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AI AND LIABILITY IN MEDICINE: THE CASE OF ASSISTIVE-DIAGNOSTIC AI

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ABSTRACT

As the prevalence of assistive-diagnostic artificial intelligence (AI) grows, so too will the legal controversies surrounding its use continue to grow. Consequently, determining liability in cases where patients experience harm due to the use of assistive-diagnostic AI in personal healthcare services requires a re-evaluation of existing civil liability regulations. This article proposes a framework for addressing liability in these situations by exploring medical malpractice, organisational negligence by healthcare institutions, and producer liability.

KEYWORDS

Artificial intelligence, civil liability, product liability, medical malpractice, EU.

INTRODUCTION

Artificial intelligence (AI) is swiftly integrating into clinical practices within the European Union (EU).[1] From 2015 through 2020 alone, the European Union approved 224 medical AI tools.[2] More devices are projected to be added over the next five years, as the global AI market in healthcare is expected to grow over 10-fold, from €4.6 billion in 2020 to €41.8 billion in 2026.[3] One of the most prominent AI tools emerging in medical practice, alongside robotic surgeons, is associated with assistive-diagnostic capabilities (assistive-diagnostic AI). These assistive-diagnostic AI technologies are crafted to aid doctors in diagnosis by, for example, recognising indicators of conditions such as cancer[4] or stroke[5] or categorising cancerous lesions in images of the skin,[6] or assessing the likelihood of heart disease.[7]

While the collaboration between assistive-diagnostic AI and humans may improve the identification of potential pathologies,[8] it may also introduce the risk of misdiagnosis due to errors from either the AI or the doctor. Such scenarios raise questions about the liability of doctors or AI producers themselves.[9] The issue of liability in a representative survey of 2020 was ranked amongst the top three barriers to the use of AI by European companies.[10] However, the lack of clarity in determining liability may also pose challenges for victims. In 2019 the New Technologies Formation of the Expert Group of the European Commission expressed the opinion that providing compensation claims for victims in AI-related cases would be more challenging, highlighting the need for a new design in liability regimes.

Addressing these concerns, the European Commission submitted two legislative proposals on September 28, 2022. The first proposal is the Directive on the adaptation of non-contractual liability rules to AI (the AILD proposal). The second is the Directive on liability for defective products (the PLD proposal), which revisits the Product Liability Directive (the PLD).[11] The AILD proposal is not applicable when the final decision is made by a human based on information or advice generated by AI, as mentioned in recital 15 of the AILD proposal. This exclusion implies that the AILD does not cover assistive-diagnostic AI. Additionally, the PLD proposal also comes with specific limitations, indicating that challenges in proving certain aspects of liability will persist.

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1 Eric J. Topol, "High-Performance Medicine: The Convergence of Human and Artificial Intelligence," *Nature Medicine* 25 (2019): 44.

2 U. J Muehlematter, P. Daniore, and K. N. Vokinger, "Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–20): A Comparative Analysis," *The Lancet Digital Health* 3 (2021): 1.

3 D. Talby, "Council Post: The Current State of the Healthcare AI Revolution," *Forbes* (28 April 2021) (accessed 2 February, 2023) // https://www.forbes.com/sites/forbestechcouncil/2021/04/28/the-current-state-of-the-healthcare-ai-revolution/.

4 J. G. Nam et al., "Development and Validation of Deep Learning–Based Automatic Detection Algorithm for Malignant Pulmonary Nodules," *Radiology* 290 (2019): 218.

5 D. Greenfield, "Artificial Intelligence in Medicine: Applications, Implications, and Limitations" (accessed 2 January, 2023) // https://sitn.hms.harvard.edu/flash/2019/artificial-intelligence-in-medicine-applications-implications-and-limitations/.

6 A. Esteva et al., "Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks," *Nature* 542 (2017): 115.

7 Greenfield, *supra* note 5.

8 M. D. Abràmoff et al., "Pivotal Trial of an Autonomous AI-Based Diagnostic System for Detection of Diabetic Retinopathy in Primary Care Offices," npj *Digital Medicine* 1 (2018).

9 W. N. Price, S. Gerke, and I. G. Cohen, "Potential Liability for Physicians Using Artificial Intelligence," *JAMA* 322 (2019): 1765.

10 Ipsos Belgium (research for European Commission), "European enterprise survey on the use of technologies based on artificial intelligence," *Ipsos* (September 28, 2020) (accessed 2 February, 2023) // https://www.ipsos.com/en/european-enterprises-and-ai-technologies.

11 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

These limitations reveal that despite the introduction of the AILD and revisited PLD, there might be difficulties in establishing certain elements of liability. As a result, the proposed legislative frameworks, while addressing certain facets of AI-related liability, may not comprehensively encompass all situations or could present challenges in their practical implementation. Therefore, ongoing discussions and initiatives are required to enhance and adjust legal frameworks for AI liability.

The objective of this article is to examine the legal challenges arising when harm to a patient's health or life occurs during the provision of healthcare services involving a doctor's use of assistive-diagnostic AI. To comprehensively understand the liability landscape, the article provides the following: (1) an overview of the liability framework; (2) a analysis of the liability of healthcare institutions (medical malpractice), putting emphasis on potential scenarios of negligence; and (3) an analysis of product liability, closely examining the concepts of product, design defect, and causation. The article uses Lithuanian, French, and German laws, including EU legislation, as comparative reference points.

1. THE LEGAL FRAMEWORK OF LIABILITY

The introduction of assistive-diagnostic AI will change the dynamics of diagnostic decision-making. Under the new model, the doctor will remain the decision maker with her diagnosis directly affecting the patient. However, assistive-diagnostic AI will influence the decision of the doctor by offering its view on diagnosis and, therefore, impact the patient's outcome indirectly.

This new model, in which assistive-diagnostic AI advises the doctor, does not necessarily mean that the 'second opinion' that the doctor will receive from AI will be accurate; or, even if it is, there is no assurance that the doctors will adhere to it. Therefore, as Table 1 suggests, the harm to the patient may occur not only because of the 'bad' advice of assistive-diagnostic AI, but also because the doctor might fail to listen to the 'good' advice, which turned out to be correct.[12] This article contends that sometimes patients may suffer damage when neither the AI nor the doctor is at fault. Certain errors in diagnosis-making may be attributed to the hospital (further also referenced as healthcare institution) itself, stemming from a failure to fulfil its organisational obligations such as training doctors and supervising medical devices.

Table 1. Damage to the patient in the cases of assistive-diagnostic AI

Scenario	AI	Doctor	Healthcare institution	Patient outcome
1.	Incorrect	Incorrect	N/A	Bad
2.	Correct	Incorrect	N/A	Bad
3.	Incorrect or correct	Incorrect	Failed to fulfil its organisational obligations	Bad

As these three scenarios indicate, a patient can experience harm due to wrongful acts of triple origin: (1) from producers who created flawed AI; (2) from doctors who either overlooked symptoms or misjudged AI recommendations; (3) from the hospital itself. Consequently, these three sources of damage imply the landscape of liability

[12] Policy Department C at the request of the Committee on Legal Affairs "Artificial Intelligence and Civil Liability" (2020) (accessed 10 October, 2022) // https://www.europarl.europa.eu/thinktank/en/document/IPOL_STU(2020)621926.

regimes which are three: (1) medical malpractice, (2) corporate negligence of healthcare institution, and (3) product liability (refer to Table 2). These three liability frameworks will serve as the foundation for the subsequent analysis presented in this article.

Table 2. Overview of liability

Type of liability	Person liable for the damage	
	Healthcare institution	Producer of AI
Vicarious liability of a healthcare institution (medical malpractice)	Doctor's failure to follow the duty of care	Not applied
Corporate negligence of healthcare institution	Poor organisation of the services of the healthcare institution	Not applied
Producer's liability for defective products	Not applied	Producer's failure to provide a proper product

2. RECOVERY OF DAMAGES: PATIENT VS. HEALTCARE INSTITUTION

Under the general framework of a healthcare institution's liability, poor quality of services in a healthcare institution can be attributed to both inadequate provision of services by doctors and (or) poor organisation of the healthcare institution itself.[13] This chapter deals with the vicarious healthcare institution's liability for the medical negligence of the doctor, and corporate negligence of the healthcare institution.

2.1. Medical malpractice: breach of the standard of care

2.1.1. The concept of standard of care

Regardless of whether the assistive-diagnostic AI was used or not, holding the doctor accountable requires the patient to invoke the concept of the standard of care, demonstrating that the doctor has breached his professional duty.[14] The standard of care is a legal obligation imposed on the doctor, requiring the application of proper skill and care in providing services.[15] The precise concept of 'standard of care' differs among legal traditions. However, in the most general sense, two directions of criteria for the standard of care prevail. The standard may be tied to ordinary practice (common law jurisdictions) or be ideal (or normative, objective) (civil law tradition).

The common law tradition's standard of care is based on a 'state of the art' of what is done in practice rather than normative imperatives about what ought to be done in theory.[16] Therefore, a professional is judged by the standard of a reasonably competent specialist in her field, exercising the ordinary skills of her speciality.[17] In order to assess a doctor's performance in a particular case, courts apply a Bolam test. According to it, a doctor will have a defence to a clinical negligence claim if he or she can show

[13] Monika Morkunaite, "Pacientų patirtos žalos atlyginimo problematika" (Vilniaus universiteto leidykla, 2021), 91.
[14] S. B. Bal, "An Introduction to Medical Malpractice in the United States," *Clinical Orthopaedics & Related Research* 467 (2009): 339.
[15] M. Stauch, *The law of medical negligence in England and Germany: A comparative analysis* (Hart, 2008), 30.
[16] B. Hurwitz, *Clinical Guidelines and the Law: Negligence, Discretion, and Judgement* (Radcliffe Medical Press, 1998), 48.
[17] M. Stauch, *The law of medical negligence in England and Germany: A comparative analysis* (Hart, 2008), 31.

that a responsible body of medical opinion would have found the way the doctor acted acceptable.[18] So, even though other doctors, perhaps even most doctors, would not approve of the way the doctor acted, she will not be negligent if she can find doctors that would approve of it.[19]

Meanwhile, in civil law jurisdictions (Lithuania, France, Germany), which is the object of this article, the standard of care is based on normative imperatives, the so-called 'objective standard', on what ought to be done in theory, rather than empirical-customary positions of what is done in practice as it is in the common law. Thus, to define whether a professional acted in line with the standard of care, the court from the medical experts requires evaluating whether the doctor's act was in line with contemporary medical science and practice, usually embodied in clinical guidelines.

In order to define the standard of care in Lithuania, different references are used: descriptions (approved by the health minister and applied universally); protocols (approved by orders of the head of the healthcare institution and binding the staff); and methodologies (drawn up by universities, research institutions, and medical professional associations); other scientific evidence derived from international organisations, literature, which applies by recommendary nature.[20] The situation in France is similar. When experts determine an error of a doctor, they refer to literature sources or recommendations published by *Haute Autorité de Santé* (higher authority of health) and scientific associations.[21] German-speaking countries look at the guidelines that medical and scientific societies have devised, meaning that if the patient suffers harm, a medical expert has the task of analysing whether the diagnostic procedure is following existing guidelines or standard diagnostic procedures.[22]

Although the doctor's duty of care is clearly defined, the same level of clarity does not extend to situations where the doctor's liability is in question due to the use of assistive-diagnostic AI. Some scholars argue that the standard of care should be evaluated in the same way as any other situation where a patient suffers, without special consideration for the use of AI.[23] On the other hand, others argue that the use of artificial intelligence should be considered and may warrant a different or modified standard of care in such instances.[24]

Nevertheless, the stance taken in this article is grounded in the idea that the standard of care is a benchmark derived from authoritative sources such as regulations, scientific publications, medical textbooks, and clinical guidelines. [25] As previously stated, adhering to these standards serves as a protective measure for doctors, shielding them from potential liability, while any deviation from these standards could result in legal consequences.[26] Consequently, if these sources offer guidance on the use of assistive-diagnostic AI, AI is considered an inherent component of the standard of care.

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18 J. Herring, *Medical Law* (Oxford University Press, 2011), 46.
19 *Ibid*.
20 S. D. Ferrara, R. Boscolo-Berto and G. Viel, *Malpractice and Medical Liability European State of the Art and Guidelines* (Springer Berlin, 2015), 122.
21 Morkunaite, *supra* note 13, 194; Ferrara, *supra* note 20, 158.
22 Ferrara, *supra* note 20, 122.
23 G. Maliha et al., "Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation," *The Milbank Quarterly* 99 (2021): 629; M. J. Mehlman, "Medical Practice Guidelines as Malpractice Safe Harbors: Illusion or Deceit?" *Journal of Law, Medicine & Ethics* 40 (2012): 286.
24 A. S. Ahuja, "The Impact of Artificial Intelligence in Medicine on the Future Role of the Physician," *PeerJ* (2019): 7.
25 Ferrara, *supra* note 20, 122.
26 M. Stauch, *The law of medical negligence in England and Germany: A comparative analysis* (Hart 2008), 30.

In cases where such guidance is lacking, the evaluation of a doctor's actions would occur independently of whether AI was used or not.

2.1.2. Situations when assistive-diagnostic AI is part of the standard of care

If assistive-diagnostic AI is integrated into the standard of care, which means that its use is governed by authoritative sources that constitute the medical standard of care, the algorithm for evaluating whether a doctor is at fault should follow this process: first, identifying the duties that modern science or practice imposes on doctors regarding the use of assistive-diagnostic AI; second, assessing whether the doctor has breached those duties and it has caused harm to the patient. In theory, modern science or practice may regulate the question of assistive-diagnostic AI in two ways: by (1) encouraging doctors to choose the diagnosis proposed by assistive-diagnostic AI by presuming its rightfulness, or (2) obliging the doctors to integrate assistive-diagnostic AI into the overall diagnostic process.

In first scenario, when standard-setting sources establish the diagnosis of AI as the standard of care and presume any deviation from it as a breach of care, doctors would not be obligated to adhere to the diagnosis.[27] However, from a liability perspective, rejecting it would be deemed medical malpractice unless the doctor can prove otherwise. This means that, under this model, doctors would be protected from legal liability if they adhere to the diagnosis suggested by AI. Meanwhile, for the patients this model would provide evidence of negligence if the doctor rejects AI's prognosis does not successfully counter this presumption.

However, even if this model would lead to faster and potentially more accurate diagnoses, there is a risk that doctors may blindly rely on AI without critically assessing its recommendations.[28] Therefore, some also argue for the second perspective that the standard of care should shift from adhering to AI's diagnosis to the obligation to use the AI tool itself.[29] This implies that doctors would be encouraged to incorporate assistive-diagnostic AI into their diagnostic practices if they do not want to be held liable for not using it.[30] However, because it cannot be guaranteed that the programming is in the best interest of each unique patient, a doctor wouldn't be considered negligent solely for not following the AI's prediction.[31]

2.1.3. Situations when using assistive-diagnostic AI is not part of the standard of care

In situations where the use of assistive-diagnostic AI is not regulated by the standard of care or there is no incentives to adhere to the recommendations of AI, the general rule is that the evaluation of a doctor's professional duties is conducted in the same manner as in conventional cases, irrespective of assistive-diagnostic AI's prognosis.[32] In such cases, the assessment of a doctor's malpractice would be conducted by addressing whether the doctor's diagnosis aligns with the standard of care (regardless of the assistive-diagnostic AI's diagnosis) and, if not, whether it resulted in harm to the patient.

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27 Price, *supra* note 9.
28 *Ibid.*, 59.
29 M. S. Ridgely and M. D. Greenberg, "Too Many Alerts, Too Much Liability," *RAND Corporation* (1 June 2012) (accessed 2 February, 2023) // https://www.rand.org/pubs/external_publications/EP201200144.html.
30 Sharona Hoffman and Andy Podgurski, "E-Health Hazards: Provider Liability and Electronic Health Record Systems," 24 *BERKELEY TECH*. LJ (2009): 1523, 1528.
31 Ridgely, *supra* note 29.
32 R. A. Miller and S. M. Miller, "Legal and Regulatory Issues Related to the Use of Clinical Software in Health Care Delivery," *Clinical Decision Support* (2007): 423, 420.

As illustrated in Table 3, there are four possible legal outcomes for doctors whose patients experience harm when assistive-diagnostic AI is employed. The patients might suffer damage when the doctor either: rejects the correct diagnosis of assistive-diagnostic AI (No 1 and 3 of Table 3) or follows an incorrect diagnosis of AI (No 2 and 4 of Table 3). However, doctors are only held liable if they breach the standard of care (red cases, No 1 and 4 of Table 3), meaning that doctors are not granted additional favour by the liability system solely because the diagnosis of AI was incorrect, and they followed it (Case No 4 in Table 3). If doctors follow the standard of care, they are shielded from liability (yellow cases, No 2 and 3 of Table 3). This protection remains intact even if the AI surpasses the standard of care, providing a more accurate diagnosis and the doctor does not rely on it (as illustrated in Case No 3 in Table 3).[33]

Table 3. Examples of potential legal outcomes related to AI use in clinical practice for doctors

No	AI recommendation	AI accuracy	Doctor action	Patient outcome	Legal outcome (probable) for the doctor
1.	Standard of care	Correct	Rejects	Bad	Injury and liability
2.		Incorrect	Follows	Bad	Injury but no liability
3.	Nonstandard care	Correct	Rejects	Bad	Injury but no liability
4.		Incorrect	Follows	Bad	Injury and liability

Source: modified chart of Price et al.[34]

These results suggest that, regardless of the accuracy or inaccuracy of the AI diagnosis, doctors are held liable only when they deviate from the standard of care. Whether this result is deemed satisfactory depends on the perspective. On one hand, the current view reinforces the principle that doctors are primarily accountable for adhering to established standards, providing a degree of consistency and predictability in legal outcomes. On the other hand, some may argue that the liability system should consider the accuracy of AI diagnoses as a significant factor in determining physician culpability. This could be particularly relevant in situations where AI outperforms the standard of care, raising questions about the adaptability of legal frameworks to advancements in technology.

2.2. Corporate negligence of healthcare institution

The quality of medical services is influenced not only by the efforts of doctors but also by healthcare institutions themselves, which bear certain organisational responsibilities toward their patients.[35] Consequently, if a patient experiences harm due to the delivery of healthcare services involving the use of assistive-diagnostic AI,[36] one conceivable factor contributing to this negligence might be the negligence of the healthcare institution itself.[37]

While this article doesn't attempt to cover all potential scenarios where a healthcare institution might neglect its responsibilities, leading to patient suffering, such obligations – potentially related to medical devices in general – could be outlined by national laws or rooted in the duty of care principle. Additionally, in the future, these

[33] *Ibid*.
[34] Price, *supra* note 9.
[35] E. g. *Thompson v. Nason Hosp*., 591 A.2d 703, 707 (Pa. 1991).
[36] Ridgely, *supra* note 29.
[37] E. g. *Thompson v. Nason Hosp*., 591 A.2d 703, 707 (Pa. 1991).

obligations might be explicitly detailed in the AI Act, which is anticipated to regulate high-risk users of AI, including medical devices.

One plausible obligation could involve the duty to ensure that human oversight of AI is entrusted to individuals possessing the requisite competence, training, and authority to use it [38] (Article 29(1a) of the AI Act). This obligation might be breached if hospitals fail to train their staff[39] (for example, educate how to override erroneous recommendations)[40] since AI-based medical devices, like assistive-diagnostic AI, are novel, and not all doctors are familiar with its usage or may be fully aware of its associated risks.[41]

Another example of organisational negligence may revolve around the obligation to employ safe equipment. In fact, the argument of unsafe equipment was already used in *Young v. Hartford Hosp* case.[42] The plaintiff argued that the hospital acted unlawfully by allowing the use of faulty AI robotic equipment to assist in a surgical procedure, failed to inspect the robotic equipment before use, and failed to properly secure the camera to prevent it from falling on patients.[43] While this argument did not succeed in court, it underscores the importance of healthcare institutions using only safe AI devices.

These examples underscore that organisational negligence may become a crucial consideration for claimants seeking legal recourse, especially when damages cannot be solely attributed to factors like medical negligence. At the same time, the argument that the healthcare body is at fault can also become a defence for producers of AI or doctors themselves if the healthcare body decides to reverse the claim against them.

3. RECOVERY OF DAMAGES: CONSUMER VS. PRODUCER

Where a defective product causes damage, the product's producer is liable for damages on product liability grounds. Therefore, it is not only the healthcare institutions that may be held liable if patients suffer damage during the provision of healthcare services but also the producer.

Product liability in the EU is ruled by the Product Liability Directive (PLD). However, in 2022, the European Commission introduced the revision of the PLD – the PLD proposal. Although the PLD proposal has not been adopted and is therefore irrelevant to the application of the law, this part of the article will not depart from it. According to the PLD (and to the PLD proposal), the consumer would be compensated when she proves the three conditions for liability: the damage, defective product, and the causal link between the defective product and the damage.

This part of the article discusses the producers' liability for defective assistive-diagnostic AI, first by arguing why assistive-diagnostic AI is a product, and then by examining two conditions of liability: the product's defectiveness, and causation, i.e. answering if there is a causal link between a defective product and damage to the patient if the doctor (and not an AI) makes the diagnostic decision.

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38 F. Griffin, "Artificial Intelligence and Liability," *Health Care Health Matrix* 31 (2021): 101.
39 S. Sandeep Mangalmurti et al., "Medical Malpractice Liability in the Age of Electronic Health Records," *New Eng. J. Med*. 363 (2010): 2060, 2063, 2065.
40 R. A. Miller and S. M. Miller, "Legal and Regulatory Issues Related to the Use of Clinical Software in Health Care Delivery," *Clinical Decision Support* (2007): 423, 420.
41 Sandeep Mangalmurt et al., *supra* note 38.
42 *Thompson v. Nason Hosp*.
43 *Ibid*.

3.1. Assistive-diagnostic AI software as a product

Liability of the producer under the product liability regime arises if the defective product causes damage to the consumer. The PLD proposal, which revisits PLD, explicitly includes software in the category of products (Article 4(1)). Nevertheless, there is an ongoing debate about whether software should be considered a product under the current wording of PLD. To answer it, we first need to define (1) what a product is, and (2) if assistive-diagnostic AI, which is in the essence standalone software, falls under this concept.

According to PLD, a product is movable.[44] In other words, it is something capable of being moved and is the opposite of being immoved, i.e. distinct from land or buildings. The PLD does not specify whether the movables must be tangible or not. For this reason, the question of how to qualify software under PLD is unresolved in European jurisdictions.[45] The central questions in this debate revolve around whether intangible standalone software, like assistive-diagnostic AI, released to the market without a physical medium, can be classified as a product,[46] and if not, whether standalone software should be categorised as a service instead.

Authors who argue against qualifying standalone software as a product typically base their reasoning on the requirement in the PLD for products to be tangible.[47] Since the PLD explicitly mentions only one intangible object, namely electricity, some authors contend that other unmentioned intangibles should be excluded from the scope of the directive.[48] Following this line of reasoning, these authors argue that standalone software should be classified as information, placing it within the realm of a service rather than a product. They draw parallels with the *Krone* case from the Court of Justice of the European Union (CJEU) involving a newspaper article that contained false medical advice and caused harm. The court in this case made a clear distinction between the advice and the physical medium (newspaper) through which it was delivered. It was concluded that while the newspaper could be considered a product, it played no role in the harm caused, and the advice, being a service, fell outside the scope of the PLD.[49] Applying a similar rationale, authors argue that software-based AI, being akin to information provision, should be treated as a service rather than a product under the PLD.[50]

Nevertheless, the author maintains that standalone software should be qualified as a product. Under the PLD, products are 'movables', and, according to literature, movables can be both tangible and not.[51] Therefore, as long as the PLD does not explicitly state that intangibles are excluded from the directive, intangibles such as software

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44 Article 2 of the PLD 'For this Directive 'product' means all movables, except for primary agricultural products and game, even though incorporated into another movable or into an immovable. 'Primary agricultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. 'Product' includes electricity.'

45 P. MacHnikowski, "Conclusions": 700–701; in P. Machnokowski, ed., *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies*.

46 T. E. Synodinu et al., "Product Liability and Digital Products": 186; in T. E. Synodinu et al., *EU internet law: Regulation and enforcement* (Springer Nature, 2017).

47 V. Ulfbeck, "Autonomous Ships and Product Liability under the EU Directive," *Autonomous Ships and the Law* (2020): 144.

48 Precise quotation "Directive mentions electricity explicitly as falling under the concept of "product". It is unclear what implications could be drawn from this: does it mean that a product need not be a tangible object after all, or does the explicit mention of electricity mean that not-mentioned intangibles are excluded from the product liability directive?" at M. Schellekens, "Human-machine interaction in self-driving vehicles: a perspective on product liability," *International Journal of Law and Information Technology* Vol. 30, Issue 2 (2022): 233–248 // https://doi.org/10.1093/ijlit/eaac010.

49 *KRONE – Verlag*, European Court of Justice (2021, No. C-65/20), paras 36–37.

50 Ulfbeck, *supra* note 47.

51 J. H. Dalhuisen, *Dalhuisen on Transnational Comparative, Commercial, Financial and Trade Law* (Hart Publishing 2019), 339–40.

should be covered by the PLD.[52] Even if the above-mentioned *Krone* case qualifies the provision of advice via a medium (the newspaper) as a service, the same cannot be said about AI software. Software is a separate functioning entity that generates unique advice each time and is being used as a traditional good to achieve the specific purpose for which it was created (i.e. advice to doctors).[53] Therefore, assistive-diagnostic AI is more product-like in substance. Furthermore, compelling case law, such as the CJEU's decision in *UsedSoft v. Oracle*, supports the notion that software is a product. In this case, the court settled that downloading software over the internet is the same as buying a physical material copy. Consequently, if the software which is integrated into the hardware is treated the same as standalone software, why should there be a liability for software supplied with hardware but no liability for standalone software?[54]

Nevertheless, an alternative perspective supports the idea that standalone software may fulfil the tangibility requirement. It might be argued that even if a product is to be of tangible nature, the standalone software would fulfil the tangibility requirement.[55] Tangibility would be satisfied because of either the fact that software is stored on a tangible computer server at the time of its transfer even though it is not sold in the hardware; and (or) software is only functional when installed on another tangible device; therefore, without a concrete object, such as a computer, the software would not be able to function by itself.[56]

3.2. Defect in assistive-diagnostic AI

Producers are liable for injuries only if they are caused by a defective product, which can be flawed due to production, design, or marketing defects.[57] However, not all defect types may be applicable in cases involving injuries caused by assistive-diagnostic AI software. For instance, *defects in production* occur if a product possesses unique differences from others in the same category.[58] AI software is less likely to exhibit unique differences as an intangible product that can be more easily and accurately replicated than tangible products. Information defects, such as improper labelling, vague instructions, or safety warnings, will not be relevant either, given that consumers lack a contractual relationship with the producer, making it challenging to provide instructions about risks. While issues related to production and marketing defects may not be relevant, design defects, which occur when a product meets producer requirements but doesn't meet consumer expectations, remain crucial.[59] The predominant flaws in assistive-diagnostic AI are likely to arise from design-related factors, such as inadequately programmed systems that may fail to recognize cancer cells or lack sufficient data for specific demographics. Therefore, the focus will be on a more in-depth exploration of design defects.

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52 *Ibid*.
53 E. Van Gool, "Case C-65/20 Krone: Offering (Some) Clarity Relating to Product Liability, Information and Software," *European law blog* (19 January 2022) (accessed 2 February, 2023) // https://europeanlawblog.eu/2022/01/19/case-c-65-20-krone-offering-some-clarity-relating-to-product-liability-information-and-software/.
54 P. Machnikowski, *"Austria" in BA Koch European product liability analysis of state of the art in the era of New Technologies* (Intersentia, 2016), 111.
55 J. Tilson, "Can You Have Software without Hardware?" *AlphaFirst* (13 October 2020) (accessed 2 February, 2023) // https://alphafirst.net/questions/can-you-have-software-without-hardware/.
56 *Ibid*.
57 C. C. Van Dam, *European Tort Law* (Oxford University Press, 2013), 1408-1.
58 S. H. Brown and R. A. Miller, *supra* note 40.
59 G. W. Conk, "Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?" *The Yale Law Journal* 109 (2000): 1087, 1091–101.

3.2.1. Design defects

A product is considered to be defective "when it does not provide the safety which a person is entitled to expect, taking all circumstances into account."[60] This implies that the key factor in distinguishing between good and bad product design is consumer expectations. But how should we measure consumer expectations in the context of assistive-diagnostic AI?

The initial answer to this question is outlined in Article 6 of the PLD, which specifies that defectiveness is evaluated by considering three circumstances: (1) the presentation of the product; (2) the reasonably anticipated use of the product; and (3) the time when the product entered circulation.[61] The PLD proposal attempts to add a few more circumstances: (4) the effect on the product of other products that can reasonably be expected to be used together with the product; (5) the moment in time when the product was placed on the market or put into service or, where the producer retains control over the product after that moment, the moment in time when the product left the control of the producer; (6) product safety, including cybersecurity requirements; (7) intervention regulatory authority; and, (8) expectations of end-users.

However, in principle, neither the PLD nor the PLD proposal provides an explicit algorithm for detecting a design defect.[62] Instead, we must turn to the practices of Member States, where the primary criterion for evaluating the defectiveness of a design is its alignment with the state of scientific and technical knowledge, commonly referred to as the state of the art test. [63] According to this test, producers are absolved of liability if the state of scientific and technical knowledge does not facilitate the identification of the defect. Importantly, this exemption does not mean that the producer would evade liability if a superior assistive-diagnostic AI existed at its release (Article 6(2)). However, if enhanced scientific and technical knowledge could have enabled producers to create a superior product, escaping liability might not be straightforward.

The state of the art test introduces additional questions regarding the identification of a design defect – what constitutes such a defect, how to apply the test, and notably, the reference point for this assessment – the moment when the product entered the market. The latter becomes particularly intricate in the context of the evolving nature of AI through updates, upgrades, or adaptations facilitated by machine learning. Subsequent paragraphs will delve into an analysis of these questions

3.2.2. The moment when product is put into market defence

Under Article 7(e) of the PLD, the conformity of a product with the state of scientific and technical knowledge is assessed from the moment the product is placed on the market, i.e. the moment when the producer no longer controls the product as it is passed to the market (*Declan O'Byrne v. Sanofi Pasteur MSD Ltd*).[64] The producer is exempted

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60 D. Rimkute and K. Povylius, "Civil and Criminal Liability for Damage Caused by Self–Driving Cars," *Vilnius University Open Series* (2021): 182.

61 Van Dam, *supra* note 57, 1408-1.

62 P. Hacker, "Review of The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for the Future," *Working document* (2022): 21.

63 P. Behrendt and H. Moelle, "Product Liability – 5 Particularities in Germany," *Taylor Wessing* (28 January 2020) (accessed 3 February, 2023) // https://www.taylorwessing.com/de/insights-and-events/insights/2018/10/product-liability-5-particularities-in-germany; "Country Comparative Guides: France: Product Liability," *Country Comparative Guides | The Legal 500* (accessed 3 February, 2023) // https://www.legal500.com/guides/chapter/france-product-liability/.

64 *Declan O'Byrne v. Sanofi Pasteur MSD Ltd* [2006], para 27.

from liability if the defect occurs after the product has been placed on the market (Article 7(b)).

Traditionally products do not change once they appear on the market. However, it is not the case for AI because, after its release, the product may be updated, upgraded, or adapted because of machine learning. Therefore, the producer of assistive-diagnostic AI will retain a certain amount of control over the product or its parts.[65] As a result, assessing product quality may not be solely tied to the product's placement on the market, especially when the producer retains control.

The revisited PLD proposal aligns with this perspective, suggesting that product quality assessment should extend beyond the moment of placing the product on the market. According to the revisited PLD proposal, product quality assessment should not be limited to the moment the product is placed on the market. The producer could be held liable for defects in the product even after the product has been placed on the market if the defects are caused by software or related services under the producer's control (Article 10(1), recital 37 of the PLD proposal).

However, certain unresolved issues persist, especially regarding how to judge producers who control a product after it has entered the market. There are two main scenarios to consider:

(1) *Judging from the Moment of Damage*. Under this scenario, the producer would be judged from the moment when the damage occurred. This approach would assume that the producer retained control of the product and shall be held accountable based on the circumstances at the time of the damage.

(2) *Judging from the Moment of Change (Update or Machine Learning).* Alternatively, judging from the moment when the product has changed, either through an update or new machine learning, might be considered. This approach explores the possibility of holding the producer accountable based on the conditions existing at the time of the product's alteration.[66]

Depending on which interpretation of the PLD is chosen, the results of producer liability may vary. If, under the first scenario, a producer would be judged according to the state of the art at the time of the damage, the standard for evaluating the product would be stricter since the software, developed in the past, would be evaluated against a more recent state of knowledge. Conversely, the second scenario would result in a more lenient interpretation of the PLD.

This article proposes that a more reasonable approach would be to embrace the second interpretation, assessing the product component that caused damage from the moment that component was updated. Holding a producer accountable for the state of the art at the time of damage might be impractical or unfair, especially in the context of rapidly advancing technologies like artificial intelligence. Furthermore, such an approach could discourage producers from retaining necessary control over the product. Therefore, the suggestion to adopt the second interpretation might better balance the different interests.

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[65] J. Turner, *Robot Rules* (Cham: Palgrave Macmillan, 2019), 98.

[66] For example, the question arises if the damage would be caused not by the component of updated software but by a defect in the older software; the quality of the product may be evaluated based on the state of the art at the time of the release of either (1) the older software; (2) or newer (that was updated).

3.2.3. The state of the art defence

The state of scientific and technical knowledge is a somewhat problematic concept. It raises the issue of whether it is (1) objective, i.e. refers to a state of knowledge, or (2) subjective, i.e. refers to the knowledge or the ability (capacity) to acquire knowledge of a particular person or class of persons.[67] The CJEU, in its judgement *Commission v United Kingdom,* has decided to resolve this issue by clarifying that state of the art is an objective standard, i.e. that is not what the producer subjectively was or could have been informed, but the objective state of the knowledge of which the producer is presumed to have been informed.[68] This interpretation of the PLD shall prevail in the future as it might be codified by the revisited PLD proposal (Article 10(1e)).

This objective standard of the state of scientific and technical knowledge is limited by another criterion introduced by the CJEU: discoverability. According to the CJEU, discoverability implies accessibility of the 'state of the knowledge' (para 26).[69] The CJEU, in *Commission v United Kingdom* decision, has not explained what the word 'accessible' means. However, some authors suggest that information shall be accessible when it can be found on the internet with the help of search engines or found in international scientific journals.[70] Meanwhile, accessibility may be doubtful if the knowledge has only been published in a journal disseminated in one country and not written in a primary language.[71]

The next question is how this state of the art test would work. As shown in Table 4, there might be four possible legal outcomes when assistive-diagnostic AI would be used, and damage to patients were to arise. Table 4 shows that state of the art test works as producer defence (second column). If the producer of assistive-diagnostic AI complies with the state of the art (meaning they are up to date with the current accepted knowledge and practices in the field), and despite this compliance, a patient suffers due to AI misdiagnosis, the producer might escape liability (yellow boxes, No. 1-3). In contrast, if the producer fails to comply with the state of the art, and this failure results in patient harm (damage), the producer is more likely to be held liable (red box, No. 4). This scenario suggests that if the technology is not developed or applied in accordance with the accepted standards and it leads to harm, the producer could be held responsible.

Table 4. Examples of potential legal outcomes related to AI use in clinical practice for producers

No	AI design	AI accuracy	Doctor action	Patient outcome	The potential legal outcome for the producer
1.	Complies with the current state of scientific and technical knowledge	Correct	Rejects	Bad	Injury but no liability
2.		Incorrect	Follows	Bad	Injury but no liability
3.	Fails to comply with the state of scientific and technical knowledge	Correct	Rejects	Bad	Injury but no liability
4.		Incorrect	Follows	Bad	Injury and liability

[67] D. Fairgrieve, *Product Liability in Comparative Perspective* (Cambridge University Press, 2005), 174.
[68] *Commission v United Kingdom*, European Court of Justice (1997, No. C-300/95), para 27.
[69] *Ibid*.
[70] Van Dam, *supra* note 57, 1010-2.
[71] *Ibid*.

3.3. Causation

Patient harm could arise from multiple factors: the doctor's medical negligence leading to misdiagnosis and a flawed design of assistive-diagnostic AI, potentially influencing the doctor to make incorrect diagnoses. This means that the doctor's decision would directly cause damage to the patient, but assistive-diagnostic AI would increase the probability of a doctor's misdiagnosis. Therefore, the question of this subsection is whether producer can be held liable if it only increases the probability for doctor's misdiagnosis, which ultimately causes damage to the patient. To investigate whether causation under these circumstances may be established, producers must pass a two-stage test typical to most jurisdictions: establish factual causation and legal causation.

3.3.1. Factual causation

Factual causation is assessed under the "conditio sine qua non" test.[72] This test means a condition without which the damage would not have occurred.[73] The critical question of 'conditio sine qua non' is whether the damage would also have occurred if the tort-feasor had not acted as he did.[74] If the answer is negative, the requirement of causation is met.[75] However, it can be challenging to give a clear-cut answer to the question. For example, the question if non-defective assistive-diagnostic AI would have prevented the doctor's misdiagnosis cannot be answered ambiguously. Until the standard of medical care does not evolve, doctors are not legally bound to follow the standard. Therefore, even if assistive-diagnostic AI provides correct advice, it does not mean that damage would not arise due to the doctor's misdiagnosis.

When it is impossible to give a clear-cut answer to the question of whether the damage would have occurred without the unlawful act, other tests in addition to 'conditio sine qua non' are applied, especially when multiple tortfeasors are involved. Under these tests, the courts usually ask whether the defendant's negligence mattered in the light of intervening factors. For example, whether causation was certain and direct – for the French.[76] For Germans, causation should matter when it is effectively certain.[77] Lithuanians view factual causation flexibly.[78]

Consequently, if it were asked whether assistive-diagnostic AI diagnosis mattered, the answer would most likely be positive. For instance, if assistive-diagnostic AI suggests a diagnosis different from that of the doctor, the doctor would likely conduct additional tests on the patient. Conversely, if the AI provides an incorrect diagnosis, this could lead the doctor to make a misdiagnosis. Therefore, a faulty assistive-diagnostic AI is more likely to play a role in causing harm by influencing the information presented regarding a patient's diagnosis.

3.3.2. Legal causation

The problem with factual causation is that it accepts many circumstances as possible causes regardless of whether they are legally relevant.[79] For these reasons, jurisdictions

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72 This test is usually known as the "but for" test in the Anglo-American systems.
73 Van Dam, *supra* note 57, 1107-1.
74 M. Moore, "Causation in the Law," *Stanford Encyclopedia of Philosophy* (accessed 2 February, 2023) // https://ramsey.stanford.edu/entries/causation-law/.
75 Van Dam, *supra* note 57, 1107-1.
76 W. Lucy and S. Green, *Causation in Negligence* (Oxford: Hart Publishing, 2015), 188.
77 Van Dam, *supra* note 57, 307–345.
78 Morkunaite, *supra* note 13, 262.
79 Van Dam, *supra* note 57, 1102, 1111.

introduce the second step of causation – legal causation – which aims to limit the factual causation to the legally relevant.

In Lithuania, the most adaptable approach to legally relevant causes is observed. Lithuanian courts acknowledge a theory of causal flexibility, encompassing all theories of legal causation. The Supreme Court of Lithuania recognises indirect causation, i.e. when the person's actions do not directly cause the damage but create the conditions for the damage to occur or increase.[80] Therefore, under Lithuanian laws, producers of defective assistive-diagnostic AI, which may increase the probability of damage if errors, might be held liable.

Meanwhile, the French Civil Code refers to the 'direct and immediate' consequences of the proximity theory.[81] However, delineating between direct and indirect causes, as well as between certain and uncertain causes, has proven challenging. In practice, the 'directness' requirement, as applied by the courts, seldom imposes inherent restrictions on the scope of liability and often offers generous conclusions.[82] Therefore, concerning producer liability, the French requirement for causation to be 'direct' does not necessarily imply that the producer would evade liability

Like Lithuanians, Germans also employ more than one theory of causation. One of the prominent theories is the theory of adequacy, which has seen various interpretations since its development in the nineteenth century.[83] Some authors emphasize the reasonable foreseeability of damage, others focus on whether the cause was adequate to produce the damage, and some consider the increased likelihood of damage occurring. In any interpretation, the element of probability assumes a significant role.[84] Therefore, under this theory, the pivotal question would be whether a producer's defective AI increases the probability of damage. Given that AI does, in fact, heighten the probability, legal causation may be established

In addition, it shall be mentioned that both Lithuania, Germany, and France apply the 'interruption of the chain of causation' theory, according to which an intervening event is a factor 'breaking the chain of causation', that is, making the defendant's act appear no longer relevant in causal terms.[85] Some believe that AI's autonomy ability may break the chain of wrongdoing between the producer's tortious action and consumers' injuries.[86] However, this article disagrees with such a position. Even if AI can act autonomously, the quality of how AI acts in an 'autonomous way' remains in the hands of the producer. For example, if AI harms it might do so because its producers failed to ensure adequate data coverage and quality,[87] also considering that not all diseases or forms of diseases may be generalisable in quantity or attributes.[88] Producers may also fail to ensure sufficient data diversity. Thus, if a producer trains AI with a non-diverse, one-sided, and therefore biased dataset, this bias could be reflected in the models generated by machine learning for AI.[89]

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80 3K-7-144/2014, Supreme Court of Lithuania (2014, No. 3K-7-144/2014).
81 Van Dam, *supra* note 57, 307–345.
82 *Ibid.*
83 *Ibid.*
84 *Ibid.*
85 *Ibid.*
86 P. Huberman, "Tort Law, Corrective Justice and the Problem of Autonomous-Machine-Caused Harm," *Canadian Journal of Law & Jurisprudence* 105 (2020): 5.
87 F. Molnár-Gábor, "Artificial Intelligence in Healthcare: Doctors, Patients and Liabilities," *Regulating Artificial Intelligence* 337 (2019): 80.
88 S. Aftergood, "Jason: Artificial Intelligence for Health Care," *Federation Of American Scientists* (1 January 2018) (accessed 2 February, 2023) // https://fas.org/blogs/secrecy/2018/02/ai-health-care/.
89 R. Challen et al., "Artificial Intelligence, Bias and Clinical Safety" 28 *BMJ Quality & Safety* (2019): 231.

CONCLUSIONS

Artificial intelligence changes the dynamics of diagnostic decision-making; bringing a new actor – assistive-diagnostic AI – into the decision-making, creating new situations of negligence that may result in patient harm. Despite technological progress, tort law is expected to continue serving as a mechanism for providing redress to patients impacted by incidents involving assistive-diagnostic AI. However, it is crucial to acknowledge that this shift may also bring forth new challenges.

In the context of healthcare institutions, particularly hospitals, there are challenges from the medical side of assistive-diagnostic AI. This entails hospitals taking on additional responsibilities, including staff training and device maintenance. Regarding doctors, the presence of assistive-diagnostic AI prompts inquiries into how to determine whether a doctor acted negligently. The evaluation of medical negligence draws upon established sources that delineate the standard of care, such as protocols and literature. Consequently, the resolution of disputes hinges on whether the oversight of assistive-diagnostic AI aligns with the standards set by these established sources of care.

The introduction of assistive-diagnostic AI further complicates matters within the realm of product liability, posing questions about whether it can be classified as a product. If so, it is crucial to determine whether it was defective or the cause of damage, given that the ultimate decision lies with the doctor and not the AI. This article contends that assistive-diagnostic AI should be deemed a product, and the assessment of its quality should be conducted through a state of the art test. Even though the final decision rests with the doctor, the influence of assistive-diagnostic AI on the decision-making process and its potential contribution to patient harm leads to the conclusion that assistive AI satisfies the condition of causation.

BIBLIOGRAPHY

1. Abràmoff, M. D. et al. "Pivotal Trial of an Autonomous AI-Based Diagnostic System for Detection of Diabetic Retinopathy in Primary Care Offices." *npj Digital Medicine* 1 (2018).
2. Aftergood. S. "Jason: Artificial Intelligence for Health Care." *Federation of American Scientists* (1 January 2018) (accessed 2 February, 2023) // https://fas.org/blogs/secrecy/2018/02/ai-health-care/.
3. Ahuja, A. S. "The Impact of Artificial Intelligence in Medicine on the Future Role of the Physician." *PeerJ*. 7 (2019).
4. Bal, S. B. "An Introduction to Medical Malpractice in the United States." *Clinical Orthopaedics & Related Research* 467 (2009).
5. Behrendt, P. and Moelle, H. "Product Liability – 5 Particularities in Germany." Taylor Wessing (28 January 2020) (accessed February, 2023) // https://www.taylorwessing.com/de/insights-and-events/insights/2018/10/product-liability-5-particularities-in-germany; "Country Comparative Guides: France: Product Liability." *Country Comparative Guides | The Legal 500* (accessed 3 February, 2023) // https://www.legal500.com/guides/chapter/france-product-liability/.
6. Challen, R. et al. "Artificial Intelligence, Bias and Clinical Safety." *BMJ Quality & Safety* 28 (2019).

7. Esteva, A. et al. "Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks." *Nature* 542 (2017).
8. Fairgrieve, D. *Product Liability in Comparative Perspective* (Cambridge University Press, 2005).
9. Ferrara, S. D., Boscolo-Berto, R. and Viel, G. *Malpractice and Medical Liability European State of the Art and Guidelines* (Springer Berlin, 2015).
10. Greenfield, D. "Artificial Intelligence in Medicine: Applications, Implications, and Limitations." (Accessed 2 January, 2023) // https://sitn.hms.harvard.edu/flash/2019/artificial-intelligence-in-medicine-applications-implications-and-limitations/.
11. Griffin, F. "Artificial Intelligence and Liability." *Health Care Health Matrix* 31 (2021).
12. Hacker, P. "Review of The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for the Future." *Working document* (2022).
13. Herring, J. *Medical Law* (Oxford University Press, 2011).
14. Hoffman, Sharona anf Podgurski, Andy. "E-Health Hazards: Provider Liability and Electronic Health Record Systems." *Berkeley Tech. LJ* 24 (2009): 1523, 1528.
15. Hurwitz, B. *Clinical Guidelines, and the Law: Negligence, Discretion, and Judgment* (Radcliffe Medical Press, 1998).
16. Ipsos Belgium (research for European Commission). "European enterprise survey on the use of technologies based on artificial intelligence." *Ipsos* (28 September 2020) (accessed 2 February, 2023) // https://www.ipsos.com/en/european-enterprises-and-ai-technologies.
17. MacHnikowski, P. *"Austria" in Koch BA, European product liability analysis of the state of the art in the era of New Technologies* (Intersentia, 2016).
18. Maliha, G. et al. "Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation." *The Milbank Quarterly* 99 (2021): 629.
19. Mehlman, M. J. "Medical Practice Guidelines as Malpractice Safe Harbors: Illusion or Deceit?" *Journal of Law, Medicine & Ethics* 40 (2012).
20. Miller, R. A. and Miller, S. M. "Legal and Regulatory Issues Related to the Use of Clinical Software in Health Care Delivery." *Clinical Decision Support* (2007).
21. Morkunaite, M. *Pacientų patirtos žalos atlyginimo problematika* (Vilniaus universiteto leidykla, 2021).
22. Moore, M. "Causation in the Law." *Stanford Encyclopedia of Philosophy* (accessed 2 February, 2023) // https://ramsey.stanford.edu/entries/causation-law/.
23. Muehlematter, U. J., Daniore, P., and Vokinger, K. N. "Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–20): A Comparative Analysis." *The Lancet Digital Health* 3 (2021).
24. Nam, J. G. et al. "Development and Validation of Deep Learning–Based Automatic Detection Algorithm for Malignant Pulmonary Nodules on Chest Radiographs." *Radiology* 290 (2019).
25. *Policy Department C at the request of the Committee on Legal Affairs*. "Artificial Intelligence and Civil Liability" (2020) (accessed 10 October, 2022) // https://www.europarl.europa.eu/thinktank/en/document/IPOL_STU(2020)621926.
26. Price, W. N., Gerke, S., and Cohen, I. G. "Potential Liability for Physicians Using Artificial Intelligence." *JAMA* 322 (2019).
27. Ridgely, M. S. and Greenberg, M. D. "Too Many Alerts, Too Much Liability." RAND Corporation (1 June 2012) (accessed 2 February, 2023) // https://www.rand.org/pubs/external_publications/EP201200144.html.

28. Rimkute, D. and Povylius, K. "Civil and Criminal Liability for Damage Caused by Self–Driving Cars." *Vilnius University Open Series* (2021).
29. Stauch, M. *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart, 2008).
30. Synodinu, T. E, et al. "Product Liability and Digital Products." In: *Synodinu T-E and others EU internet law: Regulation and enforcement* (Springer Nature, 2017).
31. Talby, D. "Council Post: The Current State of the Healthcare AI Revolution." *Forbes* (28 April 2021) (accessed 2 February, 2023) // https://www.forbes.com/sites/forbestechcouncil/2021/04/28/the-current-state-of-the-healthcare-ai-revolution/.
32. Tilson, J. "Can You Have Software without Hardware?" *AlphaFirst* (13 October 2020) (accessed 2 February, 2023) // https://alphafirst.net/questions/can-you-have-software-without-hardware/.
33. Topol, E. J. "High-Performance Medicine: The Convergence of Human and Artificial Intelligence" *Nature Medicine* 25, (2019).
34. Turner, J. *Robot Rules* (Cham: Palgrave Macmillan, 2019).
35. Ulfbeck, V. "Autonomous Ships and Product Liability under the EU Directive." *Autonomous Ships and the Law* (2020).
36. Van Dam, C. C. *European Tort Law* (Oxford University Press, 2013).
37. Van Gool, E. "Case C-65/20 Krone: Offering (Some) Clarity Relating to Product Liability, Information and Software." *European Law Blog* (19 January 2022) // https://europeanlawblog.eu/2022/01/19/case-c-65-20-krone-offering-some-clarity-relating-to-product-liability-information-and-software/.

LEGAL REFERENCES

1. *Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.*
2. *Supreme Court of UK*. 1957, case No. 2 All ER 267, Bolam v. Friern HMC,
3. *European Court of Justice*. 2006, case No. C-127/04, Declan O'Byrne v. Sanofi Pasteur MSD Ltd.
4. *European Court of Justice*. 2020, case No. C-65/20, KRONE – Verlag.
5. *European Court of Justice*. 1995, case No. C-300/95, 1995, Commission v United Kingdom.
6. *Supreme Court of Lithuania decision*. 2014, case No. 3K-7-144/2014.