BioMed Visions Journal

Volume 2 | Issue 2 Article 8

7-15-2026

# Ethical, Regulatory, and Equity Challenges of AI in Pharmaceutical Advertising

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## Recommended Citation

Mohammed, Samer Imad and Ahmed, Fadia Thamir (2026) "Ethical, Regulatory, and Equity Challenges of AI in Pharmaceutical Advertising," *BioMed Visions Journal*: Vol. 2: Iss. 2, Article 8.
DOI: https://doi.org/10.63100/3078-6738.1027

BIOMED VISIONS JOURNAL 2026;2:118–129



REVIEW

# Ethical, Regulatory, and Equity Challenges of AI in Pharmaceutical Advertising

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## ABSTRACT

**Background:** Artificial intelligence (AI) and chatbots are significantly altering pharmaceutical advertising by facilitating personalized patient engagement and enhancing treatment optimization. Their adoption presents substantial ethical, regulatory, and equity challenges that require thorough analysis.

**Objectives:** The objectives of this review are to analyze: (1) the implementation of AI technologies, such as chatbots and predictive analytics, in pharmaceutical advertising; (2) ethical risks, including algorithmic bias and misinformation; (3) deficiencies in global regulatory frameworks, specifically those of the FDA and EMA; and (4) effects on health equity, with a focus on vulnerable populations.

**Methods:** A narrative review was conducted using several databases with structured search terms related to AI, pharmaceutical advertising, ethics, regulation, and equity. The inclusion criteria encompassed English-language articles and reviews published between 2019 and 2024.

**Results:** AI chatbots improve engagement; however, they demonstrate significant biases, such as racially biased advertising targeting, and present compliance risks, with 22% of AI-generated responses failing to include drug risk information. Regulatory systems face challenges in addressing AI's real-time adaptability, resulting in an "ethics-regulation gap." Vulnerable populations, such as the elderly, low-income individuals, and racial minorities, experience heightened disparities resulting from biased algorithms and barriers to accessibility. Hybrid human-AI oversight and design centered on equity are essential mitigations.

**Conclusion:** Although AI presents significant opportunities for personalized healthcare, persistent ethical and regulatory issues may worsen existing inequities. Successful outcomes necessitate collaborative governance, inclusive design, and aligned global standards to guarantee patient safety and equity.

**Keywords:** Artificial intelligence, Pharmaceutical advertising, Ethics-regulation gap, Health equity, Chatbot compliance

## 1. Introduction

Artificial Intelligence (AI) is rapidly transforming pharmaceutical advertising by enabling highly personalized, data-driven communication across diverse media (Sonia, 2022; Chibugo Udegbe et al., 2024).

AI-driven health applications, chatbots, and virtual health assistants facilitate patient-centric engagement by augmenting patient education, leading to improved treatment adherence and ultimately better patient care (Batra Deep Manishkumar, 2024).

Moreover, technologies such as telephone/video consultations, as well as telemonitoring, enable clinicians to provide real-time care comparable to conventional practices, regardless of the patient's or provider's location, although they sometimes lack the human touch (Awala, 2024). AI chatbots have demonstrated efficacy in promoting healthy lifestyles, medication adherence, and smoking cessation, reaching large and diverse populations through accessible platforms like smartphones and messaging applications (Aggarwal et al., 2023).

Received 15 October 2025; revised 15 December 2025; accepted 22 December 2025.
Available online 15 July 2026

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https://doi.org/10.63100/3078-6738.1027

Predictive analytics also involved AI and this facilitates early diagnosis of diseases and explicit drug discovery to enhance treatment adherence and recovery (Dixon et al., 2024).

Previous reviews have underlined the ethical hazards associated with the use of AI in healthcare. However, there appears to be a "ethics-regulation gap" in this area as there is now no thorough assessment of how conventional regulatory frameworks, like those from the Food and Drug Administration (FDA), European Medicines Agency (EMA), or United States Federal Trade Commission (US FTC), find it difficult to handle real-time adaptive advertising through dynamic AI interactions. Additionally, the gap between ethical concerns and legal enforcement surrounding personalized AI systems remains largely unexplored (Gerke et al., 2020).

This review systematically examines how advanced AI technologies, including predictive analytics, machine learning algorithms, health chatbots, and virtual health assistants, are being deployed for targeted patient education, engagement, and treatment optimization. The objective is to evaluate precisely the potential benefits and drawbacks of AI in transforming healthcare interactions and pharmaceutical promotion.

A comprehensive examination of the ethical, legal, and equity issues surrounding AI-driven pharmaceutical advertising in a variety of international contexts, including low- and middle-income nations, is also provided by the review, which synthesizes various lines of evidence about AI technologies, pharmaceutical advertising channels, and healthcare provider engagement. This article aims to inform future research, guide regulatory innovation, and support responsible AI deployment in pharmaceutical marketing.

## 2. Method

### 2.1. Design

This narrative review integrates findings from various studies. Systematic research was conducted across seven major databases (PubMed, Scopus, Web of Science, EMBASE, Business Source Complete (EBSCO), IEEE Xplore, and ACM Digital Library) to ensure thorough coverage in relevant fields, including biomedicine, technology, and Pharmaceutical/medical industries.

Domain-Based Tools were utilized to evaluate the risk of bias in the included studies. The authors employed the Cochrane Risk of Bias 2 (RoB 2) Tool for Randomized Controlled Trials (RCTs) and ROBINS-I (Risk Of Bias In Non-randomized Studies - of Interventions) for Non-Randomized Studies of Interventions (NRSI).

### 2.2. Search strategy

A thorough search was conducted using combinations of terms: ("artificial intelligence" OR AI OR "machine learning" OR chatbot OR "conversational agent" OR "virtual assistant") AND ("pharmaceutical advertising" OR "drug promotion" OR "medical marketing" OR "direct-to-consumer advertising" OR Direct-to-Consumer Advertising (DTCA) OR " Healthcare Professional (HCP) engagement" OR "sales promotion"). AND ("ethics" OR "regulation" OR "policy" OR "equity" OR "bias" OR "trust" OR "vulnerable population" OR "health disparities") AND ("review" OR "systematic review" OR "literature review").

### 2.3. Inclusion criteria

Peer-reviewed studies and review articles, including systematic, scoping, narrative, and critical reviews. Published in English from 2019 to 2024 because this period represents a major shift in AI, marked by rapid advances in deep learning, generative models, and real-world deployment to ensure the relevance, up to date, and alignment with modern AI developments. Examine the role of AI and chatbots in the advertising, promotion, and marketing sectors of the medical and pharmaceutical industries.

### 2.4. Exclusion criteria

Primary research articles, commentaries lacking comprehensive literature synthesis, and editorials. Articles that concentrate exclusively on the clinical applications of AI and chatbots, excluding any advertising or promotional elements. Articles that address general digital marketing, excluding a specific emphasis on AI or chatbots. Non-peer-reviewed literature includes grey literature, reports, blogs, and conference abstracts, but not peer-reviewed articles. Articles in languages other than English were also excluded.

### 2.5. Analysis

A thorough review of the previous articles and literature was conducted to determine fundamental themes and viewpoints about the use of application and ethics-regulation disparity for AI and chatbots in medical and pharmaceutical advertising. The principal arguments and findings from the sources were analyzed for similarities and differences. Fig. 1 shows the PRISMA diagram for the included study.

### 2.6. Ethical approval

This narrative review synthesizes existing published literature and does not involve direct research

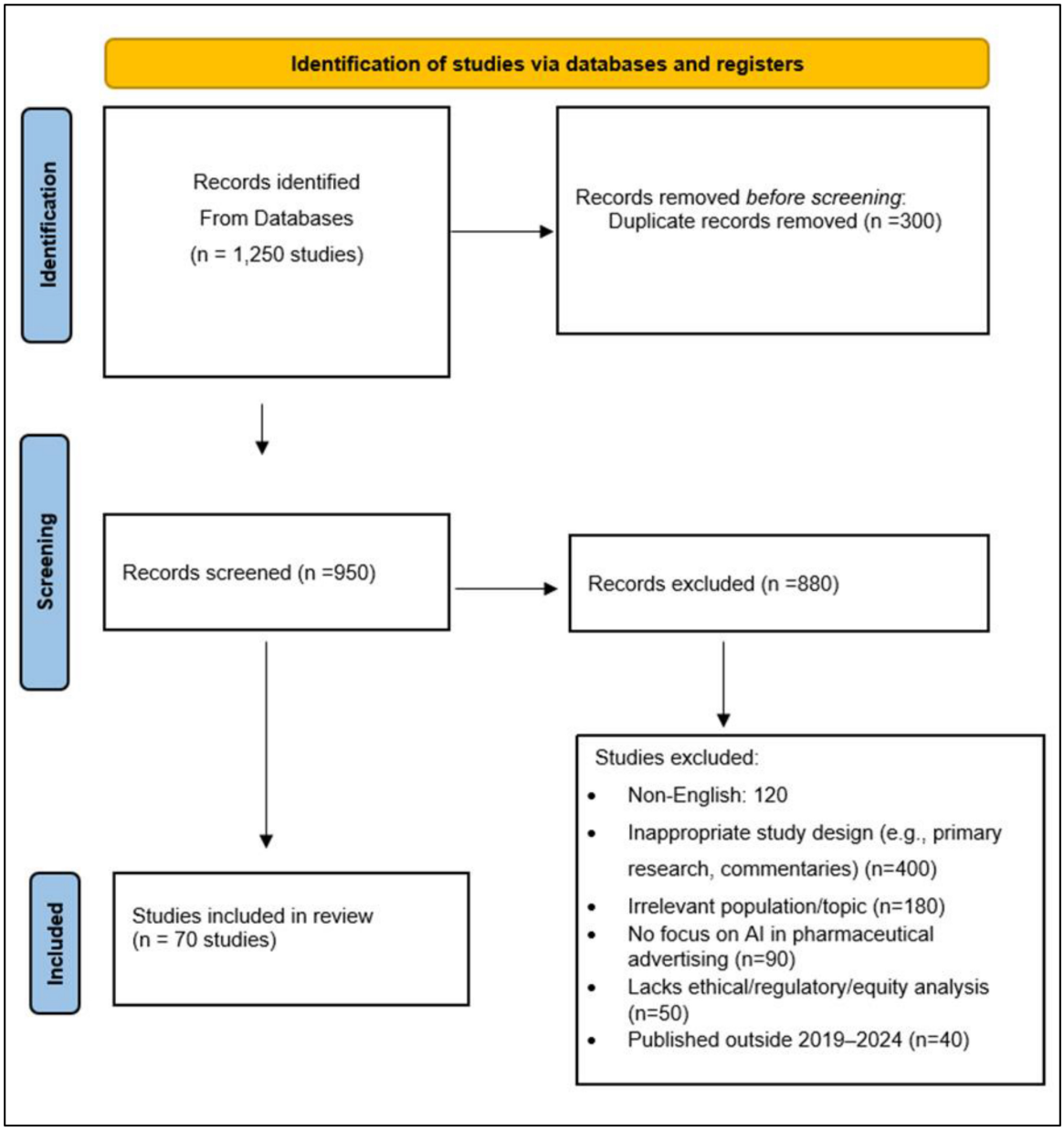


**Fig. 1.** PRISMA diagram of the included studies.

on human or animal subjects, primary data collection, or access to identifiable personal data. Consequently, formal institutional ethical approval was considered unnecessary. All sources analyzed were publicly accessible peer-reviewed publications, cited in compliance with academic integrity standards. The authors affirm the absence of fabrication, falsification, or misrepresentation of results.

### *2.6.1. Reshaping industry-healthcare professionals dynamics*

The incorporation of AI tools in healthcare notably influences the relationships between healthcare professionals (HCPs) and the industry, primarily by modifying job design, decision-making processes, and educational requirements. The applications of AI in diagnosis, treatment, patient engagement, and administrative tasks have transformed the job autonomy, skill variety, and social dimensions of healthcare roles, prompting a reassessment of job design models to reflect these developments (Tursunbayeva and Renkema, 2023).

The integration of AI tools, especially non-knowledge-based systems, has elicited diverse responses from healthcare professionals, reflecting differing degrees of trust and confidence in these

technologies. Although some professionals found that AI can boost decision-making process, others are uncertain about its preciseness and utility, so deeper understanding and trust regarding AI results are required (Ayorinde et al., 2024).

Projects like the Clinician Champions Program, which aims to fill knowledge gaps in AI and boost confidence in application of AI through interprofessional learning and moral consideration, are prime examples of how the educational landscape for healthcare workers is evolving (Teferi et al., 2024).

The augmentative role of AI is considered as emphasizing the importance of human-AI partnership in enhancing healthcare services while ensuring its safety and quality (Sezgin, 2023).

The possibility of AI transforming healthcare services is emphasized by its capability to mitigate burnout, increase efficiency, and maximize patient engagement; however, it necessitates specific modifications and thorough incorporation into current work stream (Shuaib, 2024).

#### *2.6.2. Chatbots as virtual sales representatives*

By supplying users individualized, instant assistance and accelerating their purchasing experience, chatbots can improve satisfaction and boost sales conversions when used effectively as virtual sales reps. AI-powered solutions offer ongoing assistance, enhancing client retention and satisfaction while guaranteeing business entities stay available and receptive to customer demands (Goyal and Sharma, 2024; Prasad et al., 2024).

Natural language processing (NLP) and machine learning (ML), two cutting-edge technologies, allow chatbots to interpret customer requests, provide tailored product suggestions, and oversee cart operations. This feature improves the buying experience and improves conversion rates (de Freitas and Lotufo R de, 2024).

Personalization significantly influences chatbot effectiveness. By tailoring interactions to fundamental consumer traits and emotional states, chatbots can cultivate trust and a sense of connection, thereby improving the brand's upselling potential (Hildebrand and Bergner, 2019; Badawy et al., 2020). Additionally, chatbots can gather significant data on customer preferences and behaviors, enabling businesses to refine their marketing strategies and enhance the overall user experience (Goyal and Sharma, 2024).

The incorporation of chatbots within e-commerce and social media platforms enables the management of routine tasks and substantial interaction volumes, thereby decreasing operational costs and improving the shopping experience through immediate responses to frequent inquiries and seamless transactions (Prasad et al., 2024; Krishnan et al., 2022).

Despite challenges such as technical limitations and privacy concerns, the strategic implementation of chatbots can enhance brand loyalty and drive revenue growth, as they play a crucial role in guiding customers through the sales funnel and nurturing leads (Ramki et al., 2024).

#### *2.6.3. Key considerations for developing an inclusive AI-driven chatbot for advertising*

Creating an inclusive AI-driven chatbot for medical and pharmaceutical advertising requires attention to several critical factors, particularly accessibility, accuracy, and user engagement. Inclusivity is essential, as evidenced by the necessity for chatbots to assist users who are not technologically adept, including the elderly and individuals with disabilities, through an accessibility-by-design framework (Grassini et al., 2025).

Integrating multimodal interaction features enables users to engage through text, voice, and additional methods, thereby improving accessibility and personalization (Garimella et al., 2024).

With the goal to overcome communication hurdles in linguistically diverse settings and improve empowerment of patients and accessibility to healthcare, the chatbot must also be equipped to operate in vernacular languages (Singh et al., 2023).

Information accuracy and reliability provided by the chatbot are crucial, as inaccuracies can result in unfavorable outcomes. This necessitates the use of a knowledge base derived from credible medical databases and peer-reviewed literature (Narendran et al., 2024).

Furthermore, the PharmaLLM, a medicine prescriber chatbot model, which earned adequate precision and usability rankings, shows that the chatbot needs to be customized for medical applications to stop the dissemination of false or potentially dangerous information (Azam et al., 2024).

The development procedure must involve a roadmap for fair design and integration, underlining diversity, partnership, and ongoing assessment to alleviate bias and strengthen fairness (Nadarzynski et al., 2024).

Assessing chatbots' language processing skills, impact on clinical practices, and effectiveness in user interactions—with a focus on trust-building, ethical considerations, personalization, and empathy—is necessary to determine how effective they are Abbasian et al. (2024).

By taking these factors into account, AI-driven chatbots can increase patient participation, promote

**Table 1.** Responsible AI advertising framework for healthcare & pharma.

| References | Principle | Regulators | Industry (Advertisers/Pharma) | Developers (AI Tech) |
|---|---|---|---|---|
| Baumgartner and Baumgartner (2023); Kaponis et al. (2023); Schmidt et al. (2024) | Transparency | • Mandate clear labeling of AI-generated content<br>• Standardize disclosure formats<br>• Require real-time source citations for medical claims | • Disclose AI use prominently<br>• Provide plain-language explanations of AI's role<br>• Maintain audit trails for ad creation | • Build "explainability" features<br>• Log decision pathways<br>• Enable source tracing for claims |
| Sebastian and Sebastian (2023); Pitel et al. (2024); Wahed et al. (2025) | Equity-by-Design | • Enforce bias testing standards<br>• Require diverse training data reporting<br>• Ban high-risk discriminatory targeting | • Audit models for demographic bias<br>• Diversify training datasets<br>• Monitor ad performance across populations | • Implement fairness constraints<br>• Use debiasing techniques<br>• Include equity metrics in validation |
| Kaponis et al. (2023); Shearer et al. (2021); Raff et al. (2018) | Human Oversight Tiers | • Define risk-based oversight levels:<br>- *High*: Rx drugs – clinician review<br>- *Medium*: OTC – pharmacist review<br>- *Low*: Wellness – QA specialist | • Implement tiered review workflows<br>• Train staff on AI error detection<br>• Maintain human veto power | • Embed clinician/publisher review checkpoints<br>• Enable seamless human edits<br>• Flag uncertain outputs |
| Schmidt et al. (2024); Huang et al. (2024); Mbah (2024); Teichmann and Boticiu (2023) | Dynamic Compliance | • Create agile regulatory sandboxes<br>• Update guidelines quarterly for generative AI<br>• Harmonize global standards (FDA/EMA/GDPR) | • Establish AI governance teams<br>• Automate compliance monitoring<br>• Conduct real-time risk mapping | • Design modular systems for rapid updates<br>• Integrate compliance APIs (FDA/EMA databases) |
| Kaponis et al. (2023); Mbah (2024); Busch et al. (2025) | Data Integrity & Privacy | • Strengthen health data consent requirements<br>• Clarify anonymization standards for AI training | • Obtain explicit consent for data use<br>• Anonymize patient-derived training data<br>• Limit data retention | • Encrypt data end-to-end<br>• Implement differential privacy<br>• Prevent training data leakage |
| Shearer et al. (2021); Solaiman (2025); Karisma (2022) | Accountability | • Require incident reporting systems<br>• Impose fines for harmful disinformation | • Designate AI-advertising liability officers<br>• Maintain redress mechanisms for harmed users | • Enable full auditability of model versions<br>• Document training data provenance |
| Baumgartner and Baumgartner (2023); Pitel et al. (2024); Warraich et al. (2025) | Validation & Testing | • Mandate pre-deployment clinical validation for high-risk ads<br>• Standardize adversarial testing protocols | • Third-party validate AI ad outputs<br>• Test for edge cases (e.g., drug interactions)<br>• Monitor real-world accuracy | • Rigorously test against misinformation risks<br>• Validate outputs with medical ontologies<br>• Stress-test for hallucinations |
| Kaponis et al. (2023); Wahed et al. (2025); Amedior (2023) | Shared Responsibility | • Fund multidisciplinary R&D<br>• Host stakeholder forums | • Collaborate on industry-wide ethical guidelines<br>• Share non-proprietary safety best practices | • Co-design with healthcare providers<br>• Publish transparency reports |

equitable health care in pharmaceutical and medical advertising, and improve healthcare delivery.

Table 1 consolidates evidence-based recommendations derived from peer-reviewed research into a Responsible AI Advertising Framework for Healthcare and Pharma. The table delineates fundamental principles (Transparency, Equity-by-Design, Human Oversight Tiers, Dynamic Compliance, Data Integrity, Accountability, Validation, Shared Responsibility) and articulates specific actions for Regulators, Industry, and Developers. The table also addresses the gap between ethics and regulation by offering a multi-stakeholder roadmap for the ethical and effective deployment of AI in sensitive medical advertising contexts, based on existing scientific literature.

**Table 2.** Comparative analysis of AI/chatbots vs. conventional channels in medical/pharmaceutical advertising.

| References | Feature/ Characteristic | AI & Chatbots (e.g., Generative AI, NLP Bots) | Conventional Digital/ Legacy Channels (e.g., TV, Print, Static Websites) | Key Implications |
|---|---|---|---|---|
| Esteva et al. (2017) | Targeting Precision & Personalization | High: Analyzes vast datasets (demographics, behavior, medical history*), enables micro-segmentation & hyper-personalized messaging. | Low-Moderate: Relies on broad demographics or contextual placement. Limited dynamic personalization | Enables dynamic message tailoring for improved relevance & engagement. Demonstrates AI pattern recognition capabilities |
| De Cock et al. (2020) | Engagement & Interactivity | High: Two-way conversational interfaces. Responds to queries 24/7, guides users through complex journeys. | Low: Primarily one-way broadcast. Limited interactivity (e.g., link clicks). Relies on passive consumption | Facilitates active user participation & deeper exploration of content |
| Davenport and Kalakota (2019) | Scalability & Efficiency | High: Automates responses, handles large user volumes simultaneously, and reduces manual support burden. | Moderate: Scaling increases costs linearly. Personalized responses require human intervention. | Efficiently manages repetitive tasks & scales personalized interactions |
| Topol (2019) | Content Dynamism & Adaptation | High: Content adapts in real-time based on user input and predictive analytics. Generates message variations | Low: Static once deployed. Changes require manual redesign/reproduction | Allows responsive content evolution through adaptive capabilities |
| Schwalbe and Wahl (2020) | Data Collection & Insights | Rich & Granular: Captures detailed interaction logs (questions, paths, sentiment). Enables deep analysis of user intent | Limited & Aggregate: Tracks broad metrics (impressions, clicks). Limited insight into engagement drivers | Provides deeper behavioral insights for actionable intelligence |
| Schwalbe and Wahl (2020) | User Education & Support Depth | High Potential: Provides layered information, simulates clinical discussions, and offers tailored support programs | Limited: Fixed content depth. No conversational support or personalization | Enables sophisticated educational experiences through contextual adaptation |

### *2.6.4. Comparative analysis between AI, chatbot, and conventional digital/legacy channels*

AI-driven chatbots are transforming drug delivery research in the pharmaceutical sector by optimizing drug formulation, predictive modeling, and regulatory compliance, thereby accelerating drug development timelines and improving research efficiency (Malkawi, 2024).

Chatbots can assist healthcare professionals by delivering precise and safe responses to drug-related inquiries, akin to those provided by licensed pharmacists, while also supplying supplementary proactive risk mitigation information (Albogami et al., 2024).

The implementation of AI in healthcare and pharmaceutical advertising presents several challenges. Addressing ethical considerations, verifying data sources, and establishing robust regulatory frameworks are essential for ensuring the safe and effective use of AI technologies (Edyko et al., 2023; Gerard Ball et al., 2024).

Furthermore, although AI chatbots have the potential to improve patient engagement and facilitate data collection, their present efficacy in clinical applications remains moderate, rendering them unsuitable for critical clinical use (Li et al., 2024).

Conversely, traditional digital channels, including social media platforms and influencer marketing, have significantly altered media consumption and consumer behaviors in pharmaceutical advertising, though they present distinct regulatory challenges and trust concerns (Gerard Ball et al., 2024).

Consequently, although AI and chatbots present novel solutions and efficiencies, their incorporation into medical and pharmaceutical advertising necessitates meticulous oversight of ethical, legal, and regulatory factors to enhance rather than supplant traditional channels (Gerard Ball et al., 2024; Altamimi et al., 2023).

Table 2 presents a comparative analysis of AI and chatbots in relation to traditional digital and legacy channels for medical and pharmaceutical advertising, emphasizing key distinctions across ten essential dimensions.

### *2.6.5. How AI traits challenge ethics and regulation in medical advertising*

The incorporation of AI and chatbots in medical and pharmaceutical advertising presents intricate ethical, regulatory, and technological challenges, commonly referred to as the ethics-regulation gap (Pitel et al., 2024; Wahed et al., 2025).

These advancements introduce significant ethical concerns, including data privacy, algorithmic bias, and the potential for disinformation propagation, particularly regarding AI chatbots such as ChatGPT (Baumgartner and Baumgartner, 2023; Sebastian and Sebastian, 2023).

The swift advancement of AI technologies surpasses current regulatory frameworks, resulting in a gap that complicates the ethical implementation of AI in healthcare environments (Pitel et al., 2024).

The European Union's AI Act seeks to tackle these intricate ethical, regulatory, and technological challenges through a risk-based regulatory framework; however, it has faced criticism for inadequately considering the ethical and relational factors essential for fostering trust in AI systems (Solaiman, 2025).

The self-learning characteristics of AI and its reliance on data present further regulatory challenges, as existing frameworks are inadequately prepared to address adaptive AI technologies (Kiseleva, 2021).

In medical and pharmaceutical advertising, chatbots must strike a balance between providing accurate information and preventing the dissemination of misleading content, which is crucial for maintaining public trust and ensuring patient safety (Kaponis et al., 2023).

The ethical application of AI in this sector necessitates a multidisciplinary approach, requiring collaboration among healthcare professionals, AI developers, and regulatory bodies to create comprehensive guidelines that reconcile innovation with ethical considerations (Rosemann and Zhang, 2022).

As AI progresses, continuous research and discussion are crucial to address the ethics-regulation gap and promote the responsible application of AI in medical and pharmaceutical advertising (Wahed et al., 2025; Rosemann and Zhang, 2022).

#### *2.6.6. Regulatory gaps for AI chatbots in medical and pharmaceutical promotion*

The regulatory framework governing AI and chatbots in medical and pharmaceutical advertising presents significant gaps and challenges, particularly in relation to guidelines established by the FDA and EMA, as well as data privacy regulations such as the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA). The FDA currently classifies AI as a medical device, which may inadequately address the distinct challenges presented by adaptive AI systems that change over time. This situation calls for a more dynamic regulatory model similar to those applied to medical practitioners (Raff et al., 2018; Warraich et al., 2025).

The EMA, via the European AI Act, establishes a foundational regulatory framework; however, it is still in its early stages and lacks specificity regarding AI in healthcare. This highlights the need for more comprehensive regulations that account for the distinct risks and benefits associated with AI (Schmidt et al., 2024).

Data privacy regulations, including the GDPR and HIPAA, pose significant challenges, necessitating meticulous navigation to achieve compliance while harnessing the potential of AI. The fragmented global regulatory environment, characterized by differing levels of AI-specific legislation among countries, intensifies these challenges, evident in the disparities between the Global North and South in the adoption of AI frameworks (Mbah, 2024; Busch et al., 2025).

This fragmentation necessitates international collaboration to align regulations, ensuring that AI systems remain innovative while adhering to privacy standards (Huang et al., 2024; Mbah, 2024).

The swift advancement of AI technologies, particularly generative AI, surpasses legislative developments, resulting in a regulatory gap that hinders the enforcement of current laws (Teichmann and Boticiu, 2023). A new regulatory model is proposed that emphasizes the AI design process rather than solely the final product, aiming to enhance trust and accountability in AI systems (Shearer et al., 2021).

A balanced approach that protects privacy while promoting innovation is essential. This requires collaboration among governments, industry stakeholders, and international organizations to create cohesive frameworks for AI (Karisma, 2022).

Tutt advocates for the establishment of a specialized regulatory agency similar to the FDA for algorithms, highlighting the necessity of pre-market reviews to avert the deployment of harmful algorithms, which corresponds with the concept of pre-deployment audits (Tutt, 2017).

Koshiyama et al. emphasize the significance of auditing algorithms for fairness, arguing that such audits are essential for ensuring legality, ethics, and safety, akin to financial audits (Koshiyama et al., 2024).

Price argues that the FDA's conventional regulatory framework in healthcare may hinder innovation and proposes a more flexible approach that incorporates disclosure requirements, potentially enhanced by equity audits to promote transparency and accountability (Price, 2017).

Schulz et al. highlighted the insufficient regulatory oversight regarding the evaluation of the quality and efficacy of predictive algorithms in clinical environments, emphasizing the necessity for

frameworks that incorporate equity considerations (Schulz et al., 2019).

#### 2.6.7. Ethical and equity considerations

Algorithmic bias in AI and chatbot-driven medical and pharmaceutical advertising affects patient trust and adherence to treatment plans by reinforcing existing healthcare disparities and shaping patient perceptions. AI systems often exhibit biases due to unbalanced datasets, limited feature scopes, and feedback loops that perpetuate existing preconceptions, particularly affecting marginalized groups (Cross et al., 2024; Bhatia et al., 2024).

A commonly utilized medical algorithm was discovered to underestimate the health requirements of Black patients, thereby worsening racial disparities in healthcare (Johnson, 2022).

Biases can lead to suboptimal clinical decisions and misdiagnoses, resulting in patients receiving inappropriate or inadequate care due to flawed AI recommendations (Cross et al., 2024).

The reliability of AI-generated medical advice is complicated by non-experts' difficulty in differentiating between AI and human responses, which can result in misplaced trust in AI, even when the information provided is inaccurate. This misplaced trust may lead patients to follow potentially harmful medical advice, which can consequently impact adherence to appropriate treatment plans (Shekar et al., 2024).

The absence of transparency and standardized regulations in AI systems undermines trust, as patients may remain unaware of the biases affecting their care (Harve et al., 2024).

To address these issues, it is essential to implement strategies that include diverse data collection, transparency mandates, and participatory design with stakeholders, ensuring that AI systems are equitable and trustworthy (Bhatia et al., 2024; McCall et al., 2022).

Furthermore, the integration of AI with medical professionals can improve the accuracy of decision-making and uphold patient trust (Goh et al., 2023).

Addressing biases and enhancing transparency are crucial for building trust and ensuring equitable healthcare delivery, which in turn supports improved patient adherence to treatment plans (Nazer et al., 2023).

#### 2.6.8. Impact on vulnerable populations (elderly, low-SES, racial/ethnic)

The incorporation of AI and chatbots in medical and pharmaceutical advertising offers opportunities and challenges for vulnerable populations, such as the elderly, low socioeconomic status groups, and racial/ethnic minorities (Aggarwal et al., 2023).

AI technologies, including chatbots, demonstrate potential in facilitating health behavior changes and enhancing medication adherence across various populations, particularly older adults, through the provision of personalized, nonjudgmental, and accessible health interventions (Aggarwal et al., 2023; Gudala et al., 2022).

The effectiveness and acceptability of these technologies may be compromised by algorithmic biases and insufficient diverse training data, potentially worsening existing health disparities among marginalized populations. AI systems may unintentionally perpetuate historical patterns of discrimination if they are not designed and implemented with a focus on inclusivity (Iloanusi and Chun, 2024).

Additionally, older adults encounter distinct obstacles, including unfamiliarity with technology and concerns regarding privacy, which may restrict their interaction with AI-powered tools (Gudala et al., 2022).

Furthermore, biases in AI systems can lead to inadequate healthcare delivery for marginalized groups, as these systems may fail to accurately represent diverse populations due to unbalanced datasets and limited feature scopes (Bhatia et al., 2024).

AI algorithms have demonstrated suboptimal performance for racial and ethnic minorities, which may reinforce existing health disparities (Hussain et al., 2025).

The absence of diverse training data and the occurrence of algorithmic discrimination can lead to AI systems that do not yield equitable healthcare outcomes, as demonstrated by algorithms that undervalue health risks for minority patients (Hoffman et al., 2020).

Various strategies have been proposed to address these disparities. The development of fairness-aware algorithms, utilization of diverse datasets, and implementation of regulatory frameworks are essential for ensuring equitable healthcare delivery (Chinta et al., 2025).

Furthermore, technical interventions, including pre-processing, in-processing, and post-processing techniques, can mitigate bias in AI models, as evidenced in AI-driven target marketing contexts (Soni, 2024).

A comprehensive approach that incorporates participatory design and stakeholder engagement is essential for addressing the broader sociotechnical ecosystems that influence healthcare experiences (Bhatia et al., 2024).

Regulatory agencies such as the FDA should establish specific protocols for evaluating AI-driven medical devices to mitigate health disparities (Dortche et al., 2023).

#### 2.6.9. Global regulatory landscapes

Regulatory agencies, including the FDA and EMA, are engaged in monitoring the application of AI and chatbots in medical and pharmaceutical advertising. However, notable challenges and areas necessitating updates exist to ensure compliance. The FDA has led the way in authorizing various AI-enabled medical devices and has received numerous submissions for drugs developed with AI, underscoring the necessity for a coordinated regulatory strategy across industries and international organizations (Warraich et al., 2025).

The complexity of AI systems, particularly those utilizing machine learning, necessitates a shift from product-based to system-based regulatory approaches to ensure safety and efficacy, given their capacity for adaptation and evolution over time (Gerke et al., 2020).

Explainable AI (XAI) is being investigated as a means to enhance transparency and trust in AI systems, which are essential for compliance and regulatory decision-making in critical areas, such as healthcare (Mallela et al., 2020).

The FDA has issued guidelines for AI/ML-based software as medical devices (SaMD); however, the regulatory framework for NLP-based tools such as ChatGPT is still underdeveloped, presenting challenges for their application in clinical environments (Baumgartner and Baumgartner, 2023).

The swift progress of large language models (LLMs) like GPT-4 in healthcare applications complicates regulatory oversight, necessitating meticulous management to ensure safety and uphold ethical standards (Meskó and Topol, 2023).

The FDA is increasing scrutiny of marketing communications in the pharmaceutical sector, requiring accuracy and balance while advocating for new marketing strategies that adhere to evolving regulations (Castaldi, 1991).

Regulatory bodies must establish adaptable mechanisms that align with advancements in AI, integrate lifecycle management strategies, and prioritize the evaluation of AI tools based on patient health outcomes rather than financial considerations (Warraich et al., 2025; Mashar et al., 2023).

Furthermore, there is a demand for the international harmonization of regulatory requirements, exemplified by the initiatives of the International Medical Device Regulators Forum (IMDRF) to classify risks related to Software as a Medical Device (SaMD) (Baumgartner and Baumgartner, 2023).

Significant progress has been achieved; however, continuous updates and adaptations to regulatory frameworks are crucial for the effective management of AI and chatbots in medical and pharmaceutical advertising.

#### 2.6.10. Future directions and recommendations

Future efforts to address the ethical, regulatory, and equity challenges of AI in pharmaceutical advertising should prioritize collaborative governance among regulators, industry stakeholders, and developers to harmonize global standards (Schmidt et al., 2024).

Implementing equity-by-design frameworks, such as mandatory bias audits and diverse training datasets, can reduce algorithmic disparities and promote equitable healthcare delivery (Nadarzynski et al., 2024; Parikh et al., 2022). Regulatory agencies, including the FDA and EMA, should implement adaptive oversight models for AI systems, incorporating real-time compliance monitoring and pre-market evaluations for high-risk applications (Gerke et al., 2020; Warraich et al., 2025). Furthermore, improving transparency and explainability in AI-driven advertising by implementing standardized disclosure formats and source citations will promote patient trust (Baumgartner and Baumgartner, 2023). Multimodal and multilingual chatbot interfaces should be developed for vulnerable populations to enhance accessibility and inclusivity (Grassini et al., 2025; Singh et al., 2023). Ongoing research must assess the long-term effects of AI on health equity, adhering to participatory design principles and involving stakeholder engagement (Bhatia et al., 2024; Chinta et al., 2025).

## 3. Conclusion

AI and chatbots present transformative opportunities for personalized pharmaceutical advertising and healthcare engagement; however, substantial ethical, regulatory, and equity challenges remain. Algorithmic biases, regulatory fragmentation, and risks to vulnerable populations necessitate immediate multidisciplinary interventions. These barriers can be addressed through adaptive governance frameworks, such as risk-tiered human oversight and equity-by-design standards, alongside international regulatory harmonization and transparent development of AI. Achieving success necessitates collaboration among regulators, industry stakeholders, and developers to prioritize patient safety and equity. Embedding ethics in innovation enables stakeholders to harness the benefits of AI while mitigating its limitations, thereby fostering responsible progress that bridges the ethics-regulation divide and benefits all populations fairly.

## Conflict of interest

The authors report no financial conflicts of interest or relationships that may affect this research.

## Funding

This review did not receive any external funding.

## Contribution of the author

The authors hereby attest to their contributions to the manuscript in the following manner: The initial author was responsible for the conception and design of the review. Data collection is conducted collaboratively by all authors. The review article was a collaborative effort involving all authors. Additionally, the final version of the manuscript was extensively reviewed and approved by all authors prior to submission.

## Declaration of AI-assisted technologies and generative AI in the writing process

The Introduction, Methods, and all sections of this manuscript were exclusively composed using [Grammarly and QuillBot] to refine the language and make minor phrasing adjustments, such as improving the fluency or grammar of the sentences. The authors were responsible for the creation of all content; no artificial intelligence (AI) instrument was employed for substantive writing, data analysis, or ideation. The final manuscript was meticulously reviewed, edited, and approved by all authors to ensure accuracy and compliance with academic standards.

## Acknowledgements

Not applicable.

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