

Legal Challenges in AI-Enabled Smart Drug Delivery Systems: A Study of Safety, Accountability, and Regulatory Gaps

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Abstract

Artificial intelligence (AI) is changing pharmaceutical sciences through its application in intelligent drug delivery systems which deliver precise and controlled and tailored medical treatments. The AI systems boost drug delivery performance through their ability to predict outcomes and process real-time information. The application of AI technology to drug delivery systems creates serious problems which affect both safety and product responsibility and government regulations. The study investigates the legal obstacles which smart drug delivery systems face because of their AI capabilities, while focusing on three main issues, which are patient safety and liability attribution and regulatory shortcomings. The safety hazards stem from three issues, which include data dependence and algorithmic bias and the opaque nature of “black box” AI models. The study investigates liability issues which arise when multiple parties, including manufacturers and software developers and healthcare professionals, face uncertainty about who should take responsibility for negative results. The current legal system, which was created to handle fixed medical devices, faces challenges in managing AI systems because these systems use adaptive and self-operating technologies, which create problems for declaring fault and establishing legal responsibilities.

The research evaluates current regulatory methods to find critical gaps which current regulatory systems create because they contain unaligned requirements and their denial of AI technologies to acquire knowledge through ongoing learning. The existing safety assessment system, which relies on standard approval and post-market monitoring, fails to provide proper safety evaluation and regulatory compliance assessment for the extended period.

The study proposes the creation of strong regulatory frameworks which deal specifically with AI technologies through their requirement of transparent operations and ongoing supervision and their need for distinct liability standards. The paper creates a framework which unites new technological progress with legal control to lead current discussions about developing safe and responsible and ethical methods for using AI-based drug delivery systems.

Keywords : Artificial Intelligence; Smart Drug Delivery Systems; Patient Safety; Liability; Regulatory Framework

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Introduction

The introduction of artificial intelligence (AI) to pharmaceutical sciences has brought about a major change in smart drug delivery system development which now enables scientists to create, distribute and track therapeutic drugs. Traditional drug delivery methods operate according to fixed pharmacological boundaries however AI-enabled systems establish a system that uses real-time data to make decisions through continual learning. The systems use their capacity to process extensive data which includes pharmacokinetic information together with patient-specific biomarkers and environmental conditions to deliver customized medical treatments which meet individual patient needs.

AI-enabled smart drug delivery systems provide better precision and increased treatment effectiveness together with fewer side effects. However AI-enabled systems create new obstacles which conflict with existing legal and regulatory frameworks. Traditional pharmaceutical

regulation relies on fixed products which require standard clinical trials to assess safety and efficacy before products can receive approval for market launch. AI-enabled systems operate through probabilistic mechanisms which develop through their use and their internal processes remain hidden from users therefore existing regulatory methods fail to address their needs.¹ The implementation of these systems creates fundamental safety problems which need to be resolved before determining who should take responsibility for damages or which authorities should execute safety

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measures. Legal doctrines which depend on foreseeability and causation and human agency face challenges when dealing with AI systems which gain independence through their continuous development. The legal framework becomes fractured because courts need to determine who should be held accountable for negative outcomes while decision-making requirements should remain transparent and regulation must be uniformly enforced. The paper presents an in-depth study of these issues by examining how AI-enabled smart drug delivery systems affect legal systems and pharmaceutical innovation development.²

Technological and Scientific Architecture of AI-Enabled Drug Delivery Systems

The AI-enabled smart drug delivery system combines advanced pharmaceutical engineering with computational intelligence through its three components machine learning algorithms and nanoscale delivery mechanisms and real-time sensing technologies. The design of these systems centers on developing solutions which establish better approaches for drug delivery than existing methods which suffer from non-specific distribution and poor bioavailability and limited control over release kinetics.³

The core system operation depends on machine learning models which analyze biological and chemical data to determine the best drug delivery methods. The models require training with comprehensive datasets that showcase molecular structures and pharmacokinetic profiles and patient-specific physiological data. The AI algorithms efficiently detect patterns and correlations which become visible only after traditional experimental methods. The development of advanced delivery systems starts from these insights as AI algorithms identify hidden patterns present in the data.⁴

The systems gain additional functionality through nanotechnology which enables them to target diseased tissues precisely while preventing unintentional exposure throughout the body. Scientists can design nanocarriers using three specific types of carriers which include liposomes and dendrimers and polymeric nanoparticles. The AI models function as essential components which help improve delivery systems by providing forward-looking models which assess biological system interactions with various formulations.

The AI-enabled drug delivery systems face validation and reproducibility and reliability challenges due to their complicated technological requirements. The system performance relies on training data quality because system performance declines when data lacks diversity. The AI models generate prediction errors when applied to populations which differ from the training data used during model development.

Safety Risks and Clinical Uncertainty in AI-Driven Drug Delivery

The implementation of AI technology within drug delivery systems creates additional safety issues which existing regulatory systems fail to manage while establishing new safety hazards that these systems cannot handle. The primary risk source for AI systems

originates from their need to process extensive complex datasets which contain incomplete information and biased content and fail to represent all patient groups. The limitations of his system result in incorrect predictions which lead to inferior treatment results in clinical environments that require utmost precision.

The "black box" characteristic of numerous AI models creates additional safety risks because it restricts users from understanding how the system functions and who should be interpreted. AI systems base their output on complex non-linear computations which require systematic mechanistic analysis to understand the results according to conventional pharmaceutical operation procedures. The system lacks explainability which prevents clinicians and regulators from determining how much they can trust AI systems when making decisions which raises the chances of negative consequences.⁵

AI systems create safety risks because their ability to learn through new information and system upgrades lets them learn new things and develop progressively through time. The system performance benefits from this adaptability although it creates uncertainty because algorithm modifications lead to system behavior modifications which remain unknown. Regulatory approval processes face difficulties because the system's active regulatory model requires products to stay unchanged after their testing.

The use of AI in drug delivery systems creates cybersecurity threats which endanger patient safety because they allow unauthorized access to critical medical information. The systems which depend on multiple digital systems for their operation face security risks because hackers can access their networks to steal data and control systems without permission. System integrity violations produce hazardous results which include both incorrect dosing and misdirected drug delivery.⁶

Liability and Legal Attribution in AI-Enabled Drug Delivery

The legal responsibility problem in AI-enabled drug delivery systems stands as their most challenging aspect because it creates a fundamental change to existing legal systems which depend on establishing direct links between events and specific people. In conventional medical practice health care professionals and product manufacturers face liability according to established rules which govern negligence and product liability cases. The AI system, which includes multiple decision-making levels and autonomous operations, creates a challenge for determining who bears responsibility for any resulting outcomes.

AI systems operate through a distributed network of stakeholders that includes developers manufacturers healthcare providers and data contributors. The determination of responsibility for an adverse outcome becomes difficult because multiple people may share responsibility for the resulting damage which happens due to multiple factors that include algorithmic errors and data limitations and human oversight failures.⁷

The problem of causation becomes particularly important for AI systems because algorithms use opaque decision-making processes which prevent users from

identifying how specific actions lead to harmful outcomes. The requirement established by courts for defendants to show that their actions directly caused the victim's injury becomes particularly difficult when complex non-transparent algorithms make all decision-making processes.

AI systems do not possess legal standing as independent entities according to current legal systems which require human beings or organizations to bear legal responsibility for AI-related incidents. The legal system assigns responsibility to parties who lack direct control over system behavior because of the difference between actual technological operation and established legal principles. The absence of clear legal precedents creates additional difficulties for courts because they have no established rules to follow when making decisions about cases that involve AI-based healthcare technologies.⁸

Regulatory Frameworks and Structural Gaps

The regulation of AI-enabled drug delivery systems displays a disorganized structure which lacks consistent standards and specific guidelines to control its operation because of the difficulties encountered in controlling advanced technological systems. The current regulatory system which includes controls for pharmaceuticals and medical devices falls short of handling AI technology because it does not contain the necessary framework to monitor AI systems.

The current legal framework treats AI-powered drug delivery systems as either medical devices or software products because existing regulations do not provide clear definitions for their combined characteristics. The current situation where products lack proper classification leads to confusion about which regulations should apply and which certification methods should be used, thereby hindering the development of new technologies.⁹

Regulatory authorities have begun to address these challenges through the development of AI-specific guidelines and frameworks. The AI Act established by the European Union uses a risk-based system to control AI systems which groups AI applications according to their potential effects on public safety and basic human rights. The current initiatives exist in their nascent stages because they have not established worldwide regulatory uniformity.

The current regulatory framework fails its purpose because it focuses exclusively on pre-market evaluation while forgetting the essential need for post-market product monitoring and continuous product assessment throughout its operational period. Organizations require ongoing AI system monitoring because these systems will experience continuous developments throughout their operational period. The process allows organizations to track system operation while discovering new risks, which they then proceed to manage.¹⁰

Data Governance, Privacy, and Informational Autonomy

The AI smart drug delivery systems function based on their usage of patient data which creates various legal and ethical problems related to privacy and data

protection and informational autonomy rights. The systems create predictive models and improve treatment results through their use of extensive datasets which contain protected health data and genomic information and live physiological data. The data processing activities create major challenges for organizations that need to protect personal data particularly in regions that have strict privacy standards such as the European Union General Data Protection Regulation and the upcoming Indian Digital Personal Data Protection Act.

The most significant issue facing society today is the challenge of achieving valid consent from individuals. Patients should receive complete knowledge about how their data will be shared and its consequences according to traditional informed consent methods. The requirement for specific informed consent becomes unachievable when AI systems use data for multiple functions which include training and validation and system enhancement. Patients do not comprehend how their data contributes to algorithmic outcomes or how their data will be applied in upcoming projects. The existing consent process fails to protect patient rights to make their own decisions.¹¹

AI systems today face challenges because traditional methods developers use to keep data anonymous no longer succeed at maintaining user privacy protection. Advanced data analytics techniques can potentially re-identify individuals from anonymized datasets by combining multiple data sources which creates risks of privacy breaches and unauthorized access to personal data for patients. The capability to re-identify individuals shows current data protection methods have limitations which require organizations to establish stronger security measures that include differential privacy techniques and stricter access controls.

AI-enabled drug delivery systems face obstacles to regulatory compliance because their data flows between different countries. Pharmaceutical companies must transfer data between different countries because their operations extend worldwide. The need to safeguard patient data according to different regulatory standards creates problems for businesses. Data protection laws need to become standardized through international standards for data governance which will enable organizations to solve their challenges.¹²

Algorithmic Bias, Fairness, and Ethical Risk

AI-based drug delivery systems face major ethical and legal challenges because algorithmic bias leads to unfair distribution of medical results between different patient groups. AI system bias emerges through unbalanced training data and incorrect model development and the existing social biases present in medical data. AI models predict less accurately for underrepresented populations when training datasets fail to include ethnic minorities and people from low socioeconomic backgrounds which creates unequal treatment results.

The consequences of bias go beyond ethical issues because they create legal responsibility concerns. Biased algorithms create discriminatory outcomes which result in both developers and healthcare organizations facing potential legal liability for negligence and violations of anti-discrimination laws. The presence of bias in training

data creates challenges for proving these allegations because it does not establish direct relationships with specific negative outcomes. The lack of transparency in AI systems makes it difficult to identify and correct bias because the input processing for decision-making becomes impossible to trace.¹³

To eliminate algorithmic bias organizations must establish multiple strategies which include building diverse datasets and implementing fairness-aware algorithms and establishing effective validation systems. The regulatory system needs to include rules which require AI system designers to make their systems transparent and accountable while they develop their systems to detect and solve potential biases before they cause damage.

Healthcare resource distribution requires ethical considerations which include ensuring equal distribution among all people. Advanced AI technologies will worsen current inequalities because only well-funded institutions and populations will gain access to these technologies. Organizations need to guarantee equal access to AI-enabled drug delivery systems to stop healthcare disparities from growing while they work to achieve fair medical benefits distribution.¹⁴

Comparative Legal Approaches and Jurisdictional Analysis

The regulation of AI-enabled drug delivery systems varies significantly across jurisdictions because different legal systems and different government policies and different stages of technological development exist in each jurisdiction. The European Union tests its AI regulation framework through an AI Act proposal which classifies AI systems according to their risk levels while establishing respective obligations. High-risk systems which include healthcare applications must meet tough requirements that define three areas of essential needs for ethical functioning and proper human monitoring.

The United States regulatory system allows for more flexible rules which support innovation because the Food and Drug Administration (FDA) handles all enforcement of its regulations. The FDA established guidance for software as a medical device (SaMD) which includes AI systems because it defines three essential principles for system development which include transparency and real-world performance assessment and system updates through iterative processes. The absence of a comprehensive federal framework for AI regulation creates a situation where different agencies and states implement their own unique standards which leads to an incomplete regulatory system.¹⁵

The Indian regulatory system for AI-enabled healthcare devices continues to develop because existing Drugs and Cosmetics Act and Medical Devices Rules create only a basic legal framework to handle AI technology specific difficulties. While recent policy initiatives demonstrate growing recognition of the need for AI-specific regulation important areas such as liability and data governance and post-market surveillance continue to face major regulatory gaps. The existing situation creates uncertainty for stakeholders because there are no defined regulations which leads to the need for a

complete system that handles all regulatory aspects of the situation.

Global pharmaceutical companies face major difficulties because they must deal with multiple regulatory systems which create overlapping and contradictory rules between different countries. This situation demonstrates how international cooperation needs to establish common AI regulation standards which enable international research while providing equal levels of protection for all patients.¹⁶

Intellectual Property, Innovation, and Market Control

The basic issues which emerge from using artificial intelligence in drug delivery systems make it difficult to decide who owns the rights to both intellectual property and the new inventions which AI systems create. Patent law requires inventors to create new inventions which patent systems acknowledge through their ownership rights to patents. AI systems now demonstrate the capability to create new medical solutions which include both drug formulations and delivery mechanisms which raises questions about patent eligibility and inventor recognition.

The legal system needs better tools to solve complex issues created by AI-based inventions because inventors face obstacles and regulatory bodies need to resolve these problems. Some regions explore patent rights for AI systems while other regions still require human inventors to obtain patent rights. The dual nature of intellectual property law creates a challenging situation for legal professionals who must handle two distinct legal frameworks.¹⁷

Proprietary algorithms together with proprietary datasets create difficulties for determining inventorship which results in market control difficulties that impede industry competition. The organizations which control extensive data resources together with advanced AI capabilities can achieve significant market power which leads to monopolistic practices that hinder their product development efforts. The regulatory frameworks for AI-enabled drug delivery systems must create rules which protect fair competition while stopping excessive market power from developing into monopolistic authority.¹⁸

Future Regulatory Models and Theoretical Frameworks

The challenges associated with AI-enabled drug delivery systems necessitate the development of innovative regulatory models that can effectively address the dynamic and complex nature of these technologies. Risk-based regulation establishes an effective framework for system classification which assesses danger levels through patient safety risk evaluation.¹⁹ The validation and monitoring requirements for high-risk systems which include autonomous drug delivery systems result in stricter operational controls while the less dangerous systems receive more relaxed regulatory requirements.

The field of AI regulation demands lifecycle-based regulation because it mandates organizations to monitor their AI systems throughout all operational stages. The approach identifies AI systems as continuous

development systems which need ongoing safety control to maintain their viable performance. The regulatory frameworks need to establish methods that enable organizations to conduct continuous monitoring while executing initial assessments and following subsequent compliance modifications.²⁰

Regulatory frameworks depend on "human-in-the-loop" governance systems to protect against harmful results which stem from AI technologies. The process establishes human control over critical decisions which creates greater accountability while decreasing risks of negative consequences. The debate about the necessary amount of human intervention continues especially because AI systems perform better than humans in many situations.

Conclusion

The use of AI technology in smart drug delivery systems implements a major change for pharmaceutical science which creates new methods to enhance treatment results and develop personalized medicine. This transformation creates a combination of legal challenges and ethical challenges and regulatory challenges which require managers to resolve through their work.

The existing legal system lacks capacity to deal with AI-enabled systems because their safety requirements and

liability standards and regulatory needs present unique system characteristics. The unpredictable behavior of opaque AI technologies which operate through adaptive methods needs new legal framework development and regulatory solution creation.

The solution to these problems requires collaboration between multiple disciplines which includes the participation of policymakers and regulators and researchers and industry stakeholders. The creation of a legal framework which supports innovation while protecting patient welfare requires organizations to implement risk-based and lifecycle-oriented regulatory models while promoting transparency and accountability and fostering international cooperation. The paper argues for a paradigm shift from static regulatory models to adaptive, lifecycle-based governance tailored specifically for AI-driven pharmaceutical systems.

The operational success of AI-enabled smart drug delivery systems depends on two factors which include technical progress and the legal and regulatory systems developing at the same speed to maintain innovation benefits through safe and fair delivery.

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