AMERICAN PSYCHIATRIC ASSOCIATION

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Commissioner Robert M. Califf, M.D.
U.S. Department of Health and Human Services
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)

Re: Increasing Patient Access to At-Home Use Medical Technologies (FDA-2023-N-1956)

Dear Commissioner Califf:

The American Psychiatric Association (APA), the national medical specialty society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to respond to FDA's request for information regarding access to medical devices designed to be safe and effective when used outside of traditional clinical settings, for example, medical devices intended for use in the home. APA shares FDA's commitment to equitable, accessible, and high-quality care in community settings where patients are most comfortable. Further, APA shares FDA's commitment to extending access to high-quality care through technology-enabled psychiatry. However, **APA urges the maintenance of a high standard of evidence to support device safety and effectiveness before approving devices for at-home use without the supervision of a clinician.**

For these purposes, the APA recommends that FDA consider at-home medical technologies to be analogous to over-the-counter (OTC) pharmaceuticals and apply a similar threshold of risk, safety, and effectiveness. Since most OTC pharmaceuticals were initially approved by FDA and marketed to the public as a prescription drug that then received OTC approval, we expect that the significant majority of devices used in home and community settings would begin as clinician-supervised technologies, analogous to prescription pharmaceuticals.[1] **As in OTC pharmaceutical applications, device developers should be required to submit not just data from randomized, controlled trials, but data that "demonstrate that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional."**[2]

[1] https://www.fda.gov/media/140598/download
[2] https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches

Because digital health apps are often marketed and deployed directly to patients, the APA previously convened a group of experts to evaluate the effectiveness and safety of digital mental health interventions. This group developed the APA's App Advisor, a framework for evaluating an app's appropriateness for a specific patient.[3] APA's App Evaluation Model employs a hierarchical assessment structure to assist clinicians and patients in understanding the appropriateness and safety of using a mental health app. The model recognizes that many app-based interventions are untested according to typical clinical standards, requiring a more comprehensive evaluation by potential users to match a digital intervention to a clinical objective. Accordingly, the model recognizes the central role that clinicians can play in helping patients access safe and appropriate technologies. The APA's App Advisor does not recommend or rate apps but rather provides a framework for assessing them on a case-by-case basis. The "clinical foundation" element of the assessment helps users evaluate the potential benefits of the app, including that it is reasonable and not harmful ("face validity"), does what it claims to do, and is based on a clinical foundation relevant to the intended purpose. **APA encourages FDA to consider using a similar framework in developing the regulatory standards a device must meet for at-home use.**

The work of the APA's App Advisor has demonstrated the reality and the challenges of direct-to-consumer mental health technologies. When technologies are delivered without adequate scientific approval processes and without expert oversight, ineffective interventions can make it into the hands of patients. Many of these apps are considered "low risk" by regulators and the public alike, but there is a risk that people with potentially serious mental illness will be exposed to untested interventions through direct-to-consumer use of technologies intended for therapeutic purposes. **There is significant risk in falsely leading a person with mental illness to believe that they are receiving an effective treatment, particularly when this app-based treatment replaces treatment by a clinician.** Furthermore, these technologies may be considered an option for those whose conditions aren't serious enough to require psychiatric care but also for those who cannot access psychiatric care due to lack of transportation, insurance coverage, childcare, or other health-related social determinants. As such, these technologies risk worsening health disparities, particularly if they are insufficiently tested.

These technologies are more appropriately considered an *adjunctive to care,* recommended by a clinician who is themselves familiar with the technology and can affirm that it does not create unique safety hazards to the patient. For example, AI-driven chatbots have often been proposed as a promising strategy for the delivery of cognitive behavioral therapy (CBT) for mild to moderate depression or anxiety in home and community settings. Reports have accumulated of the risks of AI-generated content targeted at people with mental illness; for example, the Center for Countering Digital Hate (CCDH) found instances of harmful content about eating disorders in generative AI tools 41% of the time.[4] While some of these risks can be managed through content controls, clinicians and other mental health experts also need to be in a position to mediate patients' use of technology intended for therapeutic purposes.

[3] https://www.psychiatry.org/psychiatrists/practice/mental-health-apps
[4] https://counterhate.com/research/ai-tools-and-eating-disorders/

Psychiatrists have adapted in large numbers to delivering care via telehealth to accommodate patient needs and preferences, improve health equity, and improve access to care, and should remain a component of patient engagement with appropriate digital mental health interventions. **Ultimately, until products are proven effective for unsupervised use to the same threshold as OTC pharmaceuticals, digital interventions should be used with the support and engagement of a clinician.**

If you have any questions or would like to discuss our comments further, please contact Abby Worthen (aworthen@psych.org), Deputy Director, Digital Health.

Sincerely,

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CEO and Medical Director
American Psychiatric Association