Chapter 11
Medical Responsibility and Liability in Italy

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Abstract The first section of the chapter discusses, from the Italian perspective, both the physician's responsibility as a 'contractual liability' and the liability for defects in health care outside of the professional activity of a doctor or other healthcare professional. The second section concerns epidemiological data, focusing on the increase in professional liability cases in Italy and errors in the diagnostic, prognostic, or therapeutic phases. The third section provides an overview of the normative and judicial situation in Italy in terms of criminal and civil medical responsibility, while the fourth section deals with 'Nomofilattica' and professional medical liability. The fifth section outlines the methods of ascertainment as well as the evaluation criteria in living persons and cadavers. The chapter ends with a discussion on the future perspectives of medical liability within the Italian context.

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11.1 Introduction

In the Italian legal system, responsibility is identified with the obligation to answer for the consequences resulting from an unlawful conduct.

In this regard, it considers two types of legal responsibilities: civil and penal.

In civil matters the claim for compensation belongs to the patient as part of a transaction contract under article 1218 of the Civil Code.

11.1.1 The Physician's Responsibility as "Contractual Liability"

The physician's responsibility, as "contractual liability", bases its *ratio* on the inadequacy of the health service.

The claim for compensation manifests its effects in the configuration of the physician's responsibility as the "debtor" who did not perform his contractual obligation properly.

11.1.2 Liability for Healthcare Defects Outside the Professional Activity of a Doctor or Other Health Professional

The Italian Civil Code, however, also provides a different form of liability ex art. 2043. This defines, in fact, the "tort" where the claim is derived from an unlawful

act for which there is, regardless of the nature of the event, a claim for unfair damage.

In the context of criminal cases, we can speak of responsibility where there is existence of a crime.

The constitutive elements of the crime, in addition to an active player (one who commits it) and the debtor (one who is disturbed or offended) are: the psychological element, the fact, and the conduct.

By analyzing the psychological element, mentioned in art. 43 of the Penal Code, it is possible to identify three types of situations: misconduct, culpability, and manslaughter.

11.2 Epidemiological Data

11.2.1 Increase in Professional Liability Cases in Italy

The extreme complexity of the criminal justice system has contributed to an increase in professional liability cases in Italy.

It is certainly not the only cause. The increased awareness on the part of citizens about the right to health protection, the pressure of the media, the "predatory" attitude by many work practitioners (lawyers, consultants) have contributed to the evolution of the means of diagnosis and treatment, and the resultant increase in complications.

To this we must add the birth and development of organizations representing the interests of consumers and an increased attention to professional liability.

Furthermore, a bicameral parliamentary commission for the study of professional liability was also established, with investigative powers and trainers involved in all cases in which an alleged case of "malpractice" is claimed.

This also causes problems for the coroner when handling such cases, or the consultant/expert (as well as the prosecutors and judges) who can be subjected to undue interference that may cause an alteration in the serenity of the proceedings. Added to this is the fact that, in parallel with investigations and criminal proceedings, legal proceedings may be launched for damages in civil courts.

This now happens so routinely that we can talk of "penal blackmail" in the use of indiscriminate presentations to the judicial authorities for all cases where a death occurs after a medical service has been performed, at all levels and in all settings.

Statistical data are not available regarding the prevalence of the phenomenon, because such information has not been analyzed.

An attempt at continuous and credible monitoring was conducted a few years ago by gruppo interdisciplinare di studio danno iatrogeno (GISDI), a working group developed within the società italiana di medicina legale e delle assicurazioni (SIMLA) framework. However, the data, especially with regard to the scope of

penal law, are not reliable. Other sources are represented by federazione nazionale degli ordini dei medici chirurghi e degli odontoiatri (FNOMCeO) and associations for the protection of consumer rights as Active Citizens. A very reliable data source may be represented by associazione nazionale fra le imprese assicuratrici (ANIA), the association of insurance companies, but such data have never been revealed in their entirety or are otherwise not easily obtainable due to company policy. In any case, the phenomenon is growing, with a negative reflection on the budget of the National Health Service and the Regional Health Services.

This results in problems in the private insurance sector, with the gradual increase in insurance premiums for healthcare facilities and individual professionals, as well as the gradual withdrawal of many companies from the market of medical liability.

Over-compensation and *over-deterrence* have both given rise to a series of regional legislative initiatives of particular interest.

Among these, we should mention the law of the Veneto region of July 31st, 2009 n. 15 (Extra-judicial rules on the management of healthcare litigation), whose constitutionality was upheld by the constitutional court Judgment n. 178 of May 14th, 2010.

Finally, the decision n. 11584/2010 of the IV Criminal Division of the Ordinary Court of Milan should be reported due to the severity of the alleged offenses and the severity of sentences imposed on defendant physicians.

They were physicians working in a private organization in Milan practicing unnecessary and harmful operations only for profit and more precisely to justify the so-called DRG.

For the same event there is another ongoing trial against the same defendants, in which case the crime is murder for the death of patients after surgery.

11.2.2 Mistake in the Diagnostic, Prognostic or Therapeutic Phases and Percentage of Mistakes According to the "Court of the Patient" and Data GISDI

The physician's responsibility is identified in the mistake during the diagnostic, prognostic, or therapeutic phases. The diagnostic error is when the doctor fails to reach a correct diagnosis of the disease that afflicts the assisted person (wrong collection of anamnestic data, misidentification or underestimation of a symptom, an objective examination performed incorrectly, an error in the execution or interpretation of imaging and/or laboratory studies).

A diagnostic delay results in a delay of treatment. A mistake in the prognostic phase is when the doctor reaches a conclusion that is then proved to be unfounded, which affects further therapeutic orientations, thus causing harm (the prognosis is "recklessly" in favor of inertia or failure of therapy, unfavorable prognosis). A mistake in the therapeutic phase is when the doctor makes a mistake either during

the choice of the therapy or at the time of its execution. These mistakes frequently depend upon previous diagnostic mistakes and they can be distinguished either as a medical mistake or as a surgical therapy mistake.

Examples of the former type of mistake are the choice of an inappropriate or ineffective medication, its incongruous route of administration or its inadequate dosage, the lack of consideration of drug contraindications, side effects, and iatrogenic effects that were neither expected nor avoided. Among surgical mistakes, it is possible to identify a mistake during the operatory phase consisting in an error of judgment of inoperability and/or a reference to intervention, in the selection or execution of the anesthesia and/or in the calculation of the risks related to it, in the instruments used during the procedure, and an error in the postoperative phase consisting of mistakes or negligence or postoperative care.

In Italy, the Parliamentary Committee that inquires into both errors in the field of health and causes of regional health deficit last year estimated that around 250 events of malpractice occurred, 170 of which resulted in a fatal outcome.

The estimation is arrived at by the use of a rough guide, since the ordinary judge is in the end called upon to pronounce on the physician's responsibility. According to the "Court of the Patient" the percentage of mistakes was distributed as follows: 16.5 % Orthopedics, 13 % Oncology, 10.8 % Obstetrics, and 10.6 % Surgery.

However, the most frequent mistakes are those committed in the operating room (32 %), followed by the wards (28 %), as well as emergency departments (22 %).

In clinics, however, the percentage recorded is 18 %.

The GISDI, Observatory on forensic medical *malpractice*, funded by ministero dell'università e della ricerca scientifica e tecnologica (MURST) (currently (MIUR) ministero dell'istruzione, dell'università, della ricerca) and affiliated with the SIMLA, showed that, out of 1,564 cases reported, the specialties with the highest number of reported cases were Obstetrics and Gynecology (121 cases), General Surgery (82 cases), Orthopedics and Traumatology (68 cases), the ER (57 cases), Oncology (35 cases).

Also from the same source, the specialties recognized as responsible (in the expert's assessment) were Obstetrics and Gynecology (55 cases), General Surgery (40 cases), Orthopedics and Traumatology (39 cases), Oncology (24 cases), and Emergency Department (20 cases).

11.3 Normative and Judicial Overview

11.3.1 Criminal Medical Responsibility

The physician must respond in front of a criminal court with regard to his willful misconduct, his negligent conduct, the committal of manslaughter in relation to his conduct, which has resulted in personal injury or the death of the patient.

The following matters constitute willful responsibility: voluntary and conscious transgressions concerning facts of a criminal nature, commission or omission, and fines that are of different nature.

The offense is defined as *intentional* by art. 43 of c. p. and the following cases fall into it: interventions without consent (even if the issue is controversial both in doctrine and in jurisprudence), the revelation of secrecy, failure of medical report, wrongful death, ideological falsehood committed by public officials in a public act, ideological falsehood committed by public officials in certificates, omission of mandatory reporting, illegal prescription of drugs, nepotism, and embezzlement.

The crime, instead, must be defined as *culpable*, or against the intention, according to the dictates of the III paragraph of art. 43 c. p.

Within that both a generic and a specific fault can be distinguished.

The general fault is characterized by the presence of negligence, carelessness, and inexperience.

Negligence consists in the omission of the care required by common rules and practice observed by the majority of physicians.

Imprudence consists in the absence of prevision of possible harmful consequences of interventions.

Inexperience consists in ignorance regarding how to perform what another doctor of the same professional level would properly execute in the same clinical case.

Specific fault lies in the violation or nonapplication of rules that the doctor is required to know and observe. Such rules can be represented by real laws or by rules drawn up by a public authority or hierarchy also aimed at regulating and governing the execution of certain activities or the good performance of the work ("regulations, orders and disciplines").

The crime must be called *manslaughter, or beyond the intention*, according to the second paragraph of art. 43 c. p. when the physician's action comes from a conscious detrimental desire, but is reflected in an unwanted surplus in effect.

This particular case of the subjective element seems to be safeguarded by the Supreme Court, which has until now rejected any interpretation made against physicians (Court of *Assise* of Florence, October 18th, 1990), making it a nearly impossible hypothesis (Cass. Pen., Section IV, June 24th, 2008, n. 37077; Cass. Pen., Section IV, January 16th, 2008, n. 11335; Cass. Pen., Section I, July 11th, 2002, n. 26646).

To access compensation in relation to civil appeal one must inquire, through one's own lawyer, to the Civil Court, located where the event is presumed to have taken place.

There are only two ways: the summons and the complaint.

The injured person, having brought a damage claim for compensation, must necessarily take his request to the court.

The criminal trial, on the other hand, sponsored by the Public Prosecutor who represents the prosecution, is established with the knowledge of *notitia criminis*.

The procedures that inform the prosecutor of *notitia criminis* are the complaint and the lawsuit.

The former is distinguished from the latter, because it presents to the Public Prosecutor a crime or a violation for which the law provides for a punishment "at all costs", and so ignores the will of the person harmed by the offense.

The lawsuit, instead, is represented in full by the willingness of the victim, who desires that the guilty person be punished (for example, personal injury pursuant to art. 582 c. p.).

If the person harmed by the offense decides to discontinue criminal proceedings against the offender, he can do so by extinguishing every action of a punitive nature.

In a criminal trial, the victim may claim compensation for damages by activating the civil action in court, but this has to be done by the lawyer who will represent him.

11.3.2 Civil Medical Responsibility

As mentioned above, other than a penal liability, a civil liability is also taken into consideration by the Italian system.

The doctor is obliged to compensate the damage caused to his client in all cases where there is a discernible fault.

It is distinguished from a professional liability tort (art. 2043 c. c.) and a contract (art. 1210 c. c.). In summary, contractual liability is in the presence of a pre-established type of relationship and this contractual liability obeys the general principle of *neminem laedere*.

The assumption of liability is the existence of a compensable damage. The assessment of civil liability is intended to shift the cost of damage from the person who has unjustly suffered to the subject who is held responsible. No doubt has ever arisen in cases where the doctor acted as a totally autonomous and independent practitioner, who is obligated in this case to respect a contractual relationship.

Initially, the relationship between the physician employee of a health facility (public or private) and patient was setup by law in contractual terms, on the grounds that the only contractual relationship was that established between patient and healthcare facility.

Based on a note of the Supreme Court in 1999, the relationship between the patient and physician-employee of a health facility is considered to be outside the scope of contractual liability.

According to the landmark verdict (Supreme Court sent. n. 589 of January 22nd, 1999), the responsibility of the physician, acting as either an employee of the NHS or as a freelancer, is always contractual, since these roles essentially involve identical practices.

The physician and patient are united by a contractual relationship stemming from social contact.

According to the principle of contractual obligation, the physician agrees with the patient not to guarantee the result of healing, but rather to use the most

appropriate means that medical science makes available to achieve the result. In some areas of medicine, however, the two requirements coincide (e.g., in esthetic medicine).

When an unfavorable result occurs, it has to be proved that it is related to the professional conduct of the doctor. Under Italian law, in the event of contractual liability, the damage is a consequence of the failure, the limitation period is 10 years, the damages recoverable are those expected at the time when the debt was incurred, and there is a burden of proof.

In the case of extra-contractual liability, in which damage is the result of an illegal episode, the limitation period is 5 years, the damages recoverable are predictable or not, and the burden of proof is up to the victim.

As for the burden of proof in the case of contractual liability, it is borne by the debtor (in this case the doctor), who is required to prove that the alleged failure (according to the creditor, who has suffered some kind of damage) is due to reasons that are not attributable to him/her. Otherwise he/she is liable to pay damages.

In the case of tort the burden of proof is borne by the injured person, who is required to prove infringement, damage, and the existence of a causal relationship (art. 2697 c. c.).

The aim of the Italian civil law is to compensate the damage to the person and to restore the situation that existed before the damaging event. Therefore, the compensation must be in a specific form and when this is not possible (as in the case of personal injury) it must be in an equivalent form. In the context of civil liability, art. 2226 c. c. involves the anchoring of the physician's responsibility to malice or gross negligence, but only in cases of special difficulty. In "normal" cases the responsibility is extended to include mild negligence.

This approach is now more established and also operates upon the reversal of the 'burden of proof' (Cass. Sez. III Judgment n. 9085 of April 19th, 2006, Case n. 23918 of April 18th, 2006).

Regarding the causal link it is necessary to remember what is indicated by Cass. Section III, Case n. 7997 of April 18th, 2005.

It sets out the following principles:

1. the causal link is a structural element of the offense that runs between a behavior (the author of the act) and the event;
2. identification of the primary relationship between behavior and event, disregarding in the first instance any assessment of predictability;
3. the causal link between conduct and material event is one which has been generated by each prior behavior, or has even been contributed to, by the fact that the objective report should be considered the "cause" of the event itself;
4. legal causation is, conversely, the etiological report of the facts as they occurred in order to determine whether they fit the event or break the link with the fact of all previous causal antecedents;
5. assessment of legal causation must be made according to the criteria
    a. of scientific probability (where this appears exhaustive),
    b. of logic, if invoking the laws of scientific probability is not feasible.

The existence of the causal link between a medical procedure and the injury that must be proved by the injured person, permits the logical and chronological identification of the subjective element of the offense, namely the existence or not of the guilt of the agent that, in spite of a proven causal link, could be independently excluded according to criteria of predictability and avoidance.

The functional criteria of the determination of medical negligence are those

1. of a contractual nature;
2. whether or not there has occurred a worsening of the patient's condition;
3. assessment of the degree of guilt;
4. the proper performance of the burden of information and the existence of the subsequent consent of the patient.

In the next verdict (n. 975/2009) the principle of "more likely than not" was established, in terms of causation, by the membership of the Supreme Court.

In specific terms this means that the proof of a causal link between the conduct and alleged harm in criminal cases should be in terms of near certainty, while in civil cases it should be in terms of probability.

This has resulted in a further increase in claims so as to force a de facto legislature to enact a law on the so-called compulsory conciliation media, precisely in order to reduce the litigation in this area.

The D. Lgs. n. 28 of March 4th, 2010 that came into effect from March 1st, 2011 after a heated debate, which had a strong opposition on the part of the Italian Advocacy, is pending before the Constitutional Court owing to objections of unconstitutionality having been raised.

It is therefore impossible to evaluate the effectiveness of this new legislation.

The major reason for criticism of D. Lgs. n. 28/2010 is the principle according to which the experience of the mediation process is imposed as a condition of a claim's admissibility, with the inclusion of a specific system of sanctions.

Another interesting development is the national and regional legislation regarding clinical risk, which led to the publication of guidelines that have been developed with the dual aim of rationalizing the use of health resources and of directing medical choices.

Their acceptance cannot be unconditional and must be subjected to critical analysis and possibly limited.

However, they seem to be a useful tool not only for the forensic evaluation of cases of alleged medical liability, but could be a useful tool for collaboration with the forensic point of view for the prevention of litigation.

11.4 *Nomofilattica* and Professional Medical Liability

One peculiarity of the Italian legal system is the "nomofilattica function" or "nomofilachia", which is the duty to "ensure the exact observance and uniform interpretation of the law, the unity of the national objective law" that art. 65 of the Law on the Judiciary (R.D. 30 January 1941, n. 12) assigns to the Supreme Court.

Therefore, the jurisprudence of Cassation represents an essential reference point for the coroner as well as the magistrates involved in the various levels of courts in cases of medical professional liability.

Judgments of the Criminal Appeal, therefore, have repeatedly made reference to the criterion of beyond reasonable doubt, finally acknowledged in the decision of the United Sections Criminal no. 30328 of 2002 (commonly known as a Franzese ruling, its name being derived from that of the accused doctor).

Following this ruling other judgments of the Supreme Court have confirmed this principle (Cass. Pen. n. 32494/2004, Cass. Pen. Section IV, Judgment March 11th, 2009, n. 10819, among many others).

The Supreme Court has also addressed other recurring problems within the area of medical professional liability, indicating the fault lines of interpretation such as, for example, in the case of medical responsibility of a team (the principle of the error and clear the principle of custody Cass. Pen. Section IV sentence July 12th, 2006, n. 33619) and the relation between failure/lack of informed consent and involuntary manslaughter. In this context, the verdict that has effectively established the principle that the lawfulness of the medical act involves the consent of the entitled person is the Massimo ruling, named after the condemned surgeon in the case.

In this sentence (Cass. Pen, Section V, April 21st, 1992, n. 5963) a doctor was convicted of manslaughter for the first time in Italy.

From this verdict others have resulted, which are well known and have been commented upon (the cases, always taking their names from the doctors charged, of Barese, Cicarelli, Firenzani, Volterrani, Caneschi, Huscer, Ruocco, and Giulini). There is a very strong debate among both lawyers and legal doctors about the value that should be given to consensus in the field of penal liability.

The decision cited above of Giulini on December 18th, 2008 is particularly important, because the United Sections have dismissed the relevance of the criminal conduct of the physician who performs surgical treatment on a patient which is different to the one for which informed consent has been given, in the case where the surgery, performed according to protocols and *leges artis*, is successfully concluded and from which an appreciable improvement in the patient's health condition is derived, also in relation to any conceivable alternatives and without indications contrary from the same patient.

The ruling calls for legislative intervention, introducing into the Penal Code the crime of arbitrary medical treatment.

However, there were no legislative responses.

In the Parliament a number of draft laws lie in this area and these include, among the DDL unified n. 153, "New rules of professional responsibility of the physician".

The recent decision n. 34521/10 of May 26th, 2010 known as the Huscher case, has introduced a further element of discussion in this area by even providing the potential for a mere possibility: "... the inevitable consequence in law is that he who violates in body and mind, without any justification, the person of the patient commits the typical fact of murder or an injury or even the crime of voluntary

manslaughter, if the doctor does not act with the therapeutic intentions and accepts the negative and potentially grave consequences (in this case the crime can even be punished as a possible fraud)...".

The ruling limits the validity of the unwritten consensus of exemption from liability in the event of surgical procedures that are not justified by the prevailing surgical and experimental practices, the former being unacceptable because they do not have a realistic chance of success or extension of survival.

In conclusion, the criterion of reasonable doubt must therefore be an essential tool of the medical examiner who shall, if the question can not be resolved, notify the client so that he/she can make informed assessments about the evidence acquired and their value for the purposes of the claim, which is placed below or above reasonable doubt.

It is a problem that occurs in all of the coroner's activities, whether in civil or social security, but in a penal context it is of the utmost importance in all of the services and those relating to crime victims, both those concerning the eligibility of the authors and application of security measures.

11.5 Methods of Ascertainment and Evaluation Criteria

Once the medical mistake is identified it is essential to ensure the existence of a causal link between mistake and the damage sustained by the patient (personal injury or death) in accordance with the requirements of art. 40, 41 and 45 c. p. First of all, it is appropriate to recall the main theories of causation which dominate the landscape of legal scholarship.

Many theories of causation in law contain the assumption that an event is preceded by a complex of antecedents, including those necessary for the identification of the one attributable to the person, that is *the human action responsible for the fact*. The solution of the problem is conceptualized in two ways: either assign an equal value to all the antecedents, which are in this way equal with respect to the law (*criterion equivalence*), or attribute to them a decisive value in the production of an event (*criterion of prevalence*).

- **Theory of equivalence or *condicio sine qua non*:** this theory identifies the cause with the totality of the antecedents, each of which is necessary when the event occurs. The causality is permissible as long as it is made prior to any condition necessary to represent the occurrence of harmful consequences to the person. The theory of equivalence, although it is an exact natural term, has the disadvantage of leveling-off all prior advances, without distinguishing between causes, concurrent causes, conditions, and opportunities or including in the causal circumstances any kind completely unrelated to those human factors on which criminal liability should be based.
- **Theory of prevalence:** the theories that are based on this theory are those which seek to identify the real cause of the condition and opportunity by differentiating

between qualitative and quantitative criteria, identifying among the various antecedents of a fact the one that has exercised the decisive role.

- **Theory of adequate causation or *id quod plerumque accidit*:** in this theory there is an assumption that human behavior is considered to be caused only by those effects that at the time could be considered likely and not by those of an extraordinary, exceptional, or atypical nature. The theory excessively restricts the field of criminal liability, as it excludes the causal connection between the fact and the consequences when the latter, although depending on the fact, were presented as quite exceptional cases and highly atypical at the time they had to be implemented.
- **Theory of human causalness:** according to this theory any human behavior would be considered as a cause, without which the event would not have occurred, provided that the latter is not due to the intervention of exceptional factors, which cannot be eliminated, because of the inability of the human agent to govern the etiologic course of his conduct, through his/her cognitive and volitional powers. Man is responsible for something when the basis of the chain of events is his free action, free will, so that there *is a choice*.
- **Theory of causality according to subsumption under the laws of science:** according to this theory any event prior to the event can be considered the sole cause of the event, because the etiological connection is adequately supported by scientific laws. This theory perfects the conditional one, in the sense of the counterfactual impress of the opinion based on scientific laws. Such laws are in fact possible to verify if, the action or omission of the agent being removed, the event would not have occurred (assuming causality) or if the event itself would have occurred anyway (causation excluded).

The Italian legal system has taken art. 40 and 41 c. p. *the theory of the condicio sine qua non.*

According to art. 40 c. p., the relevant penal conduct can be by commission (the consequence of an action) or by omission (the result of a failure).

In Italian law this article serves as the glue between the action or omission and the event, by identifying the realization of the second consequence from the first.

The assessment is based on the study of the human conduct of the physician and it requires knowledge of the cause as the etiological factor necessary and sufficient in itself for the implementation of a harmful event.

We talk about concurrent cause pursuant to art. 41 c. p., if they are able to alter the causal connexion, causing failure by influencing, contributing, or even erasing the correlation between the act or omission and the realization of the event.

In the presence of a study of a cause or multiple causes, the etiological reconstruction of the medical conduct remains a very complex study, where, beyond an obvious behavioral deficiency, an accurate analysis of clinical data should be carried out with the most careful contextual comparison of scientific data. The forensic investigation should be based on cogent analysis of the real problem, according to an appropriate methodological rigor.

The methodology of the study is focused on demonstrating the causal relationship between material action (or its omission) and its legally relevant harmful consequences.

In the criminal investigation the assessment of evaluation of medical conduct starts first with an epicritic diagnosis, both on the living and on the corpse. When a cause of death or injury has been identified it is then possible to evaluate the appropriateness of the healthcare conduct in relation to general standards of conduct expected by the international scientific literature (guidelines, consensus conferences), evaluating their application in this case (age and sex of the patient, concomitant diseases, etc.).

Any violation of the rightful rules must then be placed in causal connection with the injury or death of the patient.

To meet this last step, the coroner can and must rely on expert advice (gynecological, orthopedic, surgical, etc.). In fact, the investigation conducted by the coroner in the reconstruction of criminal etiology must satisfy the principle, according to which a criminal sentence must be issued beyond a reasonable doubt (533 c. p. p.).

In the Italian legal system the judgment of penal responsibility of the physician is up to the judiciary, who may use a technical advisor in the case of prosecution or an expert in the case of judging judiciary.

The consultant or expert are not necessarily required to be specialists in forensic medicine, nor is the use of a panel of specialists in various fields mandatory in the case of particularly complex problems, despite the indication in the code of medical ethics (art. 62 C.D. of 2006).

Until the 1970s, the legal guidelines were based on a "special favor" toward the medical profession, whereas in the next decade there was greater severity towards the work of medical practitioners, with the development of so-called defensive medicine in analogy to that observed in other countries.

A new orientation of the judiciary has recently appeared, according to which the penalty of incorrect medical professional conduct is subject to the attainment of the certainty of the case on the evidence of guilt "beyond a reasonable doubt".

This expression is included in art. 366 c. p. p. (as amended by L. February 20th, 2006, n. 46, art. 5).

This term is contained in art. 66 of the Statute of the International Criminal Court (Rome, July 17th, 1998), ratified by L. n. 232 of July 12th, 1999.

In the context of criminal liability, such medical criteria have to be used both in providing technical advice on guilt and technical advice on the causal link.

To the consultant/expert are not granted, if not at the preliminary stage of his analysis, possibilistic perspectives of low or medium probability, but findings and conclusions which then allow the judge to rely on them for the purpose of "procedural certainty".

In forensic practice, the application of these methodological rules is complex, although unitary; in most cases, the real opportunity to recognize and prove—not hypothesize or assume—a real responsibility on the part of the healthcare conduct

is small because, in many cases, it can be extremely difficult to distinguish culpable conduct from an excusable error.

In civil law the assessment follows the same pattern of investigation. The main difference with respect to the criminal investigation is that there is a "weaker" causal link, subject to the criterion of "more likely than not" and the quantification of biological damage.

The Italian Republic recognizes and guarantees the inviolable human rights (Article 2 of the Italian Constitutional Charter). Included within this scope is the right to health protection, which is defined as a fundamental right of the individual and collective interest (Art. 32 Italian Constitution). Having said that, we can appreciate how the compensation of the damages to the person becomes, in view of the Italian legal system, both an individual and social interest to be protected from all hurt and to receive reparation in case of injury.

In the past, pecuniary damage, in the vast field of personal injury, was distinguished from non-pecuniary damage. As part of this distinction, the traditional interpretation of Article 2059 of the Civil Code defined the non-pecuniary damage as a mere pecuniary damage. Therefore, the impairment of the health of the subject did not receive any sustenance. The first Court to sanction the refundable nature of the biological damage was the court of Genoa (the judgment of October 20th, 1975, GI 1976, I, 2443, and December 15th, 1974, FI 1976, I, 1997).

The real change came with the decision of the Constitutional Court 184/1986, where good health was recognized as a fundamental right of the individual. From this decision emerged the concept of the refundable nature of good health, regardless of the subject's ability to work to produce income. The combined interpretation of this sentence with art. 2043 of the Civil Code led to the concept of biological damage. Later, with the introduction of the "twin judgments" (Civil Court of Cassation., Section III, May 7th-31st, 2003 n 8827 and 8828) of 2003, article 2059 of the Civil Code was given a new interpretation. In the area of non-pecuniary damage, regarding any and all damages which are not susceptible to economic evaluation, existential damage was included. This type of damage was better defined in the historic judgment of the Constitutional Court (November 7th, 2003, No. 233), in which it was stated that the categories of harm that fell into 2059 cc were subjective moral damage, biological damage and the damage caused by the injury in existential terms.

A number of judgments of the Court of Cassation followed on the ontological value of non-pecuniary damage.

However, doubts persisted about what should be meant by the category of existential damage; also, it was not clear whether this figure, if any, could be combined with the biological damage (defined as a breach of the right to health, ex art. 32 of the Constitution) and non-pecuniary damage (defined as transient psychological disturbance).

In 2008 the Court of Appeal (Civil Court of Cassation, ON, December 11th, 2008, No. 26972, 26973, 26974, 26975) argued that non-pecuniary damage, pursuant to art. 2059 cc, cannot be divided into various asset damages, but must be considered as essentially unique.

The subcategories of existential and moral damage have been abandoned, because only the verification of the injury of the inviolable rights of the person is necessary. In addition, the interpreter must follow article 2059 of the Civil Code with inviolable constitutional rights, which are not intended as *an numerus* clauses: protection is not restricted to cases of inviolable rights of the person expressly authorized by the Constitution in this historical moment, but, by virtue of the opening of article 2 of the Constitution to an evolutionary process.

These judgments deny the existence of autonomous existential damage and moral damage, while acknowledging the existence within the biological damage of "existential" prejudices concerning relational aspects of life.

The main focus of forensic evaluation is therefore the biological damage. The cardinal principle in the assessment of biological damage is the globally accepted concept of health, as formulated by the World Health Organization as "a state of complete physical, mental and social well-being." Thus, it is clear from this definition that health is not understood exclusively in terms of absence of disease or infirmity. In fact, a new concept of health has emerged from the analysis of this definition, in terms of assessment of biological damage: the understanding of health as a balance of biological and psychological functions, integration into society and the moral aspect of the inner life. Therefore, the sense of well being, resulting from an optimal state of health is important in the regulation of human actions. In this scenario it is clear that the possible lack of individual well being leads to repercussions from the utilitarian point of view in the life of the individual to which it is inextricably linked.

The legal concept of biological damage means the damage as a breach of the right to health considered as a primary good. To this notion is added the medical profile, which considers the damage as the psychic and physical damage in itself. In the definitions given above it is clear that the assessment of the damage is beyond the ability to produce income (as was the case in the past), but refers to the person's physical or mental injury as such.

Concerning Italian law, it was necessary to transfer the universal concept of health to the quota of damages suffered by adapting to the rule of law, in order to make a qualitative and quantitative assessment of the overall damage to health. Therefore, in view of the Italian legal system, the biological damage is inevitably bound to the equipment and impairments of explicit functions in everyday life. Biological damage is described as physical and/or mental disability with the following characteristics:

1. is a given-event itself constituting the parameters under which other components are further damaged;
2. is refundable in any case, even when it does not affect the ability to produce income;
3. is evaluated in its entirety by considering the lifestyle of everyone (social, cultural, recreational);
4. is compensated using an egalitarian criterion, regardless of any circumstance or consequence.

To quantify and qualify the biological damage the coroner must determine: the nature and extent of injury, duration of the total temporary or partial disability, the degree of permanent disability (i.e., the impairment of the physical and mental integrity of the subject himself and its impact on their activities and social life). Therefore, in the evaluation of the biological damage the duration of disability (temporary or permanent), considering the activities of the individual both potential and actual (leisure, social life, etc.), must be taken into account. Temporary disability means the suspension of all activities of the entity during the period of illness and convalescence, considered as full or partial, depending on the degree of inactivity of the individual himself. Instead, permanent disability is defined as the result from the stabilization of the disease in the aftermath or of the chronicity of said disease in psychophysical terms. In case of multiple impairments, the degree of disability does not correspond to the sum of individual percentages, but it is assessed based on the overall decrease in production capacity. Forms and coefficients of personal injury are those factors that are thought to refer to the individual's physical, psychological sphere (biological damage), and other factors that give an economic value to man, because directly productive of income or potentially profitable, since they allow large expressions of personality (*Puccini: the assessment of biological damage*).

Therefore, biological damage is compensable in the current system according to the definition of Article 32 of the Constitution (which protects the right to health) and Article 2043 of Italian Civil Code (which governs the tort liability). In fact, it states that any damage, albeit willful, negligent, or unlawful must be compensated by the person who has caused it. Compensation tends to restore the balance sheet of the injured, restoring the economic situation that existed before the unlawful act that caused the damage. The liquidated damages will be governed by Article 2058 of Italian Civil Code and can happen in two ways: in *specific form*, through the return, the replacement or repair of the damaged thing, or its equivalent. In the case of personal injury monetary compensation is used, which is based on the assessment of liability and the amount of damages. Therefore, the compensation must take into account both the economic loss suffered from loss of income and the restoration for damage to health (art. 1223 cc).

For liquidation purposes the disabilities are expressed in percentage points and evaluated with reference to the existence of a tabular date. The tables refer to the impairment of organs and/or equipment. Recently, the national legislature has introduced innovations in this field, inserting D.L. n. 70 of March 28th, 2000 and the "micro-permanent" law of 57/2001, which is the biological consequence of a permanent nature valued in a range between 1 and 9 %. The rates over 9 % are defined as macro-permanent. Tables have been developed in order to know the translation of monetary tables of damage, including the most famous of the Court of Milan that was introduced in the 1990s and is still up-to-date. Recently the Supreme Court (Civil Court of Cassation, Section III June 12th, 2011, n.12408) established the principle that the liquidation of non-pecuniary damage to the person from physical to mental damage requires the adoption of the Tables on the

merits of the Court of Milan by all judges as the only yardstick to be taken into account throughout the national territory.

Within non-pecuniary damage moral damage is added, which is regarded as unjust disturbance of mood, of an impermanent nature, affecting the inner sphere of the injured. This damage does not have tabular references and is assessed on an equitable basis by the judge.

11.6 Future Perspectives

Italian forensic medicine has attempted, on several occasions, both through its scientific society and through the contribution of its teachers, to indicate a methodology-evaluation of professional liability established according to the modern principles of the Consensus Conference and the publication of shared guidelines. However, these efforts have still not been successfully accepted by all.

It should be added that there is not yet full doctrinal agreement on what constitutes a medical error, what its constituent characteristics are and what constitutes the evaluation criteria of reference.

We often have the impression that forensic evaluations regarding the qualification of the error are marked by an excessive subjectivity of interpretation.

An important factor is the use of the best scientific literature references based on the principle of meta-analysis (in accordance with the legal principle of subsumption under laws of science).

But forensic reports do not always make use of this tool.

Recently, legal medical doctrine, also at the urging of the scientific reference, indicated the use of guidelines and protocols as a logical path, indispensable for reducing the vagueness of the classic categories of fault (precisely defined as generic): imprudence, incompetence, negligence.

However, the most recent criminal jurisprudence does not seem to accept this criterion.

The Judgement n. 1873/2010 of the IV Criminal Court of Cassation annulled the acquittal decision in favor of a cardiologist who had dismissed a patient in accordance with guidelines, which resulted in the death of the patient a few hours later at his home, criticizing the use of uncritical and scientifically justified guidelines without a proper assessment of the health status of the patient who was dismissed.

If we also add those lengthy trials involving both criminal and civil matters, the perspective given is that of a system of often contradictory sanctions, with serious consequences for both the medical profession and health expenses.

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