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MEDICAL MALPRACTICE: THE ITALIAN EXPERIENCE

CLAUDIA DIMARZO*

INTRODUCTION

In Italy, over the last two decades, medical professional liability has become a prominent issue in healthcare policy and a major concern for healthcare economics. The main reason for this scrutiny is the dramatic increase in medical malpractice litigation¹ and its impact on professional liability insurance. The latter, in particular, has resulted in a rapid rise in insurance premiums² and in numerous restrictions regarding the extent of insurance coverage.

In response to this rise in malpractice pressure, physicians have been adopting more and more changes³ in their practices, by taking allegedly

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All translations are the author's unless otherwise indicated.

1. One indicator of the evolution of malpractice litigation in Italy is the annual report of the Association of Insurance Companies. According to this source, between 1994 and 2008 the number of claims filed annually against hospitals and medical practitioners showed an increase of 800 percent, rising from 3,150 to almost 30,000.

A survey conducted by the Italian Associations of Anaesthetists and Reanimators reveals that every year approximately 12,000 claims for damages are brought exclusively against physicians. Such findings have been thus far confirmed by multiple insurance-related organizations. However, it must also be underlined that discrepancies between sources are not at all unusual. See ANGELO FIORI & DANIELA MARCHETTI, *MEDICINA LEGALE DELLA RESPONSABILITÀ MEDICA* 8 (2009).

2. According to the Association of Medical Practitioners Unjustly Accused of Malpractice, insurance companies have seen a disproportionate increase of 250 percent over the last 15 years. *Caro-assicurazioni per i medici, chirurghi plastici pagano fino a 10mila euro*, ADNKRONOS (Apr. 12 2011), http://www.adnkronos.com/IGN/News/Cronaca/Caro-assicurazioni-per-i-medici-chirurghi-plastici-pagano-fino-a-10mila-euro_241386359.html.

3. According to Salvatore Mazzamuto, *Note in tema di responsabilità civile del medico*, in 2 *EUROPA E DIRITTO PRIVATO* 501, 509 (2000), the practice of defensive medicine results in two contradictions: on the one hand, it discourages progress and scientific discovery, which necessarily postulate mistakes and misconceptions; on the other hand, it entails the risk of having one medical practice for rich people and another for poor. It often happens, that physicians, who are willing to perform the newest and most innovative procedures, take precautions against the risk of patients' filing complaints

unnecessary precautions or by withholding treatment that may be in the patients' best interests but may also result in patients filing complaints.

Recognized as having a significantly negative influence on costs and quality of care, such phenomena clearly demonstrate the existence of a crisis in the current Italian medical liability system. This crisis can be better understood by highlighting the importance of the interconnections between the lack of explicit regulations concerning the nature of the physician-patient relationship and medical liability, and the mixed approach taken by courts when dealing with medical malpractice cases. This approach has recently become even more confusing, given the complication introduced by the blurring of the boundaries between any kind of liability: contract and tort, as well as civil and criminal.

The issue of defining the nature of the physician-patient relationship has been addressed with specific reference to situations in which the physician's duty of care is not grounded in a contractual agreement with the patient, but instead stems from an employment relationship with a public or private hospital. In such cases, since the Italian Civil Code (C.c.) does not expressly define the physician's relationship with the patient, courts and academics have been advancing different interpretations.

The traditional view was that no direct legal relationship could be established between the physician and the patient, and, as the injured party, the patient relied exclusively on a cause of action in tort. This view has been gradually replaced by several opposing theories, which lean toward a contractual interpretation of the relationship.

Based on these approaches, medical negligence is currently held to be the failure to fulfill a specific obligation, instead of the violation of a general duty of care. Needless to say, the resulting liability is contractual.

The treatment of medical malpractice cases as one of contract (as opposed to one of tort) appears to be a policy adopted in order to provide the claimant the possibility of recovering damages even in problematic cases, such as when the nature of the situation makes it difficult (or impossible) for the claimant to prove fault and causation by the defendant.

The changing landscape of medical liability has a number of implications, which include: (1) the assignment of the burden of proof (along with the distinction between obligations of means and obligations of outcomes); (2) the proof of causation (along with further reference to the difference

by raising prices for all procedures; but in doing so, they deprive poor people of healthcare access. For similar concerns, see also Luca Nivarra, *La responsabilità civile dei professionisti (medici, avvocati, notai): il punto della giurisprudenza*, in *EUROPA E DIRITTO PRIVATO* 513, 533–34 (2000).

between civil and criminal standards of proof regarding causation-in-fact); (3) the role of informed consent; and (4) the prescription regime.

While achieving the aims of improving compensation for patients suffering adverse effects and, perhaps, providing incentives for the avoidance of such adverse effects, the new approach in question appears to be the major cause for the rapid increase in medical malpractice litigation, resulting in obvious repercussions on expenditures for liability insurance on the part of hospitals and physicians.

I. THE PROBLEMATIC NATURE OF MEDICAL LIABILITY

According to the traditional view,⁴ a patient's hospital admission, for either hospitalization or a routine checkup, involves the formation of a contract for professional services⁵ between the patient and the hospital, where the hospital undertakes the obligation to provide due care in the patient's treatment under the terms of the contract.

According to other jurisprudence,⁶ people have a potestative right to healthcare access, the exercise of which results in a binding relationship

4. Cass., sez. III, 21 dicembre 1978, n. 6141, Giur. it. 1979, I, 1, 953; Cass., sez. III 24 marzo 1979, n. 1716, Foro it. 1980, I, 1115, Giur. it. 1981, I, 297, Giust. civ. 1979, I, 1440, Resp. civ. prev. 1980, 90; Cass., sez. III, 04 agosto 1987, n. 6707, Foro it. 1988, I, 1629.

More recently, Cass., sez. III, 27 luglio 1998, n. 7336, Resp. civ. e prev. 1999, II, 996 (comment provided by Marilena Gorgoni, *Disfunzioni tecniche e di organizzazione sanitaria e responsabilità professionale medica*); Cass., sez. III, 01 settembre 1999, n. 9198, Giust. civ. Mass. 1999, 1877; Cass., sez. II, 11 marzo 2002, n. 3492, Giust. civ. Mass. 2002, 435; Cass., sez. III, 14 luglio 2003, n. 11001, Giust. civ. Mass. 2003, 5; Cass., sez. III, 21 luglio 2003, n. 11316, Giust. civ. Mass. 2003, 7-8; Cass., sez. III, 28 maggio 2004, n. 10297, Foro it. 2005, I, 2479; Cass., sez. III, 19 aprile 2006, n. 9085, Giust. civ. Mass. 2006, 4.

The same opinion has been expressed by many others, including Francesco Galgano, *Contratto e responsabilità contrattuale nell'attività sanitaria*, in 38 RIVISTA TRIMESTRALE DI DIRITTO E PROCEDURA CIVILE 710, 711 (1984); Giovanni Iudica, *Danno alla persona per inefficienza della struttura sanitaria*, in 66 RESPONSABILITÀ CIVILE E PREVIDENZA 3, 7 (2001).

5. App. Catanzaro 07 maggio 2004, Juris data (“[T]he relationship between the patient and the hospital stems from an atypical contract, for which there is no fixed form, nor it is needed an expression of willingness to contract made by parties. This contract does not contain only provisions on hospitality services (board and lodging), but provides also qualified medical and paramedical staff, all the requisite tools in the case of complications after the surgery, and the administration of drugs”). The decision conforms to Cass., sez. un. 01 luglio 2002, n. 9556, Nuova giur. civ. comm. 2003, I, 689 (comment provided by C. Favilli, *La risarcibilità del danno morale da lesioni del congiunto: l'intervento dirimente delle Sezioni Unite*).

6. Cass., sez. III, 01 marzo 1988, n. 2144, Nuova giur. civ. comm. 1988, I, 604; Cass., sez. III, 27 maggio 1993, n. 5939, RAFAELLA DE MATTEIS, *LA RESPONSABILITÀ MEDICA* 16 (1995); Cass., sez. III, 11 aprile 1995, n. 4152, Foro it., Rep. (1996), headword Professioni intellettuali, n. 176; App. Torino 20 giugno 1997, Foro it. 1998, I, 586; Cass., sez. III, 02 dicembre 1998, n. 12233, Danno e resp. contr. 1999, 777; Cass., sez. III, 22 gennaio 1999, n. 589, Corr. giur. 1999, 441 (comment provided by Adolfo di Majo, *L'obbligazione senza prestazione approda in Cassazione*), Foro it. 1999, I, 3332 (comments provided by Francesco Di Ciommo, *Note critiche sui recenti orientamenti giurisprudenziali in tema di responsabilità del medico ospedaliero*; A. Lanotte, *L'obbligazione del medico ospedaliero è un'obbligazione senza prestazione o una prestazione senza obbligazione?*).

with medical and health services managers, such as public hospitals.⁷ As a result, public hospitals' liability is deemed to be contractual, meaning that the hospitals incur liability while executing a course of action imposed by a preexisting binding relationship.

Even though both views confirm the contractual nature of the patient-hospital relationship, in practice, a hospital-employed physician is engaged to fulfill an obligation that is owed by the hospital. However, she does not personally enter into the contract, and she is not a party in the binding relationship between the patient and the hospital. This is certainly true if one considers, on the one hand, that the patient is not entitled to choose the specific physician who is to provide her with treatment, and, on the other hand, that the physician is acting on the hospital's behalf.

Given these premises, one can conclude that the hospital and the hospital-employed physician are both responsible to the patient when failing to carry out the requisite behavior on the grounds of contractual liability and tort liability, respectively, in accordance with the doctrine of accumulation or concurrence of liabilities.⁸

Although rigorous and methodically correct, this approach has been hotly contested.⁹ In particular, it has been questioned whether the physician's position before the patient is comparable with that of a tortfeasor, considering the existence of an unquestionable relationship between the patient and the physician, committing the physician to carry out the same duties that he would if bound by a contract.¹⁰ Criticism has also been ex-

7. According to Article 1173 of the Italian Civil Code, obligations may arise from a contract or a tort, but may also depend on any other act or fact suitable to producing them in accordance with the law. Art. 1173 Codice Civile [C.c.]. As a consequence of this extension, courts have held that potestative rights can be considered as sources of obligations, fitting into those acts or facts suitable to producing them in accordance with the law.

8. Cass., sez. III, 09 gennaio 1979, n. 129, Giust. civ. Mass. 1979, 66; Cass., sez. III, 01 aprile 1980, n. 2105, Dir. economia assicur. 1980, 160, 562, Mass. Giur. lav. 1980, 602; Cass., sez. lav., 07 agosto 1982, n. 4437, 49 Resp. civ. e prev. 1984, 78 (comment provided by Chiara Somarè, *Alcune considerazioni in tema di diligenza*); Cass., sez. III, 26 marzo 1990, n. 2428, Giur. it. 1991, I, 1, 600; Cass., sez. lav., 23 giugno 1994, n. 6064, Foro it. 1995, I, 201; Trib. Pescara 02 maggio 1996, n. 621; Cass., sez. III, 13 marzo 1998, n. 2750, Foro it. 1998, I, 3521, Resp. civ. e prev. 1999, 272 (comment provided by Enzo Ronchi, *Colpa grave del medico: valutazione tecnico-giuridica lasciata al mero arbitrio*).

Accumulation of claims is generally admitted if need be to ensure the greatest protection possible for fundamental human rights, such as the right to health. In the absence of an *appiglio normativo* (specific regulation), both equity and empirical contingencies are believed to influence the application of the doctrine of accumulation of liabilities. See UMBERTO BRECCIA, *LE OBBLIGAZIONI* 672 (1991).

9. See, e.g., Mazzamuto, *supra* note 3, at 503–04. The author argues that the use of tort liability to compensate medical malpractice damages should be abandoned either for theoretical or practical reasons. In fact, from a theoretical point of view, this use of tort liability conforms to an idea of medical activity serving only a protective function; while from a practical point of view, it makes it too difficult for the patient to satisfy the burden of proof as well as to observe the prescription regime.

10. *Id.* at 503.

pressed with regard to the contradictory solution of subjecting the hospital and the hospital-employed physician to different liability rules, notwithstanding the fact that the hospital's liability stems from the physician's failure to perform the requisite treatment (as well as the physician's liability).¹¹

Apart from these concerns, courts have had to tackle a number of additional problems arising from medical malpractice cases.

With regard to situations in which the facts of the case have made it impossible for the claimant to prove the substantive requirements for tort liability (i.e., that the defendant's faulty conduct caused the harm), courts have gradually recognized the inadequacy of the traditional test commonly used to establish medical liability and have begun to reward claimants based on the existence of an equitable imperative of protecting an obviously injured claimant.

The need to improve patient protection has led to increasing divergence, on the part of the courts, from the traditional approach, in order to pursue differing theories, which suggest resorting to contractual liability in civil proceedings brought against hospital-employed physicians.

Five different arguments have been put forward to support this conclusion:

- 1) Application of Article 28 of the Constitution (Cost.);
- 2) Application of the contract for the benefit of third parties;
- 3) Application of the contract with protective effects in favor of third parties;
- 4) Application of the *obbligazione senza prestazione* doctrine; and
- 5) Application of the *contatto sociale* doctrine.

The possibility for contractual liability to be imposed upon hospital-employed physicians was first acknowledged when courts cited Article 28 of the Constitution,¹² which provides, "Functionaries, government officials

11. *Id.* at 505.

12. Cass., sez. III, 01 marzo 1988, n. 2144, *Giur. it.* 1989, I, 1, 300 (comment provided by Roberto Cercone), *Resp. civ. e prev.* 1988, 992 (comment provided by Gabriele Travaglia, *Sulla responsabilità del medico pubblico dipendente*); Cass., sez. III, 01 febbraio 1991, n. 977, *Giur. it.* 1991, I, 1, 1379; Cass., sez. III, 27 maggio 1993, n. 5939, RAFAELLA DE MATTEIS, *LA RESPONSABILITÀ MEDICA* 16 (1995); Cass., sez. III, 11 aprile 1995, n. 4152, *Foro it.*, Rep. 1996, headword *Professioni intellettuali*, n. 176; Cass., sez. III, 02 dicembre 1998, n. 12233, *Danno e resp. contr.* 1999, 777 ("[I]n the case of wrong performance carried out in a public hospital, the hospital, as manager of public health service, and the physician are both responsible on the grounds of contractual liability *ex art. 28 Cost.*").

and State employees shall be directly responsible under criminal, civil, and administrative law for acts committed in violation of rights.”¹³

In addition, arising from the notion that the liability of the hospital-employed physician and the liability of the hospital itself have a common root found in physicians’ negligent performance of their duties, courts have concluded that hospital-employed physician’s liability (and likewise the hospital’s liability) is contractual and professional.¹⁴

In effect, Article 28 of the Constitution recognizes a direct liability to be imposed upon State employees, and hospital-employed physicians certainly are State employees.¹⁵ However, the Article also refers to the legislation defining the features of this liability, and under civil law, liability can result either from a contract or from a tort.

Furthermore, the circumstance that the hospital-employed physician’s liability and the hospital’s liability have a common root does not necessarily imply that, in both instances, the type of liability is contractual and professional.¹⁶

The trend has therefore shifted to applying the contract for the benefit of third parties¹⁷ in order to explain where this contractual liability comes from.

Since the actual purpose of a physician’s employment contract is to provide hospital patients with due care, it has been suggested that patients (being the true intended beneficiaries of that employment contract’s primary obligation) are entitled to require the physician to carry out the obligation. For the same reason, if the physician fails to perform that obligation, patients are also granted the right to bring actions for damages against the physician for breach of contract.

A major problem with this approach is that hospital patients who have been damaged as a result of a breach of duty (which is their legal right according to the physician’s employment contract) do not claim damages

13. See Art. 28 Costituzione [Cost.]. The official translation of the provision provides: “Officials of the State or public agencies shall be directly responsible under criminal, civil, and administrative law for acts committed in violation of rights. In such cases, civil liability shall extend to the State and to such public agency.”

14. The *orientamento giurisprudenziale* (case law) discussed above goes back to Cass., sez. III, 01 marzo 1988, n. 2144, Giur. it. 1989, I, 1, 300.

15. Art. 28 Cost.

16. Cass., sez. III, 22 gennaio 1999, n. 589, Foro it. 1999, I, 3332. See also, Carlo Rossello, *Responsabilità contrattuale ed aquiliana: il punto sulla giurisprudenza*, in 2 *CONTRATTO E IMPRESA* 642, 642–78 (1996) (referring to the case when the same fact is a source of contractual liability upon one person and a source of extra-contractual liability upon another person).

17. Trib. Milano 24 giugno 1999, Corr. giur. 2000, 382. See also Adolfo di Majo, *La Protezione Del Terzo Tra Contratto E Torto*, in *EUROPA E DIRITTO PRIVATO* 1, 1–26 (2000); BASIL MARKESINIS & HANNES UNBERATH, *THE GERMAN LAW OF TORTS: A COMPARATIVE TREATISE* 59–64 (4th ed. 2002).

under that contract, but do so under the separate contract for professional service that they have formed with the hospital.

Similar criticism¹⁸ has been expressed regarding the proposal to apply the scheme of a contract with protective effects in favor of third parties¹⁹ to the hospital-physician agreement.

Considered a “refinement” of the traditional contract for the benefit of third parties, the contract with protective effects in favor of third parties has been used in order to allow certain persons,²⁰ who are not parties to a contract but derive advantage from its implementation, to frame a claim in contract in the case of breach of one of that contract’s secondary obligations (i.e., duties of care and protection).

Although acknowledged by the Court of Cassation, the highest court in Italy,²¹ the contract with protective effects in favor of third parties does not seem to be an appropriate argument for contractual liability to be imposed upon hospital-employed physicians because the physician’s duties toward a patient, as established in the physician’s employment contract, cannot be considered secondary obligations at all.

In addition, if the right to demand the execution of the contract’s primary obligation were not to be attributed to the patient, his interest (in the contract) would not be satisfied.

18. The concept of contract with protective effects in favor of third parties has been developed by German courts, having recourse to a doctrine called *Vertrag mit Schutzwirkung für Dritte*. This construct enabled courts to overcome the narrow provisions of German law of delict, and more specifically the general restriction of recovery for negligently inflicted pure economic loss under section 823 of the Bürgerliches Gesetzbuch [BGB] [Civil Code] and the weak rule for vicarious liability embedded in section 831 of the BGB. The possibility of extending the scope of the contract for the benefit of third parties depends on the distinction between primary (*primäre Leistungspflichten*) and secondary obligations arising from a contract. The latter obligations are often considered as collateral duties of protection (*Schutzpflichten*). Only those duties that fall within the scope of the contract can be extended towards third persons. As a result, third parties are entitled to claim compensation for damages in case of breach of secondary obligations. For a general outline of the concept of contract with protective effects in favor of third parties, see B. S. MARKESINIS ET AL., *THE GERMAN LAW OF OBLIGATIONS* 276–82 (1st ed. 1997); B. S. Markesinis, *An Expanding Tort Law-The Price of a Rigid Contract Law*, 103 LONDON QUARTERLY REVIEW 354, 356–59 (1987).

19. Cass., sez. III, 14 luglio 2003, n. 11001, Giust. civ. Mass. 2003, 5; Cass., sez. III, 14 giugno 2007, n. 13953, Foro it. 2008, I, 1990. For a clear description of the contract in question, see MARKESINIS & ÜNBERATH, *supra* note 17, at 59–64.

20. German courts have adapted the contract with protective effects in favor of a third party to comply with the doctrine of privity. Four criteria generally apply in order to determine whether a third-party beneficiary falls within the scope of protection afforded by contract: 1) a close relationship (*Näheverhältnis*) between the obligor and the third-party beneficiary; 2) a justifiable interest of the obligee in the third-party benefit; 3) objective standards (*Objektive Erkennbarkeit*) capable of establishing third-party beneficiaries at the moment when the obligor enters into the contract; and 4) a third-party beneficiary’s right to be included within the contract’s sphere of protection (*Schutzwürdigkeit des Dritten*). For further observations, see MARKESINIS ET AL., *supra* note 18, at 359.

21. Cass., sez. I, 22 novembre 1993, Nuova giur. civ. comm. 1994, 690 (comment provided by Vincenzo Zeno-zencovich, *Il danno al nascituro*).

Another significant argument, put forward in order to justify the application of contractual liability upon hospital-employed physicians is based on the concept of *obbligazione senza prestazione ai confini tra contratto e torto*²² (obligation without making the performance compulsory [under the physician-patient relationship] at the boundary between contract and tort).

According to this doctrine, even in the absence of a contract between the physician and the patient, the physician's competence is binding in regards to the observance of duties of care and protection. These duties differ from the obligation to give the patient necessary treatment; although, the failure to fulfill them might expose the physician to contractual liability.

The above-described approach has been widely adopted,²³ but some doubt has been cast on its reliability.²⁴ In particular, it has been argued the *obbligazione senza prestazione* doctrine admits the existence of duties of care and protection on the part of the physician, but it does not recognize the same physician as also bound by an obligation of performance. This being the case, one can conclude that whilst the duties of care and protection certainly provide the patient with support if his condition has worsened, these same duties do not guarantee the outcome of the requisite medical performance. In other words, the physician will be held contractually liable for negligent performance, but he may not be prosecuted directly by the patient in the event that he did not fulfill the obligation.

A more convincing approach to the core problem of defining the nature of the hospital-employed physician's liability was introduced by the

22. See Carlo Castronovo, *L'Obbligazione Senza Prestazione Ai Confini Tra Contratto E Torto*, in LE RAGIONI DEL DIRITTO: SCRITTI IN ONORE DI LUIGI MENGONI 157, 197-99 (Giuffrè ed., 1995); CARLO CASTRONOVO, LA NUOVA RESPONSABILITÀ CIVILE 443-548 (3d ed. 2006).

23. See, e.g., Adolfo di Majo, *L'obbligazione senza prestazione approda in Cassazione*, in 4 CORRIERE GIURIDICO 441, 446 (1999).

24. Criticism in this regard has been expressed by Massimo Paradiso, *Il dovere del medico di informare il paziente. Consenso contrattuale e diritti della persona*, in LA RESPONSABILITÀ MEDICA 139-40 (Dott. A. Giuffrè ed., 1982).

In addition to the issue discussed in the text, it might be argued that the duties of care and protection, which constitute the physician's *obbligazione senza prestazione* according to the reasoning above, are not dissimilar from those duties which fall within the bounds of reasonable care. Equally, the situation described by the doctrine in question is not different from other non-contractual circumstances where the lack of reasonable care gives rise to tort liability. It is sufficient to consider the case of the treatment of personal data, regulated by the Decreto Legislativo [D.Lgs.] 30 giugno 2003, n. 196. As established by Article 15 of the decree, tort liability applies in the case of infringement of the right of privacy as a consequence of the processing of personal data. Article 4 D.Lgs. 196/2003 states that compensation for damages can be allowed in both cases of electronic and manual processing of personal data. In the latter case, the interaction between the data-processor (i.e., the recipient) and the data-subject (i.e., the subject of the personal information) is self-evident; notwithstanding, the recipient's failure to use reasonable care while processing the data, which has resulted in injury to the right to privacy of the data-subject, is sanctioned under tort law.

Court of Cassation in decision No. 589/1999. According to this case, physicians can be held contractually liable under the doctrine of *contatto sociale* (social contact).²⁵

The *contatto sociale* doctrine comes into effect when the physician agrees to take on the patient's case, and the resulting physician-patient relationship is configured as a de facto contractual relationship.²⁶

In general, so-called de facto contractual relationships are relationships which reproduce the scheme of true contracts, whose regulations they also follow. This means that, although originating as mere interactions between two persons, de facto contractual relationships are in fact binding on both sides, and are therefore sources of obligations.²⁷

In particular, the relationship between a hospital-employed physician and hospital patients follows the model of contract for professional services. It thus imposes a duty on the physician to carry out all of the activities deemed reasonably necessary to restore the patients' health and exposes him to contractual liability for failing to fulfill this obligation.²⁸

Despite widespread adherence on the part of the jurisprudence to the doctrine of *contatto sociale*, some scholars have criticized this approach.²⁹ In particular, it has been argued that medical activities carried out by hospi-

25. Cass., sez. III, 22 gennaio 1999, n. 589, Foro it. 1999, I, 3332. The Court confirms that "the social conscience, preceding even the law itself, is not restricted to asking the professional operator not to do (i.e., to respect the legal sphere of the person who consults him, trusting in his competence), but also requires action, in which the professional operator's ability is demonstrated . . . In other words, medical care wouldn't be different whether it originated from a contract for professional service or not. This is due to the fact that being a public service, which cannot be provided without a special license . . . and being a protected profession, application of medical care would not be different whether there was a contract or not." *Id.* The same approach has emerged in later jurisprudence. See Cass., sez. III, 28 maggio 2004, n. 10297, Foro it. 2005, I, 2479; Cass., sez. III, 21 giugno 2004, n. 11488, Rep. Giust. civ. 2004, headword Responsabilità Civile, n. 413, 4918; Cass., sez. III, 19 aprile 2006, n. 9085, Giust. civ. Mass. 2006, n. 4; Cass., sez. III, 24 maggio 2006, n. 12362, Rep. Giust. civ. 2006, headword Responsabilità Civile, n. 563, 4705; Cass., sez. un., 26 giugno 2007, n. 14712, Resp. civ. e prev. 2009, 2, 161; Cass., sez. un., 11 gennaio 2008, n. 577, 4 Resp. civ. e prev. 2008, 849 (comment provided by Marilena Gorgoni, *Dalla matrice contrattuale della responsabilità nosocomiale e professionale al superamento della distinzione tra obbligazioni di mezzo/di risultato*).

26. Cass., sez. III, 22 gennaio 1999, n. 589, Foro it. 1999, I, 3332.

27. The legal basis of the obligations discussed above can be found in Article 1173 C.c., the *contatto sociale* being considered a fact suitable to producing obligations in accordance with the law. See generally STEFANO FALLACE, *LA RESPONSABILITÀ DA CONTATTO SOCIALE* (2004); Ilenia Sarica, *Il contatto sociale tra le fonti della responsabilità civile: recenti equivoci nella giurisprudenza di merito*, in *CONTRATTO E IMPRESA* 97 (2005).

28. Cass., sez. III, 13 aprile 2007, n. 8826, 9 Resp. civ. e prev. 2007, 1824; Cass., sez. un., 11 gennaio 2008, n. 577, 4 Resp. civ. e prev. 2008, 849.

29. See Mazzamuto, *supra* note 3, at 504; Antonino Scalisi, *Professione medica: doveri, divieti e responsabilità*, in *10 DANNO E RESPONSABILITÀ* 965, 981 (2007). According to Scalisi, the physician's duty to provide due care finds its source in the law and, foremost, in the Constitution, in which Article 2 compels the observance of the duty of social solidarity, and Article 32 safeguards health as a fundamental right of the individual and as a collective interest. *Id.* (citing Art. 2, 32 Cost.).

tal employees constitute performance on the part of those employees but not an obligation. Accordingly, a more appropriate paradigm would be the management of someone else's affairs.³⁰

In addition, the same scholar has hypothesized a vinculum of joint liability³¹ between hospital and physician for the application of due care on the part of the physician.

This vinculum would render the relationship between the hospital and the physician relevant to the outside world. It would also enable the court to quantify damages only once and would finally recognize the contractual nature of liability of both parties—hospital and physician.³²

II. THE ASSIGNMENT OF THE BURDEN OF PROOF BETWEEN PARTIES

A. Proving Fault

Once the contractual nature of medical liability has been established, compensation for damages can be awarded to the patient (claimant) if he provides proof of the breach of contract by the physician (defendant), unless the physician can prove the impossibility of performance as a result of conditions not attributable to him.

Although this assigning of the burden of proof is currently applied in medical malpractice cases, more sophisticated analysis reveals a number of shifts in the way courts have handled the issue.

In fact, when dealing with medical malpractice cases, courts previously modified the ordinary assignment of the burden of proof, established by Article 1218 C.c.,³³ by applying the distinction between obligations of means and obligations of outcome.³⁴

30. Mazzamuto, *supra* note 3, at 504.

31. *Id.* at 506.

32. Under this approach, liabilities of both hospital and physician seem to become interdependent. However, one may come to a different conclusion if one considers that the physician's duty to apply due care stays the same notwithstanding the circumstance that the contract (for professional service) between the hospital and the patient or the (employment) contract between the hospital and the physician be null and void. In any of these cases, exposure to liability on the part of the physician, depending entirely on the relationship with the patient, would be readily distinguishable from the possibility to impose liability also upon the hospital.

33. Art. 1218 C.c. ("[T]he obligor who does not perform the obligation exactly is liable for damages unless he proves that the non-performance or the delay was due to impossibility of performance for a cause not attributable to him.") (translation provided by MARIO BELTRAMO ET AL., *THE ITALIAN CIVIL CODE* 322 (1969)).

34. The distinction between obligation of means and obligation of outcomes has been criticized by many legal scholars. *See, e.g.*, Michele Giorgianni, *Obbligazione*, in *NOVISSIMO DIGESTO ITALIANO* 581, 598 (Antonio Azara ed., 1965); MASSIMO BIANCA, *DIRITTO CIVILE VOL. 4, L'OBBLIGAZIONE* 71 (1990); Carlo Castronovo, *Profili Della Responsabilità Medica*, in *STUDI IN ONORE DI PIETRO*

The expression “obligation of means” refers to a contractual obligation whereby the obligor needs to make the utmost effort to achieve the obligee’s desired objective, though she is not required to actually realize that end. Therefore, the obligor cannot be held automatically liable if she fails to achieve the obligee’s intended outcome. She is only responsible if her performance has failed to meet the requisite degree of diligence. With regard to the proof required to be shown by the obligor, the result is that she simply needs to prove that she has applied proper diligence.

On the contrary, the obligation of outcome requires the obligor to achieve a stated end. Therefore, if she fails to achieve that end, she can be absolved of liability only by proving impossibility of performance due to an unforeseeable and unavoidable independent cause.

Once the possible regulations regarding a physician’s duty of care have been established, an account should be given on the consequences which follow from the definition of such a duty either as an obligation of means³⁵ or as an obligation of outcome.³⁶

The consequences affect both the liability rules, which courts have applied to each type of obligation, and the assignment of the burden of proof between parties.

In this regard, when considering the physician’s duty of care as an obligation of outcome, courts used to apply Article 1218 C.c., requiring the

RESCIGNO VOL. 5, 117–36 (1998); Enrico Quadri, *La responsabilità del medico tra obbligazioni di mezzi e di risultato*, in 12 DANNO E RESPONSABILITÀ 1165, 1165 (1999); Adolfo di Majo, *Mezzi e risultato nelle prestazioni mediche: una storia infinita*, in 1 CORRIERE GIURIDICO 38 (2005).

The distinction must be considered obsolete after Cass. n. 8826/2007. In this decision, the Court of Cassation explained that the distinction between obligations of means and obligations of outcome cannot be used as a device to support physicians’ lack of responsibility in the case of failure to achieve a specific objective. After stating that the distinction has been enforced under the law of obligations, the Court explained that an obligor must make diligent efforts to achieve a specific result in both cases: either he owes an obligation of outcome or an obligation of means. Moreover, the Court stated, in the obligation of outcome, the obligee’s desired result cannot be ensured in any case, since the obligor is absolved of liability when he failed to perform the obligation due to an unforeseeable and unavoidable event. Finally, the Court rejected the argument that an obligor needs to prove the unforeseeability and unavoidability of the event that caused his failure to perform the obligation only in cases where he owed an obligation of outcome. In fact, according to the Court, this argument conflicts with Article 1218 C.c. See Luigi Mengoni, *Obbligazioni di «risultato» e obbligazioni di «mezzi» (studio critico)*, in 1 RIVISTA DEL DIRITTO COMMERCIALE E DEL DIRITTO GENERALE DELLE OBBLIGAZIONI 185, 187 (1954).

35. See Cass., sez. III, 25 novembre 1994, n. 10014, Nuova giur. civ. comm. 1995, I, 937, where the court clearly states that “the professional obligation owed to a client (in view of the assigned duties) consists in performing professional activity [which may be] necessary and useful in the specific case in order to achieve the result that, through professional-technical means, the client is aiming for (the so called obligation of means or of conduct). Therefore, briefly, the professional is bound to perform professional activity as required or useful in the specific case and to apply requisite diligence.” *Id.* A concurring opinion can be found in Trib. Milano 22 maggio 2004, Giust. a Milano 2004, 44.

36. See Cass., sez. II, 08 agosto 1985, n. 4394, 51 Resp. civ. e prev. 1986, I, 44 (comment provided by Cesare Vaccà, *L’intervento di chirurgia estetica è obbligazione di risultato?*).

patient (obligee) to produce proof of having an agreement with the physician (obligor), and then simply alleging a breach of duty by the physician.

On the contrary, when considering the duty of care as an obligation of means, courts used to apply Article 1176, Section 2 C.c.;³⁷ in other words, the patient, in addition to being required to provide proof of the contract, also needed to prove a breach of duty by the physician.

To better understand how courts have applied this “self-constructed” regulation, a distinction must be made between medical cases involving routine treatment and cases requiring complex procedures.

In routine cases, courts required the patient-claimant to prove that the kind of treatment she had been given was routine and that she suffered damage as a result of that treatment. Once the claimant had satisfied this burden of proof, in order to avoid liability, the physician-defendant had the burden of proving the exact performance or the impossibility of performance due to a superseding cause that was unforeseeable, unavoidable, and external to his conduct.³⁸

On the other hand, in complex cases, the defendant only had the burden of proof regarding the issue of the complex nature of the treatment. Once established, the burden then shifted to the claimant to prove the carelessness of the performance and the causal link between the physician’s conduct and the damage suffered.³⁹

This changed in 2001, when the Court of Cassation⁴⁰ declined to apply the distinction between routine cases and complex ones in the assignment of the burden of proof between parties.

In a contract dispute, the Court established the principle that

[a]n obligee, who brings a legal action against an obligor in order either to obtain the performance, the termination of the contract, or to claim compensation for damages, only needs to prove the legal basis for his right (i.e., the contract) and allege breach of duty by the obligor; while

37. Article 1176 C.c. states that “1. In performing the obligation the obligor must employ the diligence of a normal prudent person. 2. In meeting the obligations pertaining to the practice of a profession, the level of care has to be evaluated according to the nature of the practiced profession.” Art. 1176 C.c. (translation provided by GUIDO ALPA & VINCENZO ZENO-ZENCOVICH, *ITALIAN PRIVATE LAW*, 237–39 (2007)).

38. Cass., sez. III, 21 dicembre 1978, n. 6141, *Giur. it.* 1979, I, 1, 953; Cass., sez. III, 16 novembre 1988, n. 6220, *Giust. civ. Mass.* 1988, n. 11; Cass., sez. III, 11 marzo 2002, n. 3492, *Giust. civ. Mass.* 2002, 435.

39. Cass., sez. III, 15 gennaio 1997, n. 364, *Foro it.* 1997, I, 771 (comment provided by Alessandro Palmieri, *Relazione medico paziente tra consenso “globale” e responsabilità del professionista*); Cass., sez. III, 04 Febbraio 1998, n. 1127, *Giur. It.* 1998, I, 1800; Cass., sez. III, 22 gennaio 1999, n. 589, *Foro it.* 1999, I, 3332.

40. Cass., sez. un., 30 ottobre 2001, n. 13533, *Foro it.* 2002, I, 769.

the obligor-defendant assumes the burden to prove the performance or the impossibility of performance due to a superseding cause.⁴¹

In 2004, the Court of Cassation⁴² extended this principle to medical malpractice cases:

Regardless of the type of treatment or procedure, the patient who brings an action [for damages] needs to prove the existence of a contract (or a social contact) with the physician and allege the breach of duty by the physician. The burden then shifts to the physician, who is required to prove that he fulfilled the duty [in a manner] conforming to the requisite standard of diligence and that an external event, unforeseeable and unavoidable, actually caused the damage.⁴³

As a consequence, the distinction between routine and complex treatment no longer stands as the standard by which the burden of proof is assigned between parties. According to the Court of Cassation,⁴⁴ “this distinction shall rather be applied when the judge evaluates the degree of diligence required in a specific case and the extent of the corresponding fault.”

In a more recent decision,⁴⁵ the Court also repudiated the traditional view, which considered a physician’s obligation an obligation of means. To be more precise, the Court asserted that “the hospital-employed physician and the hospital itself are contractually bound to reach an intended outcome . . . which is the outcome that can normally be achieved in relation to the patient’s conditions, the physician’s skill and the hospital’s ability in technical and organizational management.”⁴⁶

With reference to the Court’s statement, it is widely held that Article 1218 C.c. is the only liability rule to be applied in the case of breach of a

41. *Id.*

42. Cass., sez. III, 28 maggio 2004, n. 10297, *Foro it.* 2005, I, 2479. *See also* Cass., sez. III, 21 giugno 2004, n. 11488, *Giust. civ.* 2005, I, 2115 (comment provided by Emanuela Giacobbe, *Brevi osservazioni sul danno da “nascita indesiderata”, ovvero un bambino malformato non ha diritto a nascere*).

43. Cass., sez. III, 28 maggio 2004, n. 10297, *Foro it.* 2005, I, 2479. Consistent with this opinion, *see* Cass., sez. III, 19 aprile 2006, n. 9085, *Giust. civ. Mass.* 2006, 4; Cass., sez. III, 13 aprile 2007, n. 8826, 7 *Resp. civ. e prev.* 2007, 1824 (comment provided by Marilena Gorgoni, *Le conseguenze di un intervento chirurgico rivelatosi inutile*); Cass., sez. I, 10 ottobre 2007, n. 21140, *Giust. civ. Mass.* 2007, 10; Cass., sez. un., 11 gennaio 2008, n. 577, 4 *Resp. civ. e prev.* 2008, 849 (comment provided by Marilena Gorgoni); Cass., sez. un., 11 gennaio 2008, n. 584, *Foro it.* 2008, I, 451.

Conforming to the same view, Cass. 14 febbraio 2008, n. 3520, *Dir. e Giust.* 2008 (“[T]he physician/obligor has the burden of proof on the issue of the lack of fault (sub specie of a superseding cause, unforeseeable and unavoidable); while the patient is required to prove the existence of a [contractual] relationship with the physician and the fact that he was entrusted with the treatment, and to allege the aggravation of his own condition.”).

44. Cass., sez. III, 28 maggio 2004, n. 10297, *Foro it.* 2005, I, 2479.

45. Cass. 13 aprile 2007, n. 8826, 7 *Resp. civ. e prev.* 2007, 1824.

46. *Id.*

contractual duty. However, prominence is given to Article 1176 Section 2 C.c. when considering the standard of diligence to which medical professionals must conform.

In this regard, the same Court affirmed that because medical obligations pertain to the practice of a profession, the requisite standard of diligence varies according to the different types of treatment or procedure to be performed as laid out by Article 1176 Section 2 C.c.⁴⁷

At the same time, the limitation of liability to instances of intent or gross fault (as introduced by Article 2236 C.c. in cases where the performance of an obligation entails the solution of uncommon technical complications)⁴⁸ should be restricted to problematic cases where “different diagnostic and therapeutic methods or surgical techniques are still discussed among medical scientists” and the damage occurred despite scrupulous attention paid by the physician in diagnosing and treating the disease.⁴⁹

Another significant restriction introduced by the Court of Cassation regarding the range of Article 2236 C.c. consists in the choice of whether to apply the limitation of liability established by that article to damages caused by *imperizia* (the unintentional failure to observe and/or the violation of the cautionary rules of proper conduct for a hypothetical agent in the specific field of reference).

On the contrary, even in cases of particularly complex treatments or procedures, this limitation of liability does not subsist with damages caused by *negligence* (the failure to apply proper diligence in the execution of a contract in order to obtain the intended result) or *imprudence* (the carelessness about the consequences of a conduct), for which the physician is responsible in any case.⁵⁰

47. *Id.*

48. Art. 2236 C.c. (“If performance entails the solution of uncommon technical complications, the person engaged in that specific activity is not liable for damages, except for cases of intent or gross fault”).

49. Cass., sez. III, 19 maggio 2004, n. 9471, 1 Danno e resp., 2005, 23 (comment provided by Rafaella De Matteis, *La responsabilità medica ad una svolta?*).

50. The Court of Cassation has reached this conclusion by observing that if the faulty conduct consisted of a lack of expertise, its evaluation on the part of the judge cannot necessarily be severe since the judge needs to consider that a pathology might have been influenced by the biological singularity of the patient, that clinical data are not obligatory, and that it is always possible to make an error of evaluation in clinical checking, with the resulting diagnosis proving to be faulty. Therefore, if the physician has not applied medical expertise, he will be responsible only in cases of gross fault (with the exception of the treatment being a routine case).

In this regard, see Cass., sez. III, 08 luglio 1994, n. 6464, Resp. civ. e prev. 1994, 1029 (comment provided by Marilena Gorgoni, *Il diritto di programmare la gravidanza e risarcimento del danno per nascita intempestiva*); Cass., sez. III, 18 novembre 1997, n. 11440, Giust. civ. Mass. 1997, 2206; Cass., sez. III, 13 gennaio 2005, n. 583, 10 Giust. civ. 2006, 2186.

This account represents the prevailing view regarding the assignment of the burden of proof between physician and patient. This view is fully consistent with the normal evidentiary and procedural rules regarding this burden of proof, such as the proximity of proof principle, which provides that the burden of proof for any fact should be placed upon the party which is in the best position to produce it (because, for example, it is the closest to the sources of proof).⁵¹

B. Proving Causation-In-Fact

In the cases discussed above, the Court of Cassation dealt with the assignment of the burden of proof regarding the issue of the breach of duty by the defendant. It is now to be established which party should bear the burden of proving the existence of a causal link between the defendant's conduct and the resulting damage.⁵²

The distinction between the breach of duty, which is concerned with fault, and the occurrence of damage, which is concerned with causation, is of considerable significance. This is especially true because the aspects of fault and causation are often mingled, as in the case of the increase in the use of the objective fault concept and in relation to cases where the damage was caused by an omission.

For the purpose of attributing ultimate liability, both aspects should be established; but, while fault can be defined as the failure to perform an obligation in a manner conforming with an objectively specified standard of diligence, causation is the external relation between conduct and damage, with neither reference to the defendant's mental state nor to his expectations regarding avoidable damage.⁵³

51. With reference to the proximity of proof rule, see Cass., sez. III, 21 giugno 2004, n. 11488, Giust. civ. 2005, I, 2115.

52. Whatever the treatment of medical malpractice cases may be, a number of causal links need to be established in order to obtain compensation for damages. If treated as tort cases, in accordance with Article 2043 C.c., it is necessary to produce proof of the existence of two causal links: 1) the relationship between the conduct (either negligent or intentional) and the damage-event (i.e., economic and non-economic damage) (causation-in-fact); and 2) the relationship between the damage-event and the damage-result (i.e., compensable consequences) (legal causation).

On the contrary, the treatment of medical malpractice cases as contract cases involves the application of Article 1218 C.c., which requires the proof of the existence of a causal link between the failure to fulfill an obligation and the damage to be compensated (damage-result). However, a closer look at the issue reveals that no damage-result can come into effect if no damage-event has occurred previously. This being the case, one can conclude that, notwithstanding the change of the liability rule, in both instances two causal links must be established.

53. Cass., sez. III, 06 ottobre 2004–18 aprile 2005, n. 7997, Corr. giur. 2006, 257 (comment provided by Federico Rolfi, *Il nesso di causalità nell'illecito civile: la Cassazione alla ricerca di un modello unitario*).

Further elements to be considered in tracing a clear distinction between fault and causation are the tests commonly applied to establish each of these aspects of liability. In fact, while causal explanation is supposed to depend on the degree of statistical or logical probability of the actual occurrence of a disputed fact, the tests used to determine fault by the defendant are deemed to be: (1) the distinction between routine cases and complex ones; (2) the worsening of the patient's condition or the onset of a new illness; (3) the evaluation of the requisite degree of fault according to the type of treatment or procedure to be performed;⁵⁴ and (4) the fulfillment of the duty to inform the patient about risks posed by treatment, as well as the obtaining of informed consent from the patient.⁵⁵

In addition, the Court of Cassation, Criminal Division, has specified that a charge of fault cannot be derived from the mere fact of the failure to observe or the violation of a precautionary rule, but it is necessary to verify whether the rule was aimed at avoiding exactly the type of event which took place (objectification of risk), the liability being otherwise objective on the grounds of the mere "*versari in re illicita*".⁵⁶

Once the main differences between fault and causation have been specified, the point at issue is the assignment of the burden of proof regarding the causal link between the defendant's conduct and the damage (causation-in-fact).

The prevailing view⁵⁷ until 2008 was that the patient had the burden of proving the causal link between a breach of duty by the physician (merely alleged) and the damage. Moreover, according to the same view, the failure to satisfy this burden (of proof) would preclude the judge from investigating the alleged fault by the defendant.⁵⁸

Two lines of argumentation were used to support this view:

- 1) In the absence of specific tests for determining causation-in-fact in the Civil Code, it is necessary to have recourse to Articles 40 and 41 of the Penal Code, which provides that the plaintiff bears the burden of proof (at trial).

54. With regard to routine treatments, the requisite degree of fault for liability to be imposed upon the physician is the lowest and is presumed in cases where the health conditions of the patient deteriorated or a new pathology has appeared. On the contrary, with regard to complex treatments which entail procedures not studied or tested thoroughly enough, the requisite degree of fault is either gross fault or intent. In both cases, though, the medical professional needs to have been a specialized physician and to have paid scrupulous attention in diagnosing and treating the patient's problem.

55. Cass., sez. III, 06 ottobre 2004–18 aprile 2005, n. 7997, Corr. Giur. 2006, 257.

56. Cass. Pen., sez. IV, 17 maggio 2006, n. 4675, 10 Foro it. 2007, II, 550.

57. Cass., sez. III, 06 ottobre 2004–18 aprile 2005, n. 7997, Corr. Giur. 2006, 257.

58. Cass. 19 aprile 2006, n. 9085, Giust. civ. Mass. 2006, 4; Cass. 24 maggio 2006, n. 12362, Giust. civ. Mass. 2006, 5; Cass. 31 luglio 2006, n. 17306, Giust. civ. Mass. 2006, 7–8.

- 2) From Articles 1223, 1225, and 1227 C.c., it can be reasoned that the obligee, who claims damages for a breach of contract, bears the burden of proving that the damages are immediate and direct consequences of the conduct inducing the breach of contract.

This changed in 2008, when the Court of Cassation made it clear that the allegation of a breach of duty by the defendant needs to be substantiated by the claimant. To be more precise, the Court asserted that

the claimant's allegation cannot concern whatever breach of duty, it should rather contain a clear statement about a breach of duty, which may be able to cause damage (i.e., theoretically able to cause damage). Once the claimant (has) made this allegation, the burden shifts to the defendant to prove performance or lack of causation between a breach of duty and damage.⁵⁹

By considering the evidence of "general" and "potential" causation satisfactory, the Court seems to provide unsteady grounds for obtaining "specific" proof of causation.

C. Proving Causation Under the Criminal Law and Under the Civil Law

Bearing in mind that the defendant's liability is limited to those (economic and non-economic) damages that result directly from her (negligent or intentional) conduct,⁶⁰ it must be established which test should apply in order to determine the limits of this liability or, in other words, recoverable damages.

As previously noted, under the Italian Civil Code, there are no relevant provisions with this purpose. For this reason, courts and scholars have been arguing for years as to whether the test applied in criminal cases to establish causation could also extend to civil cases.

The test in question is called *condicio sine qua non*. According to this test, any act/omission can be considered a cause of damage if the damage would not have occurred but for that act/omission.

The process of establishing the existence of a causal link between an act/omission and damage requires the application of counterfactual analysis,⁶¹ which achieves effective explanatory power when it is coupled with fully verified scientific generalizations.

59. Cass. 11 gennaio 2008, n. 577, 4 Resp. civ. e prev. 2008, 849.

60. Pursuant to Article 1223 C.c., compensation for damages arising from non-performance or delay includes the loss sustained by the creditor and the profit of which he has been deprived, inasmuch as both are direct and immediate consequence of the non-performance or delay. Art. 1223 C.c.

61. The basic idea of counterfactual theories of causation is that the meaning of causal claims can be explained in terms of counterfactual conditionals of the forms "if A had not occurred, C would not have occurred."

However, it hardly ever happens that the evidence employed to establish causation results in objective certainty about what happened on the particular occasion. In most cases, the evidence merely supports the proffered causal explanation and/or excludes other potential competing causes with a sufficiently high degree of probability to result in the judge having the requisite degree of belief in the truth of the disputed fact.

However, the degree of proof required to support the judge's belief varies according to the type of case. In criminal cases, it becomes more stringent since the prosecution is required to prove guilt beyond a reasonable doubt, which is the highest level of the burden of persuasion, as established by Section 1 of Article 533 of the Code of Penal Procedure (C.p.p.).

On the contrary, in civil cases, the prevailing jurisprudence⁶² has long adhered to the rule that the claimant must prove his case based upon the standard of preponderance of the evidence,⁶³ which is considerably lower than the standard applied in criminal cases.

On the issue of the identity or divergence of the evidentiary standards which should apply in the two types of cases, the United Sections of the Court of Cassation have recently intervened,⁶⁴ explaining that the difference between the standard of "preponderance of the evidence" and "beyond a reasonable doubt" is the result of the diversity of the values at stake in criminal cases as opposed to the equivalence of the values at stake in civil cases.

Although confirming the difference between the two types of cases,⁶⁵ the Court also affirmed that the preponderance of the evidence standard

62. Cass., sez. un., 11 gennaio 2008, n. 581, 4 Resp. civ. e prev. 2008, 827. Further support for this view can be found in certain decisions by the European Court of Justice. See Case C-12/03P, *Comm'n v. Tetra Laval BV*, 2005 E.C.R. I-987, 1056; Case C-295/04, *Manfredi v. Lloyd Adriatico Assicurazioni SpA*, 2006 E.C.R. I-6619.

63. In common law countries, the preponderance of the evidence standard is satisfied when the allegedly applicable causal explanation is more likely to be true than not true, considering the "weight, quality and persuasiveness" of the evidence. Some courts and scholars believe that the standard is to be considered satisfied if there is a greater than 50 percent *ex ante* statistical probability that the proffered causal sequence actually occurred.

64. Cass., sez. un., 11 gennaio 2008, n. 576-85, 4 Resp. civ. e prev. 2008, 827.

On the same issue, the Third Section of the Court of Cassation had intervened before the pronouncements of the United Sections of Gennaio 2008, and had adopted a criterion of probabilistic causation, without distinguishing in the application of this criterion between the type of proceeding (be it civil or criminal). See Cass., sez. II, 21 gennaio 2000, n. 632, *Danno e resp.* 2001, 72; Cass., sez. III, 04 marzo 2004, n. 4400, *Riv. it. medicina legale* 2004, 789.

65. Three different arguments have been put forward to explain the reason why in medical malpractice cases civil causation would be autonomous from criminal causation. The first to be stressed is the function of the criminal justice system, as opposed to the function of the civil liability system. In fact, the former has a sanctioning function, whereas the latter has a compensatory function. Secondly, it has been remarked that the civil liability system does not exclude cases in which liability is objective or presumed, also as a result of the presumption of causation; this happens because the protection of the person who has suffered a damage is the primary aim to achieve in the civil liability system. Thirdly,

cannot be described as merely enough evidence to make it more likely than not that the fact the claimant seeks to prove is true. In fact, for determining liability, this standard needs to be “qualified” by further elements, taken from the case under consideration, and capable of transforming into certainty the proffered causal explanation expressed until then in probabilistic terms.

By also requiring the causal explanation to be provided with logical reliability, the Court of Cassation seems to be referring to a widely known opinion, which the United Criminal Sections (of the same Court) delivered in 2002 (*Franzese* opinion),⁶⁶ and in which the point of arrival in the Court’s criminal jurisprudence on the issue of causation is briefly outlined.

As confirmation of this, it seems useful to quote the United Criminal Sections No. 30328/2002 in the part where the Court stated:

[I]t is not consented to automatically deduce from the coefficient of probability expressed by the statistical law, the confirmation or otherwise of the accusatorial hypothesis on the existence of a causal link, since the judge needs to verify the validity of that hypothesis on the particular occasion by making reference to the circumstances of the fact and all available proof; thus, at the end of the explanatory legal reasoning, which has also served to exclude interference from other potentially competing factors, it will be proved to be justified and judicially certain that the physician’s [. . .] conduct was a necessary condition in the damage with a high degree of rational credibility and logical probability.⁶⁷

A brief report on the opinions given by the Court of Cassation subsequent to the January 2008 pronouncements by the United Sections reveals that the inquiry into causation does not always achieve a convincing result,

there has been a noticeable difference between the interests protected by each of these systems. In fact, while the Penal Code regulates (criminal) offenses with predetermined interests in mind, the civil liability system appears to be more flexible. As confirmation of this, the concept of “unfair damage” under the terms and conditions of Article 2043 C.c. could be considered. It has been also demonstrated that in criminal law the offender is the principal figure in the proceedings and the principle of *tipicità* applies; on the other hand, in civil law, the primary position rests with the damaged party and the problem lies in allocating costs for damages.

66. Cass. Pen., sez. un., 10 luglio 2002, n. 30328, Cass. Pen. 2002, 3643.

67. Reasoning from the circumstance that the arguments used by the United Criminal Sections of the Court of Cassation to establish causation are the same in civil jurisdictions and equally able to influence the judge’s belief, Carlo Castronovo, *Sentieri Di Responsabilità Civile Europea*, in 4 EUROPA E DIRITTO PRIVATO 787, 820–22 (2008) considers unacceptable, from the point of view of the internal coherence of our legal system, that the Court of Cassation—Civil Division—keeps sustaining that the standard of “beyond a reasonable doubt” applies in criminal cases, while the standard of “preponderance of the evidence” applies in civil cases. *Id.* The Author objects that formulae such as those are extraneous with respect to our juridical tradition and arbitrary in our legal system, where the jurisprudence cannot create law with formulae so sharp and definite that only the Legislator can use them. What remains is the power of the judge to accept the probabilistic causal explanation to the extent that his free belief would make him think this to be satisfactory. *Id.*

often through failing to conform to the United Sections' understanding of the preponderance of the evidence standard.

In fact, although some opinions have endorsed verdicts on causation based upon a virtual certainty standard rather than upon mere statistical probability, many others have applied considerably less stringent standards, such as "reasonable certainty", "concrete, actual and not hypothetical possibility of a favorable outcome", "reasonable certainty about the existence of a not insignificant probability", "moral certainty", and "reliable and significant possibility of a favorable outcome".

By not being based on a particular instance, these formulations have inevitably encouraged interpretations of the burden of persuasion with specific regard to the judge sitting on the case.

D. The Role of Informed Consent

The need to obtain the consent of a patient before engaging in any treatment is enshrined in the Italian Constitution, which provides that "no one may be obliged to undergo any health treatment except under the provisions of the law."⁶⁸

Considered a necessary prerequisite for legitimate medical treatment,⁶⁹ the consent of a patient must be personal, although it might be obtained from a "legally authorized representative" in cases where the patient who should give the consent is a minor or an interdicted person, and the treatment appears to be necessary or beneficial.⁷⁰

Concerning the additional characteristics of this consent, it needs be free, spontaneous, deliberate, detailed, informed, and revocable at any time.⁷¹

68. See Art. 32, § 2, Cost. The Italian Constitutional Court has recently stated that informed consent is grounded in Articles 2, 13, and 32 Cost., and consequently that two distinct rights can be recognized: the right to self-determination and the right to health. In fact, every individual has the right to be provided with all information regarding the nature and possible developments of the therapy, as well as the right to receive necessary treatment. See Corte Cost. 23 dicembre 2008, n. 438, 5 Foro it. 2009, I, 1328. See also Nivarra, *supra* note 3, at 524–25 ("the right to health is the fundamental parameter, if not the exclusive parameter, by which the performance of the physician is to be evaluated." In other words, the (patient-)creditor's interest is identified with the right to health "to which an integral part is the right to be analytically informed about the method or procedure and the result of the medical treatment.").

69. Cass., sez. III, 25 novembre 1994, n. 10014, Nuova giur. civ. comm. 1995, I, 937; Cass., sez. III, 15 gennaio 1997, n. 364, Foro it. 1997, I, 771. See also Mengoni, *supra* note 34, at 372.

70. Antonino Scalisi, *Famiglia e diritti del minore*, in 10 FAMIGLIA, PERSONE E SUCCESSIONI 815, 815–29 (2006).

71. *Id.*

The consent must also be made explicit, but it might also be presumed in the case of imminent danger to the patient, as long as the treatment does not go beyond what is needed to avoid the danger.⁷²

Finally, the consent cannot be valid forever; it must be *rebus sic stantibus* (i.e., things thus being). Because of this, the physician is bound to obtain consent again, if during the course of the treatment circumstances have changed, and it is necessary to modify the initial schedule of therapy.⁷³

Consistent with the recognition of informed consent is the establishment of the duty on the part of the physician to provide the patient with detailed information so that he is completely aware of the type of treatment, possible risks, expected results, and possible adverse effects.⁷⁴ This duty is explicitly stated in the Code of Medical Deontology, which advises the physician to clearly and thoroughly inform the patient regarding the diagnosis, prognosis, and therapy perspectives. The patient should also be aware of the likely consequences of applying the therapy and of omitting the therapy (within the known limits of medical knowledge, and taking into account the patient's cultural level, emotions, and capacity to comprehend).⁷⁵

The failure to obtain properly informed consent for treatment has been generally treated as an actionable legal wrong, regardless of whether the treatment was negligently performed or resulted in any physical damage.⁷⁶ On the other hand, the failure to obtain a competent patient's consent is treated as an actionable, legal wrong in many jurisdictions, including almost all common law and many civil law jurisdictions, only if the failure has caused a physical damage that would not have occurred if proper information had been provided.

Both approaches may be contested on the same grounds.

It can certainly be affirmed that omitted or incomplete information imputable to the physician makes it impossible for the patient to compe-

72. See Art. 54 Codice Penale [C.p.].

73. Cass., sez. III, 02 luglio 2010, n. 15698, Giust. civ. 2011, I, 433.

74. Cass., sez. III, 16 maggio 2000, n. 6318, 20 Dir. e Giust. 2000, 14; Cass., sez. III, 23 maggio 2001, n. 7027, Foro it. 2001, I, 2504. See Massimo Paradiso, *La responsabilità medica: dal torto al contratto*, in 47 RIVISTA DI DIRITTO CIVILE 325, 343 (2001) ("the source for a physician's duty to inform is the same as the source for the physician-patient relationship, be this the contract or the law. Thus, no account should be taken of the interpretation that assigns the duty to inform to one's good faith or to the responsibilities of care and protection, which are accessory to the main obligation . . . On the contrary, the point here is not to safeguard interests which exist beyond the physician's obligation, but to integrate the proper content of this obligation.").

75. See Art. 29-31 Codice Deontologico [C.deont.].

76. Cass., sez. III, 14 marzo 2006, n. 5444, 3 Riv. it. medicina legale 2007, 865.

tently decide whether to undergo treatment or not, and consequently infringes her right to self-determination. In such a case, the physician's performance must therefore be considered as an actionable legal wrong. However, it seems an impractical solution (on the ground of causation in fact) to attribute to the physician any physical harm to the patient's health resulting from his actions, because such an imputation would depend on the choice made by the properly-informed patient.

Besides, it cannot be denied that the physical damage occurring to the patient is a consequence of medical treatment and not a consequence of the omitted or defective information.

One may argue that if the information had not been omitted or defective, the patient would not have suffered any physical damage;⁷⁷ but, such an inference is illogical because (as already stated) the physical damage is a consequence of the physician's performance, while the infringement of the patient's right to self-determination entails, on the grounds of causation, merely an inquiry into whether the properly-informed patient would have decided to undergo treatment.

The same conclusion was recently reached by the Court of Cassation, which provided:

[D]ue to the fact that the surgery would not have been performed, only if the patient had refused it, in order to establish the causal link between the infringement of the patient's right to self-determination (caused by the omitted information on the part of the physician) and the infringement of the right to health (due to negative, blameless consequences of the surgery) . . . it should be possible to state that the patient would have refused treatment if he had been properly informed; otherwise the physician's omitted conduct (i.e. the information given to the patient) would in any case have been unable to avoid damage (infringement of the right to health).⁷⁸

The Supreme Court continued, stating that in the counterfactual analysis, which is needed to establish the existence of a causal link, the patient bears the burden of proving that she would have refused the medical treatment had she been properly informed.⁷⁹

77. App. Milano 02 maggio 1995, Foro it. 1995, I, 1418 (holding that the infringement of the right to self-determination represents the starting point of a causal sequence whose end point is the infringement of the right to health, as it can be inferred from the fact that, with the right to self-determination being respected, either the physical damage would not have occurred or the risk of its occurrence would have been transferred upon the patient).

78. Cass., sez. III, 09 febbraio 2010, n. 2847, 9 Guida al dir. 2010, 75 (comment provided by Francesco Agnino, *La responsabilità medica: lo stato dell'arte della giurisprudenza tra enforcement del paziente e oggettivazione della responsabilità sanitaria*, in 5 CORRIERE GIURIDICO 628 (2011)).

79. *Id.*

According to the Court, multiple reasons justify this apportionment of the burden of proof between parties. Firstly, the creditor (i.e., the patient) is the party who is normally bound to prove the causal link between the failure to perform the treatment on the part of the physician and the damage suffered.⁸⁰ Additionally, since the fact to be proven is that the patient had refused the treatment, this (i.e., patient's refusal) being a personal choice, the distribution of the burden of proof between parties is established on the "proximity" of proof principle.

All things considered, the mere infringement of the right to self-determination (when not coupled with damage to health) may result in a non-economic damage to the patient, which could be compensated if proven and if it has exceeded normal tolerability.⁸¹

CONCLUSION

From what has been presented since the beginning of this work, it is clear that the most recent developments in our medical liability system have gradually led to an exponential increase in the number of cases for which damages can be obtained and to a parallel rise in personal injury claims.

Both these effects relate to the "contractualization" of medical liability, which has made it easier for the claimant to prove the conditions for liability. For instance, establishing fault on the part of the defendant has become a marginal aspect⁸² to the extent that it has gradually faded away as a consequence of the recourse to alternative probative mechanisms (such as presumption).

The same phenomenon (i.e., the "contractualization" of medical liability) has also rendered the role of "filter" carried out by causation more vague and limited against an increase in the number of cases of compensable damages, and also due to the growing importance of informed consent.

However, a necessary observation is that, on the one hand, there are more damages for which compensation can be obtained, and on the other

80. *Id.*

81. Cass., sez. un., 11 novembre 2008, n. 26972, 1 Resp. civ. e prev. 2009, 38 (comment provided by Pier Giuseppe Monateri, *Il pregiudizio esistenziale come voce del danno non patrimoniale*), Danno e resp. 2009, 19.

82. As far as contractual liability is concerned, the general rule is that "the obligor, who does not exactly perform the obligation, is responsible for damages unless he proves that the failure to perform the obligation or the delay in the performance has been due to impossibility of performance for a cause not imputable to him." Art. 1218 C.c. It is clear from the provision that the objective fact of the non-performance or delay is sufficient to impose contractual liability.

hand, medical liability has become less and less personal. This fact is related to the circumstance that the more complex the treatment to be performed becomes, the more difficult (and sometimes useless) it is to establish the liability of a particular person because the damage is often the result of different factors, partly human and partly organizational.

Coupled with the reduced importance of “individual fault” in medical malpractice cases is the fact that hospitals offer financial coverage to their personnel if involved in a malpractice case.⁸³ The personnel then are bound to pay compensation only in the (improbable) case of intentionally causing the damage.

All these factors raise a serious question about the capacity of the Italian medical liability system to promote prevention of damages rather than to simply repair damages. There is a need for a more complex regulation of health-safeguarding objectives, above and beyond the strictures of the traditional setup.

For many years medical liability reform has garnered the attention of scholars;⁸⁴ but, over the last year the overall scene has been enhanced by a series of proposals characterized by a more solid scientific basis.⁸⁵

Of considerable interest, from the point of view of civil law, is the proposal to compel public and private hospitals to insure against liability for damages caused to third parties by their personnel.⁸⁶

Under the terms of the reform project, the institutions that do not fulfill the obligation to possess compulsory insurance cannot be accredited. It is also specified that a patient who claims to have suffered damage as a consequence of medical malpractice (i.e., the allegedly damaged party) can bring an action only against the hospital (and not against the physician).

83. However, it may be observed that over the last few years hospitals have encountered difficulties in finding suitable insurance coverage due to the shift in the insurance policy and raise in insurance premiums. The insurance policy, which currently applies to hospitals, is called “claims made”. The coverage deals with incidents arising on or after the retroactive date of the policy and which are reported during the duration of the policy. The “claims made” policy allows insurance companies to contain the costs of providing coverage to the hospitals; but it is not as convenient for the hospitals. In fact, if a hospital is for some reason cancelled by an insurance company, it may not have coverage in the future for activities performed in the past.

84. See, e.g., Giulio Ponzanelli, *La responsabilità medica ad un bivio: assicurazione obbligatoria, sistema residuale no-fault o risk-management?*, in 8 DANNO E RESPONSABILITÀ 428, 428–30 (2003); Luca Nocco, *La gestione del rischio clinico ed il monitoraggio degli errori medici: spunti di riflessione in chiave comparatistica*, in 8 DANNO E RESPONSABILITÀ 444, 444–52 (2003).

85. For a clear overview of the main proposals elaborated during this legislature, see Giovanni Comandé, *Dalla responsabilità sanitaria al no-blame regionale tra conciliazione e risarcimento*, in 11 DANNO E RESPONSABILITÀ 977, 977–88 (2010).

86. *Id.* at 980. The proposal has been elaborated by the Centro Studi Federico Stella sulla Giustizia Penale e la Politica Criminale within article 26.

Another reform project,⁸⁷ applying a precautionary principle, states that hospitals bear the responsibility for damages suffered by patients during the providing of medical services, unless they can prove to have adopted all possible measures available to science and skills to avoid harming the patient. In addition, the project extends the obligation for compulsory insurance to “autonomous medical and non-medical operators”.⁸⁸

In regards to the modalities of providing insurance coverage, the reform project envisages a declaration of availability on the part of insurance companies in order to create a warranty fund for the victims of medical malpractice and to allow direct actions against the insurance companies.

Similar provisions can be found in a different reform project,⁸⁹ according to which any medical center, either public or private hospital or other body, is responsible for damage occurring in the medical center and caused by the personnel (either physician or otherwise) that the medical center has employed (even on an occasional basis), unless the medical center can prove to have adopted all possible measures to avoid the damage. The medical center can ask the personnel involved in the damage for compensation only in cases of intent, which has been ascertained through a formal judgment.

In conclusion, all the reform projects suggest the recourse to a range of procedures in order to resolve medical malpractice disputes prior to, or during, the use of litigation, which on the contrary can be very costly and time-consuming.

Up to the present time, there is only one reform which has been adopted by the Parliament. It establishes that from March 21, 2011, it is compulsory to make an application for conciliation to resolve disputes in medical liability before having recourse to litigation.

87. *Id.* at 981. The reform project has been elaborated by the Società Italiana degli Studiosi di Diritto Civile.

88. *Id.* (Article 2 of the Società Italiana degli Studiosi di Diritto Civile reform project).

89. *Id.* at 983. The reform project has been elaborated by the Federazione nazionale degli ordini dei medici chirurghi e degli odontoiatri.

