

Law, Artificial Intelligence, and a New Era in Healthcare

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Abstract

The integration of artificial intelligence (AI) into healthcare is opening a new era of diagnostic innovation and administrative efficiency, while also requiring a substantial reassessment of existing liability frameworks. One of the most difficult questions concerns responsibility for harm arising from diagnosis, clinical procedures, or treatment. Traditional medical liability generally focuses on negligence by healthcare professionals and institutions. When AI contributes to a harmful outcome, however, responsibility may also attach to the medical-device manufacturer, the software developer or provider, or the healthcare institution that selected and implemented the system. This article examines how European Union product-safety and product-liability rules interact with Romanian medical-malpractice and tort law. It argues that the appropriate allocation turns on a distinction between product defect and professional or organisational fault, supported by joint and several liability where several actors contribute to the same harm and by recourse among them according to their respective contributions.

Keywords: artificial intelligence; civil liability; healthcare; medical devices; medical malpractice; product liability; right of recourse.

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1. Introduction

Medicine increasingly confronts complex clinical situations, including emergencies in which speed and accuracy are critical. Artificial intelligence promises practical solutions ranging from the automation of repetitive tasks to improved image analysis, clinical decision support, and predictive analytics. These systems may increase efficiency, but their outputs remain probabilistic and context dependent. Their deployment therefore creates both clinical opportunities and legal risk.²

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² Constantin Pisarenco, “Sisteme de asistență pentru luarea deciziilor clinice bazate pe inteligență

The legal significance of medical AI extends beyond the question whether an algorithm performs well in laboratory conditions. The system must also be appropriately selected, integrated into clinical workflows, monitored, and used by professionals capable of evaluating its output. Recent scholarship has accordingly examined both the capabilities of AI-based clinical decision-support systems and the allocation of legal responsibility when those systems contribute to harm.³

Romania's digitalisation of healthcare is also being accelerated through public investment. Under the National Recovery and Resilience Plan, the Ministry of Health launched investments in information systems and digital infrastructure for public healthcare institutions. These programmes give practical urgency to questions of procurement, implementation, staff training, cybersecurity, and liability.⁴

The integration of AI into medical practice is no longer merely prospective. Clinical decision-support systems, diagnostic-imaging algorithms, robotic surgical platforms, and AI-based triage tools are being introduced across the European Union. Each deployment alters the traditional relationship between patient, physician, and healthcare institution by adding a technological component whose operation may be opaque, adaptive, and difficult to reconstruct after an adverse event.

This development challenges established concepts of civil liability, including fault, causation, defect, and legal attribution. It also raises a structural question: when an AI system contributes to a harmful medical outcome, should responsibility fall on the manufacturer of the medical device, the developer of the software, the healthcare institution that selected and implemented the system, the physician who relied on its output, or several of them together?

European Union law now provides a dense regulatory framework. Regulation (EU) 2024/1689 (the AI Act) establishes a risk-based system of obligations

artificială: capacități și riscuri juridice în contextul reglementării Uniunii Europene,” *Revista Universul Juridic*, no. 4 (2026), <https://revista.universuljuridic.ro/sisteme-de-asistenta-pentru-luarea-deciziilor-clinice-bazate-pe-inteligenta-artificiala-capacitati-si-riscuri-juridice-in-contextul-reglementarii-uniunii-europene/>.

³ Pisarenco, “Sisteme de asistență”; Anca-Viorica Bogdan, “Inteligența artificială și răspunderea juridică: între realități normative și perspective de reglementare,” *Revista Universul Juridic*, no. 3 (2026), <https://www.universuljuridic.ro/inteligenta-artificiala-si-raspunderea-juridica-intre-realitati-normative-si-perspective-de-reglementare/>.

⁴ Romanian Ministry of Health, “Investiții în sistemele informatice și în infrastructura digitală a unităților sanitare publice,” National Recovery and Resilience Plan, Component 7, Investment 13.3, <https://ms.ro/ro/de-interes/apeluri-pnrr-c12-sanatate/componenta-7-transformare-digital%C4%83-investitia-specific%C4%83-i33-investi%C8%9Bii-%C3%AEn-sistemele-informatice-%C8%99i-%C3%AEn-infrastructura-digital%C4%83-a-unit%C4%83%C8%9Bilor-sanitare-publice/>; Claudiu-Gabriel Galu, “Câteva considerente juridice privind Planul Național de Redresare și Reziliență,” *Curierul Judiciar*, no. 1 (2022); Claudiu-Gabriel Galu, “Reflecții asupra Planului Național de Redresare și Reziliență la un an de la adoptare,” *Curierul Judiciar*, no. 8 (2022).

for AI actors.⁵ Regulation (EU) 2017/745 (the Medical Devices Regulation, or MDR) subjects medical devices, including qualifying medical software, to safety, performance, and conformity-assessment requirements.⁶ Directive (EU) 2024/2853 (the revised Product Liability Directive, or revised PLD) expressly includes software within the concept of a product and modernises the evidentiary rules for defective-product claims.⁷ In Romania, these instruments interact with Law No. 95/2006 on healthcare reform, the Civil Code, and Law No. 240/2004 on liability for defective products.⁸

2. Legal Framework Governing Civil Liability

The AI Act applies in stages and imposes additional duties on systems classified as high-risk. Medical AI is not automatically high-risk merely because it is used in healthcare. Under article 6(1) and Annex I, however, an AI system is high-risk when it is a safety component of a product, or is itself a product, covered by listed Union harmonisation legislation — including the MDR — and the product must undergo a third-party conformity assessment. Annex III separately covers specified uses, including certain emergency-call evaluation, dispatch, and patient-triage systems.⁹ High-risk systems are subject to requirements concerning risk management, data governance, technical documentation, record keeping, transparency, human oversight, accuracy, robustness, and cybersecurity.

The AI Act is principally a regulatory instrument. It does not establish a general private-law action for compensation. A breach may nevertheless be relevant in civil proceedings: noncompliance can help establish that a product failed to provide the safety that a person is entitled to expect, or that a professional or institution did not act with the required care. Compliance, conversely, does not necessarily prove the absence of a defect or fault because civil-law duties and

⁵ European Parliament and Council, Regulation (EU) 2024/1689 of June 13, 2024, Laying Down Harmonised Rules on Artificial Intelligence, consolidated version, July 27, 2026, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02024R1689-20260727>.

⁶ European Parliament and Council, Regulation (EU) 2017/745 of April 5, 2017, on Medical Devices, *Official Journal of the European Union* L 117 (May 5, 2017): 1–175, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>.

⁷ European Parliament and Council, Directive (EU) 2024/2853 of October 23, 2024, on Liability for Defective Products and Repealing Council Directive 85/374/EEC, *Official Journal of the European Union* L, 2024/2853 (November 18, 2024), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024L2853>.

⁸ Romania, Law No. 95/2006 on Healthcare Reform, republished, as amended, <https://legislatie.just.ro/Public/DetaliiDocument/71139>; Romania, *Codul civil*, Law No. 287/2009, republished, as amended, <https://legislatie.just.ro/Public/DetaliiDocument/175630>; Romania, Law No. 240/2004 on Producer Liability for Damage Caused by Defective Products, republished, as amended, <https://legislatie.just.ro/Public/DetaliiDocument/52850>.

⁹ Regulation (EU) 2024/1689, art. 6(1), annex I, sec. A, point 11, and annex III, point 5(d).

reasonable safety expectations may exceed the regulatory minimum in a particular case.

The revised PLD modernises strict producer liability in three respects that are particularly important for medical AI. First, article 4 expressly includes software within the definition of “product”; this may include AI systems supplied as software. Second, article 9 permits courts, subject to proportionality and the protection of confidential information and trade secrets, to order disclosure of relevant evidence. Third, article 10 introduces rebuttable presumptions concerning defectiveness and causation in defined circumstances, including cases of excessive technical or scientific complexity.¹⁰

These changes are not yet a substitute for current Romanian legislation. Member States must transpose Directive (EU) 2024/2853 by December 9, 2026, and its new rules apply to products placed on the market or put into service after that date. Until national transposition takes effect, Romanian claims remain governed by the applicable provisions of Law No. 240/2004 and the Civil Code, interpreted consistently with the Union law already in force. The revised PLD is therefore central to the prospective framework, but it should not be described as already governing every Romanian product-liability claim.

The Commission's 2022 proposal for an AI Liability Directive would have harmonised selected aspects of fault-based noncontractual liability, including access to evidence and presumptions of causality. The Commission listed the proposal for withdrawal in its 2025 Work Programme.¹¹ Its withdrawal leaves fault-based liability primarily within national private law and increases the practical importance of the revised PLD, the AI Act's regulatory duties, and national rules on medical malpractice.

In Romanian law, the liability of physicians and healthcare providers is governed principally by Law No. 95/2006, which defines medical malpractice by reference to professional error causing harm. General Civil Code rules remain relevant, including articles 1349 and 1357 on tort liability, article 1373 on a principal's liability for the acts of an agent, article 1376 on damage caused by things, and article 1382 on joint and several liability among persons responsible for the same harm.¹² Producer liability is currently regulated by Law No. 240/2004.¹³

The classification of a claim as contractual or tortious depends on the

¹⁰ Directive (EU) 2024/2853, arts. 4, 9–10.

¹¹ European Commission, “Proposal for a Directive of the European Parliament and of the Council on Adapting Non-contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive),” COM(2022) 496 final, September 28, 2022, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0496>; European Commission, “Commission Work Programme 2025,” COM(2025) 45 final, annex IV, February 11, 2025, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0045>.

¹² Romania, *Codul civil*, arts. 1349, 1357, 1373, 1376, and 1382.

¹³ Romania, Law No. 240/2004.

legal relationship among the patient, healthcare provider, and individual professional, as well as on the conduct alleged. It should not be inferred from an unrelated judgment or reduced to a universal formula. What matters for medical AI is that product defect, institutional fault, and professional fault may arise from the same event and must be analysed under their respective legal regimes.

3. Liability of the Medical-Device Manufacturer

A medical-device manufacturer is, in general terms, the person that manufactures or fully refurbishes a device, or has it designed, manufactured, or fully refurbished, and markets it under its name or trademark. Where a device incorporating AI is defective, product-liability law focuses on the product's safety rather than on proof that the manufacturer acted negligently. The injured person must establish the legally required elements, including damage, defect, and causal connection, subject to any applicable presumptions.

The Court of Justice of the European Union has interpreted defectiveness in the medical-device context with particular attention to patient safety. In *Boston Scientific Medizintechnik GmbH*, the Court held that, where products such as pacemakers or implantable cardioverter defibrillators belong to the same group or production series and a potential defect has been identified, a particular product may be classified as defective without proof that it has the defect individually. In *Schmitt v. TÜV Rheinland LGA Products GmbH*, the Court interpreted the duties of a notified body under the former Medical Devices Directive but left the conditions of that body's civil liability to national law.¹⁴ *Schmitt* therefore should not be cited as establishing strict producer liability for notified bodies.

3.1. The Challenge of Establishing AI Defectiveness

Determining whether an AI system is defective is difficult because familiar categories — manufacturing, design, and warning defects — were developed largely for products whose relevant characteristics were comparatively stable when placed on the market. AI outputs are probabilistic, may depend on the quality and representativeness of input data, and may change following updates or authorised post-deployment learning.

Under the revised PLD, defectiveness turns on whether a product provides the safety that a person is entitled to expect or that is required under Union

¹⁴ *Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt—Die Gesundheitskasse and Betriebskrankenkasse RWE*, Joined Cases C-503/13 and C-504/13, ECLI:EU:C:2015:148, judgment of March 5, 2015, paras. 41–43, <https://curia.europa.eu/juris/document/document.jsf?docid=162686&doclang=EN>; *Schmitt v. TÜV Rheinland LGA Products GmbH*, Case C-219/15, ECLI:EU:C:2017:128, judgment of February 16, 2017, paras. 55–60, <https://curia.europa.eu/juris/document/document.jsf?docid=187921&doclang=EN>.

or national law. The assessment may consider the product's presentation and reasonably foreseeable use, its capacity to continue learning or acquire new features, its interaction with other products, product-safety requirements, and the needs of the group of users for whom the product is intended. For medical AI, reasonable safety expectations must be assessed in the clinical and regulatory context, including the system's intended purpose, validated performance, known limitations, instructions, monitoring arrangements, and the human oversight reasonably expected in practice.¹⁵

An erroneous output is not necessarily proof of defectiveness. A diagnostic system may perform within its validated parameters while still producing a false positive or false negative in an individual case. The legal analysis should ask whether the system's design, data, instructions, monitoring, or performance fell below legitimate safety expectations, and whether that shortcoming contributed to the harm. Conversely, a statistically accurate model may still be defective if it presents an unacceptable risk for a relevant patient subgroup, conceals material limitations, or is deployed without safeguards required by its intended purpose.

3.2. Defences and Development Risk

Producer-liability regimes recognise a limited set of defences. The development-risk defence is especially important for AI: a producer may seek to show that the objective state of scientific and technical knowledge at the relevant time did not permit the defect to be discovered. Under the revised PLD, Member States may derogate from that defence for specified categories of products, subject to the Directive's conditions.¹⁶

Opacity alone should not establish a development-risk defence. A producer that selects an opaque architecture must still conduct appropriate validation, risk management, documentation, post-market monitoring, and incident response. The relevant question is not whether a particular employee foresaw the precise harmful output, but whether the defect was objectively discoverable in light of accessible scientific and technical knowledge and the testing reasonably required for that product.

¹⁵ Directive (EU) 2024/2853, art. 7; Jean-Sébastien Borghetti, "How Can Artificial Intelligence Be Defective?," in *Liability for Artificial Intelligence and the Internet of Things: Münster Colloquia on EU Law and the Digital Economy IV*, ed. Sebastian Lohsse, Reiner Schulze, and Dirk Staudenmayer (Baden-Baden: Nomos; Oxford: Hart, 2019), 63–76, <https://doi.org/10.5771/9783845294797-63>; Gerald Spindler, "Roboter, Automation, künstliche Intelligenz, selbst-steuernde Kfz—Braucht das Recht neue Haftungskategorien?," *Computer und Recht* 31, no. 12 (2015): 766–76, <https://doi.org/10.9785/cr-2015-1205>; Gerhard Wagner, "Verantwortlichkeit im Zeichen digitaler Technologien," *Versicherungsrecht* (2020): 717–41.

¹⁶ Directive (EU) 2024/2853, arts. 11 and 18.

4. Liability of the Software Developer or AI Provider

4.1. Distinguishing the Manufacturer from the Developer

The manufacturer of a medical device and the developer of its AI component are often different entities. A hospital may purchase imaging equipment from a medical-technology company that has integrated software developed by a third party. The AI Act addresses this supply chain through concepts such as provider, deployer, importer, and distributor, while product-liability law determines which economic operators may be liable to the injured person.

Under the revised PLD, software is a product and software integrated into or interconnected with another product may constitute a component. A person that develops a software component and places it on the market may therefore be treated as its manufacturer. The manufacturer of the final device and the manufacturer of a defective component may both face liability where their respective statutory conditions are satisfied. The exact classification depends on the contractual and technical structure of the supply chain; the word “developer” alone does not automatically determine liability.¹⁷

4.2. Obligations of the AI Provider under the AI Act

Providers of high-risk AI systems must comply with a series of obligations that can materially inform later civil-liability analysis. These include a risk-management system, data and data-governance practices, technical documentation, record keeping, instructions for deployers, human-oversight measures, and appropriate levels of accuracy, robustness, and cybersecurity. Providers must also operate quality-management and post-market-monitoring systems and comply with incident-reporting requirements where applicable.¹⁸

The civil significance of these duties is contextual. Failure to comply may support a finding of defectiveness under product-liability law or of fault under general tort law. It may also trigger a presumption under the revised PLD if the statutory conditions are met. Yet regulatory compliance is not a complete defence: a system may satisfy formal conformity requirements and still fail to provide the safety reasonably expected in its intended clinical setting.

4.3. Updates and Continuous Learning

AI systems may evolve after deployment through updates, changes to training or validation data, or features that permit continued learning. The revised

¹⁷ Directive (EU) 2024/2853, arts. 4 and 8.

¹⁸ Regulation (EU) 2024/1689, arts. 9–15 and 17, 72–73.

PLD treats a product as remaining within the manufacturer's control where the manufacturer retains the ability to supply software updates or upgrades or to authorise changes, including substantial modifications. Defectiveness may therefore arise after initial placement on the market when it results from software, updates, upgrades, or a lack of safety updates necessary to address cybersecurity vulnerabilities and maintain safety, provided the relevant conditions of control are satisfied.¹⁹

This lifecycle approach is particularly important for medical AI. Responsibility should follow actual control: the entity that can design, authorise, distribute, or withhold an update must manage the risks created by that capacity. Hospitals and deployers retain corresponding duties to install required safety updates, validate local implementation, monitor performance, and avoid unauthorised modifications. Continuous learning should be enabled only within the approved change-management framework and with traceability sufficient to reconstruct the system's state at the time of a clinical decision.

5. Liability of the Healthcare Institution and the Physician

The use of AI does not transform physicians or healthcare institutions into guarantors of every algorithmic output. Their liability ordinarily depends on professional or organisational fault, except where a separate statutory basis imposes another form of liability. AI nevertheless changes the content of the duty of care because safe use requires appropriate selection, integration, training, oversight, and documentation.

Article 653 of Law No. 95/2006 defines medical malpractice as professional error committed in the exercise of a medical or medical-pharmaceutical act that causes harm to a patient. The statutory framework also addresses civil liability for personnel and providers involved in medical services.²⁰ The applicable standard remains that of a competent professional acting in accordance with legal duties, good medical practice, available evidence, and the circumstances of the particular case.

5.1. Duties of a Physician Using AI

The physician remains responsible for the clinical judgment entrusted to the medical profession. The degree of permissible reliance on AI depends on the system's intended purpose, demonstrated performance, instructions, known limi-

¹⁹ Directive (EU) 2024/2853, arts. 6–7.

²⁰ Romania, Law No. 95/2006, arts. 653–55; Alina Doina Tănase, *Răspunderea civilă pentru malpraxisul medical* (Bucharest: Universul Juridic, 2024), ISBN 978-606-39-1372-3, <https://www.ujm.ag.ro/drept/raspunderea-civila-pentru-malpraxisul-medical>.

tations, the urgency of the situation, and the physician's ability to verify the output. Four duties are especially relevant:

1. Appropriate selection and use. The physician should use a system suitable for the clinical task and within its validated purpose, unless a legally and professionally justified departure is documented. The system's regulatory status, patient population, and limitations must be considered.

2. Critical evaluation. The physician should not accept an AI output uncritically. The output must be assessed against the patient's history, examination, laboratory and imaging findings, and other clinically relevant information. The intensity of review should correspond to the risk and to the system's known reliability.

3. Information and consent. The patient should receive the information required by applicable law and professional standards. Whether the use of AI must be disclosed separately depends on its materiality to the proposed intervention, its risks and alternatives, and its role in the clinical decision. The duty should not be expressed as an absolute requirement to disclose every background software function.

4. Documentation. The medical record should preserve information material to the decision, including the system used, the relevant output, significant limitations or alerts, and the physician's reasoning. Good documentation supports continuity of care and enables reconstruction of the respective contributions of the human and technological actors if litigation occurs.

A physician should not be liable merely because a reasonable clinical decision, informed by a properly used system, later proves unsuccessful. Liability requires a legally relevant breach and a causal connection to the harm. Equally, the existence of a certified system does not excuse blind reliance where a competent physician would have recognised that the output was inconsistent with the clinical picture.

5.2. Institutional Liability of the Healthcare Provider

Healthcare institutions have direct organisational duties. They must select systems appropriate to their services and patient populations; conduct procurement and implementation with clinical, legal, security, and data-protection input; train staff; define human-oversight and escalation procedures; maintain interoperable and secure infrastructure; monitor performance; report incidents; and ensure that software versions and updates are controlled.

An institution's own fault may arise from defective procurement, inadequate validation, insufficient training, poor workflow design, failure to update, weak cybersecurity, or the absence of procedures for conflicting human and AI assessments. This direct organisational liability is analytically distinct from liability for the conduct of employed personnel.

Where a physician acts as an agent within the functions entrusted by a hospital or clinic, article 1373 of the Romanian Civil Code may make the principal liable for harm caused by the agent under the statutory conditions.²¹ Article 1373 is the relevant provision for a principal's liability for an agent. The institution's liability for an agent may coexist with its liability for its own organisational fault and with the liability of a manufacturer or software provider.

6. Allocating Liability among the Manufacturer, Developer, Healthcare Institution, and Physician

Allocation should begin with a distinction between product defect and professional or organisational fault. The manufacturer of a device or software component may bear strict liability when the product is defective and the statutory conditions are met. Physicians and healthcare institutions generally bear fault-based liability for breaches of professional or organisational duties. These regimes can coexist because the same injury may have more than one legally relevant cause.

Consider a diagnostic system that produces an erroneous output because its training data underrepresent a patient group. If the limitation was not adequately identified, mitigated, or disclosed, the system may be defective. If a physician also disregards obvious contradictory clinical evidence, professional fault may contribute to the same harm. If the institution deployed the system without local validation or staff training, organisational fault may provide a third contribution. The court should analyse each actor's conduct and control rather than treating the algorithm as an autonomous legal subject.

Under article 1382 of the Romanian Civil Code, persons responsible for the same harmful event may be jointly and severally liable to the injured person.²² This protects the patient from having to bear the insolvency risk of one defendant or to establish the precise internal share of every actor before obtaining compensation. The defendants' respective shares can then be determined in recourse proceedings according to the legal basis of liability and their contribution to the harm.²³

Several patterns follow. If the injury results exclusively from a product defect and the physician and institution used the system appropriately, the final burden should ordinarily rest with the responsible producer or producers. If the

²¹ Romania, *Codul civil*, art. 1373; Liviu Pop, Ionuț-Florin Popa, and Stelian Ioan Vidu, *Drept civil: Obligațiile*, 2nd rev. ed. (Bucharest: Universul Juridic, 2020), ISBN 978-606-39-0663-3, <https://www.ujmag.ro/drept/drept-civil/drept-civil-obligatiile2020-editia-a-ii-a-revizuita-si-adaugata>.

²² Romania, *Codul civil*, art. 1382.

²³ Claudiu-Gabriel Galu, *Dreptul de regres: Regresul în dreptul afacerilor* (Bucharest: C.H. Beck, 2020), ISBN 978-606-18-1007-9, <https://www.beckshop.ro/dreptul-de-regres-regresul-in-dreptul-afacerilor>.

system produced an accurate and adequately communicated output but the physician culpably failed to act on it, the professional actor may bear the final burden. In a mixed case, recourse should reflect the gravity and causal significance of each contribution, the actor's capacity to control the risk, the foreseeability of the failure, and the reasonableness of the physician's reliance.

Disclosure and technical evidence will be central to this allocation. Model documentation, validation data, logs, update histories, incident reports, procurement specifications, training records, and the medical record may reveal whether the harmful outcome arose from the product, its local integration, professional use, or some combination of these factors. Courts should tailor disclosure so that patients can obtain necessary evidence while trade secrets, personal data, and cybersecurity-sensitive information remain protected.

7. Conclusions

The deployment of AI in medicine does not require abandoning established categories of civil liability. It requires those categories to be applied with close attention to the AI supply chain, lifecycle control, clinical context, and evidentiary asymmetry.

First, liability should be structured around the distinction between strict liability for a defective product and fault-based liability for breaches of professional or organisational duties. The distinction is not a choice between mutually exclusive regimes; several regimes may apply to different actors in the same case.

Second, the revised PLD recognises software as a product and makes it possible to identify the producer of a defective software component as a distinct locus of liability. This responds to the reality that the manufacturer of a medical device may not have developed the AI component it incorporates. Nevertheless, liability must be based on the statutory role and actual conduct of each actor, not on the imprecise label “developer.”

Third, physicians' and healthcare institutions' duties are reshaped by AI. Appropriate selection, critical evaluation, information, documentation, training, monitoring, cybersecurity, and update management translate the principle of human oversight into operational obligations. Their content must remain risk based and sensitive to the system's intended purpose and the circumstances of care.

Fourth, joint and several liability toward the injured patient, followed by recourse among responsible parties, offers a workable response to mixed causation. It preserves effective compensation while allowing the final burden to be allocated according to defect, fault, control, and causal contribution.

Finally, the relationship between Romanian and European Union law will continue to develop through the implementation of the AI Act and the transposition of Directive (EU) 2024/2853. Romanian courts will need to integrate the new disclosure and presumption rules with the Civil Code, Law No. 95/2006, and the

national product-liability regime. Careful documentation and clear contractual allocation along the AI supply chain will be essential, but contractual arrangements must not reduce the rights that mandatory law grants to injured patients.

Bibliography

I. Books and Articles

1. Bogdan, Anca-Viorica. "Inteligența artificială și răspunderea juridică: între realități normative și perspective de reglementare." *Revista Universul Juridic*, no. 3 (2026). <https://www.universuljuridic.ro/inteligența-artificială-si-răspunderea-juridică-intre-realități-normative-si-perspective-de-reglementare/>.
2. Borghetti, Jean-Sébastien. "How Can Artificial Intelligence Be Defective?" In *Liability for Artificial Intelligence and the Internet of Things: Münster Colloquia on EU Law and the Digital Economy IV*, edited by Sebastian Lohsse, Reiner Schulze, and Dirk Staudenmayer, 63–76. Baden-Baden: Nomos; Oxford: Hart, 2019. <https://doi.org/10.5771/9783845294797-63>.
3. Galu, Claudiu-Gabriel. "Câteva considerente juridice privind Planul Național de Redresare și Reziliență." *Curierul Judiciar*, no. 1 (2022).
4. Galu, Claudiu-Gabriel. *Dreptul de regres: Regresul în dreptul afacerilor*. Bucharest: C.H. Beck, 2020. ISBN 978-606-18-1007-9. <https://www.beckshop.ro/dreptul-de-regres-regresul-in-dreptul-afacerilor>.
5. Galu, Claudiu-Gabriel. "Reflecții asupra Planului Național de Redresare și Reziliență la un an de la adoptare." *Curierul Judiciar*, no. 8 (2022).
6. Pisarenco, Constantin. "Sisteme de asistență pentru luarea deciziilor clinice bazate pe inteligența artificială: capacități și riscuri juridice în contextul reglementării Uniunii Europene." *Revista Universul Juridic*, no. 4 (2026). <https://revista.universuljuridic.ro/sisteme-de-asistență-pentru-luarea-deciziilor-clinice-bazate-pe-inteligența-artificială-capacități-si-riscuri-juridice-in-contextul-reglementării-uniunii-europene/>.
7. Pop, Liviu, Ionuț-Florin Popa, and Stelian Ioan Vidu. *Drept civil: Obligațiile*. 2nd rev. ed. Bucharest: Universul Juridic, 2020. ISBN 978-606-39-0663-3. <https://www.ujmag.ro/drept/drept-civil/drept-civil-obligațiile2020-editia-a-ii-a-revizuita-si-adaugita>.
8. Spindler, Gerald. "Roboter, Automation, künstliche Intelligenz, selbst-steuernde Kfz—Braucht das Recht neue Haftungskategorien?" *Computer und Recht* 31, no. 12 (2015): 766–76. <https://doi.org/10.9785/cr-2015-1205>.
9. Tănase, Alina Doina. *Răspunderea civilă pentru malpraxisul medical*. Bucharest: Universul Juridic, 2024. ISBN 978-606-39-1372-3. <https://www.ujmag.ro/drept/răspunderea-civilă-pentru-malpraxisul-medical>.
10. Wagner, Gerhard. "Verantwortlichkeit im Zeichen digitaler Technologien." *Ver-sicherungsrecht* (2020): 717–41.

II. Legislation and Official Documents

1. European Commission. “Annexes to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Commission Work Programme 2025.” COM(2025) 45 final, February 11, 2025. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0045>.
2. European Commission. “Proposal for a Directive of the European Parliament and of the Council on Adapting Non-contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive).” COM(2022) 496 final, September 28, 2022. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0496>.
3. European Parliament and Council. Directive (EU) 2024/2853 of October 23, 2024, on Liability for Defective Products and Repealing Council Directive 85/374/EEC. *Official Journal of the European Union* L, 2024/2853, November 18, 2024. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024L2853>.
4. European Parliament and Council. Regulation (EU) 2017/745 of April 5, 2017, on Medical Devices. *Official Journal of the European Union* L 117 (May 5, 2017): 1–175. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>.
5. European Parliament and Council Regulation (EU) 2024/1689 of June 13, 2024, Laying Down Harmonised Rules on Artificial Intelligence. Consolidated version, July 27, 2026. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02024R1689-20260727>.
6. Romania. *Codul civil*. Law No. 287/2009, republished, as amended. <https://legislatie.just.ro/Public/DetaliuDocument/175630>.
7. Romania. Law No. 95/2006 on Healthcare Reform, republished, as amended. <https://legislatie.just.ro/Public/DetaliuDocument/71139>.
8. Romania. Law No. 240/2004 on Producer Liability for Damage Caused by Defective Products, republished, as amended. <https://legislatie.just.ro/Public/DetaliuDocument/52850>.
9. Romanian Ministry of Health. “Investiții în sistemele informatice și în infrastructura digitală a unităților sanitare publice.” National Recovery and Resilience Plan, Component 7, Investment I3.3. <https://ms.ro/ro/de-interes/apeluri-pnr-r-c12-sanatate/componenta-7-transformare-digital%C4%83-investitia-specific%C4%83-i33-investi%C8%9Bii-%C3%AEn-sistemele-informactice-%C8%99i-%C3%AEn-infrastructura-digital%C4%83-a-unit%C4%83%C8%9Bilor-sanitare-publice/>.

III. Case Law

1. *Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt—Die Gesundheitskasse and Betriebskrankenkasse RWE*. Joined Cases C-503/13 and C-504/13. ECLI:EU:C:2015:148. Judgment of March 5, 2015. <https://curia.europa.eu/juris/document/document.jsf?docid=162686&doclang=EN>.
2. *Schmitt v. TÜV Rheinland LGA Products GmbH*. Case C-219/15. ECLI:EU:

C:2017:128. Judgment of February 16, 2017. <https://curia.europa.eu/juris/document/document.jsf?docid=187921&doclang=EN>.