FDA Committee and New Study Examine Generative AI Digital Mental Health Medical Devices

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The Food and Drug Administration's (FDA's) Digital Health Advisory Committee met on November 6 to discuss the increased demand for "AI therapists" and other AI-based medical devices that provide a wide array of mental health therapies and interactions with chatbots functioning as virtual therapists. The Committee believes that as these devices continue evolving in complexity, regulatory measures will need to address such challenges as appropriate clinician oversight to help ensure safety and effectiveness while also promoting technological innovation to support public mental health efforts. (Materials from the Committee's meeting are available here.) A study published the very next day in *JAMA Network Open* reinforced concerns specifically with regard to adolescents and young adults relying upon generative AI chatbots for mental health advice. The study noted the absence of both standardized benchmarks for evaluating AI-generated mental health advice and transparency about the datasets training these models. In addition, it found that Black respondents reported lower perceived helpfulness, indicating possible cultural competency gaps in the burgeoning platforms. HLB has been monitoring as policymakers examine these issues. Further information can be followed through our Digital Health Blog.