Medical Negligence and Guidelines in Italian Criminal Law

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Abstract

Criminal prosecutions *related to medical negligence have registered a significant increase in the last decades.* Italian lawmakers were interested in addressing the issue and intervened in 2012 with the Balduzzi Decree, which provided for the exemption from criminal liability for slight negligence of the physician who acted following the guidelines and medical protocols.
Subsequently, in 2017, to fight the phenomenon of "defensive medicine", the Italian legislator approved the Gelli-Bianco law entitled "Provisions on patient care safety and professional responsibility of health care providers", which introduced Article 590-sexies "Negligent liability for death or personal harm in the health sector" to the Italian Criminal Code. This Article provides for the exclusion of medical liability for lack of skill when the physician acts in compliance with guidelines published according to the law or, in any case, accredited by the scientific community or, in their absence, following best medical practices, except in cases where the patient's particular situation requires a different behaviour. The Gelli-Bianco law, designed to address the perplexities related to medical negligence that followed the Balduzzi Decree, seems to have generated new debates in doctrine and jurisprudence, which have considered the exclusion of criminal liability a cause of non-punishment with unclear application boundaries. In this regard, the United Sections of the Supreme Court intervened with the Mariotti judgment of February 22, 2018, No. 8770, intending to end this discrepancy in jurisprudence and the ambiguities surrounding the interpretation of Article 590-sexies of the Italian Criminal Code.

Keywords: Medical negligence, criminal liability, guidelines, best medical practices, Gelli-Bianco law.

1. Introduction

The continuous increase of judicial processes involving medical negligence has influenced the intervention of the Italian legislator in 2012 with the Balduzzi Law, which exempted physicians who followed medical guidelines and protocols from criminal liability for slight negligence.
Eventually, in 2017, the lawmaker intervened with the Gelli-Bianco Law, which included article 590-*sexies* into the Italian Criminal Code in order to combat the phenomenon of *"defensive medicine"*. This article provides a non-punishment provision for the lack of skill of the physician who respects the guidelines accredited by the scientific community or, in their absence, best clinical practices if they are adequate to the particular case. This new law, which comes after a long wait, is intended to address the concerns that have accompanied medical negligence.
Those two interventions of the Italian legislator have been the subject of debates within doctrine and jurisprudence. In particular, there has been an increase in the jurisprudence of the Supreme Court, which has intervened on several occasions to bring order between the various and conflicting theories on medical negligence.

Our research focuses on the physician's criminal liability for negligence, characterized by the non-observance of rules, orders, and disciplines in the performance of medical professional activities.
Recently, the health emergency created by the COVID-19 epidemic has determined the intervention of the Italian legislator with Law No. 71 of 2021, which introduces rules in favour of health care personnel, stating that in situations involving COVID-19 emergencies, the physician should only be held liable for gross negligence.

2. Literature Review

In recent decades, medical negligence has captured the attention of doctrine and jurisprudence. To properly handle the issue, it's essential to mention that medical negligence is a very particular category, characterized by non-observance of laws, regulations, instructions, and disciplines (Di Giovine, 2013, p. 65; Di Pentima, 2013, p. 150; Galli, 1949, pp. 64 et seq).
In the first place, it is essential to understand the basis of criminal liability for negligence. The doctrine and jurisprudence have always emphasized that the criteria that represent the basis of the imputation of the event with negligence (Bilancetti & Bilancetti, 2013, p. 775) are those of the predictability and avoidability of the damaging or dangerous event in concrete (Di Landro, 2012, pp. 125 et seq.; See Stortoni, 2016, pp. 17 et seq.). In this regard, it is necessary to refer to the prevalent orientation in doctrine and jurisprudence[1], according to which culpability necessarily implies an indispensable mental element (Castronovo, 2013, pp. 183 et seq.; Castronovo, p. 572; Galli, 1949, pp. 14 et seq.; Stortoni, 2016, pp. 9 et seq.) and therefore requires the possibility of knowing the external causes of the damage or the objective possibility of avoiding them (Princigalli, 1983, pp. 47 et seq.).
According to the doctrine, medical negligence is the failure to follow the typical rules of diligence required by the medical profession, the so-called *"good professional diligence"* (Frati et al., 2006, pp. 461 et seq.; Roiati, 2009, p. 2381). This type of particular negligence indispensably requires *the observance of the rules of medical art and specific technical notions together with the use of tools and materials normally adequate for the activity carried out* (Cirillo, 2005, pp. 236 et seq.). The concept of imprudence is delineated when the physician acts with "*recklessness, with excessive haste, with unjustified hurry, without adopting the precautions indicated by common experience or by precise rules dictated by medical science*"[2]. And finally, lack of skill occurs when the medical behaviour is incompatible with the minimum level of technical knowledge, culture, experience, and professional skills necessary for the exercise of the medical profession.[3]
In terms of medical negligence, it is essential to mention the numerous doctrinal and jurisprudential debates that provoked the Balduzzi law. The doctrine has highlighted a series of perplexities about the guidelines, which, on the one hand, represent a standard of care for the patient but, on the other hand, are characterized by purely economic[4] (Giunta, 2013) and opportunistic interests. In this sense, doctrine emphasizes that guidelines are dangerous tools (Campana, 2012, p. 551) that can hide

4 Cass. Pen., Sez. IV, 24 January – 11 March 2013, no. 11493, in *Guida al dir*., 17, 2013, p. 32, according to the Court's orientation, the guidelines contain norms of skill.

or justify medical negligence.[5]
The significant debates that have signalled the Balduzzi law have necessitated legislative intervention. So, five years after the Balduzzi law, the Italian legislators approved the Gelli Bianco law, which limited the sources to be considered in carrying out medical activities, providing certainty to the physician and indicating the appropriate behaviour. However, it did not resolve the ambiguities regarding the guidelines.
The literature provided in this research has a descriptive nature, intending to compare the various doctrinal perspectives on the issue. The study will also analyze the Italian Supreme Court's jurisprudence and its fundamental importance, considering the frequent intervention of this Court in cases involving medical negligence.

3. Methodology

The purpose of this research is to highlight and analyze the peculiarities of medical behaviour characterized by negligence. Accordingly, we had to refer to the different doctrinal and jurisprudential perspectives on the topic. To properly study medical negligence, we had to divide the paper into two parts: the first part explores medical negligence according to the Italian Criminal Code, and the second part analyzes the doctrinal and jurisprudential orientation considering the recent legislative interventions. As a result, a part of this study refers to guidelines and best medical practices and the legal importance accorded to them.
This elaboration uses qualitative research methods to analyse medical negligence as a particular category of negligence marked by non-observance of laws, regulations, instructions, and disciplines.

4. Medical negligence and the principle of culpability according to Article 43 of the Italian Criminal Code

Our research on medical negligence must first begin with article 43 of the Italian Criminal Code, which provides for the mental element of the crime, including intent, negligence, and preterintention. According to Article 43 of the Italian Criminal Code, the crime is negligent, or beyond the intention, if the event, even if foreseen, is not wanted by the agent but occurs due to carelessness (recklessness) (De Francesco, 2012), lack of skill (Coratella, 2006, p. 63), imprudence[6], or non-compliance with laws, regulations, orders, or instructions (Alimena, 1947; Bilancetti & Bilancetti, 2013, p.

5 Cass. Pen., Sez. IV, 1 February 2012, no. 4391; Cass. Pen., Sez. IV, 19 September 2012, no. 35922, *cit.*
6 In the medical field: "*There is imprudence when the physician acts recklessly, with excessive haste, unjustified rush, without adopting the precautions indicated by common experience or precise rules dictated by medical science. (…) On the other hand, a physician is negligent if, due to inattention, forgetfulness, carelessness, listlessness, lightness, or superficiality, he fails to follow these common rules of diligence that are expected of a person qualified to practice medicine and are followed by the majority of physicians. The difference between imprudence and negligence lies in the fact that the first consists of active conduct contrary to the fundamental rules that common experience recommends protecting the patient's health; the second, on the other hand, is omissive conduct, in the sense that this is done, according to what medical science advises to do in a specific case. Finally, there is a lack of skill when the physician's conduct is incompatible with that minimum level of technical knowledge, culture, experience, and professional capacity that constitute the necessary prerequisite for the exercise of the medical profession".* In this regard see Cass. Pen., Sez. IV, 16 February 1987, in *Riv. pen*., 1988, p. 202.

771; Di Landro, 2012, p. 25; Palazzo, 2005, p. 289).
The criminal law doctrine distinguishes between two categories of negligence: generic and specific. The first category refers to the violation of the rules of diligence (Bugatti, 2011, p. 842; D'Orsi, 1982, p. 124; Comandè, 1999, p. 1101; Gorgoni, 1999, p. 995), prudence (Alimena, 1947, p. 70), and expertise of the average man, which are not written but drawn from human experience. On the other hand, the second category refers to the non-observance of laws, regulations, orders, and disciplines[7] (Di Giovine, 2013, p. 65; Di Pentima, 2013, p. 150; Galli, 1949, pp. 64 et seq.).
We should immediately specify that the criteria that represent the basis of the imputation of the event as negligent (Bilancetti & Bilancetti, 2013, p. 775) are those of the predictability and avoidability of the damaging or dangerous event in concrete[8] (Di Landro, 2012, pp. 125 et seq.; See Stortoni, 2016, pp. 17 et seq.; Turilazzi, 2001). In this regard, it is worth noting the doctrine's emphasis on the fact that negligence necessitates the presence of an essential mental coefficient (Castronovo, 2013, pp. 183 et seq.; Castronovo, p. 572; Galli, 1949, pp. 14 et seq.; Stortoni, 2016, pp. 9 et seq.) and thus requires the agent's ability to know the external causes of the damage or the objective possibility of avoiding them (Principalli, 1983, pp. 47 et seq.). This approach is compatible with the Supreme Court's jurisprudence, which on several occasions has ruled that outside of the concrete predictability and avoidability of the event, it is not possible to attribute to the person the event because of his act or omission[9] (Lattanzi & Lupo, 2010, pp. 492 et seq.). From this perspective, medical behaviour is reprehensible for failure to adapt suitable precautionary measures to avoid the typical risk of the activity performed[10] (Cupelli, 2011, p. 2947; Furramani, 2017, p. 159).
After this brief general introduction, it is possible to analyze the profiles that characterize medical negligence. It is important to note that medical-surgical activity, which is a dangerous activity allowed because socially utile[11] (Gribaudi, 2012, p. 59; Coratella, 2006, p. 58), represents the so-called specific negligence, defined as negligence characterized by non-compliance with not written rules of conduct, which have the primary goal of avoiding the typical risk of medical activity.
The doctrine notes that medical negligence consists of the non-observance of the typical rules of diligence required by medical professional activity, the so-called "good professional" diligence (Frati et al., 2006, pp. 461 et seq.; Roiati, 2009, p. 2381), which inextricably requires the observance of the rules of art and specific technical notions, as well as the "*use of tools and materials, normally adequate in relation to the activity carried out*" (Cirillo, 2005, pp. 236 et seq.). According to the Court of Cassation, non-compliance with the rules of professional diligence can occur due to inattention, forgetfulness, carelessness, lightness, or superficiality. It should be noted, among

7 Trib. Savona, 9 July 2005, in *Juris Data, Sentenze Tribunale Savona*.
8 Cass. Pen., Sez. IV, 12 March 2010 (dep. 3 maggio 2010), n. 16761.; Trib. Grosseto, 31 October 2000, in *Riv. it. med. leg*., 2001; Cass., 28 January 2009, no. 9045.
9 C. App. Bari, 26 January 1981, in *Foro it.*, 1981, II, p. 167; Cass. Pen., 20 March 1991, in *Cass. pen*., 1992, p. 2754.
10 In this sense Cass. Pen., Sez. IV, 9 July 2003, no. 37473, *CED Cassazione*, no. 225958.; Cass. Pen., Sez. IV, 21 November 1996, no. 2139, Spina, *CED Cassazione*, no. 207873.
11 Cass. Pen., Sez. IV, 2 October 2003, no. 37473, in *CED Cassazione*, 2003, no. 225958.; Cass. Pen., Sez. IV, 3 November 1994, no. 11007, in *CED Cassazione,* 1994, no. 200387.

other things, that these are typical rules of diligence, which must never be lacking in those who practice the medical profession[12].

Furthermore, the Supreme Court jurisprudence emphasizes that imprudent behaviour takes place when the physician "*acts recklessly, with excessive hustle, in an unjustified hurry, and without adopting the precautions indicated by common experience or precise rules dictated by medical science*[13]". On the other hand, a prudent doctor is the one who can prevent the risks and complications that could derive from a given medical treatment in order to avoid its harmful consequences.

Eventually, the lack of skill occurs when medical conduct is incompatible with the minimal level of technical knowledge, culture, experience, and professional skills that are the prerequisite for the exercise of the medical profession[14]. It's worth noting that the lack of skill refers to the diligence attributed to a specific professional sector (Romano, 2004, p. 461) that requires particular knowledge.

The confirmation of the above comes from the jurisprudence of the Italian Court of Cassation in decision No. 24791/2008. On this occasion, the Court stated that skill depends on the degree of specialization of the professional, and so *"various degrees of specialization correspond to different degrees of skill.*[15]*"* Part of the doctrine emphasizes that lack of skill is described as a violation of scientific and medical practice technical standards (Crespi, 1955, p. 96), both due to insufficient preparation and incompetence of the physician.

According to jurisprudence, negligence may also include the physician's lack of professional upgrading. The latter represents a disciplinary duty that is part of the diligence and skill area[16] (Bilancetti & Bilancetti, 2013, p. 776). In this context, Article 19 of the 2014 Code of Medical Ethics provides for updating and permanent professional training: *"the physician throughout his professional life pursues constant updating and continuous training for the development of technical and non-technical professional knowledge and skills, favouring their dissemination to learners and collaborators*[17]*."* Precisely under these considerations, the failure to update reflects the inadequacy of the medical service in terms of imprudence and lack of skill (Bilancetti & Bilancetti, 2013, p. 776).

5. The influence of the Balduzzi Decree on the degrees of negligence and the Court of Cassation's jurisprudence

In terms of medical negligence, it's worth reflecting briefly on the so-called Balduzzi

12 Cass. Pen., Sez. IV, 16 February 1987, *cit.,* p. 202.

13 *Ibidem*.

14 *Ibidem*.

15 Cass., 8 October 2008, no. 24791.

16 Cass. Pen., Sez. IV, 28 May 2003, in *Giuda al dir.,* 2003, II, p. 61: "*It must be considered negligent the conduct of the physician who prescribes and administers medicines potentially capable of interfering with essential functions without verifying in advance, with available scientific means, the tolerability of the patient and the existence of contraindications and imperishable, and without verification of the effects during the course of therapy*".

17 Article 19, *Italian Code of Medical Ethics, 2014.*

Decree[18], which classified medical conduct characterized by slight negligence as criminally irrelevant if carried out following therapeutic indications contained in guidelines, protocols, or medical practices recognized by the scientific community (Mariotti et al., 2014, pp. 90 et seq.; Aleo, 2014, pp. 691 et seq.).
The Balduzzi Decree has provoked much debate and criticism (Civello, 2013; De Francesco, 2015, pp. 884 et seq.; Di Giovine, 2013, pp. 80 et seq.; Di Landro, 2013, pp. 833 et seq.; Fiori A. & Marchetti D., 2013, pp. 563 et seq.; Giunta, 2013, pp. 819 et seq.; Iadecola, 2013, pp. 549 et seq.; Nocco, 2013; Roiati, 2013; Valbonesi, 2013; Vallini, 2013; Vallini et al., 2015), not so much because of the physician's criminal irresponsibility for slight negligence, which, as evidenced by the critical doctrine, is nothing new, but because of the importance placed on the guidelines. As we will see below, the Court of Cassation was obliged to intervene several times, highlighting all the concerns about the reform and conformity with the so-called guidelines.
The doubts concerning the Balduzzi Decree were related to Article 3, which provides that: *"The health care professional who, in carrying out his/her activity, observes the guidelines and good practices accredited by the scientific community is not criminally liable for slight negligence."*
As can be seen, the decree limited the criminal liability of healthcare professionals, including physicians, nurses, and anybody who practices the healthcare profession. Consequently, the physician could not be criminally liable for slight negligence if he performed the therapy under the guidelines[19] (Di Landro, 2013; Di Landro, 2011, pp. 424 et seq.; Caputo, 2012, p. 877; Cupelli, 2013; Pezzimenti, 2015; Cfr. Vallini et al., 2015) and good practices[20] (Martuscelli, 2013; Amoroso, 2016), accredited by the scientific community and used a minimum of diligence that prevented him from incurring gross negligence (Di Pentima, 2013, p. 313; Manna, 2014; Lanza 2014).
The reasons for such a provision, according to case-law, might be found in the precautionary nature[21] of guidelines. The latter are rules that, if respected, reduce or limit the risks of medical-surgical treatment. Based on these premises, the Supreme Court declared the physician negligent for acting in violation of medical guidelines and protocols[22].

18 Law Decree 13 September 2012, no. 158, published in the "Italian Official Gazette" of 13 September 2012, no. 214, converted with amendments by law 8 November 2012, no. 189, Article 3, published in the ordinary supplement no. 201 to the "Official Gazette" of 10 November 2012, no. 263.

19 Methodological Manual. How to produce, disseminate and update recommendations for clinical practice, 2002, (at www.snlg-iss.it); Cass. Pen., Section IV, 29 January 2013, no. 16237, in Riv. pen., 2013, fasc. 6, pp. 657 et seq.; According to a widespread opinion, the guidelines are: "*recommendations of clinical behaviour, elaborated through a process of a systematic review of the literature and scientific opinions, in order to help doctors and patients decide the most appropriate care modalities in specific clinical situations*". The definition is taken from M. J. FIELD, K. N. LOHR, *Guidelines for clinical practice: from development to use*, Washington, 1992, pp. 3 et seq.

20 Cass. Pen., Sez. IV, 29 January 2013, no. 16237, in *Riv. pen*., 2013, fasc. 6, pp. 657 et seq.

21 Cfr. Cass. Pen., Sez. IV, 29 January 2013, no. 16237, *cit*.

22 Cass. Pen., Sez. IV, 24 January – 11 March 2013, no. 11493, in *Guida al dir*., 17, 2013, p. 27 s.; Cass. Pen., Sez. IV, 14 November 2007, Pozzi, in *Foro it.,* 2008, II, p. 279.; Cass. Pen., Sez. IV, 19 January 2006, no. 16995, L.A.N., in *DeJure/Juris Data.*; Trib. Milano, 21 July 2000, in *Rass. dir. farm*., 2001, p.

In this regard, the Supreme Court's jurisprudence has stated on several occasions that compliance with the guidelines does not automatically absolve the physician of criminal liability; however, the same are rules of relative cogency and thus must be evaluated according to the concrete case (Caletti, 2019, p. 8). In this sense, the observance of the guidelines on medical-surgical treatment neither excludes nor determines the physician's negligence[23] (Marra, 2012, pp. 557 et seq.).

6. Medical negligence following the Gelli-Bianco law

Five years after the Balduzzi Decree, the Italian legislator intervened with the Gelli-Bianco law, denominated *"Provisions on patient care safety and professional liability of health care providers,"* which came into force in April 2017.

What appears relevant for our research is to draw attention to two provisions of the Gelli-Bianco law, Articles 5 and 6, which have been the subject of debates in doctrine and jurisprudence and continue to feed the decennial doubts regarding the criminal relevance of medical treatments carried out in compliance with the guidelines or good practices accredited by the scientific community.

In particular, Article 5, denominated *"Good clinical-assistance practices and recommendations provided by the guidelines"*, provides that health professionals' activities must comply, except for the particularity of the case, with good clinical-assistance practices and guidelines suggested by scientific societies and research institutes. The guidelines must be published for the individual sectors of specialization within two years from the entry into force of the law by the Minister of Health and must be periodically updated. In the absence of guidelines, the article provides the obligation to adhere to good clinical-assistance practices.

The Gelli-Bianco law, designed to address the perplexities related to medical negligence that followed the Balduzzi Decree, seems to have generated new debates. Doctrine and jurisprudence highlight the problems concerning this long-awaited law, which, however, does not seem to have resolved the questions concerning medical liability. The law introduced an explicit reference to guidelines and clinical care practices in the criminal code, again raising doubts about the latter.

Article 6 of the law addresses the physician's criminal liability by introducing Article 590-*sexies* into the Italian Criminal Code, entitled "*Negligent liability for death or personal injury in the health sector*" (Mattheudakis, 2019; Iadecola, 2017, p. 57).

Article 6, denominated "*Criminal Liability of the Healthcare Professional*," provides: "*If the facts referred to in Articles 589 and 590 are committed in the exercise of the healthcare profession, the penalties provided for therein apply except as provided for in the second paragraph. If the event occurred due to a lack of skill, the punishment is excluded when the recommendations provided for by the guidelines as defined and published by the law are respected or, in the absence of these, good clinical-care practices, provided that recommendations*

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23 Cass. Pen., Sez. V, 13 February 2014 – 11 March 2014, no. 11804, in *Riv. it. med. leg.*, 3, 2014, p. 980, with note of M. LAMANUZZI.; Cass. Pen., Sez. IV, 29 January 2013, no. 16237, in *Riv. pen.*, 2013, fasc. 6, pp. 657 et seq.; Cass. Pen., Sez. IV, 19 September 2012, no. 35922, (in www.cassazione.net.) ed in *Diritto & Giustizia*, 2012, p. 20.; Cass. Pen., Sez. IV, 23 November 2010 – 2 March 2011, no. 8254, in *San. pub. priv.*, 2011, p. 73 s, with note of S. MARZOT.

envisaged by the aforementioned guidelines are adequate to the particularities of the specific case" (Piras, 2016). The second paragraph of Article 6 provides for the repeal of Article 3 of the Balduzzi law.

This novelty has provoked criticism in the doctrine, considering that the guidelines change quickly (Panti, 2016, p. 375), and they pose issues with accreditation and updating.

A first objection to the Gelli-Bianco law concerns the first paragraph of Article 6, which provides for the exclusion of medical liability for lack of skill when the physician acts in compliance with good practices and guidelines published according to the law or in any case accredited by the scientific community, except in cases where the patient's particular situation requires a different behaviour. The same considerations made about the Balduzzi law apply here. There is a risk that the guidelines or good medical practices recognized and published by the law may hide or justify any negligent behaviour of physicians (Guerriero, 2016).

The criticisms coming from the doctrine consider the Gelli-Bianco law on the same level as the Balduzzi law, with the only difference that the guidelines from simple recommendations, as provided for by the Balduzzi law, with the Gelli-Bianco law become legal prescriptions (Blaiotta, 2018, p. 3).

Unlike the previous legislation (the Balduzzi law), the novel does not make any distinction between the degrees of negligence; notwithstanding, it provides for an exemption from criminal liability for lack of skill when the physician respects, except for the relevant particularities of the specific case, the recommendations provided by the guidelines recognized by the scientific community or, in the absence of the latter, good clinical-assistance practices. This cause of non-punishment operates only in cases when guidelines are adequate for the specific case. (Trapella, 2019, p. 85; Terrizi, 2018, p. 98).

This exclusion of criminal liability has been subjected to strong criticism by the doctrine and jurisprudence, considering it a cause of non-punishment with uncertain application boundaries (Caletti, 2019; Cupelli, 2017; Cupelli, 2018; Brusco, 2017; Caletti & Mattheudakis, 2017). On the other hand, there have been numerous criticisms (Tronconi, 2016, pp. 547 et seq.; Brusco, 2017) regarding the distinction between lack of skill, imprudence, and carelessness (Cupelli, 2018; Brusco, 2017; Iadecola, 2017).

Contrasting orientations have been registered in the jurisprudence of the Supreme Court, which considers the novel as a norm that raises high interpretative doubts and is characterized by a strong contradiction[24] (Brusco, 2017; Cupelli, 2018; Mattheudakis, 2019, p. 66; Blaiotta, 2018, p. 1). In this judgment, the Court outlines the scope of application of the Gelli-Bianco law and delineates that Article 590-sexies offers a restrictive interpretation.

The Court believes that this article excludes the criminal liability of the healthcare professional only in the case of lack of skill and excludes the applicability of this cause of non-punishment:

24 Cass. Pen., Sez. IV, 20 April 2017 no. 28187, imp. De Luca-Tarabori: *"(…) The interpretation of the new norm raises significant interpretative doubts, irresolvable at first sight, immediately highlighted by the numerous academics who have opposed the reform. In fact, internal inconsistencies are so severe as to undermine the very rationale practicability of the reform in the application field. Even before that, it is difficult to understand the rationale of the novelty."*

-in cases of negligence or lack of skill, non-regulated by the guidelines:
-if the recommendations provided by the guidelines are not adequate for the specific case.
-if the therapeutic approach is governed by adequate and relevant guidelines but not in that application context, referring to the executive error[25].
The Court also argues that the guidelines *cannot completely exhaust the evaluation parameters* considering that the physician can also refer to highly qualified scientific recommendations or approaches in the scientific community[26].
According to the Court, it could be supposed an exclusion of the punishment of the healthcare worker who: "*despite having caused a harmful event due to behaviour reprehensible for lack of skill, at some point in the therapeutic relationship it has, in any case, applied qualified directives, even when they are unrelated to the topical moment in which the damaging lack of skills took place*" (Schiavo, 2019, p. 6). Nevertheless, the Court emphasizes that this approach appears to conflict with some fundamental principles stated in Articles 3, 27, and 32 of the Italian Constitution, such as reasonableness, culpability, and protection of the right to health (Caletti, 2019, p. 17; Birrittieri, 2019, p. 51; Cupelli, 2017).
The orientation of the Supreme Court changed with the subsequent Cavazza ruling, which seems to go in a diametrically opposite direction from the Tarabori ruling[27] (Cupelli, 2017). In this decision, the Court defined the non-punishment for the physician's lack of skill who acted in accordance with the guidelines or good practices, regardless of the degree of negligence[28]. This Court's approach raises considerable doubt about the difference between the non-punishment of a severe lack of skill and the punishment of other, less severe types of negligence, such as slight negligence (Birrittieri, 2019, p. 55).
To end this discrepancy in jurisprudence and the ambiguities surrounding the interpretation of Article 590-*sexies* of the Italian Criminal Code, the United Sections of the Supreme Court intervened with the Mariotti judgment of February 22, 2018, no. 8770 (Birritteri, 2019; Schiavo, 2019). In this context, the United Sections of the Supreme Court considered that Article 590-*sexies* of the Italian Criminal Code provides for a cause of non-punishment in the case of a physician who acts with a slight lack of skill when he follows the guidelines or best practices accredited by the scientific community. In the opinion of the Court, for the cause of non-punishment to be applicable, the doctor must have chosen an adequate guideline to follow in the specific case, despite the executive error due to slight negligence. On the other hand, a doctor who makes a mistake in choosing the appropriate guideline cannot be considered non-punishable (Birrittieri, 2019, p. 51). This interpretation proposes two types of errors: errors in the choice of treatment and errors in the execution of the treatment (Bartoli, 2018, p. 245).
Here, the United Sections have re-proposed a distinction between the degrees of negligence (Cupelli, 2017), identifying the cases in which the doctor will have to

25 Cass. Pen., Sez. IV, 20 April 2017 no. 28187, imp. De Luca-Tarabori.
26 *Ibidem*.
27 Cass. Pen., Sez. IV, sent. 19 October-31 October 2017, no. 50078, in *Diritto penale Contemporaneo*, 7 November 2017 (available at: https://www.penalecontemporaneo.it/upload/4604-cass5007817.pdf).
28 Cass. Pen., Sez. IV, sent. 19 October -31 October 2017, no. 50078, *cit*.

answer for death or personal injury in the execution of the medical-surgical activity:
a) If the event occurred as a result of negligence (even "slight") or imprudence.
b) if the event occurred due to negligence (even "slight") from lack of skill when the specific case is not governed by the recommendations of the guidelines or by good clinical-assistance practices.
c) if the event occurred as a result of negligence (even "slight") due to a lack of skill in identifying and selecting guidelines or good clinical-assistance practices that are not adequate for the specificity of the particular case.
d) if the event occurred due to "serious" negligence due to lack of skill in carrying out recommendations of guidelines or good clinical-assistance practices, considering the degree of risk to be managed and the particular difficulties of the medical act[29]*."*
Despite the Court of Cassation's efforts to standardize practice and remove interpretative ambiguities surrounding Article 590-*sexies* of the Italian Criminal Code, the problems concerning its application continue.
The concerns surrounding the application of this article refer to the guidelines and clinical practice assistance accredited by the scientific community, which must specify the behaviour to be followed by the healthcare professional. In fact, from the approval of the Gelli-Bianco law up to the present day, these guidelines appear to be a relatively small number (Mattheudakis, 2019). This situation raises concerns regarding the physician's behaviour in particular situations when recognized guidelines have yet to be approved. At this point, the Gelli-Bianco law offers another alternative: following clinical assistance practices, which are fundamentally different from the guidelines. According to the doctrine, this provision contradicts the principle of determination (Caletti & Mattheudakis 2017, p. 104; Trapella, 2019, p. 87) because clinical care practices are not codified.
The health emergency caused by the COVID-19 pandemic has also influenced the intervention of the Italian legislator on medical negligence. In this regard, the legislator enacted Law No. 76 of 2021, which in Article 3-*bis* establishes responsibility for negligent death or personal injury in the health sector during the COVID-19 state of epidemiological emergency. In this framework, the application of Article 590-sexies to deal with the health emergency created by the COVID-19 pandemic, which is characterized by a lack of guidelines or protocols recognized by the scientific community, is deemed inappropriate.
Specifically, Article 3-*bis* provides that: *"1. During the state of epidemiological emergency caused by COVID-19, declared by resolution of the Council of Ministers on January 31, 2020, and subsequent extensions, the facts referred to in articles 589 and 590 of the criminal code, committed in the exercise of a health profession during the emergency, are punishable only in cases of gross negligence.*[30]" In this approach, criminal liability is excluded for acts performed with slight negligence or lack of skill during the emergency period, safeguarding health professionals given the limited knowledge and absence of protocols and guidelines that characterised the health emergency.

29 Cass. Pen., Sez. Un., no. 8770, 22 February 2018
30 Law no. 76, May 28, 2021, *Conversion into law, with amendments, of the decree-law April 1, 2021, no. 44, containing urgent measures for the containment of the COVID-19 epidemic, in the matter of anti-SARS-CoV-2 vaccinations, justice, and public competitions*, in *GU* General Series n. 128 of 31-05-2021.

The second paragraph of this Article seems to be of particular importance as regards the assessment of medical negligence, which states: *"To assess the degree of fault, the judge takes into account, among the factors that can exclude the seriousness, the limitation of the scientific knowledge at the time of the event on SARS-CoV-2 pathologies and appropriate therapies, as well as the scarcity of human and material resources concretely available concerning the number of cases to be treated, as well as the lower degree of experience and technical knowledge possessed by unskilled personnel employed to deal with the emergency."*

7. Reflections on medical negligence according to the criterion of adherence to medical guidelines and protocols

Perhaps now is the time to address some of the most problematic issues surrounding the guidelines, particularly their implementation as parameters to identify medical negligence. The concerns surrounding them have emerged since the introduction of the Balduzzi law, and the new Gelli-Bianco law has also brought them to attention.
The debate concerning the scientific reliability of the guidelines and their precautionary nature has been developed since the first applications of the Balduzzi law. According to a critical opinion, guidelines were developed for the economic interests of health structures and responded to simple corporate logic (Lanza, 2014, p. 778; Cfr. Caletti, 2015, pp. 170 et seq.; Caletti, 2019).
The Supreme Court's case-law on the topic has produced conflicting results. On some occasions, the Court has held that medical negligence is determined by the non-compliance or violation of the guidelines; on other occasions, the Court has declared that the same are non-binding and non-exhaustive.
The doctrine's ambiguities involved the non-punishment of the physician who followed the guidelines (Cfr. Beltrani, 2013, pp. 33 et seq.; Buccelli et al., 2016, pp. 663 et seq.). In this sense, it is worth noting that the Supreme Court's jurisprudence has emphasized that compliance with the guidelines cannot preclude *a priori* the doctor's responsibility for negligence[31] (Consorte, 2011, pp. 1227 et seq.; Cupelli, 2018; Cupelli, 2013; Giunta, 2013, p. 828). Those recommendations cannot constitute *a kind of safe conduct capable of absolving the physician of any civil or criminal liability*[32] (Campana, 2012, p. 542; Marra, 2012, pp. 557 et seq.), considering that the latter must act in science and conscience to best preserve the patient's health.
Guidelines, on the other hand, were utilized to identify medical negligence. In this sense, it's worth noting a case in which the Court of Cassation found a psychiatrist liable for failing to observe the guidelines on the medical treatment of a psychotic patient. In particular, in the case in question, the doctor had not respected the recommendations for reducing a patient's drug therapy, resulting in a severe psychotic crisis[33]. Similarly, the Court of Cassation ruled on attributing the patient's

31 Cass. Pen., Sez. IV, 1 February 2012, no. 4391.; Cass. Pen., Sez. IV, 19 September 2012, no. 35922, *cit*.; Cfr. Cass. Pen., Sez. IV, 23 November 2010 – 2 March 2011, no. 8254, *cit*.; Cass. Pen., Sez. IV, 24 January – 11 March 2013, no. 11493, *cit*.

32 Cfr. Cass. Pen., Sez. IV, ud. 2 March 2011, no. 8254, Grassini, in *Cass. pen*., 2012, p. 542, with note of T. CAMPANA.

33 Cass. Pen., Sez. IV, 14 November 2007, Pozzi, *cit*.

cardiac arrest to the physician, who had violated medical protocols[34].
As can be seen, in the jurisprudence of the Supreme Court, the guidelines are constantly recognized as a criterion for identifying medical negligence. However, this viewpoint raises some perplexities, particularly concerning the physician's freedom of treatment and planning, choice, and application of diagnostic or therapeutic devices[35] (Consorte, 2011, p. 1230; Iadecola, 2017).
In light of these considerations in doctrine and jurisprudence, has been registered another orientation, which evaluates the guidelines according to the particularity of the patient's individual case. Specifically, doctrine and jurisprudence consider that if the medical treatment is not particular to require alternative conduct to guidelines, the behaviour conforming to the latter could not be judged negligent (Di Landro, 2011, p. 15). This statement finds affirmation in the Gelli-Bianco law (Caletti, 2019), which provides a cause of non-punishment due to a lack of skill when the guidelines, or in their absence, the clinical-assistance practices, are adequate to the particularity of the specific case.
The legislator's intervention with the Gelli-Bianco law has transformed the guidelines from simple recommendations into legal prescriptions while remaining a *soft law* tool (Terrizi, 2018). In this context, the Gelli-Bianco law has imposed the obligation on the physician to observe the guidelines. For this purpose, the guidelines should be "*drawn up by public and private organisations and institutions as well as by scientific societies and technical-scientific associations of the health professions registered in a special list established and regulated by a decree of the Ministry of Health*[36]" and should *be adequate to the specificity of the particular case* (Article 5, Paragraph 1, Gelli-Bianco Law). At the same time, the law entrusts the task of monitoring the guidelines to the National Guidelines System. This provision identifies in detail the recommendations to which the doctor must adhere, removing any doubts about which to choose (due to the previous discipline), considering that the latter were numerous and contrasting (Brusco, 2017, p. 219; Cupelli, 2017), and at times they appeared to be valid only at a local or regional level (Di Landro, 2011, pp. 427 et seq.).
The objective of the law is to preserve the patient's right to health and provide more safety for physicians in defining proper behaviour in each situation. Also, the recommendations provided by the guidelines are considered crucial tools for judges during trials (Fares, 2017). On the other hand, if a physician finds himself in a situation where no codified guidelines exist, he must follow clinical-assistance practices, recognizing them as having a subsidiary role (Schiavo, 2019). According to the critical opinion of the doctrine, offering greater certainty to the physician could be turned into an obstacle to the best care for the patient (Cupelli, 2017, p. 206).

The Court of Cassation intervened in 2017, highlighting that the guidelines represent "*scientific and technological knowledge codified, metabolized, and made*

34 Cass. Pen., Sez. IV, 19 January 2006, no. 16995, *cit.*; Trib. Milano, 21 July 2000, *cit.*, p. 261.
35 Cfr. "*While the guidelines represent an important scientific aid for the physician, with whom the physician is required to deal with, they do not eliminate the autonomy of the same for the therapeutic choices*." Cass. Pen., Section IV, 19 September 2012, no. 35922, (in: www.cassazione.net.), in *Diritto & Giustizia*, 2012, p. 20, and in *Riv. it. med. leg.*, 2013, p. 268, with a note by G. Rotolo, *Guidelines and Legis artis in the Medical Field*.
36 Article 5, Gelli Bianco Law, no. 24 of 2017.

available in condensed form so that it can constitute a useful guide to easily, efficiently, and appropriately orient therapeutic decisions[37]*".* Regardless of the above, they remain general recommendations, and following them does not absolve the physician from criminal responsibility. The latter should verify whether the guidelines or clinical practices are adequate for the specific case. The Court of Cassation recently affirmed that *"compliance with the guidelines cannot be unequivocally taken as a criterion for the legitimacy and evaluation of the physician's conduct*[38]*".* Furthermore, the Court stated that following the guidelines should not interfere with the patient's right to receive appropriate medical treatment or the physician's autonomy in the patient's care. In this way, the Court reaffirms the indicative nature of the guidelines, which are different from other more rigid instruments such as protocols or checklists[39].

Based on the Supreme Court's jurisprudence, it is possible to conclude that the physician must carry out his professional activity by pursuing a single purpose: the patient's care, respecting the therapeutic and diagnostic tools available by medical science. Compliance with the guidelines cannot interfere, in any way, with the patient's right to receive the most appropriate care that characterizes the specific situation of the patient[40] (Di Landro, 2011, p. 418; Marzot, 2011, pp. 73 et seq.).

8. Final considerations

Medical guidelines and clinical assistance practices have received considerable attention after the two legislative interventions in 2012 and 2017. Unlike the Balduzzi decree, the Gelli-Bianco law has transformed the guidelines into legal prescriptions. In this regard, the fundamental issue raised by doctrine and jurisprudence is ensuring the patient's right to health care while ensuring that the guidelines do not hide medical negligence. In this context, it is worth noting that the observation of the guidelines is not mandatory for the physician, especially if the patient's specific case requires different behaviour. On the other hand, having observed the guidelines does not exclude the criminal responsibility of the physician (Brusco, 2017, p. 221).

Within this framework, it is necessary to refer to the Supreme Court's opinion, which declared that adherence to the guidelines could not affect everyone's right to health. The necessity to protect the patient's right to health[41] and the physician's freedom of treatment considering the patient's particular health needs requires a careful assessment of guidelines.

Criticism regarding guidelines concerns their generic and abstract nature, which may not correspond to the unique characteristics of each patient (Cupelli, 2017, p. 206). On the other hand, they do not exhaust scientific knowledge, taking

37 Cass. Pen., Sez. IV, 20 April 2017 no. 28187, De Luca-Tarabori.

38 Cass. pen. Sez. IV, Sent., (ud. 30-09-2021) 18-10-2021, no. 37617.

39 Cass. Pen., Sez. IV, 20 April 2017 no. 28187, De Luca-Tarabori.

40 Cass. Pen., Sez. IV, 17 January 2014, no. 17801, in *Riv. it. med. leg*., 3, 2014, with note of D. Amato.; Cass. Pen., 2 March 2011, no. 8254, *cit*., p. 1223, with note of F. Consorte.; Cass. Pen., Sez. IV, 29 September 2009, no. 38154, in *CED Cassazione*, no. 24578; Cass. Pen., Sez. IV, 7 March 2011, no. 8844.; Cass. Pen., Sez. IV, 24 June 2008, no. 37077, in *Cass. pen*., 2009, 6, p. 2381.; Cass. Pen., Sez. IV, 2 March 2011, no. 8254.

41 Cass. Pen., Sez. IV, 24 January – 11 March 2013, no. 11493, in *Guida al dir*., 17, 2013, p. 32.

into consideration medical science's scientific progress (Brusco, 2017, p. 213) and the existence of alternative therapies with the same scientific foundation (Campana, 2012, p. 550; Di Giovane, 2013, pp. 61 et seq.). These issues raise questions about whether guidelines provide the best possible treatment for patients.

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