

ARTIFICIAL INTELLIGENCE IN HEALTHCARE AND ETHICAL FRAMEWORKS: A COMPARATIVE STUDY OF THE UNITED STATES AND CHINA

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ABSTRACT

Achieving SDG 9 (Industry, Innovation and Infrastructure) requires building resilient infrastructure, promoting inclusive and sustainable industrialization, and fostering innovation. Target 9.5 aims to enhance scientific research and upgrade the technological capabilities of industrial sectors in all countries, particularly developing countries, including by encouraging innovation and substantially increasing the number of research and development workers per one million people and public and private research and development spending. Target 9.B supports domestic technology development, research and innovation in developing countries.

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Artificial intelligence (AI) is transforming healthcare globally, with applications spanning medical imaging analysis, clinical decision support, drug discovery, predictive analytics, robotic surgery, and personalized medicine. However, the rapid integration of AI into healthcare systems has raised critical ethical concerns including algorithmic bias and discrimination, data privacy and security, informed consent, transparency and explainability, clinical accountability and liability, equitable access, and patient safety. The ethical governance of medical AI is not uniform across jurisdictions; different countries have developed divergent frameworks shaped by political systems, legal traditions, cultural values, industrial policies, and public trust.

This study conducts a comparative analysis of artificial intelligence in healthcare and ethical frameworks in the United States and China, the two leading global powers in AI research, development, and deployment, with contrasting governance models, regulatory philosophies, and value priorities. The United States, a high-income country with a market-driven economy and a decentralized regulatory system, has adopted an innovation-favorable approach to medical AI governance. The FDA has approved over 1,250 AI-enabled medical devices as of 2025, with more than 75 percent in radiology. The US regulatory framework is risk-based, utilizing pre-market review, post-market surveillance, and pre-determined change control plans for iterative algorithm updates. The US approach prioritizes innovation and market-driven flexibility but faces regulatory fragmentation and accountability gaps. China, an upper-middle-income country with a state-led economy and centralized regulatory system, has rapidly advanced medical AI as a national strategic priority. The NMPA has approved over 110 deep learning-based Class III medical device software products. China's regulatory framework is centralized under the NMPA, with a comprehensive guidance system for AI medical devices and ethical guidelines for brain-computer interface research and science and technology ethics governance. China's approach prioritizes safety and state-led strategic development but faces transparency deficits and potential innovation constraints.

Using a qualitative comparative case study methodology, the study analyzes secondary data from government reports, peer-reviewed literature, and regulatory policy documents over the period 2015 to 2026. The study finds that the US and China represent two divergent governance paradigms for medical AI: the US prioritizes innovation and market-driven flexibility, while China

prioritizes safety and state-led strategic development. Both countries face common challenges including algorithmic bias, data privacy, clinical integration, and public trust.

The study concludes that effective AI governance requires hybrid models combining safety as a non-negotiable baseline, innovation incentives, transparency mandates, and accountability mechanisms. Recommendations for both countries and the international community are provided.

Keywords: Artificial intelligence; healthcare; ethics; United States; China; SDG 9; medical devices; algorithmic bias; data privacy; regulatory framework

RÉSUMÉ

Atteindre l'ODD 9 (Industrie, Innovation et Infrastructure) nécessite de promouvoir l'innovation et d'augmenter les dépenses de recherche et développement. L'intelligence artificielle (IA) transforme les soins de santé à l'échelle mondiale, mais soulève des préoccupations éthiques : biais algorithmiques, confidentialité des données, transparence, responsabilité clinique et équité d'accès. Cette étude analyse l'IA dans les soins de santé et les cadres éthiques aux États-Unis et en Chine. Les États-Unis ont approuvé plus de 1 250 dispositifs médicaux basés sur l'IA (FDA). L'approche américaine privilégie l'innovation et la flexibilité axée sur le marché. La Chine a approuvé plus de 110 produits logiciels de dispositifs médicaux basés sur l'apprentissage profond (NMPA). L'approche chinoise privilégie la sécurité et le développement stratégique dirigé par l'État. L'étude conclut que la gouvernance de l'IA nécessite des modèles hybrides alliant sécurité, incitations à l'innovation, transparence et mécanismes de responsabilité. Des recommandations sont fournies pour les deux pays et la communauté internationale.

Mots-clés : intelligence artificielle, soins de santé, éthique, États-Unis, Chine, ODD 9, dispositifs médicaux, biais algorithmiques, confidentialité des données

Suomis le : 17 Mars , 2026

Publié le : 08 Jun , 2026

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1. INTRODUCTION

Achieving SDG 9 (Industry, Innovation and Infrastructure) requires building resilient infrastructure, promoting inclusive and sustainable industrialization, and fostering innovation. Target 9.5 aims to enhance scientific research and upgrade the technological capabilities of industrial sectors in all countries, including by encouraging innovation and substantially increasing the number of research and development workers per one million people and public and private research and development spending. Target 9.B supports domestic technology development, research and innovation in developing countries.

Artificial intelligence (AI) is transforming healthcare globally, with applications spanning medical imaging analysis including radiology, pathology, and ophthalmology; clinical decision support systems for diagnosis and treatment recommendations; drug discovery and development including molecule screening and clinical trial optimization; predictive analytics for patient risk stratification, readmission prediction, and early warning systems; robotic surgery for precision and minimally invasive procedures; virtual nursing assistants and mental health chatbots; personalized medicine including genomics and treatment selection; and administrative workflow optimization for scheduling, billing, and coding. The global AI in healthcare market was valued at approximately 20 billion in 2023 and is projected to reach 150 billion by 2030.

AI technologies have demonstrated performance comparable to or exceeding human clinicians in specific tasks, including diabetic retinopathy detection from retinal images, lung nodule detection on CT scans, breast cancer detection on mammograms, skin cancer classification, arrhythmia detection from ECGs, and sepsis prediction. However, the rapid integration of AI into healthcare systems has raised critical ethical concerns that challenge traditional medical ethics frameworks. These include algorithmic bias and discrimination leading to racial, gender, socioeconomic, and geographic disparities; data privacy and security including patient data leaks, unauthorized third-party access, and re-identification risks; informed consent where patients are unaware of AI involvement in their care; transparency and explainability, often called the black box problem, which refers to the inability to explain why an AI made a specific recommendation; clinical accountability and liability regarding responsibility when an AI makes an error; equitable access as AI may exacerbate existing inequalities if only wealthy institutions can afford it; patient safety

including AI errors causing harm; and autonomy as AI may undermine clinician or patient decision-making.

The ethical governance of medical AI is not uniform across jurisdictions. Different countries have developed divergent frameworks shaped by political systems, legal traditions, cultural values, industrial policies, and public trust. This study examines two countries that offer profound and contrasting insights into artificial intelligence in healthcare and ethical frameworks: the United States and China.

The United States, a high-income country with a market-driven economy, a decentralized regulatory system involving the FDA, FTC, OCR, and state laws, and a strong tradition of individual rights including privacy, autonomy, and informed consent, has adopted an innovation-favorable approach to medical AI governance. As of July 2025, the FDA's public list of AI-enabled medical devices includes 1,247 approved technologies, with more than 75 percent related to radiology including image segmentation, quantitative measurements, acquisition assistance, triage, and image interpretation. The FDA employs a risk-based approach with Class I low risk, Class II moderate risk, and Class III high risk classification; total product life-cycle evaluation combining pre-market and post-market oversight; pre-determined change control plans (PCCPs) for iterative algorithm updates; and regulatory science tools including synthetic data and real-world evidence. The US approach prioritizes innovation and market-driven flexibility, optimizing advancement yet confronting regulatory conflicts and accountability gaps. The AI Clinical Safety Act of 2025 (AACDSA) proposes the first comprehensive federal framework for transparency, independent risk-scaled audits, real-time drift monitoring, whistle-blower rewards, and liability protection for compliant vendors.

China, an upper-middle-income country with a state-led economy, a centralized regulatory system, and national strategic prioritization of AI, has rapidly advanced medical AI under the Next Generation Artificial Intelligence Development Plan of 2017 and the National Science and Technology Innovation Plan for the Thirteenth Five-Year Plan Period of 2016, which designated "Brain Science and Brain-Like Research" as a major 2030 innovation project. The China Brain Project from 2016 to 2030 integrates brain science, AI, and brain-inspired intelligence. China's regulatory framework for medical AI is centralized under the National Medical Products

Administration (NMPA), which has approved more than 110 deep learning-based Class III medical device software products, the highest risk classification requiring stringent control. These products cover CT images, X-ray images, fundus images, and nine data types for purposes including assisted triage, detection, and treatment. The NMPA has issued a comprehensive five-tier guidance document system for AI medical devices, established an AI medical device standardization technical committee with eight industry standards published and seven under development, and released ethical guidelines for brain-computer interface research in 2024 and science and technology ethics governance in 2023. China explores regulatory flexibility through incremental policy design and regulatory sandbox mechanisms, seeking equilibrium between safety and agility while facing multidimensional challenges.

The contrast between the United States and China illuminates critical questions for artificial intelligence in healthcare, ethical frameworks, and SDG 9, which this study addresses.

2. LITERATURE REVIEW

The literature on AI ethics in healthcare has grown exponentially in recent years.

2.1 Research Hotspots in AI Ethics

A bibliometric analysis of 1,034 publications from 1999 to 2025 identifies four research hotspots in the field. The first hotspot is ethical issues in different application scenarios of AI techniques in clinical practice. The second hotspot is AI ethical concerns and considerations in medical academia. The third hotspot is ethical challenges in AI-driven medical education. The fourth hotspot is ethical governance, supervision, and review in healthcare.

2.2 International Ethical Frameworks

The World Health Organization published "Ethics and Governance of Artificial Intelligence for Health" in 2021, establishing six core ethical principles: autonomy, human well-being, fairness, transparency, safety, and accountability. UNESCO's "Recommendation on the Ethics of Artificial Intelligence" of 2021 provides a universal framework for member states. The concept of the "trilemma" of medical AI governance reveals inherent value conflicts among safety, innovation, and efficiency, suggesting that no governance model can simultaneously optimize all three values.

2.3 United States Regulatory Framework

The FDA's regulatory framework for AI-enabled devices is well documented in the literature. The FDA has published numerous guidance documents on AI and machine learning-enabled medical devices, including discussion papers on adaptive algorithms, pre-determined change control plans, and total product life-cycle approach. The AACDSA proposal of 2025 represents the first attempt at comprehensive federal legislation for AI accountability in clinical settings.

2.4 China's Regulatory Framework

China's NMPA regulatory framework and AI medical device approvals are documented in government publications and peer-reviewed literature. The NMPA has issued a comprehensive five-tier guidance system, established standardization technical committees, and published industry standards for AI medical devices. The China Brain Project and national AI strategies are documented in policy white papers.

2.5 Comparative Studies

Comparative analyses of US, China, and EU AI governance are emerging in the literature. However, comparative studies specifically focused on medical AI ethics are rare. This study contributes to filling that gap by providing a structured comparison of AI in healthcare and ethical frameworks in the United States and China.

3. RESEARCH QUESTIONS

This study addresses the following research questions:

1. What are the AI in healthcare policies, regulatory frameworks, and ethical guidelines in the United States and China?
2. What are the outcomes in terms of number of approved AI medical devices, clinical adoption, and safety incidents in each country?
3. What are the strengths and limitations of the innovation-priority model in the United States and the safety-priority model in China?

4. METHODOLOGY

This study employs a qualitative comparative case study methodology to examine artificial intelligence in healthcare and ethical frameworks in the United States and China. The comparative approach is appropriate for examining how different political systems, legal traditions, and regulatory philosophies shape AI governance outcomes. The United States and China were selected as cases offering maximum variation. The United States has a market-driven economy, a decentralized regulatory system, common law tradition, and strong emphasis on individual rights. China has a state-led economy, a centralized regulatory system, civil law tradition, and emphasis on collective welfare. Both countries are global leaders in AI research, development, and deployment, making them ideal for comparative analysis. The research design integrates secondary analysis of multiple data sources spanning the period 2015 to 2026. Government sources include, for the United States, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the White House Office of Science and Technology Policy, and the AI Clinical Safety Act of 2025 (AACDSA) proposal; for China, the National Medical Products Administration (NMPA), the Ministry of Science and Technology (MOST), the National Health Commission (NHC), and the Cyberspace Administration of China (CAC). Regulatory policy documents include FDA guidance documents, NMPA guidance documents, and ethical guidelines. Peer-reviewed literature from journals including *Medicine & Philosophy*, *RSNA Daily Bulletin*, and others was also analyzed. The analytical framework examines six dimensions: regulatory structure (centralized versus decentralized), approval processes (pathways, timelines, requirements), ethical guidance (principles, standards, enforcement), outcomes (number of approvals, safety incidents), strengths (innovation, safety, efficiency), and challenges (gaps, deficits, constraints). The study has several limitations, including reliance on secondary data constrained by availability, quality, and comparability. The US FDA public database is robust and transparent, while China's NMPA data are less transparent. The comparative case study design cannot establish causality as rigorously as experimental methods. No primary data collection, such as interviews with regulators, AI developers, clinicians, or patients, was conducted. The study period (2015 to 2026) captures recent trends but does not fully explore longer-term historical dynamics. Despite these limitations, the comparative analysis provides valuable insights for policy and future research.

5.

RESULTS

Table 1: Comparative Summary – AI in Healthcare and Ethical Frameworks

Dimension	United States	China
GDP per capita (USD)	\$70,000 (high-income)	\$13,000 (upper-middle)
AI national strategy	National AI R&D Strategic Plan (2016), American AI Initiative (2019), AI for Health (2023)	Next Generation AI Development Plan (2017), China Brain Project (2016-2030)
Regulatory authority	FDA (CDRH, Digital Health Center of Excellence)	NMPA (Center for Medical Device Evaluation)
AI-enabled approved devices	1,247 (July 2025, 75%+ radiology)	110+ (Class III deep learning software)
Approval pathways	510(k), De Novo, PMA, PCCP	Class II/III registration, innovation/priority pathways
Change control for AI updates	PCCP (pre-determined change control plan) – 350+ submissions, 110+ authorized	Major changes: new registration; non-major: QMS self-change
Risk classification	Class I (low), II (moderate), III (high)	Class II (moderate risk), Class III (high risk – invasive, therapeutic)
Ethical framework (primary)	FDA guidance, AACDSA (2025 proposed), WHO guidelines	NMPA 5-tier guidance, Ethical Guidelines for BCI, Science and Technology Ethics Governance
Data protection	HIPAA, FTC Act, state laws (CCPA), no comprehensive federal privacy law	PIPL (Personal Information Protection Law, 2021)
Algorithmic bias guidance	FDA draft guidance, agency priority	Bias mentioned in guidance, less detailed

Transparency requirements	FDA summary reports, 510(k) database; AACDSA proposes explainability	Less public disclosure (manufacturer proprietary)
International alignment	IMDRF, ITU&WHO FG-AI4H, reference to FDA guidance	References IMDRF, ITU&WHO FG-AI4H, US/Jap/Kor/Sing guidelines
Governance paradigm	Innovation-priority, market-driven flexibility	Safety-priority, state-led strategic control
Source	FDA 2025; AACDSA 2025;	NMPA 2025;

Table 2: United States – FDA Regulatory Framework for AI Medical Devices

Element	Description
FDA digital health authority	Center for Devices and Radiological Health (CDRH), Digital Health Center of Excellence (DHCoE). Regulates AI-enabled medical devices as software as a medical device (SaMD) under Federal Food, Drug, and Cosmetic Act (FD&C Act) and Medical Device Amendments.
AI-enabled device approvals	As of July 2025: 1,247 approved technologies. 75%+ related to radiology (image segmentation, quantitative measurements, image acquisition assistance, triage, image interpretation). Examples: diabetic retinopathy detection (IDx-DR, 2018 – first authorized autonomous AI diagnostic system), stroke detection (RapidAI, Viz.ai), lung nodule detection, breast cancer detection .
Approval pathways	510(k) (pre-market notification – substantial equivalence to predicate device) – most common, rapid (average 6-12 months). De Novo (novel low-to-moderate risk devices without predicate). PMA (pre-market approval – high-risk devices, clinical trials required). PCCP (pre-determined change control plan – for iterative algorithm updates) .
Pre-determined Change Control Plans (PCCP)	Introduced for AI devices that continuously learn (adaptive AI). Developer submits plan describing anticipated modifications, methodology for validation, impact assessment. FDA authorizes plan. Once approved, manufacturer can implement

	changes without new pre-market submission (within scope). As of 2025: 350+ PCCP submissions, 110+ devices authorized .
Risk-based classification	Class I (low risk – minimal regulation). Class II (moderate risk – special controls, 510(k)). Class III (high risk – pre-market approval, clinical trials, highest scrutiny). AI devices typically Class II or III depending on invasiveness, intended use, potential harm.
Total Product Life Cycle (TPLC) approach	Pre-market: design validation, clinical evidence, algorithmic bias testing (draft guidance). Post-market: real-world performance monitoring, adverse event reporting (MAUDE database), device modifications (PCCP or new submission). FDA post-market surveillance includes real-world evidence (RWE) and registry data .
Regulatory science tools	Synthetic data for algorithm evaluation (addressing limited patient data availability). Regulatory science tools voluntarily used in early R&D to ease evaluation burden. Comparison of knowledge-based vs generative models for synthetic data reliability .
AI Clinical Safety Act (AACDSA, 2025 proposed)	First comprehensive federal framework for transparency, auditing, accountability for clinical AI systems. Provisions: public explainability summaries, independent risk-scaled audits, real-time drift monitoring for high-risk tools. Hospitals/vendors must log and report clinician overrides and adverse events. Whistle-blower rewards, anti-gaming provisions, five-year sunset with GAO evaluation. Liability protection for vendors meeting rigorous audit and transparency standards .
Algorithmic bias guidance	FDA draft guidance (2023, 2024): recommended pre-market bias assessment for race, ethnicity, gender, age, socioeconomic status. Not mandatory. Implementation inconsistent.
Data privacy	HIPAA (Health Insurance Portability and Accountability Act, 1996) – health data protection, patient consent, breach notification, but no private right of action. FTC Act (unfair/deceptive practices) – enforcement against misleading AI claims. State laws: CCPA (California), CPRA, Virginia CDPA, Colorado CPA. No comprehensive federal privacy law (multiple bills proposed).

Strengths	Innovation-friendly (fast approval pathways, PCCP for adaptive AI). Market-driven flexibility encourages investment. World-leading AI research ecosystem (universities, tech companies, venture capital). Patient access to cutting-edge AI technologies.
Weaknesses	Regulatory fragmentation (FDA, FTC, OCR, state laws – inconsistent, gaps). Accountability gaps (liability unclear – developer, hospital, clinician, patient?). Algorithmic bias guidance not mandatory. Post-market surveillance limited (passive reporting, few proactive audits). Privacy patchwork (no federal privacy law). Access inequities (cost, insurance coverage).

Table 3: China – NMPA Regulatory Framework for AI Medical Devices

Element	Description
National AI strategy	Next Generation Artificial Intelligence Development Plan (2017) – national priority, target world leadership by 2030. China Brain Project (2016-2030) – major 2030 innovation project, integrates brain science, AI, brain-inspired intelligence. National Science and Technology Innovation Plan for the Thirteenth Five-Year Plan Period (2016) designated “Brain Science and Brain-Like Research” .
Regulatory authority	National Medical Products Administration (NMPA, formerly CFDA). Center for Medical Device Evaluation (CMDE). Medical Device Technical Review and Standards Center.
AI medical device approvals	As of 2025: 110+ deep learning-based Class III medical device software products approved (third category – highest risk). Product types: assisted triage and evaluation, assisted detection and recognition, assisted treatment. Data types: CT, X-ray, fundus images, pathology, MRI, ultrasound (9 categories). Examples: pulmonary nodule detection (Infervision), diabetic retinopathy (Airdoc), COVID-19 CT diagnosis (Deepwise, Yitu, Keya, Huiying, PingAn, Tencent) .
Regulatory guidance system	5-tier documentation framework: 1) Deep Learning Assisted Decision Medical Device Review Key Points, 2) AI medical device guiding principles (19 documents), 3) specific product review points (e.g., pulmonary nodule, diabetic retinopathy), 4) standards, 5)

	clinical evaluation guidelines. One of the world's most comprehensive AI device regulatory systems .
Risk classification	Class II (moderate risk – provincial-level registration). Class III (high risk – NMPA national-level registration, stringent control). Invasive BCI and therapeutic non-invasive BCI with enhancement/stimulation functions classified as Class III. General non-invasive BCI (EEG devices, sleep monitors) classified as Class II .
Change management for updates	Major algorithm changes requiring new safety/efficacy evaluation must submit new registration application (Class III). Non-major changes (e.g., performance optimization within validated scope) managed under manufacturer's quality management system (QMS) without new approval. Less formal PCCP framework than FDA.
AI standardization	Artificial Intelligence Medical Device Standardization Technical Committee (SMD/TU 002, established 2019). Published 8 industry standards (截至 June 2025). Developing 2 national standards and 5 industry standards, including “AI Medical Devices – Pulmonary Imaging Assisted Analysis Software – Algorithm Performance Testing Methods” .
Ethical governance framework	Ethical Guidelines for Brain-Computer Interface Research (2024). Measures for Ethical Review of Life Science and Medical Research Involving Human Subjects (2023). Guidelines on Strengthening the Governance of Science and Technology Ethics (2022 – joint issuance). Measures for the Ethical Review of Science and Technology (Trial Implementation, 2023). Civil Code (2020) – personal information, privacy, tort liability. Personal Information Protection Law – PIPL (2021) .
Data protection	Personal Information Protection Law (PIPL, 2021) – comprehensive privacy law (similar to GDPR). Requires separate consent for sensitive data (health data), data localization, cross-border transfer restrictions. Cybersecurity Law. Data Security Law.
Informed consent	Required for clinical research (Human Subjects Ethical Review Measures). For routine clinical AI use, consent is implicit (hospital assumes patient consent to AI-assisted diagnosis unless patient objects). Less rigorous than US/EU standards.
Innovation support	NMPA innovation fast-track approval pathway (2018). Priority review for products addressing urgent clinical needs (public health emergencies – COVID-19 AI diagnostic

	devices approved rapidly). Regulatory sandbox mechanisms (pilot programs in some provinces – Guangdong, Zhejiang, Shanghai) .
Strengths	Centralized, consistent national regulation (no fragmentation). Rapid scaling (110+ Class III approvals). Strong government support (funding, national strategy). Comprehensive guidance framework (5-tier). AI standardization robust.
Weaknesses	Lack of transparency (public disclosure limited, algorithm performance data not released). Algorithmic bias guidance less detailed. Weak independent ethics oversight (ethics committees under institutional control, patient representation limited). Innovation constraints (risk-averse, over-regulation?). Implementation gaps (guidance not fully enforced). International isolation (NMPA less engaged with WHO/IMDRF harmonization than FDA).

Table 4: Comparative Governance Paradigms – US, China, and EU

Paradigm	United States	China	European Union
Primary value priority	Innovation	Safety	Human rights
Governance approach	Market-driven flexibility	State-led strategic control	Regulatory rigidity
Regulatory style	Decentralized, risk-based, case-by-case	Centralized, classification-based, top-down	Harmonized, AI Act tiered risk
Innovation incentives	Fast 510(k), PCCP, venture capital	State funding, national strategy, fast-track	Moderate (AI Act sandboxes)
Safety mechanisms	Pre-market testing (voluntary bias), post-market passive surveillance	Pre-market rigorous review, risk classification, QMS	AI Act high-risk conformity assessment

Transparency	FDA databases, limited public access	Minimal public disclosure	AI Act transparency obligations
Accountability	Unclear liability, AACDSA proposed	State liability, criminal penalties for serious violations	AI Act provider liability
Source			

6. DISCUSSION OF RESULTS

6.1. Explaining the United States Innovation-Priority Model

The United States has approved over 1,200 AI-enabled medical devices, more than any other country. This success is driven by several factors. The market-driven economy means venture capital and private equity invest heavily in AI health startups, with over \$10 billion invested from 2020 to 2025. Regulatory flexibility allows the 510(k) pathway for rapid approval based on substantial equivalence to predicate devices, and PCCP accommodates continuous learning algorithms. The decentralized system means the FDA focuses on pre-market, leaving post-market oversight to hospitals and clinicians. The strong research ecosystem includes universities such as Stanford, MIT, Harvard, and Johns Hopkins; tech companies such as Google Health, Microsoft, Apple, Amazon, and NVIDIA; and numerous startups.

However, the innovation-priority model has several weaknesses. Regulatory fragmentation exists across the FDA, FTC, OCR, and state laws, creating inconsistencies and gaps. Accountability deficits are present because liability is unclear when an AI misdiagnoses; courts have not established precedent. Bias is under-addressed because FDA bias guidance is recommended, not mandatory, and not consistently enforced. Post-market surveillance is passive because the MAUDE database relies on voluntary reporting and under-reports adverse events.

6.2. Explaining China's Safety-Priority State-Led Model

China has approved more than 110 Class III AI medical devices, fewer than the United States but with more centralized control. Drivers include state-led strategic priority, with AI as a national security and economic competitiveness priority, central government funding for AI research and development, national laboratories, and talent training. The centralized regulatory system means NMPA is a single national authority with consistent rules and rapid scaling. The comprehensive guidance system includes a five-tier documentation system and an AI standardization committee. The strong safety orientation includes risk-based classification, invasive versus non-invasive distinction, and quality management system requirements.

However, weaknesses include a transparency deficit, as NMPA does not publicly disclose algorithm performance metrics, adverse event reports, or recall data, which manufacturers consider proprietary. Algorithmic bias is under-addressed, as guidance mentions bias but is less detailed than FDA guidance, and there is no mandatory bias testing. Independent ethics oversight is weak because ethics committees are under institutional leadership at hospitals and universities, not truly independent, and patient representation is minimal. Innovation constraints exist because some manufacturers complain that NMPA is too conservative and risk-averse compared to the FDA. Implementation gaps remain, as guidance is issued but enforcement is variable, especially in rural or lower-tier hospitals.

6.3. The Trilemma of Medical AI Governance

The governance trilemma reveals inherent value conflicts among safety, innovation, and efficiency. No governance model can simultaneously optimize all three values. The United States prioritizes innovation at the cost of safety gaps and accountability deficits. The European Union prioritizes safety and human rights under GDPR and the AI Act at the cost of efficiency and innovation speed. China prioritizes safety and state-led strategic development, trading off transparency and independent oversight. The optimal solution may not be choosing one value over others but dynamic rebalancing centered on patient well-being as the meta-rule.

6.4. Algorithmic Bias: A Shared Challenge

Both countries face algorithmic bias. AI systems trained on non-representative data may perform poorly for minority populations (racial bias), women (gender bias), low-income populations

(socioeconomic bias), rural populations (geographic bias), and the elderly (age bias). In the United States, studies have shown that a commercial AI algorithm used for hospital readmission prediction systematically under-predicted risk for Black patients because the algorithm used past healthcare costs as a proxy, and Black patients had lower costs due to unequal access, not lower illness severity. Dermatology AI trained on light-skinned images fails on dark skin. In China, similar biases exist. AI trained on Han Chinese populations may fail for minority ethnic groups including Tibetan, Uyghur, Mongolian, and Zhuang. Data from wealthy urban hospitals in Beijing, Shanghai, and Guangzhou may not generalize to rural clinics with different disease prevalence, demographic profiles, and image quality. Neither country has implemented mandatory pre-market bias testing.

6.5. Data Privacy and Protection

China's PIPL of 2021 provides comprehensive privacy protection similar to GDPR, including separate consent for sensitive data such as health data, data localization, cross-border transfer restrictions, and administrative fines. The United States lacks a comprehensive federal privacy law. HIPAA covers only covered entities such as hospitals, insurers, and clinicians, not technology companies such as Google, Apple, Fitbit, and AI developers who may collect patient data without consent. The US patchwork creates gaps where patient data is sold to third parties, used for AI training without consent, or leaked in breaches. China's centralized system reduces gaps but raises surveillance concerns about government access to health data for social credit and law enforcement purposes.

6.6. Transparency and Public Trust

The US FDA publishes summary reports including 510(k) summaries, De Novo summaries, and PMA summaries in publicly accessible databases, but these summaries are technical and not patient-friendly. The AACDSA of 2025 proposes public explainability summaries. China publishes almost no public information on approved AI devices; manufacturers may disclose voluntarily but are not required. This lack of transparency undermines patient trust, physician confidence, and academic scrutiny. China should increase transparency by creating a public registry with algorithm performance metrics, adverse event reporting, and recall notices.

6.7. Transferability: What the United States Can Learn from China and What China Can Learn from the United States

The United States can learn from China in several areas. Centralized regulatory coordination through a single agency for medical AI oversight would reduce fragmentation. Comprehensive guidance including a five-tier framework and clear classification would provide clarity. AI standardization through national standards for algorithm performance and data quality would improve consistency.

China can learn from the United States in several areas. Transparency through public disclosure of AI performance, adverse events, and recalls would build trust. Independent ethics oversight through third-party ethics committees and patient representatives would strengthen accountability. Algorithmic bias testing through mandatory pre-market bias assessment would address disparities. Regulatory sandboxes through controlled testing environments for innovative AI would encourage innovation. Liability frameworks through clear rules for accountability would provide legal clarity.

6.8. Implications for SDG 9

AI in healthcare and ethical frameworks are central to SDG Target 9.5 (research and development spending and innovation) and Target 9.B (domestic technology development). The United States demonstrates that innovation-friendly regulation accelerates AI adoption with over 1,200 approved devices, but risks safety gaps and accountability deficits. China demonstrates that state-led, safety-prioritizing regulation ensures centralized control, but risks transparency deficits and innovation constraints.

The international community, including WHO, OECD, ITU, and IEEE, should develop globally harmonized ethical standards for medical AI based on WHO's six core principles of autonomy, human well-being, fairness, transparency, safety, and accountability. They should establish an international medical AI incident reporting system, fund bias and fairness research for cross-country and cross-population validation, and promote South-South and North-South exchange.

7. CONCLUSION

This comparative analysis reveals that artificial intelligence in healthcare and ethical frameworks in the United States and China represent two divergent governance paradigms.

The United States, operating under an innovation-priority, market-driven flexibility model, has approved over 1,200 AI-enabled medical devices through the FDA, pioneered PCCP for adaptive AI, and leads in AI research investment. However, the United States faces regulatory fragmentation across multiple agencies, accountability gaps, algorithmic bias that is not mandatory to address, and weak post-market surveillance.

China, operating under a safety-priority, state-led strategic control model, has approved over 110 Class III AI medical devices through the NMPA, developed a comprehensive five-tier guidance system, established AI standardization, and prioritized national AI strategy. However, China faces transparency deficits, weak independent ethics oversight, innovation constraints, and relative international isolation.

Several cross-cutting insights emerge from this comparison:

1. The trilemma of medical AI governance involving safety, innovation, and efficiency cannot be fully resolved. Trade-offs are inevitable, and no model optimizes all three values simultaneously.
2. Algorithmic bias is a shared challenge requiring mandatory pre-market testing, diverse training data, and post-market monitoring in both countries.
3. Data privacy requires comprehensive legal protection. China's PIPL provides a model that could inform US federal privacy law.
4. Transparency is essential for public trust. China should increase public disclosure of AI performance data and adverse events.
5. Independent ethics oversight through third-party committees and patient representatives is essential for accountability.

For the United States, priorities include strengthening federal AI coordination by creating a centralized agency for medical AI oversight to reduce fragmentation; implementing AACDSA provisions including independent audits, transparency, drift monitoring, and whistle-blower rewards; addressing bias through mandatory pre-market bias testing for race, gender, age, and socioeconomic status with enforcement; enhancing post-market surveillance through real-world

performance tracking, algorithm update monitoring, and proactive audits; improving data privacy by enacting a comprehensive federal privacy law modeled on PIPL or GDPR; and developing liability frameworks with clear rules for accountability.

For China, priorities include increasing transparency through public disclosure of AI algorithm performance metrics, adverse event reports, and recall notices; strengthening ethical review by creating independent ethics committees with patient representation, not under institutional control; implementing regulatory sandboxes as controlled testing environments for innovative AI; expanding algorithm auditing through third-party audits, bias detection, and performance validation; fostering international collaboration through harmonization with WHO guidelines and FDA and EU standards, and participation in IMDRF; and increasing investment in AI safety research.

For the international community, the lessons are clear. AI governance cannot be one-size-fits-all, but core ethical principles including autonomy, well-being, fairness, transparency, safety, and accountability are universal. Harmonized standards through WHO, IEEE, and ISO reduce fragmentation and enable global collaboration. Independent ethics oversight, not captured by industry or state, is essential. Bias testing must be mandatory, not voluntary. Transparency through public disclosure is a prerequisite for trust.

The ultimate measure of success for AI health policy is not the number of approved devices, but whether AI improves patient outcomes, reduces health disparities, respects patient autonomy, and earns public trust in both Boston and Beijing.

8. LIMITS OF THE STUDY

This study has several limitations. First, reliance on secondary data from government reports, FDA and NMPA databases, and peer-reviewed literature means the analysis is constrained by data availability, quality, and comparability. The US FDA public database is robust and transparent, while China's NMPA data are less transparent. Second, the comparative case study design cannot establish causality as rigorously as experimental or quasi-experimental methods. Third, the study does not include primary data collection, such as interviews with FDA and NMPA regulators, AI developers, clinicians, or patients, which would provide richer insights. Fourth, the study period

(2015 to 2026) captures recent trends but does not fully explore longer-term historical dynamics. Fifth, the focus on national-level systems obscures subnational variation within the United States (state laws such as CCPA) and within China (provincial implementation). Sixth, the study does not quantify the cost-effectiveness of different AI governance approaches. Despite these limitations, the comparative analysis provides valuable insights for policy and future research.

9. ACKNOWLEDGMENTS

The author acknowledges the United States Food and Drug Administration (FDA) Center for Devices and Radiological Health and the Digital Health Center of Excellence; China's National Medical Products Administration (NMPA), Center for Medical Device Evaluation, and Artificial Intelligence Medical Device Standardization Technical Committee; the World Health Organization (WHO); and the researchers, clinicians, developers, and patients whose work informs this study.

10. AUTHOR CONTRIBUTIONS

ZOEWENDBEEM WILLIAM TERTUS ROUAMBA conceived the study, designed the methodology, conducted the literature review and document analysis, synthesized findings, and drafted the complete manuscript.

11. COMPETING INTERESTS

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential competing interest.

12. FUNDING INFORMATION

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

13. DATA AVAILABILITY

All sources are publicly available documents cited in the bibliography and accessible through the referenced publications and organizations, including the FDA AI-enabled medical devices list,

FDA guidance documents, NMPA approvals, NMPA guidance, the WHO Ethics and Governance of AI for Health report, and peer-reviewed literature.

14. DISCLAIMER

The views expressed in this article are solely those of the author and do not necessarily reflect the views of any institution or organization with which the author may be affiliated. The analysis is provided for scholarly purposes and should not be construed as policy guidance or programmatic advice.

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