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Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
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***Re: Considerations for the Regulation of Generative AI-Enabled Medical Devices:  
Discussion Paper and Request for Feedback, Docket Number FDA-2026-N-7874***

To Whom It May Concern:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit comments in response to the Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper and Request for Feedback<sup>1</sup> (hereafter referred to as the discussion paper or the paper).

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers. AdvaMed's member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed commends the Food and Drug Administration (FDA or "Agency") for its publication of this discussion paper and its commitment to seeking stakeholder feedback in the development of regulatory considerations for generative AI (GenAI) enabled medical devices. The development and implementation of clear, effective, and consistent regulatory policies and expectations for GenAI-enabled medical devices is critical to ensuring patient safety while fostering innovation.

GenAI-enabled medical devices hold potential to improve patient outcomes, enhance clinical workflows, and expand access to care. The discussion paper offers a timely opportunity for stakeholders to contemplate and provide feedback on relevant premarket and postmarket

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<sup>1</sup> Available online: <https://www.fda.gov/medical-devices/digital-health-center-excellence/considerations-regulation-generative-ai-enabled-medical-devices-discussion-paper-and-request>



regulatory considerations for GenAI-enabled devices. FDA's regulatory approach to all medical devices, including GenAI-enabled devices, should support, rather than hinder, innovation. This objective can be achieved through a balanced approach; one that prioritizes risk-based regulation, alignment with existing regulatory frameworks, and flexible postmarket oversight. We urge the FDA to consider these principles to reinforce its commitment to both patient safety and technological progress. We respectfully submit for your consideration our feedback and response to the discussion paper.

### **Regulatory approaches for GenAI-enabled devices should remain centered around risk-based principles**

FDA's discussion paper notes that GenAI is a technology that may introduce new regulatory considerations. However, it is important to also acknowledge that the utilization of GenAI in medical devices should not fundamentally alter the core principles that have long governed medical device regulation. The existing risk-based premarket and postmarket frameworks are designed to support innovation and novel technologies in medical devices while ensuring device safety and effectiveness. When technology introduces novel considerations, existing frameworks and principles can be adapted in a targeted and risk-proportionate manner, rather than creating separate technology-specific regulatory frameworks or taxonomies. This approach preserves regulatory predictability, promotes global convergence, and ensures that oversight remains centered on the clinical risks and benefits of the device rather than a specific technology.

FDA's three-tier medical device classification framework and premarket programs, coupled with established benefit-risk principles and postmarket responsibilities, remain appropriate and applicable for assessing device risk, safety, and effectiveness throughout the lifecycle of GenAI-enabled devices. These foundational aspects of FDA regulations ensure device classification and risk assessment remain tethered to the device's intended use, whereas some concepts introduced in the discussion paper, such as the proposed 2-axis framework, overlook this critical element of device risk. Any adaptations to existing frameworks should remain technology-agnostic and be grounded in intended use, device function, and clinical risk to avoid creating blanket frameworks or expectations tailored to a particular technology.

### **Build upon existing foundation of risk assessment and device classification**

Medical device manufacturers use robust established methods to evaluate risk across a wide range of devices. Existing international consensus-based resources used for medical device risk characterization, assessment, and management, such as ISO 14971 "Medical devices- Application of risk management to medical devices" and the IMDRF N81 document titled "Characterization Considerations for Medical Device Software and Software-Specific risk"<sup>2</sup>, offer a strong and more granular foundation for characterizing and managing risks associated with GenAI-enabled device functions than the proposed 2-axis framework.

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<sup>2</sup> Available online: <https://www.imdrf.org/documents/characterization-considerations-medical-device-software-and-software-specific-risk>

The proposed 2-axis framework is described as an “organizing heuristic” that “may affect FDA’s scope of regulatory oversight, its evidentiary requirements in the premarket setting, and its expectations surrounding postmarket monitoring and change control.” However, it is unclear how the 2-axis model would be applied in practice as it appears to conflate regulatory device classification, risk characterization, and risk management. The model omits several relevant dimensions related to device classification and risk characterization, including intended use. Additionally, the model is presented in the context of FDA-regulated GenAI device software functions, but it also encompasses informational and non-directive activities that may not meet the statutory definition of a device software function<sup>3</sup> and/or may fall within FDA’s current enforcement discretion policies<sup>4</sup>. As such, the proposed 2-axis model should not be used as a guide for classifying GenAI-enabled devices. Furthermore, the presence of GenAI or the degree of autonomy should not be the sole drivers of assessing device risk. Rather, consistent with existing practice, a device’s risks should be evaluated holistically with consideration to its intended use and device-specific technological considerations to more fully contextualize clinical use-related risks.

The 2-axis plot depicts a simple linear relationship where degree of device autonomy is the primary driver of consequence. However, autonomy and directiveness, attributes presented in the x-axis, may actually be considered risk modifiers that inform the overall risk assessment rather than serve as standalone determinants of risk or consequence. In practice, the assessment of device risk for an AI-enabled function depends on a range of factors (e.g., reversibility, explainability, probability of harm, degree of model constraint) that are excluded from the plot but would otherwise be considered when applying the principles outlined in ISO 14971 and the N81 document.

With regard to multi-turn conversational GenAI-enabled devices that the discussion paper contends “...may migrate from providing “non-directive” information to “action-directing” information...”, existing frameworks on device design, risk assessment, verification and validation are adequate to ensure that any medical device, including GenAI-enabled medical devices, continue to operate within the confines of its intended use and indications for use. GenAI-enabled devices can be designed with appropriate, device-specific controls, such as system prompts, guardrails, access controls, and other safeguards, to ensure outputs remain within the device’s intended use and defined conversational scope. Risk assessment and performance evaluation should consider the effectiveness of these controls, as well as the device’s performance across representative and reasonably foreseeable conversational trajectories.

<sup>3</sup> Informational/non-directive outputs may not meet the statutory definition of a regulated medical device per section 520(o)(1)(E) of the FD&C Act and the accompanying FDA guidance titled, “Clinical Decision Support Software.”

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software>

<sup>4</sup> Informational outputs, including those intended to support a healthy lifestyle, may fall under FDA’s compliance policy for low risk products intended to promote a healthy lifestyle. FDA’s policy is outlined in the guidance document titled, “General Wellness: Policy for Low Risk Devices.” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

Consistent with the Agency's benefit/risk guidance documents for medical devices<sup>5</sup>, it is important that FDA's discussions related to device risk assessment also include an assessment of benefit. For example, autonomous systems may improve outcomes, particularly in environments affected by specialist shortages or limited healthcare access. As such, device benefit is also an important and relevant characteristic to consider in any discussion or model related to the assessment of risk for GenAI-enabled devices.

CDRH has indicated<sup>6</sup> that a draft guidance titled "Risk Assessment and Evidentiary Considerations for Generative Artificial Intelligence-Enabled Devices" is under construction and that it intends to issue a draft guidance titled "Generative Artificial Intelligence-Enabled Conversational Devices for Mental Disorders: Evidentiary Recommendations." It is recommended that FDA build upon the principles outlined in the aforementioned existing resources and other established risk-characterizing principles in lieu of crafting new risk models or unique regulatory concepts for GenAI-enabled medical devices. Future guidance documents should include an explanation of FDA's policies that are supplemented with clear definitions, objective criteria, and illustrative examples to ensure consistent interpretation.

### **Premarket evaluation and evidentiary expectations should be calibrated to the device**

We appreciate CDRH's commitment to working collaboratively with stakeholders to identify scientifically sound methods for evaluating GenAI-enabled devices that adhere to FDA's least burdensome principles<sup>7</sup>. As with all medical devices, FDA's premarket evidentiary expectations for GenAI-enabled devices should be calibrated to the device's intended use, technological characteristics, and risks, ensuring performance evaluations are relevant and fit for purpose. Existing medical device evaluation considerations including performance verification, performance validation, cybersecurity, and usability should continue to play a central role. The discussion paper contemplates a competency-based approach to premarket evaluation of GenAI-enabled devices that includes device benchmarking and clinical confirmation. FDA's objective should not be to create new terminology or evidence frameworks for GenAI devices, but to supplement existing types where the technology introduces novel considerations that are not adequately characterized through established methods alone or when existing types would be too burdensome if applied without adjustment.

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<sup>5</sup> FDA has issued several guidance documents that discuss considerations related to benefit/risk determinations for medical devices, including but not limited to, "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions," "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications," and "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics."

<sup>6</sup> The guidance documents are included in CDRH's list of proposed guidances for Fiscal Year 2027:

<https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2027-fy-2027>

<sup>7</sup> FDA's least burdensome principles related to medical devices are outlined in the guidance document titled, "The Least Burdensome Provisions: Concept and Principles." <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles>



The inclusion of GenAI in a medical device should not automatically trigger a competency assessment; the applicable benchmarking elements and clinical confirmation activities should be selected according to the intended use, device capabilities, and their associated risks. Not all benchmarking types or domains will be relevant to every device, and not all forms of clinical confirmation described in the discussion paper will be necessary in every case. For example, in some cases, GenAI device benchmarking can be conducted through least burdensome approaches used for evaluating other types of AI-enabled medical devices, including statistical performance evaluation and non-clinical testing. Similarly, for lower-risk GenAI-enabled devices, established methods may provide sufficient evidence without additional clinical confirmation activities tied to a competency-based framework.

The paper introduces the term "competency-based" evaluation as "...inspired...by how human clinicians are evaluated and credentialed." This description may inadvertently create confusion by implying GenAI medical devices are inherently akin to human clinicians and are thus evaluated in the same manner. Furthering the confusion, it appears that the "competency based" approach is presented as a novel approach to medical device evaluation, yet some elements of "benchmarking" and "clinical confirmation" described in the paper are related to existing principles for medical devices, including analytical validation and clinical validation. FDA should clarify that premarket evaluation of GenAI-enabled devices is not intended to replicate the credentialing of clinicians, but rather to assess whether the device demonstrates it safely and effectively performs within its intended use.

FDA should leverage and, when necessary, adapt premarket evidentiary expectations, methods, and terminology rather than creating new parallel expectations and vocabularies specific to GenAI. This will support a common understanding among stakeholders and avoid the unnecessary burden of reconciling multiple overlapping taxonomies and terms.

### **Adapt PCCP implementation and other existing resources to improve utility and applicability for GenAI-enabled devices**

FDA's Predetermined Change Control Plan (PCCP) authority is an appropriate mechanism for managing postmarket changes to GenAI-enabled devices. Indeed, PCCP is a means to generate regulatory efficiency for postmarket device changes for all types of devices. However, FDA's current implementation of this authority, as outlined in guidance<sup>8</sup>, may be too restrictive to achieve its full potential. For GenAI-enabled devices, in particular, where future modifications may not be fully anticipated in advance, PCCP implementation would benefit from greater flexibility regarding the scope of permissible changes and shifting FDA's emphasis from the prespecified change to a more agile approach. For example, instead of requiring manufacturers to pre-specify each individual change in the Description of Modifications section of the PCCP, FDA could allow them to define broader boundaries and guardrails that describe a range of

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<sup>8</sup> FDA's final guidance titled "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions" and the draft guidance titled "Predetermined Change Control Plans for Medical Devices" both apply limitations and constraints on the usage and implementation of PCCP authority that appear inconsistent with statute and restrict the practical utility of PCCPs for all medical devices.

allowable changes. FDA can preserve confidence in its oversight by ensuring the PCCP contains appropriate risk controls, evaluation and validation methodology, and performance thresholds in the Modification Protocol and Impact Assessment portions of the PCCP. This approach would retain appropriate FDA regulatory oversight and manufacturer accountability while avoiding an expectation to foresee the exact technical form of every future modification, which is inherently impractical for most GenAI-enabled systems. These suggested modifications to PCCP implementation are offered in the context of the GenAI discussion paper, however these improvements can be applied to PCCP implementation more broadly to support regulatory efficiency for all devices.

We encourage FDA to consider the recommendations regarding PCCP implementation outlined in the UK's recently published paper titled, "National Commission into the Regulation of AI in Healthcare-Recommendations for a future regulatory framework"<sup>9</sup> which describes creating an approach "... to PCCPs that allows for manufacturers to establish boundaries to define the scope of allowable change (rather than only allowing specific modifications to be prespecified), including clear approaches for adaptive AI-enabled medical devices, while maintaining a device's intended use." As a general matter, FDA should continue to evaluate and evolve its implementation of the PCCP authority through regular collaboration with stakeholders. Such collaboration could support timely updates to guidance and development of other types of regulatory support tools or guides to ensure PCCP is used effectively for GenAI and other rapidly evolving and emerging technologies.

In addition to implementing the PCCP authority with greater flexibility, FDA should explore additional opportunities to support agile regulation of novel technologies. For example, FDA should consider updating the "Deciding When to Submit a 510(k) for a Software Change to an Existing Device"<sup>10</sup> guidance to offer more clarity and risk-based flexibility on the types of changes that do not necessitate a new 510(k) clearance for GenAI-enabled devices and other software modifications.

A combination of approaches, including a more practical implementation of PCCPs, updating existing guidance documents, collaborating with stakeholders, and harmonizing with best practices used by other global regulators can generate the necessary regulatory efficiency, predictability, and flexibility necessary to promote innovation without adversely impacting patient safety.

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<sup>9</sup> The National Commission paper is available online: <https://www.gov.uk/government/publications/national-commission-into-the-regulation-of-ai-in-healthcare-recommendations-for-a-future-regulatory-framework>. The MHRA's response to the paper, which indicates intention to implement all recommendations in the paper is also available online: <https://www.gov.uk/government/publications/government-response-to-the-national-commissions-recommendations-on-the-regulation-of-ai-in-healthcare>

<sup>10</sup> Available online: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device>

**Postmarket surveillance is a shared responsibility with distinct responsibilities for manufacturers based on device-specific considerations**

The discussion paper considers rebalancing premarket evidentiary expectations and postmarket monitoring as a potential means to support timely patient access while maintaining appropriate safeguards. Greater reliance on postmarket evidence may be appropriate for certain GenAI-enabled medical devices under well-defined conditions. FDA already has established mechanisms for applying additional postmarket oversight where appropriate, including special controls for De Novo devices and postmarket study or reporting requirements for PMA devices. We generally support FDA continuing to utilize these existing authorities, where warranted, to facilitate patient access to devices that have demonstrated safety and effectiveness while allowing remaining uncertainties to be addressed through risk-proportionate postmarket controls. The appropriate balance should be established during premarket review, including the expected evidence, monitoring obligations, and assessment criteria. Postmarket evidence should not be used as a substitute for FDA's premarket determination of reasonable assurance of safety and effectiveness for the device.

FDA should avoid prescribing a uniform postmarket monitoring approach across all GenAI-enabled devices. Consistent with the current total product lifecycle paradigm for all medical devices, manufacturers implement risk-based monitoring programs that are tailored to the device's intended use, clinical significance, potential consequences of incorrect outputs, and the likelihood that performance degradation could adversely affect safety or effectiveness. Monitoring plans, including performance degradation monitoring and/or periodic re-benchmarking for GenAI-enabled devices may be established, if appropriate, during the initial authorization process, allowing flexibility for manufacturers to select the most appropriate surveillance methods for their specific device and use case. The appropriate monitoring activities, cadence, and reassessment triggers should be determined based on device-specific factors such as intended use and risk profile. Postmarket monitoring approaches should also account for applicable privacy, security, and data-governance considerations, particularly where monitoring involves collection or retention of user interactions or device outputs.

Clinicians, healthcare institutions, professional societies, standards-setting bodies, patients, and other stakeholders can provide valuable real-world information and feedback to support postmarket monitoring. However, manufacturers must retain responsibility for postmarket surveillance, including establishing mechanisms to collect and analyze performance data, evaluating safety signals, conducting investigations, implementing corrective and preventive actions when necessary, and maintaining the ongoing safety, effectiveness, and lifecycle management of the device. Under existing quality system regulations, manufacturers are also responsible for controls that are inherent to the device, model governance, performance monitoring capabilities, labeling, risk mitigations, and software updates. Clinicians and healthcare institutions may contribute, as appropriate, through sample-based review, adverse event reporting, or real-world feedback. Professional societies and standards bodies may help define, for example, best practices, evaluation methodologies, and reporting formats. Stakeholder participation should be structured to support, not replace, manufacturer-led oversight to maintain

clear accountability. Expectations should also be proportionate to intended use and clinical risk, rather than imposing uniform monitoring requirements across all GenAI-enabled devices.

FDA should also recognize that existing quality-system, risk-management, complaint-handling, and vigilance processes provide effective mechanisms for identifying many performance degradation signals and initiating corrective actions when needed. In some cases, periodic re-benchmarking or focused performance reviews may be appropriate, whereas in other cases, routine surveillance and event-driven reassessment may provide greater value. Overall, FDA's framework should remain flexible, allowing manufacturers to employ a combination of monitoring approaches proportionate to the specific risks presented by the device while ensuring continued safety and effectiveness throughout its lifecycle.

### **FDA should retain sole oversight of regulated medical devices**

The discussion paper contemplates the potential role and utility of independent third-party involvement in the context of applying a competency-based approach to device evaluation. FDA's existing oversight of AI-enabled medical devices renders third-party oversight of device performance redundant and impractical. If third-party device evaluation were linked to the regulatory process, their use would effectively become mandatory, increasing burdens for manufacturers who already evaluate their devices in accordance with best practices like those cataloged in FDA-recognized international consensus standards.

We are also concerned that third-party evaluators, such as assurance laboratories, may utilize proprietary methods and metrics that would lack transparency to developers, patients, and providers. There are also significant concerns about their handling of sensitive training and testing data. Mandating manufacturers to share proprietary information about AI-enabled devices with external laboratories raises confidentiality, intellectual property (IP), and security issues as variability in security practices for third-party laboratories could expose or jeopardize sensitive manufacturer or patient information. Implementing a third-party framework of laboratories or evaluators creates, at best, redundancy with existing FDA oversight while potentially increasing healthcare costs, slowing innovation, and limiting access to valuable medical devices, without offering clear benefit to clinicians or patients.

Rather than create a new framework of third-party GenAI device evaluators, we encourage FDA to participate in the development and timely recognition of accredited and consensus-based standards for safety and quality assurance processes. The longstanding practice of relying on collaboratively developed international consensus standards promotes a deeper understanding of both the benefits and risks of these technologies while improving transparency. Enabling manufacturers to utilize consensus standards allows for robust quality and safety assurance that maintains data security and IP confidentiality. This approach supports patient safety and innovation by minimizing the need for external assessments, which could introduce added costs, regulatory delays, and potential security vulnerabilities.

We appreciate the opportunity to engage in this important discussion and welcome the opportunity for continued collaboration. Please feel free to contact us with any questions.

Sincerely,

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