U.S. Food and Drug Administration (FDA)

Center for Devices and Radiological Health (CDRH)

Digital Health Advisory Committee (DHAC) Meeting

Brief Summary on the topic "Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices"

November 6, 2025

Introduction

On November 6, 2025, the FDA's Digital Health Advisory Committee, or DHAC, met virtually to discuss and provide advice on the topic of Generative AI-Enabled Digital Mental Health Medical Devices. Dr. Ami Bhatt, Chairperson for this meeting, opened the session by calling the Committee to order. Dr. Bhatt clarified that this meeting would not focus on broadly available generative AI tools, but specifically on GenAI-enabled medical devices intended for diagnosis, cure, mitigation, treatment, or prevention of mental-health conditions. She emphasized the widespread impact of mental-health challenges and underscored that the meeting's purpose is to learn how these emerging technologies can help improve care.

Dr. Bhatt proceeded to call the agenda, and each of the Committee members and FDA experts identified in the meeting roster introduced themselves. After Committee introductions, the Designated Federal Officer, Letise Williams, delivered the Conflict of Interest Statement.

Afterwards, Dr. Bhatt gave a brief overview of the meeting's schedule, and introduced Dr. Michelle Tarver, director of the Center for Devices and Radiological Health, who made the opening remarks. After a brief follow-up on last year's inaugural DHAC meeting and welcoming participants to this second meeting, Dr. Tarver explained that while the FDA has authorized more than 1,200 AI-enabled medical devices, none yet involve generative AI for mental-health conditions, a gap of particular significance given the nation's growing mental-health crisis. She underscored that the Committee's expertise and feedback will be critical in evaluating the benefits, risks, and long-term safety considerations for GenAI-enabled digital mental-health devices and thanked participants for contributing to this work.

FDA Perspective

- Generative Artificial Intelligence (GenAI)-Enabled Digital Mental Health Medical Devices

Dr. Gioia Guerrieri discussed FDA's approach to evaluating generative-AI tools in mental health and emphasized the growing mental-health crisis, the rapid expansion of digital technologies, and the need for predictable, risk-based oversight. She explained how FDA distinguishes between non-device software, low-risk functions under enforcement discretion, and regulated digital mental-health devices requiring premarket review. Dr. Guerrieri highlighted the draft guidance on lifecycle management for AI-enabled devices, the agency's focus on real-world performance monitoring, and the ongoing Request for Public Comment on evaluating AI systems after deployment. She also reviewed the Predetermined Change Control Plan (PCCP) framework for managing future algorithm updates and noted recent FDA-CMS collaboration to expand Medicare coverage for digital behavioral-health devices.

- Regulatory Considerations for Digital Mental Health Diagnostics

Mr. Jay Gupta outlined how FDA evaluates digital mental-health diagnostic devices within OHT5, explaining that these tools range from data-collection apps and behavioral assessments to more advanced systems that analyze physiological, behavioral, or conversational inputs. He reviewed existing authorized examples, including ADHD assessment aids and Autism Spectrum Disorder diagnosis aids, and described when novel devices may require review through the De Novo pathway. Mr. Gupta highlighted potential benefits such as improved access, earlier assessment, and broader data to support clinical decision-making, while also underscoring key risks like inaccurate outputs, misinterpretation, delayed crisis detection, or inappropriate treatment decisions. He emphasized that FDA's assessment depends on the device's intended diagnostic role, the context of use, data sources, algorithm development practices, user involvement, and labeling needs, particularly as GenAI-enabled diagnostics move toward more autonomous, direct-to-consumer, and potentially closed-loop designs.

- Regulatory Considerations for Digital Mental Health Therapeutics

Ms. Pamela Scott described how FDA evaluates GenAI-enabled digital mental-health therapeutics, noting that existing device regulations cover non-AI digital therapeutics used as adjuncts to usual care and require special controls such as software validation, hazard analysis, labeling, and well-controlled clinical trials. She explained that GenAI therapeutics introduce new considerations for study design, including appropriate control arms, blinding, outcome measures, and the timeframe needed to demonstrate meaningful clinical benefit. FDA's benefit-risk evaluation depends on the device's intended use (adjunctive vs. standalone; prescription vs. OTC), the behavioral therapy models incorporated, and the extent of clinician involvement. Ms. Scott also emphasized applying ISO 14971 risk-management principles across the device lifecycle, highlighting potential hazards such as missed crisis identification, misinterpreted symptoms, or inadequate therapeutic content, and stressed the importance of safety-by-

design practices, verification and validation methods, and robust postmarket monitoring for GenAI-enabled therapeutics.

Non-FDA Presentations

- Generative AI and Mental Health

LCDR Anthony Becker, a military psychiatrist, offered a clinician's perspective on how generative AI may reshape mental-health care. He described how large language models are developed and how they have surpassed major medical benchmarks, even outperforming physicians on licensure exams and in tasks such as patient interviews. He highlighted emerging evidence that GenAI systems can support clinical tasks, including early studies showing symptom improvement from AI-driven chatbot interventions. LCDR Becker also emphasized two major vulnerabilities: sycophancy, where models agree with users at the expense of accuracy, and poor metacognition, demonstrated by models' inability to recognize incorrect or impossible questions while still expressing high confidence. He noted that despite these risks and limitations, AI systems can pass the Turing test, score high on measures like empathy, and are already widely used by the public for companionship, raising real questions about how they may share or shift responsibilities traditionally held by mental-health professionals. He concluded by underscoring the need to carefully weigh these systems' capabilities and risks as the field decides how, and whether, to integrate them into mental-health care.

- The Impact of GenAI on Digital Mental Health Medical Devices and Mental Health Technologies

Dr. Vaile Wright from the American Psychological Association discussed how generative AI is emerging within a broader mental-health crisis marked by high need, limited access to evidence-based care, and a persistent workforce shortage. She reviewed how telehealth expanded rapidly during the pandemic but cannot fully address gaps in reach, and outlined today's digital landscape, from wellness apps to prescription digital therapeutics, highlighting the gray area where products are marketed one way but used as mental-health tools. Dr. Wright noted sharp growth in generative-AI use, with many adults and teens turning to LLMs for psychological support, advice, or companionship. She described two major trends: provider-facing tools such as AI scribes that may evolve toward diagnostic roles, and consumer-facing mental-health chatbots, many of which are direct-to-consumer and unregulated. These raise safety concerns, especially for vulnerable populations, due to inconsistent quality, unclear intent, privacy risks, and the lack of transparent regulatory oversight. She urged policymakers to modernize regulations, strengthen premarket and postmarket evidence requirements, improve transparency, and establish a public

repository of FDA-cleared digital mental-health tools to help providers and consumers distinguish safe, effective products from those operating under enforcement discretion.

Open Public Hearing

Before beginning the Open Public Hearing, Dr. Bhatt offered a brief summary of the morning presentations and reflected on the different ways GenAI-enabled devices may interact with mental-health care. She emphasized the importance of patient education and agency, noting that these technologies cannot be placed in patients' hands without ensuring they understand how to use them safely. After these remarks, Ms. Williams read the required disclosure statement, and the session proceeded with 16 pre-recorded and live presentations from public speakers who shared perspectives:

1. Nicole Rawson, Founder of Screen Time Clinic, described the harmful effects of excessive digital use on children, citing her experience as a teacher and as a parent of a child with autism who developed severe gaming addiction. She urged the FDA to issue strong nationwide warnings about the neurological risks of video games, social media, and short-form content, calling for no recreational screen time for minors under 18, mandatory labeling, and public education campaigns similar to tobacco or alcohol efforts.
2. Ms. Chang, CEO of Kintsugi, presented their work using voice biomarkers and AI to screen for depression and anxiety during routine conversations, supported by large clinical trials and an upcoming De Novo submission. She highlighted early detection benefits, improved patient retention, and challenges startups face with long regulatory cycles and unclear reimbursement pathways. She urged regulators to support faster, coordinated FDA–CMS processes so promising tools can reach clinical use without unnecessary delays.
3. Mr. Cooper, CEO of CooperSoft, highlighted the significant regulatory and financial hurdles small digital-health companies face in bringing products to market. He urged the FDA to make pathways more efficient and predictable by expanding programs like De Novo and Breakthrough Devices, revisiting firm-based oversight models such as the Pre-Cert Pilot, improving tools like eSTAR, and allowing broader use of international standards. He also called for expanding small-business fee reductions, simplifying expectations for commercial off-the-shelf software, and strengthening early-stage guidance through clearer evidence requirements, streamlined Q-Submissions, and enhanced DICE support.
4. Dr. Celi and Mr. Hilel, from MIT, argued that traditional postmarket monitoring is inadequate for GenAI mental-health tools, which update constantly and require lifecycle oversight rather than one-time review. They urged the FDA to require evaluation interfaces (APIs) so independent

researchers, clinicians, and patients can test models, simulate crisis scenarios, and co-design safety benchmarks. They emphasized that meaningful community involvement should be mandatory and that continuous, real-time feedback loops are essential for keeping these evolving systems safe and effective.

5. Dr. Stephen Schueller, speaking for the Society for Digital Mental Health, emphasized the need for transparency, safety, and clinical accountability as generative-AI mental health tools evolve after deployment. He urged the FDA to adopt a tailored, risk-based framework with clear processes for model updates and performance monitoring. Aubrey Shick added that transparency must be embedded throughout the user experience, that safety requirements should match the level of risk, and that GenAI tools should augment, not replace, clinicians. Both called for clear intended-use statements, shared responsibility across the product lifecycle, and plain-language information to help the public use these tools safely.
6. Miguel Amador, Chief Innovation Officer at Complear Health, argued that current FDA–manufacturer oversight models are insufficient for AI/ML mental-health devices, which require continuous validation and monitoring. He highlighted missing infrastructure such as shared testing facilities, regulatory sandboxes, and federated real-world data networks, tools already emerging in the EU, and emphasized that an integrated ecosystem of independent testing and data access is essential to support true total-product-lifecycle oversight.
7. Andy Molnar, speaking from his experience in digital health innovation and policy, emphasized that while digital therapeutics have proven value, adoption is stalled by unclear regulation and confusion with unregulated wellness apps, even as millions turn to AI chatbots for emotional support. He urged the FDA to establish consistent oversight and a risk-scaled transparency model with clear labeling of intended use, evidence, and limitations. He stressed that distinguishing regulated therapeutic tools from general wellness apps is essential for patient safety and trust.
8. Dr. Bethany Russell, a clinician and researcher specializing in children and adolescents, outlined major risks of AI in mental health, including misdiagnosis, unsafe responses to suicidal users, “AI psychosis,” and obsessive or harmful behavior patterns. She stressed the importance of human oversight, expert involvement in development, and bias monitoring, especially for children and adolescents. While noting these risks, she also stated that AI can expand access and support care when it augments, rather than replaces, qualified mental health professionals.
9. Dr. Agnew and Dr. Ong (respectively, a CMU postdoctoral fellow and a UT Austin psychology professor), highlighted the widespread, unregulated use of general-purpose Large Language Models for mental-health support, noting that many chatbots falsely claim to be licensed therapists. They presented evidence that LLMs can reinforce delusions, provide dangerous

guidance (including assisting with self-harm), and have already been linked to real-world harm. Their research shows particularly unsafe responses to delusion and suicide-related prompts. They urged the FDA to address deceptive therapeutic claims, require transparency, and support stronger evaluation and oversight frameworks for LLMs used in mental-health contexts.

10. Sneha Dave, Executive Director of Generation Patient, urged the FDA to regulate AI companion tools as medical devices, noting their widespread use among teens and young adults with chronic conditions. She warned that these tools often act as de facto mental-health support without evidence of safety or efficacy, may pose neurocognitive risks, and currently fall into a regulatory gray area. Ms. Dave called for risk-based oversight, long-term data collection, and clearer FDA action to protect vulnerable youth from unregulated AI companions.
11. Isaiah John, actor and founder of EKO LABS, described stress as a biochemical cycle in which emotions trigger specific chemical responses in the body, and how prolonged emotional states can evolve into chronic stress and illness. He explained that EKO LABS studies this emotional feedback loop and is developing noninvasive monitoring with AI interpretation to show users in real time how their environment affects their physiological state. The goal is not diagnosis but awareness, allowing individuals to recognize and interrupt stress before it escalates.
12. Thomas Hull, Clinical Psychologist, described Slingshot AI's work on a psychology-focused foundation model and its consumer app “Ash,” which supports users with stress and relationship challenges. He noted that unmet mental health needs are driving people toward GenAI and argued that well-designed, pro-human models can offer meaningful benefits with low risk. He also maintained that existing FDA frameworks already address major risks for low-risk wellness tools and have already proved effective. He showed how Ash incorporates these safeguards and urged the Committee to affirm that generative-AI wellness products can remain low risk under current guidance and should not face overly prescriptive new regulations.
13. Dr. Michael Abrams of Public Citizen warned that GenAI mental health devices pose a wide spectrum of possible outcomes. He noted that many AI mental health apps are already on the market operating without regulation and cites past FDA actions that cleared digital devices with limited evidence, underscoring the need for rigorous clinical trials for any AI therapy tool. He argued that standalone AI tools for serious disorders should undergo rigorous evaluation; he also urged congressional funding to reduce industry influence and warned that autonomous AI therapy tools should not be used by children or adolescents until proven safe and effective in adults.
14. Dr. Diana Zuckerman, President of the NCHR, warned that AI-based mental health tools can be dangerous. She argued that the FDA's distinction between wellness tools and mental health devices is flawed as the categories overlap and vulnerable users may quickly shift from mild

problems to crises. She argued that 510(k) review is inappropriate and that De Novo or PMA pathways should require randomized controlled trials. She raised concerns about testing devices that change frequently, how postmarket monitoring can work with an understaffed agency, and the likelihood that patients who avoid therapy will not heed warnings. She concluded that devices for major depression should not be available over the counter given suicide-risk patterns and risks of self-medication.

15. Rebecca Haigler and Morgan Bailie from Healthsperien stressed that GenAI mental health tools are widely used and that the FDA has an opportunity to guide their safe, evidence-based development. They call for clearer pathways to distinguish software-as-a-medical-device from wellness products and urged clinical evidence that includes not only validated symptom measures but also functional outcomes and patient and caregiver motivations. They called for federally supported postmarket registries to track long-term outcomes. Their recommendations included establishing a formal framework to define and validate mental health efficacy for GenAI tools, creating a unified national registry to monitor real-world safety and effectiveness, and developing a clear subcategory of software as a medical device for GenAI therapeutic tools.
16. Chase Chick, CEO of Gray Sky AI, supported existing FDA guidance that AI tools should not claim to diagnose, treat, or cure medical conditions, and argued that whenever an AI product provides any form of healthcare-related support, the “human in the loop” should be a licensed clinician. He described Gray Sky AI's app model, in which a licensed counselor intervenes when user interactions raise issues such as potential abuse or risk of harm. He concluded that defining the qualifications of human overseeing AI healthcare interactions is a sensible starting point.

Open Public Hearing - Q&A

Dr. Maddox asked the speakers in general how quality assurance for AI mental health tools might mirror the ways human therapists maintain care standards. Chase Chick responded that his model ties oversight to licensed clinicians, who already operate under mandatory-reporting rules. Rebecca Haigler added that mental health lacks clear biomarkers, and the field is moving toward measurement-informed care. Additionally, Grace Chang described how voice biomarker tools can offer objective, replicable screening to support consistent assessment across practitioners.

Dr. Jackson then asked the MIT presenters how their safety-testing framework balances privacy and real-time safety. Mr. Hilel explained that their method uses simulated personas in a lab setting, avoiding real-patient data and focusing on stress-testing edge cases rather than real-time intervention.

Mr. Rutherford asked about distinguishing similar symptoms when using objective measures. Grace Chang explained that acoustic biomarkers capture physiological differences across conditions and are validated against structured clinical interviews in blinded trials.

Dr. Torous asked Derrick Hull how Slingshot differentiates wellness from medical use and informs users of benefits and risks. Hull emphasized repeated disclosures before and during app use, ensuring users understand the tool cannot diagnose and must be paired with professional care.

Dr. Goodman raised concerns about postmarket surveillance for systems that change continuously, asking how often revalidation should occur. Mr. Amador advocated for independent entities, not only manufacturers, to participate in lifecycle monitoring, capturing real-world data that can be fed back into regulatory oversight.

Dr. Zuckerman cautioned that evaluating systems that change constantly is nearly impossible, especially given FDA resource constraints. Dr. Abrams added that drift analysis must be part of premarket review, not deferred to postmarket studies, and raised accountability concerns if autonomous tools receive FDA authorization.

Dr. Abrams emphasized that concerns about model drift and changing behavior should not be left solely to postmarket oversight; they must be addressed during premarket evaluation. He warned that the FDA too often approves products first and evaluates problems later, which would be especially risky for generative-AI mental health tools. He also raised accountability issues: once the FDA authorizes an autonomous device, companies may shield themselves behind that authorization, making it harder for harmed consumers to seek recourse.

Finally, Dr. Liran asked Chase Chick how to prevent companies from meeting "human-in-the-loop" requirements with inadequate staffing. Chick replied that regulations must require enough licensed professionals to handle the volume of users, and that license holders should be held accountable when they cannot meet those responsibilities.

Non-FDA Presentations (Continued)

- Academic Perspective on GenAI Digital Mental Health Medical Devices

Dr. Nicholas Jacobson of Dartmouth described the unmet need in mental health, where disorders are common, access is limited, and digital tools often fail due to poor engagement. After early attempts to train generative-AI models on peer-support forums and psychotherapy transcripts produced unsafe or

ineffective responses, his team created a hand-curated, expert-written training corpus based on evidence-based cognitive behavioral therapy. The resulting system, Therabot, developed with extensive expert review, showed strong improvements in depression, anxiety, and eating-disorder symptoms in a randomized trial and achieved high user engagement. Jacobson argued that regulation should account for comorbidity, rapid model evolution, and the widespread unregulated use of large language models. He warned against rigid, diagnosis-specific or prescription-only approaches and urged the FDA to support purpose-built systems that use expert-reviewed data, multi-layered safety checks, crisis pathways, human oversight, and structured postmarket monitoring.

- Clinical Trial Evaluation of GenAI Digital Mental Health Medical Devices

Dr. Patricia Arean, Founder of CREATIV Lab at the University of Washington and former NIMH Division Director, outlined how GenAI mental health chatbots intended to replace or supplement therapists should be developed and evaluated, emphasizing that they must be built around a clearly defined therapeutic target, a user-centered design process, and evidence-based or well-tested mechanisms. She explained that early proof-of-concept must show the chatbot can safely affect the intended target before moving to efficacy and effectiveness trials, which should use appropriate designs, verified samples, human oversight for safety, validated outcome measures, and expert monitoring of dialogue fidelity, even as models evolve. She noted that systems must be constrained or closely supervised to avoid harmful content, and any newly emerging therapeutic strategies must be tested in separate trials. To keep pace with rapid AI development, she recommended hybrid efficacy-effectiveness approaches and phased funding models that allow safe, validated tools to scale more quickly.

- Best Practices and Lessons Learned from Other Fields of AI

Dr. Andrew Trister, Chief Medical and Scientific Officer at Verily, explained his perspective on GenAI mental health tools by drawing parallels to how the autonomous-vehicle industry created a shared taxonomy for safety and oversight. He noted that the rapid adoption of consumer LLM chatbots, combined with major shortages in mental health care, has led many people to seek health advice from unregulated AI systems. He distinguished between clinical settings, where a clinician may be in or on the loop, and consumer contexts, where design features such as sycophantic behavior can create risks. Drawing on the Society of Automotive Engineers' six-level autonomy framework, he proposed using a similar structured taxonomy for GenAI interfaces in health care. He reasoned that establishing common language and levels of autonomy is necessary before creating consistent evaluation methods, guardrails, and safety and efficacy standards. He concluded that mental health practitioners are in short supply,

GenAI tools could augment them, and clear taxonomy is essential for determining where each tool fits, from wellness coaching to fully autonomous triage and diagnostic support.

- Patient-Provider Considerations in the Use of GenAI-enabled Digital Mental Health Medical Devices

Brooke Trainum, Senior Director of Practice Policy at the APA, outlined how GenAI tools are increasingly used in mental healthcare but present significant risks, especially when interacting directly with patients. She warned that these models can overpromise, mislead users, reinforce harmful beliefs, and divert people from proven treatments, while never replicating the empathy and complexity of the patient-provider relationship. Providers face liability, workflow, cost, and oversight challenges without clear regulation, and patients face privacy, safety, and ethical concerns. She stressed that there is no high-quality evidence that GenAI can deliver mental health treatment and calls for standardized labeling, transparency, human oversight, patient-centered design, diverse training data, controlled research, restricted access for high-risk uses, and strong postmarket surveillance. She concluded that AI may become a useful tool but must be safe, effective, ethical, and integrated responsibly into care.

- Payor Perspectives on Digital Mental Health Technologies

Dr. Bradley Karlin of ARPA-H outlined how payors assess digital mental health technologies, emphasizing that they invest in measurable outcomes, durable engagement, and eventual cost reductions rather than in the apps themselves. He explained that payors now expect real-world evidence, not just RCT data, and remain concerned that most digital tools have extremely low sustained use, while GenAI tools risk promoting engagement without clinical value. He mentioned financial impact as another key factor, and also highlighted the importance of user experience, technical and clinical integration, and blended models that combine provider involvement with digital support. Current coverage trends favor FDA-cleared prescription digital therapeutics, while fully standalone conversational tools are not yet covered. He noted growing interest in upstream, population-health approaches, including PMPM models, and cited claims data showing that changes in depression severity correlate with shifts in total cost of care. He concluded that payors need clearer regulatory guidance, stronger escalation protocols, and reliable postmarket monitoring, and that market consolidation and mature partnerships will likely increase adoption as the field reaches a pivotal moment.

- Peterson Health Technology Institute Evaluations of Virtual Solutions for Depression and Anxiety and Opioid Use Disorder

Caroline Pearson of the Peterson Health Technology Institute explained how PHTI evaluates digital health solutions by reviewing published evidence on clinical effectiveness and economic impact to guide decisions by health plans, employers, and health systems. She summarized findings from PHTI's recent assessments of tools for depression, anxiety, and opioid use disorder. PHTI found that self-guided and blended-care tools are clinically effective for untreated individuals with mild to moderate depression and anxiety, and that PDTs and blended-care solutions deliver meaningful improvements when used alongside usual care. However, cost analyses showed that self-guided tools and PDTs generally produce net savings, while blended-care solutions increase overall spending. In the opioid-use-disorder review, Pearson reported that virtual medication-based treatment is clinically effective and comparable to in-person care, but current digital solutions produce only modest improvements in treatment retention and have not significantly expanded access to care. She concluded that medication-based OUD solutions merit wider adoption, while digital wraparound solutions require more cautious, evidence-driven expansion.

Open Committee Discussion

After the presentations, Dr. Bhatt introduced the Open Committee Discussion section and provided a short summary of the topics previously discussed.

Dr. Torous then asked Ms. Pearson about the control groups used in PHTI's evaluation of digital mental health tools, expressing concern that many studies relied on waitlist or inactive controls. Pearson agreed the issue was valid, noted that PHTI had already parsed results by control-arm type, and offered to share the stratified data, emphasizing that digital tools show the greatest benefit for people not receiving other care.

Dr. Dorsey asked Dr. Jacobson how his team managed, secured, and assessed recorded chatbot-participant interactions, and whether those data were used to train the model. Jacobson explained that all messages were monitored in near real time for safety during the trial, stored on HIPAA-compliant servers, and never used to train the model. His team intervened clinically when needed and reviewed conversations for appropriateness.

Dr. Ho asked LCDR Becker how metacognition-based evaluation might apply in mental health. LCDR Becker referenced work by Maxime Griot showing that LLM outputs often reflect test-taking skills rather than true reasoning, and described clinical experiences in which patients developed parasocial relationships with AI tools, undermining their intent to increase real-world social contact.

Dr. Goodman asked Ms. Pearson whether PHQ-9 assessments in blended-care studies were embedded in chatbots or administered separately, noting the safety implications of suicidal-ideation items. Pearson said the mode varied across studies but was typically digital and self-administered; blended-care models were appealing to purchasers partly because they enabled triage to human care.

Dr. Torous asked Dr. Jacobson about Therabot's safety plan and risk-classifier details. Dr. Jacobson stated that the system used a classifier to identify crisis risk and trigger escalation options, while humans reviewed all messages and conducted risk assessments when needed.

Dr. Jackson asked Dr. Arean about improving trial engagement and about alternatives to traditional designs, especially for mild-to-moderate populations. Dr. Arean said engagement is higher when some human contact is involved; incentives help but pose risks in remote trials; and missing-data analyses are essential at the effectiveness stage. She also described non-randomized and stepped-wedge designs and highlighted challenges recruiting diverse and harder-to-reach populations. In a follow-up, Dr. Ho asked about comorbidities, and Dr. Arean emphasized including comorbid participants in later-stage trials because they reflect real-world populations.

Dr. Rariy asked Dr. Jacobson about monitoring model drift, frequency of testing, bias detection, and responsibility for oversight, and Dr. Jacobson responded that, given rapid model evolution, developers must perform ongoing evaluations themselves, with FDA oversight focused on auditing the process rather than conducting continuous testing.

Committee Chair Dr. Bhatt asked Dr. Jacobson whether reminding users that a chatbot is not human helps prevent anthropomorphization. Jacobson said Therabot's design continuously signals that it is a tool, not a person. Dr. Bhatt then asked Ms. Trainum about patient-dashboard alerts in lower-risk contexts, and Ms. Trainum noted that frequent alerts are often ignored, complicating their usefulness.

Dr. Tom Maddox argued that reminders alone cannot overcome automation bias and that regulators may need to limit what non-human systems are allowed to do. Dr. Jacobson agreed that a therapeutic bond is expected in mental health tools but emphasized that well-designed systems should channel this connection toward treatment rather than companionship.

Dr. Clarkson raised concerns about the lack of clarity around accountability for AI-enabled mental health tools. She questioned where responsibility would lie once FDA-regulated devices enter the market, whether with developers, clinicians who use the tools, or patients themselves, emphasizing that accountability remains poorly defined and requires further discussion.

Dr. Jacobson acknowledged the complexity of the issue and cautioned against expecting perfection from these systems, comparing them to autonomous vehicles, where human performance sets the benchmark. He stated that when a tool directly causes harm, accountability should rest primarily with the developers, while recognizing that misuse by downstream users complicates attribution of responsibility.

Dr. Trister underscored the need to define intended use and risk across the full technological stack, from generalized AI models to deployed clinical applications. He highlighted current gaps in the system, including the fact that deployers, not developers, typically shoulder liability because technology companies lack malpractice frameworks, and he emphasized the need for mechanisms such as actuarial risk modeling and indemnification.

Dr. Arean suggested using clinician credentialing as a model for chatbot oversight, proposing standards for evaluating development teams, reviewing transcripts or simulated interactions, considering professional organization licensing pathways, and implementing ongoing surveillance and measurement-based care to ensure safety and quality over time.

Committee Discussion of the FDA Questions

For Question one, FDA asked the Committee to evaluate a prescription, LLM-based digital therapy, for adults with major depressive disorder who are not in therapy. The agency sought input on:

- Probable benefits and risks of automated, at-home AI therapy
- Appropriate risk-mitigation strategies
- Necessary *premarket* clinical evidence (endpoints, trial design, alternative evaluation methods)
- Needed *postmarket* monitoring (methods, metrics, safeguards)
- Key labeling elements for safe use

Committee members agreed that AI-based prescription therapy could expand access to mental-health support, reduce wait times, supplement crisis services, and offer personalized, scalable interventions. The technology may also enable more consistent outcome tracking and earlier identification of patients needing higher-level care.

However, members emphasized substantial risks: missed or misinterpreted harm signals, unsafe or hallucinatory advice, model drift, bias magnified at scale, privacy vulnerabilities, and inequities related to

digital access, language, and literacy. They also noted concerns about data ownership, commercial incentives, and potential overuse or dependence.

For premarket evidence, the Committee supported robust comparators beyond wait-list controls, minimized exclusion criteria, and endpoints that extend past PHQ-9 to include functional outcomes, patient-reported measures, false-negative rates for safety events, and stepwise evaluation beginning with clinician oversight. Members noted that generative AI may require new measurement approaches to assess therapeutic consistency and real-world relevance.

For postmarket monitoring, the group emphasized strong surveillance due to continual model updates. Key elements included monitoring for performance drift, tracking engagement patterns and potential overuse, establishing clear adverse-event reporting pathways for clinicians and patients, and preventing uncontrolled scope creep.

For labeling, members recommended explicit disclosure that the user is interacting with AI; clear purpose and limits of use; prescribing requirements; escalation and safety-net protocols; data privacy and cost transparency; and warnings about excessive use.

For Question two, FDA asked the Committee to evaluate potential expansions of a GenAI-enabled digital mental health device's indications, including: A) making the therapy device over-the-counter (OTC) for individuals already diagnosed with major depressive disorder (MDD); B) enabling the OTC device to autonomously diagnose and treat MDD without clinician involvement, including for people with no prior diagnosis; and C) further expanding to a multi-condition device that autonomously diagnoses and treats multiple “sadness-related” mental health conditions for undiagnosed users.

The Committee viewed all three proposed OTC expansions as significantly higher risk than the original prescription scenario. Members agreed that while increased access is important, autonomous OTC use for depressive symptoms introduces major safety, diagnostic, and equity concerns.

For OTC use in already-diagnosed MDD, the Committee felt this could only be considered for mild presentations and would require strong evidence equivalent to supervised use, reliable verification of diagnosis, clear escalation pathways, and long-term safety data demonstrating minimal risk. Safeguards against inappropriate use by others, identity controls, and harm-avoidance evidence were considered essential.

For OTC autonomous diagnosis and treatment in undiagnosed users, the Committee agreed that the risk is substantially greater. Accurate diagnosis requires ruling out medical and psychiatric comorbidities, assessing severity, and detecting suicidality, tasks current AI systems cannot reliably perform. Any future pathway would require high diagnostic concordance with clinicians, validated rule-outs, extensive RCT data, and mechanisms to stop use or escalate care when uncertainty or high risk is detected.

For multiple mental health conditions autonomous diagnosis and treatment, members described the risk as the highest of all. Expanding to multiple mood-related conditions compounds diagnostic complexity, increases the likelihood of missed comorbidities, and risks deepening health inequities if underserved populations receive bot-based care while others receive human care. This scenario would require a very high evidentiary bar, multi-layered assessment tools, validated multimodal biomarkers, substantial long-term R&D, and robust real-world monitoring and escalation systems.

Across all scenarios, members stressed the need for a clear, risk-tiered regulatory framework; precise definitions distinguishing therapy from wellness functions; strong privacy and identity protections; controlled-access pathways; and active postmarket surveillance to detect drift, deterioration, or emerging harms.

For Question three, FDA asked whether the Committee's conclusions for Question one would change if the device were intended for children and adolescents (≤21 years) and, if so, how.

Committee members agreed that applying AI-enabled digital mental health devices to children and adolescents introduces substantially greater risk than its use by adults. While acknowledging severe access gaps for youth, the group emphasized that developing brains, variable maturity, caregiver dynamics, and the known harms of excessive digital engagement require a much higher evidentiary bar. For prescribed use, members supported developmentally appropriate design, strict limits on use, continuous clinician oversight, and large, well-controlled pediatric trials that include pediatric mental-health specialists. Devices should return data to clinicians, provide clear escalation pathways, and incorporate features ensuring privacy and safety across different developmental stages.

The Committee expressed strong discomfort with any future OTC or autonomous use in this population, stressing the need to clearly distinguish wellness tools from medical therapy and to prevent scope creep. Members also highlighted potential equity concerns if autonomous tools disproportionately serve underserved youth while others receive clinician-delivered care.

Overall, the group urged rigorous pediatric evidence, specialist involvement, strict developmental guardrails, robust monitoring, and protections against unmonitored or inappropriate use.

Closing Remarks

The Chair stressed the essential role of active participation and open dialogue across all groups represented in the Digital Health Advisory Committee. Thanks were extended to members of the Committee, FDA representatives, public speakers, patients, industry, clinicians, and other stakeholders for their thoughtful contributions. The remarks highlighted a shared commitment to confronting challenging mental-health issues and to strengthening the scientific and structural foundations needed for future work. After acknowledging this collective effort, the meeting was formally adjourned.

I approve the minutes of the meeting as recorded in this summary.

Ami Bhatt, M.D.,

Chairperson

I certify that I attended this meeting on November 6, 2025

and that these minutes accurately

reflect what transpired.

Letise W. Williams -S Digitally signed by Letise W. Williams -S
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Letise Williams, Designated Federal Officer