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Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. FDA-2024-D-4488
Docket No. FDA-2024-D-4689

Dear Sir or Madam:

The Consumer Technology Association (CTA®) appreciates the opportunity to comment on the proposed guidance documents, "Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations" and "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products." We appreciate FDA's continued efforts to enhance the regulatory framework for these emerging technologies, ensuring that they meet both safety and innovation standards.

As North America's largest technology trade 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 powerful tech event in the world. CTA® is the trade association representing more than 1200 companies in the U.S. technology industry. Eighty percent of our 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®'s Health Division drives the adoption of consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. Comprised of innovative small and large companies across the healthcare and technology sectors – including telehealth providers, personal health wearable companies, health care payers, health systems, and biopharmaceutical innovators – the Division offers policy advocacy, market research, and standards initiatives to promote the effective use of consumer technologies in health care.

We are accredited by the American National Standards Institute (ANSI) as a Standards Development Organization and have long history of developing voluntary national standards. Among the wide range of topics addressed by our standards program are mobile health, digital therapeutics, cardiovascular technology solutions and artificial intelligence. CTA® represents several of the leading developers of AI and other emerging technology solutions, including foundation AI models, such as general-purpose large language models (LLMs) and other generative AI foundation models.

General Comments

CTA® supports FDA's efforts to clarify the Agency's expectations for premarket submissions for AI-enabled medical devices to facilitate innovation and to ensure patients and healthcare professionals

have access to the most advanced technology and unique benefits of AI-enabled devices. We believe generative AI-enabled medical devices have the potential to revolutionize healthcare by, among other things, improving the speed and accuracy of medical diagnoses, personalizing treatments, and improving patient engagement and adherence. We understand that the agency is still developing its approach to regulating generative AI-enabled medical devices and has recognized that medical devices that utilize general foundation models may present unique regulatory considerations.[1]

As a general matter, we encourage FDA to adopt regulatory approaches for AI-enabled medical devices that utilize generative AI that are both feasible and promote innovation and also ensure safety and protect the public health. Appropriately flexible regulatory approaches will help maintain U.S. leadership in developing state of the art, innovative, medical devices.

Risk-Based Approach to Regulation

CTA® strongly supports the adoption of a risk-based approach in both the drug/biologics and medical device guidance documents. Given the wide variation in AI technologies and their applications, it is critical that the FDA adopts a risk-based focus that recognizes the different risk profiles associated with AI models. Such an approach would ensure that regulatory oversight is proportionate to the level of risk posed by the AI system in question.

In the drug/biologics guidance, FDA has outlined risk parameters such as model influence and decision consequence. We recommend that FDA similarly incorporate these or analogous parameters in the medical device guidance. This will allow for a more consistent evaluation process while providing the necessary flexibility to address varying levels of risk across different use cases.

A risk-based approach ensures that organizations can adopt risk mitigations that are appropriate to the context of their specific product rather than following a one-size-fits-all framework.

Total Product Life Cycle Approach

CTA® supports the FDA's total product life cycle approach to AI-enabled medical devices. This approach is essential for ensuring that AI products remain safe, effective, and adaptable over time, particularly as they evolve and improve with ongoing training and updates. However, we believe that the FDA's framework for managing AI technologies would benefit from aligning more closely with national and international standards. Specifically, the CTA standard for managing and safeguarding data in health AI systems is an ANSI-accredited voluntary industry standard addressing significant issues in health AI systems developed by a working group representing all facets of the health and technology ecosystems.[2] On the international front, the ISO 42001 standard provides guidelines for managing AI systems within organizations, offering a robust, consensus-based framework for addressing AI's complexities and ensuring long-term effectiveness.

Aligning the FDA's approach with accredited standards would not only promote consistency across global markets but also ensure that U.S. innovation remains at the forefront of AI and health care advancements. CTA® encourages FDA to work with industry stakeholders and standards organizations to develop best practices that are feasible, flexible, and foster innovation.

[1]FDA, Digital Health Advisory Committee Meeting, November 20-21, 2024, https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-20-21-2024-digital-health-advisory-committee-meeting-announcement-11202024.
[2] The American National Standards Institute (ANSI) oversees standards and conformity assessment activities in the United States.

Foundation Models

As FDA finalizes the guidance documents, the agency should clarify its expectations for AI-enabled medical device software functions that leverage a third-party general purpose foundation model. As FDA has recognized, foundation models are often designed to perform a wide range of tasks without being tailored to a specific task or use case, differing from AI models that are specifically developed for a particular medical device indication for use, and the Draft Guidance does not currently address how the information submitted to the Agency may differ for these types of AI-enabled medical devices.

The Draft Guidance does not specifically address the potential role of foundation models in medical devices. While the Draft Guidance does recommend that the device sponsor provide an explanation of any "pre-trained models that were used" and if so, "specify the dataset that was used for pre-training and how the pre-trained model was obtained," it is unclear whether such pre-trained models would include general purpose foundation models.

FDA should revise the sections of the Draft Guidance regarding the information medical device sponsors should submit on model development and data management practices to clarify what information a device sponsor should submit about any third-party foundation models leveraged by the AI-enabled device software function. In doing so, FDA should adopt a reasonable and feasible approach to evaluating devices that leverage foundation models to promote innovation of such devices.

Third-Party & Cloud Developers

CTA® recommends that the FDA clarify the regulatory obligations for third-party developers of foundation models used in AI-enabled medical devices, emphasizing that these developers should not be subject to Quality System Regulation requirements. As AI use cases vary in risk, the FDA should adopt a flexible, risk-based approach that allows device sponsors to tailor mitigations to specific use cases, rather than imposing a one-size-fits-all approach. Additionally, given the increasing role of cloud service providers, the agency should recognize that these providers may not have access to the training data used in foundation models, and thus, the focus should shift to performance results rather than data transparency. This approach will help ensure safety and efficacy while fostering innovation.

Conclusion:

We urge FDA to adopt a risk-based approach for AI technologies in both drug/biologics and medical device guidance, with clear frameworks for evaluating risk. We also recommend aligning the total product life cycle approach with standards, such as national and international standards referenced above to ensure consistency and promote innovation. The focus should shift from excessive transparency of training data to prioritizing real-world performance testing, while protecting proprietary information. We also encourage the agency to clarify the role of third-party AI models ensuring their use in medical devices does not impose unnecessary regulatory burdens. CTA® appreciates the opportunity to comment and looks forward to continuing to work with FDA to ensure the safe and effective integration of AI-enabled device software throughout its lifecycle.

Sincerely,

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