Medico-legal aspects of tort law patient safeguards within the Gelli-Bianco piece of legislation

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Abstract

The authors aim to put into context the recently passed piece of Italian legislation known as “Gelli-Bianco”, in an effort to highlight the root causes and the underlying motives that led to its enactment.

The new law’s innovative aspects are elaborated on, in terms of treatment safety and civil liability of healthcare professional and providers. The report’s main purpose is to shed light on the alleged benefits, against the backdrop of the worrisome data from recent years, gathered from case-based analysis of adverse events and related costs, without overlooking the likely challenges associated with innovations that are meant to affect complex systems with conflicting interests at play.

Key words: defensive medicine, medical treatment safety, out-of-court settlements

Introduction

Law 8/3/2017 n. 24, widely known as Gelli-Bianco law (1), has been geared to improve treatment safety levels by means of thorough risk management based on the collection and analysis of health care data. Treatment safety will naturally have to be weighed against financial factors such as the rationalization and curbing of public spending in order to give rise to an organic system conceived to safeguard and strike a balance between patients’ as well as doctors’ needs.

In modern societies, therapeutic relationships are no longer inspired by paternalistic principles. Ever since the age of Hippocrates, the doctor-patient relationship has been asymmetrical rather than one between peers: doctors autonomously make decisions because they act in their patients’ best interest. The legitimacy of the doctors’ deeds and the good faith supporting their behaviors were taken for granted, or at least alleged. That approach led entire generations to fully respect and blindly trust them (2).

Nowadays, however, the whole scenario appears to have been totally upset: the asymmetrical nature of the doctor-patient relationship is still there, but ever growing attention to the patient’s status as a human being and to his or her will is paid, with a consolidation of the principles of autonomy and self-determination (3). Furthermore, new and far-reaching prospects have turned out in the realm of medical research: stem-cell research has made tissue regeneration possible; medically-assisted procreation (4,5), along with the development of bio-technologies has enabled researchers to check on embryos, via preimplantation genetic diagnosis, prior to their implantation in uterus; contraception is instrumental in keeping pregnancies under control (6); a great deal of previously incurable diseases can now be cured.

Such a background may entail greater risks for health care operators because of wider margins of error and legal claims from patients.

Moreover, nowadays the health care system has to grapple with management and funding issues, and such constraints have undermined the direct, exclusive doctor-patient relationship, creating mutual distrust (10).

Lastly, the role played by the media should not be discounted, which portray medicine in a twisted fashion, catering to the special interests of the health care and pharmaceutical industries. In fact, by overemphasizing medical success stories, the media build up excessive, wrong expectations among people, thus creating the misconception that personal failure is the direct consequence and confirmation of medical incompetence. In a similar way, dissatisfying or sub-par outcomes are blown out of proportion, thus discrediting the medical profession and fueling among the public opinion a sentiment of distrust and diffidence.
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Patients have often come to perceive adverse medical outcomes as rooted in injustice, thus the need to look for culprits, even when confronted with unforeseeable or natural events, which used to be fatalistically accepted.

In addition to that, the prospect of gaining compensation for any unsatisfying outcome and exact punishment for alleged mistakes by health care facilities or doctors leads to the tendency to magnify and overdramatize a given issue, for the precise purpose of profiting from it.

Only a conjunction of technical expertise, professionalism and a humane approach can make sure that doctors elicit an overall positive feedback of their work from their patients.

Defensive medicine

Defensive medicine is a direct outgrowth of the above mentioned scenario and constitutes a pathological form of medical practice (11). Health care providers fear the prospect of legal claims being brought against them and request an award of compensatory damages. Such fears inevitably influence professionals in the exercise of their functions, giving rise to harmful defensive practices that may come under different forms: “positive” (Assurance Behavior) or “negative” (Avoidance Behavior). The former is defined by excessive initiatives, such as the prescription of redundant tests in addition to those strictly necessary, referral of patients to other specialists without a real need and the application of redundant invasive diagnostic practices, aimed at amassing documentation to be used in court to prove one’s innocence in case of litigation. Negative defensive medicine, on the other hand, is rooted in acts of omission: doctors may rule out risky treatments or therapies or avoid dealing with overly problematic cases. Defensive medicine is therefore conceived as a means to shield doctors from possible litigation, but it clashes with the very founding principles of the medical profession and runs counter to the need and obligation of health professionals to exert their discretionary powers, autonomy, caution and professional concerns, as enshrined in the Italian Code of Medical Ethics. In fact, article 30 (dealing with conflict of interest) dictates that “doctors must avoid any circumstance in which a professional judgement regarding the best interest of patients, or people’s health, may come under the undue influence of a secondary interest. A conflict of interest may or may not have to do with economic aspects, and may manifest itself in scientific research, professional training and updating, therapeutic prescription of diagnostic tests and individual or collective relationships with industries, bodies, organizations and institutions, in addition to government agencies. Doctors ought to be aware of possible conflicts of interest and assess the significance and possible risks, staying off any situation that can be avoided” (12-15).

Defensive medicine and its effects are not necessarily harmful to the patient’s health; only invasive diagnostic tests, when unnecessary, might entail risks. They are, however, burdensome for public finances, given that those resources could be better used and undermine the trust-based doctor-patient relationship. In other words, defensive medicine is potentially detrimental both in terms of health care quality and of its effectiveness (11). Such a form of aberration causes higher health care costs and considerably lengthens waiting lists for medical procedures (14). According to a 2016 report from ISTAT, health care costs totaled 149.5 billion Euros, accounting for 8.9 of Italy’s gross domestic product, and 75% of such expenditures were sustained by the public system, with the remainder covered by the private sector (16). All of those aspects play a role in negatively influencing the public opinion, fueling a vicious cycle.

Against that backdrop, the need for new norms regulating medical liability in health care appeared ever more pressing. In fact, new legislation n. 24, 8th March 2017 has been enacted in order to minimize this phenomenon while at the same time putting in place a more effective compensatory system for aggrieved patients.

Treatment safety

By enacting the new legislation, lawmakers have aimed to stress that “the safety of medical treatments and patients” is a pivotal point on which the law is centered, as well as the ultimate goal toward which all efforts for improvement and innovation must be directed (17).

It is no coincidence that the principle of safety of medical treatments is found in the body of the law as it is in its beginning:

Art. 1: “the safety of medical treatments is an integral part of the right to good health and it is pursued in the interests of individuals as well as the citizenry.

2. The safety of treatments is achieved through the implementation of all activities aimed at prevention and management of the risks inherent to health care procedures, and the proper use of all structural, technological and organizational resources.

3. All preventive activities put in place by health care institutions, whether public or private, must be contributed to by all personnel, including independent professionals who operate therein in agreement with the public health care system”.

The lawmakers have implicitly referenced article 32 of the Italian Constitution, i.e. the right of all citizens to enjoy good health, of which treatment safety is undoubtedly a pivotal aspect, acting as a safeguard of individuals in the interest of the community. The following subsections within the same article spell out the principle according to which the key to guaranteeing the full and effective enforcement of such a right lies within the very concept of prevention, to which the following two articles are closely linked (18).

The fact that health care treatments may cause damage to patients, rather than bring benefits, underscores how closely the treatment safety factor is connected to treatment quality, constituting one of the most critical aspects in that regard.

Treatment safety translates into the administration of procedures befitting each individual patients, in compliance with scientific evidence, financial sustainability with respect to the cost-benefit ratio. (19) Yet, first and foremost, prevention and risk-management are the key tools for the realization of a health system living up to the highest quality and safety standards. It is therefore necessary to put
in place constructive policies according to organizational standards inspired by Risk Management business practices, in which all personnel involved with the management and implementation of services is required to partake, as stated in article 1, subsection 3.

The approach to treatment safety, in fact, cannot be solely based on the skills of individual operators, but rather rests on the underlying organization. Health care providers are mere links in the long chain that is the complex system that administers services and the professionals who operate therein. Optimal health care levels can only be achieved if all members organically interact within the system, making the most out of the structural, technological and organizational resources.

In order to better clarify the role of fundamental systemic factors, it may be useful to refer to Reason’s “Swiss cheese” model: the author describes an organization’s defenses against failure as a series of barriers, represented as slices of cheese. Each barrier should theoretically present no weakness, but in actuality, that is not the case. The holes in the slices represent weaknesses in individual organizational parts of the system. The mere presence of holes does not necessarily entail failure, yet the system produces failures when a hole in each slice momentarily aligns, permitting “a trajectory of accident opportunity”, so that a hazard passes through holes in all of the slices, leading to a failure (18).

In most cases, therefore, failures stem from the alignment, the interweaving of multiple factors, particularly structural defects, which must be warded off.

Furthermore, manifest failures are but the tip of the iceberg compared to a variety of “undetected” ones. “Direct” mistakes, those made by health care providers during treatment, are human mistakes, and will never be totally eliminated. Hence, in order to enhance system security, it is necessary to act upon the latent failures, which in turn give rise to direct ones.

In that regard, articles 2 and 3 of the new Italian piece of legislation introduce new professional figures tasked with monitoring and sifting through the various stages of identification and report of health care system malfunctions, of related data transmission and of devising proper measures for the prevention and management of health care related risks.

In particular, innovations introduced by the newly-enacted law from an organizational standpoint have to do with the institution of a specific “Center for health care risk management and patient safety” in every Italian region and the “National observatory of good practices in health care safety”.

The former body, according to the law’s phrasing, seems to serve a function of conveying data from regional reporting systems, about both red-flags and litigation cases, to the Observatory, through the yearly report of adverse events and relative causes. It is however fit to view the Center as a body capable of actively engaging in health care risk management, not a mere data-collecting tool, according to the legal interpretation of the new norms.

The Observatory, on the other hand, receives regional data on adverse events and can rely on the “information system for the monitoring of health care failures” (sistema informativo per il monitoraggio degli errori in sanità, SIMES), phased in by ministerial decree in December 2009, in order to plan and implement all suitable preventive measures, so as to close the circle and make sure that the practical data, provided by the reporting system, are effectively used to improve the quality of the national health care systems.

The first three subsections of article 2, cited below, are designed to outline the profile and functions of the ombudsman:

1. Regions and autonomous provinces of Trento and Bolzano may charge the office of ombudsman with guaranteeing the right to good health and regulating the organizational structures and technical support.

2. The ombudsman, while discharging his or her duties as guarantor of the right to good health may be hired, free of charge, by any individual user of health care, either directly or through a proxy, for the purpose of reporting flaws and malfunctions in the health care system.

3. Ombudsmen may acquire all relevant data, even in digital format, pertaining to the reports that have been filed and, once the veracity of such reports have been verified, may intervene in order to enforce the rights that have been violated, with powers and procedures established within regional legislation.”

Such new set of norms constitutes an innovation on a national scale, in that it asserts the possibility to vest upon the ombudsman the function of guarantor of health care enforcement. The non-binding nature of such regulations, however, reflect the national lawmakers’ determination to preserve regional autonomy.

Specifically, the article only spells out the most basic among the various protective activities that may be fulfilled by the ombudsman, who is charged with acquiring reports and verify their accuracy, whereas all other forms of intervention are set forth by the autonomous regional governments, which are best suited to delineate different tasks and functions and define personalized managerial and organizational profiles.

The most relevant aspect in all of this is the ability of individual citizens to signal and report, free of charge, any flaw or malfunction within the health care system. Thus, each individual citizen may become an integral part in the prevention, detection and containment of risks and failures in health care.

Nonetheless, in order to make sure that such a protection system works effectively, the guarantor’s office should not be limited to the mere management of failures detected when accessing health care services and procedures (e.g. disservices stemming from waiting lists or payment of fees), but rather ought to take into account and look into reports of alleged cases of professional liability (19).

Such a preliminary assessment may constitute a “barrier” capable of discouraging frivolous lawsuits and unfounded litigation, but might also bring to the surface some elements that, although not necessarily indicative of a patient’s right to redress, may be viewed as red flags of fundamental dysfunctions on which to act, via organizational readjustments, for instance, staff training courses, etc.

It goes without saying that in order to deal with health care issues, guarantors need to be suitably skilled.

Such a perspective appears to be perfectly in line with
preliminary paths of verification, prior to actual litigation, stated in article 8 of the law (mandatory attempt to settle).

Still, article 8 pertains to a later stage, in which a decision to file a claim has already been made by the patient, whereas any intervention from the ombudsman would have to take place at an earlier stage, prior to the filing of any lawsuit.

What sets the functions of ombudsmen apart from practices of mediation or settlement is that when patients file a complaint, their attention is focused on the causes that brought about the event: they often state that their ultimate goal is to keep what happened to them from happening to somebody else.

Article 8, on mandatory attempt to settle, states the following:

1. Those who are determined to file a claim before a civil court relative to compensatory damages arising from health care professional liability are required to make a preliminary appeal according to article 696-bis of code of civil procedure before the competent judge.

2. “The appeal according to subsection 1 constitutes a condition of eligibility to gain compensatory damages. The possibility to apply for an alternative mediation procedure, in accordance with article 5, subsection 1-bis, from law decree n. 28, 4th March 2010 remains an option. In such cases there is no room for the application of article 3 of law decree n. 132, 12th September 2014, converted with amendments from law n. 162, 10th November 2014.

The inability to proceed must be barred from the trial, on pain of decadence, or detected by the judge, no later than the first hearing. The judge, having ascertained that the proceedings have not been fully discharged, i.e. commenced but never concluded, shall set a fifteen-day time frame to formulate a request of preemptive expert witness testimony as completion of the proceedings”.

3. “If the attempt to settle proves unsuccessful or the proceedings do not come to closure within the set time frame of six months from the filing of the appeal, the claim becomes eligible to be proceeded on and its effects are kept if, within ninety days of the recording of the report or from the expiration of the mandatory terms, an appeal application as stated in article 702-bis of the code of civil procedure, is received by the judge who has been in charge of the proceedings according to subsection 1”.

4. “Attendance of preliminary technical counselling proceedings according to the present article, carried out in pursuance of article 15 of the law, is mandatory for all parties, including the insurance companies mentioned in article 10, which are bound by law to set forth a compensatory damages proposal, i.e. elaborating upon their reasons not to make one. In case of verdicts favorable to the plaintiff, whenever the insurance company has not put forth any proposal within the proceedings of preemptive technical counselling according to the previously stated subsections, the judge shall refer a copy of the ruling to the Institute for Insurance Oversight (Istituto per la vigilanza sulle assicurazioni, IVASS) for the fulfillment of all related duties. In case of failure to attend the proceedings, the judge shall sentence the parties who failed to attend to pay technical counselling and litigation-related expenses, irrespective of the trial’s outcome, in addition to a fine, to be equitably determined, in favor of the party who attended the proceedings”.

The ultimate goal in which the norms are rooted is unequivocal: to avoid tort lawsuits of merely “exploratory” nature or filed for retaliatory or speculative purposes.

In particular, in order for a legal claim of damage redress to become practicable, it is necessary for the plaintiff to initiate either one possible legal procedures.

The former consists of the filing of an appeal according to article 696 bis, that is a simpler and swifter trial, aimed at appointing an expert witness before the proceedings begin, tasked with establishing whether the alleged health care liability instance is properly substantiated, and binding the expert witness to attempt to arrive at a settlement, thus stemming the litigation build-up.

As an alternative, parties may look into the possibility to carry out a mediation process: an out-of-court procedure devised to enable the parties involved in the litigation to settle it by means of an impartial mediator, who after establishing the willingness of both parties to come to an agreement, lays out a proposal to bring closure to the matter.

Significantly, lawmakers have chosen to categorize mediation and settlement as on a par with each other, although they constitute very distinct options, ascribing to both a function of filtering in an effort to stem litigation.

Summing up what articles 1, 2, 3 and 8 state, it is safe to assume that the new law’s ultimate goal is to shift the vantage point, valuing the importance of preventive phases, anticipation of issues, the implementation of suitable measures in order to preemptively spot possible mistakes and avert unfavorable outcomes and, should they occur, discouraging the role of trials in seeking compensatory damages.

The prescription by legislators to introduce a mandatory insurance system, spelled out in article 10, appears just as interesting and innovative.

It is a mandate on all individuals who, in different capacities, may be held liable for damages arising from their health care activities and it is meant to pursue the objective of safeguarding, on the one hand, the properties of those whose possible liability is on trial and on the other hand, the aggrieved patients, whose right to proper compensation ought to be enforced by identifying the most solvable party to redress the damage suffered.

Particularly, mandatory coverage for public and private health care institutions is defined for contractual liability (ex art. 1218 e 1228 civil code) towards third parties or workers, including possible damages caused by staff operating in any capacity within the facilities.

The second mandate for health care facilities is to gain insurance coverage for non-contractual liability (ex. Art. 2043 civil code) -towards third parties- of health care operators, in the assumption that the plaintiff might sue the individual professional.

Lastly, insurance coverage is mandatory for health care professionals who practice outside of health care facilities or within them on the basis of an independent agreement, or still, using the facilities in the fulfillment of contractual obligations towards their patients directly, covering risks arising from the exercise of such professional activities.

Article 10, subsection 4 binds health care facilities to publish on their websites the specifics as to the insurer that provides coverage, in order to foster a prompt identification on the part of damaged parties, consistently with article 12,
“direct action from damaged parties”, who can address their claims directly to the insurance company that provides coverage to the facility or the individual professionals, thus circumventing any possible unwillingness or hesitation to start the compensatory process. It is arguably an additional resource meant to expedite and simplify the exercise of individual rights.

Lastly, in order to provide the best possible safeguards in terms of offering damaged patients the highest guarantees for a prompt financial compensation, a new Guarantee Fund has been established, funded by yearly contributions from insurers into the national budget, which are eventually allocated into the Fund.

Such a Fund plays an essential role in safeguarding damaged patients, since it is designed to intervene whenever insurance coverage proves inadequate.

In particular, it is possible to resort to it when the damage suffered exceeds the maximum compensation or the per claim limit specified in the contracts undersigned by the health care facility or the professionals, or if they are covered by insurers in a state of insolvency when the damage occurs or lastly, whenever the hospitals or the individual professionals turn out to be devoid of any coverage, for any given reason.

Civil liability of doctors and health care facilities

From a tort law perspective, Gelli law dramatically changes the main features defining professional liability of physicians. Doctors, in fact, are called to answer in an extra-contractual fashion (art. 2043 civil code), barring those cases in which a contractual obligation has been made with patients directly.

Liability of health care facilities (whether public or private) is left unchanged, in its contractual nature (artt. 1218 e 1228 civil code).

Article 7 specifically reads as follows:

Health care institution, whether public or private, which in the fulfillment of their duties avail themselves of health professionals, even those chosen by patients and not employed by the hospital itself, must answer for their misconducts, whether accidental or wrongful.

2. Prescriptions under subsection 1 shall be applied to health care, experimental and research procedures carried out within the facilities by independent professionals within an agreement with the national health care system, even by telemedicine practices.

3. Health care professionals under subsections 1 and 2 shall be held accountable for their deeds, in compliance with article 2043 of the Italian civil code, except in cases where they acted while discharging their contractual obligations towards their patients. Judges, when establishing compensatory damages, shall take into account the conducts of health care professionals in conformity with article 5 of the present law and article 390-sexies of the Italian criminal code, introduced by article 6 of the present law.

4. Damages stemming from activities carried out by health care facilities, whether public or private, and health care professionals are to be compensated on the basis of the tables laid out in articles 138 and 139 of private insurance codes, from law decree n. 209, 7th September 2005, integrated whenever necessary by the procedures in subsection 1 of above mentioned article 138 and based on the criteria spelled out in the same articles, in order to take into account all circumstances not contemplated inherent to the activities under said article.

Civil liability of doctors

Until law 24/2017 was enacted, medical liability of doctors has been deemed to be contractual in nature, with reference to the activity of independent professionals, provided that a contract of independent professional activity has been undersigned. In that regard, the Italian Supreme Court asserted that “as far as medical liability is concerned, unlike Common Law countries, where a tendency is consolidated to attribute liability in the realm of Aquilian liability, in Roman law countries, among which our own, similar types of liability fall within the contractual category” (20).

As for professionals employed by public or private health care facilities, the Supreme Court has asserted that damages arising from medical errors ought to be assessed within the framework of contractual liability anyway, in adherence to the theory of “social contact”:

“the obligation on the part of doctors employed by public health care institutions of professional accountability towards patients is to be deemed as contractual in nature, although not based on any contract but rather on social contact. Consequently, in respect of such accountability, the partitioning of the burden of proof and statutes of limitations are those applied to obligations of professional, intellectual service contracts” (21).

According to the theory of “social contact”, the doctor-patient relationship that come into being upon hospitalization is a peculiar kind of social relationship, regarded by legal statutes as determining specific duties of conduct, the obligations to safeguard and preserve of doctors toward their patients, and possible compensatory damages even in absence of formal contracts.

Hence, the dramatic change in the realm of tort law appear to be twofold.

Firstly, Gelli law codifies the dismissal of the “social contact” theory, by including civil liability of doctors within the prescriptions of article 2043 of the civil code, thus characterizing it as extra-contractual.

From that vantage point, and strictly within the limits of claims filed against doctors, patients appear to be burdened when staking a claim compared to the previous legal framework. As far as the burden of proof is concerned, in fact, a principle typical of contractual liability – as health care liability was defined - was previously applied, the inversion of the burden of proof: it was enough for patients to prove the existence of a contract and/or contact with their doctors and document the inaccurate fulfillment of the health care service, consisting of an alleged adverse event resulting in a health damage. The onus rested on defendants (doctors and health care facilities) to prove that the health care intervention had been carried out in a painstaking fashion and that the negative outcome had been brought about by unforeseen, unforeseeable and unavoidable event. Thus, patients were merely required to document an adverse outcome having
occurred as a default from the counterpart (doctors), whereas
the defendant was burdened with having to prove compliance
and accuracy in the discharging of their duties (22). There
was a primacy of the so-called “vicinity of proof” principle,
meant as an acknowledgement of the actual ability of either	party to produce it: the disadvantaged position of patients
was therefore recognized, given their lack of knowledge of
medical techniques, certainly experiencing greater difficul-
ties in proving circumstances and facts closely associated
with professional medical practice, and it was therefore
incumbent upon doctors to prove the absence of liability
and their compliance with conduct adherent with sound
medical practice at the time of the intervention.

Extra-contractual liability, on the other hand, requires
that patients meet more stringent and demanding standards:
it is in fact up to them to demonstrate that a damage occur-
red, while proving the causal relationship between medical
court-outcome and liability.

Such an innovation certainly coincides with the urge to
discourage the build-up of claims and litigation, which appears
to be the reform’s central focus, by making complaints
and lawsuits less convenient and accessible, thus deflating
a legal trend and related public expenditures that have been
on a worrisome upward trend: in other words, it is an effort
to make litigation less attractive and practicable for patients,
in light of the shortened time frame to file for compensatory
damages: by transitioning to extra-contractual liability, the
statutes of limitations have been halved from 10 to 5 years.
In fact, the regulatory framework codified in article 2946 of
civil code will no longer be applicable (so-called ordinary
statute of limitations) in the setting of medical liability,
replaced by article 2947 of civil code (statute of limitations
inherent to compensatory damages arising from wrongdoing,
formerly article 2043 of civil code) which sets a five-year
time limit to stake a legal claim.

Liability of health care institutions: current scenario and
innovation in the Gelli-Bianco law

As far as professional liability, a relevant position is ascri-
bled to health care facilities, whether public or private ones.
According to prevailing legal doctrine and jurisprudence,
the definition of accountability for hospitals is autonomous
compared to that ascribed to professionals performing the
service, and must be characterized as contractual liability.
Admission of patients into health care facilities, either public
or private, for the purpose of hospitalization or even mere
diagnostic testing entails the subscription of an atypical
health care contract. Hospitals are bound to render complex
services not limited to medical or surgical treatments, but en-
compassing a wide array of ancillary services, in addition to
accommodation, the availability of medical and paramedical
supplemental staff, medication and any necessary technical
equipment and instrumentation (23,24).

Liability of health care facilities is contractual in natu-
re, both in relation with ineffective organization and with
medical equipment or ancillary medical and paramedical
personnel, and pertaining to accommodation-related services
(so-called damage from disorganization), and with regards
to the conduct of their employed doctors. In fact, according
to the rule enunciated in article 1228 of civil code, hospitals
who avail themselves of the aid of third parties must answer
for damages arising from their misconduct or wrongdoing.
Hospitals may be accountable for damages done to patients
while engaging in their relationship with the hospital. By
the same token, it is irrelevant whether a given intervention
is performed by the patient’s doctor of choice or by one
employed by the hospital.

The identical contractual status of liability in these in-
stances has equally shared the risk of compensatory damages
that such individuals could run, failing to take into account
the different financial means of a professional compared
to hospitals.

The Gelli-Bianco law has fully confirmed the above
stated legal trends in terms of health care facility liability.

Article 7, subsection 1, of the law under advisement
reads: “Health care facilities, either public or private,
which, upon discharging their duties, avail themselves of
the services of health care operators, even though chosen
by patients and not employed by the hospital itself, are called
to answer for their misconducts or wrongdoings, according
to article 1218 and 1228 of civil code”.

The Gelli-Bianco law thus keeps the liability of health care
facilities in the realm of contractual law, within a regulatory
framework that is still more favorable to patients, hence con-
stituting an effective tool for funneling claims from malpractice
victims towards the facilities, which are in a better position
than doctors to meet their compensatory demands.

The real innovation within the law is therefore the insti-
tution of a “double track” of liability, i.e. the differentiation
between the doctor’s position and the hospital’s in the two
profiles laid out in the code (article 7):

Contractual liability (article 1218 of civil code) of public
or private health care facilities (so-called atypical contract
of hospitalization between patients and hospitals);

Extra-contractual liability (2043 of civil code) for health
care professionals (except in cases of contractual obligations
agreed on with patients) who fulfill their functions within the
setting of a health care institution (either public or private),
i.e. in a professional relationship with the national health
care system.

Discussion and conclusions

The intention to shift the scope of liability from indivi-
dual operators onto institutions is not only dictated by the
latter’s more substantial financial means, but it is meant to
highlight the greater organizational responsibility and its
role in creating the possibility of errors (25). Such a shift
constitutes a prod to improve and enhance the oversight and
prevention systems.

It is worth acknowledging, therefore, the ethical and
strategic soundness of the reform, given that it aims for a
solution in order to lower the likelihood of adverse events
in health care. The benefits arising from shifting course are
manifest: health professionals are only held accountable for
properly gauged misconduct and damages fully demonstra-
ted by plaintiff patients, who can in turn gain compensatory
damages more swiftly, thanks to the newly introduced pos-
sibility to file a claim against the insurers, much along the
lines of civil vehicular liability.
Furthermore, the enhancement of risk-management tools should be instrumental in improving treatment safety (26).

Gelli-Bianco law is geared to provide an adequate response to issues arising from the scope of medico-legal claims, which is at the heart of the sharp increase in health care insurance premiums for professionals and facilities, defensive medicine, which has caused wasteful spending of resources allocated for public health care services, the uncertainty of legal trends and codified and acknowledged rules of conduct. Whether the newly enacted legislation will be able to achieve the results that it was meant to will become clear over the next few years.

Nonetheless, it is reasonable to assume that an improvement will be brought to the negative trends that characterized the above mentioned phenomena over the past years.

On the one hand, in fact, lawmakers have chosen to intervene on the very functioning of the health care system, regulating it more effectively by means of constructive risk management policies, likely to give rise to improvement in due time. (27) On the other hand, a more direct and effectual system of guarantees is offered to patients, which will likely elicit satisfaction. The opportunity to file a complaint against the insurers directly, the subject of data transparency, which is dealt with in article 4 (with reference to the commitment of the hospital’s management to provide all documentation to those entitled to gain it within 7 days and to the online publication of data relative to compensations paid in the last five years), or the introduction of the ombudsman, tasked with collecting reports from users and provide an impartial evaluation meant to be supportive in the decision-making process are all emblematic new elements.

Insurance companies should represent a balancing factor within a new, standardized system, by virtue of mandatory coverage for professionals and facilities, with compensatory damages defined by ministry-issued tables that will be paid more easily and quickly, although in lower amounts compared to average court-ordered ones. Health care facilities, however, may still proceed with internal resources that might be tantamount to insurance coverage, with proper oversight.

It is to be expected that, in years to come, litigation rates will dwindle as a result of the checks and curbs to those claims filed for merely exploratory purposes: the ombudsman who is in charge of assessing the soundness of reports, a range of pretrial procedures such as the fostering of out-of-court settlements and mediation. Therefore, a new culture of compromising and settling that may well take off in our country, at long last. The prescriptions in article 15 (“Appointment of expert witnesses and consultants in cases of health care liability”) are emblematic of the greater attention that is going to be paid to civil as well as criminal proceedings centered on health care liability: it is thus codified that in trials, a panel of expert witnesses be appointed, to include, in addition to a doctor specialized in the medical field in question, a specialist in forensic medicine, barring expert professionals in the field who lack the specific degree of specialization; expert witnesses must hold suitable and proven competencies and must be devoid of any conflict of interest within the trial or other related ones.

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