Consumer Technology Association, producer of CES®

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The Honorable Bill Cassidy, MD
Ranking Member
Senate Health, Education, Labor & Pensions Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Ranking Member Cassidy:

Thank you for your leadership and opportunity to respond to your whitepaper, entitled *Exploring Congress' Framework for the Future of AI: The Oversight and Legislative Role of Congress Over the Integration of Artificial Intelligence in Health, Education, and Labor.*

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 artificial intelligence (AI), and their impact on the consumer technology industry. This month alone, CTA has 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. CTA President and CEO Gary Shapiro also recently penned an op-ed in *TechCrunch* entitled "Why Smart AI Regulation is Vital for Innovation and US Leadership."

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.

More, CTA believes a risk-based approach is the best way to balance the nation's technological competitiveness and culture of innovation with ensuring the rights and liberties of individuals are

protected. 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, healthcare, and other essential services such as food and water should also constitute decisions that have critical legal or equally significant effect.

CTA believes it is vital that the United States leads the world on AI policy, innovation, and implementation. We look forward to continuing to work with you to develop a smart and balanced approach to meeting that goal.

Specific Responses

Health Care

Supporting Medical Innovation

How can FDA improve the use of AI in medical devices?

CTA recently commented on FDA's draft *guidance Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML) – Enabled Device Software Functions.* You can find our full comments here, a summary of our general comments is below:

Given the complexity of modern medical device software and the types of hardware that hosts or interacts with software as a medical device (SaMD), CTA recommends that FDA consider publishing additional guidance documents and resources, clarifying how PCCPs might apply in other contexts, including:

- The use of ML to identify and address software malfunctions that occur in real-world use—such as the self-testing of device functions and potential functional autonomous rectification of malfunctions in the field or self-testing against an internal quality benchmark.
- Improving the algorithmic capabilities of an existing parameter—such as via a device internal quality benchmark and its autonomous application in the field to determine the most suitable selection of data processing subroutine.
- Adding a new function that requires patient training or (self) validation if rolled out as an additional parameter with a new algorithm—such as a new feature of the device that would require training of a user in the field.
- Ways to manage AI/ML-driven changes to a device or drug product while it is still in clinical trials.
- The use of AI/ML in developing personalized medical products—such as the use of algorithms to tailor devices to individual patients.

CTA also urged FDA to issue additional guidance focusing solely on bias instead of addressing the issue only in the context of PCCPs.

What updates to the regulatory frameworks for medical devices should Congress consider to facilitate innovation in AI applications while also ensuring that products are safe and effective for patients?

While CTA supports the FDA's general risk-based approach to regulation, the agency's current regulatory framework is ill-suited for AI. For example, the FDA is still considering how to allow modifications to algorithms post-market. The FDA completed the Software Pre-Certification (Pre-Cert) Pilot Program, which would allow FDA to better adopt the approval process for Software as a Medical Device (SaMD) to take into consideration the fact that these products are often "designed iteratively and can be designed to updated after deployment to quickly make enhancements and efficiently address issues, including malfunctions and adverse events."

What are the potential consequences of regulating AI in the United States if it remains unregulated in other countries?

Many countries and international alliances, such as the European Union, are passing laws to regulate AI. In these countries, they are seeing the very real effects of these burdensome regulations on the growth and innovation in AI. CTA President & CEO Gary Shapiro recently wrote on this issue in *TechCrunch* - "A recent study from Stanford University also found that the EU's AI Bill would bar all of the currently existing large language models, including OpenAI's GPT-4 and Google's Bard. Canadian lawmakers are moving forward an overly broad AI bill that could similarly stifle innovation. Most concerning, China is rapidly pursuing civil and military AI dominance through massive government support. More, it has a different view of human rights and privacy protection that may help its AI efforts but is antithetical to our values. The U.S. must act to protect citizens and advance AI innovation or we will be left behind."[1]

Regulation of AI in health is not new – the FDA has been regulating AI as part of medical devices since the late 1990s. CTA supports this effort to gather input on where there are regulatory gaps before moving forward with legislation. In many cases, federal agencies have existing authority to regulate AI, and this should be taken into consideration before passing additional burdensome and potentially duplicative regulation that may stifle innovation.

Medical Ethics and Protecting Patients

What practices are in place to mitigate bias in AI decision-making?

CTA is an ANSI-accredited standards development organization. We currently have five published AI in health standards, with the most recent being *Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias (CTA-2116).* CTA encourages federal regulators to continue to engage on industry consensus-based standards to drive transparency and accountability in AI. Standards can be nimbler and more reactive to changes in the market.

Is the current HIPAA framework equipped to safeguard patient privacy with regards to AI in clinical settings? If not, how not or how to better equip the framework?

The HIPAA framework works well in clinical settings as healthcare providers are covered entities under HIPAA, and therefore they and their business associates must adhere to the law. However, 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 supports a comprehensive national privacy law that would address the gap in privacy law for health data outside of the clinical setting.

[1] https://techcrunch.com/2023/06/23/why-smart-ai-regulation-is-vital-for-innovation-and-u-s-leadership/amp/

Labor

AI and the Job Market

What role will AI play in creating new jobs?

Historically, economists agree that technology has created more jobs than it has destroyed and will continue to do so.[2,3] Further, a recent study found that generative AI could boost the global economy by $4.4 trillion annually.[4]

The tech sector is ready and eager for workers with technical skills to support AI. According to CTA's 2022 Member Survey on the Future of Work, 84% of respondents say they will need more employees with technical skills, including software development (59%) and engineering (55%), two skills critical to AI. Further, 46% of respondents believe AI & machine learning are technical skills in high demand at their company. Interestingly, 64% of respondents did not believe their company will displace workers due to advances such as computer software applications, artificial intelligence and/or robotics.[5]

CTA and our member companies are committed to ensuring everyone can gain skills necessary to succeed in today's tech sector. With the recognition that technology advancements such as AI are dramatically changing our nation's workforce, creating quality, high-skilled jobs, CTA's 21st Century Workforce Council shares best practices and solutions, addresses business challenges and develops strategies to create a collective voice related to successful workforce development and talent acquisition strategies.

How is AI being used to fill gaps in the labor market?

The Committee has previously explored the health care workforce shortage issues. In a March 2023 response to the Committee, CTA highlighted the potential of digital health, including AI, to address health care workforce shortage issues.[6] CTA believes that artificial intelligence (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.[7,8] AI can help health care workers treat patients more efficiently and effectively and address main drivers of worker burnout.

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[2] https://www2.deloitte.com/tr/en/pages/technology/articles/technology-and-people.html
[3] https://www.weforum.org/reports/the-future-of-jobs-report-2018
[4] https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-economic-potential-of-generative-ai-the-next-productivity-frontier
[5] https://shop.cta.tech/collections/research/products/future-of-work-2022-cta-member-survey
[6] 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
[7] Hazarika, I. (2020). Artificial intelligence: opportunities and implications for the health workforce. *International health*, *12*(4), 241-245.
[8] https://www.fiercehealthcare.com/ai-and-machine-learning/finding-right-candidates-keeping-them-ai-aiding-healthcare-industry-meets

To address concerns related to automation of the trucking industry, CTA highlights here why autonomous trucks are poised to revolutionize the logistics and transportation industry and fill gaps in the labor market:

- The U.S. trucking industry faces a persistent shortage of drivers. The American Trucking Association has estimated that the driver shortage reached 80,000 drivers in 2021, and if trends persist, the industry could face even more significant shortages.[9] The transition to fully autonomous trucks will be gradual and phased, allowing time for the workforce to adapt and acquire new skills. More, autonomous vehicles will still require human oversight, particularly in complex situations and for tasks such as maintenance, monitoring, and route planning. Lastly, the deployment of autonomous trucks will create new job opportunities in related sectors, such as vehicle maintenance, software development, and data analysis.

- The U.S. Department of Transportation studied this issue closely and, in 2021, issued a report on the macroeconomic impacts of automation in long-haul trucking.[10] The report concludes that any decreases in trucking jobs will likely be due to natural occupational turnover rather than significant layoffs. What's more, the report estimates that autonomous trucking will create 26,400 to 35,100 new jobs per year on average.

- CTA members are working with local communities to train the existing workforce for these roles. For example, Aurora worked with Pittsburgh Technical College to design an associate degree program that trains and accredits Fleet Support Technicians, giving them the tools they need to maintain autonomous vehicles and support operations.[11]

AI and Workplace Bias

What are low-risk use cases of AI with respect to discrimination?

As CTA discusses in comments to the FCC, video conferencing is a particularly important part of ensuring connection and communications, growing rapidly in user adoption and features over the last several years. Innovative video conferencing providers have introduced accessibility features that help ensure individuals with and without disabilities can access communications technologies and product information on an equivalent basis. This industry growth opens important employment opportunities for traditionally underserved and underemployed communities. CTA also shared in comments to NTIA examples of how AI and ML power technologies that provide information automatically to individuals with disabilities, such as real-time captioning on video conferencing platforms.

Conclusion

Thank you for the opportunity to provide input on critical issues raised in your whitepaper, *Exploring Congress' Framework for the Future of AI: The Oversight and Legislative Role of Congress Over the Integration of Artificial Intelligence in Health, Education, and Labor.* We look forward to continuing to

[9] https://www.ccjdigital.com/economic-trends/article/15303016/trucking-industry-faces-headwinds-in-2023
[10] https://rosap.ntl.bts.gov/view/dot/54596
[11] https://blog.aurora.tech/progress/what-do-self-driving-vehicles-mean-for-jobs-and-the-economy

work with you to ensure a balanced policy approach that allows emerging technology, like AI, to be fully leveraged across industry sectors while providing clear guidelines.

Sincerely,

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