Journal de Droit de la Santé et de l'Assurance Maladie

JDSAM n°23 - 2019

SOMMAIRE

Editorial 3
Anne Laude
Didier Tabuteau

Interview 4
Sébastien Leloup

Dossier thématique

La responsabilité médicale : perspectives comparées

Dossier coordonné par
Simon Taylor

Introduction (Français / Anglais) 6
Simon Taylor

La responsabilité médicale en droit allemand 11
Jonas Knetsch

La responsabilité médicale en droit anglais : entre conservatisme et renouveau 24
Simon Taylor

La responsabilité médicale au Chili : perspectives générales 31
María Agnes Salah Abusleme

Medical Liability in Spanish Tort Law 38
Albert Ruda

Medical Liability Law in Italy...45
Nadia Coggiola

La Responsabilité civile médicale au Japon.....................54
Ippei Ohsawa

Current Debates on Medical Liability in the Czech Republic..63
Petr Šustek

Liability for medical injuries in Sweden..........................72
Sabina Hellborg

Chroniques

1- Organisation sanitaire, politiques de santé 77

Cadre et office du juge des soins sans consentement : retour sur 5 ans de jurisprudence....................................77
Marie Grosset

2- Droits des malades et bioéthique 84

Cap vers 2022 : premier acte du plan « Ma Santé 2022 » Quels bénéfices pour le patient ?....................................84
Olivier Saumon

3- Établissements de santé et médico-sociaux... 88

La démographie médicale en France. 88
Jean Martin Andarelli

La thanatopraxie à l'hôpital, évolutions récentes 97
Marc Dupont

4- Produits de santé...101

Patients, laboratoires pharmaceutiques et autorités de santé : comment la *patient centricity* bouscule le rôle et la place de chacun.. 101
Maylis Guyot-Sionnest & Albane Degrassat-Théas

5- Assurances des activités de santé 110

Déclaration sincère du risque : l'obligation de l'assureur de questionner 110
Luc Grynbaum

6- Responsabilité et indemnisation 112

Produits de santé défectueux : le spectre de l'incertitude scientifique... 112

Devoir d'information : toujours plus loin....................... 115
Mireille Bacache

SOMMAIRE

17- Propriété intellectuelle et concurrence 119

I. Droit des brevets 119
Jean-Frédéric Gaultier

II. Droit des marques 123
Caroline Le Goffic

III. Droit de la concurrence 125
Caroline Carreau

Financement et fiscalité 133

La réforme annoncée du financement des établissements de santé 133
Rémi Pellet

Travail et risques professionnels 134

L'indemnisation du préjudice d'anxiété 134
Stéphane Brissy

Durcissement procédural en matière d'instruction des AT/MP 136
Philippe Coursier

Droit pénal de la santé 142

Le risque – une notion au cœur de la protection des salariés, par le droit pénal et le droit du travail 142
Ana Zelcevic-Duhamel

Assurance maladie obligatoire et complémentaire 145

Image de l'un, affaire de tous 145
Céline Roux

Environnement et santé 149

Amiante : revirement de jurisprudence sur la réparation du préjudice d'anxiété 149
Oneida d'Andigné & Estelle Gras

Nouvelles de l'étranger

Régulation de la santé numérique et de l´intelligence artificielle en santé au Brésil : l´état de l´art et les perspectives 152
Fernando Aith & Daniel de Araújo Dourado

Varia

Un Huron aux pays des algorithmes 158
Delphine Jaafar

Le virage connecté : mutation de la prise en charge du patient 162
Timothy James

Rédaction 172

Medical Liability Law in Italy

Nadia Coggiola
University of Turin, Italy

1. Introduction

Italy is a civil law country. Therefore the sources of medical liability law are traditionally the provisions concerning contractual and non-contractual liability in the Italian Civil Code which, enacted in 1942, largely finds its roots and principles, including those on liability, in the French Napoleonic Code.

On the basis of those rules the compensation of medical liability was, since the enactment of the Civil Code, traditionally restricted to cases where it was established that the physician acted with gross negligence, and the awards for the injured patient were accordingly often limited.

That long established system was, starting from the end of the '70s, increasingly faced with a large augmentation of the number of medical malpractice compensation cases, coupled with an increase in the number and level of damages awards to patients recognized by Italian courts. That change was most probably the consequence of the technological advances in health care and their perception by judges and the wider public, coupled with a shift from deference to mistrust in the general attitude of patients and their relatives toward physicians. In those day, in fact, it was supposed that the duty of the doctors was no longer to use all the available means to achieve a medical result, but to actually achieve that same result. Therefore, when doctors fell short of that positive result, disappointing the patient's expectations, the same patients or their relatives had the basis for a claim for damages and compensation awards were made by Italian courts.

This increase in the number of compensation awards and in the sums awarded entailed an augmentation of the general costs of compensation, an increase in insurance premiums both for the hospitals and for the single practitioners, and an escalation of the number of cases brought before the courts. The general situation become so thorny, and the risk of a failure of the public health system so pressing, that the Italian government had to intervene, enacting laws aimed at limiting the number of cases of compensation and their total amount.

In the following paragraphs we shall briefly investigate the lines of evolution of the civil rules concerning the compensation of medical liability in Italy. To that purpose, we can roughly divide the evolution of Italian law into three periods. The first period, starting from the enactment of the Italian Civil Code, in which the rules devoted to the compensation of contractual and extra contractual damages were applied to cases of medical liability on the basis of the formal relationship between the physician or the medical structure and the patient. The second period, starting from the end of the '70s, where a large number of Italian courts, influenced by certain leading scholars, moved from a distinction of cases of contractual and extra contractual medical liability based on the formal relationship between the parties to a distinction based on the factual situation. The third period, roughly starting from the first decade of the new millennium, in which the negative effects of the evolution of the compensation system for medical liability and worries about the sustainability of the public health system required the introduction of limits to the compensation of medical damage.

Moreover, it should not be forgotten that alongside civil liability, the Italian system provides criminal liability for cases where doctors caused physical injury or the death of a patient. The criminal system is closely interlinked with the civil system and therefore we shall start our examination with this question.

2. The criminal liability of physicians for death or personal injuries caused to patients

As mentioned in the introduction, when a patient suffers personal injury or dies as a consequence of an action or omission of a doctor or other health professional, the defendant may be liable either under criminal or civil law.

In fact, article 112 of the Italian Constitution and article 50 of the Italian Code of Criminal Procedure oblige public prosecutors to bring a criminal action against the defendants in cases of serious personal injury and homicide. Minor personal injuries are instead prosecuted only following a complaint by the injured parties, in accordance with the provisions of article 582 of the Italian Criminal Code. Therefore, most medical injuries will be prosecuted before a criminal court.

It is important to point out that in those cases, the victim can claim compensation and restitution by appearing as *parte civile* before the same criminal court, in accordance

with article 74 of the Italian Code of Criminal Procedure. The *parte civile* is an institution which is well known in all the systems that are influenced by the French Code of Criminal Procedure. Under the Italian Code of Criminal Procedure, the *parte civile* is entitled, as a person who has suffered damage as a consequence of a crime, to join the same criminal court proceedings. Alternatively, if they prefer, they may ask for compensation in separate and subsequent civil proceeding, relying on the findings and the records of the criminal court, whose judgment shall be *res judicata* in this respect in the subsequent civil proceedings. Furthermore, they may also choose to start parallel and independent civil proceedings (see articles 75, 651, 652 Code of Criminal Procedure). In this latter case, the criminal and civil court proceedings and their outcomes shall be completely independent from one another, and may also eventually lead to different and conflicting outcomes[1].

The *parte civile* has the autonomous power to bring evidence to the criminal court and to assist the prosecutor in proving the guilt of the defendant. During the criminal proceedings the claimant can take advantage of the fact that the same criminal court provides the often needed, but expensive, scientific and medical expert opinions, although he still retains the right to appoint his own experts. Therefore, the choice for the victim of being present in the criminal proceedings instead of initiating parallel civil proceeding generally depends on the complexity of the case and on a case-by-case evaluation. In fact, although it may be more convenient for the victims to act as *parte civile* in the criminal case in difficult cases, involving complex causation issues and requiring expensive expert opinions, it should not be forgotten that, due to the nature of the sanctions involved, the threshold required for proving the defendant's fault or the existence of a causal link is generally higher before a criminal judge than in a civil court.

The criminal court is entitled to award compensation under the provision of article 185 of the Italian Penal Code, which states: "Every crime requires restoration according to the civil law. Every crime which has caused patrimonial or non-patrimonial damage obliges the perpetrators and the persons who, according to the civil law, are responsible for his or her actions to pay compensation".

3. The traditional approach to civil liability: the 1942 Italian Civil Code provisions on contractual and tortious liability

As already mentioned in the introduction, the Italian Civil code was enacted in 1942 on the model of the French Code Civil of 1804[2]. The Code contains provisions aimed at compensating both the damage arising out of the infringement of contractual duties and extra contractual liabilities. The contractual liability rules are applied to cases where the victim and the tortfeasor are linked by a contract, while the extra contractual liability rules relate to cases where there is no contractual link between the parties.

It is important to underline that for a long time, even before the enactment of the 1942 Civil code, the practical application of this distinction between the two categories of sources of liability for the compensation of damage suffered by patients followed what we may call a formal approach. Therefore, both judges and scholars traditionally held that the rules on contractual liability applied to cases where a contractual relationship existed between the doctor or the health organization (hospital or private clinic) and the patient, whilst the rules on extra contractual liability applied to cases where there was no contractual relationship between the parties, including the many cases in which the doctor was an employee or consultant of the hospital or of the private clinic and therefore did not have a contractual relationship with the patient.

The rule providing the liability of one of the parties for the infringement of the contractual duties is article 1176 c.c.., entitled "Diligence in performance", which states: "In performing the obligation, the debtor shall observe the diligence of a good *pater familias*. In the performance of obligations inherent in the exercise of a professional activity, diligence shall be evaluated with respect to the nature of that activity" [3].

The diligence of the good *pater familias* is therefore the basic standard of care for contractual liability in Italian law, a standard which has been constantly interpreted by Italian scholars and courts as that of a reasonable man who is careful, scrupulous and diligent and who takes upon himself only obligations that he is able to carry out and perform correctly. The diligence required is that of the average good person.

Meanwhile, the second paragraph of that same

1 - For further information on the issue, see *M Chiavario*, Private Parties: The Right of the Defendant and the Victim, in: M Delmas-Marty/ JR Spencer (eds), *European Criminal Procedures* (2005) 541 ff

2 - For an introduction on the evolution of Italian civil law, see G. Alpa, *Diritto civile Italiano*, Il Mulino, 2018. For an introduction to Italian liability rules see, amongst others, M Franzoni, *Trattato della responsabilità civile. L'illecito*, Giuffrè, 2010 and R. Sacco, G. De Nova, *Il contratto*, Utet, 2016. For an English introduction to Italian private law, G. Alpa, V. Zeno-Zencovich, *Italian Private Law*, Routledge-Cavendish, 2007. On Italian medical liability, in English, P. Ricci, F. Ausania, P. Arbarello, *Medical Responsibility and Liability in Italy*, in S. Ferrara, R. Boscolo-Berto, G. Viel (eds), *Malpractice and Medical Liability*, Springer, 2013; A. Scarso, M. Foglia: *Medical Liability in Italy*, in A. Bernhard, A. Koch (eds.) *Medical Liability in Europe. A Comparison of Selected Jurisdictions*, De Gruyter, 2011; C. Di Marzo, *Medical Malpractice: The Italian Experience*, in Chicago Kent Law Review, 2012, 87, 53; A. Feola, V. Mariano, L.T. Marsella, *Medical Liability: The Current State of Italian Legislation*, in European Journal of Health Law, 2015, 22, 347 and lastly A. De Luca, *Compensation schemes for damages caused by healthcare and alternatives to court proceedings in Italy*, in *Annuario di diritto comparato e di studi legislativi*, ESI, 2018, 89

3 - The translation of this and the following Italian Civil Code articles is by M Beltramo, GE Longo, JH Merryman, *The Italian Civil Code*, Oceana, 1969.

article introduces a higher standard of care and skill for professional activities. In this second case, the court, asked to decide whether an obligation had been performed correctly, must therefore consider the nature of the activity and the professional qualities that could be expected by the performing party at the time of performance. In this second case, diligence must be evaluated on the basis of the standard of care and skill required in the actual case from a reasonable professional. The consequence of this provision is that the more specialized the profession, the higher the standard of care and skill required. The ascertainment of the diligence of the professional in performing his obligations could sometimes be made applying the standards of diligence set by some of the nominate contracts (see for example Art. 1587, Art. 1710, Art. 1768, Art. 1804 c.c.) and the requirements provided for by the statutes of the professional bodies. Hence standards have been set for the diligent lawyer, the diligent engineer and, in our cases, the diligent physician, where "diligent" is also interpreted as average.[4]

To establish the liability of the defendant in cases of contractual liability, is it therefore sufficient to establish the lack of diligence, that is to say the negligence of the defendant. It is important to point out that the Italian Civil Code does not provide a definition of negligence, so the reference is given by article 43 of the Italian Criminal Code, which defines it as "negligence, carelessness, lack of expertise or violation of the mandatory rules of law"[5]. The rules provided for by article 43 of the Italian Criminal Code are often cited in civil decisions or by scholars when commenting on the Civil Code, although it is generally agreed that there is not an exact match between these civil and criminal law concepts.

In more detail, article 43 of the Criminal Code provides that the offence is intentional when the defendant could foresee and actually intended the harmful event that is the result of his act or omission. The offence is negligent, instead, when the harmful event was foreseeable, but the defendant did not actually intend it, and the event occurs because of his negligence or carelessness or lack of skill and expertise, or his failure to comply with laws, regulations, orders or rules. Negligence is traditionally divided into "negligence" (*negligenza*), that is to say a lack of care which implies passive behaviour that is reflected in the omission of necessary precautions (such as leaving instruments or gauze sponges in the surgical wound, operating on a healthy limb, forgetting to control the drugs expiring date); "carelessness" (*imprudenza*), that is to say reckless behaviour of the physician or failure to take all the precautions that common experience suggests necessary (such as performing complex and delicate surgery despite knowing that he is not in a perfect physical condition, or without having the appropriate equipment, or performing particularly challenging surgery without having the capacity to perform it); and lastly "lack of skill and expertise" (*imperizia*), that is the incapacity to perform activities which require special technical knowledge because of a lack of study, practice, intuition and capacity of observation (such as lacking the minimum skills and technical expertise in the use of instruments or the misdiagnosis of an easy case).

Depending on its seriousness, negligence may be distinguished from gross negligence, where the violation of the rules of care is severe, and ordinary negligence, where the shortcomings of the defendant are less serious. We shall come back to this point later, when we investigate the tortious liability of physicians.

Lastly, when we talk about contractual medical liability, we should not forget to mention that article 2236 c.c. states: "If the professional services involve the resolution of technical problems of particular difficulty, the person who renders such services is not liable in damages, except in case of fraud, malice or gross negligence". This rule, which clearly limits the liability of the party to cases of malice or gross negligence, is aimed at encouraging the undertaking of risky or difficult commitments that have also a social function such as, in our cases, risky major surgical operations or complex diagnosis, as the liability is excluded in cases of ordinary or slight negligence.

Not surprisingly, this rule has been criticized by some scholars, as it introduced an advantage for professionals in those same cases where they were required to have a greater degree of diligence and skills because of the presence of technical problems[6]. As a consequence, some commentators held that this provision should be given a restrictive interpretation, so as to reduce or limit the allegedly more favourable treatment of professionals in comparison to others defendants.[7]

This restrictive path has generally been followed by the Italian judges starting from the '70s, in decisions which tended to evaluate the existence of technical problems of exceptional or extraordinary difficulty on a case-by-case basis [8], and therefore to ascertain the skills of the physician in the case under examination rather than his prudence and diligence[9] in the performance of his contractual obligations, on the basis of general criteria of negligence. Therefore, article 2236 c.c. becomes rarely applicable to cases of contractual liability, although we may find cases in which it is

4 - C. M. Bianca, *Inadempimento delle obbligazioni*, in: *Commentario del codice civile Scialoja-Branca*, Zanichelli, 1979.

5 - G. Visintini, *Trattato breve della responsabilità civile*, CEDAM, 2013, 18 ff.; M. Bussani, *Problemi dell'illecito: superiorità soggettive e giudizio sulla colpa*, in: P Cendon (ed), *La responsabilità extracontrattuale*, UTET, 1994, 81 ff.

6 - See eg C. Lega, *Le libere professioni intellettuali nelle leggi e nella giurisprudenza*, Giuffré, 1974; E. Bonvicini, *La responsabilità civile*, Giuffré, 1971; P. Rescigno, *Manuale di diritto privato*, Jovene, 1973.

7 - Among the others, A. Princigalli, *La responsabilità del medico*, Jovene, 1983; G. Visintini, *Trattato breve della responsabilità civile*, CEDAM, 2013.

8 - Cass 23 May 1975, Arch. Civ. 1975, 1485; Cass 28 April 1978, no 1845, in Resp civ prev 1978, 591.

9 - Cass 13 October 1972, n°o 3044, Foro It 1973, I, 1170.

also applied to cases of tortious liability.[10]

On that point, some Italian scholars noticed that, following the general increase in the level of risk due to technical and scientific evolution, even when the judges formally follow the provision of art. 2236 c.c., they tend in fact to substitute the distinction between gross negligence and ordinary negligence with the distinction between professional negligence and risk, and therefore to hold the physician liable only when he breached the duties of knowledge and ability of his profession, and not when he undertook a risk.[11]

To sum up, a physician is contractually liable if he acted in breach of his duties to offer the obligations provided for in the contract. In providing the contractual obligations, the physician must act with diligence, that is to say making the best use of his technical knowledge, and capacity, meaning that he is expected to apply the scientific and technical solutions generally adopted. The ascertainment of his capacity must be made on the basis of a case-by-case examination.

Moreover, it should also be remembered that, when comparing the actual performance of the debtor with the abstract standard of performance that could have been expected from the average debtor (in the case the average good physician), Italian case law and scholars, following the French model, distinguish between obligations that aim to achieve a particular result (*obligation de résultat*) and obligations that bind the debtor only to use his best efforts (*obligation de moyens*). Traditionally the obligations of the physician were always included in the category of the *obligation de moyens*, but in some cases, when the diligent performance of the obligations is always deemed to produce a certain result, such as in cases of routine surgical procedures, Italian courts considered that obligation as an *obligation de résultat*, and therefore applied to those cases the stricter rules of liability, most probably with the aim of the mitigation of the physician's contractual liability[12].

In all the cases in which, instead, the physician was not linked by a contractual relationship to the patient, such as all the cases in which the physician worked on the basis of a contractual relationship with the hospital or private clinic where the patient was hospitalized or underwent a surgical intervention, Italian scholars and courts generally held that the liability of the physician was a non-contractual liability, as no direct contractual relationship existed between the physician and the patient. Therefore, article 2043 c.c. provisions should be applied.

Article 2043 c.c., entitled "Compensation for unlawful acts" provides that "Any fraudulent, malicious, or negligent act that causes an unjustified injury to others obliges the person who has committed the act to pay damages". French scholars and practitioners will immediately recognize in this rule the original French provision of art. 1382 Code Civil, but also that something new was added by the Italian legislator, starting from the title: the requirement of an "unlawful act", that is to say the existence of a *danno ingiusto*, which may be translated by "wrongful damage" or "unjustified injury". In the following lines, we prefer to use the definition of "wrongful damage" than that of "unjustified injury", because in our opinion it better conveys the original meaning of the definition *danno ingiusto*.

The introduction of the requirement of the *danno ingiusto* for the compensation of non-contractual damage in the Italian Civil Code of 1942 has a rather complex history[13]. Its aim was to limit the compensation of damage to cases of "wrongful damage". In the following decades, although with some exceptions, Italian courts generally interpreted the reference to "wrongful damage" of article 2043 c.c. as setting out a list of protected interests, consisting of rights protected *erga omnes*, analogous to § 823 BGB. However, in 1971, and then again in 1999, the Italian *Corte di Cassazione* rejected this approach, adhering to the criticisms made by some scholars, who stressed the open ended, indeterminate nature of the concept of "wrongful damage" in our Civil Code, with a consequent enlargement of the number of compensation awards under this rule[14].

Following the provisions of art. 2043 c.c., the tortfeasor must compensate the wrongful damage caused by negligent or intentional acts. Therefore the existence of two elements must be ascertained to establish extra-contractual liability, that is to say the subjective element, consisting of negligence, namely lack of due care (*colpa*), or intent to cause damage (*dolo*), and an objective element, that is wrongful damage.

As we mentioned before, the Italian Civil Code does not explain what constitutes intent to cause damage, nor what amounts to negligence, and therefore the concepts provided for by article 43 of the Italian Criminal Code, which we illustrated above, are applied by courts and scholars in cases of both contractual and tortious liability.

With respect to tortious liability, it is interesting to point out that in a number of cases some Italian judges applied the rule stated in article 2236 c.c. for contractual liability to cases of medical tortious liability, providing that whenever a professional is required to render a performance involving the solution of technical problems of special difficulty, his liability for non-performance shall be limited to cases where he acted with gross negligence or malice. The application of this rule also to cases of non-contractual liability certainly

10 - Cass SS UU, 6 May 1971, n° 1282, Resp civ prev 1971, 523. On the issue, F. Cafaggi, *Responsabilità del professionista*, in: *Digesto delle discipline privatistiche: sezione civile*, vol XVII, UTET, 1998, 2138.

11 - F. Cafaggi, P. Iamiceli, *La colpa*, in: P Cendon (ed), *Il Diritto nella giurisprudenza, La responsabilità civile*, vol IX UTET, 2001, 382.

12 - On this point, P. Gallo, Quale futuro per il contatto sociale in Italia?, in Nuova Giur. Civ., 2017, 12, 1759

13 - For details on this history see *M Graziadei*, *Liability for Fault in Italian Law: The Development of Legal Doctrine from 1865 to the End of the Twentieth Century*, in: N Jansen (ed), *The Development and Making of Legal Doctrine*, Cambridge University Press, 2010

14 - On this issue, see C. Castronovo, *La nuova responsabilità civile*, Giuffré, Milano, 2006, 11; M Franzoni, *Trattato della responsabilità civile. L'illecito*, Giuffrè, 2010, 48.

limits the liability of the physicians asked to undertake difficult medical cases[15].

Before moving to the next section, it is certainly worth remembering that the application of contractual liability or non-contractual liability rules entails significant practical consequences on the liability of the defendants.

First of all, there are consequences with respect to the burden of proof. Article 1218 c.c. in fact provides that the creditor must prove the title of his credit and the damage that he has suffered from the default of the debtor, while the latter must prove that he has not fulfilled his obligation because it became impossible due to a cause which was not imputable to him. Therefore, where the physician and the patient were linked by a contractual obligation, the patient only has to prove the damage and state that it is the consequence of a breach of the defendant's contractual duty. In those cases the liability of the defendant is *prima facie* established unless they can prove that the damage was not the consequence of their actions. In contrast, in cases of extra contractual liability, the same patient must prove the damage, the causal link and the fault of the defendant, and therefore the burden of proof is entirely on the patient. So, the patient is certainly in a better position if he suffered injuries as a consequence of the performance of a contractual obligation of the physician or of the hospital or private clinic, rather than where the same injuries are the consequence of the physician's tortious action or omission.

Moreover, in cases of contracts, the limitation period for an action for damages is 10 years, while in extra contractual liability cases, the limitation period is only 5 years, starting from the moment at which the harmful injury eventuated or the patient knew that that injury was the consequence of the fault of the defendant.

That said, it should also be mentioned that, in contrast to other civil law systems, Italian legislation and case law allow claimants to jointly ask for compensation arising from both contractual and non-contractual liability, where the action of the defendant violated at the same time rights arising from a contractual and a non-contractual source (so called "*cumulo delle azioni*")[16]. Hence, in many cases of medical liability, it is quite common for the injured patient to ask for the compensation of damage jointly and severally against the hospital or private clinic, for contractual liability, and the physician that undertook the medical operation, for extra contractual liability. In such cases courts do not generally actually handle the contractual and non-contractual liability as distinct, so that the contractual rules concerning proof, more favourable to the petitioner, are in the end often applied even to the non-contractual liability issues. Nevertheless, the formal distinction between medical liability cases governed by contractual liability and cases governed by tortious liability was applied by Italian courts from the enactment of the 1942 Italian Civil Code until the 90s without this being contested[17].

The proof of the defendant's liability

The Italian Civil Code does not provide a definition of causation, while article 1223 of the same code only provides that the measure of damages arising from non-performance or delay shall include the loss sustained by the creditor and the lost profits insofar as they are a direct and immediate consequence of a non-performance or delay. Therefore, a number of theories have been advanced on the issue of the ascertainment of causation, such as the theories of the *conditio sine qua non* or "but for test", of the "predictability of the event", of the "causation subject to the laws of science", of the "more probable than not", and so on, although a common agreement among scholars and judges on the rules to be applied has never been reached. Rather, the impression reached after a thorough examination of the rules applied by Italian judges is that in most cases the different theories are applied on a case-by-case basis, not on the basis of theoretical approaches, but rather for pragmatic and contingent reasons.

Turning to the question of the proof of the defendant's fault, for our purposes, it is interesting to point out that traditionally, even in cases of contractual liability, the burden of proving the fault of the physician was placed entirely on the patient in cases of medical liability[18]. That anomaly, shared with the French system[19], provided for a formal description of medical liability as contractual liability, but at the same time required the ascertainment of the liability of the physician on the basis of the standard of tortious liability,

15 - F. Cafaggi, *Responsabilità del professionista*, in: *Digesto delle discipline privatistiche: sezione civile*, vol XVII, UTET, 1998, 2138.

16 - See for example: Cass., sez. un., 10 giugno 2003, n°. 9219., Foro it., 2004, I, 185; Cass., 25 maggio 2001, n°. 7127, in Mass., 2001, Rep. Foro It.. 2001, voce Responsabilità civile [5760], n°. 151; Cass., 09 gennaio 1997, n°. 99, in Vita not., 1997, 306. For an historical survey of the general principle admitting the joint action see P.G. Monateri, *La responsabilità civile*, UTET, 1998, 686 ff. For further details on the two types of liability, see Di Majo, *La responsabilità contrattuale*, Giappichelli, 1997, 89; F. Giardina, *Responsabilità contrattuale e responsabilità extracontrattuale. Significato attuale di una distinzione tradizionale*, Giuffré, 1993; C. Rossello, *Responsabilità contrattuale ed extracontrattuale*, in G. Alpa e M. Bessone (eds), *La responsabilità civile*, Giuffré, 1987, 317; P.G. Monateri, *Cumulo di responsabilità contrattuale ed extracontrattuale*, Cedam, 1989; R. Sacco, *Concorso delle azioni contrattuale ed extracontrattuale,* in G. Visintini (ed), *Risarcimento del danno contrattuale ed extracontrattuale*, Giuffré, 1984, 155; R. Scognamiglio, *Responsabilità contrattuale ed extracontrattuale*, in *Noviss. Dig. It.*, XV, UTET, 1968, 670

17 - See, among the many decisions, Cass., 26 March 1990, n° 2428, Giur. It,, I, 1, 1991, c. 600, with note by D. Carusi, *Responsabilità del medico, prestazione professionale di speciale difficoltà e danno alla persona* ; Cass., 13 March 1998, 2750, Resp. Civ. prev., 1999, 272.

18 - R. De Matteis, *La responsabilità medica: un sottosistema della responsabilità civile*, Cedam, 1995; R. De Matteis, *La responsabilità medica tra prospettive comunitarie e nuove tendenze giurisprudenziali*, in Contr. e impr., 1995, 489; R. C. Castronovo, *L'obbligazione senza prestazione ai confini tra contratto e torto*, in Studi Mengoni, Giuffrè, 1995; N. Todeschini, *La responsabilità medica*, Utet, 2016; G. Montanari Vergallo, *La colpa sanitaria verso la fase del bilanciamento: analisi de iure condito e proposta di riforma*, Giuffrè, 2016.

19 - On the issue, also D. Giesen, *International Medical Malpractice Law*, J.C.B. Mohr, 1988; D. Manai, *Les droits du patient face a la médecine contemporaine*, Helbing & Lichtenham, 1999; S. Taylor, *Medical Accident Liability and Redress in English and French Law*, Cambridge University Press, 2015.

including the burden of proof[20].

4. Legal developments favourable to patients from the 1970s

Starting from the end of the 70s, the attitude of the courts changed, and the burden of proof was progressively shifted from the patient to the physician. A first step was made distinguishing between routine and difficult medical operations: if the medical operation was difficult, the onus was on the patient to prove the lack of skill of the physician, while in cases of routine operations there was a presumption of the liability of the physician (*res ipsa loquitor*). In the latter case, the physician was therefore asked to prove the existence of extraordinary circumstances or other defences exonerating him from liability[21]. Hence, all routine medical operations were treated as contractual operations with an *obligation de résultat*, with the consequent limitation of the privileged situation traditionally applied to physicians.[22]

That attitude was later also applied by the Italian *Corte di Cassazione* to every medical operation, without distinguishing between routine and complex medical operation. Therefore, the patient must generally simply prove the existence of a contract and the non-performance by the physician of his obligations, that is to say the deterioration of his physical condition, while it is for the doctor to prove that he performed his obligations correctly and that the negative outcome is the consequence of unforeseeable events[23].

At the same time, Italian judges applied the tool of the reversal of the burden of proof also to causation, asking the defendant physician to prove that the harm was not caused by his actions or omissions[24], which increasingly distinguished it from the (stricter) criteria of ascertainment applied by criminal courts[25]. As is commonly known, the requirements for proof of causation in criminal and civil cases can differ, mainly because the two procedures have different purposes and aims. Generally, proving the causal link between the act or omission of the physician and the harm suffered by the victim is less strict in civil proceedings, where the defendant is simply asked to pay monetary compensation, than it is in criminal cases, in which the accused can be sentenced to a deprivation of their liberty.

Following this new approach, clearly more benevolent towards the injured patients, some courts also allowed in some cases the compensation of the loss of chance, when the negligent action or omission of the physician deprived the patient of a chance of healing or of surviving for a longer time. In those cases, the compensation was awarded to the patient or his dependant on the basis that the loss of a change is a form of positive damage, because the chance of a favourable opportunity to achieve a given result or good is a pecuniary entity in itself, which can be evaluated[26].

Obviously, to obtain compensation the claimant must prove the economic value of what was lost, and the concrete possibility of obtaining it, but for the wrongful conduct of the defendant. But courts may make use of presumptions to prove the economic value of the lost chance, for example using inferences. The amount of the compensation owned by the defendant to the claimant is usually determined by an equitable judgment on the basis of the value of the lost future economic benefits, discounted by the probability of obtaining those economic benefits.

Lastly, it should be added that to ascertain the existence of a causal link in cases of medical liability, Italian judges generally rely on medical or technical expertise, and therefore their decisions may often be influenced by their scientific opinions.

Liability on the basis of a "social contact"

The distinction between the contractual liability of the hospital or private clinic or physician operating as a private individual that is in a contractual relationship with the patient and the tortious liability of the physician working for a health institution which, on the contrary, entered into a contractual relationship with the patient, remained unquestioned by

20 - L. Mengoni, *Obbligazioni di risultato e obbligazioni di mezzi*, in Riv. dir. com., 1954, I, 366; A. Gambaro, *La responsabilità medica nella prospettiva comparatistica*, in La responsabilità medica, Giuffrè, 1982, 25.

21 - Cass., 21 December 1978, n°. 6141, in Mass. Giur. it., 1979.

22 - V. Zeno-Zencovich, *La sorte del paziente*, Cedam, 1994; V. Zeno-Zencovich., *Una commedia degli errori? La responsabilità medica fra illecito e inadempimento*, in Riv. dir. civ., 2008, I, 297; M. Paradiso, *La responsabilità medica: Dal torto al contratto*, Riv. dir. civ., 2001, I, 325; A. Ciatti, R*esponsabilità medica e decisione sul fatto incerto*, Cedam, 2002; L. Klesta, *La responsabilité médicale en Italie: le renouveau du contrat social*, in Revue int. dr. comp., 2012, 757.

23 - Cass., 30 October 2001, n°. 13533, in Mass. Giur. it., 2001; Cass., 19 May 2004, n°. 9471, in Mass. Giur. It. 2004; Cass., 28 May 2004, n°. 10297, in Mass. Giur. it; Cass., 13 April 2007, n°. 8826, in Mass. Giur. it, 2007; Cass., sez. un., 11 January 2008, n°. 577, in Giust. civ., 2009, 2532.

On the issue see, amongst others, E. Palmerini, *La responsabilità medica e la prova dell'inesatto adempimento: Commento a Cass., 28/5/2004, n°. 10297*, Nuova giur. civ. comm., 2004, 791; Cass., sez. un., 11.1.2008, n°. 577; R. Pucella, *I difficili assetti della responsabilità medica*, in Nuova. Giur. civ. comm., 2007, II, 445; A. Nicolussi, *Sezioni sempre più unite contro la distinzione fra obbligazioni di risultato e obbligazioni di mezzi. La responsabilità del medico*, in Danno e resp., 2008, 871.

24 - M. Bona, *Il nesso di causa nella responsabilità civile del medico e del datore di lavoro a confronto con il decalogo delle sezioni unite penali sulla causalità omissiva*, in Riv. dir. civ., 2003, II, 362; S. Landini, Causalità giuridica e favor veritatis, Riv. dir. civ., 2003, II, 417; L. Nocco, *La probabilità logica del nesso causale approda in sede civile*, in Danno e resp., 2005, 57; M. Capecchi, *Il nesso di causalità. Da elemento della fattispecie fatto illecito a criterio di limitazione del risarcimento del danno*, Cedam, 2005.

25 - Cass., 25 September 2001, n°. 5716, in Mass. Giur. it., 2001; Cass., sez. un., 11 September 2002, n°. 30328, Mass. Giur. it., 2002

26 - Cass., 4 March 2004, n°. 4400, Mass. Giur. it., 2004, *Resp. civ. prev.*, 2005, 461; the decision was commented, among the others, by G. Citarella, *Errore diagnostico e perdita di chance in Cassazione*, in Resp. civ. e prev., 2004, 1045; P. Ziviz, *Il risarcimento per la perdita di chances di sopravvivenza*, Resp. civ. e prev, 1998, 705; F. Fiori, F. Cascini, F. Ausania, *La Cassazione civile accentua le differenze tra responsabilità medica penale e prospetta la risarcibilità autonoma della perdita di chance da colpevole inadempimento professionale*, in Riv. it. med. leg., 2004, 803; M. Capecchi, Nesso di causalità e perdita di chances: dalle sezioni unite penali alle sezioni unite civili, in Nuova giur. civ. comm., 2008, II, 143; A. Procida Mirabelli di Lauro, M. Feola, *La responsabilità civile*, Giappichelli, 2008, 161 ff.

Italian courts and scholars until the 90s. However, at the end of that period, some Italian judges started to recognise the contractual nature of the liability of the physicians employed by a hospital or private clinic for medical damage[27].

The reasoning of the Italian judges supporting the contractual nature of the relationship between patient and physician employed by the health institution was that, in those cases, there was an infringement of the duty of care for the safety of others (*obblighi di protezione*), which is based on the patients' trust, given the professional status of the doctor. As a consequence, when a patient enters into contact with a physician for medical treatment, there is what is called by Italian scholars and judges a "qualified social contact", which entails the generation of obligations on both the parties, and therefore the contractual liability of those same parties if the obligations are not fulfilled[28].

The theory of the "social contact" was, if not exclusively, largely applied to cases of medical liability, making establishing the claim easier for patients, who were only obliged to prove the existence of a "social contact" between them and the physician, the occurrence of damage and the causal link. On the contrary, it was now upon the defendant physician to prove that the non-fulfilment of his obligations did not depend on his negligence, or the non-existence of a causal link between his action or omission and the injuries suffered by the patient[29]. That judicial interpretation rapidly became the leading case law[30]. It should be underlined that the definition of the relationship between the patient and the physician employed by the hospital or private clinic as contractual, not only shifted the onus of proving his lack of liability onto the doctor, as his fault is presumed, but also extended the limitation period for the action of compensation from 5 to 10 years.

This case law diminished the relevance of the distinction between *obligation de résultat* and *obligation de moyens*, which clearly became less relevant for the purposes of the Italian judges[31] , although some judges and scholars expressed a minority, contrary opinion[32].

5. The legislative interventions of 2012 and 2017

This constant judicial trend toward the enlargement of the physicians' liability was recently halted, or at least that was the clear intention, by the Italian legislator. In truth, the cost of medical liability compensation was becoming impossible to sustain both for the public system and for the physicians, who have to pay for their personal liability insurance, with a huge increase in the price of medical insurances, medical services and the augmentation of the direct and indirect costs of defensive medicine. Not intervening would most probably have put at risk the very survival of the public health sector, with serious consequences especially for the less privileged social classes.

The first legislative intervention was the so called *Decreto Balduzzi*, of 2012[33].

For our purposes, this legislation provided in its article 3 that the individual health professional could not be held criminally liable for ordinary fault if during his professional activities he complies with the guidelines and best practices of his profession, validated by the scientific community. The only liability of the individual health professional in cases of damage caused by his ordinary fault will be civil liability on the basis of the provisions of article 2043 c.c., which could be somewhat limited in its extent.

The reference made by the legislator to the rule on tortious liability of the Italian civil code clearly conflicted with the evolution of Italian case law we illustrated above, and it was interpreted by the courts and scholars as a demonstration of

27 - A. Thiene, *La Cassazione ammette la configurabilità di un rapporto obbligatorio senza obbligo primario di prestazione*, in Nuova giur. civ. comm., I, 2000, page 345. 336 For an analysis of the factors that have determined this evolution in the field of medical liability cfr. V. Zeno-Zencovich, *Una commedia degli errori? La responsabilità medica fra illecito e inadempimento*, in Riv. dir. civ., 2008, 297 ff..

28 - This approach was inaugurated with the ruling of the Italian Court of Cassation, N. 589, 22 January 1999, in Danno e resp., 1999, 294, with note by V. Carbone, *La responsabilità del medico ospedaliero come responsabilità da contatto* ; in Corr. giur., 1999, 441, with note by A. Di Majo, *L'obbligazione senza prestazione approda in Cassazione*; in Resp. Civ. prev., 1999, 661, with note by M. Forziati, *La responsabilità contrattuale del medico dipendente: il contatto sociale conquista la Cassazione*. For a criticism of the theory of the so-called "social contract", see. A. Zaccaria, *Der aufhaltsame Aufstieg des sozialen Kontakts. La resistibile ascesa del « contatto sociale »*, in Riv. Dir. Civ., 2013, 77

29 - The first case that applied the theory of the "social contact" was Cass., 22 January 1999, no. 589, in Giust. civ., 2000, I, 740, with a note by G. Pizzetti, *La responsabilità del medico dipendente come responsabilità contrattuale da contatto sociale*; among the large number of comments on the case, see A. Thiene, L*a Cassazione ammette la configurabilità di un rapporto obbligatorio senza obbligo primario di prestazione*, in Nuova giur. civ. comm., 2000, 343; A. Di Majo, *L'obbligazione senza prestazione approda in Cassazione*, in Corr. Giur., 1996, p. 446; V. Carbone, *La responsabilità del medico ospedaliero come responsabilità da contatto*, in Danno e resp., 1999, p. 299; F. Di Ciommo, *Note critiche sui recenti orientamenti giurisprudenziali in tema di responsabilità del medico ospedaliero*, in Foro it., 1999, I, 3331; F. G. Pizzetti, *La responsabilità del medico dipendente come responsabilità contrattuale da « contatto sociale »*, in Giur. It., 2000, 740.

30 - Cass., 11 January 2008 n° 577, in Resp. civ. prev., 2008, 397, with note by R. Calvo, *Diritti del paziente, « onus probandi » e responsabilità della struttura sanitaria* ; Cass., 22 May 2014 n. 11363, in Dir. e giust., 1, 2014, Cass., 9 April 2014, n°. 8284, in iusexplorer.it; Cass., 30 September 2014, n. 20547, in Giust. Civ. mass., 2014; Cass., 2 October 2012, n°. 16754, in iusexplorer.it; Cass., 15 May 2012, n°. 7529, in iusexplorer.it; Cass., 13 July 2010, n°. 16934, in Giust. civ. Mass., 2010, 7-8, 1041; Cass., 19 April 2006, n°. 9085, in Giust. civ. Mass., 2006, 4; Cass., 21 June 2004, n°. 11488, in Giust. civ., 2005, I, 2115.

31 - Cass., sez. un., 28 July 2005, no. 15781, in Mass. Giur. it., 2005; Cass., 13 April 2007, n°. 8826, Mass. Giur. it.,, 2007; Cass., sez. un., 11 January 2008, no. 577, in Giust. civ., 2008, 1653, with note by A. *Ciatti, Crepuscolo della distinzione tra le obbligazioni di mezzi e le obbligazioni di risultato* ;

32 - Cass. , 20 May 2015, n°. 10289, in Giust. civ., 2015, 2321, with note by G. Sicchiero, *Dalle obbligazioni di mezzi e di risultato alle obbligazioni governabili e non governabili* ;on the issue see V. De Lorenzi, *Diligenza, obbligazioni di mezzi e di risultato*, in Contr. e impr., 2016, 484

33 - D.L. 13 September 2012, n° 158. For a first comment on the law, among the others M. Faccioli, *La quantificazione del risarcimento del danno derivante da responsabilità medica dopo l'avvento della legge Balduzzi*, in Nuova giur. civ. comm., 2014, II, 97; M. Faccioli, *Presunzioni giurisprudenziali e responsabilità sanitaria*, in Contr. e impr., 2014, 79; R. De Matteis, *La responsabilità professionale del medico. L'art. 3 del d.l. no. 158/2012 tra passato e futuro della responsabilità medica*, in Contr. e impr., 2014, 123-156.

the clear intention of the legislator to reestablish the rule of tortious liability for cases of non-contractual liability, thereby abolishing the "social contact" doctrine[34].

The new rule was opposed by the Italian *Corte di Cassazione*, which held that the rule was badly written and that therefore nothing changed in the regulation of medical liability[35], and that the liability of the health professional could not be excluded if he acted without due diligence, even though he respected the guidelines[36]. Some lower courts instead promptly adhered to the new provisions[37].

The heated discussion that followed the enactment of the *Decreto Balduzzi*, and the contrasting court decisions, led in 2017 to the enactment of the so-called *Legge Gelli*[38], which essentially confirms the provisions of the previous law, maintaining the exclusion of criminal liability of the health professional who respected guidelines or the best practices of his profession which apply to the clinical case under scrutiny. Moreover, the law clearly states that the liability of the health organization is contractual, while the liability of the health professional is tortious, but for the cases where the same professional acted to perform a contractual obligation toward the patient.

The concrete consequence of the application of these rules is still to be seen. The chances are that of a conflict between the rules provided by the law on the tortious liability of the health professional, and the case law of the Italian *Corte di Cassazione*, still opting for a definition of the medical liability as contractual . Alternatively, it is possible that the Italian judges formally respect the provisions of the *Legge Gelli*, but actually subvert its contents by using the presumption of fault of the health professional, and thus reversing the burden of the proof, in a context of the formal application of article 2043 c.c. on tortious liability[39].

The informed consent of the patient

Although until recently not explicitly provided for by Italian law, the "informed consent" required from a patient in a medical context has nevertheless been considered by Italian courts and legal operators to be binding for a long time[40]. The requirement of "informed consent" finds its roots in national and European regulations, as well as the Oviedo Convention on the Protection of Human Rights and Dignity in the medical field and in the Moral code of practice for doctors. On the basis of this requirement, the physician must inform the patient of the possible risks of the medical treatment. If the doctor obtained informed consent from the patient, he would not be liable to compensate harm caused by those risks if they actually occurred. If, instead, the doctor did not inform the patient of the possible risks of the medical treatment, and those risks occurred, causing harm to the patient, the doctor would be liable to compensate the harm suffered by the patient if, had the patient known the risks, he would not have chosen to have the medical treatment in question[41].

The only exception to this rule was when the treatment occurred in a state of necessity.[42] As article 32 of the Italian Constitution stipulates that "no one can be compelled to undergo any medical treatment except under a specific provision of the law," in line with the fundamental principle of inviolability of personal liberty provided for by article 13 of the same Italian Constitution, the medical treatment could be held as mandatory, for example, when a person was considered under conditions of high physical discomfort, or in emergency situations when the patient is unable to express his consent, regardless of the will of any relatives[43].

In all the other cases, the full respect for the individual in need of care required the physician to ask for his voluntary consent before any medical procedure, which entailed an

34 - Trib. Varese, 26. November 2012, n°. 1406, in DeJure; Trib. Enna, 18 April 2013, n°. 252, in DeJure; Trib. Milano, 17 July 2014, in Nuova giur. civ comm., 2015, I, 96 with comment by R. Pucella, *Un improvvido legislatore fa più danno dei medici* ; Trib. Milano, 23 July 2014, n°. 9693, in DeJure; Trib. Milano, 30 October 2014, Giur. it, I, 595, with note by N. Enrichens, La responsabilità civile sanitaria e la giurisprudenza di merito milanese.

35 - Cass., 19 February 2013, n°. 4030, in Giur. it., 2013, 2514; Cass., 17 April 2014, n°. 8940, in Mass. Giur. it., 2014; Cass., 22 May 2014, n°. 11363, Mass. Giur. It., 2014; Cass., 30 September 2014, n°. 20547, Mass. Giur. It, 2014; Cass., 20 March 2015, n°. 5590, Mass. Giur. It., 2015.

36 - Cass., 19 October 2015, n°. 21090, in Nuova giur. civ. comm., 2016, I, 564, with note by E. Sgubin, Linee guida e responsabilità della struttura sanitaria

37 - Trib. Milano, 2 December 2014, n°. 14320, in Resp. civ. e prev., 2015. For an analysis of the case law on the issue, T. Pasquino, La tutela dell'integrità psico-fisica della persona tra contratto e neminem laedere, in Nuova giur. civ. comm., 2015, II, 655-670; C. Chiaromonte, Responsabilità per fatto degli ausiliari e incarico contrattuale diretto al medico: il dubbio ruolo della casa di cura privata, in Riv. dir. civ., 2017, 489-507, in part. 492.

38 - Law n° 24, of the 8 March 2017. On the new law, in English, G. Montanari Vergallo, S. Zaami, Guidelines and best practices: remarks on the Gelli-Bianco law, in Clin Ter 2018, 169 (2):e82-85. doi: 10.7417/T.2018.2059; B. Mazzariol, M. Karaboue, A. Di Luca, N.M. Di Luca, Guidelines, good practices and best clinical health practices: valuable guidance for physicians and judges?, in Clin Ter. 2018 Nov-Dec;169(6):e292-e296. doi: 10.7417/CT.2018.2096.

39 - On the issue, please read P. Gallo, Quale futuro per il contatto sociale in Italia?, in Nuova Giur. Civ., 2017, 12, 1759. For a first comment on a criminal case, see A. Di Majo, Responsabilità civile del medico - Il giudizio di responsabilità civile del medico dopo la legge Gelli e cioè la perizia "guidata", comment to Cass. pen. Sez. Unite, 21 december 2017, n°. 8770, in Giur. It., 2018, 4, 841

40 - For a discussion on the operative application of the principle of informed consent, please read B. Gardella Tedeschi, M. Graziadei, Prevenire è meglio che curare: l'informazione al paziente, la responsabilità del medico e il governo del rischio clinico, in R. Balduzzi (ed.) La responsabilità professionale in ambito sanitario, Il Mulino, 2010, 399

41 - App. Milano, 2 May 1995, Foro it, 1996, I, 1418, annotated by S. Fucci; Cass., 25 November 1994 n°. 10014, in Nuova giur. civ. comm. I, 1995, 937 with note by G. Ferrando, Chirurgia estetica, « consenso informato » del paziente e responsabilità del medico; Cass., 10 September 1999 no. 9617, in Danno resp., 2000, 730, with note by R. Natoli, Consenso informato e obbligazioni di risultato tra esigenze di « compensation » ed esigenze di « deterrence ».

42 - More on the issue in M Graziadei, Il consenso informato e i suoi limiti, in L. Lenti, E. Palermo Fabris and P. Zatti (eds.), I diritti in medicina, Giuffrè, 2011, 191.

43 - G. M. Di Pentima. Il consenso. L'onere della prova nella responsabilità medica, Giuffrè, 2007, 1

information exchange about the procedure and its possible complications[44]. When the relevant information was missing, in whole or in part, the physician would be liable for guilty omission[45].

The rules on informed consent finally became national law with the enactment of Legge 22 dicembre 2017, n. 219, which explicitly requires the doctor to obtain the informed consent of the patient before proceeding with a medical intervention or therapy. The law does not apparently substantially innovate with respect to the Italian case law on the issue, and does not provide any rule on the liability of the physician in cases of violation of the principles on the informed consent provided by him. Nevertheless, we shall have to wait for the decisions of the Italian courts on the rules provided for by the law to evaluate the consequences of this enactment.

While we wait for that to happen, we can briefly point out some considerations on the requirement of informed consent in the Italian juridical landscape.

First of all, it is interesting to observe that, although Italy is not yet part of the Oviedo convention since it has still not passed the necessary decrees for its adoption, (under the provisions of Article 3, Italian Law N. 145/2001)[46], nevertheless Italian judges apply the provisions of the Convention in order to interpret Italian laws[47] and establish the liability of physicians when they have omitted to obtain the informed consent of the patient[48].

While a minority of Italian scholars interpret the rules on informed consent as rules of pre-contractual liability, in view of the fact that the requirement of the informed consent temporally precedes the conclusion of the professional contract, the majority of Italian scholars rather prefer to hold that, since the explanation to the patient of the medical procedure or of the methods and the consequences of the therapy fall within the executive phase of the medical treatment which began at the time of the diagnosis, it therefore constitutes an obligation which forms part of the contract entered into by the medical institution or the physician with the patient[49].

Italian scholars generally hold that the violation of the rule obliging the physician to acquire the informed consent of the patient violates both the right to health and the right to self-determination of the patient, and that both violations may be compensated. In any case, Italian scholars generally hold that the mere infringement of the duty to provide informed consent to the patient is not, in itself, compensable damage, as it is necessary for the medical procedure which was carried out without the patient's consent to have caused an injury to the patient and that the patient would not have undergone that medical procedure had he known of those possible injuries[50].

In any case, the provisions of the new law should put an end to the uncertainties on the issue by establishing that the informed consent must be acquired with the most appropriate instruments taking into account the patient's condition, and that the fact of consent must be documented in written form or with videotaping or other tools which permit the communication with disabled persons,.

Nadia Coggiola

44 - Cass., 25 November 1994 n .10014 in Mass. Giur.it., 1994

45 - Cass., 23 May 2001 n°.7027, in Foro it., 1995, 2913

46 - On the issue C. Casonato and F. Cembrani, Il rapporto terapeutico nell'orizzonte del diritto, in L. Lenti, E. Palermo Fabris and P. Zatti (eds.), I diritti in medicina, Giuffrè, 2011, 56

47 - Cass., 4 October 2007, n°. 21748, in Corr. Giur., 2007, 1676 with note by E. Calò, La Cassazione "vara" il testamento biologico

48 - G. Facci, I medici, i Testimoni di Geova e le trasfusioni di sangue, in Resp. Civ. prev., 2006, 938

49 - Cfr. C. Castronovo, Profili della responsabilità medica, in Studi in onore di Pietro Rescigno, vol. V, Responsabilità civile e tutela dei diritti, Giuffrè, 1998, 127; R. Omodei Salè, La responsabilità civile del medico per trattamento sanitario arbitrario, in www.juscivile.it, 12, 2015, 800

50 - On the issue, Cass., 24 September 1997 n°. 9374, in Riv. It. Med. Leg., 1998, 821, with note by F. Introna, Consenso informato e rifiuto ragionato. L'informazione deve essere dettagliata o sommaria; Cass. 14 March 2006 no. 5444, in Corr. Giur., 2006, pages 1243 et seq., with note by S. Meani, Sul danno risarcibile in caso di mancato consenso all'intervento eseguito correttamente. U. Carnevali, Omessa informazione da parte del medico, danno da trattamento terapeutico e ipotetica scelta del paziente, in Resp. Civ. prev., 2010, 2181; E. Palmerini, Il danno non patrimoniale da violazione del consenso informato, in E. Navarretta (ed.), Il danno non patrimoniale. Principi, regole e tabelle per la liquidazione, Giuffrè, 2010, 535

RÉDACTION

Journal de Droit de la Santé et de l'Assurance Maladie

Directeur de la publication

Frédéric Dardel
Président de l'Université Paris Descartes – Sorbonne Paris Cité

Directeurs de la rédaction

Anne Laude
Professeur des Universités, Doyen honoraire de la Faculté de droit, d'économie et de gestion, Membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Université Paris Descartes, Sorbonne Paris Cité, Président d'honneur de l'Association française de droit de la santé

Didier Tabuteau
Professeur associé à l'Université Paris Descartes, membre de l'Institut droit et santé, Inserm UMR S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité, professeur affilié à l'Institut d'études politiques de Paris

Coordinatrice de la rédaction

Laurence Warin
Doctorante à l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité, membre du Réseau doctoral en santé publique animé par l'EHESP

Conception graphique

Charlotte de Bruyn
Responsable de la communication de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Comité scientifique et international

Fernando Aith
Professeur à l'Université de Sao Paulo - USP, Co-Directeur du Centre d'Etudes et de Recherches en Droit de la Santé

Lary Brown
Professor of Health policy and management, Columbia University

Sueli Dallari
Professeur à l'Université de Sao Paulo, Directrice du centre d'études et de recherches en droit de la santé

Penney Lewis
Professor of Law, School of Law and Centre of Medical Law and Ethics, King's College London

Olivier Guillod
Professeur à l'Université de Neuchâtel, Directeur de l'Institut Droit et Santé de Neuchâtel

Catherine Régis
Professeur à l'Université de Montréal, Chaire de recherche du Canada en droit et politiques de la santé

William M. Sage
Visiting Professor, Yale Law School, James R. Dougherty Chair for Faculty Excellence, The University of Texas at Austin

Geneviève Schamps
Professeur à l'Université Louvain-la-Neuve, directeur du centre de droit médical et biomédical

Dominique Sprumont
Professeur à l'Université de Neuchâtel, co-directeur de l'Institut Droit et Santé de Neuchâtel

Comité éditorial

Mireille Bacache
Professeur à l'École de droit de la Sorbonne, Université Paris 1 Panthéon-Sorbonne, Sorbonne Assurance (IRJS), Directeur de l'Institut des Assurances de Paris 1 (IAP-Paris 1)

Pierre-Henri Bréchat
Membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité, membre de la Chaire Santé de Sciences Po, praticien hospitalier du groupe hospitalier Lariboisière-Fernand Widal de l'Assistance Publique, Hôpitaux de Paris (AP-HP) en mobilité au Centre Cochrane Français de l'hôpital de l'Hôtel-Dieu de l'AP-HP

Stéphane Brissy
Maitre de conférences à l'Université de Nantes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Xavier Cabannes
Professeur à l'université Paris Descartes, Sorbonne Paris Cité, membre du Centre Maurice Hauriou

Caroline Carreau
Maître de conférences émérite à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Philippe Coursier
Maître de conférences HDR à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Anne Debet
Professeur à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Duncan Fairgrieve
Maître de conférences à l'Institut d'Etudes Politiques de Paris, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Luc Grynbaum
Professeur à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité, Avocat Of Counsel chez De Gaulle Fleurance & associés

Anne Laude
Professeur des Universités, Doyen honoraire de la Faculté de droit, d'économie et de gestion, Membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Université Paris Descartes, Sorbonne Paris Cité, Président d'honneur de l'Association française de droit de la santé

Caroline Le Goffic
Maître de conférences HDR à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Clémentine Lequillerier
Maître de conférences à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Pierre Mazière
Maître de conférences à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Lydia Morlet-Haïdara
Maître de conférences HDR à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

David Noguéro
Professeur à l'Université de Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Pascal Paubel
Professeur associé à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Jérôme Peigné
Professeur à l'Université Paris Descartes, codirecteur de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Rémi Pellet
Professeur à l'Université Paris Descartes et à Sciences-Po Paris, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Didier Tabuteau
Professeur associé à l'Université Paris Descartes, membre de l'Institut droit et santé, Inserm UMR S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité, professeur affilié à l'Institut d'études politiques de Paris

Ana Zelcevic-Duhamel
Maître de conférences HDR à l'Université Paris Descartes, membre de l'Institut Droit et Santé, Inserm UMR_S 1145, Faculté de droit, d'économie et de gestion, Université Paris Descartes, Sorbonne Paris Cité

Institut Droit et Santé
Université Paris Descartes
Inserm UMRS 1145

Université Paris Descartes
Institut Droit et Santé
45 rue des Saints Pères – 75270 Paris Cedex 06
ids@parisdescartes.fr - www.institutdroitsante.com

Achevé en **juillet 2019**
ISSN : 2493-920X

Université Paris Descartes
Membre de USPC Université Sorbonne Paris Cité