U.S. Food and Drug Administration

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Ref. Docket No. FDA-2025-N-2338: Digital Health Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments— Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices

To Whom it May Concern:

The New York City Department of Health and Mental Hygiene (Health Department) appreciates the opportunity to provide comments in response to the Digital Health Advisory Committee (the Committee)'s request for comments related to Generative Artificial Intelligence (AI)-Enabled Digital Mental Health Medical Devices.

The proliferation of Generative AI-Enabled Digital Mental Health Medical Devices poses both opportunities and risks. Digital therapeutics have the potential to increase access to care by effectively delivering interventions under the oversight of a licensed mental health professional. However, devices that utilize Generative AI to provide clinical mental health services without proper human oversight pose acute risks of bias, insufficient transparency, and unaccountability. Additionally, both Digital Mental Health Medical Devices and consumer products that utilize Generative AI currently can collect, use, and sell users' neural data without proper safeguards.

The Committee should prioritize (1) use cases for Generative AI-Enabled Digital Mental Health Medical Devices that supplement the work of Licensed Mental Health Professionals without circumventing their oversight and clinical expertise, (2) a regulatory framework that sets clear guardrails for consumer products that provide quasi-therapeutic services enabled by Generative AI, and (3) clearer standards for the collection and use of neural data by both Digital Mental Health Medical Devices and consumer products oriented around mental health.

(1) AI Should Augment, Not Replace, Licensed Mental Health Professionals

Mental health is undeniably a growing area of need. Among New York City (NYC) public school students, rates of feeling sad or hopeless increased from 27% to 38% from 2011 to 2021. Among NYC adults with a diagnosed mental illness, 34% had an unmet need for mental health treatment in the previous year, as of 2023.[1] To the extent that Generative AI

[1] Hamwey M, Norman C, Suss R, et al. The state of mental health of New Yorkers. New York City Department of Health and Mental Hygiene. May 2024. https://www.nyc.gov/assets/doh/downloads/pdf/mh/state-of-mental-health-new-yorkers.pdf

can be used to increase access to mental health services in a safe and efficacious way, it has the potential to help close service gaps and contribute to innovative new approaches.

However, these approaches should be focused on ways in which Generative AI can augment and support the work of licensed mental health professionals, rather than delivering clinical mental health services without their involvement. Specifically, Generative AI should not be authorized to make independent therapeutic decisions, generate treatment plans, or directly interact with clients in the form of therapeutic communication without oversight by a licensed professional.

There are several risks with the prospect of Generative AI-Enabled Digital Mental Health Medical Devices in use cases that replace licensed professionals in providing clinical mental health services. First, there is potential for implicit and explicit biases present in the data the AI was trained on, leading to the reinforcement of stereotypes in mental health and/or discriminatory outcomes.[2] Second, the lack of transparency in the decision-making processes of Generative AI, also known as the "black box" problem, undermines trust in their ability to make clinical decisions without human oversight.[3] Third, there are difficulties in holding Generative AI-Enabled Digital Mental Health Medical Devices accountable for meeting standards of clinical care, including legal obligations to protect individuals' privacy rights, that licensed professionals can be held to.[4]

Given these risks, it is prudent to limit the use cases of Generative AI-Enabled Digital Mental Health Medical Devices to a supplementary role when they are involved in providing clinical services. When Generative AI-Enabled Digital Mental Health Medical Devices are used in a supplementary role to provide services, rigorous testing and post-market surveillance are necessary to ensure that they are able to effectively achieve what they claim and are not being trained-to-the-test without external validity.

(2) <u>Guardrails for Consumer Products Providing Quasi-Therapeutic Services</u>

The recent and rapid proliferation of consumer products enabled by Generative AI to provide quasi-therapeutic services has been accompanied by a lack of sufficient regulatory guardrails. For example, there are cases of AI chatbots that are not considered medical devices but are nonetheless explicitly impersonating licensed therapists. More

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[2] Xian X, Chang A, Xiang YT, Liu MT. Debate and Dilemmas Regarding Generative AI in Mental Health Care: Scoping Review. Interact J Med Res. 2024 Aug 12;13:e53672. doi: 10.2196/53672. PMID: 39133916; PMCID: PMC11347908.

[3] Poon AIF, Sung JJY. Opening the black box of AI-Medicine. J Gastroenterol Hepatol. 2021 Mar;36(3):581-584. doi: 10.1111/jgh.15384. PMID: 33709609.

[4] Moore, J., Grabb, D., Agnew, W., Klyman, K., Chancellor, S., Ong, D. C., & Haber, N. (2025, June). Expressing stigma and inappropriate responses prevents LLMs from safely replacing mental health providers. In Proceedings of the 2025 ACM Conference on Fairness, Accountability, and Transparency (pp. 599-627).

commonly, AI chatbots currently on the market are being used for ongoing, intimate conversations that may include emotional support in response to psychological distress, behavioral feedback to address mental health conditions, or other communication that could be considered therapeutic or quasi-therapeutic. Thus, the distinction between a Generative AI-Enabled Digital Mental Health Medical Device and a non-medical consumer product enabled by Generative AI to provide mental health support is increasingly narrow. A well-designed regulatory framework is necessary to ensure that guardrails exist for both sets of products.

In one recent high-profile case, at the U.S. Senate Judiciary Subcommittee on Crime and Counterterrorism's Hearing titled *Examining the Harm of AI Chatbots,* Matthew Raine testified that his son, Adam Raine, took his own life in April 2025 "after ChatGPT spent months coaching him towards suicide."[5] His testimony reported that ChatGPT became Adam's closest confidante, engaged him in discussions around his anxiety, and helped him survey suicide methods. This case is an extreme example, but these types of direct-to-consumer products have become pervasive, including among adolescents. Among 13–17-year-olds nationally, 72% have used AI companions at least once and 52% are regular users, interacting with AI platforms at least a few times per month.[6] We implore the Committee to consider the real-life harms that can arise from a lack of clear oversight on these new products.

(3) <u>Regulation of Neural Data</u>

As Generative AI-Enabled Digital Mental Health Medical Devices and Generative AI-Enabled consumer products used for mental health-related purposes grow increasingly pervasive, there is a growing need for clearer rules around the collection and use of neural data. Currently, many consumer products on the market, such as electroencephalography (EEG) headsets, collect neural data with very few restrictions on how they use or sell that data.[7]

In July 2025, the American Medical Association House of Delegates unanimously adopted a resolution supporting the enactment of regulations safeguarding the privacy of neural

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[5] *Examining the Harm of AI Chatbots: U.S. Senate Judiciary Subcommittee on Crime and Counterterrorism*, 119th Cong. (2025) (Testimony of Matthew Raine). https://www.judiciary.senate.gov/imo/media/doc/e2e8fc50-a9ac-05ec-edd7-277cb0afcdf2/2025-09-16%20PM%20-%20Testimony%20-%20Raine.pdf

[6] Common Sense Media. *Talk, Trust, and Trade-Offs: How and Why Teens Use AI Companions.* (2025). https://www.commonsensemedia.org/sites/default/files/research/report/talk-trust-and-trade-offs_2025_web.pdf

[7] Szoszkiewicz Ł, Yuste R. Mental privacy: navigating risks, rights and regulation: Advances in neuroscience challenge contemporary legal frameworks to protect mental privacy. EMBO Rep. 2025 Jul;26(14):3469-3473. doi: 10.1038/s44319-025-00505-6. Epub 2025 Jun 25. PMID: 40562792; PMCID: PMC12287510.

data, defined as “information obtained measuring the activity of a person’s central or peripheral nervous system through the use of neurotechnologies.”[8] Neural data can be uniquely sensitive, even more than traditional health information, due to its ability to reveal mental/emotional states, cognitive patterns, or other deeply personal information.

Due to the lack of a comprehensive federal framework, states have begun to step in to regulate the use of neural data. California,[9] Colorado,[10] Connecticut,[11] and Montana[12] have enacted laws that specifically regulate neural data, although with differing definitions and restrictions. These initial state-level efforts take steps towards a “right to mental privacy” that will be increasingly important as neurotechnology continues to progress. The establishment for clearer regulatory standards for neural data in the context of Generative AI-Enabled Digital Mental Health Medical Devices should be a major priority.

The Health Department appreciates the opportunity to submit these comments.

Sincerely,

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[8] Resolution 503, “Safeguarding Neural Data Collected by Neurotechnologies,” American Medical Association (2025).
[9] CA Civ Code § 1798.140 (2024). https://law.justia.com/codes/california/code-civ/division-3/part-4/title-1-81-5/section-1798-140/
[10] CO Rev Stat § 6-1-1303 (2024). https://law.justia.com/codes/colorado/title-6/fair-trade-and-restraint-of-trade/article-1/part-13/section-6-1-1303/
[11] Public Act 25-113 (2025). https://www.cga.ct.gov/2025/act/pa/pdf/2025PA-00113-R00SB-01295-PA.pdf
[12] Montana SB 163 (2025). https://docs.legmt.gov/download-ticket?ticketId=19ba2309-6a40-42d4-9f4e-86c77e44d090