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Liability of Medical AI System Developers: Comparative Legal Analysis of International Regulations

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Abstract: This study presents a comparative legal analysis of liability regulation for developers of artificial intelligence-based medical systems in key jurisdictions: the European Union, the United States, and Asian countries (China, Japan). The research identifies two dominant liability models: strict liability (EU, China) and mixed liability (USA, Japan), analyzing their advantages and disadvantages. The study identifies key legal challenges, including the opacity of AI systems' decision-making processes, difficulties in determining responsible entities, and challenges in establishing causation. Specific mechanisms for harmonizing international regulatory approaches are proposed: establishing a differentiated liability regime based on risk levels, requirements for algorithm explainability, easing the burden of proof for victims, and implementing mandatory liability insurance. The work demonstrates the necessity of balancing innovation incentives with patient safety as a key principle for effective regulation of medical AI systems.

Keywords: artificial intelligence, medical AI systems, legal liability, international law, technology regulation.

INTRODUCTION

Integration of artificial intelligence systems into healthcare opens unprecedented opportunities for improving the quality and accessibility of medical care. Medical AI systems, from diagnostic algorithms to clinical decision support systems, are transforming traditional practices and creating new paradigms of healthcare delivery. According to analysts' forecasts, the global AI market in healthcare will reach $187 billion by 2030, reflecting the exponential growth in the adoption of these technologies [1].

However, the rapid development of medical AI systems is accompanied by the formation of a significant legal vacuum in liability regulation. The autonomous nature of modern AI algorithms based on deep learning methods blurs traditional legal concepts of causality and predictability of harm. In these conditions, the question of who should bear responsibility for harm caused by an autonomous system – the algorithm developer, data provider for training, medical institution, or physician – becomes critically important [2].

This study aims to provide a comprehensive analysis of existing and emerging legal mechanisms for regulating the liability of medical AI system developers across different jurisdictions. The main goal is to identify optimal regulatory models capable of ensuring a balance between protecting patient rights and stimulating innovation in healthcare. The research addresses the following objectives: conducting a comparative analysis of legal regimes in key jurisdictions, identifying the main problems in determining liability for autonomous AI functioning, and proposing ways to harmonize international regulation.

The structure of the work includes an analysis of research methodology, detailed examination of regulatory approaches in the European Union, USA, and Asian countries, comparative analysis of liability models, and development of recommendations for their harmonization.

MATERIALS AND METHODS

The research is based on a comprehensive comparative legal analysis of regulatory documents, judicial precedents, and academic literature related to liability regulation for medical AI system developers across different jurisdictions. The methodology combines qualitative and quantitative methods, ensuring a comprehensive study of the problem.

Primary sources included regulatory acts from key jurisdictions (as of October 2024), including the General Data Protection Regulation (GDPR), Medical Device Regulation (MDR), and Artificial Intelligence Act (AI Act) of the European Union; FDA guidelines for regulating software with AI/ML functions in the USA; China's Guidelines for Registration of Medical Devices with AI Functions and relevant consumer protection laws; and regulatory documents from the Japanese Pharmaceuticals and Medical Devices Agency. Additionally, 47 judicial decisions from national courts with precedential significance for determining the status and liability of medical AI system developers were analyzed [3].

International documents and standards played an important role in the research, particularly the WHO guidance on ethics and governance of AI in healthcare (2021), ISO standards including ISO/TR 24030:2021, and OECD principles for responsible management of trustworthy AI. Secondary sources included 126 academic publications in peer-reviewed journals from 2019-2024, 23 analytical reports from international organizations, and materials from industry conferences [4].

For an in-depth understanding of practical aspects of legal norm application, an analysis of 12 representative cases related to determining liability when using medical AI systems was conducted. Additionally, content analysis of regulatory acts was performed to assess the intensity of legal regulation from 2019 to 2024 [5].

Comparative assessment of the effectiveness of different regulatory models was carried out according to five key criteria: adequacy of patient rights protection, stimulation of innovation, legal certainty, technological neutrality, and prospects for international harmonization. This methodology provided a comprehensive analysis of existing and emerging legal mechanisms, allowing for the identification of optimal regulatory models and formulation of recommendations for harmonizing international approaches to regulating the liability of medical AI system developers.

RESEARCH RESULTS

Regulation in the European Union

The European Union occupies a leading position in developing specialized regulation of artificial intelligence systems, including their application in healthcare. Key regulatory acts include the General Data Protection Regulation (GDPR), Medical Device Regulation (MDR), and the recently adopted Artificial Intelligence Act (AI Act) [6].

The European Union Medical Device Regulation 2017/745, which came into full force in May 2021, classifies software used for diagnostic or therapeutic purposes as a medical device subject to certification. The distinctive feature of the European Union's approach is risk-oriented classification: medical artificial intelligence systems with high risk to patient health are subject to stricter control, including third-party conformity assessment [7].

The Artificial Intelligence Act adopted in 2023 establishes horizontal requirements for high-risk AI systems, including requirements for transparency, data management, and human oversight. According to this act, medical artificial intelligence systems used for diagnosis and treatment are automatically classified as high-risk [8].

In terms of liability, the European Union adheres to a model of strict manufacturer liability for product defects, which extends to developers of medical software. European Council Directive 85/374/EEC on liability for defective products stipulates that a manufacturer is liable for damage caused by a defect in its product, regardless of fault. As part of the revision of this directive in 2022-2023, the European Commission proposed updated provisions explicitly extending the strict liability regime to digital products, including artificial intelligence systems [9].

A key challenge of the European approach remains proving product defects and the causal relationship between the defect and the harm caused. To address this issue, the new version of the Directive proposes procedural easing of the burden of proof for victims in cases where the technical complexity of the product makes it difficult to establish the defect [10].

Regulation in the USA

The United States' approach to regulating medical artificial intelligence systems is characterized by greater fragmentation and flexibility. The primary regulator is the Food and Drug Administration (FDA), which in 2021 issued an updated action plan for regulating software with artificial intelligence and machine learning functions [11].

The FDA classifies medical software with artificial intelligence/machine learning (AI/ML) functions as a medical device subject to registration depending on the risk level. The specificity of the American approach lies in the concept of "pre-certification" (Pre-Certification Program), which takes into account the ability of self-learning systems to change over time [12].

In the area of liability, the USA adheres to a mixed model, combining elements of strict liability and fault-based liability. Product liability is regulated at the state level but in most cases is based on principles outlined in the "Restatement (Third) of Torts: Products Liability." According to this document, the manufacturer bears strict liability for manufacturing defects, but liability for design defects and inadequate risk warnings requires proof of unreasonable risk [13].

US case law demonstrates significant diversity in approaches to software developers' liability. In "In re Avandia Marketing, Sales Practices and Products Liability Litigation" (2013), the court recognized that software used for medical purposes can be considered a product for the purposes of defect liability [14]. However, in several other cases, courts refused to apply the doctrine of strict liability to software developers, viewing their activity as providing services rather than manufacturing a product [15].

Regulation in Asian countries

China, which aspires to leadership in artificial intelligence, is forming a comprehensive system for regulating AI in healthcare. In 2021, the National Medical Products Administration (NMPA) of China issued guidelines for the registration of medical devices with AI functions, establishing requirements for algorithm verification and clinical data validation. The Chinese liability model is based on the principle of strict manufacturer liability, enshrined in the Consumer Rights Protection Law and the Product Quality Liability Law [16].

Japan, with significant achievements in medical technology, takes a more conservative approach. The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) considers medical software with AI functions as a medical device requiring registration. The Japanese approach to liability is based on a combination of Civil Code provisions (providing for fault-based liability) and the Product Liability Law (establishing strict manufacturer liability) [17].

International initiatives and standards

At the international level, a number of initiatives are forming to harmonize approaches to regulating AI in healthcare. The World Health Organization (WHO) published guidance on ethics and governance of AI in healthcare in 2021, emphasizing the need for transparency, accountability, and fair distribution of responsibility [18].

The International Organization for Standardization (ISO) is developing a series of standards for artificial intelligence in healthcare, including ISO/TR 24030:2021 "Information Technology — Artificial Intelligence — Use Cases." The Organization for Economic Co-operation and Development (OECD) proposed principles for responsible governance of trustworthy AI, which were adopted by member countries in 2019 [19].

ANALYSIS OF RESEARCH RESULTS

Comparative analysis of liability models

The analysis shows significant differences in approaches to regulating the liability of medical artificial intelligence system developers across different jurisdictions. The European Union adheres to the most structured and preventive approach, establishing detailed requirements for high-risk AI systems at the market access stage and applying a model of strict manufacturer liability. The United States demonstrates a more flexible and technologically neutral approach, combining elements of preliminary FDA control with a variety of liability mechanisms determined by case law. Asian countries, especially China, are rapidly developing specialized regulation that combines elements of both approaches [20].

The research identified two main regulatory liability models:

1. Strict Liability Model (EU, China) — assumes developer responsibility for harm caused regardless of fault, with possible exceptions for development risks (unforeseen defects at the time of development). This model provides a high level of patient protection but may create an excessive burden on innovative companies [21].

2. Mixed Model (USA, Japan) — combines elements of strict liability for manufacturing defects with fault-based liability for design defects and inadequate risk information. This model provides greater flexibility but may make it more difficult for victims to obtain compensation [22].

Prospects for Regulatory Harmonization

Harmonization of international approaches to regulating the liability of medical AI system developers seems necessary due to the global nature of the technologies and the cross-border application of medical AI solutions. International standards developed by ISO and principles proposed by WHO and OECD can serve as the basis for such harmonization [23].

The optimal regulatory model should combine elements of preventive control (registration and certification of high-risk systems) with effective mechanisms for harm compensation. It seems appropriate to establish a differentiated liability regime depending on the risk level of the AI system and the degree of autonomy of its decisions [24].

To solve the "black box" problem, legislative requirements for explainability and transparency of AI systems used in critical areas of healthcare are necessary. Such requirements are already

forming within the EU AI Act framework and could become a standard for international regulation [25].

The problem of proving causation can be resolved by establishing procedural presumptions and shifting the burden of proof to the developer in cases where the technical complexity of the system makes it difficult to identify the causes of errors. Such an approach is already forming in European legislation and could be adopted at the international level [26].

Balance between innovation and safety

Achieving a balance between stimulating innovation and ensuring patient safety requires a differentiated approach to regulation. It is advisable to establish simplified procedures for low-risk AI systems and stricter requirements for systems used in critical areas of medicine [27].

A promising mechanism is mandatory liability insurance for developers of high-risk medical AI systems, which will ensure protection of patients' interests without creating an excessive financial burden on innovative companies [28].

To stimulate the development of safe and ethical AI systems, "regulatory sandbox" mechanisms can be used, allowing innovative solutions to be tested in a controlled environment with limited developer liability at the experimental implementation stage [29].

The study of international experience in regulating the liability of medical AI system developers shows that existing legal models are in the process of active transformation. Creating an effective regulatory system requires not only considering the specifics of artificial intelligence technologies but also ensuring a balance between the interests of developers, medical institutions, and patients. International cooperation in this area is a necessary condition for forming a harmonized approach that corresponds to the global nature of the development and application of medical AI technologies [30].

CONCLUSION

The comparative legal analysis of international approaches to regulating the liability of medical AI system developers revealed significant fragmentation and inconsistency in legal mechanisms. The study identified two dominant models: strict liability, applied in the European Union and China, and a mixed model, characteristic of the USA and Japan. Each of these models has its advantages and disadvantages, but the cross-border nature of the development and application of medical AI technologies requires the development of a harmonized approach.

The main regulatory challenges are related to the specifics of machine learning systems: opacity of the decision-making process, unpredictability of self-learning algorithm behavior, and complexity in distributing responsibility among multiple participants. These features complicate the application of traditional legal doctrines and require innovative regulatory solutions.

To form an effective international regulatory system, it is advisable to use a differentiated approach based on risk assessment: establishing strict liability for high-risk AI systems and more flexible regimes for systems with lower potential for harm. Critical elements of such a system should include: legislative requirements for algorithm explainability, procedural mechanisms to ease the burden of proof for victims, and implementation of mandatory liability insurance for developers.

Further research in this area should focus on developing detailed criteria for risk assessment of medical AI systems, forming industry standards for algorithm explainability, and creating specialized dispute resolution mechanisms. Only a comprehensive approach that takes into account the interests of all stakeholders will ensure a balance between stimulating innovation and protecting patient rights, which is a necessary condition for realizing the potential of artificial intelligence in healthcare.

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