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# Law and Artificial Intelligence in Biosciences: Algorithmic Transparency and Liability for Medical Error

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The rapid integration of artificial intelligence into biosciences and clinical diagnostics has transformed contemporary healthcare, offering improved accuracy, efficiency, and predictive capacity. At the same time, the growing reliance on machine learning systems,particularly opaque "black box"models raises significant legal concerns regarding transparency, accountability, and patient protection. The use of AI-assisted diagnostic tools challenges traditional legal doctrines built around human decision-making and individual professional responsibility.

This paper examines whether the current European regulatory framework, including the Artificial Intelligence Act, the Medical Devices Regulation and the modernised Product Liability regime, provides adequate safeguards in cases of medical error involving AI systems. It addresses two central questions: first, whether existing transparency and documentation requirements sufficiently mitigate the epistemic opacity of algorithmic systems in high-risk medical contexts; and second, how liability should be allocated within hybrid human–machine decision-making environments.

The analysis argues that while recent EU legislation strengthens ex ante compliance obligations and risk-based oversight, significant doctrinal and practical uncertainties remain in attributing responsibility when harm results from AI-supported clinical decisions. Traditional fault-based and product liability models do not fully capture the distributed and adaptive nature of contemporary AI systems. Ensuring democratic legitimacy in bioinnovation therefore requires clearer standards of explainability, traceability, and accountability that reconcile technological complexity with the fundamental rights of patients.

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