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THE RIGHT TO EXPLANATION IN AI MEDICAL SYSTEMS: CIVIL LAW MECHANISMS FOR PROTECTING PATIENT INTERESTS

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Abstract:
The rapid integration of artificial intelligence into clinical practice has generated one of the most pressing questions in contemporary civil law: whether patients possess an enforceable right to receive a meaningful explanation of AI-generated medical decisions, and what legal mechanisms exist to protect this interest. The article examines the normative foundations of the right to explanation in international and comparative law, analyses the civil liability consequences of its violation, and evaluates the adequacy of existing legal instruments. The author concludes that the right to explanation in AI medical systems constitutes an emerging but insufficiently codified civil right, the protection of which requires a coherent framework combining data protection, product liability and health law.

Keywords: Right to explanation, artificial intelligence, medical decision-making, civil liability, GDPR, EU AI Act, patient rights, automated processing, algorithmic transparency.

The deployment of AI systems in medical diagnosis, treatment planning and clinical risk assessment has introduced a structural asymmetry between those who produce algorithmic decisions and those who bear their consequences. When an AI system determines that a patient does not qualify for a specific treatment, flags a diagnostic anomaly, or assigns a clinical risk score, the patient typically receives a clinical outcome without any access to the reasoning that produced it. This

opacity constitutes not merely a technical inconvenience but a potential violation of foundational civil law principles governing personal autonomy, informed consent and the right to challenge decisions that significantly affect one's physical integrity and health. The question of whether patients possess an enforceable right to explanation in this context has emerged as one of the central unresolved tensions in the intersection of civil law, data protection regulation and medical ethics. The present article analyses the normative foundations of this right, its current legal architecture, and the civil liability consequences that arise when it is denied or inadequately fulfilled.

The right to explanation in civil law is rooted in the broader principle that individuals must be able to understand and contest decisions that materially affect their legally protected interests. In the context of medical treatment, this principle finds expression in the doctrine of informed consent, which requires that a patient receive sufficient information about a proposed medical intervention — including its rationale, risks and alternatives — before valid consent can be given. Where a clinical decision is generated or substantially influenced by an AI system, the question arises whether the information provided to the patient adequately conveys the basis of that decision, or whether the algorithmic dimension is effectively concealed beneath a veneer of professional medical authority.

From a civil law perspective, the failure to explain an AI-generated medical decision may give rise to liability on two distinct grounds: first, as a breach of the duty of disclosure inherent in the patient-physician relationship and the contractual obligations of healthcare providers; second, as a violation of the statutory rights conferred upon individuals subjected to automated processing under data protection law. Both grounds are analytically distinct but operationally complementary, and both merit careful examination.

The most developed normative architecture for the right to explanation in automated decision-making is found in European Union law. Article 22 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data (General Data Protection Regulation — GDPR) establishes that the data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her[1]. Where such processing is nevertheless permitted, the controller is required to implement suitable safeguards, including at minimum the right to obtain human intervention, to express one's point of view and to contest the decision. Articles 13, 14 and 15 GDPR further require controllers to provide data subjects with meaningful information about the logic involved in automated processing, the significance of such processing and the envisaged consequences for the individual[2].

A significant contribution to the interpretation of Article 22 was made by the Court of Justice of the European Union in its ruling in Case C-634/21 (SCHUFA Holding, December 2023), in which the Court held that the generation of a probability value through automated processing can itself constitute a decision within the meaning of Article 22 GDPR where that value is determinative of the conduct of a third party towards the data subject. This ruling has direct relevance for AI-based medical systems: where an algorithmic risk score or diagnostic classification automatically triggers or forecloses a clinical pathway without meaningful human review, it arguably meets the threshold of a solely automated decision with significant effects on the individual.

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (AI Act), which entered into force on 1 August 2024, introduces a distinct and more specific right

to explanation in Article 86[3]. Under this provision, any person subject to a decision made by a deployer of a high-risk AI system with significant effects on that person's health, safety or fundamental rights shall have the right to obtain from the deployer clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken. Critically, medical diagnostic AI systems — including AI-based software intended for medical purposes — are classified as high-risk under Annex III to the AI Act, meaning that the right to explanation under Article 86 applies directly to the most clinically significant applications of AI in healthcare.

The civil liability dimension of AI-generated medical harm has been significantly restructured by Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on Liability for Defective Products, which entered into force on 8 December 2024[4]. For the first time in European product liability law, the Directive expressly extends the definition of 'product' to include standalone software and AI systems, thereby subjecting AI medical diagnostic tools to the strict liability regime applicable to physical medical devices. A product — including an AI system — is considered defective where it does not provide the level of safety that a person is entitled to expect. The Directive further introduces rebuttable presumptions of defectiveness and causation where the claimant faces excessive difficulties due to technical or scientific complexity, a provision of particular significance given the opacity of AI decision-making processes. Material loss arising from medically recognized psychological damage caused by a defective AI system is expressly compensable under Article 6 of the Directive.

The application of the right to explanation to AI medical systems generates several interconnected legal problems that current regulatory frameworks address only partially.

The first problem concerns the intelligibility threshold. The requirement to provide 'meaningful information about the logic involved' under GDPR Articles 13–15, and 'clear and meaningful explanations' under AI Act Article 86, does not prescribe a specific technical standard for what constitutes an adequate explanation. A statement that a diagnostic algorithm identified a pattern in imaging data consistent with a particular condition may be technically accurate but practically unintelligible to a patient without medical expertise. The gap between algorithmic transparency and patient comprehension creates a structural weakness in the right to explanation as currently formulated.

The second problem concerns the identification of the responsible party. In AI-mediated healthcare, the chain of actors responsible for a given clinical decision may include the AI system developer, the healthcare institution deploying the system, and the individual clinician who accepts or relies upon the algorithmic output. The GDPR places transparency obligations on the data controller, typically the healthcare institution. The AI Act places the duty to explain under Article 86 on the deployer of the high-risk AI system, again typically the healthcare institution. However, where the inadequacy of the explanation stems from the inherent opacity of the underlying model — a characteristic of the AI developer's design choices — no current instrument directly obliges the developer to furnish a patient-accessible explanation.

The third problem concerns the relationship between the right to explanation and informed consent in medical law. In jurisdictions that follow the doctrine of informed consent, a patient's agreement to a medical procedure is legally valid only if the patient has received sufficient information to make an autonomous and rational decision. Where that procedure is guided or determined by an AI system whose logic is not disclosed, the adequacy of informed consent is undermined. This represents a civil law deficiency of considerable practical importance: a

patient who undergoes a procedure on the basis of an AI-generated recommendation that was not explained may have a claim in contract or tort regardless of whether the procedure itself was clinically appropriate.

The civil liability consequences of denying or inadequately fulfilling the right to explanation in AI medical systems may arise under multiple legal bases, which may operate cumulatively.

Under data protection law, the failure to provide mandatory information about automated processing constitutes a violation of GDPR Articles 13–15, which may give rise to the right to compensation under Article 82 GDPR. This provision establishes that any person who has suffered material or non-material damage as a result of an infringement of the Regulation shall have the right to receive compensation from the controller or processor. Non-material damage — including anxiety, distress and loss of autonomy arising from an inability to understand or contest an AI-generated medical decision — has been recognised as compensable in a growing body of national court decisions.

Under the AI Act, Article 86 creates an enforceable individual right to explanation vis-à-vis the deployer of a high-risk AI system. The Act does not itself establish a specific civil liability regime for its breach; however, such a breach may constitute evidence of negligence or breach of statutory duty in tort proceedings under national law, and may engage the presumptions of causation established by the Product Liability Directive (EU) 2024/2853 where the denial of explanation is linked to a product defect causing physical or psychological harm[5].

Under general contract and medical law, the failure to explain an AI-generated recommendation may vitiate informed consent and expose the healthcare provider to liability for breach of contract or negligence, independently of any data protection or product liability framework. In the United States, the Health

Insurance Portability and Accountability Act (HIPAA, Pub.L. 104-191, 1996) does not directly establish a right to explanation of algorithmic decisions, but its Privacy Rule requirements regarding access to health information and the right to an accounting of disclosures may be engaged where AI processing involves the use or disclosure of protected health information[6].

The analysis conducted above reveals the following systemic deficiencies in the current legal framework governing the right to explanation in AI medical systems.

First, the right to explanation under AI Act Article 86 explicitly excludes decisions made using AI medical devices already subject to the Medical Device Regulation (MDR), creating a regulatory gap for precisely those AI systems — diagnostic imaging software, clinical decision support tools — that are most consequential for patients. This exclusion should be reconsidered in forthcoming legislative review. Second, neither the GDPR nor the AI Act establishes a minimum intelligibility standard for explanations provided to patients, leaving the content of the right effectively undefined in practice. A co-regulatory instrument specifying sector-specific intelligibility benchmarks for AI explanations in healthcare would substantially strengthen patient protection. Third, the absence of a direct liability pathway against AI developers for opacity-related harms means that patients must pursue claims against healthcare institutions that may themselves be unable to explain the logic of third-party AI tools. Clear rules on joint and several liability between developers and deployers for explanation-related failures are necessary.

Thus, the right to explanation in AI medical systems represents an important but incompletely operationalised civil right. The existing normative framework — comprising GDPR Article 22, AI Act Article 86, the Product Liability Directive (EU) 2024/2853, and national medical law — provides a foundation but leaves

significant gaps in intelligibility standards, liability attribution and enforcement mechanisms. Closing these gaps requires coordinated legislative action combining data protection, product liability and health law, and should be informed by the evolving case law of the Court of Justice of the European Union on automated decision-making and the emerging practice of national supervisory authorities.

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