

Fault-Based Liability for Medical Malpractice in the Age of Artificial Intelligence: A Comparative Analysis of German and Greek Medical Liability Law in View of the Challenges Posed by AI Systems

Vasileios P. Maroudas

PhD Candidate, H.F.R.I. fellow, Faculty of Law, Aristotle University of Thessaloniki; correspondence address: 64, Panepistimiou Str., 10677 Athens, Greece; e-mail: vpmaroud@law.auth.gr

 <https://orcid.org/0009-0007-4039-8083>

Keywords:

medical liability,
autonomous systems,
fault principle,
burden of proof,
liability for presumed
fault

Abstract: The rapid developments in the field of AI pose intractable problems for the law of civil liability. The main question that arises in this context is whether a fault-based liability regime can provide sufficient protection to victims of harm caused by the use of AI. This article addresses this question specifically in relation to medical malpractice liability. Its main purpose is to outline the problems that autonomous systems pose for medical liability law, but more importantly, to determine whether and to what extent a fault-based system of medical liability can adequately address them. In order to approach this issue, a comparative examination of German and Greek law will be undertaken. These two systems, while similar in substantive terms, differ significantly at the level of the burden of proof. In this sense, their comparison serves as a good example to “test” the adequacy of the fault principle in relation to AI systems in the field of medicine, but also to illustrate the practical importance that rules on the allocation of the burden of proof can have in cases of damage caused by the use of AI. As will eventually become apparent, the main problem appears to lie not in the fault principle itself, which, for the time being, at least in the form of objectified negligence, seems to protect the patient adequately, but mainly in the general rule on the allocation of the burden of proof, which is precisely why the fault principle ends up working to the detriment of the patient.

1. Introduction

“If 2023 was the year that AI finally broke into the mainstream, 2024 could be the year it gets fully enmeshed in our lives – or the year the bubble bursts.”¹ The *Los Angeles Times*’ pithy statement may seem like an exaggeration, but there is certainly some truth to it: artificial intelligence is entering the mainstream and it looks as if it may soon become fully entrenched in our lives. AI has long ceased to be the stuff of science fiction; autonomous systems, algorithms, big data, and robots are terms that have begun to enter our everyday vocabulary. This is because they now describe a reality that touches almost every area of our lives.

The same is true in the field of medicine, where the use of artificial intelligence is constantly increasing² and it is already part of everyday medical life.³ In diagnostic medical imaging, especially in radiology, where artificial intelligence is to some extent established, there is extensive use of AI-based diagnostic systems to assess/evaluate CT images or to calculate the dynamics of tumor growth.⁴ In histopathology, for example, artificial neural networks can classify tissue areas into tumor-suspect and non-tumor-suspect areas, enabling the physician to focus their attention exclusively on the areas labelled as suspicious.⁵ An AI software can determine radiological findings, or diagnose the presence of skin cancer. Data synchronization (comparison of the individual data of a patient with a particular disease with the course/

¹ Brian Contreras, “What AI will bring in 2024: 4 predictions,” *Los Angeles Times*, January 2, 2024, accessed February 16, 2024, <https://www.latimes.com/business/technology/story/2024-01-02/ai-predictions-2024-competency-tests-election-ads-bankruptcies>.

² Herbert Zech and Isabelle Céline Hünefeld, “Einsatz von KI in der Medizin: Haftung und Versicherung,” *MedizinRecht* 41, no. 1 (January 2023): 1.

³ Lukas Ströbel and Robert Grau, “KI-gestützte Medizin-Apps,” *Zeitschrift für Datenschutz* 12, no. 11 (November 2022): 600; Susanne Beck, Michelle Faber and Simon Gerndt, “Rechtliche Aspekte des Einsatzes von KI und Robotik in Medizin und Pflege,” *Ethik in der Medizin* 35, no. 2 (April 2023): 249.

⁴ See: Anna Lohmann and Annika Schömig, “‘Digitale Transformation’ im Krankenhaus. Gesellschaftliche und rechtliche Herausforderungen durch das Nebeneinander von Ärzten und Künstlicher Intelligenz,” in *Digitalisierung, Automatisierung, KI und Recht – Festgabe zum 10-jährigen Bestehen der Forschungsstelle RobotRecht*, eds. Susanne Beck, Carsten Kuche and Brian Valerius (Baden-Baden: Nomos 2020), 362 et. seq.

⁵ Sebastian Försch et al., “Künstliche Intelligenz in der Pathologie,” *Deutsches Ärzteblatt* 118, no. 12 (March 2021): 201 et seq.

progression of similar cases over decades, including secondary diagnoses⁶) makes it possible to identify patterns that are extremely difficult for humans to recognize.⁷ Similarly, the contribution of artificial intelligence in neurology and cardiology,⁸ and even in surgery,⁹ is not negligible, while it has also contributed to the development of systems medicine and the gradual transition to a personalized provision of medical services.¹⁰ Given the new challenges involved in everyday treatment, especially due to limited human resources,¹¹ the use of AI seems to promise better individual healthcare, as it opens new possibilities for diagnosis and treatment, disease prevention, and prognosis. Ultimately, it is likely that it will contribute significantly to a longer and more autonomous life,¹² benefiting not only individual patients but also the health system as a whole.¹³

2. The “Black-Box Effect” and the Problems It Poses for Medical Liability Law

Despite all their benefits, we cannot ignore the problems that autonomous systems may pose for medical liability law. For the first time in history, we are confronted with digital systems that can decide on their own “acts and omissions,” without full predictability and control on the part of their manufacturer, programmer, or user.¹⁴ AI systems are autonomous in the sense that they can choose between several alternative forms of behavior, without

⁶ See: Christian Katzenmeier, “Haftung für Schäden durch KI in der Medizin,” in *Die Macht der Algorithmen*, eds. Thomas Grundmann et al. (Baden-Baden: Nomos, 2023), 73.

⁷ Beck, Faber and Gerndt, “Rechtliche Aspekte,” 249.

⁸ Katzenmeier, “Haftung für Schäden,” 74.

⁹ See: Beck, Faber and Gerndt, “Rechtliche Aspekte,” 250.

¹⁰ Christian Katzenmeier, “Big Data, E-Health, M-Health, KI und Robotik in der Medizin. Digitalisierung des Gesundheitswesens – Herausforderung des Rechts,” *Medizinrecht* 37, no. 4 (April 2019): 259 et. seq.

¹¹ Jan-Robert Schmidt, “Die Auswirkungen der Nutzung von KI-Software auf die ärztliche Haftung,” *Gesundheitsrecht* 22, no. 6 (June 2023): 341; Ströbel and Grau, “KI-gestützte Medizin-Apps,” 600.

¹² Katzenmeier, “Big Data,” 259; Katzenmeier, “Haftung für Schäden,” 71.

¹³ Beck, Faber and Gerndt, “Rechtliche Aspekte,” 249.

¹⁴ Gerhard Wagner, “Verantwortlichkeit im Zeichen digitaler Techniken,” *Versicherungsrecht* 71, no. 12 (December 2020): 724.

this choice being predetermined (i.e. pre-programmed).¹⁵ While they operate algorithmically, they differ from typical software, which “behaves” in a strictly deterministic way,¹⁶ in the sense that the programmer gives the algorithms a specific structure and methodology, but they then proceed on their own to deduce the results/conclusions.¹⁷ The autonomy of AI systems in that sense is manifested in two ways: *ex-ante*, it appears as limited predictability (“Vorhersehbarkeit”), which makes it impossible to fully control the system, something that in turn creates, at least in theory, the risk of damage due to unforeseen circumstances.¹⁸ *Ex-post*, it appears as limited explainability (“Erklärbarkeit”) of the system’s behavior and the causes that led to it, and ultimately of the causes that led to the resulting damage.¹⁹ It is precisely due to this lack of transparency around the decision-making processes that AI systems are referred to as “black boxes,”²⁰ which gives rise to the idea of the “black-box effect.”²¹

The “black-box effect” raises the crucial question as to whether the current liability law, which is human-centered by definition,²² can effectively address the damage caused by the use of autonomous systems in the context of the provision of medical services. To answer this question,

¹⁵ See in more detail: Christiane Wendehorst and Yannic Duller, “Safety- and Liability-Related Aspects of Software,” in *Civil Liability for Artificial Intelligence and Software*, eds. Mark A. Geistfeld et al. (Berlin: De Gruyter, 2023), 291 et. seq.

¹⁶ See: Julian Reichwald and Dennis Pfisterer, “Autonomie und Intelligenz im Internet der Dinge Möglichkeiten und Grenzen autonomer Handlungen,” *Computer und Recht* 32, no. 3 (March 2016): 208, 211.

¹⁷ Schmidt, “Die Auswirkungen,” 343.

¹⁸ Herbert Zech, “Risiken Digitaler Systeme: Robotik, Lernfähigkeit und Vernetzung als aktuelle Herausforderungen für das Recht,” *Weizenbaum Series* 2, no. 1 (January 2020): 44 et seq., <https://doi.org/10.34669/wi.ws/2>.

¹⁹ Zech, “Risiken Digitaler Systeme,” 44 and 48; see also: Herbert Zech, “Entscheidungen digitaler autonomer Systeme: Empfehlen sich Regelungen zu Verantwortung und Haftung,” in *Verhandlungen des 73. Deutschen Juristentags* (Leipzig: C.H. Beck, 2020), 1: 44.

²⁰ See, among others: Heinz-Uwe Dettling, “Künstliche Intelligenz und digitale Unterstützung ärztlicher Entscheidungen in Diagnostik und Therapie,” *PharmaRecht* 41, no. 12 (December 2019): 635; Katzenmeier, “Big Data,” 269; Wagner, “Verantwortlichkeit,” 720; Luisa Mühlböck and Jochen Taupitz, “Haftung für Schäden durch KI in der Medizin,” *Archiv für die civilistische Praxis* 221, no. 1–2 (February 2021): 183; Beck, Faber and Gerndt, “Rechtliche Aspekte,” 254.

²¹ See in detail: Zech, “Risiken Digitaler Systeme,” 42 et seq.

²² Katzenmeier, “Haftung für Schäden,” 76.

we must first determine the specific problem that AI autonomy poses for medical liability law. Apart from certain high-risk autonomous systems, that might need to be specifically regulated,²³ self-learning autonomous systems are generally presumed to be safer than traditional technology.²⁴ As long as no human error (e.g. manufacturing error, etc.), is involved, they do not pose an increased risk, especially when their self-learning capabilities allow them to continuously improve their results, even at a personalized level. In this sense, the problem posed by the so-called autonomy risk (“Autonomierisiko”)²⁵ at a substantive level, i.e. the impossibility of attributing (in the sense of “Zurechnung”) the damage resulting from the autonomous operation of the system, does not seem to be the primary issue for the time being.

On the contrary, the issue of risk arises in cases of human errors that may occur during the construction, training, maintenance, and/or use of the system. Due to the “black-box effect,” these errors are very difficult to detect and identify. The algorithms function correctly, but they may be “fed” with incorrect data, which are perpetuated, while the systems are running and interacting with other systems.²⁶ In theory, these types of damage are covered by the general liability law, since an accountability link between the damage and the respective human conduct can be established in such cases. The problem in practice, however, is that it is difficult to identify the exact cause of the damage, i.e. to detect the exact technical error that led to it. The “black-box effect” appears to create insurmountable evidentiary obstacles,

²³ For the so called high-risk systems, see Section 1 and 2 of Chapter III of the “AI-Act,” i.e. the European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)), accessed May 28, 2024, https://europarl.europa.eu/doceo/document/TA-9-2024-0138_EN.pdf. Either way, as aptly noted, high-risk autonomous systems appear to be covered by the existing risk-based strict liability framework, see: Arbeitsgruppe “Digitaler Neustart”, *Haftungsfragen der Künstlichen Intelligenz–Europäische Rechtsetzung*, Bericht vom 1. März 2023, 47–8, accessed February 10, 2024, https://www.justiz.nrw/JM/justizpol_themen/digitaler_neustart/zt_fortsetzung_arbeitsgruppe_teil_5/Bericht-Digitaler-Neustart_Haftung-bei-KI.pdf.

²⁴ Mark A. Geistfeld et al., eds., *Civil Liability for Artificial Intelligence and Software* (Berlin, Boston: De Gruyter, 2023), 37.

²⁵ See: Zech, “Risiken Digitaler Systeme,” 44 et seq.

²⁶ See: Katzenmeier, “Big Data,” 269; Schmidt, “Die Auswirkungen,” 343.

that are made even greater, given the practical difficulty of accurately separating the areas of responsibility of the various subjects associated with the autonomous system.²⁷ The autonomy risk therefore seems to indicate not so much the risk of damage, as the risk of ambiguity regarding the causes of the damage.

Things get even more complicated if one considers the open nature of many AI systems and their increasing interconnectivity,²⁸ which has the effect of further blurring the boundaries of the spheres of “responsibility” and “influence” of the various subjects involved in the network (such as manufacturers, developers, trainers, users, etc.).²⁹ The injured party is ultimately faced with extreme evidentiary difficulties concerning the cause of the damage,³⁰ as many systems, services, data supplies, and infrastructure facilities may coexist and interact at a network level.³¹ Therefore, the resulting damage can always be attributed to many possible causes or errors. For the same reasons, similar difficulties seem to exist when it comes to proving the exact technical or human error responsible for the damage. To put it briefly, it is the very nature of AI and its particular features (limited predictability, complexity, opacity, and openness) that make it extremely difficult for the injured party to identify the cause or causes of the damage suffered, as well as to identify the responsible party (whether it is the autonomous system itself, or a specific human or legal entity, e.g. manufacturer, user, etc.).³²

These problems appear to become even more complicated in cases of medical liability, where the injured party is also confronted with inherent evidentiary difficulties related to medical matters.³³ Thus, in addition to

²⁷ Katzenmeier, “Big Data,” 265.

²⁸ In more detail see: Zech, “Digitale Risiken,” 47 et. seq.

²⁹ Wagner, “Verantwortlichkeit,” 725.

³⁰ See: Zech and Hünefeld, “Einsatz von KI,” 5. Gunther Teubner, “Digitale Rechtssubjekte? Zum privatrechtlichen Status autonomer Softwareagenten,” *Archiv für die civilistische Praxis* 218, no. 2–4 (August 2018): 201 et seq.; Wagner, “Verantwortlichkeit,” 717, 734; Gerald Spindler, “Medizin und IT, insbesondere Arzthaftungs- und IT-Sicherheitsrecht,” in *Festschrift für Dieter Hart. Medizin – Recht – Wissenschaft*, ed. Christian Katzenmeier (Berlin: Springer Verlag, 2020): 581, 583, 584, 591, 597; Mühlböck and Taupitz, “Haftung für Schäden,” 183 et seq.

³¹ Wagner, “Verantwortlichkeit,” 725.

³² See: Geistfeld et al., *Civil Liability*, 19; see also: Beck, Faber and Gerndt, “Rechtliche Aspekte,” 254.

³³ On this issue see: Erwin Deutsch and Andreas Spickhoff, *Medizinrecht. Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht* (Berlin: Springer Verlag, 2014), 740 et seq.

these, the patient must also overcome the obstacle of the “black-box effect” in order to trace the exact cause of their damage, being therefore obliged to prove both a specific human error in the use of the system (as well as who committed it) and the causal link between the error, the output of the system, and the damage sustained.³⁴ Hence, in addition to their information deficit regarding medical issues, the patient now has to cope with a respective deficit in relation to highly complicated technical issues of artificial intelligence (which, given the “black-box effect,” are extremely difficult even for the experts themselves). As a result, their evidentiary difficulties are now intensified, as they will have neither sufficient technical knowledge to meet the respective burden of proof, nor the financial means to make up for this deficit of knowledge. This correspondingly reduces the chances of a lawsuit for medical malpractice succeeding – precisely to the extent that the fault principle applies along with the general rule on the allocation of the burden of proof.

It is clear that the typical risks inherent in AI do not primarily increase the potential for damage, but rather make it more difficult to clarify and prove causal links in the event of damage.³⁵ Its autonomy does not imply higher risk but increased evidentiary difficulties. In other words, the “black-box effect” poses, at least for the time being, mainly evidentiary problems. The main question that arises is whether and to what extent a fault-based medical liability system, operating in conjunction with the general rule on the allocation of the burden of proof,³⁶ can deal with these problems effectively without necessitating legislative changes, especially in the form of a general risk-based strict liability. The following *de lege lata* comparative examination of German and Greek law was undertaken in order to address this problem.

³⁴ In fact, in these cases the error in the use/operation of the system will also be a medical error. See also: Wendehorst and Duller, “Safety,” 293.

³⁵ See: Digitaler Neustart, *Haftungsfragen*, 3.

³⁶ See: Ivo Giesen, “The Burden of Proof and other Procedural Devices in Tort Law,” in *European Tort Law 2008*, eds. Helmut Koziol and Barbara C. Steininger (Vienna: Springer Wien New York, 2009), 50.

3. Medical Liability Regime under Current Law: A General Overview

First of all, it must be pointed out that the following analysis focuses on the problem of the liability of the physician/hospital for damage caused by the use of autonomous systems in the provision of medical services. The related issue of the liability of other persons, in particular of the manufacturer, is of great practical importance, especially in view of the debate on who should be liable in cases of damage caused by AI, but remains beyond the scope of the present study, which is to examine the problem of medical liability arising from the use of AI. Similarly, the study does not deal with *de lege ferenda* solutions to the problem nor with constructions such as legal e-personality, for its sole purpose is to identify whether and to what extent systems based on the fault-principle can effectively address the relevant problems.

Both in German and Greek law, medical liability can arise from contract and tort law; thus, the physician who breaches their duty of care is liable not only contractually, but also in tort. Both legal systems hence refer to concurrent claims of the patient.³⁷ Accordingly, in both systems medical liability arises on the basis of subjective liability. This means that the physician can only be held liable for a culpable breach of duty. The following analysis presents an overview of the basic characteristics of German and Greek medical liability laws (contractual and tort), to “prepare the ground” for specifically addressing the problem of medical liability from the use of AI below.

3.1. Liability Regime under German Law

3.1.1. General Overview: Medical Liability and Breach of Medical Standards

As mentioned, under German law, the physician bears both contractual and tort liability. Thus, under the treatment contract (“Behandlungsvertrag”),³⁸

³⁷ For German law, see, among others: Deutsch and Spickhoff, *Medizinrecht*, no. 298 et. seq; Bernd-Rüdige Kern and Martin Rehborn, in *Handbuch des Arztrechts*, ed. Adol Laufs, Bernd-Rüdige Kern, and Martin Rehborn (München: C.H. Beck, 2019), § 92 no. 22; Dieter Medicus and Stephan Lorenz, *Schuldrecht Besonderer Teil* (München: C.H. Beck, 2018), § 32 no. 21. For Greek law: Κατερίνα Φουντεδάκη, *Αστική Ιατρική Ευθύνη* [hereinafter: Katerina Fountedaki, *Civil Medical Liability*] (Athens: Sakkoulas Publications, 2003), 337; Κατερίνα Φουντεδάκη, Μαρία Γερασπούλου, and Βασίλειος Μαρούδας, *Αστική Ιατρική Ευθύνη* [hereinafter: Katerina Fountedaki, Maria Gerasopoulou, and Vasileios Maroudas, *Civil Medical Liability*] (Athens: Nomiki Bibliothiki, 2023), 54, 202.

³⁸ For the treatment contract, which is specifically regulated in BGB, see among others: Deutsch and Spickhoff, *Medizinrecht*, no. 96 et seq.

which covers the entire course of medical care/treatment, from diagnosis to aftercare,³⁹ the physician has duties of treatment and information. Any breaches of duty by the physician can lead to liability for damages under §§ 630a, 280 I of the German Civil Code (hereinafter referred to as “BGB”). Breach of duty (“Pflichtverletzung”) occurs when the physician’s conduct is contrary to the standard of care (“Sorgfaltsmaßstab”), which in turn is determined objectively, according to § 630a II BGB,⁴⁰ which stipulates that: “Unless agreed otherwise, the treatment is to take place according to the generally recognised standards of medical care applying at the time of the treatment.”⁴¹ The physician bears subjective liability, under the general fault principle, for the breach of an objective standard of care, that of the medical standard. According to the established case law of the Federal Court of Justice (BGH), the medical standard specifies the appropriate conduct of the physician for the specific therapeutic situation and is determined by the objective circumstances, the rules of science and in particular, the rules of the physician’s specialty, as well as by the findings of medical experience at the time the treatment is provided. It represents the current state of scientific knowledge and medical experience, that is required to achieve the specific therapeutic purpose, and which has been shown to be suitable for that purpose during trials.⁴² Thus, the medical standard prescribes the manner in which the medical procedure is to be carried out, but at the same time, it also constitutes a measure in the examination the physician’s liability, since, in view of § 630a II BGB, a breach of the medical standard implies a breach of the duty of care.⁴³

³⁹ See: Christian Katzenmeier, in *Arztrecht*, ed. Adolf Laufs, Christian Katzenmeier and Volker Lipp (München: C.H. Beck, 2021), Cap. X no. 3 et seq. and 41 et seq.

⁴⁰ See: Christoph Jansen, *Der Medizinische Standard. Begriff und Bestimmung ärztlicher Behandlungsstandards an der Schnittstelle von Medizin, Haftungsrecht und Sozialrecht* (Berlin, Heidelberg: Springer Verlag, 2019), 106 et seq.

⁴¹ “German Civil Code BGB,” Bundesministerium der Justiz, accessed February 23, 2024, https://www.gesetze-im-internet.de/englisch_bgb/englisch_bgb.html#p3069.

⁴² See for instance: Federal Court of Justice [Bundesgerichtshof], Judgment of 22 December 2015, VI ZR 67/15 in *Neue Juristische Wochenschrift* 69, no. 10 (March 2016): 714. For the various definitions that have been proposed for the concept of medical standard, see: Jansen, *Medizinische Standard*, 199 et seq.

⁴³ See: Dieter Hart, “Haftungsrecht und Standardbildung in der modernen Medizin: e–mer und Probleme der Definition des Standards,” *Medizinrecht* 34, no. 9 (October 2016): 671.

Similarly, in the event of a breach of the duty of care, the physician will also be liable in tort under § 823 I and II BGB. According to § 823 I BGB, anyone who unlawfully and culpably infringes the legal interests of another person is liable to provide compensation for the damage that occurred. Of particular importance in this context are the so-called duties of care (“Verkehrspflichten”), that require not to endanger someone more than is unavoidable.⁴⁴ It is thus well established that any medical error always constitutes a breach of the physician’s duty of care in the sense above. In medical liability law, the physician’s duties of care are identical to their corresponding contractual obligations, since contractual medical liability is essentially derived from the law of medical tort liability, as this has been developed in the context of case law.⁴⁵ In that sense, what has been said about the contractual liability of the physician and medical standards also applies here. Therefore, where the physician’s conduct falls short of the medical standard applicable in the particular case, they are also liable under tort law.

3.1.2. Medical Liability as Subjective Liability – The Allocation of the Burden of Proof and the Patient’s Evidentiary Difficulties

Regardless of its legal basis, i.e. whether it is contract law or tort law, the physician’s liability for any breaches of duty is regarded as subjective liability under German law. The principle of fault is the rule here. This applies to both contractual (§ 276 I BGB),⁴⁶ and non-contractual liability (§ 823 I BGB).⁴⁷ The only difference between the two is that in contractual liability, according to § 280 I 2 BGB, the fault of the debtor is presumed. This means that it is not

For medical guidelines and the way the medical standard is determined in practice, see in detail: Jansen, *Medizinische Standard*, 16–7, 28, 204.

⁴⁴ See in detail: Christian von Bar, *Verkehrspflichten: richterliche Gefahrsteuerungsgebote im deutschen Deliktsrecht* (Köln: Carl Heymanns Verlag, 1980). Specifically for the breach of the duty of care as a ground of liability of the physician due to medical error, see: Kern and Rehborn, *Handbuch des Arztrechts*, § 96 no. 17 et seq.; Jansen, *Medizinische Standard*, 49 et seq.

⁴⁵ Katzenmeier, *Arztrecht*, Cap X no. 2 and XI no. 63.

⁴⁶ Georg Caspers, *J. von Staudingers Kommentar zum Bürgerlichen Gesetzbuch: Staudinger BGB-Buch 2: Recht der Schuldverhältnisse: BGB §§ 255–304 (Leistungsstörungenrecht 1)*, rev. ed., eds. Georg Caspers et al. (Otto Schmidt/De Gruyter - de gruyter, 2019), § 276 no. 7 et seq.

⁴⁷ See, among others: Volker Emmerich, *BGB-Schuldrecht Besonderer Teil*, 16th ed. (Heidelberg: C.F. Müller, 2022), § 20 no. 3 et seq.

the creditor who has to prove the fault of the debtor, but the debtor who has to prove the absence of fault on their part.⁴⁸ Thus, in medical liability and in so far as the specific provisions on the treatment contract do not contain a derogation from the general rules on contractual liability,⁴⁹ the physician is liable in the same way as any debtor, i.e. for intent and negligence. Moreover, given the objective definition of the standard of care in medical services, any breach of the physician's duty of care shall almost always constitute both unlawful and culpable conduct.⁵⁰

Furthermore, in German law, following the general rule on the allocation of the burden of proof, the plaintiff bears the burden of proving the facts on which their action is based.⁵¹ In medical liability cases this means that the patient bears the burden of proving the culpable breach of the duty of care (i.e. medical error as conduct falling short of the medical standard), the damage suffered, and the causal link between the culpable breach and the respective damage. Also, given the objectification of negligence, of which medical standards are also an expression,⁵² the reversal of the burden of proof in the case of contractual liability does not seem to contribute anything to the patient's evidentiary assistance; with the exception of the cases of § 630h I BGB,⁵³ the patient continues to bear the burden of proving medical error even under § 280 I 2 BGB, since this provision covers only

⁴⁸ For this provision, see: Daniel Ulber, *Erman BGB*, 17th ed., eds. Harm Peter Westetrmann, Barbara Grunewald, and Georg Maier-Reimer (Köln: Otto Schmidt Verlag, 2023), § 280 no. 115 et seq.

⁴⁹ Deutsch and Spickhoff, *Medizinrecht*, no. 412. For fault liability in medical liability law, see: Kern and Rehborn, *Handbuch des Arztrechts*, § 92, no. 4 et seq.

⁵⁰ See: Jansen, *Medizinische Standard*, 58, 71.

⁵¹ Although it is not explicitly stated in the ZPO or in any other legislative act, it is considered a fundamental rule on the allocation of the burden of proof with legislative force. See, among others: Hans-Jürgen Ahrens, *Der Beweis im Zivilprozess*, 1st ed. (Köln: Otto Schmidt Verlag, 2014), § 32 no. 32.

⁵² See: Karl Larenz, *Lehrbuch des Schuldrechts, Band I, Allgemeiner Teil*, 14th ed. (München: C.H. Beck, 1987), § 20 III; Erwin Deutsch, *Allgemeines Haftungsrecht*, 2nd ed. (Köln: Carl Heymanns Verlag, 1996): 259 et seq.; Adolf Laufs, "Deliktische Haftung ohne Verschulden? – Eine Skizze," in *Festschrift für Joachim Gernhuber zum 70. Geburtstag*, eds. Hermann Lange, Knut Wolfgang Nörr, and Harm Peter Westermann (Tübingen: J.C.B. Mohr P. Siebeck, 1993), 245, 248.

⁵³ See: Lothar Jaeger, *Patientenrechtegesetz* (Karlsruhe: VVW, 2013), § 630h, no. 1 et seq.; Deutsch and Spickhoff, *Medizinrecht*, no. 795 et seq.

the internal aspect of negligence (“Verschulden”), which, however, is given in almost every case of externally negligent conduct (“Pflichtwidrigkeit”) in the sense of a medical error, the burden of proof of which, however, remains with the patient.⁵⁴ It is therefore obvious that the patient, being generally uneducated in medical matters, is faced with serious evidentiary difficulties, hence with the consequent risk of having their claim rejected, as any *non-liquet* situation will always be to their detriment.⁵⁵ However, as was rightly pointed out, a general reversal of the burden of proof (i.e. the introduction of a general presumption of medical error) would be doctrinally impermissible. This is because the biological and physiological reactions of a human organism cannot be predicted with certainty, and therefore controlled, something that in turn means that any damage to the patient’s body or health cannot always be within the physician’s sphere of influence. Therefore, the mere occurrence of damage cannot justify a general presumption of a medical error⁵⁶.

3.2. Liability Regime under Greek Law

3.2.1. General Overview: Medical Liability and the Average Reasonably Prudent Physician – The Breach of the Rules of Medical Science

Similarly, under Greek Law, a physician who causes harm to a patient is liable both under contract and tort law. Thus, in the case of a treatment contract

⁵⁴ Kern, *Handbuch des Arztrechts*, § 106 no. 16; Jansen, *Medizinische Standard*, 58, 71, mainly 102 et. seq; see also: Conrad Waldkirch, *Zufall und Zurechnung im Haftungsrecht* (Tübingen: Mohr Siebeck, 2018), 147.

⁵⁵ Christoph Jansen and Christian Katzenmeier, “Beweismass, Beweislast und Haftung für den Verlust von Heilungschancen–Kausalitätsfragen im Arzthaftungsprozess in der Schweiz und in Deutschland,” in *Das Zivilrecht und seine Durchsetzung. Festschrift für Professor Thomas Sutter-Somm*, eds. Roland Fankhauser et al. (Zürich: Schulthess, 2016), 285.

⁵⁶ See: Gottfried Baumgärtel, “Die beweiserrechtlichen Auswirkungen der vorgeschlagenen EG-Richtlinie zur Dienstleistungshaftung,” *Juristen Zeitung* 47, no. 7 (April 1992): 322; Jansen and Katzenmeier, “Beweismass,” 286. On the contrary, in cases where the patient’s injury is the result of a fully controllable therapeutic risk, it is conceivable to provide for a presumption of medical malpractice in favor of the patient (see thus § 630h I BGB). Similarly, in cases of gross negligence (“grober Behandlungsfehler”) it is perfectly justifiable and permissible to provide for a presumption of causality between the negligence and the resulting damage (630h V BGB) – for details on these provisions, which constitute a codification of established case law of the BGH, see, among others: Deutsch and Spickhoff, *Medizinrecht*, no. 795 et seq. and 374 et. seq. respectively.

between the physician and the patient, the Greek courts apply in parallel the provisions on tort [Article 914 et seq. of the Greek Civil Code (hereinafter referred to as Greek CC)] with the provisions applicable to service contracts (in particular, Article 652 Greek CC).⁵⁷ In contrast to German law, the treatment contract in Greek law is not specifically regulated. However, the contractual relationship between the physician and the patient constitutes a service contract. Thus, the contractual liability for medical malpractice (in the sense of a medical error) is assessed under Article 652 Greek CC in conjunction with the general liability provisions of the law of obligations. The provision of Article 652 paragraph 2 Greek CC is a specification of that of Article 330 section b Greek CC⁵⁸ focusing on an objective standard of care, the non-observance of which entails the physician's liability.⁵⁹

The focus, however, is placed on medical error as a prerequisite for establishing the physician's liability in tort, since, contrary to German law, it is only on this basis that the injured party can claim compensation for non-material/moral damage or emotional distress under Article 932 Greek CC.⁶⁰ Under the general provision regarding torts, expressed in Article 914 Greek CC: "A person who unlawfully and through his fault has caused prejudice to another shall be liable for compensation."⁶¹ Medical error that causes damage to the patient's body or health is consistently recognized as a case of application of Article 914 Greek CC. Due care is determined objectively: according to the established case law of the Greek courts, a breach of the duty of medical care occurs with the breach of the rules of medical science and experience and/or of the general duty of care and safety, that the average

⁵⁷ Κατερίνα Φουντεδάκη, *Παραδόσεις Αστικής Ιατρικής Ευθύνης* [hereinafter: Katerina Fountedaki, *Lessons of Civil Medical Liability*] (Athens: Nomiki Bibliothiki, 2018), 47; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 187.

⁵⁸ Μιχαήλ Π. Σταθόπουλος, *Γενικό Ενοχικό Δίκαιο*, 5th ed. [hereinafter: Michail P. Stathopoulos, *General Law of Obligations*, 5th ed.] (Athens: Sakkoulas Publications, 2018), 652. It is worth noting that the provision of Article 330(b) of the Greek CC is identical to that of § 276 II BGB.

⁵⁹ For that specifically in medical liability the standard of care of Article 652 paragraph 2 Greek CC must be defined in an objective manner. See: Fountedaki, *Civil Medical Liability*, 338–9.

⁶⁰ Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 188.

⁶¹ As translated by Eugenia Dacoronia, in "Tort Law in Greece. The State of Art," in *Studia in Honorem Pelayia Yessiou-Faltsi*, eds. Nikolaos Th. Nikas et al. (Athens: Sakkoulas Publications, 2007), 57.

reasonably prudent physician of the relative specialty must demonstrate.⁶² At the heart of due care thus lies the average reasonably prudent physician (*bonus medicus*) and the rules of medical science (*leges artis*).⁶³ Alongside this general view of due care, the Code of Medical Ethics (Kodikas Iatrikis Deontologias – Law 3418/2005), sets out criteria for the specification of the physician's duty of care, establishing specific legal (and not just ethical) obligations, the breach of which constitutes a breach of the duty of due care.⁶⁴ Hence, according to Article 3 paragraph 3 of the Code, the physician is obliged to perform any medical procedure within the framework of the generally accepted rules⁶⁵ and methods of medical science, as formulated on the basis of the results of applied modern scientific research. From the perspective of Article 3, which even refers to evidence-based medicine (see paragraph 2c), the criterion of the average reasonably prudent physician seems to lose its static character, approaching to a certain extent the concept of medical standards as explained above.⁶⁶ In any case, a physician, whose conduct falls short of that required by the results of applied modern scientific research (a concept close to that of the medical standard) is liable for compensation if this conduct causes harm to the patient.

3.2.2. Medical Liability as Subjective Liability – The Allocation of the Burden of Proof and Article 8 of Greek Law 2251/1994

As in German law, medical liability in Greek law is a form of subjective liability. Given the lack of explicit regulation, it is covered by the general provisions on contractual and tort liability, which establish the principle of fault.⁶⁷ Their only difference is that contractual liability is regulated as

⁶² See: Supreme Civil and Criminal Court of Greece (Άρειος Πάγος), Judgment of 4 June 2007, no. 1227/2007, in the home page of the Supreme Civil and Criminal Court of Greece, accessed February 9, 2020, https://www.areiospagos.gr/nomologia/apofaseis_DISPLAY.asp?cd=j5ZUkHPjtZqv6ohr6jRR0JbPAgT03z&apof=1227_2007&info=%D0%CF%CB%-C9%D4%C9%CA%C5%D3%20-%20%20%C12.

⁶³ Fountedaki, *Civil Medical Liability*, 351 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 206 et seq.

⁶⁴ See: Fountedaki, *Lessons*, 17–8; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 57.

⁶⁵ See also: Article 10 paragraph 1(a) of the Code.

⁶⁶ See also: Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 210, 223.

⁶⁷ For fault liability in Greek law, see, among others: Stathopoulos, *General Law of Obligations*, 389; Παναγιώτης Κορνηλάκης, *Ειδικό Ενοχικό Δίκαιο*, 3rd ed. [Panagiotis Kornilakis, *Special Part of the Law of Obligations*] (Athens: Sakkoulas Publications, 2023), 1588.

liability for presumed fault (Article 336 Greek CC), in the sense mentioned above, i.e. that the debtor bears the burden of proving the absence of fault on their part.⁶⁸ The physician is therefore liable for intent or negligence, irrespective of the legal basis of their liability, i.e. whether it is contractual or in tort. Moreover, given the objective conception of the duty of due care, as stated above, a medical error will almost always constitute a conduct both unlawful and culpable.⁶⁹

However, in cases of liability for medical malpractice, in addition to the general provisions, a special provision of the Consumer Protection Law (Greek Law 2251/1994) applies, that is of considerable importance: article 8 of the law, which regulates the liability of the supplier of services and which, in its basic content, implements the corresponding EU Proposal for a Directive of 1990.⁷⁰ According to the most correct approach, this provision does not introduce independent legal grounds for liability,⁷¹ but merely regulates in a specific way certain issues of (the general) tort liability of the supplier of services.⁷² In addition to providing certain criteria for establishing the supplier's unlawful and culpable conduct, it also contains a specific regulation on the allocation of the burden of proof, that deviates from the generally applicable provisions of the Greek Code of Civil Procedure (hereinafter referred to as Greek CCP). This point is of particular importance and requires attention.

⁶⁸ For contractual liability as liability for presumed fault, see: Stathopoulos, *General Law of Obligations*, 1283.

⁶⁹ Fountedaki, *Civil Medical Liability*, 335 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 201. On the more specific problem regarding medical error as a form of unlawful conduct as well as its relation to the objectification of negligence, see: Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 189 et seq. and 197 et seq. respectively.

⁷⁰ See: (EC) Proposal for a Council Directive on the liability of suppliers of services [COM(90) 482 final — SYN 308], 9 November 1990, accessed February 20, 2024, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51990PC0482>. However, the Proposal was heavily criticized, especially with regard to civil medical liability, with the result that the whole project of unifying the laws in the field of liability of the supplier of services was abandoned a few years later (1994). See, among others: Baumgärtel, “Die beweiserrechtlichen Auswirkungen,” 321 et seq.

⁷¹ This is, however, the prevailing view in Greek law. Among others see: Stathopoulos, *General Law of Obligations*, 989 fn. 100.

⁷² See: Fountedaki, *Civil Medical Liability*, 100–2, where this view is first articulated.

According to the general rule on the allocation of the burden of proof of Article 338 paragraph 1 Greek CCP, each party is subject to the burden of proving the evidence supporting its claims.⁷³ Thus, the plaintiff in tort is required to prove the wrongful and culpable conduct of the defendant, the damage suffered, and the causal link between the two. Therefore, under the general rule on the allocation of the burden of proof of Article 338 paragraph 1 Greek CC, the patient would be obliged to prove a medical error on the part of the physician (i.e. their unlawful and culpable conduct), the damage sustained, as well as the causal link between the two. Moreover, the rule of Article 336(a) Greek CC on presumed fault in contractual liability would not be of assistance to the patient, since in medical liability it would by definition have the limited content of a reversal of the burden of proof regarding fault, the existence of which, however, would be given by the mere objective breach of the duty of care, whose burden of proof the patient would continue to bear.⁷⁴ Thus, the patient would be relieved of the burden of proving an element (fault), the existence of which would necessarily be inferred from the objective deficiency of the medical service, the burden of proof of which they would still have to bear.

Contrary to that general rule, Article 8 sets out a completely different allocation of the burden of proving the conditions of liability. This is where its practical importance for medical liability lies; it is not the injured party who has to prove unlawful and culpable conduct of the supplier (i.e. the physician), but instead, it is the latter who bears the burden of proving the absence of such conduct. In the context of medical liability, this rule has the effect of introducing a general presumption of medical error to the detriment of the physician. Similarly, it is not the injured party who must prove the existence of a causal link between the supplier's error and the damage suffered, but rather the latter who bears the burden of proving the absence of such a causal link. In medical liability, this means the introduction of a presumption of causality between the (presumed) medical error

⁷³ See in more detail: Pelayia Yessiou-Faltsi, *Civil Procedure in Hellas*, 2nd rev. ed. (Athens: Sakkoulas Publications, 2022), 378 et seq.

⁷⁴ Details on the meaning of the presumption of the debtor's fault in contractual liability and medical liability and the relationship of the general provisions on contractual liability with article 8 of Law 2251/1994, see: Fountedaki, *Civil Medical Liability*, 103 et seq. and 139 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 70 et seq. and 290.

and the patient's harm.⁷⁵ Thus, the patient bears only the burden of proving the provision of the medical service, the damage suffered, and the causal link between the two (Article 8 paragraph 3). The combination of these two presumptions ultimately means that by the mere damaging effect of a medical procedure it is presumed both that there was a medical error and that this error caused the damage sustained.⁷⁶ The provision of Article 8 was rightly criticized as doctrinally inappropriate for regulating medical liability,⁷⁷ since the allocation of the burden of proof imposed by it results in the disguised conversion of medical liability into strict liability, at least in cases where the physician is unable to prove the absence of error on their part and/or causality between that error and the damage sustained. However, it cannot be denied that in practice it is an important aid to the patient,⁷⁸ who, in a (pure) subjective liability regime, would risk bearing the negative effects of a *non-liquet* situation.

4. Medical Liability for Damage Caused by the Use of AI: A Comparative Analysis

What is the significance of the above general regulations of medical liability under German and Greek law to the use of autonomous systems in the provision of medical services? Also, to what extent and in what way does the current legal framework cover the damage caused by the use of AI systems in medicine, if it does so at all? The following analysis focuses on this issue, in the hope of providing some answers. It should be noted that, due to the proximity between Greek and German medical liability law as described above, the analysis is largely uniform, however, where differentiations need to be made (specifically with regard to the burden of proof), this is explicitly pointed out. Moreover, since on the one hand, *lex artis* and medical

⁷⁵ For the presumption of medical error and the presumption of causation as the basic content of Article 8 in the context of medical liability, see: Fountedaki, *Civil Medical Liability*, 103 et seq.; Fountedaki, *Lessons*, 116 et seq.; Fountedaki, Gerasopoulou, and Maroudas, *Civil Medical Liability*, 289 et seq.

⁷⁶ *Ibid.*, 291.

⁷⁷ For a criticism at a doctrinal lever, see: Fountedaki, *Civil Medical Liability*, 145 et seq.; compare also: Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 298 et seq.

⁷⁸ See, however: Fountedaki, *Lessons*, 125 et seq., who observes that in practice Greek courts do not apply the provision in its true sense, with the result that a *non-liquet* situation is not always to the detriment of the physician.

standards do not differ significantly, and on the other hand, medical standards for the use of AI systems have not yet been developed,⁷⁹ with the result that German law also resorts to the criterion of the average reasonably prudent physician (*bonus medicus*),⁸⁰ the uniform examination of the relevant issues does not seem to raise any doctrinal problems whatsoever.

4.1. The Permissibility of the Use of AI Systems in the Provision of Medical Services – The Use of Autonomous Systems as a Breach of Duty *per se*

The first and main question is whether the use of autonomous systems is in any way permissible in the context of medical practice. Indeed, it was argued that, since autonomous systems are not subject to full human control, due to the lack of transparency and predictability of their operations, their use would entail incalculable risks, thus constituting a breach of duty *per se*.⁸¹ Such a view could of course in no way be accepted.⁸² Apart from being based on an incorrect premise, as autonomous systems are perceived as safer than systems under human control,⁸³ duties of care do not generally extend to the point of guaranteeing absolute safety.⁸⁴ If this were the case, especially in the context of medical liability, it would have the effect of making virtually any medical procedure impossible, since no physician would ever be able to guarantee absolute safety for anything.⁸⁵ But just as a physician cannot (and is not required to) guarantee absolute safety when using a human-controlled machine, they cannot be required to guarantee an error-free operation of the autonomous system. Considering the use of autonomous systems as a breach of duty would mean establishing the autonomy of the

⁷⁹ Zech and Hünefeld, “Einsatz,” 3.

⁸⁰ For relevant case-law regarding the criterion of the average reasonably prudent physician, see: Hans-Peter Greiner, *Arzthaftpflichtrecht*, 8th ed., eds. Karlmann Geiß and Hans-Peter Greiner (München: C.H. Beck, 2022), Cap. B, no. 2 et seq.

⁸¹ See: Zech, “Entscheidungen digitaler autonomer Systeme,” 55; Teubner, “Digitale Rechts-subjekte?,” 185 et seq.

⁸² Opposed to this view: Jan Eichelberger, “Arzthaftung,” in *Künstliche Intelligenz – Recht und Praxis automatisierter und autonomer Systeme*, eds. Kuuya J. Chibagunza, Christian Kuß, and Hans Steege (Baden-Baden: Nomos, 2022), § 4 I no. 12; Wagner, “Verantwortlichkeit,” 727; Christian Katzenmeier, “KI in der Medizin – Haftungsfragen,” *Medizinrecht* 39, no. 10 (October 2021): 860 et seq.; Schmidt, “Die Auswirkungen,” 344.

⁸³ Geistfeld et al., *Civil Liability*, 37.

⁸⁴ Wagner, “Verantwortlichkeit,” 727.

⁸⁵ See: Katzenmeier, “Haftung für Schäden,” 78–9.

system as a reason for the physician's liability; this, however, would be contrary to the fault principle, for it would have the effect of transforming the physician's liability into a risk-based strict liability.⁸⁶

4.2. The Use of AI Systems in the Light of the Criteria for Establishing Medical Liability – Autonomous Systems as Novel Methods

However, the question of the permissibility of the use of AI technology could also be raised on a different basis. Given that autonomous systems constitute a novelty for medical practice, the question arises whether and to what extent they meet the criteria of due medical care under German and Greek law, as discussed above.

As mentioned, under German law, medical liability arises when the physician's conduct fails to meet medical standards. The medical standard is clearly a normative concept as it indicates the required medical conduct in a specific case; at the same time, however, it is a dynamic and flexible concept, since it allows for the convergence of legal assessments of medical malpractice with the constant developments in the field of medical science.⁸⁷ In this sense, § 630a II BGB allows for the use of new therapeutic methods, irrespective of the fact that they have not yet been widely applied.⁸⁸ However, this is possible only under certain conditions. A physician who wishes to use a new method must first carry out a risk assessment for this new method and the methods indicated by the current standards and use it only if it offers significant advantages for the patient (correspondingly entailing significantly fewer risks).⁸⁹ In the case of autonomous systems that can process a huge amount of data and thus make personalized treatment recommendations for the individual patient, the advantages for the latter are considerably greater, since the treatment decision is based on processing much more data than a human being could ever take into

⁸⁶ Ibid.

⁸⁷ See, among others: Jansen, *Medizinische Standard*, 48–9.

⁸⁸ Thomas Gutmann, ed., in *J. von Staudingers Kommentar zum Bürgerlichen Gesetzbuch: Staudinger BGB - Buch 2: Recht der Schuldverhältnisse: §§ 630a-630h (Behandlungsvertrag)*, rev. ed. (Otto Schmidt/De Gruyter - de Gruyter, 2021), § 630a no. 146.

⁸⁹ See: Deutsch and Spickhoff, *Medizinrecht*, no. 339; in detail see: Lena Schneider, *Neue Behandlungsmethoden im Arzthaftungsrecht. Behandlungsfehler-Aufklärungsfehler-Versicherung* (Heidelberg: Springer, 2010), 25 et seq., especially 119 et seq.

account.⁹⁰ A more personalized treatment of the patient, however, always presents more advantages, and correspondingly fewer risks, for the patient than one based on evidence-based medicine.⁹¹ Therefore, to the extent that an autonomous system presents more advantages for the patient, provided that it is a certified medical device according to the provisions of Regulation (EU) 2017/745 on medical devices,⁹² it is clear that it can be used in the context of medical practice as the above cost-benefit analysis will most probably prove it to be beneficial for the patient.⁹³ The physician, of course, is a mere user and may not be in a position to know whether the system has been properly manufactured, programmed, or trained. However, their application in medical practice cannot be ruled out in advance only because of that. Yet, if the physician has evidence of a possible malfunction of the system, its use in the course of the treatment shall always constitute a breach of duty.⁹⁴

It is similar in the context of Greek law. First of all, the use of therapeutic methods that are not scientifically documented is prohibited (Article 3 paragraph 3 section b of the Code of Medical Ethics), as well as that of new diagnostic or therapeutic methods for which there is no strong scientific evidence that their use or application will increase the chances of survival or restoration of the patient's health and that the benefit will seriously outweigh the risk of adverse effects (Article 25 paragraph 1 Code of Moral Ethics). However, apart from the fact that self-learning algorithms are not exactly a diagnostic/therapeutic method, but rather a specific way of processing knowledge,⁹⁵ the criterion of the average reasonably prudent physician, which, as highlighted above, is not so different from that of medical standards, appears to provide fertile ground for the smooth integration of the use of artificial intelligence into medical practice, at least in the way

⁹⁰ Schmidt, "Die Auswirkungen," 345.

⁹¹ See also: Anna Maria Ernst, *Rechtsfragen der Systemmedizin* (Berlin: Springer Verlag, 2020), 138 et seq.

⁹² On this aspect of the issue see: Katrin Helle, "Intelligente Medizinprodukte: Ist der geltende Rechtsrahmen noch aktuell?," *Medizinrecht* 38, no. 12 (December 2020): 993 et seq.

⁹³ See: Zech and Hünefeld, "Einsatz von KI," 4, who link the use of AI with therapy freedom ("freie Methodenwahl").

⁹⁴ Helle, "Intelligente Medizinprodukte," 998; Schmidt, "Die Auswirkungen," 345.

⁹⁵ Schmidt, "Die Auswirkungen," 346.

this criterion is specified by Article 3 of the Code of Medical Ethics.⁹⁶ Indeed, a systematic-teleological interpretation of the above articles which has as its reference point the best interest of the specific patient⁹⁷ (cf. Article 3 paragraph 3 of the Code, that refers to the choice of a method that is significantly superior to another for the patient in question), can only lead to the acceptance of the position that the use of artificial intelligence in medical practice in general does not constitute a breach of due medical care. To the contrary, given that, as demonstrated above, it is in principle a safer and more effective option for the patient, it has to be recognized as a permissible method. The opposite view works to the detriment of the patient. However, the choice rests with the patient, provided they have been adequately informed beforehand.⁹⁸ Here too, nevertheless, the final decision for or against the use of autonomous systems must be made by the physician based on a cost-benefit analysis. Of course, both in German and Greek law, risk assessments cannot be carried out *in abstracto*, but must be related to the particular autonomous system and the particular patient.

4.3. Duties of Medical Care When Using Autonomous Systems

The use of AI systems in the provision of medical services, although permissible, nevertheless entails certain obligations on the part of the physician/hospital to ensure that it is done in accordance with the required medical care. As in the case of any medical devices,⁹⁹ high safety and control requirements apply to the use of autonomous systems.¹⁰⁰ The physician is therefore required to be familiar with the basic functions of the AI system used¹⁰¹,

⁹⁶ In particular, the reference in paragraph 3 of the article to the physician's right to choose a method of treatment, which they consider to be significantly superior to another for the specific patient, based on the modern rules of medical science.

⁹⁷ For the patient's best interests as the decisive criterion for determining the medical due care, see: Fountedaki, *Civil Medical Liability*, 367 et seq.; Fountedaki, Gerasopoulou and Maroudas, *Civil Medical Liability*, 214–5, 224–5.

⁹⁸ See also for German law: Katzenmeier, "Haftung für Schäden," 80.

⁹⁹ See: Schmidt, "Die Auswirkungen," 347, with further citations on BGH case law.

¹⁰⁰ Katzenmeier, "Haftung für Schäden," 78. Zech and Hünefeld, "Einsatz von KI," 4.

¹⁰¹ Zech and Hünefeld, "Einsatz von KI," 4. See also the physician's lifelong learning duty to keep up to date with developments in medical science, Article 10 paragraph 1 of the Greek Code of Medical Ethics. For the same duties in German law, see: Kern and Rehborn, in *Handbuch des Arztrechts*, § 15 no. 22, § 96 no. 27 et seq.

with the way it works, as well as with the information related to its database.¹⁰² The latter is very important, since, as stated above, even self-learning algorithms function only with the data made available to them, and therefore any errors in the database will necessarily lead to incorrect results. Thus, the physician must ensure that the system is up to date, as well as critically evaluate its results against the background of current medical developments. They are also obliged to maintain it regularly and if they cannot do it themselves, the task should be entrusted to experts. Maintenance in the case of software systems means the immediate installation of current updates, patches, bug fixes, etc.¹⁰³ Furthermore, they must oversee their proper operation on a regular basis.¹⁰⁴ This duty applies to medical devices in general and, at least for the time being must also apply to autonomous systems in medicine. This is because, at present, these systems perform an auxiliary role. The physician is still the central figure in making diagnostic and therapeutic decisions, something that justifiably means that sufficient control of the (pre)decision made by the systems is required on their part.¹⁰⁵

In any case, irrespective of the physician's specific duties, which remain to be specified either in the context of case law or through the AI Act,¹⁰⁶ their general duty to use medical devices in such a way that any damage is prevented to the extent possible is intensified considerably when using AI systems, precisely due to the autonomy risk¹⁰⁷: that is, namely, not because autonomous systems present an increased risk *per se*, but because it cannot be ruled out that they may have come into contact with human error and thus produce incorrect results. As has been aptly observed, the best way to

¹⁰² Schmidt, "Die Auswirkungen," 347. See also: Katzenmeier, "Haftung für Schäden," 78.

¹⁰³ Schmidt, "Die Auswirkungen," 347.

¹⁰⁴ Katzenmeier, "Haftung für Schäden," 78.

¹⁰⁵ One may reasonably ask, however, whether and to what extent a physician can practically meet such an obligation, since, as discussed above, the action of autonomous systems *ex-ante* appears to be limitedly predictable and *ex-post* limitedly explainable. As rightly observed, the limited explainability of the autonomous system's activity may in fact constitute a limit, which, in relation to due medical care, could imply a limitation of what may be required of the average reasonably prudent physician, (see: Zech and Hünefeld, "Einsatz von KI," 4.)

¹⁰⁶ See: Section 3 of Chapter III of the "AI-Act". However, it should be noted that the "AI-Act" has no civil liability regulations.

¹⁰⁷ Spindler, "Medizin und IT," 588; Katzenmeier, "Haftung für Schäden," 78; Eichelberger, in *Künstliche Intelligenz*, § 4 I no. 41.

manage autonomy risk is by ensuring the appropriate formulation of the duties of care of the manufacturer, programmer, user, etc.¹⁰⁸ The question that arises, however, is how the patient can prove the breach of duty of care by the physician/hospital, and even more so the causal link between this breach and the incorrect output of the system, as well as that between the output and the damage sustained. The “black-box effect” seems to raise insurmountable evidentiary difficulties, to the point where the strength of the fault principle is tested, at least so long as the classic rule on the allocation of the burden of proof applies. Once again, nevertheless, we are confronted with a problem that must in principle be dealt with by the law of evidence.

4.4. The Physician’s Liability from the Use of Autonomous Systems

If the physician breaches any of the duties outlined above, we are faced with a medical error. If this breach leads to patient injury, under both German and Greek law, given the general outlines presented above, the physician shall be liable for damages. The use of autonomous systems in medicine seems, thus, to induce a transition, or rather a transformation of the traditional concept of medical error into a program application error (“Programmanwendungsfehler”).¹⁰⁹ Moreover, since no standards have yet been developed in relation to the use of self-learning systems, the criterion of the average reasonably prudent physician becomes of particular importance in this respect for German law as well.¹¹⁰ Therefore, both in Greek and German law a physician who demonstrates such conduct in the use of autonomous systems that falls short of that which the average reasonable physician of the relevant specialty would be expected to display in a similar case is considered to have committed a medical error. However abstract this formulation may seem, in the absence of specific standards it takes on particular significance in cases of medical liability.

¹⁰⁸ See: Digitaler Neustart, *Haftungsfragen*, 44.

¹⁰⁹ Hart, “Haftungsrecht und Standardbildung,” 675.

¹¹⁰ See: Zech and Hünefeld, “Einsatz von KI,” 3.

4.4.1. Similarities between German and Greek Law: The Fault Principle and Autonomy Risk –Evidentiary Difficulties of the Patient as the Real Problem in Question

The link between medical liability and the breach of a specific duty of care around the use/maintenance etc. of the autonomous system follows from the very nature of medical liability as subjective liability. Therefore, errors that are theoretically linked to the autonomous activity of the system are not attributable to the physician/hospital and are hence regarded as accidental damages,¹¹¹ with the result that the patient is liable for them on the basis of the “*casum sentit dominus*” principle.¹¹² The fault principle, in the form of objectified negligence, means that the physician is liable only for breaches of the above-mentioned duty of care, i.e. for errors in the system which the average reasonably prudent physician should have foreseen and therefore avoided. Accordingly, it is only by proving such an error that the patient can be awarded damages. As has been pointed out, in this sense, we are faced with a liability gap.¹¹³ The various theoretical arguments proposed in the context of German theory to fill this gap with tools of the applicable contract and/or tort law (e.g. arguments by analogy based on the provisions on vicarious liability or tort liability for animals) are not convincing and, as rightly observed, cannot be defended doctrinally.¹¹⁴ Autonomous systems do not, of course, operate in a legal vacuum, but are subject to current regulations; they are therefore governed by the fault principle, which, seems, *prima facie*, to be insufficient for effectively regulating the autonomy risk at a theoretical level.

A closer examination of the issue, however, reveals that the real question that needs to be asked is to what extent we are dealing with a “liability gap” (i.e. with the inadequacy of the fault principle), not in theory, but

¹¹¹ See: Sophie Burchardi, “Risikotragung für KI-Systeme–Zur Zweckmäßigkeit einer europäischen Betreiberhaftung,” *Europäische Zeitschrift für Wirtschaftsrecht* 33, no. 15 (August 2022): 686; Georg Borges, “Haftung für KI-Systeme — Konzepte und Adressaten der Haftung,” *Computer und Recht* 12, no. 9 (September 2022): 554.

¹¹² See: Katzenmeier, “Haftung für Schäden,” 80.

¹¹³ See, among others: Teubner, “Digitale Rechtssubjekte?,” 157 et seq., 185 et seq.

¹¹⁴ For these arguments, which have been exhaustively analyzed in the context of legal theory in recent years and for this reason it is considered unnecessary to be presented here, see, among others: Wagner, “Verantwortlichkeit,” 729 et seq.; specifically in the context of medical liability see: Katzenmeier, “Haftung für Schäden,” 80 et seq. and 82 et seq.

in practice, especially a gap of such a nature that could justify the reform of substantive law with the tools of risk-based strict liability. As has been pointed out already, AI systems do not present a risk in themselves, simply because they are autonomous. In this sense, the theoretical problem of attributing autonomous errors does not seem to justify a substantive law reform to the detriment of the fault principle. On the contrary, the fault principle, in its objectified form (see objectified negligence) appears to adequately protect the patient, at least at a substantive level, by imposing increased duties of care on the physician in relation to the use of AI systems. What is of particular importance, however, is the insurmountable evidentiary difficulties with which the patient is confronted, when it comes to proving the breach of one of these duties. The fault principle is inadequate precisely to the extent that it places the burden of proving hard-to-prove evidence on the injured patient. The “black-box effect” does not make autonomous systems dangerous, however, it makes the injured patient unable to identify the cause of their injury and thus deprives them of the chance to make any effective claim against the physician.

4.4.2. The Allocation of the Burden of Proof as a Critical Factor in Determining Medical Liability Arising from the Use of Autonomous Systems – Differences between German and Greek Law

In German law, the patient who sues the physician/hospital for compensation bears the burden of proving a medical error, the damage suffered, and the causal link between the error and the damage. In the context of damage arising from the use of an autonomous system, this means that they must, first of all, prove the breach of a duty of care related to the system, its causal link with the incorrect output, as well as the link between the latter with the damage sustained. Thus, the patient is required to prove not only the specific technical error but also that the average reasonably prudent physician should have been able to foresee and thus prevent that error.

However, just as the physician cannot perfectly foresee the behavior of the system, so *a fortiori* the patient, who, unlike them, does not know anything about the system, will not be able to explain it, let alone link it to the breach of a specific duty of care on their part, as required by the fault principle. Moreover, taking into account the inherent evidentiary difficulties the patient faces in relation to medical matters, in case they are unable to prove (a) the breach of a specific duty of care by the physician and

(b) its causal link with the damage suffered, they are the ones who must bear the financial consequences of the damage caused by the physician/hospital.¹¹⁵ The allocation of the burden of proof on the basis of the general rule has, in this case, the peculiar effect of a “shifting” liability (in the sense of a “Haftungsverlagerung”) to the detriment of the patient.¹¹⁶ Moreover, the provisions of § 630h I BGB¹¹⁷ cannot be applied in the patient’s favor. Unlike most technical devices, whose operation falls within the concept of fully controllable risk,¹¹⁸ autonomous systems are beyond the full control of the user.¹¹⁹ This provision cannot be applied even through teleological reduction,¹²⁰ for its letter is perfectly clear: it refers to a “voll beherrschbares Behandlungsrisiko.”¹²¹ Any other approach constitutes an impermissible *contra legem* interpretation. On the contrary, there seem to be grounds for the application of § 630h V BGB,¹²² since errors in the use/maintenance of the autonomous system can and should be considered medical errors. Thus, in the case where a physician fails, for example, to install a very important update to the AI software, it seems to be possible to argue that this omission is linked, for example, to an incorrect diagnosis to the detriment of the patient (rebuttable presumption of causality).

It is clear that the provisions of German law appear unfair, at least in terms of assessments related to the spheres of influence of the parties

¹¹⁵ On how the burden of proof works in *non-liquet* cases, see, among others: Hanns Prütting, *Münchener Kommentar zur Zivilprozessordnung: ZPO, Band 1: §§ 1–354*, 6th ed., eds. Wolfgang Krüger and Thomas Rauscher (München: C.H. Beck, 2020), § 286 no. 107 et seq. Furthermore, on the practical significance of the burden of proof in cases of tort liability, see, among others: Ernst Karner, “The Function of the Burden of Proof in Tort Law,” in *European Tort Law 2008*, eds. Helmut Koziol and Barbara C. Steininger (Vienna: Springer Wien New York, 2009), 68 et seq.

¹¹⁶ On the rules on the allocation of the burden of proof as a means of “shifting” liability from one party to another, see: Hans Stoll, “Haftungsverlagerung durch beweiserrechtliche Mittel,” *Archiv für die civilistische Praxis* 176, no. 2/3 (1976): 145 et seq.

¹¹⁷ Presumption of a medical error due to fully manageable general treatment risk (“voll beherrschbares Behandlungsrisiko”). See herein fn. 57.

¹¹⁸ Deutsch and Spickhoff, *Medizinrecht*, no. 796.

¹¹⁹ Oliver Brand, “Haftung und Versicherung beim Einsatz von Robotik in Medizin und Pflege,” *Medizinrecht* 37, no. 12 (December 2019): 950; Spindler, “Medizin und IT,” 593.

¹²⁰ See: Brand, “Haftung und Versicherung,” 950.

¹²¹ Schmidt, “Die Auswirkungen,” 351.

¹²² See among others: Deutsch and Spickhoff, *Medizinrecht*, no. 374 et seq.

(“Sphärenbetrachtungen”). This is because they entail a distribution of risk at the expense of a person who has no control or influence over the autonomous system. On the contrary, the physician/hospital is able to influence its operation (to a certain extent), for example, by employing qualified staff to control, maintain, and/or monitor it. Be that as it may, it seems unfair that the patient should bear the adverse consequences of a *non-liquet* situation when the physician/hospital derives financial and professional benefits from the use of the system (“Vorteilsziehung”).¹²³ We are therefore faced with the realization that legislative interventions in the law of evidence for the benefit of the patient seem imperative at this point.

In contrast to German law, the situation is different in the context of Greek law. Indeed, as demonstrated above, it is not the patient who bears the burden of proving the medical error and its causal link to the harm suffered, but the physician who must prove (a) that they did not commit a medical error, and (b) that there is no causal link between the patient’s harm and the presumed error. The patient therefore has two very powerful weapons in their evidentiary arsenal; namely, a presumption of medical error and a presumption of causation. In the context of injury sustained from the use of an autonomous system, this means that it is presumed that the physician has committed an error in connection with the use/maintenance of the system, as well as that this error is causally related to the patient’s injury. The presumption of error has precisely the meaning that in case of doubt, the physician has breached a duty of care, whereas the presumption of causation means that in case of doubt the patient’s injury is due to that (presumed) breach of the duty of care. It is, therefore, the physician/hospital that bears the adverse consequences of autonomy risk, since they are the ones who are faced with the evidentiary difficulties arising from the operation of the system, i.e. they have to prove that the patient’s injury is not due to an error in relation to the use/maintenance etc. thereof.

However, it seems that the physician may find it easier, or rather less difficult, to meet this burden of proof than the patient in the opposite case (see German law). This is because it is sufficient for them to prove that they

¹²³ See: Jürgen Oechsler, “Die Haftungsverantwortung für selbstlernende KI-Systeme,” *Neue Juristische Wochenschrift* 75, no. 38 (September 2022): 2713, 2714 et seq.

have complied with the duties of care inherent in the use and maintenance of the AI system and, accordingly, that the patient's injury was caused by an error in the system, which even the average reasonably prudent physician of the respective specialty could not have foreseen and prevented. With all the difficulties that the limited explainability of the system's behavior ("black-box effect") entails for this proof, it seems to constitute an allocation of the burden of proof that is fairer than that imposed by the general principle in German law. This is because the autonomous system is within the sphere of influence of the physician/hospital,¹²⁴ and certainly to a much greater extent than that of the patient, who will, in all likelihood, not know anything about it.¹²⁵ The "black-box effect" certainly affects the physician/hospital, but it affects the patient much more, as the latter does not have, nor is required to have, the slightest insight into the respective technical matters. Thus, it can in no way be used as an argument for allocating the burden of proof in favor of the physician, since, in most cases, the patient will have a much greater information deficit than they. If the "black-box effect" is to be used as an argument in favor of anyone, at least in matters of burden of proof, this can be no one else apart from the patient. For all the lack of absolute transparency around the operation of the autonomous system, the physician is demonstrably closer to it than the patient, and in any case, has access to much more information than the latter. After all, the physician/hospital derives economic and operational benefits from the use of the system, so it only seems fair, even from this point of view, that they should bear the respective burden of proof.

Contrary, therefore, to what is the case in traditional medical liability, where the provision of Article 8 has been rightly criticized as doctrinally inappropriate to regulate the allocation of the burden of proof, the opposite seems true in cases where AI systems are used. The provision implies a balancing solution that takes into account the interests of both the patient and the physician/hospital and, in any case, in the dilemma of who should bear

¹²⁴ At least to some extent.

¹²⁵ See also: Brand, "Haftung und Versicherung," 950, who proposes a teleological reduction/corrective interpretation of § 630h I BGB in order to include autonomous systems in the presumption of fault, and this on the basis that the autonomous system belongs to the organizational domain of the physician/hospital.

the adverse consequences of a *non-liquet* situation due to autonomy risk, chooses, even when unknowingly,¹²⁶ the latter.

The physician/hospital is the one who has chosen to apply an autonomous system in their organization; they are the ones who have put it into operation to serve their professional interests, and they decide on the place, time, and manner of its use.¹²⁷ They are also demonstrably closer to it and they, upon the correct observance of the relevant duties of care, can to a sufficient extent prevent or deal with the occurrence of any errors. Accordingly, they are in the position to employ qualified personnel to ensure that the system is used in the best possible way. The bottom line is that the physician is in a much more advantageous position than the patient and it is only fair that they should bear the burden of proof in relation to autonomy risk.¹²⁸ Greek medical law thus appears, even if unwittingly, to be better prepared to welcome the use of autonomous systems in medical practice in matters of civil liability.¹²⁹

¹²⁶ Basically, literally without the knowledge of the legislator, in view of the fact that this is a 1994 provision.

¹²⁷ See: Zech, “Entscheidungen digitaler autonomer Systeme,” 88.

¹²⁸ It is also worth noting that a similar solution (presumption of fault and presumption of causality) for damages caused by the use of artificial intelligence in general, was proposed by the European Commission in its White Paper on Artificial Intelligence (See reference in Wagner, “Verantwortlichkeit,” 736–7 with further references), as well as by the European Parliament in the context of the European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)), (see Article 4 and 8 of the Proposal in <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020IP0276>, accessed February 22, 2024); thus, with the exception of high-risk AI systems, for which strict liability of the user is considered the most appropriate solution, the Commission and the Parliament adhere to the fault principle, while considering it necessary to make it easier for injured parties to prove fault and causation by introducing presumptions of fault and causation, thus opting for the solution of liability for presumed fault and presumed causation. It is clear that at the level of medical liability such a solution has identical content and effects to Article 8 of the Greek Consumer Protection Law.

¹²⁹ See also 73. Deutscher Juristentag. Bonn 2022, *Beschlüsse*, 6, accessed February 23, 2024, <https://djt.de/wp-content/uploads/2022/09/Beschluesse.pdf>, according to which the liability of the user must be formulated as liability for presumed fault corresponding to that of the provisions of §§ 831 I, 836 I BGB.

5. Conclusion

AI systems pose a significant challenge to fault-based medical liability systems. This, however, is not so much due to the substantive features of the fault principle *per se*, but rather to the general rule for allocating the burden of proof, precisely to the extent that it applies in parallel with the fault principle. According to this rule, the injured party is required to prove the facts that form the minimally required factual content of the legal rule upon which their claim is based. Namely, under a fault-based regime, they are required to prove the specific human error in the use of the system (as well as who committed it) and the causal link between the error, the output of the system, and the damage sustained.

Indeed, the fault principle in terms of substantive law seems to protect the patient to a satisfactory degree, as it imposes increased duties of care in relation to the autonomous system on the physician/hospital. However, the particular characteristics of AI (i.e. learning ability, limited predictability, complexity, opacity, and openness) create insurmountable evidentiary obstacles for the victim, who, in cases of medical liability, is at the same time confronted with difficult evidentiary problems concerning medical matters as well. These problems become even greater given the practical difficulty of accurately separating the areas of responsibility of the various subjects associated with the autonomous system in question. In the context of German law, things look very difficult for the patient, who, in order to succeed in bringing a successful liability claim, has to overcome the “black-box effect” obstacle and prove a specific fault of the physician/hospital (i.e. breach of duty of care in relation to the system), a causal link between this fault and the incorrect output of the system, and a corresponding causal link between the latter and the damage suffered. To the extent, however, that the plaintiff has an obvious knowledge deficit in relation to both medical and technical matters, it is clear that they will never be able to meet this burden of proof, with the result that they will almost always have to bear the adverse consequences of a *non-liquet* situation and, ultimately, the autonomy risk itself. On the contrary, the solution under Greek law seems to be much fairer. This is because the provisions of Article 8 of the Greek Consumer Protection Law have the effect that the physician bears the burden of proving the absence of an error and of a causal link between that (presumed) error and the damage suffered. This in turn means that the risk of any harm

resulting from the autonomous activity of the system is in case of doubt borne by the physician.

It is therefore evident that the main practical issue that one is faced with in the case of autonomous systems in medical liability is not the autonomy of the AI systems as such, but mainly the evidentiary problems arising from it. The fault principle can thus be tolerated only to the extent that the general rule on the allocation of the burden of proof is abandoned in favor of alleviations of the burden of proof in favor of the patient, since unlike the physician/hospital, the former has no control or influence whatsoever over the autonomous system, nor do they derive any financial benefits from its use. It is obvious that a purely subjective liability must give way to liability for a presumed fault (in the sense of error) and causality for it can in no way be tolerated that the patient shall bear the risk of a *non-liquet* due to the “black-box effect”. Such a change seems thus imperative in pure subjective liability systems such as the German law. On the contrary, Greek law seems in this respect, even if unwittingly, innovative and certainly capable of coping with the serious evidentiary problems posed by the “black-box effect” in medicine.

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