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Dear Dr. Makary, Dr. Brenner and Mr. Walsh:

On behalf of the Consumer Technology Association (CTA), thank you for the opportunity to provide input as FDA considers how to regulate generative AI (genAI) in healthcare. CTA is the largest tech trade association in North America representing more than 1200 companies from iconic global brands to early-stage startups supporting more than 18 million American jobs. 80% of CTA companies are small businesses and startups. We produce CES, the world's most powerful tech event, and lead national efforts on policy, market research, and standards development across emerging technologies.

CTA member companies are pioneering advances across the spectrum – from AI-powered continuous glucose monitors to remote patient monitoring, to the first FDA-cleared obstructive sleep apnea risk detection feature for consumer wearables. CTA is an American National Standards Institute (ANSI) accredited standards developer. To date, we have published over 35 digital health standards including five specifically dedicated to health AI. These standards reflect a risk-based approach and are designed to be adaptable to a wide range of technologies while supporting innovation. Through the leadership of the Health AI Planning Council, we are focused on developing standards that meet the industry's needs.

To respond to your request, we gathered feedback from our members to identify both challenges and recommendations for the thoughtful oversight of genAI. Our goal is to provide information that will allow you to offer guidance that is designed to foster innovation while appropriately balancing safety concerns.

A well-calibrated regulatory scheme will allow developers and users of health AI to explore these modern tools with confidence, rather than increase operational burdens or create distrust of this promising new technology. Accordingly, we outline how FDA can:

- Prioritize high-risk applications;
- Resolve regulatory ambiguity;
- Standardize model validation & evaluation;
- Offer guidance for post-market monitoring;
- Leverage existing frameworks; and
- Streamline transparency metrics.

More broadly, we think FDA – like all agencies and industries – should proactively ideate broadly on how genAI can help the agency achieve its mission. Beyond responding to risks and concerns, CTA welcomes the opportunity to help FDA re-envision existing paradigms and create new ones that leverage the unique capabilities of genAI. To support transparency and consistent engagement, we encourage the agency to create a dedicated engagement or question channel for genAI developers, providing a clear point of contact and process amid the present ambiguity and complexity in regulatory requirements.

Primary Challenges for Generative AI Tool Developers & Deployers

CTA member companies identified several challenges with genAI development and deployment for use in healthcare common to other health technology innovations. For example, our members highlighted relevant concerns related to data quality, interoperability, privacy, and cybersecurity. However, our members also identified unique challenges innovators are increasingly facing as the use of genAI in healthcare evolves.

We outline those challenges here:

- **Regulatory Ambiguity and Complexity**: Innovators are facing increasing demands to comply with varied requirements between state laws, federal regulations, and international frameworks. This fragmentation, paired with the following classification and jurisdictional challenges, is resulting in confusion and an increase in regulatory burdens and costs:
    - Ambiguity related to device classifications (e.g., software as a medical device (SaMD) v. wellness tools), and
    - Uncertainty about the parameters of agency jurisdiction (e.g., FDA's oversight of clinical decision support (CDS) v. ASTP/ONC's oversight of predictive decision support interventions (PDSI).

- **Lack of Standardized Evaluation Methods**: There are no standardized protocols or evidence guidelines to prove genAI tools' clinical validity and accuracy. The absence of clear evaluation frameworks hinders providers and payers' ability to adopt and cover innovative health AI tools.

- **Post-Market Monitoring**: One of the primary concerns of genAI deployment in healthcare is also one of the greatest challenges to solve. Right now, there are few established protocols for determining who and how genAI tools should be monitored after they are implemented and deployed in healthcare.

Given these challenges, industry stakeholders believe risk-based, generative AI-specific guidance would offer necessary clarity. As FDA pursues regulatory activity, however, it should avoid burdensome regulatory mandates. We believe that this is an area in which public-private partnerships can be effectively utilized by providing a forum for collaboration between the agency, technology developers, and healthcare organizations to build oversight frameworks that are both technically grounded and feasible to implement.

Recommendations for Future FDA Activity on Generative AI

CTA recommends that FDA work closely with industry to ensure any guidance on genAI-enabled medical devices is flexible enough to promote safe and responsible innovation. This includes first assessing whether genAI-enabled medical devices may already fall under existing oversight mechanisms. Where genAI's unique features (such as model drift, continuous learning, bias) require adapted guidance or additional oversight mechanisms, any new frameworks should avoid overly restrictive requirements that create barriers for novel applications of this technology.

Existing device paradigms may serve as a foundation, but they will likely require meaningful adaptation to address genAI's dynamic nature. For example, directly adopting paradigms built for physical devices (and only lightly adapted for SaMD) can force genAI into static, deterministic molds – undermining the iterative improvement, rapid safety updates, and context-dependent behavior elements that are core to this technology.

We identified the following considerations for future policy guidance:

Leverage Existing Frameworks

CTA believes FDA should first seek to apply existing frameworks to oversee medical devices that use generative AI to maximize oversight efficiency and minimize regulatory complexity. Should FDA find that existing frameworks are not sufficiently flexible to keep pace with innovation, the agency should assess how any existing frameworks could be adapted for AI generally (e.g., predictive, generative, machine learning models); then, if needed, FDA should adapt existing frameworks or draft new guidance for challenges specific to genAI.

For example:

- PCCP: CTA applauds FDA for applying the existing Predetermined Change Control Plan (PCCP) framework for a new technology: predictive AI solutions. Before undertaking work to draft new PCCP frameworks for genAI, CTA encourages FDA to understand the unique complexities and gaps specific to genAI that would necessitate new guidance or regulations or whether the existing guidance is sufficient.

- GMLP: FDA's good machine learning practices (GMLP) do not currently address unique issues of generative AI such as hallucinations and nondeterministic outcomes. Because this framework does not adequately address these challenges, the FDA could consider revising this existing document.

If FDA concludes that a new oversight mechanism is necessary, the agency could look to existing regulatory frameworks outside of FDA that emphasize quality management certification and risk-based change control. One example is the Clinical Laboratory Improvement Amendments (CLIA), a program that focuses on process controls, quality control, proficiency testing, and ongoing surveillance, allowing labs to adjust methods within SOPs.

Prioritize High-Risk Applications

Like it does for other medical devices, the agency should take a risk-based approach to tailor the oversight of genAI in healthcare to the context and risk of each application. Applications of genAI in healthcare vary widely.

FDA should apply this risk-based approach throughout the total product lifecycle of genAI-enabled medical devices. As different stages of the product lifecycle present different levels of risk, techniques to mitigate the risk should be similarly varied.

Resolve Regulatory Ambiguity

The introduction of large scale genAI has led to an evolving landscape of cross-jurisdictional regulations that create compliance risks and slow deployment. Regulatory clarity is critical to ensuring compliance while allowing for innovation.

To resolve jurisdictional ambiguity between FDA and ASTP/ONC, the agency should make clear its oversight responsibilities for CDS and the ASTP/ONC's oversight of predictive decision support interventions (PDSIs) integrated into electronic health records. This will help prevent duplicative and potentially contradictory requirements for health technologies.

FDA should articulate key definitions in clear, testable terms. Precise terminology should outline the boundaries of intended use (e.g., explain what end-user tailoring is permissible without expanding intended use), and delineate responsibilities applicable to developers, deployers, or both.

Although not specific to AI, medical device innovation is making it difficult for medical device manufacturers to understand the proper classification of their AI-enabled products. As the agency modernizes its approach to medical device oversight, we hope that FDA can prioritize developing clear guidance that differentiates these classifications, effectively differentiating for risk and distinguishing between software as a medical device (SaMD), clinical decision support (CDS), and wellness or patient communication tools. Developers need to understand how the tools they are developing will be regulated.

Standardize Model Validation & Evaluation

In the absence of a standardized, scalable validation framework, healthcare stakeholders may be hesitant to adopt genAI devices. FDA should consult stakeholders and leverage existing international or accredited industry-developed standards to consistently evaluate gen AI-enabled medical devices across their total product lifecycle.

FDA could play a role in standardizing definitions and threshold criteria for key factors integral to model validation and performance including, for example, hallucinations, data poisoning, and bias.

Offer Guidance for Post-Market Monitoring

When deploying genAI-enabled medical devices for use in healthcare, customers (i.e., healthcare providers) often make changes to fit the specific needs of the organization (e.g., tailor prompts, templates, and institute-specific knowledge sources). Today, it is unclear when these changes are bound configurations within intended use and do not require a new submission to FDA, versus design changes that trigger new regulatory obligations for the developer / manufacturer or transform the customer into a "manufacturer."

The potential scale and frequency of post-market modifications of gen-AI enabled medical devices can make monitoring of the devices difficult. Overseeing such actions necessitates a flexible framework that prioritizes high-risk modifications. Should the existing guidance not provide this necessary flexibility needed for genAI-enabled medical devices, FDA risks incentivizing developers/manufacturers to delay safe, low-risk, and essential updates to avoid burdensome documentation requirements or constant resubmissions.

CTA applauds FDA for its work to date adapting PCCPs for innovative technologies, like predictive AI. CTA encourages the agency to assess whether manufacturers can properly scope PCCPs for genAI enabled products under the existing guidance. If not, FDA should consult industry stakeholders to determine thresholds for post-market changes that require new filings, define use cases that distinguish between permissible model updates by the manufacturer and customer-level configurations, and ensure that manufacturers are able to make necessary changes to their models without undue regulatory burden.

Streamline Transparency Metrics

Model training data sets are not necessarily the best metric to assess genAI transparency. Model training data sets may vary widely for many reasons, often contain proprietary information, and do not always guarantee that a model will perform for its intended population. Instead, CTA recommends centering information related to model testing.

Transparency should enable safe tailoring without continual resubmissions. Presenting performance ranges, known limitations, and guardrail behavior in a consistent, comprehensible way allows deployers / users to configure responsibly within labeled bounds while maintaining compliance. Rather than requiring full explainability, the focus should be on defining evidence-based thresholds demonstrating how factors like model performance, safeguards, and human oversight can collectively ensure patient safety.

FDA should assess transparency of genAI-enabled medical devices based on the documentation already released by developers that does not include proprietary information: including the capabilities of the AI system; known material limitations at the time of development of the AI system; guidelines for intended use; and example performance results. These metrics are more meaningful in helping deployers / users understand how the developer tested the model for its intended use case.

Conclusion

GenAI holds tremendous potential to advance the quality and accessibility of healthcare but realizing that potential requires an oversight framework that is flexible, transparent, and risk based. We encourage FDA to continue coordination with standards development organizations, such as CTA, to enable guidance that is flexible and able to evolve with generative AI and successor technologies.

We appreciate your leadership in this area. CTA will remain engaged as FDA advances its work on genAI. Thank you for your consideration of these recommendations. Please contact us if you have any questions or to schedule a meeting to further discuss these proposals.

Sincerely,

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