

The legislative reform of medical liability in Italy and the decriminalization of slight negligence: controversial issues

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Summary

Background: in recent years, the Italian Supreme Court has stated principles leading to: a) an increase in damages awarded to patients and premiums demanded by insurance, resulting in increased health care costs, b) the birth and growth of the so-called defensive medicine with major economic repercussions.

The Italian legislator tried to remedy the spread of defensive medicine by enacting Law n. 189/2012.

Objectives: the authors illustrate the actual innovations introduced by the law in the medical liability system developed by the Italian Supreme Court in the last fifteen years.

The authors analyze the question of the suitability of the reform: a) to eliminate the practice of defensive medicine; b) to reduce expenditure for compensations; c) to increase the serenity of physicians in their medical practice.

Methods: the authors analyze the effects of the new rules and compare them with the principles laid down by the Supreme Court on negligence, contractual liability and personal injury.

Results/Discussion and Conclusions: law n. 189/2012 confirms that the guidelines are not binding. Indeed, the doctor who complies with the guideline can in any case be declared liable when the circumstances of the case make it not applicable.

However, the legislative reform states that if the physician meets with guidelines which were not to be applied, the penal responsibility can be established only when his/her conduct constitutes a gross negligence of the doctor. Hence, the legislator has decriminalized negligence.

This new rule raises first of all unconstitutionality issues.

Furthermore, the application of a guideline also aimed at reducing health care spending could be considered as a gross negligence because the Italian Supreme Court has stated that the predominance of the patient's health over economic interests of medical facilities is a basic rule. Hence, the doctor would in any case be convicted.

With regard to civil liability, the legislative reform states that in case of slight negligence, the duty laid down in article 2043 of the Civil Code applies.

Although article 2043 of the Civil Code relates only to the pecuniary loss and non-contractual liability, the reform does not appear to change either the contractual nature of the medical liability or the obligation to compensate also the biological and the pain-and-suffering damages.

Indeed, law no. 189/2012 refers only to the obligation under article 2043 of the Civil Code, i.e. the obligation to compensate *contra ius* damages. As a result, article 2043 does not refer to the nature of liability, whether contractual or non-contractual.

In addition, the concept of *contra ius* damage may also include the biological damage as well as the pain-and-suffering damage. Otherwise, the legislative reform would be unconstitutional.

Concerning the quantification of damages, the reform states that the court must take into account the fact that the physician has complied with the guidelines.

But this rule determines unequal treatment of patients because the same damage caused with the same degree of negligence would be compensated with different amounts depending on whether or not the doctor has followed the guidelines.

Therefore, the suitability of the reform in reducing health care costs for compensation and for defensive medicine is very questionable.

KEY WORDS: legislative reform, decriminalization of ordinary negligence, guidelines, penal liability, civil liability, compensation of damages.

Background

The medical liability case law has evolved from a direc-

tion tending to evaluate with understanding and benevolence the performance of the physicians towards the current system characterized by: a) the relevance of serious negligence only in exceptional cases and only in the civil field; b) reversal of the burden of proof in the civil field; c) the tendency to establish guilt on the basis of an objective breach of a duty of care, prudence or skill (standard of care) regardless of an essential and thorough exam of the possibility for the individual physician to actually follow the best course of action in the specific case.

This evolution has led to: a) an increase in damages awarded to patients and insurance premiums, resulting in increased health care spending; b) the birth and growth of the so-called defensive medicine with a significant economic impact. The most significant Italian data on the development of defensive medicine are unfortunately documented only through sectoral reports and not on a large nationwide scale.

Among the most important we can remember: 1) the annual report of the Court of patients' rights (1999); 2) the surveys by Ania (The Italian National Association of Insurance Agencies) presented in the annual report titled "The insurance in Italy"; 3) a meticulous survey conducted by the Medical Association of Rome in 2008. The legislature has attempted to remedy the spread of the so-called defensive medicine through Decree Law Balduzzi, that, specifically regarding medical liability, was radically upgraded when converted into law in order to: a) reduce the impact on physicians for the continuous risk, sometimes also the threat, of legal action, b) reduce the high level of health care spending due to the practice of defensive medicine and to the cost of compensatory damages awarded to patients by the courts.

Objectives

One of the main and first goals of the present paper is to illustrate the actual innovations brought about by the legislator in relation to the medical liability system developed through case law over the past fifteen years. Consequently, the question arises as to whether the new rules achieve the goals that the legislator had set forth, namely: a) solving the problem of defensive medicine; b) reducing the amount of expenditure on compensatory damages; c) increasing the serenity of doctors in their professional practice.

Materials and methods

The first step is to interpret the law in question according to the literal meaning of the words that compose it and consistent with other rules. To this end, no one can ignore the parliamentary debate that led to the approval of such statutory provisions.

Subsequently, the resulting regulatory framework must be compared with the principles laid down by the Supreme Court in regard to negligence, medical liability *ex contractu* and personal injury.

Results

Article n. 3 of Decree Law Balduzzi n. 158/2012 stated that "subject to the provisions of Article 2236 of the Civil Code, the judge, pursuant to Article n. 1176 of the Civil Code, when assessing medical malpractice liability resulting from slight negligence, takes into particular account, in this case, the compliance with the guidelines and best practices accredited by the national and international scientific community".

This provision did not bring about any significant innovation of the matter and, indeed, has been authoritatively considered "useless" (1).

As a matter of fact, the possibility to simply take into account the compliance with the guidelines has left virtually unchanged the judge's discretion which, particularly over the last fifteen years, has led to a significant increase in the chance for patients to get compensation from doctors, hospitals and insurance.

Therefore, Law n. 189 of 8th November 2012, finally converting the Decree Balduzzi into law, radically altered art. 3, leading to the current wording which reads: "The health professional who, in his/her medical practice, adheres to guidelines and best practices accredited by the scientific community cannot be held criminally liable for slight negligence. In such cases however he/she remains subject to the obligation set out by art. 2043 of the Civil Code. The judge, even when determining damages, shall take due account of the conduct referred to above".

Four specific contents emerge from this provision: a) the significance of the guidelines as a mere guidance role, in that it is implicitly but clearly stated that the decision to adhere to them may constitute presumption of guilt; b) in the cases in which the physician follows the guidelines, criminal liability is limited to gross negligence, while it is excluded for slight negligence; c) even in the absence of criminal liability, the physician is required to provide compensation for unjust damage suffered by the appellant *ex art. 2043 c.c.* (extra-contractual liability); d) compliance to the guidelines (error caused by slight negligence) must be taken into account by the judge when quantifying the damages hence reducing the amount paid to the patient.

Only the first of these statements responds to consolidated teaching positions, while the others are very controversial and their actual innovative power can be easily thwarted.

We may, albeit briefly, analyze them.

Regarding the relevance of the guidelines, it is not contradictory to assume guilt despite compliance with the guidelines (2, 3).

In fact, even when drawn up by public authorities such as the Ministry of Health or a Region, the guidelines still retain an illustrative and never all-encompassing meaning because, in the medical field covered by the guidelines, the need to customize diagnostic choices and treatments is an essential "strictly scientific" principle (4).

Moreover, such guidance role is only temporary in that the progress of medicine implies the need to constantly update them (5).

Even the Supreme Court has agreed with this approach by stating that adherence to guidelines cannot exclude the physician's criminal liability, where the patient's clinical picture is such as to require a different approach from that recommended by the guidelines (6).

Even if the legislator did not state it explicitly, the guidance role of the guidelines should likewise be read, for the sake of consistency, in the sense that non compliance with them does not imply in itself a professional misconduct.

Therefore, in this respect, the legislator appears to have acted properly and in accordance with the peculiarities of medicine.

As for the limitation of criminal liability in case of gross negligence, the reform excludes criminal liability where the physician, with a slightly negligent conduct, applies guidelines which, instead, in the light of the specific clinical case, it would have been better not to follow.

Therefore, as pointed out by the early commentators of the reform, the legal principle above mentioned requires only one, but decisive, integration: "The guidelines cannot be intended as a means to exclude the criminal liability placed upon the physician, whenever the patient presents a clinical picture *macroscopically* requiring a different approach from the one recommended by the guidelines" (7). More specifically, the need to deviate from the guidelines must be "*immediately recognizable* by any health practitioner instead of the respondent" (8).

This provision raises at least three problems: a) the exclusion of criminal liability for personal injuries or manslaughter resulting from slight negligence weakens considerably the safeguard, even as a preventive measure, of the right to health whose constitutional status should instead guarantee its utmost protection; b) the degree of misconduct is conceived by art. 133 of the Italian Penal Code as a criterion to quantify the sentence and in no case as an assumption of responsibility; c) the possibility of a limitation of liability for negligence leads the physicians to always follow the guidelines, hence affecting their professional autonomy, which is also a constitutionally relevant principle (9, 10).

Unfortunately, these aspects failed to be given proper consideration in the preparatory documents.

Furthermore, even apart from these considerations and even if the first judgment implementing the reform refers to "the decriminalization of slight negligence" (11) just as the rapporteur of the law at the Commission did (12), there appears to be an intrinsic problem inherent to art. 3 of the Decree Law Balduzzi.

Indeed, the reform refers to the guidelines accepted by the scientific community, but it fails to provide an explicit definition. In this regard, no starting point for a deductive reconstruction can be derived from preparatory documents.

The case law prior to law n. 189 of 8th November 2012 had instead suggested the existence of guidelines functional to the protection of the patients' health along with other guidelines which, instead, appear to respond to economic-based logics incompatible with the patients' best interests. Accordingly, the economic-based

guidelines cannot be followed because the right to health of the patient must prevail (6).

Moreover, even after the approval of the reform, explicit references have been made as to the continued correctness of this approach (13).

Therefore, it seems likely that the compliance with a rule of conduct which, albeit embedded in the guidelines, is inspired not only to the patient's interest, but also undoubtedly to a cost-reduction approach, is considered by the Court as gross negligence by arguing that the prevalence of the right to health of the patient over "economic-based logics" should be a basic rule for any physician. Consequently, its violation could be considered as gross negligence.

This conclusion, however, leads to two problems: a) it distorts the concept of guideline, in that there exist no purely economic-based guidelines as opposed to other ones exclusively aimed at the patient's health: each guideline is designed to indicate a correct and proportionate use of the limited resources available in view of ensuring the patient protection (14); b) it may cause a substantial non-application of the reform, which is instead consistent with the approach sanctioned by the Constitutional Court that the right to health must be safeguarded in accordance with available resources (15).

As for the obligation to pay compensation ex Art. 2043 c.c., the question arises as to whether the legislator encompassed all medical liability issues within the ambit of non-contractual liability.

An affirmative reply to this question cannot be limited to pointing out that the relevant case law has long been oriented in the sense of non-contractual nature of medical liability (16).

As a matter of fact, this jurisprudential interpretation was only referred to the medical staff of a health facility who, as such, do not have the possibility to choose when and who to treat, whereas, in private medical services, liability needs to be contractual, assuming the classic and typical exchange of proposal and acceptance.

Furthermore, as it is commonly known, the Supreme Court has long been consolidating its orientation towards the contractual responsibility of the physician under any circumstances (17, 18).

In the preparatory documents, this aspect was not considered at all. So, it is not correct to assert that the legislator intended to invoke non-contractual liability in relation to all medical liability issues.

Even the literal wording of the law does not compel such a conclusion. In fact, art. 3 merely states that in the event of slight negligence, "the obligation of art. 2043 of the Civil Code" remains inviolable, i.e. the obligation to compensate for damage.

Therefore, this article may well be understood as referring only to the right to compensation and not to the nature of liability.

Consequently, the reform does not seem to be in contrast with the case law in favor of the contractual nature of the medical liability.

Even under another and autonomous aspect, the legal provision in question appears unclear.

In fact, as it is commonly known, the relevant case law has clarified that Art. 2043 of the Civil Code covers only the pecuniary damage, whilst the non-pecuniary damage is covered by Art. 2059 of the Civil Code (19). Consequently, since Art. 3 refers only to Art. 2043 of the Civil Code, without any mention of Art. 2059 c.c., a legitimate doubt arises as to the recoverability of non-pecuniary damage, including, in the name of the aforesaid and settled case law, the moral and biological damage (20). Therefore, the fulfillment of such an interpretation would make it impossible to compensate patients for the biological and moral damage suffered, at least in the cases deviating from the guidelines covering slight negligence.

But this interpretation would end by making the article in question patently unconstitutional on the basis of infringement of both the right to health and to moral integrity – whose constitutional relevance is sanctioned under Art. 32 and 2 of the Constitution (21) – and of the principle of equality in the light of the completely different compensation awarded to objectively equivalent damages simply on the grounds that slight negligence might be invoked in one case as opposed to gross negligence in another case.

Therefore, even considering that the legislator is not bound to comply with the jurisprudential guidelines, it is possible and necessary to interpret Art. 3 in the sense of including within the scope of unjust damage, recoverable ex Art. 2043 c.c., each and every infringement of rights – hence including the right to health – thus resulting in compensation of both the biological and the moral damage (22).

In conclusion, even in this respect, the reform appears to be less innovative than it would seem at a first reading. Finally, as concerns the rule whereby the judge, for the purpose of determining the actual amount of damages, is expected to take into proper account the compliance with the guidelines (resulting from slight negligence), the problem arises as to the relationship with the traditional approach that only compensation for moral damages may vary, *inter alia*, depending on the conduct of the offender whereas, as concerns other types of damage, compensation must be proportionate to the objective seriousness of the damage suffered, regardless of the underlying intentional or negligent conduct.

The reform does not seem to be able to change the established structure of civil liability in Italy.

Indeed, even the mere reduction of the compensation on the grounds of compliance to guidelines would result in an unconstitutional unequal treatment as compared to patients suffering the same biological (or pecuniary) damage due to medical practice not conforming to guidelines.

This problem is not easy to overcome by arguing that the rule covers only non-pecuniary damages.

In fact, while it is true that non-pecuniary damages, typically associated with pain and suffering, need to be compensated to a greater or lesser extent depending on, *inter alia*, the seriousness of the conduct, there still appears to be an unequal treatment.

As a matter of fact, the physicians who cause a damage by abiding to guidelines with error due to slight

negligence shall be entitled to a reduction of non-pecuniary damages by virtue of such conduct. On the contrary, both physicians who do not adhere to the guidelines and those who provide their services in clinical cases devoid of any guidelines will have to fully repay the moral damages in spite of a condition of slight negligence in all the three cases.

In conclusion, the provision in question appears to involve unconstitutional elements which are difficult to overcome.

Conclusions

Based on these findings, it can therefore be concluded that the reform will hardly be able to achieve its goals. Indeed, even if the above described aspects of unconstitutionality were not followed, the desired decriminalization of slight negligence could be avoided by extending the concept of gross negligence or otherwise by declaring that the compliance to guidelines with an economic-based content constitutes gross negligence since medical practice must be founded on the obligation to provide a case-by-case optimal treatment.

However, in the field of criminal law, most of the proceedings have long been ending with their filing, which has neither decreased the health care spending for defensive medicine practices nor has it increased the physicians' serenity in their medical practice.

Even as concerns the liability obligation, the reform does not appear to be able to reduce compensable items.

The only real savings that can be achieved through the reform consist in the reduction of the compensations due by virtue of the choice to extend to medical liability the ministerial tables concerning road accidents.

But since these tables cover only micro permanent disabilities, whereas in medical liability permanent disabilities often exceed 9%, the actual cost savings for the compensations awarded is relatively insignificant.

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