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Allocating the Burden of Proof in Medical Liability: A Comparative Perspective

Abstract: This article examines the allocation of the burden of proof in medical liability. The paper is oriented toward a comparative law analysis, drawing on examples from various countries. It discusses The Concept of Proof and its Content, the Grounds for Allocating the Burden of Proof, and The Allocation of the Burden of Proof in American, German, and English Law, with particular attention to The Rule for Distributing the Burden of Proof in Medical Law, Reversing the Burden of Proof in Cases of Gross Medical Negligence, and Fully Controllable Risk as a Basis for Reversing the Burden of Proof.

In this context, the legislation and judicial practice of both Continental and Anglo-American law countries are analyzed. The paper provides a detailed discussion of both statutory provisions and case law, as well as doctrinal debates, reflecting the specific challenges faced by plaintiffs in medical disputes.

The study is enriched with examples from judicial practice, which give a practical dimension to the theoretical discussion and highlight the significance of judicial interpretations in shaping the doctrine of medical liability.

Keywords: medical law, causation, burden of proof, medical liability, medical disputes, comparative analysis

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Introduction

This article uses a comparative legal analysis to examine the allocation of the burden of proof in medical liability disputes through. The study explores how different legal systems address causation, evidentiary standards, and the reversal of the burden of proof in cases of gross medical negligence. By situating these rules within the broader framework of tort law and civil procedure, the article contributes to ongoing debates in medical law and comparative law. The findings are particularly relevant to scholars and practitioners interested in how evidentiary doctrines shape access to justice in medical disputes, and how legal systems balance the rights of patients and healthcare providers.

The article aims to examine the problem of determining the burden of proof in medical disputes. In this regard, international legislation and case law will be analyzed. It is beyond doubt that medical disputes are a specific and particularly complex area of law. In such cases, on one side stands the relatively strong party in the relationship, namely, the medical institution, and on the other, the weaker party, the patient, who has suffered harm as a result of the actions of the medical service provider. The challenge in medical disputes lies in the correct allocation of the burden of proof and in the ability of the party to overcome it. Very often, it is not only difficult but even impossible for the party to establish a causal link between the conduct of the medical provider and the harmful result. Moreover, collecting evidence is particularly difficult for the weaker party. Ultimately, this excessively increases the burden of proof on the claimant to such an extent that the satisfaction of their claim becomes practically impossible.

In this context, the legislation and judicial practice of both Continental and Anglo-American law countries are analyzed. The article provides a detailed discussion of both statutory provisions and case law, as well as doctrinal debates, reflecting the specific challenges faced by plaintiffs in medical disputes. This is enriched with examples from judicial practice, which give a practical dimension to the theoretical discussion and highlight the significance of judicial interpretations in shaping the doctrine of medical liability.

The Concept of Proof and Its Content

The Concept of the Burden of Proof in German Law

The principles of the burden of proof are not regulated by law in the German legal system. In German civil procedural law, it is established as a general principle that the burden of proof for facts giving rise to a right lies with the claimant (creditor) or the person exercising the claim. Conversely, the burden of proof for facts that extinguish or impede a right falls on the defendant (debtor). Generally, according to German procedural law theory, the process of presenting, collecting, examining, and evaluating evidence by the parties and the court is referred to as proof. To “prove” something means to convince the court of the accuracy of the facts presented.²

In Germany, the Doctrine on the Allocation of the Burden of Proof is regarded as a component of substantive law, not procedural law. Although procedural legislation incorporates the concept of the burden of proof and provides general rules for its distribution, the concrete allocation of this burden in individual cases is determined by substantive legal norms.³ Accordingly, the rules governing the burden of proof in Germany are regarded as a component of substantive law.⁴ The German Code of Civil Procedure sets a high standard of proof for civil proceedings. Facts must be established according to a standard of practical certainty; otherwise, the claim is regarded as unfounded.⁵

Although the general standards for the law of evidence are quite clear and understandable, German law provides for various possible deviations from these principles. These deviations arise from circumstances such as general life experience and the judge’s efforts to ensure that the distribution of the burden

2 Marc S. Stauch, “The General Approach to Proof,” in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 62–64.

3 Stauch, “The General Approach to Proof.”

4 Judgement of the Federal Court of Justice of Germany of 3 April 2001—XI ZR 120/00; BGHZ 147: 203; Judgement of the Federal Court of Justice of Germany of 1 March 2014—X ZR 150/11; NJW 2014: 2275; Judgement of the Federal Court of Justice of Germany of 16 October 1996—IV ZR 154/95; NJW-RR 1997: 152.

5 Nina Cek, “The Standards of Proof in Medical Malpractice Cases,” *Medicine, Law & Society* 13, no. 2 (2020): 185, <https://doi.org/10.18690/mls.13.2.173-196.2020>.

of proof among the parties adheres to the principle of fairness. However, there are a number of cases where it becomes impossible for a party to meet the burden of proof. This problem is not unique to Georgia but also exists in German courts. One solution is to ease the standards of the burden of proof.⁶ For example, in medical malpractice cases, German courts have established a practice that in certain situations, it is justified to reverse the burden of proof. If an injury corresponds to a risk typical of a medical treatment and if the doctor could have objectively controlled it, this is regarded as grounds for a presumption of medical error. In this regard, the German Constitutional Court deliberated and noted that since the court is obligated to ensure the equality of the parties in a proceeding, reversing the burden of proof may be necessary in some cases.⁷

Grounds for the Allocation of the Burden of Proof

General and Special Rules for Allocation of the Burden of Proof

The allocation of the burden of proof is a fundamental aspect of civil litigation. As a rule, the plaintiff must prove the facts upon which their claims are based. Conversely, the defendant must prove the circumstances that provide grounds for denying those claims. In civil cases, the basis for delivering a reasoned judgment lies in identifying the legal foundation from which the dispute between the parties arises. Therefore, the court's primary function in reviewing a dispute is to determine the material basis of the claim and the legal norm on which it is founded. The court is limited by the factual circumstances of the lawsuit. It verifies whether the factual circumstances stated in the lawsuit meet all the prerequisites of the founding legal norm. Only after this initial check should the court examine how the defendant's position refutes the circumstances mentioned in the lawsuit.⁸

⁶ *EEOC v. United Parcel Serv., Inc.*, No. 09-cv-5291, 2013 WL 140604, at *4-7 (N.D.Ill. Jan. 11 2013); *Coleman v. Md. Court of Appeals*, 626 F.3d 187, 190-91, 4th Cir. 2010.

⁷ BVerfG (Constitutional Court of Germany), Decision of 25 July 1979. NJW 1979: 1925.

⁸ Ruling of the Supreme Court of Georgia of 16 November 2018, Case No. AS 860-860-2018.

Although a general rule for distributing the burden of proof exists in civil procedure, courts sometimes apply a specific rule for distributing the burden of proof, which is directly regulated by law. A special rule for the distribution of the burden of proof applies in tort law, as well as in labor law and anti-discrimination law. This difference is dictated by the specific nature of the legal relationship, the difficulty of proving certain facts, and the objective ability or inability to present evidence.⁹ Therefore, in such cases, the burden of proof is reversed, meaning the obligation to prove facts presented by one party may be shifted to the other party.¹⁰

The Allocation of the Burden of Proof in American, German, and English Law

In German law, the allocation of the burden of proof is not codified in civil legislation but follows established doctrine. Generally, the creditor must prove facts giving rise to a right, while the debtor must prove facts that extinguish it. The burden of proof is assessed under substantive legal norms, making the debtor–creditor relationship central. As in other European countries, Germany treats this doctrine as part of substantive rather than procedural law. Although procedural rules set general principles, the specific distribution in individual cases depends on substantive norms. Thus, the doctrine is firmly rooted in substantive law.¹¹ In German civil law, it is established that the burden of proof with respect to facts giving rise to a right rests with the creditor or the person exercising the claim, whereas the burden of proof regarding facts that extinguish or impede a right falls on the debtor.

9 Ketevan Meskhishvili, “Procedural Standard for Allocating the Burden of Proof,” in *Commentary on the Civil Procedure Code, Selected Articles* (2020), 420–21.

10 Decision of the Civil Chamber of the Supreme Court of Georgia of 15 September 2011, Case No. AS-711-670-2011.

11 Judgement of the Federal Court of Justice of Germany of 3 April 2001—XI ZR 120/00; BGHZ 147: 203; Judgement of the Federal Court of Justice of Germany of 1 March 2014—X ZR 150/11; NJW 2014: 2275; Judgement of the Federal Court of Justice of Germany of 16 October 1996—IV ZR 154/95; NJW-RR 1997: 152.

It is also worth noting the “preponderance of evidence” standard in the United States. According to this standard, the plaintiff must demonstrate that the facts supported by their evidence are more than 50% likely to exist.¹² The approach in Great Britain is also interesting, where the standard of proof is lower due to the adversarial principle. The UK uses the “balance of probabilities” standard, which means a party is required to prove that the existence of a fact is more probable than its non-existence.¹³

The Rule for Distributing the Burden of Proof in Medical Law

As mentioned, courts use a special rule for distributing the burden of proof in medical cases. In cases of civil liability, the issue is often the negligence of medical personnel, which occurs when they fail to use all available means to prevent risks.

The established approaches to causation have gradually changed in European countries. It became clear that due to the heavy burden of proof, it was nearly impossible for patients to win medical malpractice lawsuits. As the Canadian Supreme Court pointed out in a *Nell v. Farrell*, a judge can reverse the burden of proof based on the specific circumstances of a case.¹⁴ This trend toward easing the burden of proof is also supported by the Court of Justice of the European Union, which was approached by the French Supreme Court for an interpretation of the EU Product Liability Directive.

In any legal dispute initiated against a medical institution it is essential that the patient proves that the physician’s actions did not conform to generally accepted medical standards.¹⁵ Accordingly, in order for a claim for

12 Michael Blome-Tillmann, “‘More Likely Than Not’—Knowledge First and the Role of Bare Statistical Evidence in Courts of Law,” in *Knowledge First: Approaches in Epistemology and Mind*, ed. J. Adam Carter et al. (Oxford University Press, 2016), 278–90.

13 Cek, “The Standards of Proof in Medical Malpractice Cases,” 185.

14 *Snell v. Farrell*, [1990] 2 S.C.R. 311.

15 Marc S. Stauch, “England: The ‘But For’ Test,” in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 46–48.

compensation to be granted, the patient must also establish the existence of a causal link.

In medical malpractice cases, establishing a causal link between the actions of the healthcare provider and the harm suffered by the patient presents a particular challenge. This complexity often arises from the interplay of multiple factors or actions, each of which may independently or jointly serve as a necessary condition for the harm. While a specific act may indeed serve as the cause of the damage, it is essential to recognize that, in matters concerning a patient's health, a wide range of additional factors may influence the outcome. These may include the individual characteristics of the patient's body, psychological condition, delayed access to medical care, and other relevant circumstances.

Judicial determinations of causation rely heavily on an expert medical opinion, yet establishing a direct causal link is often difficult or even impossible. Of particular note in this context is the possibility that evidence may be lost or disappear.¹⁶ Moreover, expert reports rarely provide categorical conclusions, often lacking thorough factual analysis and sufficient detail to fully clarify the case.

In a specific case, the plaintiffs filed a lawsuit against the vaccine manufacturer Sanofi. The plaintiffs claimed that the vaccine had caused multiple sclerosis in their relative, which had led to their death in 2011. In its decision, the court discussed Article 4 of the EU Product Liability Directive, stating that under this directive, the plaintiff must prove the existence of causation.

It should be emphasized that the court indicated that when scientific research does not physically allow for the establishment of a causal link between the conduct and the result, the claimant must be granted the right to rely on other evidence to substantiate his or her position. For example, the short period of time between the administration of the vaccine and the onset of the illness, the absence of the disease in the family medical history, and similar circumstances.

¹⁶ Stauch, "England: The 'But For' Test," 46.

This judgment illustrates a relaxation of the burden of proof, permitting the defendant to establish causation with less effort by submitting alternative evidence when expert reports cannot confirm a direct link between the doctor's action and the injury. The court evaluates and weighs such evidence in its decision. While certain facts may be inherently difficult or impossible to prove, this should not impose barriers on the plaintiff that undermine the principles of adversarial proceedings and equality.

Instances of Reversing the Burden of Proof

Reversal of the Burden of Proof in Cases of Gross Medical Error

In the process of establishing causation and, consequently, in the redistribution of the burden of proof, particular significance is attached to the case of gross medical error as codified in paragraph 630h VI of the German Civil Code.¹⁷ In particular, according to judicial practice, when a physician commits a gross medical error, which by its very nature entails the possibility of causing harm to life, body, or health, the burden is placed upon the physician to prove the absence of damage, that is, to demonstrate that the harm was not caused by the breach of duty and that it would have occurred even in the absence of the error.¹⁸

As the Federal Supreme Court notes, a medical error is regarded as gross when, based on the standards of the medical field and the doctor's level of education, the action is clearly wrong. In such a case, gross medical behavior can exist even without carelessness being shown. The key factor is the objectively wrong nature of the action itself, which runs contrary to universally accepted medical standards.¹⁹

According to Part V of Article 630 of the German Civil Code, if a health-care provider commits a gross medical error, the burden of proof shifts to

17 Ulich Hagenloch, "Important Trends in German Judicial Practice in the First Half of 2022," *Journal of Medical Law and Management*, no. 1 (2024): 1.

18 Katzenmeier, "§ 630h Burden of proof in liability for errors in treatment and information," in *BeckOK BGB, Hau/Poseck*, 75th ed. as of: 1 August 2025 (C.H. Beck, 2025), 52.

19 "§ 630h Burden of proof in liability for errors in treatment and information," 57.

them.²⁰ Consequently, the patient no longer has to prove that the harm would not have occurred without the medical error.²¹ From a medical perspective, the failure to implement necessary measures constitutes a gross medical error. This includes cases where a doctor fails to perform the required examination, does not conduct all tests specified by standard procedure, and so on.²² In accordance with the consistent practice of the German Federal Supreme Court, such gross medical errors lead to a reversal of the burden of proof.²³

An important decision by the German Federal Supreme Court²⁴ involved a plaintiff seeking compensation for material and non-material damages from a medical error during birth. The mother was admitted to the hospital seven weeks early after her waters broke. Initial cardiotocography (CTG) scans were mostly normal. However, two days later, she reported pain, and CTG showed a decreased fetal heart rate. From 7:00 AM to 7:30 AM, the patient underwent another CTG, and the results no longer showed an alarming rate. On the same day, around 13:10, the mother again reported pain that had begun around 11:00 AM. After a CTG performed at 13:16 failed to detect the fetus's heartbeat, and a subsequent ultrasound showed fetal bradycardia (a slow heart rate), the baby was born at 13:37 via an emergency C-section without breathing or heart activity.

The plaintiff argued that due to this improper treatment, he suffers from severe intellectual disability and significant hearing and vision impairments. He claimed that the doctors failed to inform his mother about the need for immediate action during labor pain, causing her to delay reporting the onset of pain from 11:00 AM until around 13:10.

20 Marc S. Stauch, "Reversals of Proof in Cases of 'Gross' Treatment Errors," in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 87–89.

21 Karl O. Bergmann, Carolin Wever, *Die Arzthaftung: Ein Leitfaden für Ärzte und Juristen* [Medical Liability: A Guide for Doctors and Lawyers] (Springer Berlin Heidelberg, 2014), 14.

22 Tobias Wagner, „BGB § 630h,” in *MüKo/BGB*, 8th ed. (C.H. Beck, 2020), Rn. 99.

23 Wagner, „BGB § 630h,” Rn. 99.

24 Judgement of the Federal Court of Justice of Germany of 24 May 2022, VI ZR 206/21, NJW 2022, 2747.

The complex issue in this case was whether the hospital fulfilled its duty to provide therapeutic information. The mother's amniotic sac had broken seven weeks early, posing risks of premature birth, complications, and possible death. The hospital failed to inform her of these risks, and the key question was whether proper information could have prevented the plaintiff's adverse outcome.

The court considered how the case's specific circumstances affected the burden of proof for causation. It noted that had the mother received proper therapeutic advice, a CTG would have been performed shortly after 11:00 AM. The Federal Supreme Court reaffirmed that a medical error is gross when a doctor violates established medical rules or standards. The Court emphasized that mere uncertainty about whether the mother would have followed advice is insufficient to deny reversal of the burden of proof, noting it was highly likely she would have reported the pain immediately if fully informed of the risks.

According to German case law, if a violation is gross, the burden of proof falls on the doctor.²⁵ A gross error involves a doctor failing to diagnose meningitis in a patient, despite clearly expressed symptoms.²⁶ It would also be a case where a doctor did not perform a mandatory medical examination or treatment that was necessary in a specific situation.²⁷

On 23 January 2020, the Higher Regional Court of Munich delivered an important decision. The court based its review on Paragraph 630h (5) of the German Civil Code, which states that if a doctor's conduct constitutes gross medical error and endangers a patient's life or health, it is presumed that the harm was a result of the improper treatment. In this particular case, it was determined that a serious error during treatment caused paraplegia in a minor. Based on this finding, the burden of proof shifted to the medical facility. Ultimately, the clinic was ordered to pay €500,000 in pain-suffering compensation, as well as to fully reimburse all past and future expenses related to the medical error.²⁸

25 Judgement of the Federal Court of Justice of Germany of 4 October 1994, VI ZR 205/963.

26 Judgement of the Higher Regional Court Stuttgart of 31 October 1996, ref. 14 U 52/95.

27 Judgement of the Federal Court of Justice of Germany of 29 March 1988—VI ZR 185/87.

28 Judgement of the Higher Regional Court Munich of 23 January 2020, ref. 1 U 2237/17.

The German Civil Code clearly states that in cases of a gross medical error, the burden of proof is reversed. Such an error is so significant and obvious that it creates a presumption of a professional duty breach by the doctor. As a result, it is presumed that the harm to the patient was directly caused by this error. This presumption shifts the obligation to prove the absence of a causal link from the patient to the medical facility.

Fully Controllable Risk as a Basis for Reversing the Burden of Proof

German courts have repeatedly deliberated on standards for easing the burden of proof. The central question in these deliberations was whether a common risk inherent in treatment should be considered a “controllable risk” and thus be a basis for a presumption of medical error.²⁹

In response to this issue, German courts developed the “doctrine of fully controllable risks” for medical malpractice cases.³⁰ The goal of this doctrine is to ease the standard of proof or, in some cases, shift the burden to the medical facility.³¹ The doctrine of fully controllable risks implies that if a problem arises entirely within the doctor’s sphere of responsibility, it is presumed to be caused by the doctor’s negligence. For instance, this could apply if a patient’s brain damage is caused by a malfunction in the oxygen system during anesthesia.³² This approach is also gaining recognition in German law, where the burden of proof is often reversed in favor of the patient to ensure a legal balance. This is why Paragraph 630h of the German Civil Code allows for the burden of proof to be shifted in the patient’s favor.³³ Specifically, it is presumed

29 Stefanie Greifeneder, “Germany,” in *The Healthcare Law Review*, ed. Sarah Ellson, 5th ed. (The LawReviews, 2021).

30 Marc S. Stauch, “Fully Masterable Risks,” in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 74.

31 Mauro Bussani et al., *Common Law and Civil Law Perspectives on Tort Law* (Oxford University Press, 2020), 68.

32 Marc S. Stauch, “Medical Malpractice and Compensation in Germany,” *The Chicago-Kent Law Review* 86, no. 3 (2010): 1154.

33 Wagner, “BGB § 630h,” Rn. 1, 2.

that the risk was fully controllable for the healthcare provider, and therefore, the burden of proof is entirely shifted to the defendant.³⁴

English courts share this view, noting that it is often very difficult for a patient to establish a causal link between the actions of a healthcare provider and the harm they suffered. When part of the unlawfulness resulting from the physician's conduct remains unclear, the burden of proof must be shifted in such a way that the uncertainty is not used to the advantage of the defendant.

An interesting example is the case of *McGhee*. In this case, the plaintiff, an employee of the National Coal Board, filed a lawsuit against the company, arguing that he contracted an illness due to the company's negligence. The company failed to provide adequate washing detergent which forced the plaintiff to ride his bicycle home with dust on his hands. This led to him developing dermatitis. The central issue was whether workplace dust caused the plaintiff's condition. The House of Lords held that the defendant's breach of safety and hygiene regulations substantially contributed to the injury. Although the "but for" test was not satisfied, the court found that the defendant's negligence created a risk of harm, shifting the burden of proof to the defendant to show that their actions did not cause the specific outcome.³⁵

A different decision was reached by the court in the case of *Wilsher v. Essex Area Health Authority*.³⁶ In this case, there were several factors that could have caused the harm, and they all had equal significance in causing the outcome. The case involved a premature baby who became blind during treatment in the defendant clinic's postnatal unit. The court determined that the hospital staff had administered an excessively high dose of oxygen to the infant during the first weeks of its life. Although this factor may have played a decisive role in the child's loss of sight, four or five alternative causes were also identified, each of which had the potential to cause the same outcome. In this case, it was

34 Marc S. Stauch, "Treatment Malpractice—Proof Issues," in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 74–75.

35 *McGhee v. National Coal Board* [1973] 1 WLR 1.

36 *Wilsher v. Essex Area Health Authority* [1988] AC 1074.

impossible to determine with certainty that the medical facility's specific action caused the child's blindness. This circumstance failed to meet the requirements of the "but-for" test,³⁷ because it could not be said with certainty that the child would not have lost his sight without excessive oxygen saturation.³⁸

A common ground for reversing the burden of proof is a medical facility's failure to properly maintain records. Physicians are obliged to document all essential measures in line with regulations, including the patient's history, treatment details, and related information.³⁹ According to Paragraph 630F of the German Civil Code, a medical facility is obligated to maintain complete medical records, which involves the medical facility having to include all procedures performed on the patient and attach all necessary documents.⁴⁰

Courts in both the Continental European and Anglo-American legal systems share a unified approach on this matter. When a medical facility breaches its duty to maintain medical records, the patient is completely relieved of the burden of proof, and this obligation shifts to the medical facility. Paragraph 630h(3) of the German Civil Code explicitly states that if a treating party has not maintained medical records containing information about necessary treatment measures and their results, it will be presumed that the party did not perform these measures or medical procedures.⁴¹

The English courts take a similar approach, noting that the plaintiff is at a disadvantage compared to the medical facility. The defendant has access to all the medical records and necessary expertise, while the patient does not. Therefore, the medical facility is strictly required to present all necessary documentation during the legal proceedings.⁴²

37 Marc S. Stauch, "Factual Causation," in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 48.

38 Marc S. Stauch, "Causation Issues in Medical Malpractice: A United Kingdom Perspective," *Annals of Health Law* 5, no. 1 (1996): 253.

39 Katzenmeier, "§ 630," in *BeckOK BGB*, 53rd ed. (C.H. Beck, 2020), Rn. 113

40 Hagenlocher, "Important Trends in German Judicial Practice in the First Half of 2022," 1.

41 Peter Lanzer, ed., *Catheter-Based Cardiovascular Interventions, Knowledge First: Approaches in Epistemology and Mind* (Springer eBooks, 2013), 79.

42 Richard A. Lodge, "A Matter of Fact: Establishing Facts in a Medical Negligence Case," *Medical Negligence and Personal Injury Blog* | Kingsley Napley (Blog), published 10 May

In both German and English law, missing medical documentation significantly affects the burden of proof and judgment. German courts take a stricter stance, presuming a medical error when record-keeping duties are breached. By contrast, English courts adopt a more flexible approach, allowing facilities to rely on alternative evidence, such as witness testimony, to defend their position.

The Doctrine of Res Ipsa Loquitur

The doctrine of Res Ipsa Loquitur originated in England in 1863 and is now widely used in both English and American legal systems.⁴³ It is somewhat similar to the German “fully controllable risks” doctrine, as well as the principle of reversing the burden of proof in cases of gross negligence. The essence of this doctrine is that a doctor’s conduct is so far below the acceptable standard of care that it is regarded as negligence on the face of it (*prima facie*). Under Res Ipsa Loquitur, a plaintiff can create a presumption of negligence on the part of the defendant if they can prove the following circumstances: The injury would not have occurred without negligence; the cause of the injury was entirely under the defendant’s control; there is no other logical, alternative explanation for the injury.⁴⁴ This doctrine is also frequently used by courts in the United States. In such instances, the existence of harm implies that it was caused by negligence, creating a presumption of negligence.⁴⁵ Consequently, the burden of proof to show the opposite shifts to the defendant.⁴⁶ For this to apply, three preconditions must be met: (1) The incident is of a type that typically does not occur without negligence; (2) The incident was caused by something exclusively under the defendant’s control; (3) The plaintiff is not

2025, <https://www.kingsleynapley.co.uk/insights/blogs/medical-negligence-and-personal-injury-blog/a-matter-of-fact-establishing-facts-in-a-medical-negligence-case>.

43 Marc S. Stauch, “England: Res Ipsa Loquitur,” in *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing, 2008), 70–72.

44 *Ybarra v. Spangard*, 25 Cal. 2d 486 (Cal. Dec. 27, 1944).

45 Stauch, “England,” 70–72.

46 *Ybarra v. Spangard*, 25 Cal. 2d 486 (Cal. Dec. 27, 1944).

at fault for the harm (excluding contributory negligence).⁴⁷ This doctrine was notably applied in the case of *Byrne v. Boadle*, where a pedestrian was injured by a flour barrel that fell from a shop. In this case, the individuals responsible for securing the barrel were considered *prima facie* liable for the harm caused to the pedestrian.⁴⁸

Conclusion

Civil procedure is based on the principle of adversarial proceedings, and therefore the allocation of the burden of proof between the parties has a significant impact on the final judgment in a case. It is undisputed that the burden of proof constitutes one of the most problematic issues in the adjudication of medical disputes.

Civil liability of a medical service provider arises only in cases of culpable and unlawful conduct. For liability to be imposed, the presence of certain prerequisites is required—namely, an unlawful act, a causal link, and fault. Among these elements, causation is of particular importance, as it is both essential and one of the most difficult aspects to prove in medical malpractice cases. This difficulty arises from the very nature of healthcare: treatment often involves multiple providers, while patient-specific factors—such as physiological traits or psychological state—can significantly complicate, or even prevent, the determination of a direct causal link.

It is important to note that the patient is inherently the weaker party in a medical relationship, especially when it comes to litigation. It is often very difficult, or even impossible, for a patient to obtain evidence and, consequently, to meet the burden of proof. Ultimately, this results in a failure to uphold the principle of equality of the parties in medical disputes.

In such cases, the court plays a vital role in safeguarding the principles of adversarial proceedings and equality of arms. Medical disputes are inherently

⁴⁷ *Escola v. Coca Cola Bottling Co. of Fresno* [S. F. No. 16951. In Bank. July 5, 1944.].

⁴⁸ Judgement of the Exchequer Court of United Kingdom of 25 November 1863, 2 H. & C. 722. 159 Eng. Rep. 299.

imbalanced: medical facilities hold the information and documentation, making it far easier for them to present proof than for the injured patient to do so. To address this disparity, courts must ensure a fair allocation of the burden of proof, which in some situations requires easing the patient's evidentiary burden to preserve equality and the integrity of the proceedings.

The research shows that both European countries and the United States are moving towards easing the burden of proof in medical malpractice cases. The Anglo-American legal approach considers it an excessively heavy burden for patients to prove every element of liability. Therefore, it is held that if a wrongful act creates or increases the risk of harm, a causal link is presumed to exist, and the responsibility to rebut this presumption shifts to the medical facility. Specifically, when it is excessively burdensome for the patient to prove the existence of a particular element, courts may reduce the evidentiary threshold. This is grounded in the principle that claimants should not be subjected to an unreasonably heavy burden of proof, which could otherwise lead to claims being dismissed.

As noted, another instance where the burden of proof is reversed is when a medical facility breaches its duty to maintain medical documentation. The failure to provide this documentation eases the patient's standard of proof and shifts the burden of proof to the medical facility.

The Court of Justice of the European Union also leans toward easing the burden of proof. It allows patients to use evidence other than expert opinions, which require less effort to obtain, in order to prove the existence of a causal link.

From the foregoing, it is evident that the problem lies in the specific nature of the issue itself. However, it is equally important that the courts, taking into account the particular circumstances of each case, properly allocate the burden of proof and balance the inequality between the parties through the correct standard of allocation.⁴⁹

49 Jenny R. Yang and Jane Liu, *Strengthening Accountability for Discrimination: Confronting Fundamental Power Imbalances in the Employment Relationship* (Economic Policy Institute, 2021).

References

- BeckOK BGB, *Hau/Poseck*, 75th ed. as of: 1 August 2025. C.H. Beck, 2025.
- BeckOK BGB, *Bamberger/Roth/Hau/Poseck*, 53rd ed. C.H. Beck, 2020.
- Bergmann, Karl O., and Carolin Wever. *Die Arzthaftung: Ein Leitfaden für Ärzte und Juristen* [Medical Liability: A Guide for Doctors and Lawyers]. Springer Berlin Heidelberg, 2014.
- Blome-Tillmann, Michael. “‘More Likely Than Not’—Knowledge First and the Role of Bare Statistical Evidence in Courts of Law.” In *Knowledge First: Approaches in Epistemology and Mind*, edited by J. Adam Carter, Emma C. Gordon, and Benjamin Jarvis. Oxford University Press, 2016.
- Bussani, Mauro, Anthony James Sebok, and Marta Infantino, *Common Law and Civil Law Perspectives on Tort Law*. Oxford University Press, 2020.
- Cek, Nina. “The Standards of Proof in Medical Malpractice Cases,” *Medicine, Law & Society* 13, no. 2 (2020): 173–96. <https://doi.org/10.18690/mls.13.2.173-196.2020>.
- Greifeneder, Stefanie. “Germany.” In *The Healthcare Law Review*, edited by Sarah Ellson, 5th ed. The LawReviews, 2021.
- Hagenloch, Ulich. “Important Trends in German Judicial Practice in the First Half of 2022.” *Journal of Medical Law and Management*, no. 1 (2024).
- Kropholler, Jan. *German Civil Code (Study Commentary)*, 13th ed. C.H. Beck München, 2011, 2014.
- Lanzer, Peter, ed. *Catheter-Based Cardiovascular Interventions. Knowledge First: Approaches in Epistemology and Mind*. Springer eBooks, 2013.
- Lodge, Richard A. “A Matter of Fact: Establishing Facts in a Medical Negligence Case.” Medical Negligence and Personal Injury Blog | Kingsley Napley (Blog), published 10 May 2025. <https://www.kingsleynapley.co.uk/insights/blogs/medical-negligence-and-personal-injury-blog/a-matter-of-fact-establishing-facts-in-a-medical-negligence-case>.
- Motsonelidze, Natalia. “Peculiarities of a Doctor’s Professional Liability—A Comparative Legal Analysis.” *Journal of Law*, no. 1 (2019).

Meskhishvili, Ketevan. “Procedural Standard for Allocating the Burden of Proof.” In *Commentary on the Civil Procedure Code, Selected Articles*. 2020.

Stauch, Marc S., “Medical Malpractice and Compensation in Germany.” *The Chicago-Kent Law Review* 86, no. 3 (2010).

Stauch, Marc S., “Causation Issues in Medical Malpractice: A United Kingdom Perspective.” *Annals of Health Law* 5, no. 1 (1996): 247–258.

Stauch, Marc S. *The Law of Medical Negligence in England and Germany: A Comparative Analysis*. Hart Publishing, 2008.

Wagner, Tobias. *MüKo/BGB*, 8th ed. C.H. Beck, 2020.

Yang, Jenny R., and Jane Liu. *Strengthening Accountability for Discrimination: Confronting Fundamental Power Imbalances in the Employment Relationship*. Economic Policy Institute, 2021.

Judgements

Georgia:

Ruling of the Supreme Court of Georgia of 16 November 2018, Case No. AS 860-860-2018.

Decision of the Civil Chamber of the Supreme Court of Georgia of 15 September 2011, Case No. AS-711-670-2011.

Germany:

Judgement of the Constitutional Court of Germany of 25 July 1979. NJW 1979: 1925.

Judgement of the Federal Court of Justice of Germany 29 March 1988—VI ZR 185/87.

Judgement of the Federal Court of Justice of Germany 4 October 1994—VI ZR 205/963.

Judgement of the Federal Court of Justice of Germany 16 October 1996—IV ZR 154/95; NJW-RR 1997: 152.

Judgement of the Higher Regional Court Stuttgart of 31 October 1996, ref. 14 U 52/95.

Judgement of the Federal Court of Justice of Germany of 3 April 2001—XI ZR 120/00; BGHZ 147: 203.

Judgement of the Federal Court of Justice of Germany 1 March 2014—X ZR 150/11; NJW 2014: 2275.

Judgement of the Higher Regional Court Stuttgart of 23 January 2020, ref. 1 U 2237/17.

Judgement of the Federal Court of Justice of Germany 24 May 2022 – VI ZR 206/21; NJW 2022: 2747.

United Kingdom:

Judgement of the Exchequer Court of United Kingdom of 25 November 1863, 2 H. & C. 722. 159 Eng. Rep. 299.

McGhee v. National Coal Board [1973] 1 WLR 1.

Snell v. Farrell [1990] 2 S.C.R. 311

Wilsher v. Essex Area Health Authority [1988] AC 1074.

United States:

EEOC v. United Coleman v. Md. Court of Appeals, 626 F.3d 187, 190–91 (4th Cir. 2010).

Escola v. Coca Cola Bottling Co. of Fresno [S. F. No. 16951. In Bank. July 5, 1944].

Parcel Serv., Inc., No. 09-cv-5291, 2013 WL 140604, at *4–7 (N.D. Ill. Jan. 11 2013).

Ybarra v. Spangard, 25 Cal. 2d 486 (Cal. Dec. 27, 1944).

