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THE NEW ITALIAN REGIME FOR HEALTHCARE LIABILITY AND THE ROLE OF CLINICAL PRACTICE GUIDELINES: A DIALOGUE AMONG LEGAL FORMANTS

Laura Maria Franciosi*

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Keywords: medical malpractice, professional liability, tort law, law reform

I. INTRODUCTION

In Italy, the Gelli-Bianco Law (referred to as the 2017 Law in this article)[1] deals with the issue of medical malpractice, liability of the healthcare provider and, from a broader perspective, defensive medicine.[2] The previous law (commonly referred to as the Balduzzi

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1. Legge Mar. 8, 2017, n. 24, G.U. Mar. 17, 2017, n. 64. It is commonly referred to as the Gelli-Bianco Law due to the name of the two members of the Parliament who submitted the relevant text.

2. Defensive medicine occurs when physicians order unnecessary treatments and excessively rely on tests and procedures (i.e., positive defensive medicine), or when they refuse to treat patients that present a high degree of risk, in an effort to avoid malpractice suits rather than because they consider the treatment medically appropriate (i.e., negative defensive medicine). *See* U.S. Congress, Office of Technological Assessment, *Defensive Medicine and Medical Malpractice* 3, OTA-H--602 (1994), quoted by Sira Grosso, *What Is Reasonable and What Can Be Proved as Reasonable*: *Reflections on the Role of Evidence-Based Medicine and Clinical Practice Guidelines in Medical Negligence Claims*, 27 ANNALS HEALTH L. 74, 76 n. 13 (2018); *see also* Daniel W. Shuman, *Expertise in Law, Medicine and Health Care*, 26 J. HEALTH POL. POL'Y & L. 268 (2001).

Law[3]) was enacted in 2012 and represented the first legislative attempt to put a limit to professional liability grounded on medical malpractice in light of the settled judicial orientation of the previous case law.[4] Indeed, until 2012, without a specific legal framework for medical malpractice, Italian judges and Italian doctrine addressed the issue.[5]

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3. Decreto Legge Sept. 13, 2012, n. 158, G.U. Sept. 13, 2012, n. 214 converted with amendments in Legge Nov. 8, 2012, n. 189, G.U. Nov. 10, 2012, n. 263 ("Urgent provisions to foster the development of the Country through a higher level of health's protection").

4. *See generally* Giulio Ponzanelli, *La responsabilità medica*: *dal primato della giurisprudenza alla disciplina legislativa*, 8-9 DANNO E RESPONSABILITÀ 819 (2016).

5. Pursuant to the Italian case-law, medical malpractice used to be encompassed within the range of application of art. 2043 of the Italian Civil Code ("C.c."). Art. 2043 C.c. (Compensation for unlawful acts) provides the general norm for tort liability. However, starting from 1999, the Italian Supreme Court (with ruling n. 589/1999), through the recourse to the *fictio iuris* of the so called *contatto sociale* between the physician and the patient, deemed such liability as a contractual one, thus applying the relevant legal regime, more favorable to the patient. On behalf of the healthcare provider, it used to be invoked the application of art. 2236 C.c., limiting the liability of the practitioner to the event of her malice or gross negligence, but only for cases requiring the solution of technical issues of particular difficulty. *See, ex multis*, Guido Alpa, *Ars interpretandi e responsabilità sanitaria a seguito della nuova legge Bianco-Gelli*, 3 CONTRATTO E IMPRESA 728, 732 (2017) [hereinafter Alpa, *Ars interpretandi*]. Besides the liability of the physician, it used to be affirmed that the contractual liability of the healthcare institution (public and/or private) due to the atypical contract (i.e., *contratto di spedalità*), expressly or implicitly entered into force between the patient and the institution. In light of its peculiarities, the medical malpractice used to be deemed by some commentators and tribunals as a sub-system of civil liability. *See*, *ex multis*, Carlo Granelli, *Il fenomeno della medicina difensiva e la legge di riforma della responsabilità sanitaria*, 2 RESP. CIV. PREV. 410, nn.120-131 (2018); RAFFAELLA DE MATTEIS, LA RESPONSABILITÀ MEDICA: UN SOTTOSISTEMA DELLA RESPONSABILITÀ CIVILE (CEDAM Padova, 1995); Vincenzo Roppo, *La responsabilità civile dell'impresa nel settore dei servizi innovativi*, CONTRATTO E IMPRESA 891, 894 (1993). According to other scholars, though speaking of "system" would raise conceptual issues, medical malpractice should nevertheless be intended as a special regime comparable to that of tort liability; *see* Guido Alpa, *From the Physician to the Team, to the Healthcare Setting, to the System*, *in* LAW AND MEDICINE—CURRENT TOPICS IN A GERMAN AND ITALIAN PERSPECTIVE 13, 14 (Consiglia Botta & Christian Armbrüster eds., Edizioni Scientifiche Italiane 2017). The 2017 Law has introduced specific provisions dealing with the proper qualification of medical malpractice: *see infra*, § III. For interesting remarks about individual liability and the evolution of the law of torts, *see* Olivier Moréteau, *Individual Liability in a Vulnerable Environment*: *Revisiting the Ethical Foundations of Tort Law*, *in* ESSAYS IN HONOUR OF JAAP SPIER 239-257 (Helmut Koziol & Ulrich Magnus eds., Jan Sramek Verlag 2016).

The legislative intervention reveals the constant interest for the subject matter as well as the difficulties to cope with its related issues. Like the previous legislation, the 2017 Law addresses the topic from a wide perspective, insofar as it does not focus only on medical malpractice, but rather on liability of healthcare providers in general, and it outlines a comprehensive system aimed at achieving the safety of healthcare through different interventions. Furthermore, it approaches medical malpractice encompassing new criteria. In particular, the law tries to allocate the liability regime from a legal and economic perspective, though charging the economic consequences of an adverse event on the entity better able to bear it (i.e., the public or private healthcare institution).

Last but not least, in the original intention of the legislature, the 2017 Law was to reduce defensive medicine,[6] thus benefiting patients. In particular, the 2017 Law intended to address the topics of medical malpractice, defensive medicine and safety of patients introducing a more favorable regime of professional liability for the healthcare providers, both from the civil law and the criminal law perspective, focused on a new and more detailed role for Clinical Practice Guidelines (CPGs).[7]

In its original intention, it should have redressed some gaps and limits of the Balduzzi Law on the one hand, and, it should have decreased defensive medicine and healthcare liability on the other hand, by providing judges with clearer and more favorable rules and standard of behavior for healthcare professionals. In spite of several positive aspects, the 2017 Law did not reach its ambitious goal, in particular because of the limits of the new regime for criminal liability.[8] The legislative choice to give CPGs a determinant role in the

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6. *See generally* Carlo Granelli, *La medicina difensiva in Italia*, 1 RESP. CIV. PREV. 22 (2016); ADELMO MANNA, MEDICINA DIFENSIVA E DIRITTO PENALE. TRA LEGALITÀ E DIRITTO ALLA SALUTE (Pisa U. Press 2014); ALESSANDRO ROIATI, MEDICINA DIFENSIVA E COLPA PROFESSIONALE MEDICA IN DIRITTO PENALE. TRA TEORIA E PRASSI GIURISPRUDENZIALE (Giuffrè 2012).

7. *See* Alpa, *Ars interpretandi*, *supra* note 5, at 729-731.

8. *See infra*, § V.

professional liability of healthcare providers' cases seems to follow the U.S. legal system, where the topic of Evidence-Based Medicine[9] and that of CPGs originated and have gained primary importance even for purposes of legislative reforms.

CPGs are commonly associated to Evidence Based Medicine (EBM). However, many commentators stress the conceptual difference between them, highlighting that EBM involves much more than CPGs. Yet the latter, when really evidence-based, can facilitate the practice of EBM by serving as codifications of the best evidence available. Thus, CPGs are useful, if not essential components of EBM.[10]

In the U.S., the legal system for medical liability is based on the negligence standard.[11] Currently, neither law nor jurisprudence

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9. The first to use the term Evidence Based Medicine (EBM) has been Gordon Guyatt, *Evidence-Based Medicine*, 114 ACP J. CLUB A16 (1991) (pointing out the trend towards the best use of scientific literature and biomedical development in medical decision-making). *See also* David Sackett, *Evidence Based Medicine*: *What It Is and What It Isn't*, 312 BRIT. MED. J. 71 (1996) (defining EBM as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients"); Lars Noah, *Medicine's Epistemology*: *Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373 (2002); Roger Sur & Philip Dahm, *History of Evidence-Based Medicine*, 27 INDIAN J. UROL. 487 (2011).

10. For the features of the tort of negligence and the relevance of the requirement of the duty of care, *see* Carter L. Williams, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines*: *What Effect Will EBM Have on the Standard of Care?*, 61 WASH. & LEE L. REV. 479, 486-487 (2004) [hereinafter Williams, *Evidence-Based Medicine*]. CPGs used to be defined by the Institute of Medicine as "systematically developed statements to assist practitioner and patient decision about the appropriate health care for specific clinical circumstances," *see* Committee on Clinical Practice Guidelines, Institute of Medicine, *Guidelines for Medical Practice* 2 (Marylin J. Field & Kathleen N. Lohr eds. 1992). Currently, their revised definition reads: "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and in assessment of the benefits and harms of alternative care options." *See* Institute of Medicine (U.S.) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, *Clinical Practice Guidelines We Can Trust* (Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, & Earl Steinberg eds., National Academies Press 2011) [hereinafter *Clinical Practice Guidelines We Can Trust*]. As it can be inferred by a comparison between the two definitions, the latest puts more emphasis on the methodology in the process of CPGs' selection.

11. *See* Donoghue v. Stevenson [1932] UKHL 100 (Scot.); Palsgraf v. Long Island Railroad Co., 248 N.Y. 339, 162 N.E. 99 (1928); and MacPherson v. Buick Motor Co., 217 N.Y. 382, 111 N.E. 1050 (1916)).

clearly and uniformly define the standard of care for claims of medical malpractice. Traditionally, the so called "customary standard" (i.e., what is usually done in a specific field) used to be adopted. However, with development of EBM, nowadays there has been a shift towards a more objective and scientifically grounded standard.[12] Many commentators struggled with the role of CPGs, in particular whether they might be intended as a legal standard of care to be applied by courts in medical malpractice suits, or whether they might be used as evidence of the standard of care. In spite of the increasing role gained by CPGs, a review of the literature about their legal effects reveals how they so far cannot be intended as a binding standard of care in light of many criticalities surrounding the CPGs' phenomenon (e.g., the issue of conflict of interests among different stakeholders, the issue of reliability, trustworthiness, and accountability of CPGs, the gap between the theoretical perspective of CPGs and the peculiarities of each patient, the difficulty to cope with patients affected by several diseases, and the risks of the so called "cookbook medicine"). Accordingly, the topic of EBM and CPGs, as related to that of medical malpractice and defensive medicine, has been extensively investigated and argued in U.S. doctrine.[13]

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12. *See also* Daubert v. Merrell Dow Pharm, Inc., 509 U.S. 579 (1993), setting forth a standard according to which an expert's theory is reliable if it meets four requirements: 1) it is possible to test the theory; 2) it was submitted to peer review and publication; 3) it points out the potential rate of error; 4) it is generally accepted by the scientific community.

13. Among the manifold contributions, *see* Grosso, *supra* note 2 (focusing on the issues related to EBM, CPGs and the standard of care within medical practice, contending that the postulated link between an uncertain legal standard and defensive medicine may be overstated, and that promoting a cultural shift in the doctor-patient relationship would be more effective in reducing the defensive medicine trend); Ronen Avraham, *Overlooked and Underused*: *Clinical Practice Guidelines and Malpractice Liability for Independent Physicians*, 20 CONN. INS. L. J. 273 (2013-2014) (deeming that the use of CPGs may improve the quality of healthcare in the U.S., analyzing three accountability models—public, private and semi-public—for CPGs, and arguing in favor of a private competitive regime for CPGs); Ronen Avraham, *Private Regulation*, 34 HARV. J. L. & PUB. POL. 543 (2011) (arguing in favor of a private regulation regime (PRR) under which private firms would develop and update CPGs and they would compete to license their own CPGs to medical providers, being liable for putting forth sub-optimal guidelines); Ronen Avraham, *Clinical Practice Guidelines*: *The Warped Incentives in*

the U.S. Health Care System, 37 AM. J. L. & MED. 7 (2011); Maxwell J. Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 ARIZ. ST. L. J. 1165 (2012) (outlining the historical evolution of medical practice and its legal implications, with particular regard to the standard of care, and reporting the most important legislative attempts to introduce legal defenses on behalf of practitioners, such as that of Maine, Vermont, Florida and Minnesota); Maxwell J. Mehlman, *Medical Malpractice Guidelines as Malpractice Safe Harbors*: *Illusion or Deceit?*, 40 J. L. MED. & ETHICS 286 (2012); Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Healthcare Reform*: *An Update*, 21 ANNALS HEALTH L. 21 (2012) (pointing out that EBM is an essential part of the nation's healthcare reform strategy and the role of CPGs to implement it; highlighting some key developments and issues in the CPGs movement, and focusing on the activity of the IOM (Institute of Medicine) to develop trustworthy and reliable CPGs); John Tucker, *A Novel Approach to Determine Best Medical Practices*: *Looking at the Evidence*, 10 HOUS. J. HEALTH L. & POL'Y 147 (2009); Michelle H. Lewis et al., *The Locality Rule and the Physician's Dilemma*: *Local medical Practices and the National Standard of Care*, 297 JAMA 2633 (2007) (pointing out that the applicable standard of care in medical malpractice lawsuits varies among jurisdictions in the U. S. and arguing that the locality rule is difficult to justify, as medical education has become more standardized and modern technology provides rural physicians with the same access to information for patient care as urban ones); James F. Blumstein, *Medical Malpractice Standard-Setting*: *Developing Malpractice* "*Safe Harbors*" *as a New Role for Q10s?*, 59 VAND. L. REV. 1017 (2006) (focusing on determination of liability for medical malpractice purposes through the modification of the standard adopted in targeted areas); Katharine Van Tassel, *Hospital Peer Review Standards and Due Process*: *Moving From Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines*, 36 SETON HALL L. REV. 1179 (2006) (describing the doctrines applicable to medical malpractice and focusing on the role of CPGs); James Ducharme, *Clinical Guidelines and Policies*: *Can They Improve Emergency Department Pain Management?*, 33 J. L. MED. & ETHICS 783 (2005) (reporting the definitions of relevant tools for medical practice, such as protocols, practice guidelines, clinical pathways, etc.); Williams, *Evidence-Based Medicine*, *supra* note 10 (emphasizing how some courts affirmed the physician's "duty to stay abreast" with the latest medical science, stressing the difference between EBM and CPGs, and contending to bifurcate the standard of care for medical practice in substantial and procedural one); Michelle M. Mello, *Using Statistical Evidence to Prove the Malpractice Standard of Care*: *Bridging Legal, Clinical and Statistical Thinking*, 37 WAKE FOREST L. REV. 821 (2002) (arguing that attempting to integrate clinical practice guidelines into malpractice litigation suggests that practical and conceptual problems involved in merging the cultures of medicine, science, and law should not be underestimated); Michelle M. Mello, *Of Swords and Shields*: *The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645 (2001) [hereinafter Mello, *Of Swords and Shields*] (developing a seminal analysis about the role of CPGs, the main features of medical malpractice litigation, the legislative attempts to provide healthcare professionals with a shield to defend themselves from alleged professional liability, and contending that CPGs cannot be deemed as a legal standard of care); Elise C. Becher & Mark Chassin, *Improving the Quality of Health Care*: *Who Will Lead?*, 20 HEALTH AFF. 164 (2001) (defining quality problems of CPGs as underuse, overuse and misuse); Arnold J Rosoff, *Evidence-Based Medicine and the Law*: *The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL., POL'Y & L., 327 (2001); Arnold J Rosoff, *The Role of Clinical*

The approach adopted by the Italian lawmaker also follows the path devised by the European institutions. According to the EU approach, although this area of law pertains to the competence of the Member States,[14] it is important to set an EU common level of health protection through, among other means, the development of the recourse to CPGs.[15]

The new system depicted by the 2017 Law has, thus, been enriched with further provisions dealing with different aspects of the healthcare field, aimed at pursuing the same target. For example, the law sets thresholds for the amount of damage to be compensated by the physician on behalf of public hospitals or other public healthcare entities in the event of liability of the hospital due to the gross negligence of the physician (art. 9).[16] Article 12 also requires that

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Practice Guidelines in Health Care Reform, 5 HEALTH MATRIX 369 (1995) (proposing a system that would grant the Federal Government the task not to develop guidelines, but rather to certify privately developed CPGs); Angela Campbell & Kathleen Cranley Grass, *The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research*, 46 MCGILL L. J. 473 (2001) (arguing about the role of professional norm and/or legal norm of CPGs); Michael Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines? Framework for Improvement*, 282 JAMA 1458 (1999); Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet*: *Will Physicians Tune In?*, 25 AM. J. L. & MED. 403 (1999) (arguing on behalf of CPGs and providing an overview of the main on-line (at that time) available CPGs' databases); William R. Trail & Brad A. Allen, *Government Created Medical Practice Guidelines*: *The Opening of Pandora's Box*, 10 J. L. & HEALTH 231 (1995-1996) (analyzing four basic types of government created medical practice guidelines and arguing that the first type—i.e., State created affirmative defense—would be the optimal practice guidelines program); Daniel Jutras, *Clinical Practice Guidelines as Legal Norms*, 148 CANAD. MED. J. ASSOC. 905 (1993) (focusing on the potential liability resulting from the drafting and implementation of CPGs); Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 L. & CONTEMP. PROBL. 87 (1991); Clark C. Havighurst, *Practice Guidelines for Medical Care*: *The Policy Rationale*, 34 ST. LOUIS U. L. J. 777 (1990).

14. For an overview of the different national legal systems within the European Union, *see* EWOUD HONDIUS, THE DEVELOPMENT OF MEDICAL LIABILITY (Ewoud Hondius ed., Cambridge U. Press 2010); MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS (Bernard A. Koch ed., De Gruyter 2011).

15. *See*, *e.g.*, Athanasios Panagiotou, *Professional Standards, Clinical Guidelines and Medical Liability*: *A Chance for Significant Improvement in Determining the Standard of Care?,* 25 EUR. J. HEALTH L. 157 (2018).

16. *See generally* Giulio Ponzanelli, *Medical Malpractice*: *La Legge Bianco Gelli. Una Premessa*, 3 DANNO E RESPONSABILITÀ 268 (2017).

healthcare institutions[17] have mandatory insurance-coverage; thus, trying to limit the practice, common in recent years, of self-insured retention (S.I.R.). Furthermore, art. 10, § 6 of the law allows victims of alleged medical malpractice to directly sue the insurance company of the healthcare institution and/or the healthcare provider implementing a special fund for damages arising from medical malpractice.[18] Additionally, art. 8 of the 2017 Law imposes a mediation proceeding as a mandatory pre-requirement to file a malpractice suit.[19]

This contribution will specifically focus on the new regime of the healthcare provider's liability and on the key role played by CPGs. In particular, section II will briefly explain the previous legal regime and the relevant judicial orientation based on settled case law; section III will address the main features of the 2017 Law; section IV will deal with the case law developed after the enactment of the 2017 Law; and section V will focus on the topic of the patient's informed consent. Then, final remarks will be expressed.

II. THE BALDUZZI LAW

The Balduzzi Law was the first legislative attempt to provide for medical malpractice in order to limit the phenomenon of defensive medicine, with specific provisions in terms of both civil and criminal liability to be applied to healthcare professionals in general. In spite of its laconic and incomplete text,[20] the Balduzzi Law was

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17. *See, e.g.*, Leonardo Bugiolacchi*, Le strutture sanitarie e l'assicurazione per la R.C. verso terzi*: *natura e funzione dell'assicurazione obbligatoria nella legge n. 24/2017 (Legge "Gelli/Bianco")*, 3 RESP. CIV. PREV. 133 (2017).

18. *See* Maurizio Hazan, *L'azione diretta nell'assicurazione obbligatoria della RC sanitaria (e il regime delle eccezioni)*, 3 DANNO E RESPONSABILITÀ 317 (2017).

19. *See generally* Rosanna Breda, *La responsabilità civile delle strutture sanitarie e del medico tra conferme e novità,* 3 DANNO E RESPONSABILITÀ 283, 286 (2017).

20. Terms adopted by the Supreme Court of Cassation, *see* Cass., sez. IV penale, Apr. 9, 2013, n. 16237, § 4 [hereinafter Cantore].

significant under two different aspects.[21] For the first time, it introduced the distinction between slight and gross negligence[22] for the affirmation or exclusion of criminal liability. Secondly, the Balduzzi Law also enhanced the role of CPGs. In addition, it represented the outcome of a debate arisen from a heterogeneous context: the defensive needs of healthcare providers, victim expectations, the issues of properly allocating healthcare costs, the balance between therapeutic necessities, and the limits of public financial resources.

The keystone of the law was its art. 3:

> The healthcare provider who, in the execution of her performance complies with clinical guidelines and good clinical customs accredited by the scientific community, is not criminally liable for slight negligence.[23] In these cases, the obligation arising from art. 2043 C.c. [Civil Code] is maintained. In determining the compensation of the damage, the judge shall duly consider the behavior set forth in the first paragraph.

The text has raised many issues about its meaning and range of application. A concern dealt also with the alleged unconstitutionality

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21. *See, e.g.*, Ombretta Di Giovine, *In Difesa del c.d. Decreto Balduzzi (Ovvero: Perché Non È Possibile Ragionare di Medicina Come Se Fosse Diritto e di Diritto Come Se Fosse Matematica)?*, 1 ARCH. PEN. 3 (2014).

22. For an interesting comparative analysis about fault liability and for the relevant terminology, *see* Gert Brüggemeier, *Fault Liability Today. A Critical View of the Cathedral*, 1 OPINIO JURIS COMPARATIONE 1 (2014), *available at* https://perma.cc/CWF6-X9HA.

23. Pursuant to the Italian Penal Code ("C.p."), art. 43—Mental Element of the Offenses—a crime shall be 1) intentional, i.e., according to intention, when the harmful or dangerous event, which is the result of the act or omission, and on which the existence of the crime depends, is foreseen and desired by the actor as a consequence of his own act or omission; shall be 2) preterintentional, i.e., in excess of intention, when the act or omission is followed by a harmful or dangerous event more serious than that desired by the actor; shall be 3) negligent, i.e., contrary to intention, when the event, even though foreseen, is not desired by the actor and occurs because of carelessness, imprudence, unskillfulness or failure to observe laws, regulations, orders or protocols. As for negligence, the first kind (i.e., carelessness, imprudence, unskillfulness) is named "generic negligence," while the second (failure to observe laws, regulations, orders or protocols) is named "specific negligence."

of this provision in light of art. 3 of the Italian Constitution (affirming the principle of equality[24]) due to the more favorable regime for healthcare providers in comparison with other socially relevant professions, equally complex and potentially risky.[25]

Most notably, for the first time, the Balduzzi Law introduced the distinction between slight and gross criminal negligence. Until then, art. 133 of the Criminal Code was used, among other criteria, to determine *quam in concreto* the extent of the criminal sanction. Through the Balduzzi Law, criteria are used to affirm or deny the criminal liability of the healthcare provider. Therefore, under this regime, the distinction became the "turning point" between liability and no liability.

The first obstacle arose from the fact that the Balduzzi Law did not explain the difference between the two categories of negligence. Thus, the courts were left with the task to conceptually identify and distinguish between them, in particular in the borderline cases.[26] Therefore, it has been up to judicial interpretation to clarify the range of application of the Balduzzi Law provisions. In particular, the Supreme Court stressed that the judicial history of medical malpractice is the *topos* for the study of professional negligence, especially when dealing with gross negligence.[27]

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24. Art. 3, para. 1 Costituzione*:* "All citizens have equal social dignity and are equal in front of the law, without distinction of sex, race, language, religion, political opinion, personal and social conditions."

25. *See* Trib. Milano, sez. IX penale, ordinanza Mar. 21, 2013 and comment by Marco Scoletta, *Rispetto delle linee guida e non punibilità della colpa lieve dell'operatore sanitario*: *la* "*norma penale di favore*" *al giudizio della Corte costituzionale*, *ibidem*, DIRITTO PENALE CONTEMPORANEO, Mar. 29, 2013, *available at* https://perma.cc/8U68-Y3SU. However, the recourse has been rejected by the Constitutional Court, holding that the ordinance *a quo* did not properly described the issue and lacked an adequate reasoning supporting the importance of the request. Corte Cost., ord. Dec. 6, 2013, n. 295, *available at* https://perma.cc/MRL6-5ZX2.

26. *See, e.g.*, Domenico Pulitanò, *Responsabilità medica*: *letture e valutazioni divergenti del novum legislativo*, 4 DIRITTO PENALE CONTEMPORANEO 73 (2013) (proposing the distinction between imperfect performances (subject to punishment only in cases of gross negligence) and perfect non-performances, occurring in case of clear non-compliance with the CPGs and subject to punishment).

27. *See* Cantore, *supra* note 20, § 5.

In this regard, the evolution can be divided into three different periods. During the first period, from the enactment of the Civil Code until the 1980s, the courts tended to adopt a very favorable approach for the physicians, and their liability used to be affirmed only in very outrageous cases due to the "macroscopic" violation of the most elementary rules of the *ars medica*. Pursuant to this view, the exclusion of liability used to be the rule, whereas its affirmation used to be the exception. The normative ground of this approach is identified in art. 2236 C.c.,[28] which was interpreted as requiring the affirmation of liability only in very strict cases of macroscopic mistake. In particular, the application of art. 2236 C.c. to the criminal area used to be justified on the basis of the inner consistency of the legal system as a whole. However, it must be noted that, under this perspective, it is up to the physician to prove the occurrence of peculiar technical difficulties and the release from liability applies only to cases of unskillfulness, not to carelessness or imprudence.[29]

The concern about the constitutional compliance of this approach with the principle of equality set forth in art. 3 of the Italian Constitution was addressed by the Constitutional Court in 1973.[30] The Court found that the interpretation above complies with the Italian Constitution since arts. 589, 42, 43 C.p. and art. 2236 C.c. give rise to a peculiar legal regime for intellectual professionals (like physicians, lawyers, engineers, etc.) aimed at facing two opposite purposes: on one side, not to mortify the initiative of the professional with the fear of unfair retaliation in the event of her failure and, on the other, not to indulge on behalf of the inconsiderate decision or

28. Art. 2236 C.c., Liability of the performer of a work: "If the performance implies the solution of technical issues of particular difficulty, the performer is not liable for damages unless in the event of her malice or gross negligence."

29. *See* Cantore, *supra* note 20, § 5. *See* ALBERTO CRESPI, LA RESPONSABILITÀ PENALE NEL TRATTAMENTO MEDICO-CHIRURGICO CON ESITO INFAUSTO (Priulla 1955); Alberto Crespi, *I recenti orientamenti giurisprudenziali nell'accertamento della colpa professionale del medico chirurgo*: *evoluzione o involuzione?*, 4 RIV. IT. MED. LEG. 785, 789 (1992).

30. Corte Cost., sentenza Nov. 28, 1973, n. 166, *available at* https://perma.cc/MRL6-5ZX2.

reprehensible omissions of the professional. However, this regime shall apply only in cases of particular technical difficulties and only when unskillfulness is at stake.[31]

During the second period, from the 1980s to 2007, a new approach was favored, based on the relational nature of the patient-professional link: the uniform judicial orientation was aimed at protecting the patient's health, thus increasing the range of liability of the physician. Consequently, the special regime of art. 2236 C.c. was neglected for the purposes of criminal law, on the assumption that civil law and criminal law are different domains.[32]

Finally, as of the third period, starting from 2007,[33] it has been deemed that, although art. 2236 C.c. cannot be directly applied to criminal law, its *ratio* can operate as rule of experience to be taken into account by the judge when assessing the behavior of the professional in event of emergencies, or when the case implies the solution of particularly complex issues. Consequently, art. 2236 C.c. stands for the codification of an inner logical and empirical rule, underlying the whole legal system.[34]

As above mentioned, through the Balduzzi Law, the Italian lawmaker intended to outline a legal framework to provide for a topic so far exclusively governed by judicial precedents: in particular, the Balduzzi Law clarifies the nature of (and the requirements for) professional liability of the healthcare providers in general, and fosters the role of CPGs to guide the professional's behavior.[35]

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31. *Id*.
32. *See* Cantore, *supra* note 20, § 6. *See* Fabio Basile, *Un itinerario giurisprudenziale sulla responsabilità medica colposa tra art. 2236 Cod. Civ. e Legge Balduzzi (aspettando la riforma della riforma)*, 2 DIRITTO PENALE CONTEMPORANEO 159 (2017).
33. Cass. Sez. IV penale June 21, 2007, n. 39592.
34. *See*, *e.g.*, Cass., sez. IV penale, Apr. 5, 2011, n. 16328 ("Montalto"); *see also* Cass., sez. IV penale, Nov. 22, 2011, n. 4391 ("Di Lella").
35. For interesting remarks about the relationship between CPGs and the healthcare professional's behavior, *see* ANDREA R. DI LANDRO, DALLE LINEE GUIDA E DAI PROTOCOLLI ALL'INDIVIDUALIZZAZIONE DELLA COLPA PENALE NEL SETTORE SANITARIO. MISURA OGGETTIVA E SOGGETTIVA DELLA "MALPRACTICE" (Giappichelli 2012).

However, despite the determinant role granted to CPGs and good clinical practices, it failed to properly define and identify them, thus leaving room to practical uncertainties and allowing strategic defenses like the reference to the so-called posthumous (search for) guidelines. This phenomenon occurs when a physician charged with a malpractice claim points out, on an *ex-post* basis, a guideline as a justification of her previous behavior.[36] The generic reference of art. 3 to improperly qualified guidelines allowed the professional to avoid liability by referring to guidelines not necessarily known, or not specifically taken into account, by her at the moment of the decision-making process and that of performance.

The Balduzzi Law also failed to provide a criterion to select, among the manifold available guidelines, those grounded on scientific evidence and therefore reliable, making only a generic reference to guidelines "accredited by the scientific community."[37] An additional concern dealt with the proper identification of the range of application of the waiver of criminal liability set forth by art. 3.[38] In particular, it was controversial whether this rule ought to be applied to all types of negligence (i.e., carelessness, imprudence, and unskillfulness) or to the sole cases of unskillful behavior.[39] Indeed, in spite of some diverging opinions, the Supreme Court has eventually excluded the criminal liability of the healthcare provider in all cases of slight criminal negligence, regardless of the nature of negligence (thus, either in cases of carelessness, imprudence, or unskill-

36. Paolo Piras, *Il discreto invito della giurisprudenza a fare noi la riforma della colpa medica,* DIRITTO PENALE CONTEMPORANEO, July 4, 2017, § 7, *available at* https://perma.cc/52N8-CGTQ.

37. The same concern about reliability and trustworthiness of CPGs has been expressed and extensively investigated within the U.S. scenario, *see* Mello, *Of Swords and Shields*, *supra* note 13, at 650-652. Eventually, the IOM has particularly focused its attention on such issue as can be inferred by the latest definition of CPGs, *see Clinical Practice Guidelines We Can Trust supra* note 10.

38. *See* art. 3 of Balduzzi Law cited in text above note 23.

39. *See* Brüggemeier, *supra* note 22.

ful behavior) and, in so doing, has resolved the controversial conceptual issue to distinguish among the three types of fault, while at the same time preserving equal treatment among professionals.[40]

In brief, on one side, thanks to the dialogue between the legislative and judicial formants,[41] the conceptual achievements in malpractice, except for some unsolved issues, were quite noteworthy.[42] However, on the other side, the phenomenon of defensive medicine had increased.[43] One of the main unsolved issues dealt with the nature of medical liability. Indeed, in spite of the clear and straightforward legislative provision regarding the nature of medical liability (i.e., tort liability), Italian courts used to affirm constantly its contractual nature, with all the legal consequences this entails regarding the burden of proof and prescription or the statute of limitation.[44] This, *inter alia*, has been pointed out among the factors determining the increase of the phenomenon of defensive medicine.

The aim of the 2017 Law, at least in the beginning, was to clear up those critical elements, for example the role of CPGs and their proper identification. However, the final outcome seems so far to

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40. Cass., sez. IV penale, June 6, 2016, n. 23283 [hereinafter Denegri]; Cass., sez. IV penale, July 1, 2015, n. 45527 ("Cerracchio"); Cass., sez. IV penale, Oct. 9, 2014, n. 47289 ("Stefanetti").

41. From the comparative-law perspective, "legal formants" are those elements concurring to characterize a particular legal system and which must be taken into account to have a proper knowledge of it: paradigmatic examples of legal formants are, in addition to legislative provisions, court rulings, academic writing, professional and administrative practice developed in a particular context. *See* Rodolfo Sacco, *Legal Formants*: *A Dynamic Approach to Comparative Law,* 39 AM. J. COMP. L. 1 and 343 (1991).

42. *See* Cantore, *supra* note 20 and Denegri, *supra* note 40.

43. *See* Carlo Brusco, *Informazioni statistiche sulla giurisprudenza penale di legittimità in tema di responsabilità medica,* DIRITTO PENALE CONTEMPORANEO, July 14, 2016, *available at* https://perma.cc/H7QA-KVAX; Nicola Enrichens, *Le linee guida tra medici, pazienti e diritto: alcune osservazioni*, RIV. RESP. MEDICA, Mar. 13, 2018, *available at* https://perma.cc/Y9BW-H6S8. For further statistical data, *see also* Federico Valentini, *Il nuovo assetto della responsabilità sanitaria dopo la riforma Gelli-Bianco*, 4 RIV. IT. MED. LEG. 1395 (2017).

44. A further distinction between the two regimes, in transnational cases, deals with the criteria to identify the governing law (i.e., pursuant to EU Rome I Regulation for contractual obligations and EU Rome II Regulation for non-contractual obligations) and the forum (i.e., EU Brussels I bis Regulation).

have missed the point and, while the 2017 Law has certainly provided a contribution to the proper identification of relevant CPGs, it seems to have moved backward in comparison to the Balduzzi Law, at least from the criminal liability perspective.

III. THE 2017 LAW

The 2017 Law, entitled "*Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie*" [Provisions on safety of the healthcare and of the patient, as well as on professional liability of the healthcare providers], addresses, as the heading reveals, different aspects of the healthcare world, encompassing provisions of different nature. In particular, it adopts a broad approach to the above-mentioned topic,[45] providing that:

– The safety of healthcare is an essential part of the constitutional right of health[46] and it is pursued on behalf of the individual and of the community (art. 1, § 1);

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45. For a general introduction to the 2017 Law, *see* GUIDO ALPA, LA RESPONSABILITÀ SANITARIA. COMMENTO ALLA L. 8 MARZO 2017, N. 24 (Pacini 2017).

46. Art. 32, para. 1 Costituzione: "The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent." This article depicts the general framework of the right to health as a fundamental right of the human being, and as interest of the community, combined with the guarantee of gratuitous treatment for needy people. The term "illness" has been used in a wide significance, encompassing both general diseases and professional ones. A second feature of such right is the adequacy of the healthcare treatment pursuant to several initiatives at the international level, like for example those carried out by the World Health Organization, the principles enclosed in the Ottawa Chart of 1986 aiming at equity in health. *See* Fernando Bocchini, *Salute e sanità tra solidarietà e responsabilità*, 1 CONTR. IMPR. 126 (2018) (arguing that protection of the human health is a significant experience of rebuilding the effectiveness of a legal system in order to erase the gap between theoretical declarations and the incongruity of real life, and stressing that the current interpretation of art. 32 Cost. tends to grants constitutional value to statutory provisions. As well, the regulations of the Consumer Code—i.e., Decreto Legge, Sept. 6, 2005, n. 206—art. 2 (2) (a), points out among the fundamental rights granted to consumers and users "the right to health's protection," and that, pursuant to such provision, contractual terms aimed at limiting or excluding the liability of the professional party in the event of death or personal injury suffered by the consumer as a consequence of an action or omission of the former are held unfair).

- The safety of healthcare is achieved also through the complex of all the activities aiming at the prevention and risk management connected to the issuance of healthcare services and the appropriate use of the structural, technological, and organizational resources (art. 1, § 2).[47] For this purpose, in every region of Italy, a center has been established for risk management and patient's safety aimed at collecting from private and public healthcare institutions the data related to adverse events and malpractice litigation.
- Article 3 establishes a National Observatory of the good customs on safety in the healthcare system (Observatory) under the National Agency for Regional Healthcare Services (AGENAS). The Observatory has the task:
    - to collect, from the regional centers above, the data related to risks and adverse events, as well as to causes, extent, frequency, and financial burden of the controversies;
    - to draw up guidelines with the support of qualified scientific associations; and
    - to identify appropriate measures in order to prevent and manage health-risk with the aim of monitoring the good customs, as well as for purposes of professional training, and continuing education of the healthcare providers.

With reference to the professional activity of healthcare providers and their liability, art. 5 sets forth specific rules according to which

47. In this regard, *see* Matteo Caputo, *La responsabilità penale dell'esercente la professione sanitaria dopo la L. n. 24 del 2017... "quo vadit"? Primi dubbi, prime risposte, secondi dubbi*, 3 DANNO E RESPONSABILITÀ 293, 297 (2017) (arguing that the emphasis on healthcare's safety rather than on the right to health in itself, is aimed at stressing the absence of a duty upon the professional to ensure the patient's healing. The former would therefore be obliged to apply the required professional diligence but could not be held liable for not having achieved the patient's recovery). *See also* Adolfo di Majo, *Il giudizio di responsabilità civile del medico dopo la legge Gelli e cioè la perizia "guidata,"* 4 GIUR. IT. 841 (2018) (arguing about the legal effects of the criminal provisions of the 2017 Law within the civil law's field, and stressing the nature of *obbligazione di mezzi* (obligation of means) charged upon the healthcare provider).

healthcare providers executing health services for prevention, diagnostic, therapeutic, palliative, rehabilitation, and forensic medicine purposes comply with the recommendations of the guidelines drawn up by qualified selected scientific institutions and published pursuant to the procedure set forth in the same article, except for the peculiarities of the single case. In case of absence of the above-mentioned guidelines, health care professionals abide by good clinical care practices. However, such behavioral duty must be tailored to the specific case. If the peculiar circumstances of the case require a different approach and/or behavior, the healthcare professional shall, on a justified basis, depart from the above-mentioned recommendations.[48] Consequently, exceptions to the general rule can be allowed with reference to the peculiarities of the single case.

In particular, the institutions referred to in art. 5 are included in a list compiled and updated by the Ministry of Health. The guidelines and updates are integrated within the *sistema nazionale per le linee guida.*[49] A further public entity operating under the Ministry of Health, namely the *Istituto superiore di sanità* (ISS) is involved. Indeed, the ISS, before publishing such guidelines on its websites, shall previously verify (i) the compliance of the adopted methodology with a specified public standard, as well as (ii) the relevance of scientific evidences declared in support of the recommendations. Accordingly, the framework outlined by the 2017 Law is quite complex and involves different stakeholders, both private and public, called to actively cooperate to the development of the national system of guidelines. Furthermore, the entities operating under the supervision of the Ministry of Health and its related agencies play a fundamental role in selecting and verifying which guidelines should be included in the system and must be complied with by healthcare professionals.

48. Therefore, the approach adopted is that of "comply or explain." *See* Caputo, *supra* note 47, at 295.

49. SNLG, DELL'ISTITUTO SUPERIORE DI SANITÀ, https://perma.cc/48MH-4T9Y.

In addition, unlike the Balduzzi Law, the 2017 Law introduces a hierarchical distinction between CPGs and good clinical practices. In particular, the CPGs provided with the preeminent role granted by such provision, are only those officially accredited and published pursuant to the 2017 Law. The good clinical practices will come at stake only when the first lacks, and they might also encompass CPGs issued by (reliable) entities, but not (yet) accredited in the official system depicted by the 2017 Law.[50]

Article 6 specifically deals with criminal liability of healthcare providers, introducing a new provision in the Italian Criminal Code: art. 590-*sexies* (fault liability for death or personal injuries in the healthcare field). According to this article, if death or personal injuries occur within the exercise of healthcare professional activity, the healthcare providers will be punished pursuant to arts. 589 and 590 C.p.,[51] except for situations specified in art. 590-*sexies*, para. 2 C.p. In fact, pursuant to the second paragraph of this provision, should death or personal injury occur because of unskillfulness, punishment[52] is excluded when the recommendations set forth by the officially published CPGs—or, absent such guidelines, the good clinical

50. For critical remarks about the role of good clinical practices within malpractice trials (in particular when invoked by the defendant in a criminal judgment), *see* Francesco D'Alessandro, *La responsabilità penale del sanitario alla luce della riforma* "*Gelli-Bianco*," 5 DIR. PEN. PROC. 572, 578 (2017).

51. The articles respectively provide for manslaughter and personal injury.

52. The literal expression adopted by art. 6 of the 2017 Law related to art. 590-*sexies* C.p. is *punibilità.* Pursuant to the Italian Criminal Code and from a strictly technical perspective, the "*cause di estinzione della punibilità*" are circumstances excluding the liability of the defendant although all the constitutive elements of the crime have been met. FERRANDO MANTOVANI, I DIRITTO PENALE, PARTE GENERALE 786 *et seq*. (9th ed., CEDAM 2015). However, the expression has been used even in different meanings and its theoretical conceptualization has not been properly built. *Id.* at 798. Yet, as constantly highlighted by Italian judges (lastly by the Tarabori holding, Cass., sez. IV penale, Apr. 20, 2017-June 7, 2017, n. 28187 [hereinafter Tarabori]—and authoritatively by the Supreme Court in the Mariotti case, Cass., sez. Unite Penali, Dec. 21, 2017-Feb. 22, 2018, n. 8770 [hereinafter Mariotti] *see infra*, § IV, the Italian lawmaker in recent times adopted the term *punibilità* in several, non-technical, and improper meanings, to express different concepts; for example, criminal liability in general, or other circumstances able to exclude, even from a subjective point of view, the penalty. Accordingly, reference to exclusion of *punibilità* ought not to necessarily be intended as implying a proper condition for the exclusion of the punishment. Pursuant to

practices—have been complied with, as long as the recommendations above proved to be adequate to the peculiarities of the case.

Article 7 deals with civil liability of both the healthcare institution and the healthcare providers. In particular, solving problems of proper qualification of the nature of the liabilities above, it draws a distinction between the institution, on the one side, and the healthcare professional, on the other.[53] Indeed, the institution that, in order to perform its obligation, avails itself of the activity of healthcare providers, is contractually liable because of the intentional or negligent behavior of these professionals according to arts. 1218 and 1228 C.c. The liability of the structure has a contractual nature and it is legally grounded on the direct liability of the institution towards the patient combined with elements of its vicarious liability.[54]

The healthcare provider is liable under art. 2043 C.c., unless she has performed in execution of a contractual relationship with the patient. This being the exception, the general rule is that the healthcare provider is liable towards the patient under tort law. The distinction above affects, in particular, the procedural burden of proof, heavier for the patient in case of tortious liability pursuant to art. 2043 C.c.,[55]

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the Tarabori Court, the term at stake shall therefore be intended as non-technical reference to the process of assessing the liability of the defendant in light of the degree of the fault (*see* Tarabori, *supra* note 52, § 10.1). Since there is no consensus among courts and among scholars about the proper qualification of the term *punibilità* within art. 590-*sexies* C.p., in the present essay it has been translated into "punishment," thereby referring to the element of the sanction pursuant to the concept of *punibilità* encompassed within the Criminal Code, although being aware of the possible non-technical meaning of such expression.

53. *See*, *e.g.*, Roberto Pardolesi, *Chi (vince e chi) perde nella riforma della responsabilità sanitaria*, 3 DANNO E RESPONSABILITÀ 261, 264 (2017) (arguing that the 2017 Law has introduced a "dual-track" system of remedies); Giuseppe Pavich, *La responsabilità penale dell'esercente la professione sanitaria*: *cosa cambia con la legge Gelli-Bianco*, 7-8 CASS. PEN. 2961 (2017) (expressing critical remarks about the distinction between different kinds of liability).

54. Alpa, *Ars interpretandi*, *supra* note 5, at 728-729; Massimo Franzoni, *Colpa e linee guida nella nuova legge*, 3 DANNO E RESPONSABILITÀ 271, 273 l(2017).

55. Generally, in case of tortious liability, the patient or, more broadly, the victim shall prove (i) the damage; (ii) the intentional or negligent behavior of the

and liberative prescription, which amounts to 5 years in case of tortious liability, and 10 years in case of contractual liability.

In particular, art. 7 of the 2017 Law refers to three different situations: (1) the patient chooses a private practice physician, (2) the patient refers to a public or private hospital and is treated by a physician employed there; and (3) the patient avails herself of the professional activity of her general practitioner or of a physician employed by a public or private institution, but allowed to practice privately within the institution itself.[56] In the first and in the third case, the relationship between the physician and the patient is governed by the law of contracts.[57] The second case used to qualify as contractual too on the basis of the doctrine of *contatto sociale* (i.e., a *de*

alleged tortfeasor; (iii) the element of causation between (i) and (ii); (iv) the unlawful nature of the damage (i.e., the harm to a legally protected interest, *see* Brüggemeier, *supra* note 22, at 4, 7-8). On the contrary, under a contractual liability regime, the victim shall prove (i) the existence of a contractual relationship with the other party; (ii) the breach of the contractual obligation by the other party; and (iii) the damage; consequently, it will be up to the alleged breaching party to demonstrate that nonfeasance or improper performance is not due to her fault. However, such general rules have been affected by the judicial interpretation and evolution.

56. *See*, *e.g.*, Ubaldo Perfetti, *La responsabilità civile del medico tra legge cd. Gelli e nuova disciplina del consenso informato*, 2 GIUST. CIV. 359 (2018).

57. With regard to the first and third case, the new rules do not change the previous judicial achievements, particularly with reference to the burden of proof. Such rule indeed shall be tailored with the case when the obligation undertaken by the professional is an *obbligazione di risultato* (obligation of result) whereby the professional guarantees a specific result or, on the contrary, whether it is an *obbligazione di mezzi* (obligation of means) whereby the same guarantees to apply her best care, though not ensuring any results. Such distinction affects the relevant burden of proof. Pursuant to art. 1218 C.c., in the first case it is up to the debtor to prove that the nonfeasance is due to force majeure, whilst in the second case it is up to the creditor to prove the negligence and the breach of the duty of care by the debtor. Traditionally, the obligation of the physician used to be an obligation of means. *See*, *e.g.*, Gaetano E. Napoli, *La responsabilità sanitaria nel sistema civilistico. Punti fermi e nuove linee di riforma*, 1 RESP. CIV. PREV. 103, 112-113 (2017). However, such qualification has been criticized by many authors arguing that the distinction above has only descriptive value and lacks any prescriptive force, and it has been subject to a progressive judicial evolution, culminating with the holding of the Supreme Court, July 28, 2005, n. 15781 arguing that every obligation requires at the same time the coexistence of the debtor's behavior together with a result, although in variable proportion, and thus affirming that the evidentiary mechanism is the same in any case of alleged breach of contractual obligation. A further judicial attack to the relevance of the distinction above has

facto relationship between the physician and the patient giving rise to legal obligations according to art. 1173 C.c.). However, due to the 2017 Law, it is now governed by the law of torts.[58]

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been carried out with the recognition of the *res ipsa loquitur* doctrine, distinguishing between routine and non-routine interventions. In particular, the ease of the intervention and/or its routine-nature imply the reversal of the burden of proof up to the professional charged with the demonstration that the unsuccessful result is not due to her fault. *See* Giovanni Pascuzzi, *Malpractice: la colpa del medico è presunta se l'intervento è di "facile esecuzione*," *in* 1 LEX AQUILIA - LA RESPONSABILITÀ MEDICA 16 (Giovanni Pascuzzi ed., Zanichelli 2005). Subsequently, such distinction has been abandoned on the assumption that the risk-allocation cannot be linked to the difficulty of the intervention and the tribunals used to require by the professionals the proof of an event beyond their control and not reasonably predictable and/or avoidable. *See, e.g.*, Claudio Scognamiglio, *Regole di condotta, modelli di responsabilità e risarcimento del danno nella nuova legge sulla responsabilità sanitaria*, 6 CORR. GIUR. 740, 741-744 (2017). Furthermore, Italian courts used to apply the rule of the so called "proximity of the evidence" whereby the relevant burden shall be charged to the breaching party because this party possesses the elements to paralyze the creditor's claim, *see* Supreme Court, Joint Civil Division, Oct. 20, 2001, n. 13533. As for the specific area of medical malpractice, the rule of proximity of the evidence is interpreted in the sense that the patient alleging the professional's nonfeasance shall demonstrate the existence of the contract with the hospital or the healthcare institution together with the source of the *contatto sociale* with the physician, and then it is up to the defendant to prove the absence of any fault in the contractual performance. Such shift in the burden of proof has been identified among the factors increasing medical malpractice claims, on one side, and the practice of defensive medicine on the other, even after the enactment of the Balduzzi Law. Indeed, as above mentioned, despite the express characterization in such Law of the healthcare professional's liability as tortious, Italian courts carried on in affirming its contractual nature thus applying such evidentiary rules. For critical remarks, *see* Giovanna Visintini, *La colpa medica nella responsabilità civile*, 3 CONTR. IMPR. 530 (2015). On the contrary, the 2017 Law straightforwardly affirms the tortious nature of the physician if employed by a public or private healthcare institution, and not involved in a pre-existing contractual relationship with the patient; and vice versa, should a contractual relationship occur between the patient and the healthcare provider, the latter would be judged on the basis of the abovementioned contractual rules.

58. The characterization of the healthcare professional's liability as tortious implies, on one side, the compensation of even not predictable damages pursuant to art. 2056 C.c., and, on the other, the application of the regime provided for by art. 2050 C.c. if the relevant requirements are met. Such a norm deals with liability due to the exercise of dangerous activities (art 2050 C.c.—Liability arising from the exercise of dangerous activities: "Whoever causes injury to another in the performance of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable in damages, unless she proves to have taken all suitable measures to avoid the injury"). The range of application of this article has been investigated by the doctrine and the Italian courts under two different aspects. The first issue dealt with the nature of such liability: currently, the majority view describes it as strict liability whilst, according to a minority opinion, the norm would

Furthermore, non-pecuniary damage suffered by the patient shall be compensated referring to thresholds and parameters set forth in the charts outlined by arts. 138 and 139 of the Code of Private Insurance.[59] Finally, art. 7 clarifies that the provisions above are mandatory.

The Balduzzi law affirmed the tortious nature of medical liability, leaving the burden of proof on the plaintiff. However, as previously indicated,[60] this clear legislative choice did not prevent Italian courts to carry on adjudicating that the professional had a contractual relationship with the patient, in particular if employed by a healthcare institution: liability ended up being contractual and the burden of proof was consequently reallocated. Therefore, in light of the clash between the Balduzzi qualification of professional liability as tortious, and the judicial interpretation of this liability as contractual, the emphasis of art. 7 in clarifying the mandatory nature of the

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give rise to a mere rebuttable presumption of liability upon the party exercising a dangerous activity. As known, the strict liability characterization affects the relevant burden of proof in favor of the victim. The second issue dealt with the possibility to include the healthcare activities within the category of "dangerous activities" encompassed by such article. The answer given by the judicial formant is affirmative because, besides the list of dangerous activities filled in by specific Laws or other normative provisions, Italian courts admit the possibility to include other atypical activities on a *quam in concreto* basis, to be therefore assessed case by case. Such extensive orientation is also upheld by authoritative statutory precedents, in particular art. 15 of the Privacy Code according to which "whoever causes a damage as effect of the personal data processing shall compensate such damage pursuant to art. 2050 C.c." Consequently, for the purposes of Italian law, the personal data processing is deemed a dangerous activity. *See* Perfetti, *supra* note 56, § 10.

59. *See* Decreto Legislativo Sept. 7, 2005, n. 209. With regard to the compensation of damage, the express reference to the thresholds set forth in the Code of Private Insurance has been interpreted in a double sense: on one side, in light of the legislative will to put a cap on damages and, on the other, in light of the need to personalize and tailor the assessment of damages, as commonly applied in the insurance field, but with a peculiar feature. In the case of the insurance, the criteria to personalize the damage even increasing it up to the triple, are exclusively focused on the victim; on the contrary, in the healthcare field what matters for the purposes of decreasing or increasing the amount of damages is the professional behaviour of the healthcare provider and her level of compliance with the accredited CPGs or the good clinical practices. *See* Alpa, *Ars Interpretandi*, *supra* note 5, at 731.

60. *See supra*, § II.

provisions at stake seems aimed at definitively solving this hermeneutical issue and avoiding any further different interpretations.

The 2017 Law has been implemented by means of two Ministry of Health's decrees addressing essential elements. In particular, the first decree points out the list of accredited scientific associations and technical-scientific associations of the healthcare professions,[61] while the second establishes the above-mentioned Observatory of the good clinical practices on healthcare safety.[62]

Since the task of elaborating the relevant guidelines, pursuant to the scheme drawn up by the 2017 Law, pertains to public and private entities, as well as to scientific and technical-scientific associations of the healthcare professions purposely included in a public list, the first decree points out the criteria to be included in the list of selected entities. The list will be updated on a two-year basis. In order to be included in such list, associations shall demonstrate to have:

- national relevance, namely to have a direct or indirect branch or subsidiary within at least 12 Regions;
- representativeness of at least 30% of professionals (who are not retired) of the specific field of expertise;
- proved independence from entrepreneurial activities and lack of profit-making purposes;
- compliance with the duty to publish the scientific activity of the association on its website, to be constantly updated;
- absence of wage for the company's officer positions;
- among the entity's purposes, lack of the aim to provide labor-union assistance to its members and absence of any direct or indirect labor-union activity; and
- broadest participation of the members to the activities and decisions of the association.

61. Decreto Aug. 2, 2017, G.U. n. 186.
62. Decreto Sept. 29, 2017, G.U. n. 248.

The requirements above are, therefore, quite strict[63] and should the association subsequently lose one or more of them, it might be first suspended and then erased from the list.

The second decree establishes the Observatory within the AGENAS. As previously mentioned, the Observatory is called to carry out, in accordance to the directions of healthcare planning as defined by the Ministry of Health, very important tasks, in particular dealing with the collection of statistical data, drawing up of CPGs, and risk-management activities. Both decrees play an important role with reference to the criminal liability of the healthcare provider. In particular, the first decree concurs to select and outline the sources of reference for the behavior of the healthcare professionals (and, from a different perspective, concurs to select and outline the standard of behavior to be adopted by judges when assessing their liability). Worthy of attention is the fact that healthcare professionals shall comply with the sole recommendations set forth by the guidelines published in accordance with the 2017 Law and drafted by the accredited institutions.

The 2017 Law has apparently deprived first the physicians and then the courts of the power to evaluate the reliability and credibility of the guidelines.[64] This, in the majority of the opinions, has represented a worthy effort to avoid uncertainties arising from the large number of available guidelines, not all of the same value,[65] and to interrupt the recourse to "posthumous" identification of guidelines.

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63. On Oct. 23, 2017, the Ministry of Health issued an official circular in order to clarify the doubts arisen about the proper interpretation of the requirements above and their range of application.

64. Cristiano Cupelli, *L'eterointegrazione della legge Gelli-Bianco: aggiornamenti in tema di linee guida "certificate" e responsabilità penale in ambito sanitario*, 10 DIR. PEN. CONT. 266, 268 (2017).

65. *See, ex multis*, Carlo Scorretti, *Le linee guida nella medicina moderna e nella recente normativa italiana*, *in* RESPONSABILITÀ E LINEE GUIDA 103-114 (Gian Marco Caletti et al. eds., EPG Udine 2018). *See also* Justin Kung et al., *Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards*, 172 ARCHIVES OF INTERNAL MED. 1628 (2012) (focusing on the problem of conflict of interests among the members of the entities called to issue CPGs and providing statistical data about such phenomenon).

This used to be a strategy developed under the dominion of the previous legal regime (i.e., the Balduzzi Law).[66] The express duty to abide by existing, published, and clearly identified CPGs, puts an end to this strategy. Furthermore, the *ex-ante* perspective is important because it takes into account all potential recipients and beneficiaries, and not just the injured parties or the parties involved in a trial. As highlighted, art. 5 of the 2017 Law introduces a general rule requiring the compliance with the accredited guidelines working both in the area of civil (and, for certain purposes, criminal) liability as a criterion to assess the skillfulness of the physician and for the quantification of damages.

A further aim of the new law is to avoid uncertainties due to the reliability of the scientific association involved as well as conflicts among different and inconsistent recommendations. The process of controlled selection of guidelines to be included in the national official database immediately carries out a distinction between reliable and not-reliable guidelines (at least for the purposes of the 2017 Law). Finally, the new system should solve the issue of conflict of interests among stakeholders and guidelines' issuers affecting the reliability of clinical guidelines as well.

IV. JUDICIAL UNCERTAINTY

To summarize, the 2017 Law, by introducing a rebuttable presumption of lack of punishment, not only opened new and significant issues in respect to the previous legislative regulation, but it seems to have failed the task of ensuring the certainty of lack of liability in cases of compliance with the officially accredited CPGs. Indeed, the 2017 Law, according to the majority of commentators and to a significant judicial orientation, appears less favorable to healthcare providers than the Balduzzi Law.[67]

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66. *See supra*, § II.

67. *See* Tarabori and Mariotti rulings, *supra* note 52, and relevant comments. *See also* Cristiano Cupelli, *L'art. 590-sexies C.p. nelle motivazioni delle sezioni unite*: *un'interpretazione costituzionalmente conforme dell'imperizia medica*

The first opportunity for the Supreme Court to deal with the 2017 Law was the Tarabori case.[68] In this case, the Fourth Criminal Division of the Supreme Court highlights the functions of art. 5, which "entails a real foundation of the ways to exercise of healthcare professions."[69] Within such a system, the guidelines are intended as "general directives that shall face the peculiarities of each case, and shall adapt themselves to it."[70] In particular, the Tarabori holding points out "the clear legislative intention to build up an institutional public system aimed at regulating the healthcare activities, able to ensure their development in a uniform and appropriate manner, in compliance with controlled scientific evidences" in order to "overrule uncertainties that occurred after the enactment of the Balduzzi Law with reference to the criteria to properly identify the scientifically qualified directives,"[71] as well as to avoid the dangers of degenerations due to guidelines affected by conflict of interest or not scientifically grounded. This is done "[i]n order to foster the uniform application of accredited and virtuous directives."[72]

As noted by the Supreme Court, the legislative choice not only guarantees "to the healthcare institution, the governance of the medical profession," but it also "has a significant impact on the professional who must comply with the recommendations although with the adaptations required by each case" and is "legitimately entitled

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(ancora) punibile, DIR. PEN. CONT. Mar. 1, 2018 (arguing that the 2017 Law has failed its alleged purposes); Pier Francesco Poli, *Il D.D.L. Gelli-Bianco*: *verso un'ennesima occasione persa di adeguamento della responsabilità penale del medico ai principi costituzionali*?, 2 DIR. PEN. CONT. 67 (2017) (expressing several critical remarks to the 2017 Law). *But see also* Gian Marco Caletti & Matteo Leonida Mattheudakis, *Una prima lettura della legge "Gelli-Bianco" nella prospettiva del diritto penale*, 2 DIR. PEN. CONT. 84 (2017) (pointing out some positive elements of the 2017 Law).

68. *See* Tarabori, *supra* note 52.

69. *See id.* § 7.5 (analyzing the effects of the 2017 Law from a wider perspective, encompassing both the domain of criminal liability and that of civil liability, *see also* § 7.4, as linked by the overall approach adopted by such Law).

70. *Id.* § 7.5.

71. The Court expressly argues that, under the Balduzzi Law, the CPGs counted as scientific directives for the healthcare provider and their compliance amounted to a "protective shield" against unjustified claims. *Id.* § 6.

72. *Id.* § 7.5.

to rely on the fact that her behavior shall be assessed pursuant to the same recommendations she must abide by."[73] In light of such remarks, the Supreme Court infers that the system introduced by the 2017 Law "provides an unprecedented regulatory framework, focused on the modalities of execution of the healthcare profession and of the assessment of negligence," which offers to the judge "precise directions in order to evaluate the liability of the provider."[74]

In particular, the holding points out the paradoxical consequences of a literal interpretation of the norm, according to which a physician (or any other healthcare professional) could escape liability even though she caused harm to the patient if it is demonstrated that the physician acted in compliance with qualified directives.[75] The Fourth Criminal Division of the Supreme Court has, thus, deemed that the text of art. 590-*sexies* C.p., as introduced within the Penal Code by art. 6 of the 2017 Law, is affected by "obvious" traits and by a "logical incompatibility" with the overall rationale of the provision itself, as well as with the general principles of the Italian legal system.

In brief, according to the Court, a literal interpretation of the article would make it unconstitutional. The paradigmatic example offered by the Court is the case of a surgeon planning and executing, in compliance with the relevant clinical guidelines, an operation for the removal of an abdominal neoplasm, who, in the executive moment, due to a huge and tragic mistake, severs an artery rather than the peduncle of the neoplasm, thus causing the death of the patient. In the opinion of the Court, following the literal interpretation of the provision at stake would lead to exclude the surgeon's liability. Accordingly, since the outcome would be unfair and unlawful because it would amount to a breach of the right to health set forth in art. 32 of the Italian Constitution, and would negatively affect civil claims of medical malpractice and the related compensation of damage, as

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73. *Id.* § 8.2.
74. *Id.* § 7.5.
75. *Id.* § 7.4.

well as the constitutional principle of equality set forth in art. 3 (because the legal regime applied to healthcare professionals would be "irrationally" different than that applied to other equally risky and difficult professions), this interpretation was rejected by the Court.[76] In light of the above reasoning, the sole interpretation allowed by the "unhappy" lexical phrasing of the 2017 Law is that, when it is a matter of unskillful behavior, the healthcare provider[77] shall not be held liable if she complied with the officially accredited guidelines and there were no reasons to depart from them.

Consequently, the Tarabori Court, emphasizing the purposes of the 2017 Law and particularly the new system of accredited guidelines, holds that the physician complying with the accredited guidelines, save the peculiarities of each case, is entitled to expect that her behavior will be judged pursuant to the same clinical guidelines.[78] Therefore, for the purposes of the new art. 590-*sexies* C.p., the assessment of liability shall be carried out taking into account the involved clinical guidelines, which must be pertinent and whose reliability and adequacy to the specific case shall be previously investigated by the judge, called to focus this assessment upon the moment of implementation of the guidelines by the healthcare professional. Within the described range of application, the healthcare provider is consequently entitled to be judged pursuant to the standard set by the same guidelines she shall comply with.

Accordingly, the role of CPGs as drawn up by both art. 5. and art. 6 of the 2017 Law ends up to be neglected because any "automatic" waiver of liability (or any "protective shield") generated by the compliance with the officially accredited guidelines, is denied.

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76. *Id*.
77. The 2017 Law, as pointed out, deals with the liability of the healthcare provider in general. However, all the three holdings of the Supreme Court address the case of medical malpractice and liability of the physician, thus referring their reasoning to the latter category. Nevertheless, except for the peculiarities of each healthcare profession, the interpretation provided by the Court applies to healthcare providers in general.
78. *See* Tarabori, *supra* note 52, § 8.2.

A confirmation of such effect can be found in the fact that, in comparing the Balduzzi regime with that of the 2017 Law for inter-temporary purposes related to the principle of non-retroactivity of the criminal provision, the Tarabori Court found the Balduzzi Law more favorable to healthcare providers than the 2017 Law.

Four months after the Tarabori ruling, the Fourth Criminal Division (with a different composition) dealt again with the 2017 Law and, in particular, with art. 590-*sexies* C.p. However, the Court embraced a completely different interpretation and never mentioned the earlier ruling.[79] The Cavazza holding points out that the specific field of application of art. 590-*sexies*, para. 2 C.p. is that of the unskilled execution of proper and adequate clinical guidelines.[80] Consequently, the so-called *imperitia in executivis* would shield the healthcare provider from criminal liability, while the *imperitia in eligendo*, namely the incorrect selection of the guideline or the adoption of a non-adequate guideline, would lead to affirm her criminal liability.[81] This is the rule set forth by the holding at stake, which is reached through an articulated *ratio decidendi*.

First of all, the Fourth Criminal Division of the Supreme Court, sitting with different judges than those of the Tarabori holding, highlights what the elements of certainty introduced by the 2017 Law are: first, the specific abrogation of art. 3 of the Balduzzi Law, together with the consequent overtaking of the issue of the degree of fault; second, the clear legislative choice to apply the waiver of liability set forth in the second paragraph of art. 590-*sexies* C.p. only to the event of unskillfulness (thus, excluding from its range of application cases of negligence and carelessness).[82]

On the contrary, among the controversial elements of the 2017 Law, the Court stresses the role of CPGs as outlined by the lawmaker. It points to the operational difficulties in distinguishing

79. Cass., sez. IV penale, Oct. 19-31, 2017, n. 50078 [hereinafter Cavazza].
80. *Id*. § 7.
81. *Id.*
82. *Id*. § 6.

between unskillfulness, negligence, and carelessness, since these concepts are adjoining and often overlapping. It insists that in a case of gross fault, it would be extremely difficult to find that the circumstances to release the physician from liability, as set forth by the art. 590-*sexies* C.p., are fulfilled.[83]

Consequently, in order to avoid the highlighted issues—and to save the rationale of the 2017 Law—the Cavazza Court provides an interpretation aimed at enhancing as much as possible the letter and the purposes of this law. In particular, in the opinion of the Court, the clear intent of the 2017 Law is to avoid any differences in the degree of fault in the event of harm due to unskillfulness of the healthcare provider. Consequently, when the requirements of art. 590-*sexies*, para 2 C.p. are fulfilled, even the gross fault shall be excused.[84] In addition, pursuant to this interpretation, the intent of the 2017 Law is to specifically favor the position of the physician by decreasing the possibility of a criminal liability, without prejudice to civil liability, thereby ensuring to patients the compensation of the suffered damages.[85]

The keystone of the new regime are the accredited CPGs and the mandatory requirement for healthcare professionals to comply with them or, in the absence thereof, with the good clinical customs, provided that both prove to be adequate to the circumstances of the specific case. Accordingly, the "*causa di non punibilità*," as outlined by the Court, loses any subjective connotations to assume an objective feature:

> [T]he surrender to sanction the physician is justified in light of the lawmaker's choice not to mortify the initiative of the professional because of the fear of unfair retaliations, thus discharging the physician from punishment in reason of a mere judgment of criminal policy's opportunity in order to

83. *Id.*
84. *Id.*
85. *Id.* § 7.

> restore the operational serenity of the physician and thereby preventing the phenomenon of defensive medicine.[86]

Therefore, in the sole case of unskillfulness, criminal liability will hinge on the adequacy of the accredited guidelines: should these guidelines be held adequate, the physician would not incur criminal liability even in cases of gross unskillfulness. On the contrary, should the guidelines be held not appropriate to the circumstances of the case, the physician will be found liable even in cases of slight unskillfulness. However, it has been also stressed by the Court that the physician's unskilled behavior will be excused only if the mistake occurred in the execution of the appropriate guideline. On the contrary, should the mistake occur *ab initio* in the selection of the guideline, liability will be maintained. Finally, pointing out the positive effects of the new provisions, the Cavazza Court did not seem to doubt the constitutionality of the 2017 Law.

The two holdings differ from each other, adopting opposite interpretations of the 2017 Law. The Cavazza Court highlighted the purpose of this law in light of the announced intent of the lawmaker to provide a "safe harbor" to healthcare providers vis-a-vis the malpractice claims in cases of unskillful behavior. In order to reach such aim, the Court emphasized the letter of the 2017 Law and, in particular, of art. 590-*sexies* C.p. deeming that both cases of slight and gross unskillfulness (in the execution of proper guidelines) shall discharge the healthcare provider from criminal liability, although without prejudice to the civil liability. Accordingly, the Court has stressed the determinant role played by CPGs to release from liability the professionals who abide by them, insofar as they prove to be adequate to the specific case.

However, the Cavazza interpretation raises issues as to the compatibility of the new provisions with, in particular, the principle of equality and the fundamental right to health, as respectively set forth in arts. 3 and 32 of the Italian Constitution. To avoid a possible clash

86. *Id.*

with constitutional norms, the Tarabori Court provided an interpretation so strict as to deprive the 2017 Law of its (alleged) innovative potential. Pursuant to this ruling, the liability waiver regime grounded upon the system of accredited CPGs tended to be disregarded. Therefore, the interpretation adopted by the Tarabori Court has been qualified as *interpretatio abrogans.*[87]

In addition, from the perspective of the Tarabori holding, the Balduzzi Law is more favorable than the 2017 Law. On the contrary, according to the Cavazza holding, the result of the comparison is exactly the opposite: this clash would lead to antithetical outcomes in cases involving inter-temporary matters in light of the principles of non-retroactivity of the criminal law, and retroactivity of the more favorable provisions derived from art. 2 C.p. and art. 25 of the Italian Constitution.

The crucial importance of the issue, and the clear conflict of interpretations about the letter of the 2017 Law arisen within the Fourth Criminal Division of the Supreme Court, urged the intervention of the Joint Criminal Division in order to clarify the meaning and the range of application of this law and aimed at providing the lower courts, the Italian society, and the whole public of stakeholders with an authentic interpretation of the 2017 Law (namely of the art. 590-*sexies* C.p. as introduced by art. 6 of the 2017 Law).

In the Mariotti holding,[88] the Joint Criminal Division of the Supreme Court offered a third and different interpretation of the provisions. In the opinion of the Court: (i) the Tarabori Court upholds an *interpretatio abrogans* of the 2017 Law clashing with the clear intent of the law and with the previous judicial achievements; (ii) the Cavazza Court grants a too broad range of application to the waiver of liability system set forth by the 2017 Law, therefore raising constitutional issues of the law in light of the principles of equality among professionals (art. 3) and protection of the patient's health

87. *See* Mariotti *supra,* note 52.
88. *Id.*

(art. 32). The Joint Division in the Mariotti ruling affirms that the release of the healthcare professional from liability occurs when the harmful event is caused by the *slight* unskillfulness of the professional during the execution of the adequate accredited guidelines.[89] On the contrary, gross unskillfulness will not discharge from liability, in order to avoid any discrimination with the liability regime of other professionals and to avoid any charge of unconstitutionality of the 2017 Law.[90] The milestone of the present ruling is, therefore, the concept of "slight unskillfulness."[91] However, it is noteworthy that the 2017 Law does not mention at all the term *slight* and does not make any references to the degree of the unskilled behavior.

Pursuant to the Court, the degree of fault in the form of the unskillfulness is justified in light of three main reasons. First, because of art. 2236 C.c. that specifically distinguishes between slight and

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89. In the opinion of the Court, CPGs are not a shield against any kind of liability, since their value and legal effects depend upon their proved suitability to the peculiar circumstances of the specific case. Pursuant to the Court, then, such freedom of assessment granted to the healthcare provider, is aimed at preserving the professional's autonomy, thus avoiding any "bureaucratic flattering out." Therefore, the formalization of the *leges artis* would amount to a cultural change occurred in a new socio-professional context where the complex of expertise and know-how of the individual becomes a shared asset of the whole scientific community. *See* Mariotti, *supra* note 52, § 3.

90. The principle expressed by the Mariotti Court is:

> The healthcare provider is liable on the basis of fault for the manslaughter or personal injuries deriving from the performance of a medical-surgical activity:
> a) if the event occurred as a consequence of negligence (even 'slight') due to carelessness or imprudence;
> b) if the event occurred as a consequence of negligence (even 'slight') due to the unskillful behavior when the specific case is not governed by the recommendations of the CPGs or of the good clinical practices;
> c) if the event occurred as a consequence of negligence (even 'slight') due to the unskillful behavior in the selection and choice of CPGs or good clinical practices which are not adequate to the peculiar circumstances of the case;
> d) if the event occurred as a consequence of gross negligence due to the unskillful behavior in implementing the recommendations of adequate CPGs or good clinical practices, taking into account both the level of risk to manage and the specific technical difficulties of the medical act.

See Mariotti, *supra* note 52, § 11.

91. *Id.* §§ 9, 10, 10.3 & 11.

gross negligence and that, although not directly applicable to criminal liability, yet underlies a general principle operating in the criminal area as well, as held by the Italian Constitutional Court.[92] Second, because of art. 3 of the Balduzzi Law that explicitly defined a spectrum of criminal fault.[93] Third, because the preliminary drafts of the 2017 Law used to specifically distinguish between slight and gross unskillfulness. Therefore, the lack of the distinction in the official draft of the 2017 Law ought to be ascribed to an unintentional omission of the lawmaker.[94]

The second and the third reasons have been criticized because art. 3 of the Balduzzi Law has been expressly abrogated by art. 6 of the 2017 Law. Consequently, it seems difficult to argue that the criteria of art. 3 of the Balduzzi Law should still influence a regime that has clearly superseded this provision.[95] These arguments have also been criticized because it is difficult to argue that the text of the 2017 Law, currently in force, did not intend to exclude the degree of fault although such distinction lacks in its binding and official version.[96]

From a practical point of view, a further criticism to this interpretation is the widely acknowledged difficulty in distinguishing between carelessness, negligence, and unskillfulness. Consequently, these uncertainties might foster charges grounded on carelessness and negligence, thus bypassing the application of art. 590-*sexies* C.c. and its exegetical concerns: this would lead to an "escape" in the concepts of carelessness and negligence.[97]

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92. *Id.* §§ 9.2 & 10.1.
93. *Id.* §§ 8.2, 9.2 & 10.2.
94. *Id.* § 10.3.
95. *See*, *e.g.*, Rocco Blaiotta, *Niente resurrezioni, per favore. A proposito di S.U. Mariotti in tema di responsabilità medica*, DIR. PEN. CONT. May 28, 2018, *available at* https://perma.cc/36LB-NKH5; Paolo Piras, *Un distillato di nomofilachia*: *l'imperizia lieve intrinseca quale causa di non punibilità del medico*, DIR. PEN. CONT. April, 20 2018, *available at* https://perma.cc/WUD7-6QU5 [hereinafter Piras, *Un distillato di nomofilachia*].
96. *See* Piras, *Un distillato di nomofilachia*, *supra* note 95.
97. Cristiano Cupelli, *La legge Gelli-Bianco e il primo vaglio della Cassazione*: *linee guida sì, ma con giudizio*, 6 DIR. PEN. CONT. 280, 284 (2017).

Consequently, rather than referring the issue to the Constitutional Court, as requested by the Attorney General in his conclusive remarks as well as by many commentators, the Joint Criminal Division of the Supreme Court rewrote the text of the law by adding the term "slight." According to some commentators, the text of the 2017 Law was rewritten *in malam partem* because the interpretation rules that the gross unskillfulness is out of the range of application of art. 590-*sexies*, para. 2 C.p., thus enlarging cases of liability.[98]

In addition, the interpretation provided by the Mariotti holding does not eliminate the logical incompatibility, highlighted by the Tarabori Court, between compliance with the accredited guidelines and unskillful behavior. Consequently, as well summarized by a commentator, "unskillfulness *in executivis*:

- pursuant to the Tarabori Court, *non excusat*: *interpretatio abrogans*;
- pursuant to the Cavazza Court, *semper excusat*: *interpretatio latissima*;
- pursuant to the Mariotti Court, *excusat si levis*: *interpretatio stricta*."[99]

Furthermore, according to the Mariotti holding, which upholds the Tarabori's remarks regarding this issue, the Balduzzi Law is more favorable than the 2017 Law. Thus, the Balduzzi Law shall be applied in cases involving matters of inter-temporary law.[100] Should the Mariotti ruling be the final word regarding the 2017 Law, the Italian lawmaker would have missed the opportunity to reduce the area of criminal liability of the healthcare provider and decrease the practice of defensive medicine.[101]

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98. Piras, *supra* note 95, at 10.
99. *Id.* at 4.
100. *See* Mariotti, *supra* note 52, § 12.
101. For further comments to the Mariotti ruling, *see, e.g.*, Gian Marco Caletti & Matteo Leonida Mattheudakis, *La fisionomia dell'art. 590-sexies C.p. dopo le Sezioni Unite tra nuovi spazi di graduazione dell'imperizia e "antiche" incertezze*, 4 DIR. PEN. CONT. 25 (2018); Roberto Bartoli, *Riforma Gelli-Bianco e Sezioni Unite non placano il tormento*: *una proposta per limitare la colpa medica*, 5 DIR. PEN. CONT. 233 (2018); Bartolomeo Romano, *La responsabilità penale*

It has been noted[102] that, following the Mariotti holding, the Fourth Criminal Division of the Supreme Court might either decide to submit again the issue at stake at the Joint Division pursuant to art. 618 of the Italian Code of Criminal Procedure or to refer the issue of the unconstitutionality of the art. 590-*sexies* C.p. to the Constitutional Court. Alternatively, Italian judges might decide to adhere to the Mariotti's perspective, thus enhancing the role of art. 2236 C.c. as an expression of a general principle operating even within the criminal matter.[103]

In a subsequent case,[104] the Fourth Criminal Division seems to have followed the third option. The case involved a neurologist charged with the death of a patient: a young woman died due to a syncope provoked by a severe arrhythmogenic heart disease. The neurologist was held liable for using the Tilt test in lieu of a 12-lead electrocardiogram (ECG). The latter exam would have allowed the doctor to properly identify the disease suffered by the patient, whereas the former was not adequate for this purpose. The absence of a prompt diagnosis prevented the appropriate treatment.

The case provides the Fourth Division with the opportunity to recap the achievements about medical malpractice in light of the 2017 Law and of the Joint Division's judgment. First, the therapeutic relationship between the physician and the patient implies the duty for the former to protect the life and the health of the latter. Second, ongoing medical science developments decrease the room for the individual dimension of the medical practice in favor of the standardized, multitasking, and multidisciplinary one. However,

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dell'esercente la professione sanitaria tra antichi dubbi e nuovi problemi, DIR. PEN. CONT. Nov. 16, 2018, *available at* https://perma.cc/ZRW4-ZMR8.

102. Piras, *supra* note 95, at 11.

103. *See*, *e.g.*, Carlo Brusco, *Responsabilità medica penale*: *le Sezioni Unite applicano le regole sulla responsabilità civile del prestatore d'opera*, 5 DIR. PEN. PROC. 646 (2018).

104. Cass., sez. IV penale, Jan. 12-Apr. 5, 2018, n. 15718 [hereinafter Tessitore].

this assumption must be adapted to the principle of personal criminal liability.[105]

Finally, the Court focuses on the role of clinical guidelines and their suitability to act as legal standard for the assessment of professional liability. In particular, moving from the previous holdings, the Court bestows such guidelines, and their proper selection and application by the healthcare provider, with a determinant role, although excluding their binding nature as a legal standard.[106] However, the element worth mentioning is the fact that the neurologist was held liable not on the ground of his unskillful behavior, but rather on the charge of negligence. Accordingly, the potential application of art. 590-*sexies* C.p. has been *ab origine* excluded since unskillfulness was not involved.

In light of this approach, the holding has been subject to critical remarks, first, because of the difficulty in distinguishing between "unskillful behavior" and "negligence" (and the fact that in this case the two concepts tended to overlap) and, second, because the risk of the (alleged) escape in the two different types of fault.[107]

V. THE ISSUE OF INFORMED CONSENT

Although aimed at addressing from a broad perspective the patient-provider relationship as well as the topic of the professional's liability, the 2017 Law does not specifically deal with the issue of

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105. *Id*. §§ 4.1-7.
106. *Id*. §§ 4.2-4.3-6. *See also* Lucia Risicato, *Il nuovo statuto penale della colpa medica*: *un discutibile progresso nella valutazione della responsabilità del personale sanitario*, LEGISLAZ. PEN. June 5, 2017, 1, 9 (expressing three critical remarks about the new legislative focus on accredited CPGs: first, because of the risks of a "medicine of State"; second, because of the inner limits of CPGs on one side and the peculiarities of the medical profession on the other; third, because the primary aim of the 2017 Law is the implementation of risk-management systems in order to decrease the expenditure of public resources: consequently, the relevant CPGs for the purposes of the 2017 Law are not those exclusively aimed at the patient's benefit, but those combining elements of cost-reduction too).
107. *See* Laura Anna Terrizzi, *Linee guida e saperi scientifici* "*interferenti*"*: la Cassazione continua a non applicare la legge Gelli-Bianco*, 7 DIR. PEN. CONT. 93 (2018).

informed consent.[108] However, both topics are strictly intertwined since the lack of adequate and complete information for the patient may give rise to a form of healthcare professional liability.

This gap has been filled by a subsequent legal provision, Law 219/2017. Its first article is indeed headed with "Informed Consent."[109] This provision expresses the aim of the law, which is to recognize and protect fundamental rights—in compliance with both the Italian Constitution (in particular, arts. 2, 13, 32) and the European Union Charter of Fundamental Rights (arts. 1, 2, 3)—such as the right to life, health, dignity, and the right of self-determination, in particular mandating that no healthcare treatment should be carried out without the free and informed consent of the involved person.

Before the enactment of this statutory recognition, the right to informed consent lacked a specific legal framework, but Italian judges used to ground it on the above-mentioned constitutional provisions. Furthermore, the Constitutional Court had highlighted the function of informed consent as a synthesis of both the right to self-determination and the constitutional right to health, since both imply the right to complete and adequate information.[110]

The task to outline the content and boundaries of this right has therefore been assigned to the Italian judges, who have developed a remarkable case law. Their role is still important since the recent law does not specifically address compensation of harm and does not clarify other related issues. A recent Italian Supreme Court ruling,[111]

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108. A point of convergence between the 2017 Law and the topic of informed consent, has been identified in the duty of the physician, willing to adopt a different approach to treat the patient than that recommended by the CPGs, to specifically reporting the reasons of her choice. Such decision, has been noted, shall be explained to (and agreed upon with) the patient, both in order for the consent of the latter being really effective and, at the same time, for *ex ante*, exculpatory purposes, having in mind the potential adverse effect of such decision in a judicial context. *See* Granelli, *supra* note 5, at nn. 54-56.

109. Legge Dec. 22, 2017, n. 219, in force since Jan. 31, 2018.

110. Corte Cost., sentenza Nov. 18, 2008, n. 438, *available at* https://perma.cc/XN4A-WB2Z.

111. Cass., sez. III Civile, Dec. 22, 2017, n. 7248 [hereinafter Cass. n. 7248].

issued the day of publication of the Law 219/2017, is worth mentioning. The Court expressly adhered to the settled judicial orientation according to which the absence of the informed consent of the patient has autonomous dignity for purposes of damage-compensation. Consequently, the breach by the physician of the duty to secure the informed consent of the patient might cause different kinds of damage. Firstly, a damage to the patient's health whenever she is able to demonstrate that had she been duly informed, she would have never undergone the surgery, thus avoiding its harmful consequences. Secondly, damage for breach of the right to self-determination, which occurs when, due to the lack of information, the patient suffers a pecuniary or non-pecuniary damage (in this case provided that the harm is substantially serious[112]).

Indeed, in the opinion of the Court, thanks to adequate and complete information, the patient has:

> – the right to choose among different options of medical treatment;
> – the power to require further and different medical opinions;
> – the power to choose a different institution and/or specialist;
> – the right to refuse the surgery or the therapy and/or the right to consciously interrupt it;
> – the power to consciously prepare herself to the negative consequences of the surgeon wherever they result particularly burdensome and painful, even because completely unexpected for the patient due to the lack of relevant information.[113]

The scenery of the harmful events is thus quite articulated. In particular, there might be:

(1) absent or unsatisfactory information about a surgery that has

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112. *Id.* § 3. *Ex plurimis* Cass., sez. III Civile, July 5, 2017, n. 16503; Cass., sez. III Civile, Oct. 13, 2017, n. 24074; Cass., sez. III Civile, Nov. 27, 2015, n. 24220; and Cass., sez. III Civile, Feb. 13, 2015, n. 2854.

113. Cass. n. 7248, *supra* note 111, § 3. The same reasoning has been adopted by the Supreme Court in a subsequent decision, Cass., sez. III Civile, ordinanza Dec. 4, 2018, n. 31234.

caused damage to the health of the patient due to the fault of the physician in cases where the patient would have anyway undergone the surgery: in these circumstances, the compensation will cover only the damage to the health (pursuant to Supreme Court 901/2018);

(2) absent or unsatisfactory information about a surgery that has caused damage to the health of the patient due to the fault of the physician in a situation where, if duly informed, the patient would have never undergone the surgery: in this case, the damage to be compensated will be the damage to the health of the patient as well as that due to the breach of the patient's self-determination right;

(3) lack of information about a surgery that has caused damage to the health of the patient not due to the fault of the physician, in cases where the patient would have anyway undergone the surgery: in this situation, the damage will cover the infringement to the patient's right to self-determination, while the harm to the patient's health shall be assessed on a case by case basis; and

(4) lack of information about a surgery duly performed and not causing any damages to the patient's health: in this scenario, the infringement of the patient's right to self-determination shall be compensated only if the patient has suffered the unexpected consequences resulting from the surgery without the necessary consciousness and being totally unprepared to them.

For compensation of the damage to the right of self-determination, the damage should meet or exceed the legal threshold of seriousness of the harm, as set forth by Supreme Court: Civil Joint Division no. 26972/2008 and 26975/2008.[114] Again, the ongoing dialogue between the legislative, judicial, doctrinal formants has made it possible to ensure an appropriate legal framework to efficiently protect selected and deserving interest.

114. These two cases are commonly known as "S. Martin's twin-rulings" and are dealing with the requirements and the criteria to compensate the non-pecuniary damage.

VI. CONCLUSIONS

The topic of medical malpractice (*rectius*, healthcare liability) is very complex and interesting, and it is a field where the "law in action" plays a fundamental role, even in light of the manifold, heterogeneous, and sometimes conflicting interests of different stakeholders. Within the Italian legal system, the relevant legal framework has been developed thanks to a constant and articulated dialogue among different formants. In a first period, such dialogue occurred in particular between the Italian Judges and the opinion of jurists. Recently, the statutory formant has also been directly and actively involved.

The analysis of the last six years reveals that this phenomenon is still a work in progress that needs to be adjusted and better tailored to the field. However, due to the peculiarities of medicine and healthcare protection and their transnational nature, the dialogue should occur not only among formants of the same legal system, but also looking at the experiences of other legal systems, and applying a critical comparative approach. Referring to the U.S. scenario, it proves evident that many issues raised by the Italian legislative choices have been analyzed there and investigated for some time, both in their positive and negative aspects. In this regard, the paradigmatic example can be found in the debate surrounding the role and the function of CPGs, which are the undeniable protagonists of the attempt to cope with the new concept of medicine that seeks more standardization and links to scientific evidence (although there is no unanimous consensus at all about medicine being a science). In addition, the U.S. debate has highlighted the need to cope with the necessity to decrease healthcare costs, to enhance patients benefit, and with the struggle to find suitable legal rules.

However, a peculiar feature of the Italian legal system within this area of law is that the judicial formant has constantly been very active in developing and settling the legal framework, and in paying specific attention to claim its autonomy in interpreting and applying

the relevant norms, even when not properly in compliance with (or clearly departing from) the legislative choices.

With specific reference to the topic of CPGs, the occurrence of clear "solos" by the Italian judges in such musical score is undeniable. On the opposite side of the great theoretical emphasis placed by the 2017 Law on the exculpatory role of CPGs, there is indeed the systematic and constant distinction affirmed by the Italian judges about the unsuitability of CPGs to act as a shield or as an automatic waiver of liability on behalf of healthcare providers.[115]

More generally, while the measures introduced by the 2017 Law seem to have achieved positive results regarding civil litigation, the same cannot be said about criminal litigation. This might provoke adverse effects in light of the high level of uncertainty and unpredictability of medical malpractice claims,[116] thus discouraging the

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115. *See* Mariotti, *supra* note 52, § 3: "guidelines are an abridgement of the scientific, technological and methodological achievements concerning the specific operative fields, qualified in such way after an accurate selection and installation of different contributions, without any presumption of immobilism and lacking any suitability to stand as binding rules." About the role of CPGs, *see also* the ruling of the Cass., sez. III Civile, ordinanza Nov. 30, 2018, n. 30998, affirming the absence of liability of both the physicians and the hospital for having administered to a patient with a hemorrhagic risk a lower dose (i.e., the half) of heparin than the recommended one, in order to balance such risk with that of venous thrombosis. The departure from the recommendations set by the relevant CPGs is justified, in the opinion of the Court, by the need to reach a compromise between the two concurring risks. With specific regard to CPGs the court holds:

> CPGs (i.e., the *leges artis* sufficiently shared at least by a distinguished part of the scientific community in a given time) are not an insurmountable Procrustes' bed . . . . They are only a parameter to assess the physician's behavior: generally, a behavior in compliance with the CPGs will be diligent, whilst a behavior not in compliance with the CPGs will be negligent or imprudent. However, this does not mean that a behavior not in compliance with the CPGs might not be deemed diligent if the specific circumstances of the case dictate not to abide by such CPGs (for example, when the CPGs require a particular medicine but the patient is allergic and thus the physician does not prescribe it); for the same reason even a behavior in compliance with the CPGs might be deemed negligent on the basis of the circumstances of the case (for example, when the CPGs recommend a surgery and the physician abides by them although the patient's previous conditions do not allow her to tolerate a total anesthesia).

116. *See, e.g.*, D'Alessandro, *supra* note 50, at 277; Caputo, *supra* note 47, at 295; Alessandro De Santis, *La colpa medica alla luce della legge Gelli-Bianco*, 7-8 STUD. IUR. 790, 796-798 (2017); (all arguing about the risks of liability of the

healthcare providers and negatively affecting the patients' benefit. This uncertainty is further enhanced by the judicial clash about the proper interpretation of the 2017 Law, which the intervention of the Criminal Joint Division of the Supreme Court did not unravel. In this scenario the doctrinal formant seems called to find a balance between the (sometimes problematic) text of the law and the judicial interpretation. The conversation has just begun.

Italian State for breach of art. 7 of the ECHR due to a legislative framework not suitable to guarantee the certain and predictable outcome of criminal trials).