

The Italian Supreme Court Joint Sections set forth the interpretative underpinnings of the “Gelli-Bianco” law: varying degrees of guilt aimed at limiting medical liability, article 2236 c.c. makes a comeback

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Abstract

The article’s author has sought to summarize the regulatory and legal evolution of accidental criminal liability of doctors starting from earliest positions up until the enactment of the Gelli-Bianco law. An in-depth analysis is laid out based on the Italian Supreme Court Joint Sections ruling n. 8770/2018 (so-called Mariotti decision). The author has also elaborated upon the notion of varying degrees of guilt, which was taken out of the law’s wording, to be later reintroduced as a concept by judicial interpretation. It is worth noting that Article 3 of the Balduzzi decree, article 590 sexies of the Italian Criminal Code and the reference to article 2236 of the Civil Code reflect an awareness on the part of legislators that medical liability needs to be limited. Clearly, the approach based on lawfulness alone, which protects from liability physicians that have adhered to guidelines, has been dismissed, superseded by the notion of minor fault. Nonetheless, the new legislation, in the author’s estimation, constitutes a standard particularly ill-suited to modern medical practice, which has a high degree of complexity. The author concludes that it might be worth considering a more balanced alternative: getting back to the notion of fault, considering minor fault relevant, rather than major fault. *Clin Ter 2020; 171 (2):e101-106. doi: 10.7417/CT.2020.2197*

Key words: medical liability, degrees of guilt, negligence, recklessness, major guilt, Italian Supreme Court, Gelli-Bianco Law

Introduction

The evolutionary path of medical liability for guilt has been somewhat winding and complex. Up until the 1980s, medical liability was only found in cases of major fault, i.e. guilt stemming from mistakes that arose from the inability to properly use medical equipment, or from the failure to exercise caution or the requisite medical skills that all physicians must have. By the end of 1980s, medical practice had already become highly complex from a technical standpoint; hence,

Italian jurisprudence dismissed the approach based on major fault, establishing the principle according to which courts should determine medical liability with broader leeway and a greater understanding of the peculiar nature of medicine and the substantial difficulties and peculiarities that are inherent with each individual case (1). In addition, the Italian Civil Codes specifically regulate scenarios in which doctors find themselves dealing with egregiously complex cases: when, for instance, the patient’s illness is not well-researched and understood by science (2) or even cases in which unknown diseases are involved; when several conflicting diagnostic, therapeutic or surgical methodologies are involved. In all such instances, article 2236 of the Italian Civil Codes mandates that “in cases of medical procedures entailing extraordinarily difficult technical issues, the doctors shall not be called upon to answer for any damage arising from them, unless criminal intent or major fault are proven”. Furthermore, even procedures that are widely researched and well documented in scientific literature may be considered substantially demanding to carry out, for instance procedures who require a high degree of manual skills (several gynecological maneuvers come to mind in that respect) (3-5).

Even liability on the part of psychiatrists belongs among high-complexity fields, for both judges and court technical consultants: judges have at times displayed a tendency to broaden the concept of “protection”, even to a degree to which psychiatrists are deemed to have a legal obligation to avert any adverse consequence caused to patients by psychic distress (6). Medical practice undoubtedly presents a great deal of peculiarities. It is in fact aimed at dealing with two distinct types of risks: pathological risks that jeopardize patient well-being and therapeutic risk. That being said, according to well-established jurisprudence, doctors are not to be held liable for any development arising from pathological risk, which is to be viewed as a naturally intrinsic risk, thus unavoidable, but may on the other hand be held responsible for therapeutic risks which depend upon their interventions.

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The “Balduzzi reform”: stemming the tide of defensive medicine by bringing guidelines compliance to the forefront

On November 8th 2012, Italian lawmakers enacted law n.189, which came to be known as “Balduzzi law”, in an effort to tackle the increasingly common defensive medicine phenomenon (7).

That piece of legislation has reasserted the principle of guidelines compliance, reestablishing the principle of “varying degrees of fault” and ruling out medical liability in cases of demonstrably negligible guilt. It is also noteworthy that Italian criminal statutes dictate that guilt of any degree should be punished. Article 3 in fact used to limit medical liability to cases of major guilt, provided that the physician were able to prove compliance with guidelines and good practices. The Balduzzi law has therefore given rise to an exception to the general rule, which is to be applied to doctors only, and rests upon two preconditions: 1) the guidelines were complied with, 2) the degree of guilt.

Any set of guidelines needs to be scientifically grounded; still, their proper application requires that they be adapted to the peculiarities of each single clinical case (8) (9).

Hence, when doctors act upon the indications laid out within a set of guidelines, their conduct may be punishable under article 3 of the Balduzzi reform, if it is proven that they made an egregious, major mistake. By the same token, although guidelines may set out specific indications for a given clinical scenario, the unique peculiarities of a given case could lead doctors to deviate from or even disregard those guidelines (10) (11). In cases of comorbidities, for instance, it is often necessary to take into account any risk arising from any other illness as well; it might therefore prove necessary to make different choices, possibly straying from established standards. As a consequence of that, the Balduzzi legislation ruled out medical liability in cases of minor fault stemming from inadequate compliance with specific guidelines. In other words, whenever guidelines turn out to be unsuitable for a given clinical case and yet doctors do not disregard them, they may be held accountable only when indisputable evidence is presented proving the inadequacy of those guidelines. Only in such a scenario would the doctor’s fault be deemed to be major fault.

Gelli-Bianco law: dismissal of the “varying degrees of fault” principle and the adoption of recommendations tailored to each clinical case

Law n. 24, passed on 8th March 2017, also known as Gelli-Bianco reform, has repealed article 3 of the previous Balduzzi legislation, introducing art. 590-sexies, which has codified within its 2nd subsection a provision pertaining to involuntary manslaughter (article 598 of the Italian Criminal Code) and accidental injuries (article 590 of the Italian Criminal Code)(12).

Art. 590-sexies states that in case of an adverse clinical development taking place because of negligence, physicians are not punishable provided that the recommendations laid out in the guidelines as defined and issued according to the law; in absence of such guidelines, best clinical practices

would be in force, “provided that the recommendations provided by the guidelines are found to be suitable for the clinical case and its characteristics”. Article 3 of the Balduzzi legislation stated that physicians “are not to be held liable in cases of negligible guilt” (they may therefore be liable in cases of major fault). Gelli law sets forth two quite relevant articles: articles 5 and 6. The former (denominated “Good clinical health care practices and recommendations as put forth in the guidelines”) expounds upon the very nature and role of guidelines in the medical and clinical context; in addition, it sets standards for their legal issuance (under subsection 3). Doctors are therefore bound to comply with the guidelines that have been released and validated by the Italian High Institute of Health, which is charged with verifying their consistency with scientific criteria as determined by the Institute itself, prior to the release of any set of guidelines. Article 6 (dealing with the criminal liability of health care professionals) ushers in article 590-sexies (liability for accidental death or bodily injuries) and asserts: «in case of events having occurred because of medical negligence, doctors are not punishable if they have provably complied with relevant recommendations set forth in guidelines or, in absence of those, good clinical practices, on condition that said recommendations as enunciated in available guidelines have proved appropriate for the clinical case and its distinctive traits». Subsection 2 has repealed article 3 subsection 1, from legislative decree 158/2012. Any reference to “major fault” (i.e. not negligible) has been taken out, which means that doctors are not indictable only if they can prove compliance with guidelines, which in turn must be well-suited to any given clinical case (8). The new piece of legislation thus breaks the continuity, which was instituted by the Balduzzi reform, between major guilt and compliance with guidelines (2). As a matter of fact, in cases of compliance with the guidelines on the part of doctors, medical malpractice charges could have been brought only in cases of major fault (13). Moreover, the Gelli-Bianco legislation has specifically codified that limitation only in cases of negligence. Hence, lawmakers have chosen to bind health care operators to comply with the guidelines specifically applicable to any given case (13), or in absence of them, adherence to best clinical practices, which is also recommended by article 14 of the Italian Code of Medical Ethics, dating back to May 2014 (14). As for hospital acquired infections, any mistake may be viewed as arising from negligence, in addition to malpractice, which has given rise to litigation on a massive scale (15) (16).

In that regard, jurisprudence has established that guidelines are at times tantamount to immaterial recommendations that point to the most suitable therapeutic options, but without accounting for the peculiarities and specifics of each clinical case. Guidelines, even when devised and issued by official government bodies, are still to be deemed orientative rather than binding. Furthermore, in the medical realm, where guidelines are indeed relevant, it is essential to customize diagnostic interventions and therapies. As for psychiatric patients, for instance, adapting and honing any treatment is of utmost importance. Limiting our analysis to pharmacological interventions, for example, the choice whether to administer anti-depressants to a bipolar or psychotic patient, with what drugs and whether to start long-

term treatments with lithium requires a thorough assessment of each individual patient’s clinical traits, the illnesses involved and their course, the ability to consistently carry forward the treatment, the degree of psycho-social support available, etc... (17)

Doctors who abide by the guidelines might be held criminally liable (as it would be the case if a doctor administered a medication recommended by the guidelines to a patient with an allergy to that same drug). Therefore, operators may be indicted despite their compliance with guidelines, whereas others may not even though they did not abide by them. Article 590-sexies of Italian Criminal Code has laid out three different scenarios in which doctors could be beyond reproach: 1) the adverse event has occurred because of unorthodox conduct (i.e. not caused by negligence or recklessness), 2) there has been full compliance with legally-sanctioned guidelines (or in absence of them, with good clinical practices), 3) such guidelines have been deemed well-suited to the characteristics of a given case. For instance, screening during pregnancy must be carried out according to Società Italiana di Ecografia Ostetrica e Ginecologica (Italian Society of Obstetrical and Gynecological Ultrasound Screening, SIEOG), so as to reduce the likelihood of diagnostic errors (9).

Nonetheless, jurisprudence consistently shows the hazy nature of article 590. The only unequivocal provision is the one regarding doctors who completely fail to abide by guidelines: in such instances, they can be charged even in cases of minor fault (unlike the Previous Balduzzi law indications, in fact, the failure to apply relevant guidelines is not punishable only in cases of major fault). If, on the other hand, suitable guidelines are available, and doctors have successfully identified them, but make mistakes in their implementation, an interpretative doubt may surface: in such cases, could it be argued that the guidelines have in fact been complied with (hence the application of art. 590-sexies) or should they be considered as non-compliance, in light of their inaccurate implementation? Either way, far-reaching consequences are bound to ensue: to view partially or inaccurately implemented guidelines as meeting the legal provisions would in fact mean the application of a broad-ranging standard. On the other hand, deciding that non-compliance has occurred in such cases would constitute an overly restrictive interpretation. The following contradiction therefore appears to loom: what room would there be to argue in favor of the malpractice charge if the only case in which art. 590-sexies would be applicable were the one with the complete and consistent application of guidelines?

Two different panels within the fourth section of the Italian Supreme Court, which covers accidental misdemeanors, have offered two almost opposed interpretations shortly after the enactment of the law. For that reason, the chairman of the fourth section had appealed to the Court’s joint sections for the following query: as for health care operators malpractice liability for accidental death or injuries, what is the scope of non-indictability under art. 590-sexies of the Criminal Code, as introduced by article 6 of law n. 24, passed on 8th March 2017?.

Two interpretative yardsticks by the Italian Supreme Court, fourth section

The Court’s joint sections have looked into two court decisions from which the interpretative conflict had arisen. For the sake of clarity, we shall briefly summarize their contents, although they are both currently outdated by the interpretative criteria spelled out by the joint sections, which are binding for all the Supreme Court’s sections.

Italian Supreme Court ruling n. 28187, De Luca-Tarabori, 20th April 2017

Through that decision, the Supreme Court has for the first time weighed in on the applicability of the Gelli-Bianco reform. The Justices have pointed out the transparency of the norm itself, since it is inconceivable for doctors to be held liable if they did provably comply with recommendations spelled out in suitable guidelines, adapting and honing them according to the specifics of a given case (9). Supreme Court ruling 28187/2017 has in fact outlined how Balduzzi law provisions are more favorable to defendants than Gelli law, which is bound to impact all ongoing trials. To buttress that assertion, it should be noted that a standard has been set according to which there is no longer any distinction between “minor” fault and “major” fault in terms of criminal liability, and the evaluation criteria for any manifestation of malpractice-related liability has been articulated within a broad-ranging rationalization of guidelines; under the previous Balduzzi law provisions, any criminal liability was ruled out in cases characterized by minor fault in situations regulated by guidelines and officially validated good practices.

The Gelli reform has essentially ushered in the principle according to which non-indictability is only applicable if the doctor has demonstrably complied with guidelines customized to any given case in an effective fashion, whereas it will not be applicable if the compliance with guidelines is found to have been “abstract”.

As it is quite obvious, doctors are guiltless in similar instances. Hence, the Justices have mapped out “their own” interpretation: medical conduct and decisions shall be adjudicated based on officially validated and case-specific guidelines (the adequacy and soundness of all medical decisions must be verified by a court of law). Within such boundaries, doctors will therefore have their conduct “judged in accordance with the same guidelines that have guided their medical actions” (9, 10). Lastly, the ruling has deemed it desirable that the rule laid out in article 2236 of the Italian Criminal Code (which identifies extraordinary difficulties and egregious fault) may be applied in criminal proceedings as well (18-20).

The courts ought to abide by that rule when assessing malpractice charges.

Furthermore, it is possible that a complication should be treated by well-established and non-controversial procedures and despite that, the rare nature of such a complication or the extremely low success rate could lead to the conclusion that the case is of “extraordinary difficulty”.

The Cavazza court ruling

In ruling n. 50078, issued on 19th October and known as Cavazza ruling, the Italian Supreme Court has asserted that the lawmakers ruled out punishability only for cases where malpractice occurred (that exemption comprises both minor and major fault instances). Such a scenario would occur in cases of doctors who identified suitable guidelines but then failed to properly implement them (21). According to the Gelli legislation, any conduct from doctors is not punishable, even in cases of major fault, if they manage to prove the improper or unorthodox application of guidelines that were however correctly identified and chosen (11). In that ruling, the Supreme Court Justices have pointed to the non-indictability, under article 590-sexies, during the process of implementing a set of guidelines or good clinical practices. In the case that the Supreme Court has ruled upon, the court had asserted that the doctor was punishable, since there had been malpractice-related major fault during the execution, but not in the choice, of a cosmetic surgical procedure aimed at treating ptosis, after which the patient had suffered loss of sensitivity in the forehead, still unsolved five years after surgery. In the ruling, the Justices have deemed article 590-sexies to be more favorable compared to article 3 of the Balduzzi legislation, which limited non-liability to minor fault cases. As argued by the Justices, the only criminally punishable scenario would be in cases where doctors put in place guidelines that ultimately proved unsuitable for the clinical case. Conversely, doctors are not punishable if they applied suitable guidelines in an inadequate fashion. Such an inadequate conduct, however, should not have occurred while choosing the guidelines (in such a case, the guidelines would in fact be unfit), but at the stage of implementation. Overall, it can be safely assumed that the Supreme Court has drawn a fundamental distinction between a mistaken assessment leading to inadequate guidelines being chosen, which always leads to liability by virtue of the fact that the guidelines must be suitable for each peculiar clinical case, and implementation mistakes, which are not punishable under any circumstance.

By ruling n.50078/2017, on the other hand, Justices from the Supreme Court's fourth section have found the new Gelli legislation to be more favorable to doctors than its predecessor, the Balduzzi law. Based on such an interpretation, it is necessary to gain awareness of the fact that the recent reform has overcome the complexities stemming from the principle of varying degrees of guilt, somehow loosening the standards for the determination of medical liability by introducing new grounds for unindictability, which is limited to instances of incompetence (regardless of the degree of guilt) and is only applicable to health care operators who have provably complied with recommendations within appropriate guidelines or clinical good practices, provided that they have been found to be suitable for the case.

The United Sections weigh in

The United Sections of the Italian Supreme Court's ruling, dated 21st December 2017-22nd February 2018, known as Mariotti decision, has sought to outline an area of non-

indictability meant to restore a degree of trust and confidence among doctors, to stem the growth of defensive medicine and to better uphold the people's right to enjoy good health (§ 8) (22). Such a decision therefore positions itself somewhere in between the two opposite rulings by the fourth section, one of which appears to be overly restrictive (nearly eliminating the notion of non-indictability altogether) whereas the other may be too broad-ranging (in outlining the scope of the doctor's non-indictability).

The Supreme Court's joint sections have enunciated in detail the conflict and after poring over both rulings, spelled out the following legal principle: "Health care operators are called upon to answer for deaths or injuries stemming from medical and surgical practices if:

- a) the unfavorable outcome has occurred because of medical fault (even minor fault) resulting from negligence or recklessness;
- b) the unfavorable event has taken place due to medical fault (including minor fault) stemming from incompetence when the specific case is not regulated by guidelines or clinical good practices;
- c) the unfavorable event has occurred due to medical fault (including minor fault) stemming from incompetence in identifying guidelines or clinical good practices, which proved inadequate for the individual case;
- d) the adverse development has been caused by major fault related to incompetence in implementing guidelines or clinical good practices, taking into account the magnitude of the risk and the medical difficulties involved.

Unwinding that rationale, it is safe to assume that physicians are not punishable if the following conditions are met: 1) the setting in which doctors operate is regulated by guidelines or clinical good practices; 2) doctors have managed to identify appropriate recommendations that must be well-suited to any given case, and over the course of the disease, they have successfully tailored those indications to the different clinical stages; 3) doctors have made a mistake through "minor" fault, stemming from the inadequate application of such recommendations.

The notion of varying degrees of guilt is reestablished

The Supreme Court has ruled out the applicability of article 590, subsection 2, in instances of medical negligence or recklessness (which are regulated by articles 43, 589 and 590 of the Italian Criminal Code), while it has reintroduced the notion of varying degrees of guilt. The Justices have argued that the medical profession is generally characterized by a high level of difficulty, which is somehow necessary to gauge when judging medical conduct. With the introduction in the Balduzzi reform of the concept of "minor fault", Italian legislators have made it clear that the placement of responsibility may depend upon the scope or proportion of guilt. Along those same lines, the Supreme Court has reestablished the principle of various possible degrees of guilt, while ascribing a certain relevance to "minor guilt". Hence, doctors shall answer for a patient's death or injuries stemming from medical and surgical interventions carried out with incompetence, whether minor or egregious, whenever such mistakes are related to interventions made in disregard

of accredited guidelines or clinical good practices. Moreover, doctors may be held accountable when they mistakenly choose guidelines or good practices which turn out to be unfit for a given specific case. Doctors could also be deemed liable for incompetence, provided that their mistakes were made while acting upon relevant recommendations, after having correctly identified a set of guidelines or good practices (23). Therefore, three distinct conditions requirements ought to be met, in addition to a judgement rule. The conditions may break down as follows: 1) the doctor has found him/herself facing a technically challenging situation; 2) the doctor has had to handle a clinical case in accordance with recommendations; 3) an implementation error has occurred. If even just one of the above conditions goes unmet, non-indictability does not apply: if an adverse outcome has resulted from negligence or incompetence, or a peculiar case not regulated by guidelines or good practices has come into being, or an assessment error has been made particularly related to the identification of guidelines that proved inadequate for the case. According to the judgement rule, the unfavorable event must have taken place on account of major guilt. The degree of guilt standard is thus brought back by the Court, albeit limited to the implementation stages only. The stages of selection and choice of appropriate guidelines and their proper application to each case are to be scrutinized according to conventional judgement standards (i.e. liability for incompetence, negligence and recklessness, either minor or major). In cases of negligence and recklessness at the implementation stage, doctors will be answerable for minor fault. With such norms in place, a set of criteria has been established for the purpose of measuring and determining the degree of guilt, which the Supreme Court joint section have deemed to be applicable. Major fault, for instance, is acknowledged whenever: 1) a medical approach has significantly strayed from the standards and need to adapt to each case’s peculiarities, 2) when unequivocal indications existed advising for a departure from accredited guidelines, yet the doctor failed to do so. Furthermore, various parameters, of subjective and objective nature, need to be met, such as: the agent’s conditions and his/her level of specialization; the rare and obscure nature of the clinical condition; the objective difficulties in gathering and associating various pieces of information; the sense of urgency with which the doctor has had to intervene, etc...

Hence, an evaluation of the magnitude of guilt (generically intended) should be made “in concrete terms”, making account of the above mentioned conditions.

That way, the judicial discretionary power would be significantly reduced, since the fundamental criteria would be stabilized thanks to the public procedure for the drafting of relevant guidelines.

To summarize it, we can conclude that the Supreme Court joint sections decision:

- a) Confirms that medical liability cannot be ruled out in case of accidental damages brought about by negligence or recklessness;
- b) In cases of medical incompetence, it reintroduces the varying degrees of guilt, according to different cases and responsibilities, therefore:
 - b1) doctors shall be answerable for incompetence, whether major or minor, whenever guidelines or clinical

good practices have been mistakenly identified (i.e. unfit for the specific case). The Justices have highlighted the obligation on the part of doctors to disregard them should the peculiarities of a given case require that;

b2) doctors shall be held liable for egregious or minor incompetence leading to implementation errors, whenever the case is not regulated by guidelines or good practices;

b3) Doctors shall be answerable only for egregious cases of incompetence in cases where the implementation errors have been made along with the accurate choice and adherence to guidelines or good practices, fit for the clinical case, taking into account “the degree of risk to be managed and the intrinsic technical difficulties in medical practices”.

Closing remarks: a proposal

Article 3 of the Balduzzi decree, article 590 sexies of the Italian Criminal Code and the reference to article 2236 of the Civil Code show an attempt on the part of legislators to limit medical liability.

A different regulatory approach is in our view warranted only with reference to medical fault arising from incompetence. Incompetence should in fact be related to such a complex scenario that it would justify medical errors. Instead, we feel somewhat taken aback by the distinction between assessment error and implementation error, since such a distinction is apparently based on technical complexities. The real way to go might be the one opened by the Tarabori decision, which ascribes to the judge the power to assess the mandatory nature of any medical act, with no distinction between implementation and selection errors and no indication as to the parameters to be applied. In addition, extraordinary circumstances might play a role in the therapeutic selection process: operators might for instance have objections, on grounds of conscience, to certain forms of interventions (abortion or emergency contraception come to mind). In such cases, such a refusal to execute a given treatment is only acceptable if a duty to refer is put in place at the same time, and anyway, never under emergency conditions (24, 25). In our view, the uncompromising approach based on lawfulness, which takes the responsibility away from physicians that have adhered to guidelines, can be considered behind us, especially since it has been rectified by the notion of minor fault. The path towards major fault, on the other hand, is also unsatisfactory, in that it constitutes a standard particularly ill-suited to modern medical practice, which is characterized by a high degree of complexity. A possible alternative option could be to get back to the notion of fault, considering minor fault relevant, rather than major fault (26).

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