

Docket No. FDA-2025-N-2338
Digital Health Advisory Committee – Generative
Artificial Intelligence-Enabled Digital Mental Health
Medical Devices

The American Consumer Institute Center for Citizen Research (ACI) is a nonprofit 501(c)(3) educational and research institute with the mission to identify, analyze, and protect the interests of consumers in legislative and rulemaking proceedings. We believe that the recent Food and Drug Administration consideration to treat AI mental health chatbots as medical devices has noble intentions, but it would ultimately be a mistake. Regulation threatens to hinder consumer-friendly services operating in an industry with strong, privately administered professional standards. It also downplays the fact that mental health chatbots do meet the criteria of medical devices because they are not advertised as tools that diagnose, cure, mitigate, treat, or prevent a specific disease. Instead, AI mental health chatbots operate and are advertised as wellness apps, not medical devices. For all of these reasons, the FDA should preserve the current classification structure of medical device regulations, especially when applying the rules to general wellness chatbots.

AI Mental Health Chatbots are Not Medical Devices

According to the 21 Code of Federal Regulations Part 801, the FDA considers a product or service to be a medical device if it intends to diagnose, cure, mitigate, treat, or prevent a specific disease, including mental health conditions. AI mental health chatbots do not fall in this category because they aim only at providing general wellness, not medical prescription or treatment. For example, Rejoyn and DaylightRX, both apps with software that intend to either diagnose, cure, mitigate, treat, or prevent underlying mental health conditions, are considered medical devices (Figure 1). Many other AI chatbots, such as Ash, Wysa, and Therabot, operate only as wellness apps and do not serve as a replacement for psychiatrists or therapists.

Ash, an AI mental health chatbot developed by Slingshot AI, explicitly disclaims that it “provides emotional wellbeing support through conversations over text or voice chat” and that it “isn’t designed to treat, track or diagnose disorders or as a replacement for professional help.”¹

¹ Ash. “Frequently Asked Questions: What Ash can do, Is Ash a replacement for professional help?” <https://www.talktoash.com/#:-:text=for%20the%20trees.%22-,FAQs,-What%20can%20Ash>

Another mental health care chatbot, Wysa, disclaims something similar: “Wysa App is intended for use as emotional wellbeing support by individuals aged 13+” and “it is not a substitute for professional medical advice, and does not provide medical advice or diagnoses.”² The chatbot TheraBot also explicitly has a medical disclaimer saying that “TheraBot’s AI-powered tools are designed to provide support and information but are not intended to replace professional medical advice, diagnosis, or treatment.”³

While the FDA has long held that intended use is determined by the totality of the evidence, these disclaimers are strong evidence that “general wellness” chatbot companies do not intend for these products to be used as medical devices. Importantly, regulating chatbots with materially different uses as if they all have the same intent would be a mistake. By subjecting “general wellness” chatbots to the regulatory weight of the FDA it threatens to add business expense and regulatory complexity to applications premised on delivering affordable wellness advice to consumers.

Figure 1: Different AI Mental Health Chatbots Have Different Purposes⁴

Feature	Rejoyn / Daylight RX (cleared)	Therapists, Mental Health Professionals	Ash / Wysa / TheraBot (wellness)
Diagnose, cure, mitigate, treat, or prevent	Yes	Yes	No
Requires clinical information	Yes	Yes	No
Output	Personalized medical interpretations or recommendations	Personalized counselling based on the clinical record	General suggestions or emotional support
Claims	"Treat depression." "Treats Anxiety"	Provides diagnosis, prevention methods, treatment, and cures	"Emotional support or well-being"
Cost to the user	\$50–\$200+/course + insurance	\$122–\$227 per session	Free or <\$50/month

² Wysa. Frequently Asked Questions: What is the intended use statement for the Wysa app?
<https://www.wysa.com/faq#:~:text=Wysa%20App%20is%20intended,enduring%20mental%20health%20problems.>

³ TheraBot. Terms and Conditions: Medical Disclaimer.
<https://www.trytherabot.com/terms#:~:text=5.%20Medical%20Disclaimer,Lifeline%20at%20988.>

⁴ Adapted from: Kristen Garafano. How much does therapy cost? SimplePractice, February 27, 2025.
<https://www.simplepractice.com/resource/how-much-does-therapy-cost/>; Rejoyn “Cost and Savings”
https://www.rejoyn.com/how-to-get-rejoyn#:~:text=Cost%20and%20savings,the%20pharmacy%20checkout.*; TheraBot. Terms and Services. <https://www.trytherabot.com/>; Wysa. Frequently Asked Questions: Is it free to use Wysa?
<https://www.wysa.com/faq#:~:text=Is%20it%20free%20to%20use%20Wysa%3F>; Ash. Main website:
<https://www.talktoash.com/>.

FDA Regulation as a Threat to General Mental Health Wellness

The shortage of mental health care professionals in the United States has been persistent for years. As recently as 2021, one-third of people 18 and older had unmet needs for mental health care services.⁵ Today, more than 122 million Americans with a mental health condition do not have access to mental health professional care.⁶ The shortage has also increased access costs, ranging from \$122 to \$227 for a single session, depending on the state.⁷ More concerning, the median wait time to get an appointment is 67 days, which is over 2 months, a time that could be crucial to worsening the mental health condition of a person.⁸ For many of the more drastic cases, consumers benefit from access to mental health chatbots that are registered as medical devices with the FDA. In other cases, wellness chatbots—which are not intended to treat underlying conditions but still can offer general support—are becoming increasingly helpful to consumers in varying states of mental health wellness. General wellness chatbots can provide guidance to consumers and can sometimes even just serve as an outlet where consumers can vent and get re-assurance. About half of the consumers use AI mental health chatbots because they are easy to access and are available all the time. Another 41 percent use them because of the anonymity they perceive when interacting. And 31 percent like them because of the personal recommendations and guidance they get.⁹ Different chatbots serve consumers in different situations—but their market value is undeniable.

The advent of AI is enabling mental health chatbots to fill in the shortage with all different kinds of services, including some chatbots that are not therapy but that do help people cope. In this sense, the FDA's consideration to label mental health chatbots as medical devices would cause more harm than good. This is mainly because such a regulation would increase expenses for a technology that is already providing valuable assistance to people, ignore the fact that these AI chatbots are being developed by professionals and are becoming safer, and, more importantly, force these tools to meet a criterion they do not have. Shoehorning AI general wellness apps into the medical device category would also add many burdensome regulations, such as pre-market performance paperwork, risk management designs, and post-market reports, and would disincentivize their development. All of these regulatory burdens drive up the cost of access—but more importantly, they threaten to disrupt business models that are delivering valuable general wellness information to consumers at affordable prices.¹⁰

⁵ Modi H, Orgera K, Grover A. Exploring Barriers to Mental Health Care in the U.S. Washington, DC: AAMC; 2022. <https://doi.org/10.15766/raia3ewcf9p>

⁶ Anthony Carter, "A Workforce Under Pressure: Preparing the Behavioral Health Workforce for Today and Tomorrow." National Council for Mental Well-Being, September 25, 2025. <https://www.thenationalcouncil.org/behavioral-health-workforce-under-pressure-preparing-today-tomorrow/>

⁷ Kristen Garafano. How much does therapy cost? SimplePractice, February 27, 2025. <https://www.simplepractice.com/resource/how-much-does-therapy-cost/>

⁸ Solace. How Long Should You Wait for a Psychiatrist Appointment? Solace. October 8, 2025. <https://www.solace.health/articles/psychiatric-appointment-wait-time>

⁹ Statista. (2024). Share of respondents who reported using an AI chatbot for mental-health purposes in the U.S., as of May 2024. Statista. <https://www.statista.com/statistics/1559906/ai-chatbot-use-mental-health/>

¹⁰ Pablo Garcia Quint, "Chatbots Are Not Medical Devices," Reason, December 3, 2025. <https://reason.com/2025/12/03/chatbots-are-not-medical-devices/>

AI Mental Health Chatbots are Improving

The FDA must also consider that AI mental health chatbots are continuously improving performance, and existing model risks are being meaningfully addressed. Even though industry standards and product quality has been consistently high for years, mental health chatbots are becoming even safer, which leaves them out of the scope of what the FDA considers high-risk products. A growing number of AI mental health chatbots on the market are incorporating input from psychologists, psychiatrists, and mental health professionals into their responses. This has been the case for AI mental health chatbots like Ash, Earkick, Elioma, Wysa, and many more.¹¹

Unlike general-purpose AI chatbots, which can provide some mental health guidance, AI mental health chatbots are designed to deal with sensitive conversations and have a higher standard to mitigate risks. That's why AI mental health chatbots are safer and more effective than general-purpose chatbots. The evidence for their effectiveness is overwhelmingly positive. Ash, for instance, has found that after 10 weeks, out of all people using their chatbot, 76 percent of them had fewer depressive symptoms and 77 percent were less anxious.¹² Wysa had overwhelmingly positive feedback, with 91 percent of users finding conversations with the chatbot helpful and positive in dealing with mental health issues. After 8 weeks of use, users saw improvements in their self-resilience.¹³ Independent studies have also found that AI-based conversational agents are able to significantly reduce depressive and distress symptoms.¹⁴ Other studies have found that AI chatbots can improve short-term behavioral intention and mental health literacy compared to people who don't use these chatbots.¹⁵

FDA Regulation Would be a Mistake

The FDA must balance the upsides and downsides of regulating mental health chatbot software just as it does with software in other medical devices. Accordingly, the agency must consider two separate points. First, the FDA must recognize that general wellness apps are providing mental health services to consumers at prices they can afford.

¹¹ Ash. "Our Approach to Safety" July 10, 2025. <https://www.talktoash.com/posts/our-approach-to-safety#:~:text=Acknowledging%20that%20mental,the%20right%20guardrails>; Earkick. "Our Story" <https://earkick.com/about/>; Elomia. "Real people building AI the right way" <https://elomia.com/about-us>; Wysa. "Frequently Asked Questions: What is the science behind the suggested techniques?" <https://www.wysa.com/faq>

¹² Ash. "Connection, hope, and real progress: findings from our first real-world study." November 12, 2025. <https://www.talktoash.com/posts/connection-hope-and-real-progress-findings-from-our-first-real-world-study>

¹³ Wysa. "Insights That Drive Better Mental Health Care: Wysa Reports" <https://www.wysa.com/reports>

¹⁴ Li, H., Zhang, R., Lee, YC. et al. Systematic review and meta-analysis of AI-based conversational agents for promoting mental health and well-being. *npj Digit. Med.* 6, 236 (2023). <https://doi.org/10.1038/s41746-023-00979-5>

¹⁵ Tong ACY, Wong KTY, Chung WWT, Mak WWS. Effectiveness of Topic-Based Chatbots on Mental Health Self-Care and Mental Well-Being: Randomized Controlled Trial. *Journal of Medical Internet Research* 2025; doi: [10.2196/70436](https://doi.org/10.2196/70436)

General wellness apps can do this because they operate in a generally permissive regulatory environment, allowing them to pass on business savings to consumers through lower prices. Adding regulatory red tape not only threatens to raise consumer prices on services shown to be a net-positive, but it also threatens to disrupt the low-cost business model that makes delivering those affordable services possible. In an environment where consumers struggle to find affordable mental health alternatives, raising prices would further deter access to these services.

Second, the FDA should consider whether now is the appropriate time to regulate, and therefore further evaluate whether revisiting this discussion after wellness apps have had more time to mature would be more appropriate. To be clear, many AI chatbots do not fit the criteria of a medical device now and are also unlikely to fit that criteria in the future—but that could be revisited as the technology deepens and the policy implications become more clear. AI chatbots already face stiff competition to provide the best services to consumers, and as economic theory would indicate, they are responding to legitimate public concerns by improving their products. The FDA must therefore consider whether it would make more sense to regulate AI chatbots now, potentially slowing industry response to consumer demand, or wait to re-evaluate the market once those improvements have been given time to calcify.

Conclusion

AI general wellness chatbots are highly accessible, affordable, increasingly safe, and do not meet the criteria the FDA has historically used to determine whether products or services are medical devices. In many ways, labeling general wellness chatbots would undermine each of these pillars, at a great cost to consumer well-being. The FDA should not regulate general wellness chatbots as medical devices.

Respectfully submitted,

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