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Medical Liability in Italy after the "Gelli-Bianco" reform (Law 8 March 2017, No. 24)[1]

1. Introductory remarks. The general inspiration of the reform and its main changes

After being mainly impacted by case-law for decades, medical liability in Italy was hugely reshaped in line with other European legal systems by a 2017 statute (Law of 8 March 2017, No. 27, the so-called Gelli-Bianco Law).[2]

The statute proclaims the safety of medical treatments as essential means to protect human health, both as a fundamental right and public good (art. 1). More specifically, the aim of the legislator was, on the one hand, to strengthen the protection of patients against medical malpractice, and, on the other, to mitigate the liability of medical doctors', which had become increasingly severe as a result of the case-law developments over the previous twenty years. In fact, the severe regime of medical li-

[1] Elena Bargelli is the author of pars 1–4 and 7, Edoardo Bacciardi is the author of pars 5, 5.1, 6.

[2] For a general overview of the reform, see: "La responsabilità sanitaria. Commento alla L. 8 marzo 2017, n. 24," ed. G. Alpa, Pacini 2017; *idem*, "Orientamenti della giurisprudenza sulla nuova disciplina della responsabilità medica," *Contratto e impresa* (hereinafter: C. e i.) 2019, 1 ff.; M. Astone, "Profili civilistici della responsabilità sanitaria (riflessioni a margine della legge 8 marzo 2017, n. 24)," *Nuova giurisprudenza civile commentata* (hereinafter: NGCC) 2017, 1115 ff.; M. Faccioli, "La nuova disciplina della responsabilità sanitaria di cui alla legge n. 24 del 2017 (Legge Gelli Bianco): profili civilistici," *Studium Iuris* (hereinafter: SI) 2017, 659 ff.; M. Gorgoni, "La responsabilità in ambito sanitario tra passato e futuro," *Responsabilità medica* (hereinafter: RM) 2017, 17 ff.; C. Granelli, "La riforma della disciplina della responsabilità sanitaria: chi vince e chi perde," *I Contratti* (hereinafter: Contr.) 2017, 377 ff.; M. Marucci, "La riforma sanitaria Gelli – Bianco. Osservazioni in tema di responsabilità civile," E.S.I. 2018, 115 ss.; R. Pucella, "E' tempo per un ripensamento del rapporto medico paziente?," RM 2017, 3 ff.; U. Salanitro, *La responsabilità medica dopo la novella*, NGCC 2018, 1676 ff.; L.M. Franciosi, "The New Italian Regime for Healthcare Liability and the Role of Clinical Practice Guidelines: A Dialogue among Legal Formants," *Journal of Civil Law Studies* 2018, 371 ff.; S. Albolino, T. Bellandi, S. Cappelletti , M. Di Paolo, V. Fineschi, P. Frati, C. Offidani, M. Tanzini, R. Tartaglia, E. Turillazzi, "New Rules on Patient's Safety and Professional Liability for the Italian Health Service," *Current Pharmaceutical Biotechnology* 2019, 615 ff.; F. Cascini, M. Contenti, G. Scarpetti, F. Gelli, W. Ricciardi, "Patient Safety and Medical Liability in Italy," *Eurohealth* 2020, 34 ff.

ability created by case-law rules had resulted in the inefficiency and unaffordability of the health care system, giving rise to the practice of "defensive medicine".[3]

This double goal is pursued by a combination of administrative, criminal and liability provisions rues.

Furthermore, in order to tackle the increase in medical malpractice litigation, the statute stipulates that both private and public hospitals and medical professionals must have insurance (art. 10), in line with previous statutes (Law 11 August 2014, No. 114, 14 September 2011, No. 148) and a general trend in Europe.

The main focus of this paper is on the action for damages (par. 2 ff.). However, the liability regime can be more appropriately understood bearing in mind the general inspiration of the reform and the wider context of the new criminal and administrative rules.

The objective of increasing the level of protection of patients was ensured by introducing new administrative bodies and procedures to improve medical practices and granting their transparency.[4] In particular, art. 2 bestows on the civic defender the function of Guarantor for the Right to Health, to which any citizen can report medical malpractice and malfunctioning of the health system. Article 3 introduces the National Observatory of Good Practices for the security of the health service, which identifies measures to prevent and manage the risk of medical malpractice by monitoring good practices.[5] Article 5 stipulates medical doctors shall follow the recommendations contained in the guidelines published according to Subsect. 3, prepared by private or public bodies or institutes, by scientific societies and technical-scientific associations of the medical professions registered in lists regulated by a decree of the Health Ministry. The guidelines and their updates are integrated into the National System for the Guidelines (SNLG), to be regulated by decrees from the Health Ministry.[6] The physician's behavior is considered negligent both when he/she ignores or unjustifiably deviates from the Guidelines, and when he/she superficially complies with them.[7]

The aim of mitigating the medical doctors' liability is to exclude their criminal responsibility where the damages are due to a lack of skill, provided that the surgeon observed the recommendations contained in the guidelines or, if these are not present, medical good practices. Of course, the guidelines need to be appropriate to the particular features of the actual case (see new art. 590-sexies of the criminal code).[8]

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[3] C. Granelli, "Il fenomeno della medicina difensiva e la legge di riforma della responsabilità sanitaria," *Responsabilità civile e previdenza* (hereinafter: RCP) 2018, 410 ff.

[4] M. Franzoni, "Colpa e linee guida nella nuova legge", DR 2017, III, 278, who stresses the interplay between the Guidelines and the duty of disclosure of physicians.

[5] N. Callipari, "L'applicazione della legge Gelli-Bianco. Primi orientamenti giurisprudenziali," *Nuova giurisprudenza civile commentata* (hereinafter: NCCC) 2019, 407 ff.

[6] G. Montanari Vergallo, S. Zaami, "Guidelines and best practices: remarks on the Gelli-Bianco law," *La clinica terapeutica* 2018, 82 ff.

[7] M. Gorgoni, "Colpa lieve per osservanza delle linee guida e delle pratiche accreditate dalla comunità scientifica e risarcimento del danno," RCP 2015, I, 189.

[8] S. Zerbo, G. Malta, A. Argo, "Guidelines and Current Assessment of Health Care Responsibility in Italy," *Risk Management and Healthcare Policy* 2020, 186.

1.1. The debate on possible amendments due to the COVID-19 emergency

Although doctors and nurses have been at the forefront of the COVID-19 health emergency, the legislator has not introduced any new special rules on medical liability, neither civil nor criminal. In particular, when the Decree-Law no. 18 of 17 March 2020 (DL – so-called Cura Italia) was converted into law, amendments were proposed to further mitigate the liability of both medical staff and hospitals. In such an emergency situation striking a balance between the safeguard of individual health and the functioning of the health system as a whole has proved to be particularly complex,[9] as it makes it difficult to properly assess possible medical malpractice by applying the recommendations contained in the existing guidelines.[10]

These amendments, however, were not introduced in the final text, as it was considered that existing law already provided a framework that could also solve the problems of the COVID-19 emergency.[11] A further argument was that the matter had been reformed in 2017 in the direction of already easing the liability of doctors and new exceptional rules in favour of medical staff or hospitals would not mitigate the risk of litigation anyway.[12] A very specific and temporary limitation of liability has been provided only for primary care physicians called to certify the absence of empoloyees from work (art. 26). On the other hand, the conversion law (24 April 2020, n. 27) allocated resources to remunerate overtime of healthcare personnel employed by NHS companies and bodies directly involved in activities to tackle COVID-19.

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[9] See C. Bilotta, S. Zerbo, G. Perrone, G. Malta, A. Argo, "The medico-legal implications in medical malpractice claims during Covid-19 pandemic: Increase or trend reversal?," *Medico-Legal Journal* 2020.

[10] A. Oliva, M. Caputo, S. Grassi, G. Vetrugno, M. Marazza, G. Ponzanelli, R. Cauda, G. Scambia, G. Forti, R. Bellantone, V.L. Pascali, "Liability of Health Care Professionals and Institutions During COVID-19 Pandemic in Italy: Symposium Proceedings and Position Statement," *Journal of Patient Safety* 2020, 299 ff. The paper deals with the following points of discussion: "(A) how to judge errors committed during the pandemic because of the application of protocols and therapies based on no or weak evidence of efficacy, (B) whether hospital managers can be considered liable for infected health care professionals who were not given adequate personal protective equipment, (C) whether health care professionals and institutions can be considered liable for cases of infected inpatients who claim that the infection was transmitted in a hospital setting, (D) whether health care institutions and hospital managers can be considered liable for the hotspots in long-term care facilities/care homes, and (E) whether health care institutions and hospital managers can be considered liable for the worsening of chronic diseases."

[11] See G. Comandè, *La responsabilità sanitaria al tempo del coronavirus ... e dopo*, in *Danno e responsabilità* (hereinafter: DR), 2020, III, 297 ff.

[12] Most experts were against the proposed amendments: G. Battarino – E. Scoditti, "Decreto legge n. 18/20: l'inserimento di norme sulla responsabilità sanitaria," www.questionegiustizia.it; G.M. Caletti, "Emergenza pandemica e responsabilità penali in ambito sanitario. Riflessioni a cavaliere tra scelte tragiche e colpa del medico," www.sistemapenale.it, 16 ss.; G. Losappio, "Responsabilità penale del medico, epidemia da Covid-19 e *scelte tragiche*", www.Giurisprudenzapenale.com.

2. Scope

As far as the action for damage is concerned, the 2017 statute introduces a double regime of liability for medical malpractice.

On the one hand, it reiterates the hospital's vicarious responsibility for the surgeon's faulty or intentional misconduct, according to arts 1218 (liability for breach of an obligation) and 1228 CC (creditor's liability for an assistant's non-fulfilment of his/her duty).

Regarding the surgeon, the reform confirms the previous Law 8 November 2012, no. 189 (Balduzzi Law) by stating that his/her liability falls under the general tort law rule (art. 2043 CC), unless he/she entered into a specific contractual relationship with the patient.

In making express reference to different liability rules – art. 1218 CC on the one hand, art. 2043 CC on the other – the statute differentiates between the action for damages against the hospital and the surgeon. Of course, this does not prevent the patient from suing both of them, as they remain jointly and severally liable for the damages suffered by the patient.

Finally, the statute complemented the liability regime by providing rules on the assessment of damages for personal injuries due to medical liability. It makes it clear that these damages need to be calculated according to arts 138 and 139 of the Insurance Code (legislative decree no. 209/2005), which applies to personal injuries occurring in traffic accidents. In extending these provisions to medical malpractice, the statute takes the generalisation of the criteria for calculating damages for *danno biologico* (personal injuries) a step forward and, at the same time, fixes a ceiling on claims for damages due to medical malpractice.

As mentioned above, this paper focuses on the liability rules, in order to identify their main features, interplay and impact on the protection of the patients' right to health.

More specifically, this paper deals with the nature of the liabilities that both hospitals and surgeons might incur and their practical implications (§ 3–4). It also deals with the question of the allocation of the burden of proof between the patient and surgeon, as this has been one of the most debated issues over the last twenty years, being crucial to understand the extent to which the liability rules work in the litigation scenario (§ 5). Theoretically, the plaintiff's burden of proof depends on the contractual or non-contractual nature of the liability. Therefore, although the legislative reform has not directly touched this issue, its impact might be indirect.

A further reason to deal with the regime of the burden of proof is that, after the 2017 law came into force, this was extensively reshaped by two judgments of the Cassation issued on 11 November 2019 (nos 28991 and 28992).[13] These judgments are part of a group of 10 judgments of the third section of the Court of Cassation con-

[13] Court of Cassation (hereinafter: Cass.), 11 November 2019, no. 28991 and 28992, *Giurisprudenza Italiana* (hereinafter: GI) 2020, I, 35.

cerning, inter alia, the following crucial issues of medical liability: informed consent (no. 28985);[14] the claim for recourse of the hospital towards the employee who acted with gross negligence (no. 28987); the liquidation of damages for personal injuries; the damages for „loss of chance" of healing due to a mistaken diagnosis (no. 28993); the non-retroactivity of the substantive rules and, *vice versa*, the retroactivity of the criteria for the settlement of damages provided for in the Insurance Code (nos 28990 and 28994). The aforementioned judgments deal with claims brought to the court before its entry into force and, since the new rules do not have retroactive effects, they do not come into play.

However, as far as these judgments do not deal with issues affected by the 2017 statute, their doctrines remain applicable even after the Cassation will start to rule on claims based on the new statute and complement the medical liability regime. That said, the overall picture is not entirely clear. In particular, the question arises as to whether the doctrine outlined by the Cassation on the burden of proof will also apply in the future, given that this is an issue which has not been changed by the new law, but, at the same time, is related to the classification of the medical liability.

Finally, this paper deals briefly with new insurance and procedural aspects because of their strict connection with the liability rules (par. 6).

3. The qualification of the medical doctor's liability

The qualification of a medical doctor's liability has been the most controversial issue in Italy since the late 1990s. In order to understand the meaning of the reform and its reference to art. 2043 CC, it is necessary to retrace the evolution of the surgeon's liability.

Medical liability is a classic grey zone between contract and tort. In general, the patient injured by medical malpractice has both a contractual right to the diligent execution of professional services and, as a citizen, the right to have his/her health protected against any negligent conduct. Unlike traditional French law, in Italy the *non-cumul* rule does not apply.

When the surgeon carries out the operation inside a hospital, the surgeon does not always have a contractual relationship with the patient. If she/he acts as a mere employee of the hospital performing a service to the patient, the question arises as whether the patient also has a claim against the medical doctor, and, more specifically, whether this is a contractual or an extra-contractual claim.

Before 1999, the dominant opinion was that the claim for damages against a surgeon who was employed in a hospital had an extra-contractual nature, being based on the general rule of tort law (art. 2043 CC).[15] This conclusion was based on the mere

[14] In DR 2020, no. 348, with comment by G. Facci, S. Martino, il consenso informato e il risarcimento dei danni.

[15] Cass. 13 March 1998, no. 2750, GI 1999, 2279; Cass.18 November 1997, no. 11440, *Giustizia Civile Massimario* (hereinafter: Giust. civ. Mass.) 1997, 2206.

absence of a contract between the surgeon and the patient and had clear implications in terms of both prescription and burden of proof. In fact, as the right to damages is an extra-contractual claim, the short five-year term applied (art. 2947 CC). In addition, the patients, as plaintiffs, should prove all the requirements needed to get damages according to art. 2043 CC, and, more specifically, the surgeon's negligence and the causal link between the medical treatment and the personal injury.

On the other hand, a mitigation of the surgeon's liability derived from the application of art. 2236 CC is also worth bearing in mind. This provision deals with professional services in general and states: "If the service involves the solution of technical problems of special difficulty, the service provider [the surgeon] shall not be liable for damages, except in cases of intent or gross negligence." Although art. 2236 CC regulates the professional's contractual liability,[16] it was deemed to be applicable even to surgeons that had no contractual relationship with the patient.[17] As a consequence of this professionals-friendly rule, where the medical performance is highly complex, the surgeon is not liable, unless he/she acted with gross negligence or intention. As partial mitigation of such a regime of liability, this exemption is considered applicable only where the surgeon's inexpertise is at stake, but not where the damage is due to negligence or carelessness.[18]

This initial phase ended in 1999, when a leading judgment of the Cassazione reframed the surgeon's liability as contractual.[19] This revisiting was inspired by the doctrinal theory of the "social contact" giving rise to protective obligations based on reliance and good faith.[20] More specifically, the Cassation developed the argument that the "social contact" between the surgeon and patient gives rise to a factual contractual relationship, although the parties were not bound by any agreement. In other words, the patient might not claim to have been treated by a specific surgeon given that there was no contract with this surgeon. However, if the surgeon acts as a hospital employee and negligently performs a medical service, the patient would have a contractual claim for damages against him/her.

This change of doctrinal classification had a huge practical impact on the success of the actions for damages brought by patients.[21]

Firstly and more importantly, it led to the application of the ordinary term of prescription of 10 years (art. 2935 CC) instead of the short five-year one.

Secondly and theoretically, the damaged party should have a lighter burden of proof. More specifically, according to the general rule concerning contractual liability,

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16 R. Calvo, „La *decontrattualizzazione* della responsabilità sanitaria (L. 8 marzo 2017, n. 24)", *Nuove leggi civili commentate* 2017, 453 ff.

17 Cass. 13 March 1998, no. 2750, cit.

18 Cass. 12 March 2013, no. 6093, *Diritto & Giustizia* 2013.

19 Cass. 22 January 1999, no. 589, *Foro Italiano* (hereinafter: FI) 1999, I, 3332, with comments by F. Di Ciommo and A. Lanotte.

20 See the most recent edition of C. Castronovo, *La responsabilità civile*, Giuffré 2018, 567 ff. (whose previous edition was *La nuova responsabilità civile*, Giuffré 2006).

21 G. Vettori, "Le fonti e il nesso di causalità nella responsabilità medica," *Obbligazioni e contratti* 2008, 393 ff.

the patient should not have to give evidence of the surgeon's negligence, but only should demonstrate the "social contact" or the contract with the surgeon and, after this, a deterioration in his/her health conditions. Conversely, it is the surgeon who has to prove his/her due diligence and/or the lack of causality between the medical practice and the injury suffered by the patient.[22]

This line of though was confirmed by the Grand Chamber of the Court of Cassation in 2008[23]. It was then followed by subsequent judgments of the Cassation, which extended the surgeon's contractual liability to situations where the patient's relatives claimed non-pecuniary damages *iure proprio*, on the basis of the argument that the factual contract would protect third parties who were affected by the medical malpractice. This happened, for instance, where the father, or the brothers and sisters of the child claimed damages due to wrongful birth,[24] while the mother was the only patient subject to the medical treatment.

This trend was changed by Law of 8 November 2012, no. 189, which, in reforming criminal and civil medical liability, surprisingly stated that medical doctors were liable for damages according to art. 2043 CC.[25] This statement gave rise to different reactions by the courts. Some interpreted the rule as an intentional derogation from the courts' doctrine based on contractual liability and classified the patient's claim as tortious.[26] Others did not recognize this legislative change as significant and continued to confirm the surgeon's contractual liability.[27] Finally, the Cassation confirmed the latter opinion.[28]

Law of 8 March 2017 no. 24 puts an end to the conflicting interpretations of the statute of 2012,[29] by making it clear that surgeons are responsible according to art. 2043 CC (art. 7). In doing so, it rejects the Cassation's doctrine based on the "social contact",[30] and brings the doctor's liability regime back to the period before 1999, with the main consequence that the five-year term of prescription applies again. This shift in the pattern of liability should lead to requiring the patients to demonstrate the surgeon's negligence and the causal link between medical malpractice and the damage

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22 Court of Cassation, Grand Chamber (hereinafter: Cass. SS.UU.), 30 October 2001, no. 13533, in SI, 2002, 389.

23 Cass. SS. UU. 11 January 2008, no. 577, *Giustizia civile* (hereinafter: GC) 2009, 11, I, 2532.

24 Cass. 10 May 2002, no. 6735, RCP 2003, 117, with comment of M. Gorgoni; Cass. 29 July 2004, no. 14488, FI 2004, I, 3327; Cass. 20 October 2005, no. 20320, FI 2006, 7–8, I, 2097; Cass. SS. UU. 11 November 2008, no. 26973, FI 2009, 1, I, 120; Cass. 2 February 2010, no. 2354, Giust. civ. Mass. 2010, II, 151.

25 A. Feola, V. Mariano, L.T. Marsella, "Medical Liability: The Current State of Italian Legislation," *European Journal of Health Law* 2015, 347 ff.

26 Tribunal (hereinafter: Trib.) of Milan, 23 July 2014, no. 9693, *De Jure* (hereinafter: DJ).

27 Trib. Arezzo, 14 February 2013, DR 2013, 368, with comment of V. Carbone; Trib. Rovereto 29 December 2013.

28 Cass. 17 April 2014, no. 8940, RCP 2014, 803; Cass. 8 November 2016, no. 22639, RCP 2016, 2025.

29 L.M. Franciosi, The New Italian Regime for Healthcare Liability and the Role of Clinical Practice Guidelines: A Dialogue among Legal Formants, cit., 389–390.

30 R. Calvo, "La *decontrattualizzazione* (fn. 7); D. Pittella, Dall'obbligazione senza prestazione alla responsabilità extracontrattuale del medico: rigetto locale o totale del contatto sociale *qualificato*?," C. e i. 2020, 418 ff.

suffered. In the practice, however, this sharp dividing line between contractual and non-contractual liability in terms of due diligence and allocation of burden of proof has been reshaped several times in the case-law. In particular, since 2001 the Court of Cassation has given rise to an in-between regime by identifying the main factors leading to allocate the proof of certain facts to the patient or to the doctor.[31]

4. The qualification and content of the hospital's liability

Whereas the surgeon's liability regime affords reduced protection to the patient than that granted by the previous case law, the 2017 law reinforces the hospital's liability. Unlike for the surgeon's liability, in this matter the statute follows the line of thought of previous case law by proclaiming the contractual nature of the hospital's liability, regardless of whether this is a private or a public entity.

The theoretical basis of its contractual liability was afforded by the Grand Chamber of the Cassation in 2002,[32] followed by the subsequent case law. According to this doctrine, a contractual relationship arises between the hospital and patient as soon as the latter turns to the hospital for medical treatment, although, as the Cassation recognized, no legislative rule regulates this contract.

As mentioned above, the hospital is proclaimed vicariously liable for the surgeon's medical malpractice. The legal basis for the hospital's vicarious liability is the general rule on the performance of an obligation by means of a third party (art. 1228 CC, according to which the obligor is responsible for damage caused by persons whom s/he uses to perform his/her obligation). Hospitals and surgeons are jointly and severally liable.

This liability arises regardless of whether the surgeon performs the medical treatment as a hospital employee or does it as a private practitioner outside of working hours in the hospital's facilities (this kind of medical practice is called *intra moenia*). This is crucial, as, in the latter situation, it is the patient who chooses the surgeon and pays a market price for the medical service, whereas the hospital puts its facilities at disposal.

If the hospital is held vicariously liable and pays for damages, an action of recourse against the surgeon arises if the latter acted with gross negligence or intention (art. 9). If the health care professional has not been part of the judicial or extra-judicial procedure for compensation for damages, the action of recourse against him/her can only be exercised after the compensation has been awarded. The right of recourse lapses in one year.

Even when damage was only caused due to the surgeon's negligence, the statutes fixes a ceiling on the amount of the right of recourse. This cannot exceed the highest income earned by the surgeon in the year in which the conduct that caused the event

[31] See below, par. 5.

[32] Cass. SS. UU. 1 July 2002, no. 9556, GC 2003, I, 2196.

or in the year immediately preceding or following the event commenced, multiplied by three times.[33] Regarding the cases of medical malpractice prior to the entry into force of the 2017 statute, the Court of Cassation ruled that the recourse action should be limited to half of the compensation due to the patient.[34]

Beside its vicarious liability for the harmful or unsuccessful medical treatment, the hospital must pay contractual damages for any organizational failure that negatively affects its patients. These include the inefficient collection and conservation of the patients' documentation, the lack of appropriate procedures for the classification of the level of urgency of patients, the failure of prompt accessibility of surgery, the inadequate organisation of work and the distribution of tasks and functions among the available staff.[35]

The implications of the contractual qualification of the hospital's liability in terms of burden of proof is illustrated by a judgment of the Cassation in 2017.[36] This made it clear that, where the patient sues the hospital for medical malpractice, she/he has to prove the causal link between the worsening of his/her health conditions and the medical malpractice. Only if causality is demonstrated, does the hospital have to prove an unforeseeable event, which made the fulfilment of the medical obligation impossible. The implications of the contractual qualification of medical liability are illustrated in detail in the following sections.

5. Distribution of the burden of proof

As far as the burden of proof of medical malpractice is concerned, five different successive approaches by the Cassation have been adopted.[37]

Initially, the physician's performance was qualified as an obligation of *means*, with the result that the plaintiff had to prove the breach of the other party and the causal link between the debtor's negligence and the harm occurring.[38] As a consequence, the defendant did not incur any liability for failing to achieve the *result* desired by the patient, only being liable when he/she breached any medical practice standards.

In the second phase, the distribution of the burden of proof depended on the specific content of the physician's obligation, in accordance with the distinction between professional performances involving routine treatment and those requiring more complex procedures.[39] In the former case, if a worsening of the patient's condition was proved, the *res ipsa loquitur* rule applied, according to which the surgeon's negligence

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33 See par. 6.

34 Cass. 11 November 2019, no. 28987, *Guida al diritto* 2020, 42.

35 M. Faccioli, *La responsabilità civile per difetto di organizzazione delle strutture sanitarie*, Pacini 2018.

36 Cass. 26 July 2017, no. 18392, FI 2018, 4, I; Cass. 15 February 2018, no. 3704, *Guida al diritto* (hereinafter: GD) 2018, 19, 51; Cass. 2 March 2018, no. 4928, GD 2018, 21, 68.

37 See A. Barbarisi, "L'onere della prova nella responsabilità sanitaria," Contr. 2017, II, 217 ff.

38 See, *inter alia*, Cass., 9 March 1965, no. 375, FI 1965, I, 1039 ff.

39 Cass. 21 December 1978, no. 6141, FI 1979, 4, I. On the application of art. 2236 CC in the field of medical liability, please see above, par. 3.

was considered to be demonstrated, whereas she/he should provide the evidence of an unforeseeable event or any other circumstances excluding his/her liability (such as the previous physical conditions of the patient).[40]

The third phase began after a judgement by the Grand Chamber of the Cassation of 2001,[41] which affirmed the "proximity of evidence" doctrine. As a consequence the distinction between routine and difficult performance was no longer deemed to be "relevant (…) as a criterion for distributing the burden of proof," since it helped in assessing the breaching party's degree of negligence.[42]

In the fourth phase, an important judgement issued by the Grand Chamber of the Cassation of 2008 highlighted that the plaintiff's claim can be based on the allegation of a "qualified" breach, that is a non-performance which, at least theoretically, could cause the harm suffered by the victim. Conversely, the doctor and/or the hospital should prove that such a breach had not occurred or that there was no causal relationship between the non-fulfilment and the harmful event.[43]

Although this doctrine was not expressly overruled, the current fifth phase[44] involves a new trend, which was confirmed by the aforementioned ten crucial judgments issued by the Third Section of the Cassation in 2019.[45] After emphasizing that, in general, liability requires the connection between material *causation* and *imputation*, i.e. the legal effect which the legislator assigns to a specific behaviour, the Cassation came to the conclusion that, in the case of medical malpractice, the claimant has to prove the "purely material connection" between the health impairment and the debtor's conduct. Once this proof has been established, the defendant has to prove either the fulfilment of the obligation or the impossibility of performance due to external circumstances.[46]

The doctrine affirmed by the 2019 judgment is not currently unanimously upheld.

Some scholars welcome the aforementioned doctrine by emphasizing that it leads to both a clear-cut distinction between negligence and causality[47] and a clarification

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[40] Notably, the Court ruled that "when a surgical operation is not difficult to perform and the outcome thereof caused a worsening of the final conditions of the patient, the plaintiff fulfils his burden of proof by proving that the surgical operation was easy to be performed, and caused an outcome worse-than-expected (…); therefore, the hospital shall provide the rebuttal evidence, i.e. prove that that the professional performance was carried out properly and the worsening outcome was caused by the occurrence of an unforeseen and unforeseeable event, or by the existence of a particular physical condition of the patient, which could not be ascertained using the ordinary professional diligence."

[41] Cass. SS.UU., 30 October 2001, no. 13533, cit.

[42] Cass. 28 May 2004, no. 10297, FI 2005, I, 2479;. C. Di Marzo, "Medical Malpractice: The Italian Experience" (in:) *Medical Malpractice and Compensation in Global Perspective*, eds K. Oliphant and R.W. Wright, 2013, 224.

[43] Cass. SS.UU. 11 January 2008, no. 577, cit., concerning a claim for damages resulting from a patient having contracted Hepatitis C after a blood transfusion in a hospital.

[44] Regarding the hospital liability, see Cass. 26 July 2017, No. 18392, cit.

[45] Cass. 11 November 2019, no. 28991, cit.

[46] Cass. 11 November 2019, no. 28991, cit.

[47] P.G. Monateri, "Il nuovo quadro della responsabilità medica e del danno alla persona secondo la Corte di cassazione," DR 2020, II, 154.

of the events to be proved by each party. More specifically, when the cause of the harmful event remains unknown, this plays against the patient, whereas if the surgeon does not prove the cause of the impossibility of performance, the claim is upheld.[48] Furthermore, the effort to adapt the burden of proof to the specific features of medical liability was considered to be a positive factor.[49]

Others criticize the judgement, underlining that if the patient has to prove the material causation, this would be inconsistent with the doctrine stated by the Cassation in 2008, according to which it is sufficient for him/her to *allege* – and not necessarily to *prove* – a "qualified breach" of the physician.[50]

As mentioned before, the aforementioned judgments do not apply Law no. 24/2017, as they deal with cases that arose before it came into force. This means that both the hospital's and surgeon's liabilities are considered to be contractual and fall under the same rules on the burden of proof.[51] Nevertheless, given the non-retroactivity of the new statute (par. 2), the rulings issued by the Cassation and the subsequent debate are still relevant for the litigation still in progress, as well as in case the physician has assumed the obligation on the basis of a professional service contract.[52] A further reason why these might be applicable after the litigation on the new statute will start is that the reasoning of the Court of Cassation seems to disregard the classification of the medical liability. In particular, some commentators have criticised the Supreme Court precisely because it would have applied the evidentiary regime of non-contractual liability to contractual liability.[53] However, the Grand Chamber is expected to take up a position on this issue.[54]

5.1. Other issues concerning the allocation of the burden of proof

A further issue affecting the allocation of the burden of proof is how medical records are stored and kept.[55] The Cassation made it clear that the failure to adequately

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48 P.G. Monateri, "Il nuovo quadro della responsabilità medica…," 155.

49 C. Scognamiglio, "La Cassazione mette a punto e consolida il proprio orientamento in materia di onere della prova sul nesso di causa nella responsabilità contrattuale del sanitario," *Corr. giur.* 2020, III, 312–313.

50 M. Magliulo, R. Pardolesi, "Pluralità di nessi di causa e paziente allo sbaraglio," DR 2019, 265–266; G. D'Amico, "Il rischio della *causa ignota* nella responsabilità contrattuale in materia sanitaria," DR 2018, III, 354. These authors refer to the judgement no. 18392/2017, cited by the judgement no. 28991/2019.

51 Although these two relationships – between the patient and doctor on the one hand, between the patient and hospital on the other – should be kept distinct from each other (pars 3–4), the Cassation pointed out that the allocation of the burden of proof is governed – in both cases – in accordance with the judgment issued by the Grand Chamber in 2001 (see Cass. SS.UU. 11 January 2008, no. 577, cit.).

52 See C. Scognamiglio, "La Cassazione mette a punto e consolida il proprio…," 307 ff.

53 A. Procida Mirabelli Di Lauro, "La Terza Sezione e la strana teoria dell'inadempimento… extra-contrattuale per colpa," DR 2019, II, 248 ss.

54 A. Procida Mirabelli Di Lauro, "Inadempimento e causalità *materiale*: perseverare diabolicum," DR 2020, I, 83–84.

55 A. Porat, A. Stein, "Liability for Uncertainty: Making Evidential Damage Actionable," *Cardozo Law Review* 1997, 1891 ff.; E.B. Oppenheim, "The Law of Evidence and the Medical Record," *Journal of Medicine and Law* 1998, 167 ff. It has been pointed out that "regarding the specific remedy for breach of

and accurately record medical data "cannot increase the patient's burden of proof", with the result that the failure of medical records presumes both the physician's negligence and the causal link between the medical malpractice and the harm suffered by the victim.[56] Of course, this presumption is only founded when the incompleteness in medical records prevents any ascertainment of the causal link and, in addition, the physician's behaviour was abstractly capable of producing the damage.[57] This judgment has led to contrasting views by scholars.[58] After the rulings issued on 11 November 2019, the Cassation has confirmed the doctrine according to which the incompleteness of the medical records leads to presume the existence of the causal link between the doctor's conduct and the damage, when a qualified non-performance was alleged by the plaintiff.[59]

An additional example of the reversal of the burden of proof is the violation of the patient's informed consent, where the treatment was not detrimental to him/her. The Cassation is generally keen to award compensation arguing for the infringement of the patient's fundamental right to "informational self-determination", regardless of whether the therapy was beneficial or detrimental to him/her. According to a particular line of thought, this would be sufficient to award damages to the patient.[60] A stricter doctrine was recently adopted by the Cassation, by requiring that the plaintiff proves that, if properly informed, the treatment would have not been consented to.[61] This doctrine was confirmed by a judgment in 2019.[62] This approach is in line with the "proximity of evidence" rule by imposing on the patient the burden of proving his/her hypothetical will. On the other hand, the judge must take into account that patients generally follow the recommendations given to them by the surgeons.[63] In other words, where the medical treatment is appropriate, it may be presumed that, according to the *id quod plerumque accidit* rule, the claimant would have undergone the treatment.[64]

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the duty to give account, records are the decisive element, particularly in the context of a claim for non-performance (…). The lack or incompleteness of the medical record may even justify the reversal of the burden of proof in a liability claim under the doctrine of res ipsa loquitur" (M. Barendrecht, C. Jansen, M. Loos, A. Pinna, R. Cascao, S. Van Gulijk, *Principles of European Law: Service Contracts*, Oxford 2007, 878).

56 Cass. 31 March 2016, no. 6209, *Rassegna di diritto farmaceutico* 2016, III, 528; Cass. 21 gennaio 2020, no. 1158, DJ.

57 Cass. 12 June 2015, no. 12218, cited by Cass., 11 November 2019, no. 28994; Cass. 16 November 2020, no. 25877, DJ.

58 In favour of the aforementioned line of thought, see Ceccarelli, "La cartella clinica nel processo," DR 2019, II, 169. Contra M. Rossetti, "Unicuique suum, ovvero le regole di responsabilità non sono uguali per tutti (preoccupate considerazioni sull'inarrestabile fuga in avanti della responsabilità medica)," GC 2010, X, 2227.

59 Cass. 15 settembre 2020, no. 19189, DJ.

60 Cass. 14 March 2006, no. 5444, *Rivista italiana di medicina legale* (hereinafter: RIML) 2007, III, 865.

61 Cass. 9 February 2010, no. 2847, FI 2010, 1, 2113.

62 Cass. 11 November 2019, no. 28985, *Corriere giuridico* (hereinafter: CG) 2020, III, 348 ff.

63 Cass. 11 November 2019, no. 28985, cit.

64 G. Facci, San Martino, "Il consenso informato ed il risarcimento dei danni," CG 2020, III, 363.

A final issue worth mentioning is the impact of the insufficient proof of causation on the claim for *loss of chance*.[65] In 2019, the Cassation made it clear that where the causal link between medical malpractice and damage is not adequately proved, this does not automatically open the gate to compensation for the loss of the opportunity to be cured or adequately treated.[66]

Thus, if the physician's breach has reduced the chances of healing, the amount of damages should be fairly reduced, in order to "mitigate (…) the so-called "all or nothing" compensation criterion."[67] This means that the loss of chance impacts on the amount of compensation (*quantum debeatur*), provided that the physician's negligence has been proved.[68]

6. Mandatory Insurance and Procedural provisions

Law 24/2017 imposes both private and public hospitals to conclude an insurance contract (art. 10), under the terms and conditions expressly required by the law and by the implementing decrees. Compulsory insurance is imposed on all kinds of health professionals (art. 10 subs. 2).

The goal of this compulsory insurance is to increase the victim's protection, ensuring that the damages caused by the breaching party can be fully recovered.[69]

The mandatory insurance requirement is closely related to the provision which entitles the patient to file a lawsuit directly against the liability insurer (art. 12). In this case, the defendant cannot raise exceptions other than those concerning the insurance contract and provided by the law (art. 12, subs. 2).[70] The rule is not retroactively applicable, as stated by a recent judgment[71] in accordance with the principle that the claimant can directly sue the insurance company only in the cases expressly named by the law, while in all other cases the insurer is bound to indemnify only the insured party for the damages which the latter is held to pay to the plaintiff.[72]

A further provision that supplements the liability rules introduced by the Gelli-Bianco Law concerns the hospital's right of recourse against the surgeon. Once the hospital has paid damages to the injured party, it is allowed to file a recourse action

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65 Cass. 11 November 2019, no. 28993, CG 2020, III, 297 ff.

66 Cass. 16 October 2007, no. 21619, RCP 2008, II, 323.

67 Cass. 11 November 2019, no. 28993, cit.

68 R. Calvo, "Perdita di chance terapeutiche: un precedente-decalogo," CG, 2020, III, 303.

69 M. Gagliardi, "Profili assicurativi della responsabilità degli enti e dei professionisti sanitari e delle garanzie di risarcimento per i danneggiati del sistema sanità," RIML 2017, IV, 1503 ff.

70 On these aspects, see M. Hazan, "L'azione diretta nell'assicurazione obbligatoria della rc sanitaria (e il regime delle eccezioni)," DR 2017, III, 317 ff.

71 Trib. Reggio Calabria, 20 March 2019, no. 456, DJ.

72 Cass. 17 January 2017, no. 925, GD 2017, 7, 32. Following this line of thinking, the Tribunal of Reggio Calabria held that Law no. 24 of 2017 allows the plaintiff to bring a legal action directly against the insurer, but "the new law applies to all claims relating to medical liability commenced on or after April 1 2017" (Trib. Reggio Calabria, 20 March 2019, no. 456, cit.).

against the physician, provided that she/he acted intentionally or with gross negligence (art. 9). This limitation of the surgeon's liability is wider than that awarded by the previous legislation[73] and confirms the policy aimed at mitigating the physician's responsibility.[74] In addition, the amount of damages the doctor has to pay cannot exceed, in the event of gross negligence, three times his/her annual salary for the year in which the harmful conduct commenced or for the previous or following year, whichever is higher.

Finally, the 2017 statute gives rise to a mandatory mediation procedure (art. 8), which can take place in two different forms: either as a "preliminary technical expertise for the settlement of the dispute" regulated under art. 696 *bis* of the Italian Code of Civil Procedure, or as a mediation procedure set forth in art. 5 Decree 28/2010. This preliminary attempt at conciliation is a mandatory requirement for the judicial action to be allowed, which is aimed at encouraging settlement agreements and reducing medical litigation before a court.[75]

It is disputed whether the insurance company can be involved in the preventive technical assessment. An argument in favour is that this involvement would promote the conciliatory purpose of the procedure.[76] An argument against, however, is that, before commencing litigation, the damaged party does not know whether the defendant will sue the insurer and, therefore, the insurance company's participation in the preventive technical assessment should be limited to the case of the direct action set forth in art. 7.[77]

A constitutional challenge to the preventive technical assessment was recently launched by the Tribunal of Florence. The Court argued that the procedural fees may be unaffordable for claimants who do not meet the requirements for subsidized legal aid, with the consequence that these costs might prevent people from exercising their right to health, which is inconsistent with art. 3 of the Italian Constitution.[78]

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[73] Before 2017, the liability limitation was applicable only to surgeons employed in public health facilities and to the employment contracts regulated by the provisions of collective bargaining agreements.

[74] See A. D'Adda, "Solidarietà e rivalse nella responsabilità sanitaria: una nuova disciplina speciale," CG 2017, VI, 769 ff.

[75] A. Pastorini, M. Karaboue, A. di Luca, N.M. Mario di Luca, C. Ciallella, "Medico-Legal Aspects of Tort Law Patient Safeguards within The Gelli-Bianco Piece of Legislation," *La clinica terapeutica* 2018, 173–174.

[76] Tribunal of Verona, 10 May 2018, DJ.

[77] M. Bove, Responsabilità sanitaria ed esperimento di ADR come condizione di procedibilità: su alcune questioni aperte, in Rivista dell'arbitrato, 2019, III, 587 ff.

[78] Tribunal of Florence, 21 May 2020, DJ. The Court pointed out that these costs could amount on average to 5-10 to 15-20 thousand euros.

7. Final remarks

Medical liability is the legal area in which the most important theories on crucial key issues of the law of obligations have developed. This applies to matters of negligence, causation, allocation of the burden of proof, protective obligations, boundaries between contractual and non-contractual liability. The evolution of case law on medical malpractice has contributed to changing the law of obligations as a whole.

On the other hand, medical malpractice has some very specific aspects, which has led some legal systems to regulate it by statute as a special branch of liability, as is the case of Italian law. More generally, it became clear that the civil liability of hospitals and medical staff is part of a more complex regulation of the health service as a whole, which is the result of public policy choices.

The Gelli-Bianco statute has led to a systematic regulation of the field, following the line of previous statutes under most aspects and changing the trend of case law on the qualification of the surgeon's liability.

However, some crucial issues are still unaffected by the statute. Allocation of the burden of proof, informed consent, causality, damages for "loss of chance" and liquidation of personal injuries are still under the case law domain. In particular, they are under the spotlight after the judgments of the Cassation on 11 November 2019 stated general guidelines and consolidated the previous doctrines.[79]

The qualification of the medical liability as contractual or extra-contractual is important to establish the length of the period of the prescription, while influencing the level of due diligence and the allocation of the burden of proof between the surgeon and patient to a much lesser extent,[80] as the analysis of the older and latest trends of the Cassation shows.

The 2017 statute confirmed that medical liability rules are currently affected by more general policy considerations, requiring a delicate balance between protecting the individual's health and the sustainability of the whole health care system.

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Summary

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Medical Liability in Italy after the "Gelli-Bianco" reform (Law 8 March 2017, No. 24)

The present paper deals with the reform of medical liability in Italy (Law 8 March 2017, No. 24). After giving an overview of the main changes introduced by the 2017 law, the paper focuses on the liability for medical malpractice. More specifically, it deals with the nature of the sur-

geon's and hospital's liability, the allocation of the burden of proof and, finally, insurance and procedural aspects. In general, the law is aimed at mitigating the surgeon's liability regime and strengthening the protection of the patients by reinforcing the hospital's liability. Following this general inspiration, the 2017 law has changed the trend previously followed by the Court of Cassation by proclaiming that, where no contractual relationship exists between surgeon and patient, the liability for medical malpractice is subject to the general tort law rule (art. 2043 CC).

Keywords: medical malpractice; contractual liability; extracontractual liability; prescription; burden of proof; loss of chance; insurance; negligence; causation; mediation; hospital's liability; action of recourse.

Streszczenie

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Odpowiedzialność medyczna we Włoszech po reformie "Gelli-Bianco" (ustawa z dnia 8 marca 2017 r., Nr 24)

Artykuł poświęcony został reformie odpowiedzialności medycznej we Włoszech (ustawa z 8 marca 2017 r., Nr 24). Po przedstawieniu głównych zmian wprowadzonych na mocy ustawy z 2017 r., autor skupia się na odpowiedzialności za błędy w sztuce lekarskiej, w tym przede wszystkim, charakterze odpowiedzialności chirurga i szpitala, rozłożeniu ciężaru dowodu, kwestii ubezpieczenia oraz aspektach proceduralnych. Co do zasady, obowiązujące prawo ma na celu złagodzenie reżimu odpowiedzialności chirurga oraz wzmocnienie ochrony pacjentów poprzez zwiększenie odpowiedzialności szpitala. Podążając za tą ogólną inspiracją, ustawa z 2017 r. zmieniła tendencję widoczną we wcześniejszym orzecznictwie Sądu Kasacyjnego, stanowiąc, iż w przypadku braku stosunku umownego między chirurgiem a pacjentem odpowiedzialność za błędy w sztuce lekarskiej podlega przepisom ogólnego prawa deliktowego (art. 2043 CC).

Słowa kluczowe: błąd medyczny; odpowiedzialność umowna; odpowiedzialność pozaumowna; przedawnienie; ciężar dowodu; utrata szansy; ubezpieczenie; niedbalstwo; związek przyczynowy; mediacja; odpowiedzialność szpitala; powództwo regresowe.