv, *How the AI Act could unintentionally impact access to healthcare*, Opinions, (Mar. 1, 2023), <https://www.euractiv.com/section/digital/opinion/how-the-ai-act-could-unintentionally-impact-access-to-healthcare/>

¹⁸ Executive Order 14110, *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*, (Oct. 30, 2023), Section 8, pg. 75214, <https://www.govinfo.gov/content/pkg/FR-2023-11-01/pdf/2023-24283.pdf> [“Executive Order 14110”]

expectations related to the transparency of AI models and regulated entities' ability to explain their use of AI models.”¹⁹

There are already numerous disputes before the courts on fraud²⁰ and abusive business practices²¹ involving the use of AI systems in diagnostic services and insurance and medical coverage. While these disputes are being pursued by commercial entities against each other they lay bare the real risks to the public.

Safety and efficacy are legal mandates of the FDA. However, as AI expands into non-clinical areas of healthcare, “AI algorithms do not require FDA clearance if they do not directly impact clinical care.”²² AI deployment in healthcare can only be successful if it achieves the major goals of healthcare, including improving care access, patient outcomes, and health equity.

Given the documented risks we recommend the Committee consider the following specific guardrails for deployment of AI systems:

- a. AI systems should not be used for healthcare contexts where a certified clinical professional is required
- b. Healthcare data should be regulated to prevent the current loopholes regarding healthcare or wellness apps which do not fall under HIPAA
- c. AI-based health or wellness systems (i.e. Fitbit) should not be used to make determinations for insurance or employment

We need legal rules to allocate rights and responsibilities. Those who deploy AI systems must carry the responsibilities for the consequences. Those who are subject to AI processes

¹⁹ Executive Order 14110, pg. 75214

²⁰ *Braun v. Ontrak, Inc.*, 2023 Cal. Super. LEXIS 71440. [Ontrak-A program was that the insured patients targeted for recruiting into the program were also disproportionately people who were more likely to lose their health coverage due to job loss or other causes. As a result, although Ontrak would represent to patients that they would not be required to pay for Ontrak's services, by the time Ontrak billed its insurer customers for the services provided to the patients, the clients were often no longer covered by their insurance.]

²¹ *In Re Meta Pixel Healthcare Litigation*, 647 F. Supp. 3d 778, 784. [Plaintiffs are Facebook users who allege that Meta improperly acquires their confidential health information in violation of state and federal law and in contravention of Meta's own policies regarding use and collection of Facebook users' data. Each of plaintiffs' healthcare providers—MedStar Health System, Rush University System for Health, and UK Healthcare—allegedly installed the Meta Pixel on their patient portals. Plaintiffs claim that when they logged into their patient portal on their medical provider's website, the Pixel transmitted certain information to Meta. They contend that this information, which is contemporaneously redirected to Meta, revealed their status as patients and was monetized by Meta for use in targeted advertising.]

²² HealthExec Report



receive the rights. Voluntary risk management frameworks and federal agency guidance is not a substitute for legislation in protecting people from the pervasive impacts of AI systems. The National Academy of Medicine in exploring the governance of generative AI in health and medicine has stated “There should be full transparency on the composition, semantics, provenance, and quality of data used to develop AI tools. There also needs to be full transparency and adequate assessment of relevant performance components of AI.”²³

We need federal legislation that mandates algorithmic transparency and accountability. We endorse the Hawley-Blumenthal bipartisan AI Act, a comprehensive framework for the governance of AI.

Thank you for your consideration of our views. We ask that this statement be included in the hearing record. We would be pleased to provide you and your staff with additional information.

Sincerely yours,

Marc Rotenberg
CAIDP Executive Director

Merve Hickok
CAIDP President

Christabel Randolph
Law Fellow

²³ National Academy of Medicine, *LLMs/Generative AI in Health and Medicine: An Issue Framing Conversation*, Briefing Book, (Oct. 25, 2023), pg. 20, <https://nam.edu/wp-content/uploads/2023/10/FINAL-Fall-Workshop-10.25.23-Briefing-Book.pdf>



UNIVERSAL GUIDELINES FOR AI

RIGHT TO TRANSPARENCY

All individuals have the right to know the basis of an AI decision that concerns them. This includes access to the factors, the logic, and techniques that produced the outcome.

RIGHT TO HUMAN DETERMINATION

All individuals have the right to a final determination made by a person.

IDENTIFICATION OBLIGATION

The institution responsible for an AI system must be made known to the public.

FAIRNESS OBLIGATION

Institutions must ensure that AI systems do not reflect unfair bias or make impermissible discriminatory decisions.

ASSESSMENT AND ACCOUNTABILITY

An AI system should be deployed only after an adequate evaluation of its purpose and objectives, its benefits, as well as its risks. Institutions must be responsible for decisions made by an AI system.

ACCURACY, RELIABILITY, AND VALIDITY

Institutions must ensure the accuracy, reliability, and validity of decisions.

DATA QUALITY

Institutions must establish data provenance, and assure quality and relevance for the data input into algorithms.

PUBLIC SAFETY

Institutions must assess the public safety risks that arise from the deployment of AI systems that direct or control physical devices, and implement safety controls.

CYBERSECURITY

Institutions must secure AI systems against cybersecurity threats.

PROHIBITION ON SECRET PROFILING

No institution shall establish or maintain a secret profiling system.

PROHIBITION ON UNITARY SCORING

No national government shall establish or maintain a general-purpose score on its citizens or residents.

TERMINATION OBLIGATION

An institution that has established an AI system has an affirmative obligation to terminate the system if human control of the system is no longer possible.



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