24 Hour Summary of the Digital Health Advisory Committee
November 06, 2025

Introduction:

The Digital Health Advisory Committee to the Food and Drug Administration (FDA) met on November 6, 2025 to discuss and provide feedback on "Generative Artificial Intelligence (AI)-Enabled Digital Mental Health Medical Devices."

For this meeting, "digital mental health medical devices" referred to digital products or functions (including those utilizing AI methods) that are intended to diagnose, cure, mitigate, treat, or prevent a psychiatric condition, including those with uses that increase a patient's access to mental health professionals. Along with the rise of widely accessible generative AI products for general purposes, we are seeing an increase in the development and demand for a new kind of digital mental health medical device: "AI therapists" and other AI-based medical devices that offer a wide range of mental health therapies and interactions with therapist- or healthcare provider-like chatbots. These chatbots may engage with users in individualized ways, with or without the oversight of a health care provider (HCP), which introduce novel risks. As digital mental health medical devices continue to evolve in complexity, regulatory approaches will need to account for these challenges to provide reasonable assurance of safety and effectiveness while promoting innovation to support public health.

The questions posed during this discussion were designed to assist the Agency in determining critical information and practices needed for a comprehensive total product lifecycle approach to the evaluation of risks and benefits (including management of those risks) of generative AI-enabled digital mental health medical devices. The feedback generated from this meeting was intended to help the Agency better facilitate innovation in this field while safeguarding patients.

FDA Questions and Committee Discussion:

During this meeting, the Committee heard presentations from patients, health care professionals, academia, industry, FDA, and other interested parties. Discussion questions on digital mental health medical devices were posed to the committee with a focus on the following hypothetical scenario, accompanied by a device description and indications for use. A high-level summary of the Committee's responses to the discussion questions is below.

Scenario	A patient diagnosed with major depressive disorder (MDD) by their healthcare provider is experiencing intermittent tearfulness due to increasing life stressors. Although the patient has consistently refused recommendations for therapy from their healthcare provider, the patient is willing to try a software device that provides therapy.
Device Description	This prescription therapy device is built on a large language

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	model (LLM) that utilizes contextual understanding and language generation with unique outputs that mimic a conversation with a human therapist.
Device Indications for Use	This product is a standalone prescription digital therapy device indicated to treat MDD for adult patients (aged 22 years and older) who are not currently engaged in therapy.

1. **First, consider that a healthcare provider prescribes the digital mental health medical device to the patient to use independently at home.**
    a. **Briefly discuss the probable benefits of this type of device that provides automated therapy in an ongoing manner.**
    b. **What probable risks are presented by this type of device that provides automated therapy?**
    c. **What risk mitigations should be considered for this type of device (e.g., alerts for self-harm ideations)?**
    d. **What premarket evidence would you want to see to determine whether the benefits outweigh the risks to health?**
        i. **What are the key aspects of clinical evidence and trial design such as clinically meaning endpoints (e.g., measurable reduction in symptomatology), follow-up time, study eligibility criteria)?**
        ii. **What alternative approaches could be used to demonstrate clinically meaningful benefits and risks (e.g., benchmarking, model-based evaluation)?**
    e. **What specific postmarket monitoring capabilities should be considered to ensure continued safety and effectiveness of this medical device in real-world use (e.g., methods, metrics, tools)?**
    f. **What labeling would be important for users of this type of device?**

The Committee agreed that there were several probable benefits of this hypothetical device including earlier and broader access to therapy, as well as monitoring patients' response and triaging based on symptoms. This may be especially helpful for patients in rural areas or other under-resourced communities. Other benefits could include improving access to other mental health resources (e.g., support phone lines) and providing personalized treatment tailored to patients' needs and preferences. These devices could also potentially incorporate or utilize multi-modal inputs, for example, through analysis of voice, facial expressions, or physical activity data provided by associated digital health technologies.

In terms of probable risks, the Committee agreed that it is important to address LLM vulnerabilities, including hallucinations, confabulations, data drift, and model bias. It is also important to be able to identify when a device may miss opportunities to detect or deliver therapeutic cues that would be recognized or used by a professional human therapist. Creating an agile framework to gather information about the use of the device in the intended population will provide important information for lifecycle management of the device.

Regarding risk mitigation, the Committee agreed that an important initial step would be agreeing on a common taxonomy related to the level of impact and autonomy of a device. They discussed similar approaches that have been used to describe levels of autonomy for self-driving vehicles, which was presented by an external speaker as an example from other industries. It is important that patients undergo a comprehensive evaluation by a HCP, including an assessment for potential underlying medical conditions that could contribute to psychiatric symptomatology (e.g., substance use or metabolic conditions), before prescribing the device. It is also important for a patient to have a pre-existing plan with their HCP in the event of symptom escalation. The Committed discussed that developers could consider providing an in-app "single tap" access button to escalate communication for additional support, such as emergency services as appropriate. Automated reminders explaining the role and scope of the device (e.g., device is to be used for a specific duration and condition or symptom profile) could also be helpful.

Several premarket considerations were discussed. The relationship between patient engagement with the device, adherence to treatment, degree of clinical symptomatology, and clinical outcomes, may not be well understood and will be important to characterize. Regarding clinical evidence of device safety and effectiveness, the Committee agreed that developers should select measures and clinical endpoints, including patient-reported outcomes, appropriate to the device's intended use, including the condition being treated and the intended population. There is a need for novel measures to be used along with existing ones. Statistical analyses should include consideration of false negatives and adverse events. Study participant selection should reflect patients in real-world settings. The Committee felt that waitlist controls may not be ideal controls for studies of this nature. Some additional considerations from the Committee included the ability of the device to provide education, gather regular feedback, and monitor and limit screen time.

As to postmarket monitoring, the Committee stated it should mirror evidence generation in the premarket space and data collection should follow trends over time. The Committee discussed that it is important to avoid the product's function shifting from its intended use and to create a plan for information about the patient's use of the device to be available to the prescribing individual. The Committee discussed that postmarket data may include patients' engagement, adherence, and clinical symptom reporting.

The Committee agreed that transparency should be provided to the user, including by clearly indicating that the AI system is not a human therapist. The Committee discussed that labeling should include the product's intended use, overuse warnings, crisis information, data use and privacy details, as well information on the source of data used to study the device and how its effectiveness was demonstrated. The label should also clearly state who can prescribe the device, the specific indications for use, and limitations of use. Several members agreed that providing information about the foundation model(s) used for the device could also be informative.

2. **The manufacturer of the aforementioned, generative AI-enabled mental health medical device has decided to expand their labeled indications for use. They are contemplating the following changes.**

a. **Making the device available over-the-counter (OTC) for people diagnosed with MDD.**
b. **Modifying the OTC device to autonomously diagnose and treat MDD in an ongoing manner without the involvement of an HCP. They intend for the device to be used by people who have not been diagnosed with MDD by an HCP but have been experiencing symptoms of depression.**
c. **Modifying the OTC, autonomous diagnosis and treatment device to be used for multiple mental health conditions (e.g., multi-use indications), meaning that it can provide both diagnosis and treatment for multiple mental health conditions related to sadness (in contrast to a device that is specifically indicated for MDD). The user of the device may not be clinically diagnosed with any mental health condition but has been feeling sad and has not met with an HCP.**

The Committee discussed being more comfortable with the idea of use of the device for treatment of mild symptoms and expressed greater concern about use of the device for moderate to severe depression. The Committee also discussed that it may be important for clinical trials to demonstrate that the autonomous device performs as well as a device that has human involvement. Having a mechanism built into the device to confirm that the patient has a diagnosed depressive disorder would be helpful. The Committee agreed that high quality clinical trials conducted by independent investigators over a substantial duration of time would be important to demonstrate a favorable safety profile. The Committee agreed on the potential benefits of these technologies for diagnosis and treatment but emphasized that there needs to be a better understanding of these benefits while mitigating risks. Risks mentioned included worsening of symptoms, including self-harm behaviors, and the development of unhealthy parasocial relationships through anthropomorphizing the chatbot.

3. **Expanding the population to include a child or adolescent (i.e., 21 years and younger).**

a. **As you consider the manufacturer's proposed changes, please discuss whether your prior responses to question 1 would change if the population were children or adolescents.**
b. **If so, how would the responses change?**

The Committee acknowledged the need for improved access to care, including treatment and wellness services, in the pediatric population. The discussion highlighted that there are special considerations for using generative AI-enabled mental health medical devices in this population. The Committee discussed potential benefits, including those related to providing patients with coping tools when they cannot see a therapist (e.g., when there may be stigma, resistance from parents, or other barriers to care). They agreed that input from child psychiatrists is essential to the development and evaluation of these types of devices. Large, well-controlled trials conducted by specialists are critical.

In addition, the Committee noted that the device should be developed specifically for each age group and may need to apply different functions or approaches as a child or adolescent moves from one developmental stage to another. Safety measures could include monitoring and limiting screen time, along with specialized training for those authorized to prescribe the device. Data collected by the device

could also be shared with the prescribing physician for review. The Committee discussed that device use should be monitored for adverse events both in clinical investigations and real-world settings. Education regarding devices of this nature was noted as being important with adolescent therapy; education for the practitioner, patient, and the patient's family or caregivers may be particularly important for this patient population. Finally, the Committee agreed that there is a need to differentiate between wellness and medical care especially for the pediatric population to differentiate products and avoid scope creep.

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Transcripts, when available, may be downloaded from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-2025-digital-health-advisory-committee-meeting-announcement-11062025

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