

November 27, 2023

The Honorable Cathy McMorris Rodgers
Chair, House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member, House Committee on Energy
& Commerce
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chair, House Committee on Energy & Commerce
Health Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member, House Committee on Energy
& Commerce Health Subcommittee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chair Rodgers, Chair Guthrie, Ranking Member Pallone and Ranking Member Eshoo:

Thank you for holding a hearing entitled "Understanding How AI is Changing Health Care" to examine the use of artificial intelligence (AI) in health care. CTA believes the use of AI in health care is an excellent example of how technology can be leveraged to improve lives, while also recognizing the need for consumer protections and safety for high-risk AI applications.

As North America's largest technology trade association, the Consumer Technology Association (CTA®) is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. CTA is the trade association representing the more than 1000 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA is a leading voice on emerging technology issues, including AI, and their impact on the consumer technology industry. In September, CTA released a [National AI Policy and Regulatory Framework, consumer research](#) on the level of awareness and interest regarding AI and its applications, and a [voluntary consensus-based industry standard](#) that identifies types of bias, sources of bias, and bias management practices for health care applications. As CTA President and CEO, I also recently penned an op-ed in *TechCrunch* entitled ["Why Smart AI Regulation is Vital for Innovation and US Leadership"](#) and [participated in the Senate AI Insight Forum on Privacy and Liability](#).

CTA's Health Division strives to increase the use of technology-enabled value-based health care to reduce health care costs and drive better health outcomes. The Division, which is made up of cutting edge small and large companies in the health care and technology sectors, including telehealth and personal health wearable companies, health care payers, health systems and biopharmaceutical innovators, provides policy advocacy, health care market research and standards initiatives that advance the appropriate use of consumer technologies in the health care context.

AI Holds Great Promise in Health Care

The use of AI in health care is not new. The Food & Drug Administration has approved more than 600 AI/ML enabled devices since 1995.¹ Recent developments in generative AI have shown promise in improving drug discovery and development, personalized treatments and provider training.

In a March 2023 letter to the Senate Committee on Health, Education, Labor, and Pensions, CTA highlighted the potential of digital health, including AI, to address health care workforce shortage issues.² CTA believes AI is showing promise in reducing provider burden and burnout. Not only are advances in AI revolutionizing the way we detect and treat diseases, but it can also streamline administrative tasks such as scheduling and clinical documentation requirements.^{3,4} AI can help health care workers treat patients more efficiently and effectively and address main drivers of burnout.

Leverage Existing Laws & Regulations to Address AI

As outlined in CTA's *National AI Policy and Regulatory Framework*, CTA believes Congress should recognize where existing law can be leveraged to address potential concerns with the uses of AI. For example, CTA believes that in certain instances, existing law already guards against potential bias and discrimination, regardless of whether such harm is human or machine generated. Congress should recognize where such laws provide existing remedies and procedures and avoid duplication of the same. If new lawmaking is necessary, CTA urges legislators to focus on guardrails and outcomes, rather than attempting to rein in specific technologies.

CTA also believes a risk-based approach is the best way to support America's technological competitiveness and culture of innovation while protecting the rights and liberties of individuals. As such, CTA believes governance obligations should apply only on high-risk AI systems making decisions: (1) based solely on automated processing and (2) which have consequential legal or equally significant effect on individuals, or which may impact individuals' health and safety. Decisions that impact an individual's ability to obtain financial services, education, housing, health care, and other essential services such as food and water should also constitute decisions that have critical legal or equally significant effects.

In health care, CTA generally supports FDA's risk-based approach to regulation, including for AI. Non-FDA regulated health care applications that use AI, such as health administrative software or consumer health apps that do not make a medical claim, should be considered low risk. For both scenarios, consensus-based industry standards should play an important role in driving transparency and accountability in AI.

¹ <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

² https://cdn.cta.tech/cta/media/media/advocacy/pdfs/cta-help-workforce-letter-fin.pdf?_gl=1*_qo1jp3*_ga*MjA1NzY5MDM4My4xNjc4ODkxMDk5*_ga_5P7N8TBME7*MTY5NDg5MTC1MS41NS4xLjE2OTQ4OTMwODUuNTkuMC4w&_ga=2.37671586.38966437.1694811339-2057690383.1678891099

³ Hazarika, I. (2020). Artificial intelligence: opportunities and implications for the health workforce. *International health*, 12(4), 241-245.

⁴ <https://www.fiercehealthcare.com/ai-and-machine-learning/finding-right-candidates-keeping-them-ai-aiding-healthcare-industry-meets>

The Role of Industry Standards

Consensus-based industry standards are critical to AI governance and regulatory compliance. CTA is an American National Standards Institute (ANSI) accredited standards development organization. We currently have seven published AI standards, including four on AI in health care: *The Use of Artificial Intelligence in Health Care: Best Practices and Recommendations for Bias Management* ([ANSI/CTA-2116](#)); *The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data* ([ANSI/CTA-2107-A](#)); *The Use of Artificial Intelligence in Health Care: Trustworthiness* ([ANSI/CTA-2090](#)); *Definitions/Characteristics of Artificial Intelligence in Health Care* ([ANSI/CTA-2089.1](#)).

As previously mentioned, consensus-based industry standards can play an important role for both FDA and non-FDA regulated health care AI-enabled devices and applications. Standards can work in tandem with federal regulations and can be nimbler and more reactive to changes in the market, while underpinned by baseline federal consumer protections and rules. For non-FDA regulated AI-enabled health care devices and applications, which are generally low risk, standards can be important in driving industry best practices and ensuring quality and effective products. In considering federal regulation of AI, we urge Congress to recognize the important role of consensus-based industry standards.

Congress Must Pass a National Privacy Law

To ensure trust and confidence in AI-enabled health care tools, there must be robust data privacy requirements. While the protections provided under the *Health Insurance Portability and Accountability Act* (HIPAA) work well in clinical settings as healthcare providers are covered entities under HIPAA, and therefore they and their business associates must adhere to the law, if patients choose to upload their data to an AI-powered tool of their choosing, that tool would likely not be covered by HIPAA.

CTA advocates for a comprehensive federal data privacy law that preempts state laws. A uniform, technology-neutral, national standard that provides consistent protections across technologies, companies, agencies, and state borders are the bedrock prerequisite to ensure consumer trust, continue data-driven innovation, and safeguard data. A preemptive federal privacy law is the most effective way to achieve such consistency. A federal privacy law should also avoid a private right of action so as not to enable frivolous and harassing lawsuits targeting American innovators and entrepreneurs. Legislation that merely sets one standard and allows states to add additional requirements will confuse consumers and developers, discouraging innovation. A state-centric approach simply does not work in a digital economy, where data flows across borders in a matter of seconds.

Failing to pass federal privacy legislation will cost the American economy more than \$1 trillion (about \$3100 per person in the United States) over ten years, with more than \$200 billion of that being paid by small businesses.⁵ As a result, resources that could go toward creating jobs or investing in research will instead be spent on compliance costs and legal bills created by the current state-by-state patchwork of privacy laws. Without Congressional action, we will end up with different laws in all 50 states (there are already 12 states that have enacted comprehensive privacy laws) placing the United States at a competitive disadvantage as other nations enact comprehensive privacy laws.

⁵ <https://itif.org/publications/2022/01/24/50-state-patchwork-privacy-laws-could-cost-1-trillion-more-single-federal/>

Conclusion

Thank you for your leadership to ensure the health care industry and patients everywhere can benefit from the use of cutting-edge technologies such as AI. CTA believes AI holds great promise in addressing some of the biggest challenges facing the US health care system and we look forward to continuing to work with the Committee and Subcommittee to advance the responsible use of AI in health care.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Shapiro". The signature is fluid and cursive, with the first name "Gary" being more prominent than the last name "Shapiro".

Gary Shapiro
President and CEO
Consumer Technology Association

Cc:
Members of the Energy & Commerce Health Subcommittee