Mental Health Applications of Generative Artificial Intelligence

One of the newer areas in which the US Food and Drug Administration (FDA) is exploring its regulatory role is the use of artificial intelligence (AI) in digital mental health medical devices.

There is recognition that mental illnesses are common around the world. As noted in a 2024 report from the World Health Organisation (WHO), World mental health today: Latest data, more than 1 billion people worldwide are living with a mental disorder.[1] The report notes that the prevalence of different mental disorders varies by sex, with females overall more affected. Anxiety disorders and depressive disorders are the most common conditions in both sexes.

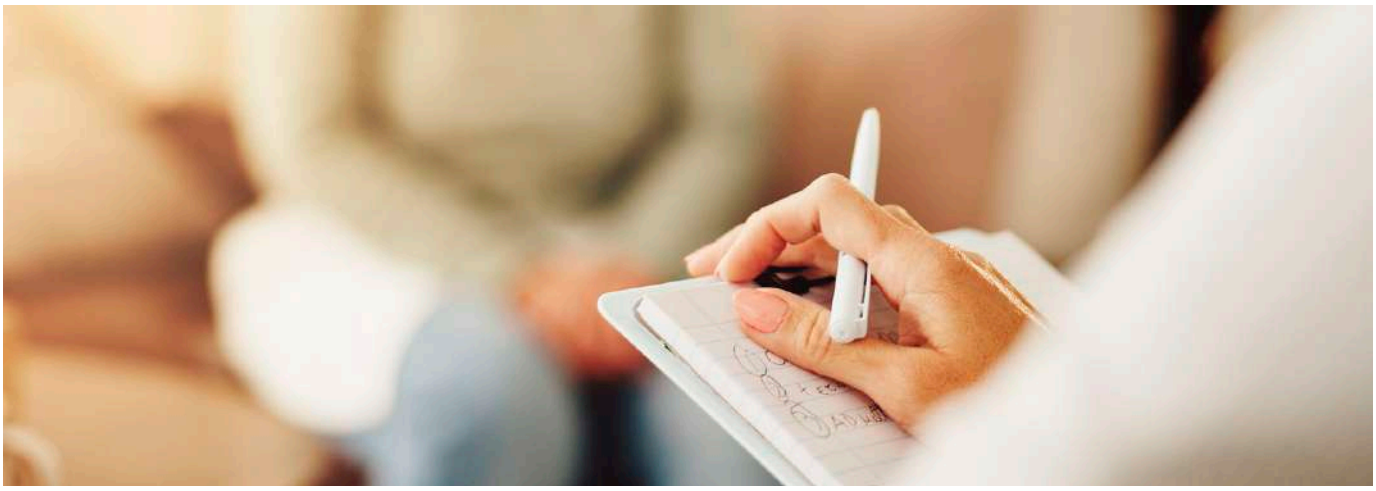
Citing data from the National Survey on Drug Use and Health (NSDUH) by the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Institute of Mental Health of the National Institutes of Health (NIH) notes that in 2022, an estimated 59.3 million adults aged 18 or older in the US were diagnosed with any mental illness (AMI).[2] This number represented 23.1% of all US adults, more than 1 in 5. Out of these nearly 60 million adults, 50.6% received mental health treatment in the past year. The NSDUH defines mental health treatment as having received inpatient treatment/counselling or outpatient treatment/counselling or having used prescription medication to help with mental health.

Issued in July 2025, the NSDUH's latest annual report provides indicators of mental health in the US based on data from 2021 to 2024.[3] As in the 2022 survey, adults aged 18 or older were classified as having AMI if they had any mental, behavioural, or emotional disorder in the past year of sufficient duration to meet criteria from the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV), excluding developmental disorders and substance use disorders. Across the assessed population, the percentage of adults with AMI in the past year did not change from 2021 to 2024. In 2024, 23.4% of adults aged 18 or older – representing 61.5 million people – had AMI in the past year. Rates within each age group also remained stable over this period. Among young adults aged 18 to 25, approximately one-third (33.2%, or 11.6 million people) had AMI in the past year.

Medical Devices for Mental Health

Given this substantial and persistent prevalence, the FDA convened its second-ever meeting of the Digital Health Advisory Committee (DHAC) in early November 2025 to examine issues related to the use of generative AI (genAI) – enabled digital mental health medical devices. The committee discussed potential benefits and risks to health, possible risk-mitigation strategies, premarket evidence expectations and approaches to postmarket monitoring.

The agency explained in the preface to the panel discussion questions that, alongside the increasing accessibility of genAI products for general use, the development and demand for a new type of digital mental health medical device are also rising.[4] These "AI therapists," and other AI-based medical devices aim to offer a broad range of mental health therapies and interactions with therapist or healthcare provider (HCP) – like chatbots, some of which may even be diagnostic. Because these chatbots can interact with users in personalised ways – with or without HCP oversight – they introduce



novel risks. In light of the continuing evolution in the complexity of digital mental health medical devices, regulatory approaches will also need to adapt, the FDA added, to ensure a "reasonable assurance of their safety and effectiveness while promoting innovation to support public health."

In the meeting materials, the agency stated that although it has authorised more than 1,200 AI-enabled medical devices that span a broad range of AI technologies, none of them are indicated for mental health uses.[5] Furthermore, the FDA has authorised less than 20 digital mental health medical devices that encompass non-AI technologies. To provide sponsors with insight into the current medical device landscape and regulatory expectations for AI-enabled medical devices, the agency maintains a webpage on the topic, which includes an AI-Enabled Medical Devices List.[6]

Digital mental health medical devices that have been authorised by the FDA to date are typically intended for prescription use and have received authorisation under several different regulations. These devices include but are not limited to computerised behavioural therapy devices for psychiatric disorders (see 21 Code of Federal Regulations [CFR] part 882.5801), digital therapy devices for attention deficit hyperactivity disorder (ADHD) (21 CFR 882.5803), digital therapy to reduce sleep disturbances for psychiatric conditions (21 CFR 882.5705), paediatric autism spectrum disorder diagnosis aid (21 CFR 882.1491) and attention task performance recorder (unclassified).

At the November DHAC meeting, the panel was presented with a medical scenario followed by discussion questions. The scenario described a patient diagnosed with major depressive disorder (MDD) by their HCP who is experiencing intermittent tearfulness due to increasing life stressors. Although the patient has consistently declined recommendations for therapy from their HCP, they are willing to try a software device that provides therapy. The device is a prescription therapy device built on a large language model (LLM) that uses contextual understanding and language generation with unique outputs that mimic a conversation with a human therapist. Its indication for use is as a standalone prescription digital therapy device indicated to treat MDD for adult patients aged 22 years and older with MDD who are not currently engaged in therapy.

There was no voting at the DHAC meeting, but the overall sentiment among panel members was one of concern. Topics highlighted by the panel included:

- Data privacy, including clarity on who owns the data gathered by the device.
- Risks of over-reliance on a machine, particularly given that the use of mobile apps on smartphones has been cited as a contributing factor in the current mental health crisis in the US.
- The need for risk-mitigation strategies to ensure users can access human support when needed.
- Mechanisms for providing feedback to the prescribing physician so they can monitor patient progress.
- Clear processes for tracking and reporting adverse events associated with device use.
- Labelling that explicitly indicates the device is AI-based.
- Requirements for long-term safety data from randomised controlled trials and strong evidence that the device does not harm people if used by unintended populations.

The FDA seeks to leverage feedback from the DHAC to help the agency foster innovation in genAI-enabled digital mental health medical devices while ensuring the safety of patients.

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Deborah Komlos

Deborah Komlos, MS, is a former Principal Content Writer/Editor for the Cortellis suite of life science intelligence solutions at Clarivate. In this role, her coverage centredon FDA advisory committee meetings, workshops and product approvals. Her previous positions have included writing and editing for magazines, newspapers, online venues and scientific journals, as well as publication layout and graphic design work.