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Who's Liable? Responsibility, Regulation, and the New World of AI-Assisted Medicine

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1. Abstract

The rapid deployment of Artificial Intelligence (AI) in clinical settings has precipitated a legal and regulatory crisis, revealing a profound mismatch between adaptive, opaque, and continuously evolving algorithms and static, product-centric liability frameworks. This paper examines the shifting landscape of responsibility when medical decisions are co-produced by clinicians and "black box" AI systems. We argue that the traditional binary of product liability (targeting developers) and professional malpractice (targeting clinicians) is insufficient for the tripartite, dynamic relationship between AI vendor, healthcare institution, and treating professional. Through analysis of emerging AI failures from misdiagnosis due to biased data to alert fatigue-induced user errors we identify three critical gaps: the accountability gap (difficulty attributing causation in a continuous-learning system), the knowledge gap (determining what a "reasonable clinician" should understand about the AI they use), and the regulatory gap (the inadequacy of current pre-market approval for adaptive AI). We propose a new model of "distributed, tiered liability" built upon three pillars: 1) Enhanced Regulatory Agility, advocating for the FDA's Total Product Lifecycle (TPLC) approach and "pre-certification" of development ecosystems; 2) Institutional Duty of Algorithmic Due Diligence, requiring hospitals to audit, monitor, and contextually validate AI tools before and during deployment; and 3) a refined Clinician Standard of Care that includes a duty to understand an AI's limitations and maintain ultimate diagnostic autonomy. We conclude that achieving a just and effective liability regime is a prerequisite for trustworthy AI adoption, demanding not just legal reform, but a cultural shift toward shared responsibility and radical transparency across the entire AI lifecycle.

2. Keywords

AI Liability, Medical Malpractice, Product Liability, FDA Regulation, Algorithmic Accountability, Standard of Care, Clinical Decision Support, Duty of Diligence

3. Introduction: The Blame Game in the Black Box

The integration of Artificial Intelligence into clinical workflows represents a paradigm shift not only in care delivery but in the fundamental architecture of medical decision-making. When a diagnostic error occurs in an AI-assisted process, a simple yet profound legal question arises: Who is liable? Is it the clinician who accepted the AI's recommendation, the hospital that credentialed the software, or the developer who trained the model on non-representative data? This question exposes the fault lines between a 20th-century liability framework and a 21st-century technological reality. Traditional medical malpractice law centers on the professional's deviation from a standard of care. Traditional product liability focuses on defects in a tangible, finished

good. AI-assisted medicine collapses this distinction, creating a hybrid entity: neither pure tool nor pure colleague, but an adaptive, opaque, and often poorly understood agent in the clinical dyad. This paper argues that failing to modernize liability and regulation risks one of two equally dangerous outcomes: a chilling effect that stifles innovation, or a Wild West scenario where harms are inflicted without recourse. Navigating a path toward just accountability is therefore not a secondary concern but the foundational challenge for the sustainable integration of AI in medicine [1-38].

4. The Tripartite Knot: Vendor, Institution, and Clinician

Liability in AI-assisted medicine is distributed across three primary actors, each with distinct roles and potential failures.

4.1. The AI Developer/Vendor: Product Liability and Beyond

- **Design Defects:** A model trained on biased data (e.g., underrepresenting darker skin tones) has a fundamental design flaw that leads to disparate harm. This aligns with traditional product liability (res ipsa loquitur the defect speaks for itself).
- **Inadequate Warnings:** Failure to clearly communicate the tool's limitations, known failure modes, and appropriate use cases constitutes a failure to warn. For a "black box" AI, what constitutes adequate warning is deeply contested [39-55].
- **The "Adaptation" Problem:** AI as a Medical Device (SaMD) that continuously learns post-deployment challenges the notion of a "finished product." Is a harmful adaptation post-market a manufacturing defect, a design defect, or an unforeseeable misuse? Current law has no clear answer.

4.2. The Healthcare Institution: The Duty of Algorithmic Stewardship

The hospital or health system is more than a passive purchaser;it is the contextualizer and integrator of the AI.

- **Negligent Credentialing:** Deploying an AI tool without rigorous validation for the local patient population is analogous to granting privileges to an unqualified physician.
- **Failure to Monitor & Update:** Institutions have a duty to monitor the real-world performance of AI and decommission it if drift or harm is detected. They also bear responsibility for ensuring updates are safely implemented [56-78].
- **Workflow & Training Failures:** Implementing a disruptive AI tool without proper clinician training, ergonomic integration, and protocols for overrides constitutes institutional negligence that can lead to alert fatigue and automation bias.

4.3. The Treating Clinician: The Evolving Standard of Care

The clinician remains the final actor, but their legal duty is evolving.

- **The "Reasonable Clinician" Standard:** The core question becomes: What would a reasonable clinician do when using AI in a specific specialty? This standard is dynamic and will escalate as AI becomes normalized.
- **The Duty to Understand & Override:** Courts will likely establish a duty to understand an AI tool's basic function, its intended use, and its known limitations. Blind adherence to an AI output ("automation bias") may itself constitute negligence. The clinician must remain the ultimate diagnostician [79-99].
- Informed Consent: As AI recommendations become more influential, does a patient have a right to know if an AI was involved in their diagnosis or treatment plan, and to understand its role? A new duty of "algorithmic transparency in consent" may emerge.

5. Case Studies in Failure: Untangling Causation

Real-world scenarios illustrate the complexity of assigning blame.

- **Case 1:** The Biased Algorithm. An AI dermatology app disproportionately misses melanomas on dark skin. A patient suffers a delayed diagnosis. Liability Analysis: Strong case against the developer for design defect. Potential liability for the institution if it marketed or deployed the app without validation across skin types. The clinician's liability may be reduced if the tool was presented as autonomous and reliable, but could be shared if they failed to conduct their own visual exam.
- **Case 2:** Alert Fatigue Misfire. A sepsis prediction AI generates frequent false alarms in the ICU. Desensitized nurses ignore a correct alert, leading to a patient's death. Liability Analysis: Primary liability may shift to the institution for implementing a poorly calibrated system that fostered alarm fatigue. The developer may share blame if the false positive rate was misrepresented. The nurse's action, while tragic, may be seen as a foreseeable consequence of a broken system [100-130].
- **Case 3:** The Evolving Black Box. A radiology AI, updated via continuous learning, gradually develops a tendency to overcall pneumonia in patients with a specific, rare artifact. A patient undergoes unnecessary antibiotic therapy and suffers a severe adverse reaction. Liability Analysis: This is the hardest case. The developer is liable if the update process was negligent. The institution is liable for failing to monitor post-update performance. The radiologist is in a nearly impossible position, as the tool's behavior changed without explicit notification.

6. The Regulatory Gap: FDA, CE Marks, and a Moving Target

Current regulatory frameworks are straining to adapt.

- **The FDA's Evolving Approach:** The U.S. FDA's approach to AI/ML-Based SaMD is pioneering with its Total Product Lifecycle (TPLC) regulatory framework and Pre-Certification (Pre-Cert) pilot program. This focuses on overseeing the developer's culture and processes for continuous quality, rather than just a static pre-market snapshot. This is a crucial step but remains largely untested at scale.
- **The "Locked" vs. "Adaptive" Algorithm Dilemma:** Regulators traditionally approve a specific, locked algorithm. Adaptive AI requires a shift to approving a change control protocol a commitment to a validated process for updates, with clearly defined thresholds for which changes require pre-review versus real-world monitoring [131-144].
- Global Discrepancies: Differing regulatory philosophies between the EU (with its risk-based Medical Device Regulation and upcoming AI Act), the US, and other regions create complexity for global developers and inconsistency in

safety standards.

7. A Proposed Framework: Distributed, Tiered Liability

To move forward, we propose a model of Distributed, Tiered Liability that clarifies responsibilities.

Pillar 1: Agile, Lifecycle-Centric Regulation

- Mandate "Algorithmic Audits" for bias and performance prior to market entry and at regular intervals.
- Formalize the Pre-Certification model, requiring developers to demonstrate excellence in software development, data quality, and real-world performance monitoring.
- Establish a national AI Safety Board to review adverse events, share learnings, and recommend modifications to standards of care.

Pillar 2: Institutional Duty of Algorithmic Due Diligence

- Establish a legal "Safe Harbor" for institutions that implement a rigorous Algorithmic Stewardship Program, including: prospective validation, ongoing monitoring dashboards, clinician training curricula, and clear override protocols.
- Institutional liability should be triggered by failure to fulfill these stewardship duties, creating an incentive for responsible procurement and management.

Pillar 3: The Context-Aware Clinician Standard of Care

- Medical boards and specialty societies must define competencies for AI-augmented practice (e.g., "ability to interpret AI outputs in context", "recognition of automation bias").
- The legal standard should protect clinicians who exercise reasoned judgment in overriding an AI, provided they understood its relevant limitations.
- Develop model jury instructions to help triers of fact navigate cases where AI is a contributing factor, preventing undue blame on the last human in the chain.

8. Conclusion: From Liability to Trustworthy Systems

The question of "Who's liable?" cannot be answered by simply stretching old legal doctrines to fit new technology. It demands a proactive re-engineering of responsibility itself. The goal is not merely to assign blame after harm occurs, but to create a system where all parties are incentivized to prevent harm in the first place.

This requires a cultural shift from a culture of blame to a culture of shared accountability. Developers must embrace transparency and robust life-cycle management. Institutions must become intelligent buyers and vigilant stewards. Clinicians must embrace their role as informed arbiters, not passive recipients. Regulators must be agile overseers of dynamic systems.

Ultimately, a clear, fair, and forward-looking liability framework is not a barrier to innovation; it is its essential foundation. It provides the guardrails necessary for clinicians to adopt these powerful tools with confidence, for patients to trust in their care, and for society to reap the benefits of AI-assisted medicine without falling prey to its perils. The new world of medicine will be built not just on code and data, but on a renewed covenant of responsibility.

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