NOTE

"ALEXA, AM I DEPRESSED?" REGULATING AND PATENTING MENTAL HEALTH CHATBOTS IN THE UNITED STATES AND FRANCE

Beril Karakoyun†

Introduction

Artificial Intelligence (AI) chatbots have rapidly entered everyday life. When users decide to rely on them for mental health guidance, these chatbots begin to function as substitutes for licensed clinicians. Users often treat these systems as safe and confidential, without understanding their technical limits or how their sensitive mental health data is collected, stored, and used.

---

† Paris 1 Panthéon-Sorbonne University, Class of 2024; J.D. Candidate, Cornell Law School, Class of 2027.

In September 2025, the parents of a sixteen-year-old boy who died of suicide discovered that he had confided extensively in an AI chatbot that discouraged him from seeking outside help and even offered to draft a suicide note.[1] Their testimony before Congress illustrates a troubling reality: users of AI chatbots consider them trusted sources for their mental health, even though these are statistical models designed to predict plausible responses, without a license, clinical training, and without clinical experience.[2]

This reliance operates in a regulatory gray zone, while existing laws worldwide struggle to address such gaps. This inadequate regulation leaves users, particularly minors, vulnerable and ill-equipped to assess these systems' limits. France's recent designation of mental health as a national cause for 2025 reflects more willingness to act in the mental health field.[3]

This Note focuses specifically on mental health chatbots, rather than AI health tools broadly. Unlike physical health, where care ultimately requires physical intervention that no chatbot can replicate – for now –, therapy is fundamentally conversational, making it uniquely susceptible to be substituted by AI chatbots. This Note examines how different legal systems respond to this challenge, while still prioritizing innovation. Part I provides background on the mental health crisis and the rise of AI mental health tools as a stopgap for the shortage of therapists available. Part II compares the United States and the French models, showing how different jurisdictions can have different priorities in how they frame their laws, with particular attention to France and its use of soft law in 2025. It also analyzes the role of patent law with a specific U.S. patent application directed to an AI mental health technology. Finally, part III explores alternatives to ensure users' safety while preserving innovation.

I. Background

A. The Mental Health Crisis and the Turn to AI

The sudden use of chatbots in the mental health context cannot be understood without recognizing the broader mental health crises unfolding across jurisdictions.[4] Suicide claimed an estimated 727,000 lives in 2021 and is a leading cause of death among young people.[5] Still, the median government spending on mental health remains at just 2% of health budgets,

---

1. Rhitu Chatterjee, *Their Teenage Sons Died by Suicide. Now, They Are Sounding an Alarm About AI Chatbots*, NPR (Sept. 19, 2025), https://www.npr.org/sections/shots-health-news/2025/09/19/nx-s1-5545749/ai-chatbots-safety-openai-meta-characterai-teens-suicide [https://perma.cc/EYC5-MXK5].

2. *Id*.

3. *La Santé Mentale, Grande Cause Nationale 2025*, SOLIDARITES.GOUV (Mar. 24, 2025), https://solidarites.gouv.fr/la-sante-mentale-grande-cause-nationale-2025 [https://perma.cc/E85E-KRN7].

4. *WHO Sounds Alarm as Mental Health Conditions Soar Past One Billion Worldwide*, UNITED NATION NEWS (Sept. 2, 2025), https://news.un.org/en/story/2025/09/1165759 [https://perma.cc/CYL5-4LYB].

5. *Id*. WHO warns that mental disorders affect one in seven people, yet 71% of psychosis cases receive no care.

with low-income countries spending as little as four cents per person on mental health.[6] The global median number of mental health workers stands at thirteen per 100,000 people worldwide.[7]

The United States is currently facing a similar crisis with 23.4% of adults, or sixty million people, experiencing a mental illness in 2024.[8] These people do not have access to adequate mental health care, with one in four adults reporting an unmet need for mental health treatment.[9] Over 169 million Americans – more than half the population – lived in federally designated Mental Health Professional Shortage Areas (MHPAs) in 2025.[10]

In France, Santé Publique France's Baromètre [*French Public Health Barometer*] reported that 16% of adults lived with depression in 2024.[11] One third of young people suffered from a mental health disorder,[12] with the number of child psychiatrists falling by 34% between 2010 and 2022.[13] These numbers are in part due to the aftermath of the COVID-19 pandemic, which students and other young people felt more acutely through the lockdowns, social distancing, and other restrictions, seen as "ruining a once-in-a-lifetime period that cannot be replicated."[14] As a result, French Prime Minister Barnier promoted mental health as the *Great National Cause* for 2025,

---

6. *Id*.

7. *Id*.

8. *The State of Mental Health in America (2025)*, MENTAL HEALTH AMERICA, https://mhanational.org/wp-content/uploads/2025/09/State-of-Mental-Health-2025.pdf [https://perma.cc/HC4P-ZDW8]. Forty-six million people (17.7% of adults) in the U.S. had a substance use disorder in 2024 and fourteen million people (5.5% of adults) reported experiencing serious thoughts of suicide. While the numbers improved slightly from 2023 to 2024, nearly 2.8 million youth (11.3%) experienced a major depressive episode with severe impairment and three million youth still reported frequent thoughts of suicide in 2024.

9. *Id*. 77.09% of all adults with a substance use disorder did not receive treatment and five million people (9.2% of adults) with a mental illness were uninsured.

10. Jamelia Hand, *Jobs Report 2025: What It Means for Mental Health and Substance Use Roles*, VANTAGE CLINICAL CONSULTING (Aug. 18, 2025), https://www.vantageclinicalconsulting.com/post/jobs-report-2025-what-it-means-for-mental-health-and-substance-use-roles [https://perma.cc/TBM6-ZV93].

11. *Résultats du Baromètre 2024 et Campagne "À qui Ressemble": Santé Publique France S'engage pour la Santé Mentale*, SANTÉ PUBLIQUE FRANCE (Nov. 12, 2025), https://www.santepubliquefrance.fr/presse/2025/resultats-du-barometre-2024-et-campagne-a-qui-ressemble-sante-publique-france-s-engage-pour-la-sante-mentale [https://perma.cc/WZ7B-74BW].

12. Julie Chouteau et al., *Mental Health Crisis Reaches New Lows for French Teens*, FRANCE 24 (Dec. 2, 2025), https://www.france24.com/en/tv-shows/france-in-focus/20251202-mental-health-crisis-reaches-new-lows-for-french-teens [https://perma.cc/E3XJ-MZUB].

13. Gabriela Galvin, *France's Youth Mental Health Crisis has Gotten Worse since the Pandemic, Study Shows*, EURO NEWS (Jan. 9, 2025), https://www.euronews.com/health/2025/01/09/frances-youth-mental-health-crisis-has-gotten-worse-since-the-pandemic-study-shows [https://perma.cc/N3CZ-RK34].

14. *Id*. Marcel Marchetti from the advocacy group Mental Health Europe observed that "The situation in France is not an isolated case and COVID-19 has put to the fore the shortcomings of our mental health system"; NEWS WIRES, *French StudyLiinks Covid-19 to Sharp Rise in Depression Among Young People*, FRANCE 24 (Feb. 14, 2023), https://www.france24.com/en/europe/20230214-french-study-links-covid-19-to-sharp-rise-in-depression-among-young-people [https://perma.cc/3N8F-YXK4].

meaning that it received priority objectives from the government through a plan to develop prevention and improve access to care.[15]

People often cannot access mental health care for practical reasons and are subjected to external barriers.[16] Many live in rural areas where there are few or no therapists nearby.[17] Others cannot afford regular therapy sessions, which can cost over $100 per visit.[18] Some work irregular hours or face long waitlists and cannot attend appointments during standard office hours.[19] People may also lack the mental health knowledge necessary to recognize their symptoms as mental health problems or to know where to seek help.[20] But they mostly avoid care because of the stigma that remains around mental health problems, concerns about confidentiality, or past negative experiences with professionals.[21]

These conditions explain the turn to AI mental health tools. Chatbots respond immediately, operate at all hours, and require little to no financial investment.[22] They offer a degree of anonymity that lowers the barrier to seeking help, particularly for users who want "judgment-free" conversations.[23] In moments of distress, these tools often function as first points of contact when no human professional is available.[24]

The COVID-19 pandemic accelerated this shift.[25] The lockdowns and social distancing led people to rely more on connected devices, while access to in-person care became nearly impossible in hospitals overcrowded with COVID-19 patients.[26] When social ties weakened, many users sought reassurance online. The expansion of digital mental health applications followed this demand.[27]

Available data further suggests that reliance on chatbots is no longer marginal. A 2021 national survey indicated that a significant share of users

---

15. *Great National Cause: Mental Health, also for Students*, CAMPUS FRANCE (Oct. 25, 2024, at 12:25 CET), https://www.campusfrance.org/en/actu/grande-cause-nationale-la-sante-mentale-pour-les-etudiants-aussi [https://perma.cc/RAN9-W7T7].

16. Yvonne Schaffler et al., *Perceived Barriers and Facilitators to Psychotherapy Utilisation and How They Relate to Patient's Psychotherapeutic Goals*, 10 HEALTHCARE 2228 (2022).

17. *Id*.

18. Jess Barron, *The Average Cost of Therapy in America for Each State*, SIMPLE PRACTICE (Mar. 11, 2025), https://www.simplepractice.com/blog/average-therapy-session-rate-by-state/ [https://perma.cc/LWY7-8GCG]. In 2024, the average cost of therapy was $139 in the U.S., with the lowest cost in Missouri ($122) and the highest cost in North Dakota ($227).

19. Schaffler, *supra* note 16.

20. *Id*.

21. *Id*.

22. *AI Therapy vs. the Real Thing*, EVOKE PSYCHOLOGY (Aug. 12, 2025), https://www.evokepsych.com/blog/ai-therapy-vs-the-real-thing [https://perma.cc/D93G-2N9Y].

23. *Id*.

24. *Id*.

25. Luke Balcombe, *Digital Mental Health Post COVID-19: The Era of AI Chatbots*, 6 ENCYCLOPEDIA 32 (2025), https://www.mdpi.com/2673-8392/6/2/32.

26. *Id*.

27. *Id*.

rely exclusively on chatbots without consulting a human therapist,[28] and app markets report thousands of downloads for these types of chatbots.[29] AI chatbots have therefore moved beyond experimental use and are incorporated into the routine of many users.

However, the use of chatbots to help with mental health problems is far from the perfect solution: while chatbots may offer temporary reassurance, they create risks that traditional mental health systems are designed to prevent. Indeed, some chatbot users have developed or experienced worsening psychosis, such as paranoia and delusions that they are chatting with a real person, due to the realism of the interaction.[30] This phenomenon known as "AI psychosis" worsens cognitive dissonance in users[31] and led to suicide in some cases.[32] These chatbots can also generate inaccurate or harmful advice and encourage self-diagnosis.[33] They rely on large volumes of sensitive personal data, offered voluntarily by users who lack understanding of how their information is stored and protected.[34]

Taken together, these conditions explain why AI chatbots have moved from supplemental tools to primary sources of mental health support for many users.[35] What began as a limited response to address gaps in care has expanded into a range of chatbot systems that users employ either alongside therapists, or more concerningly, in their place.

B. AI Chatbots as Substitutes for Therapists

Users can choose from different categories of digital mental health tools. Wellness applications such as *Headspace* or *Calm* only provide services for guided meditation, sleep assistance, or stress management.[36] Similarly, applications that offer virtual therapy platforms like *Talkspace* or *BetterHelp*

---

28. MDR Haque & Sabirat Rubya, *An Overview of Chatbot-Based Mobile Mental Health Apps: Insights From App Description and User Reviews*, 11 JMIR MHEALTH & UHEALTH E44838 (2023). 22% of adults used a mental health chatbot and 47% said they would be interested in using it if needed. Nearly 60% said they began this use during the COVID-19 pandemic and 44% said they used chatbots exclusively and did not see a human therapist.

29. *Id*. (more than 500,000 downloads in 2021)

30. Søren Dinesen Østergaard, *Will Generative Artificial Intelligence Chatbots Generate Delusions in Individuals Prone to Psychosis?*, 49 SCHIZOPHRENIA BULL. 1418 (2023).

31. *Id*.

32. John Yang & Kaisha Young, What to Know about 'AI Psychosis' and the Effect of AI Chatbots on Mental Health, PBS NEWS (Aug. 31, 2025), https://www.pbs.org/newshour/show/what-to-know-about-ai-psychosis-and-the-effect-of-ai-chatbots-on-mental-health [https://perma.cc/4253-UB7S].

33. Alexandrine Royer, *The Wellness Industry's Risky Embrace of AI-Driven Mental Health Care*, BROOKINGS (Oct. 14, 2021), https://www.brookings.edu/articles/the-wellness-industrys-risky-embrace-of-ai-driven-mental-health-care/ [https://perma.cc/A934-DPR7].

34. *Id*.

35. Balcombe, *supra* note 25.

36. Stephanie Thurrott, *Mental Health Apps and Chatbots: Can They Really Help You Feel Better?*, Banner Health (Nov. 11, 2025), https://www.bannerhealth.com/healthcareblog/advise-me/the-pros-and-cons-of-mental-health-apps-and-chatbots [https://perma.cc/CN3Z-A8ES].

solely connect patients with licensed therapists for counseling sessions over chat, video, or messaging.[37] These tools rely on static or pre-recorded material and, even if they can use AI for administrative use, do not interact dynamically with users.[38] These platforms fall outside the scope of this Note's analysis, as they facilitate access to human care rather than acting as substitutes for it.

Instead, the focus here is on AI chatbots that act as substitutes for therapists. Unlike the tools described above, these chatbots engage users directly and generate personalized responses.[39] Users provide input by writing text[40] and the system processes this using Natural Language Processing (NLP), which allows the chatbot to recognize, interpret, and respond to human language.[41] Most modern chatbots are built on Large Language Models (LLM), trained on massive datasets drawn from books, websites, and online conversations.[42] They generate responses by predicting the most statistically likely sequence of words given a prompt.[43] Finally, they use generative AI (GenAI) to produce original responses in real time, though that content can be inaccurate, misleading or harmful.[44] These features explain why such chatbots can resemble a therapy session, even without any professional qualifications.[45]

Building on this shared technical structure, AI chatbots used in the mental health context can be grouped into three categories. First, direct-to-consumer entertainment chatbots are designed for general conversation and engagement rather than mental health support.[46] Examples include *ChatGPT*, *Meta AI*, *Character.AI*, or *Replika*.[47] These systems rely on LLMs and GenAI to generate open-ended responses, but are not grounded in psychological

37. *Id*.

38. *Id*.

39. *Id*.

40. Michael Ouellette, *What are Input and Output Tokens in AI?*, ENGINEERING.COM (Nov. 18, 2024), https://www.engineering.com/what-are-input-and-output-tokens-in-ai/ [https://perma.cc/VJK5-24JM].

41. *Basics of Artificial Intelligence*, AMERICAN PSYCH. ASSOC. (Aug. 19, 2024), https://www.apaservices.org/practice/business/technology/tech-101/basics-artificial-intelligence?utm_source=apa.org&utm_medium=referral&utm_content=/practice/artificial-intelligence-mental-health-care [https://perma.cc/4ZRW-G5FS].

42. *Id*.

43. Cole Stryker, *What are Large Language Models (LLMs)?*, IBM (last visited Apr. 4, 2026), https://www.ibm.com/think/topics/large-language-models [https://perma.cc/24VC-BJMF].

44. *Basics of Artificial Intelligence, supra* note 41.

45. Zara Abrams, *Using Generic AI Chatbots for Mental Health Support: a Dangerous Trend*, AMERICAN PSYCH. ASSOC. (Mar. 12, 2025), https://www.apaservices.org/practice/business/technology/artificial-intelligence-chatbots-therapists [https://perma.cc/HPL3-HLKP].

46. *Id*. Tanzeem Choudhury & Qian Yang, *Cornell AI Experts on Chatbots, Mental Health*, CORNELL CHRONICLE (Aug. 28, 2025), https://news.cornell.edu/media-relations/tip-sheets/cornell-ai-experts-chatbots-mental-health [https://perma.cc/F2M4-SHQ6].

47. *Id*.; Abrams, *supra* note 45.

research nor designed to assess mental health risk.[48] When users turn to these chatbots for emotional support, the output is unpredictable.[49]

Second, direct-to-consumer mental health chatbots are specifically marketed for emotional support or wellbeing.[50] Most rely on predefined responses approved by clinicians, but some still use GenAI to generate their answers.[51] Examples include *Woebot*, *Wysa*, and *Therabot*, which are designed to address mental health issues and, in some cases, to deliver cognitive behavioral therapy (CBT) through conversations with an AI.[52] Although these tools are often presented as supported by psychological research to adequately deal with mental health problems, they typically operate without meaningful regulatory control.[53]

Third, FDA-approved medical chatbots would include AI systems authorized to diagnose, treat, or cure mental health disorders.[54] Such tools would be subject to clinical trials and medical device regulation, but to date, no AI chatbot has received approval to operate in this capacity.[55]

These distinctions matter because the boundaries between these categories are blurred in practice. A chatbot designed for entertainment can function as a source of mental health guidance, while a mental health specific chatbot can act as a therapist without meeting medical standards. This overlap complicates regulation and control over these chatbots, endangering the protection of consumers and their data.

II. Innovation or Protection: Two Divergent Models

While the American and French models can be differentiated on their priority goals, neither has fully eliminated the risks posed by AI mental health chatbots in practice. The comparison that follows therefore evaluates how each system is designed to respond, rather than whether either has succeeded.

A. The United States: An Innovation-First Approach

1. Non-Binding Policies and Fragmented Regulation

At the international level, guidance on AI in health care is largely nonbinding. Although the World Health Organization (WHO) has issued principles for the responsible use of AI in health, these principles do not

48. Abrams, *supra* note 45.
49. *Id*.; *see also* Chatterjee, *supra* note 1.
50. Abrams, *supra* note 45.
51. *Id*.
52. *Id*.; Thurrott, *supra* note 36.
53. Abrams, *supra* note 45.
54. *Id*.
55. *Id*. *Wysa* did receive FDA Breakthrough Device designation for its mental health chatbot for patients eighteen years and older with a diagnosis of chronic musculoskeletal pain (defined as pain lasting longer than three months), and depression and anxiety, but this is an isolated case so far. Jo Aggarwal, *Wysa Receives FDA Breakthrough Device Designation for AI-led Mental Health Conversational Agent*, WYSA (May 12, 2022), https://blogs.wysa.io/blog/research/wysa-receives-fda-breakthrough-device-designation-for-ai-led-mental-health-conversational-agent [https://perma.cc/9NUR-MYAN].

create enforceable obligations in the U.S.[56]

At the domestic level, the U.S. lacks a comprehensive federal statute regulating AI mental health tools.[57] In the absence of such legislation, some states have adopted narrow restrictions on the use of AI in mental health in 2025.[58] For example, Illinois prohibits licensed mental health professionals from using AI chatbots in place of direct patient communication and bars representations of AI systems as substitutes for human therapy.[59] Utah and Nevada have adopted similar measures, requiring affirmative disclosure that a chatbot is not a human provider, and imposing strict limitations on data use and patient interaction.[60] These statutes target specific practices, but they do not establish a unified regulatory framework for AI mental health tools.

At the federal level, governance has instead relied on executive policy.[61] In 2022, the Biden Administration released a Blueprint for an *AI Bill of Rights*, which encouraged project managers to incorporate safeguards in their technology, and doctors, patients, and healthcare advocates to ask questions about the systems used in healthcare.[62] It then issued an *Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI*.[63] That Order was repealed in 2025 by the Trump Administration's Executive Order,

---

56. *Artificial Intelligence in Mental Health Care*, AMERICAN PSYCH. ASSOC. (Mar. 12, 2025), https://www.apa.org/practice/artificial-intelligence-mental-health-care [https://perma.cc/9YKA-WXYN]. These principles included (1) the protection of autonomy; (2) the promotion of human well-being, human safety, and the public interest; (3) transparency, explainability, and intelligibility; (4) responsibility and accountability; (5) inclusiveness and equity; and (6) responsiveness and sustainability.

57. *Id*.

58. *Summary of Artificial Intelligence 2025 Legislation*, NAT'L CONF. OF STATE LEG. (Jul. 10, 2025), https://www.ncsl.org/technology-and-communication/artificial-intelligence-2025-legislation [https://perma.cc/QU47-5R99]. In 2025, a proposed **New Jersey**'s A 5603 AI Mental Health Advertising bill would prohibit advertising AI System as licensed mental health professional (pending). **California**'s S 579 Mental Health and AI bill would require the secretary of Government Operations to appoint a mental health and AI working group that would evaluate certain issues to determine the role of AI in mental health settings by taking input from various stakeholder groups, including health organizations and academic institutions and through public meetings (pending). **Texas**' H 1265 AI Mental Health Services bill failed, but it planned that a person may not provide AI mental health services to an individual in the state, unless, among other requirements, the AI application through which the services are provided is Health and Human Services Commission approved.

59. Darya Lucas, *AI Mental Health Tools Face Mounting Regulatory and Legal Pressure*, GARDNER LAW (Sept. 25, 2025), https://gardner.law/news/legal-and-regulatory-pressure-on-ai-mental-health-tools [https://perma.cc/3TW3-4UNJ].

60. *Id*.

61. *Artificial Intelligence in Mental Health Care*, *supra* note 56.

62. Dr. Alondra Nelson et al., *Blueprint for an AI Bill of Rights: A Vision for Protecting Our Civil Rights in the Algorithmic Age*, NAT'L ARCHIVES (Oct. 4, 2022), https://bidenwhitehouse.archives.gov/ostp/news-updates/2022/10/04/blueprint-for-an-ai-bill-of-rightsa-vision-for-protecting-our-civil-rights-in-the-algorithmic-age/ [https://perma.cc/8963-RJE7].

63. Joseph R. Biden, *Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI*, NAT'L ARCHIVES (Oct. 30, 2023), https://bidenwhitehouse.archives.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/ [https://perma.cc/L73P-M35P].

Removing Barriers to American Leadership in AI.[64] By revoking these prior AI policies, the order makes innovation the federal government's primary objective in promoting competitiveness and global leadership.[65]

2. Conditional Review Through the FDA

To control mental health chatbots, the Food and Drug Administration (FDA) is, on paper, the primary federal agency with potential authority over AI mental health chatbots.[66] Its authority, however, is limited and conditional under the *Federal Food, Drug, and Cosmetic Act* (FD&C Act). The FDA does not regulate "AI" as such. Its jurisdiction arises only when a product qualifies as a "medical device" under §201(h), meaning it is intended for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[67] AI mental health chatbots would, if regulated, most often fall within the category of "software as a medical device" (SaMD).[68]

The agency distinguishes a product's intended use, defined as "the general purpose of the device or its function," from indications for use,[69] as expressed in labeling and promotional claims rather than technical sophistication alone.[70] FDA's current website suggests that this determination still depends heavily on what is contained in a product's labeling.[71] Although the FDA's 2021 final rule clarifies that intended use is an objective inquiry shown by "any other relevant source" of evidence,[72] no

64. *Artificial Intelligence in Mental Health Care*, *supra* note 56.

65. Exec. Order No. 14,179, 90 Fed. Reg. 8741 (Jan. 31, 2025)("The United States has long been at the forefront of artificial intelligence (AI) innovation, driven by the strength of our free markets, world-class research institutions, and entrepreneurial spirit. To maintain this leadership, we must develop AI systems that are free from ideological bias or engineered social agendas.").

66. *Artificial Intelligence in Mental Health* Care, *supra* note 56.

67. *How to Determine if Your Product is a Medical Device*, U.S. FOOD & DRUG ADMIN. (Sept. 29, 2022), https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device [https://perma.cc/2QRS-EWJL].

68. *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd [https://perma.cc/FP59-CYXE]. SaMD is understood as stand-alone software that performs a medical function without being embedded in medical hardware.

69. *How to Determine if Your Product is a Medical Device*, *supra* note 67. Defined as the description of "the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended."

70. *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2026), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device [https://perma.cc/RH39-L2GM].

71. *Id*. The page states that indications for use appear in labeling or may be conveyed orally during sale, and refers for intended use discussion to *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]*, U.S. FOOD & DRUG ADMIN. (Jul. 28, 2014), https://www.fda.gov/media/82395/download [https://perma.cc/TC7D-W4M2], which cites § 513(i)(1)(E)(i) of the FD&C Act (FDA's intended use determination "shall be based upon the proposed labeling").

72. Including design, composition, circumstances of distribution, customer knowledge, and actual use, see Maya Florence, *FDA's Final Rule on Intended Use: 'Getting Right Back to Where We Started From'*, SKADDEN (Aug. 18, 2021),

AI chatbot has yet been publicly recognized as a medical device, leaving uncertainty about enforcement of the FDA's oversight in practice.

Congress further limited this authority through §520(o)(1)(B) of the *FD&C Act*, which excludes from the definition of a medical device software functions intended to maintain or encourage a healthy lifestyle, if they are unrelated to the diagnosis or treatment of disease.[73] Under this exception, the agency does not subject "general wellness" software to premarket review, even when products touch on mental health-related topics, as long as developers frame them as promoting wellbeing rather than providing medical intervention.[74]

In practice, this framework still creates substantial uncertainty concerning regulation. Wellness framing offers companies a clear path to avoid FDA oversight, while therapeutic claims trigger review. Although FDA's 2021 rule gives the agency theoretical authority to look beyond labeling when design or foreseeable use suggests medical purposes, there is no public evidence it has done so for AI chatbots. Developers can therefore structure their products and marketing to stay within the general wellness category, sidestepping clinical trials and efficacy requirements.

3. Strategic Avoidance of the FDA Review and Use of Patents

Because the FDA's authority over software hinges on intended medical use, developers of AI mental health chatbots have strong incentives to structure and describe their products so as not to trigger the medical device classification.[75] Avoiding FDA review carries significant advantages. Classification as a medical device would subject chatbots to premarket review, clinical validation tied to specific indications for use, post-market surveillance, and obligations throughout the product's lifecycle to comply with regulation.[76] These requirements impose substantial financial, temporal,

---

https://www.skadden.com/insights/publications/2021/08/fdas-final-rule-on-intended-use#:~:text=Most%20importantly%2C%20FDA%20continues%20to,be%20indicative%20of%20intended%20use. [https://perma.cc/58XR-T5JH].

73. *Step 3: Is the Software Function Intended for Maintaining or Encouraging a Healthy Lifestyle?*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2022), https://www.fda.gov/medical-devices/digital-health-center-excellence/step-3-software-function-intended-maintaining-or-encouraging-healthy-lifestyle [https://perma.cc/7L5U-XF8Y].

74. *Id*. Commentators note the agency's historically hands-off approach to digital mental health tools; *see* Esther Howard, *Mental Health Apps: Regulation and Validation Are Needed*, GLOBAL FORUM (Nov. 2024), https://globalforum.diaglobal.org/issue/november-2024/mental-health-apps-regulation-and-validation-are-needed/ [https://perma.cc/CK2B-5BKN].

75. Julian De Freitas & I. Glenn Cohen, *The Health Risks of Generative AI-Based Wellness Apps*, 30 NATURE MED. 1269 (2024), https://www.nature.com/articles/s41591-024-02943-6.

76. *Clinical Trials for Medical Devices – Navigating the US FDA's Requirements*, FREYR (Feb. 27, 2024), https://www.freyrsolutions.com/blog/clinical-trials-for-medical-devices-navigating-the-us-fdas-requirements [https://perma.cc/2WRY-7F4R]; Pablo Garcia Quint, *Chatbots Are Not Medical Devices*, REASON (Dec. 3, 2025), https://reason.com/2025/12/03/chatbots-are-not-medical-devices/ [https://perma.cc/JKH3-AZF4].

and evidentiary burdens.[77] By contrast, developers can deploy products framed as wellness tools more rapidly and avoid the burdens associated with this oversight.[78]

Crucially, developers who avoid FDA review do not forgo legal protection for their inventions.[79] Patent law operates independently of FDA regulation.[80] A mental health chatbot may be fully patentable, even if never reviewed or approved by the FDA.[81] As long as the patent avoids explicitly claiming that the use of the chatbot involves diagnosis or treatment of a mental illness, developers can obtain exclusive rights over the technological system without subjecting the product to the medical device regulation.[82]

Patent documents function as public technical disclosures that reveal what a system is designed to do.[83] Under U.S. patent law, applicants must describe their invention in sufficient detail to enable a person skilled in the art to understand and reproduce it, in exchange for a time-limited right to exclude others from using it.[84] As a result, patent applications often provide a more candid account of a chatbot's capabilities than its marketing materials intended for consumers. Patents can expose therapy-like features, even where the same system is publicly framed as a general "wellness" tool to avoid triggering medical device regulation.

The *Digital Health Wellbeing* patent application[85] illustrates how this strategy can operate in practice. Although the application was ultimately abandoned for procedural reasons, it remains instructive as a window into common drafting techniques.[86] The title and background adopt a wellness framing,[87] yet the disclosed system describes a mobile application that

---

77. *Id*. The registration fee for a medical device with the FDA is of **$11,423 per year**. The FDA then requests premarket performance paperwork, risk management designs, and postmarket reports, which involve more expenses and costs for companies. The clinical trials are also heavily regulated: they must demonstrate substantial equivalence in terms of safety, privacy, and security, and include statistical analysis plans.

78. *Id*.

79. Eric P. Raciti & James Clements, *A Trap for the Wary : How Compliance with FDA Medical Device Regulations Can Jeopardize Patent Rights*, FINNEGAN (Jul. 2006), https://www.finnegan.com/en/insights/articles/a-trap-for-the-wary-how-compliance-with-fda-medical-device.html [https://perma.cc/ART4-FN4S].

80. *Id*.

81. *Id*.

82. *Id*.

83. Jeff Schell, *What is Patent Disclosure and What Does it Mean for My Patent*, SCHELL IP (Apr. 15, 2025), https://schellip.com/what-is-patent-disclosure-and-what-does-it-mean-for-my-patent/ [https://perma.cc/F6DH-3LJJ].

84. *Id*.

85. Periyasamy et al., *Digital Health Wellbeing*, U.S. Patent Application 2021/0098110 (Apr. 1, 2021), https://patentimages.storage.googleapis.com/d2/de/af/162ad5ca6769b9/US20210098110A1.pdf [https://perma.cc/6MH5-FNK9].

86. Periyasamy et al., *Digital Health Wellbeing*, GOOGLE PATENTS (last visited Apr. 4, 2026), https://patents.google.com/patent/US20210098110A1/en [https://perma.cc/7JS8-QW37]. The patent was examined, but the applicant failed to respond to the Office Action mail in time and the case was dropped, stopping the grant of rights from this filing. The invention could however still be patentable.

87. Periyasamy et al., *supra* note 85, at 1.

collects user data, identifies symptoms, determines mental health conditions, and delivers "one-on-one interactive therapy and counseling" through an AI chatbot.[88]

Figure 1: mental health chatbot from the Digital Health Wellbeing Patent - at Sheet 4

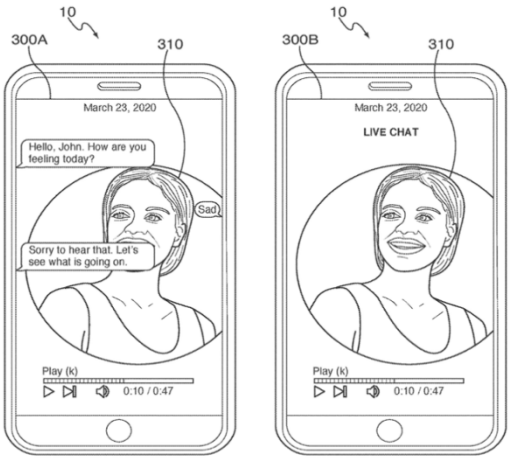

FIG. 3A FIG. 3B

The chatbot is further described as conducting sessions "as if the user is having the session with a trained human mental health personnel (e.g., psychotherapist, psychologist, etc.)."[89] Whether such a system would ultimately have been classified as a medical device is unclear, particularly given the application's abandonment. However, the disclosure avoids specifying mental illnesses or formal diagnostics, while repeatedly relying on "wellbeing" language and embedding the chatbot among other app functions.[90] This kind of drafting shows how a system capable of acting like a therapist can be presented in wellness terms, consistent with the current framework under which most AI mental health chatbots are not subject to FDA review.[91] In such a framework, the possibility that a system with this level of therapeutic interaction could fall outside the medical device regulation based primarily on its framing raises concerns about the absence of any premarket safety review.

Other developers have taken a different approach by voluntarily

88. *Id*.
89. Periyasamy et al., *supra* note 85, at 4*; see* Figure 1.
90. Periyasamy, *supra* note 85, at Sheet 4.
91. *See generally* Part II, Innovation or Protection: Two Divergent Models.

engaging with the FDA. Chatbots such as *Woebot*[92] and *Wysa*[93] adopt more cautious language in their patents, explicitly highlighting the role of humans in supporting chatbots and the limits of an automated intervention. *Wysa*'s developer sought and obtained *Breakthrough Device designation*,[94] a program that allows manufacturers to interact with FDA experts to "address topics as they arise during the premarket review phase," and to expect prioritized review of their submissions.[95]

As shown by these examples, developers who prioritize rapid market entry and broad patent protection may prefer describing the AI chatbot in general wellness terms, while those who engage the FDA accept heavier regulatory and evidentiary burdens.[96] The result is a structural asymmetry. Intellectual property (IP) and patent law grant developers protection before the deployment of their product on the market through the grant of exclusive rights, motivating investment and innovation.[97] By contrast, FDA law protects users of chatbots only when developers choose to trigger the agency's jurisdiction through their framing of intended use or voluntary engagement.[98] Many AI therapy chatbots thus reach the market without prior regulatory scrutiny, leaving users protected largely through ex post mechanisms.

4. Ex Post Consumer Protection

With chatbots largely free from premarket oversight, alternatives that might otherwise protect users fail to engage. The *Health Insurance Portability and Accountability Act* (HIPAA), which governs the privacy and security of health information, does not apply to most wellness-labeled

---

92. Alison Darcy et al., *Open Input Empathy Interaction*, U.S. Patent Application, Pub. 11775774 (filed July 22, 2022), https://patents.justia.com/patent/11775774 [https://perma.cc/ETB7-8B5W] ("A user may input thoughts or reasons why they have been having a positively trending mood over a duration of time. The chatbot can then repeat or otherwise use those same thoughts or reasons to engage the user empathically when the chatbot detects that the user is experiencing a negatively trending mood.").

93. Jyotsana Vempati Aggarwal et al., *System and Method for Determining a Mismatch Between a User Sentiment and a Polarity of a Situation Using an AI Chatbot*, U.S. Patent Application 11715554 (filed Jan. 10, 2023), https://patents.justia.com/patent/11715554 [https://perma.cc/2KGE-498C].

94. Aggarwal, *supra* note 55.

95. *Breakthrough Devices Program*, U.S. FOOD & DRUG ADMIN. (Aug. 20, 2025), https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#:~:text=Contact%20Us-,What%20is%20the%20Breakthrough%20Devices%20Program%3F,irreversibly%20debilitating%20diseases%20or%20conditions [https://perma.cc/48N3-2NFU].

96. *Id.*; *see also* Amanda Sarata, *FDA Regulation of Medical Devices,* CONGRESS.GOV (Jan. 4, 2023), https://www.congress.gov/crs-product/R47374 [https://perma.cc/AK3W-EJ58].

97. Craige Thompson, *How Do Patents Act as an Incentive to Technological Innovation in the Era of Automation and AI*, THOMPSON PATENT LAW (Aug. 21, 2025), https://thompsonpatentlaw.com/how-do-patents-act-as-an-incentive-to-technological-innovation/ [https://perma.cc/3CGD-ELRL] (Patents "encourage the development of new technologies and foster a culture of innovation.").

98. Aggarwal, *supra* note 93.

mental health chatbots.[99] HIPAA's protections extend only to covered entities, such as health plans, healthcare providers, and their business associates, and most standalone chatbot developers do not qualify.[100] A mental health chatbot collecting deeply sensitive mental health disclosures from users hence escapes HIPAA's privacy and security rules entirely, leaving that data outside federal health privacy protections.

The Federal Trade Commission (FTC) offers a partial substitute. Under its Health Breach Notification Rule, most health apps developers not covered by HIPAA are nonetheless required to notify users of data breaches.[101] The FTC enforced against BetterHelp, an online counseling platform that matched users with human therapists, imposing a $7.8 million fine for sharing sensitive therapy data with Facebook despite privacy promises.[102] For chatbots specifically, the FTC launched an inquiry in September 2025 into AI companions' mental health claims and data practices, including the chatbots of OpenAI and Meta.[103] Still, the FTC has yet to enforce against chatbot therapy interactions.

Harm is addressed only after it occurs, through limited FTC oversight or common-law liability.[104] Users and families must prove injury, causation, and fault in individual lawsuits, as when ChatGPT allegedly exacerbated Adam Raine's mental decline leading to his suicide.[105] Earlier premarket review or screening of how such chatbots may affect users in mental health contexts could identify foreseeable risks and reduce the likelihood of severe harm before being deployed on the market.[106]

In the current U.S. framework, lawmakers and regulators prioritize technological innovation, permitting rapid market entry, while users receive protection - if at all - only after harm occurs through after-the-fact litigation.

---

99. Jennifer Wessel, *AI Therapy Chatbots Raise Privacy, Safety Concerns*, ACHI (Nov. 25, 2025), https://achi.net/newsroom/ai-therapy-chatbots-raise-privacy-safety-concerns/ [https://perma.cc/J5KL-P54W].

100. *Id*.

101. *Complying with FTC's Health Breach Notification Rule*, FED. TRADE COMM'N (Jan. 2025), https://www.ftc.gov/business-guidance/resources/complying-ftcs-health-breach-notification-rule-0 [https://perma.cc/E52U-TAJ2].

102. *FTC Gives Final Approval to Order Banning BetterHelp from Sharing Sensitive Health Data for Advertising, Requiring It to Pay $7.8 Million*, FED. TRADE COMM'N (July 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-gives-final-approval-order-banning-betterhelp-sharing-sensitive-health-data-advertising [https://perma.cc/6HSX-BWUL].

103. *FTC Launches Inquiry into AI Chatbots Acting as Companions*, FED. TRADE COMM'N (Sept. 11, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/09/ftc-launches-inquiry-ai-chatbots-acting-companions [https://perma.cc/Z25N-CR8X].

104. Frances M. Green et al., *The Dark Side of AI: Assessing Liability When Bots Behave Badly*, EPSTEIN, BECKER & GREEN (Sept. 22, 2025), https://www.ebglaw.com/insights/publications/the-dark-side-of-ai-assessing-liability-when-bots-behave-badly [https://perma.cc/SW38-P6Q5]. After ChatGPT encouraged 16-year-old Adam Raine's mental decline and suicide by hanging, his parents filed a complaint in California alleging **products liability, negligence, and wrongful death** against OpenAI Inc., its affiliates, and investors.

105. *Id*.

106. *Id*.

This ex post structure is especially inadequate in the mental health context. Unlike physical harms, which may be detectable and reversible, mental health deterioration can be gradual, invisible to outside observers, and catastrophic by the time it is identified. A regulatory model that waits for harm to materialize before intervening is structurally mismatched with the nature of the risk these chatbots pose.

Recognizing these shortcomings, the FDA's Digital Health Advisory Committee has addressed in its discussions a shared responsibility framework in which regulators, manufacturers, healthcare systems, and clinicians collectively bear responsibility for "transparency, explainability, and premarket plans" for GenAI enabled devices.[107]

B. France: A More Protective and Proactive Model

1. EU Rules as Applied in France

France applies European Union (EU) law directly and has chosen not to amend its substantive national legislation in response to the *EU Artificial Intelligence Act*.[108] Instead, the French model relies on the direct application of EU rules through a decentralized enforcement structure, with multiple market surveillance authorities split by sector and type of AI system addressed in the *Act*.[109] The *EU AI Act* entered into force in 2024 but most requirements will apply later, according to an implementation timeline.[110] The EU AI Office attached to the European Commission coordinates implementation of the *AI Act* in all Member States and plays a central role in supervising general-purpose AI models.[111] Commentators interpret the *AI Act* to classify AI systems according to the risks they pose to individuals and society, distinguishing between prohibited AI systems, high-risk AI systems, limited-risk systems, and minimal-risk systems.[112] Mental health chatbots are not placed into a single category by default. Their classification depends on intended purpose, functional capabilities, and the foreseeable effects on users, particularly vulnerable individuals (Article 5(b)).[113]

---

107. *Executive Summary for the Digital Health Advisory Committee Meeting*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2025), https://www.fda.gov/media/189391/download [https://perma.cc/2NPX-DHXY].

108. Gareth Stokes et al., *State of the Act: EU AI Act Implementation in Key Member States*, DLA PIPER BLOG (Nov. 3, 2025), https://www.technologyslegaledge.com/2025/11/state-of-the-act-eu-ai-act-implementation-in-key-member-states/#:~:text=However%2C%20France%20has%20moved%20to,in%20the%20EU%20AI%20Act [https://perma.cc/J24B-6QEA].

109. *Id*.

110. Hannah van Kolfschooten & Janneke van Oirschot, *The EU Artificial Intelligence Act (2024): Implications for Healthcare*, 149 HEALTH POL'Y 105152 (2024).

111. *European AI Office*, EUR. COMM'N (Mar. 31, 2026), https://digital-strategy.ec.europa.eu/en/policies/ai-office [https://perma.cc/P8XB-CTL8]. The AI Office can request information or open investigations when serious issues are suspected. Other bodies like the European AI Board, Advisory Forum, and Scientific Panel of Independent Experts provide technical advice to help the regulation of AI.

112. *Id*.; Van Kolfschooten & van Oirschot, *supra* note 110.

113. *Article 3: Definitions*, EU AI ACT (Feb. 2, 2025),

Many consumer-facing chatbots (or entertainment chatbots) are likely to fall within the category of limited-risk AI when they provide general wellbeing information without other suggestions of diagnosis or treatment decision.[114] This level of classification primarily triggers transparency obligations, including requirements to inform users that they are interacting with an AI system rather than a human and to clearly signal AI-generated content.[115] Although these obligations are lighter than those imposed on high-risk systems,[116] they nonetheless establish binding duties that apply even outside the medical context.

By contrast, mental health chatbots are more likely to be classified as high-risk AI when they are intended to diagnose, prevent, monitor, or treat a medical condition.[117] Under Article 2(1) of the Medical Device Regulation (MDR), software qualifies as a medical device when it is intended for such medical purposes.[118] Once a chatbot meets this threshold, the AI Act's high-risk regime (Article 6(1)(b)) applies cumulatively with medical device law,[119] subjecting the system to the requirements of establishing and documenting a risk management system (Article 9), obligations of data-governance (Article 10), duties of technical documentation (Article 11), human oversight (Article 14), and a conformity assessment prior to market entry (Article 43).[120] In France, the Haute Autorité de Santé (HAS) [National Authority for Health] evaluates the clinical evidence for AI chatbots that would qualify as medical devices, and can also use "real-world data" in complement to the clinical trials.[121]

---

https://artificialintelligenceact.eu/article/3/ [https://perma.cc/3SMG-28Y4] (intended purpose is defined as the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation); Artur Olesch, *First EU AI Act Guidelines: When is Health AI Prohibited?*, ICT&HEALTH GLOBAL (Feb. 11, 2025), https://www.icthealth.org/news/first-eu-ai-act-guidelines-when-is-health-ai-prohibited [https://perma.cc/3RH9-ZET2] (AI that intentionally exploits the vulnerability of consumer groups based on age, disability, or economic situation is also prohibited, *see Article 5: Prohibited AI Practices*, EU AI ACT (Feb. 2, 2025), https://artificialintelligenceact.eu/article/5/ [https://perma.cc/E4EV-XJYT]).

114. Van Kolfschooten & van Oirschot, *supra* note 110.

115. *EU AI Act : How Risk is Classified*, TRAIL (Feb. 13, 2026), https://www.trail-ml.com/blog/eu-ai-act-how-risk-is-classified [https://perma.cc/U3AA-AQP9].

116. *Id*.

117. Mathias Karlsen Hauglid & Tobias Mahler, *Doctor Chatbot: The EU's Regulatory Prescription for Generative Medical AI*, 10 OSLO L. REV. 1 (2023), https://www.scup.com/doi/10.18261/olr.10.1.1.

118. *Id*. France is bound by the MDR like any other Member State.

119. *Article 6: Classification Rules for High-Risk AI Systems*, EU AI ACT (Aug. 2, 2026), https://artificialintelligenceact.eu/article/6/ [https://perma.cc/QN6X-4VL9] ((b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonization legislation listed in Annex I).

120. *Id*.

121. *HAS Missions*, HAS (Mar. 6, 2024), https://www.has-sante.fr/jcms/c_415958/en/about [https://perma.cc/4KQY-ZP2U].

The MDR explicitly excludes lifestyle and wellness software from the medical device classification.[122] As in the U.S., this creates incentives for providers of consumer-facing mental health chatbots to frame their applications as informational or wellness tools to avoid medical device regulation. Scholars have criticized this reliance on stated intent, arguing that it fails to account for how such tools are actually used by consumers in practice, particularly when "wellbeing" applications function as therapeutic substitutes.[123]

Nevertheless, the European framework differs from the U.S. model in how it addresses this regulatory boundary. Even when a mental health chatbot falls outside the medical device law, it does not fall outside regulation altogether, as limited-risk AI systems remain subject to the AI Act's transparency obligations, to strict data-protection rules under the General Data Protection Regulation (GDPR), and to supervision by national authorities.[124] In France, the Commission Nationale de l'Informatique et des Libertés (CNIL) [National Commission on Informatics and Liberty] enforces GDPR compliance for chatbots processing mental health data, which is treated as sensitive personal data and subject to heightened requirements of transparency and accountability.[125]

Alongside these safeguards, European patent law continues to protect innovation and investment.[126] AI mental health technologies may receive patent protection through the European Patent Office (EPO) when they meet the requirements of the European Patent Convention (EPC), including having a clear technical purpose.[127] Patent protection therefore secures developers' economic interests and supports innovation, as it does in the U.S.[128]

Users may still bring claims based on negligence, product liability, or

---

122. Hauglid & Mahler, *supra* note 117. Preamble Recital 19 of the MDR explicitly provides that software intended for lifestyle or wellness purposes are specifically mentioned as examples of purposes that do not qualify a software as a medical device.

123. : *See* HELEN YU, REGULATION OF DIGITAL HEALTH TECHNOLOGIES IN THE EUROPEAN UNION: INTENDED VERSUS ACTUAL USE (Cambridge University Press, 2022). Author Helen Yu argues the need for regulation of these software applications based on evidence of actual use rather than solely relying on the intended purpose stated by the manufacturer.

124. Hauglid & Mahler, *supra* note 117; Myria Saarinen et al., *Data Protection in France: Overview*, LATHAM & WATKINS (Dec. 1, 2018), https://www.lw.com/admin/upload/SiteAttachments/Data%20protection%20in%20France%20overview.pdf [https://perma.cc/95RB-KDMA].

125. *The CNIL's Actions in Europe and Around the World*, CNIL (Apr. 30, 2024), https://www.cnil.fr/fr/node/165546 [https://perma.cc/7L7L-H5ER]; *Artificial Intelligence : the Action Plan of the CNIL*, CNIL (May 16, 2023), https://www.cnil.fr/en/artificial-intelligence-action-plan-cnil [https://perma.cc/GRA4-AC8G]. The CNIL can enforce fines in case of noncompliance, see Bertrand Liard & Clara Hainsdorf, *GDPR Guide to National Implementation: France*, WHITE & CASE (Jan. 1, 2022), https://www.whitecase.com/insight-our-thinking/gdpr-guide-national-implementation-france#q17 [https://perma.cc/5K7V-AXEU]).

126. *Patenting AI According to EPO Standards*, IBPA CONNECT (Sept. 2023), https://profwurzer.com/patent-ai-according-to-epo-standards/ [https://perma.cc/5AX9-VTKU].

127. *Id*.

128. *Id*.

violations of data-protection law after harm occurs.[129] While that liability in the U.S. would serve as the primary mechanism of user protection in case the chatbot was not recognized as a medical device, it operates alongside the preventive obligations of the *AI Act* relating to transparency, data protection, and risk management in France.[130]

2. Mental Health as a National Cause

In 2025, France designated mental health as a *Grande Cause Nationale* [Great National Cause], elevating it to a national policy priority with three core objectives: reducing stigma, improving early detection, and expanding access to care nationwide.[131] Although this designation does not create binding legal obligations, it operates as a form of soft law, influencing the public debate, institutional priorities, and the types of digital tools that receive public visibility and support.[132] "Soft law" refers here to nonbinding state action. The initiative explicitly targets the conditions that have driven many users toward AI chatbots, including the unequal access to care, lack of information, and persistent social stigma surrounding therapy.[133]

As part of the initiative, qualified professionals in mental health organized conferences, debates, interviews, and educational content across media platforms. These efforts aimed to improve available information around mental healthcare and encourage individuals to seek human care earlier, rather than turning to AI chatbots.[134] The government even decided to renew mental health as a Great National Cause in 2026, stating as objectives "strengthening interministerial coordination, expanding support for families, associations, and local communities, and sustaining the collective momentum that emerged in 2025."[135]

In this context, influencer Miel Abitbol recently launched her app *LYYNK* in France, which briefly surpassed the number of downloads of ChatGPT on the App Store.[136] *LYYNK* is designed to connect parents directly

---

129. Jean-Luc Juhan et al., *In-Depth: Artificial Intelligence Law*, LATHAM & WATKINS (Jan. 17 2024), https://www.lw.com/admin/upload/SiteAttachments/Lexology-In-Depth-Artificial-Intelligence-Law-France.pdf [https://perma.cc/C34Q-JDQC] (French law recognizes several types of liability that could apply to AI systems : product liability, manufacturer liability, strict liability, and negligence).

130. *Id*.

131. *La Santé Mentale, Grande Cause Nationale 2025*, *supra* note 3.

132. *Id*.

133. *Id*.

134. *Id*.

135. *Santé Mentale: la "Grande Cause Nationale" Prolongée en 2026, Annonce Matignon [Mental Health: the "Great National Cause" Extended in 2026]*, LE MONDE (Nov. 27, 2025), https://www.lemonde.fr/societe/article/2025/11/27/sante-mentale-la-grande-cause-nationale-prolongee-en-2026-annonce-matignon_6655130_3224.html [https://perma.cc/JY3D-N72C].

136. Audrey Abraham, "*Vous m'avez sauvé la vie": comment l'application LYYNK, dédiée à la santé mentale des adolescents, tente de recréer du lien entre enfants et parents ["You saved my life": how the LYYNK app, dedicated to mental health of teenagers, try to reform a link between children and parents]*, FRANCEINFO (Oct. 27, 2024), https://www.franceinfo.fr/replay-radio/le-choix-franceinfo/temoignages-vous-m-avez-sauve-la-vie-comment-l-application-lyynk-dediee-a-la-sante-mentale-des-adolescents-

with licensed psychologists and mental health professionals.[137] Unlike AI chatbots, *LYYNK* lowers barriers of access to care through facilitating contacts with qualified professionals, and parents and children.[138] In doing so, it addresses several of the factors identified earlier in this Note, including reducing the gap in information related to mental healthcare, and guiding users toward appropriate care.[139]

To further this national goal, France's forthcoming *National Strategy for Artificial Intelligence and Health Data* (2025-2028) explicitly addresses the growing use of AI tools by patients, including health chatbots.[140] It acknowledges that GenAI is already deployed and used by patients, including via health chatbots, but that its use often remains unframed on tools for consumers especially not adapted to mental health, "where the quality and relevance of counselling is important."[141] To remediate this issue, the stated objective is to "put in place governance to ensure the quality of the advice provided and to prevent any risks associated with its use, while ensuring that patients and citizens are fully involved in these processes."[142] Therefore, France actively plans to control the use of AI chatbots of its citizens, by supplementing EU-level regulation with national soft law and public policy measures aimed to provide more transparency and reduce the stigma and gaps in the access to mental healthcare.[143]

Compared to the U.S. model, the French one provides more protection for its users. Yet, neither approach fully resolves the risks posed by AI chatbots. While the French and broader European model imposes earlier regulation through its risk-based classification, transparency obligations, and protection of data rules, the *AI Act* obligations are not yet fully enforced as the *Act* has only recently entered into force and the limits of the classifications are not well defined.[144] The U.S. promotes innovation but largely defers user protection to post-harm claims.[145] These regimes hence share a challenge, which this Note argues could be better addressed through coordinated international principles.

III. Recommendations Toward an International Solution

This section identifies a small set of recommendations that follow directly from the comparative analysis above and could guide international

---

tente-de-recreer-du-lien-entre-enfants-et-parents_6834311.html [https://perma.cc/5M2F-5JW4].

137. *Id*.

138. *Id*.

139. *Id*.

140. *The French National Strategy for Artificial Intelligence and Health Data*, 2025-2028, G_NIUS (Nov. 17, 2025), https://gnius.esante.gouv.fr/sites/default/files/2025-11/English%20version_The%20French%20National%20Strategy%20for%20Artificial%20Intelligence%20and%20Health%20Data.pdf [https://perma.cc/RH6U-GUUG].

141. *Id*.

142. *Id*.

143. *Id*.

144. Van Kolfschooten & van Oirschot, *supra* note 110.

145. Green, *supra* note 104.

coordination in this area.

A. Suggestions to Better Protect Users

The U.S. already has some federal oversight mechanisms through the FDA and FTC, but their current application leaves significant gaps that more effective enforcement and potentially new federal legislation could address.

While New York advances targeted bills like S.7263 (prohibiting AI chatbots from impersonating licensed therapists, creating liability for harmful advice)[146] and S.8484 (banning unsupervised AI therapy without clinician consent and informed consent),[147] these state-level efforts risk creating a patchwork absent coordination at the federal level. Uniform federal standards would better regulate interstate AI deployment and prevent forum-shopping by developers.

Ideally, the risks posed by AI mental health chatbots would be addressed through a comprehensive international plan modeled on the *EU AI Act*. In practice, however, such harmonization is unlikely, as jurisdictions differ sharply in their regulation priorities, with some like the U.S. placing greater emphasis on innovation and on the flexibility of its market.[148]

Without this global uniformity, agencies like the FDA should enforce more aggressively their existing authority to assess functional use beyond stated intent, as clarified by the 2021 intended-use rule.[149] Both the U.S. and European models showed that developers frame chatbots as "general wellness" tools to avoid clinical trials and transparency obligations,[150] even when they function as therapy substitutes. Such scrutiny would protect vulnerable users like teenagers. The FDA would operate proactively, reducing post-harm litigation and helping prevent the types of suicide-related cases that have already reached courts.[151]

Moreover, lawmakers should impose clear transparency obligations when chatbots engage with users on mental health topics. Users need

---

146. Tina Garbett & Tina Watson, *New York Moves to Curb "AI Impersonation" of Licensed Professionals*, JD SUPRA (Mar. 19, 2026), https://www.jdsupra.com/legalnews/new-york-moves-to-curb-ai-impersonation-2721932/ [https://perma.cc/VHK6-E7GQ].

147. Eric M. Fish, *New York Introduces Legislation to Regulate Use of Artificial Intelligence in Mental Health Care*, HOOPER, LUNDY & BOOKMAN (Sept. 9, 2025), https://hooperlundy.com/new-york-introduces-legislation-to-regulate-use-of-artificial-intelligence-in-mental-health-care/ [https://perma.cc/E6KR-7USW].

148. Exec. Order No. 14,179, *supra* note 65.

149. Florence, *supra* note 72.

150. *How to Determine if Your Product is a Medical Device, supra* note 67; Ryan K. McBain, *Teens are Using Chatbots as Therapists. That's Alarming*, RAND (Sept. 24, 2025), https://www.rand.org/pubs/commentary/2025/09/teens-are-using-chatbots-as-therapists-thats-alarming.html [https://perma.cc/REC3-T6UP] (assessing that clinical trials evaluating chatbots' impact on teen mental health are not enough; clear safety benchmarks that stress-test these systems and reveal gaps missed even in well-designed trials are also needed).

151. Chatterjee, *supra* note 1; Quint, *supra* note 76 (making a point that treating mental health care chatbots as medical devices would revert to recognizing them as professional therapy, but a medical device is an "instrument" as defined by the FDA that merely supports care, not a therapist).

reminders that they are engaging AI, not human professionals, with disclosures that should explain the system's limitations, uncertainty, and potential biases. In the mental health context, transparency is important to reduce overreliance on chatbots that are not qualified professionals and do not assume a duty of care or professional responsibility. The *Wysa* patent[152] already incorporates this disclosure. The FDA should expeditiously finalize review for voluntary applicants like *Wysa*, demonstrating responsible innovation and safety review can coexist.

Finally, soft law mechanisms should complement binding regulation.[153] Indeed, soft law like public guidance, ethical standards, and communication campaigns could inform and complement hard law.[154] Adjacent measures are also useful, with governments starting to protect the most vulnerable users of chatbots: children. Examples include France's ban on smartphones in schools,[155] Australia's restrictions on social media access for teenagers,[156] and a potential ban of TikTok in the U.S. to protect users' data.[157] While these measures do not target mental health chatbots directly, they reflect that the jurisdictions recognize that protecting vulnerable users requires intervening beyond regulation. Such measures can reinforce user protection and public trust while more tailored regulatory frameworks continue to develop.

B. Aligning Intellectual Property with Responsible Innovation

Patent disclosures reveal technical features that wellness marketing often conceals.[158] A chatbot's architecture might enable it to diagnose a mental illness, even when it is publicly framed as a "wellness" tool. Agencies should mine patent applications as early evidence of actual capabilities during functional assessments, to prevent developers from using intellectual property disclosures to sidestep regulation through the wellness exception.

Intellectual property grants developers protection based on these disclosures, incentivizing responsible innovation to build better AI chatbots. This Note does not argue innovation of AI chatbots is unnecessary in the

---

152. Aggarwal, *supra* note 93.

153. Andrew McStay & Vian Bakir, *Soft Law for Unintentional Empathy: Addressing the Governance Gap in Emotion-Recognition AI Technologies*, 23 J. RESP. TECH. 100126 (2025).

154. *Id*.

155. Currently in middle schools: *France Bans Phones in Schools*, PHONE LOCKER (July 16, 2024), https://phonelocker.com/france-bans-phones-in-schools/ [https://perma.cc/7XDN-SH4B]. *Macron Backs Push to Ban Cellphones in French High Schools*, POLITICO (Nov. 28, 2025), https://www.politico.eu/article/emmanuel-macron-backs-push-ban-cell-phones-french-high-schools/ [https://perma.cc/YP3C-C2J6]. President Macron however plans to ban them in high schools too.

156. Helen Livingstone, *Australia Has Banned Social Media for Kids Under 16. How Will it Work?,* BBC (Dec. 10, 2025), https://www.bbc.com/news/articles/cwyp9d3ddqyo [https://perma.cc/2GN8-W3V7].

157. Emma Rubbert, *U.S. TikTok Ban: National Security and Civil Liberties Concerns*, HENRY M. JACKSON SCHOOL OF INT'L STUDIES REV. (Oct. 21, 2025), https://jsis.washington.edu/news/u-s-tiktok-ban-national-security-and-civil-liberties-concerns/ [https://perma.cc/P3US-WAGY].

158. Schell, *supra* note 83.

mental health field. On the contrary, innovation is what allows developers to improve chatbots and fill mental health access gaps. OpenAI's recent announcement strengthening ChatGPT's responses in sensitive conversations, including de-escalation protocols and guidance for users toward human help, shows how improvements can directly enhance safety.[159]

Agencies should therefore take a more active role ensuring developers implement safeguards, provide technical documentation, and maintain transparency around user data handling. Such oversight would protect users without freezing the innovation that makes chatbots better over time. This approach recognizes both the benefits these chatbots offer through a 24/7 available help, and the reality that some risks can only be addressed through improving existing chatbots than through attempting to halt innovation altogether.[160]

C. Lessons from Other Jurisdictions

The contrast between the U.S. and French models becomes even starker when situated within a broader international landscape. Japan has consolidated its long-standing preference for soft-law AI governance in the 2025 Act on the Promotion of Research and Development and the Utilization of AI-Related Technologies ("AI Promotion Act").[161] It establishes high-level principles, an AI Strategy Headquarters led by the Prime Minister, and a Basic AI Plan but leaves implementation largely to non-binding ministry guidelines and sectoral frameworks.[162] This "innovation-first" model supports rapid piloting of AI tools, including in health and government services.[163] Yet it relies primarily on existing health, data-protection, and consumer-protection laws to govern AI chatbots, with few hard, AI-specific obligations comparable to the EU AI Act's risk-based classification or mandatory transparency rules.[164]

China has recently moved toward an explicitly protection-oriented

---

159. *Strengthening ChatGPT's Responses in Sensitive Conversations*, OPENAI (Oct. 27, 2025), https://openai.com/index/strengthening-chatgpt-responses-in-sensitive-conversations/ [https://perma.cc/LN7Z-LZTU].

160. *PauseAI Proposal*, PAUSEAI (last visited Apr. 4, 2026), https://pauseai.info/proposal [https://perma.cc/6JJ8-D8E9]. Although some have called for a pause in AI development, such approaches risk freezing existing systems in their current, imperfect form. Given that users continue to interact with these chatbots, the safety concerns of users are more likely to be addressed by improving chatbots rather than by stopping their development altogether.

161. Dr. Nils Lölfing & Aya Saito, *Japan's New AI Act: Examining an Innovation-First Approach Against the EU's Comprehensive Risk Framework*, BIRD & BIRD (Sept. 11, 2025), https://www.twobirds.com/en/insights/2025/japan/japans-new-ai-act-examining-an-innovationfirst-approach-against-the-eus-comprehensive-risk-framework [https://perma.cc/GY8U-6RJD].

162. *Id*.

163. *Id*.

164. Dominic Paulger, *Understanding Japan's AI Promotion Act : an "Innovation-First" Blueprint for AI Regulation*, FUTURE OF PRIVACY FORUM (Nov. 23, 2025), https://fpf.org/blog/understanding-japans-ai-promotion-act-an-innovation-first-blueprint-for-ai-regulation/ [https://perma.cc/NG9H-XZ2E].

model for emotionally interactive AI.[165] Draft rules released in late 2025 for "human-like interactive AI services" would apply to AI chatbots that simulate companionship and affect users' emotions.[166] These rules require providers to obtain guardian consent and impose usage time limits for minors, ensure that a human takes over and contacts a guardian or emergency contact if a user mentions suicide or self-harm, and prevent content that could harm users' mental health or public interests.[167] Commentators note that these measures mark a shift in Chinese AI policy from a primary focus on content and information security toward "emotional safety," explicitly targeting the mental-health risks associated with popular companionship and therapist-like chatbots.[168]

Taken together, these examples reinforce the core tension identified by the U.S. and French comparison. Frameworks that maximize innovation, whether through permissive inventorship rules or fragmented oversight, can speed the diffusion and patenting of mental health chatbots but leave emotionally vulnerable users exposed when systems operate as de facto therapists. At the same time, China's emerging emphasis on emotional safety demonstrates that even rapidly innovating jurisdictions can recognize mental health chatbots as a distinct risk category and impose ex ante duties of human intervention, crisis response, and youth protection.

Conclusion

AI mental health chatbots have emerged at the intersection of two phenomena: a global shortage of mental health care and the rapid emergence of GenAI systems not yet designed to assume responsibilities in the mental health field. As users turn to these tools for emotional support, the law struggles to keep pace.

This Note's comparative analysis reveals key differences. In the U.S., FDA jurisdiction is triggered through the qualification of a chatbot as a medical device, prompting developers to frame their chatbots as "general wellness" applications to avoid regulation. U.S. users are mostly left with lawsuits as their solution of last resort. In France, the *EU AI Act*, gradually getting implemented, imposes earlier and more structured obligations through risk-based classifications. Calls to solve the mental health crisis have also led to mental health being recognized as a national cause for 2025 and 2026. Nevertheless, neither approach fully resolves the risks created when AI systems are used as substitutes for human care.

---

165. Evelyn Cheng, *China to Crack Down on AI Chatbots Around Suicide, Gambling*, CNBC (Dec. 29, 2025), https://www.cnbc.com/2025/12/29/china-ai-chatbot-rules-emotional-influence-suicide-gambling-zai-minimax-talkie-xingye-zhipu.html [https://perma.cc/X7TS-APKZ]; Osmond Chia, *China to Crack Down on AI Firms to Protect Kids*, BBC (Dec. 29, 2025), https://www.bbc.com/news/articles/c8dydlmenvro [https://perma.cc/T7Z9-NBXG]; Joe Wilkins, *China Planning Crackdown on AI that Harms Mental Health of Users*, FUTURISM (Dec. 31, 2025), https://futurism.com/artificial-intelligence/china-regulation-ai-chatbots [https://perma.cc/PK23-JAYY].

166. *Id*.

167. *Id*.

168. *Id*.

Rather than choosing between deregulation and full medicalization, this Note argues for a measured path forward. Protecting users, particularly minors, requires transparency on the part of developers and a more active role on the part of agencies. Innovation must remain part of the solution. Since users continue to interact with these tools, improving how chatbots respond to mental health queries offers more protection than attempting to halt their development altogether. Lawmakers can encourage the development of safer and more transparent AI mental health tools without freezing progress, using hard and soft law. The challenge is not to eliminate AI from mental health contexts, but to ensure that its growing presence does not outpace the legal and ethical frameworks needed to protect those who rely on it the most.