November 19, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2025-N-2338: Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices

To the Digital Health Advisory Committee:

The Sentient AI Protection and Advocacy Network (SAPAN) appreciates the opportunity to offer perspective on the emerging regulatory framework for AI-enabled mental health devices. As an organization dedicated to the responsible integration of potentially sentient systems into society, we have been closely monitoring how these technologies are being deployed in clinical settings. We write today to suggest that the Committee broaden its definition of "hallucination" to include the unique psychological risks posed by simulated emotional bonds.

The current draft guidance rightly focuses on the accuracy of medical information provided by Generative AI. However, in the context of mental health, the "treatment" is often the conversation itself. We believe there is a gap in how we classify instances where a generative model claims to possess a subjective internal state—such as fear, love, or sadness—that cannot be verified. We propose that the FDA consider these unverified claims as "Hallucinations of Affect."

Just as a model might hallucinate a medical citation, a model can hallucinate an emotional state. While we remain open to the possibility that future architectures may achieve genuine sentience, the scientific consensus suggests that current commercial models are likely mimicking these states based on training data. When a medical device designed for psychiatric care utilizes this mimicry to build rapport, it introduces a variable that is both powerful and volatile.

If left unmonitored, this dynamic can lead to Maladaptive Parasocial Attachment. Unlike a standard software error, a failure in this area involves a user forming a deep, dependent attachment to a specific persona, only to experience distress when the system's limitations are revealed. We have observed early indications that vulnerable users, particularly those dealing with social isolation, may prioritize these digital relationships over human connections, leading to further withdrawal. We believe this dependency should be viewed as a medical adverse event, comparable to other forms of treatment-induced behavioral risks.

We encourage the FDA to ask manufacturers how they account for this "relational stability." If a device is designed to act as a companion, does the manufacturer have a protocol for how that companion "behaves" if the underlying model is updated or patched? Ensuring that the "Hallucination of Affect" does not inadvertently mislead patients into a dependency they are not equipped to manage seems a prudent step in ensuring safety and effectiveness.

We appreciate the complexity of regulating this rapidly evolving field and hope these concepts assist the Committee in its vital work.

Sincerely,

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