

THE EVOLUTION OF PHYSICIAN-PATIENT RELATIONSHIP: FROM INFORMATION TO COUNSELLING

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The physician-patient relationship has changed over time: in the nineteenth century it was characterised by professional dominance; in the twentieth century a unilateral aleatory contract came into being between the professional and his client; it is expected that in the future medical practice will come to be based on individual genetic predisposition, where treatment will precede early symptoms and illnesses will be treated with personalised remedies and medicines. Until now, government policies have mainly aimed at safeguarding patients' health; today evermore attention is being paid to patients' right to self-determination. Society's perception of the physician has also changed: the physician is no longer seen as the custodian of an absolute knowledge, but rather as a service provider and the patient has come to be seen as a consumer. Over the last decades patients' protection has seen the rule of informed consent and efforts to favour patients under the law. Europe now fears that this favouritism will eventually trigger a crisis similar to the one which overwhelmed the U.S.A: in the U.S. the consequence was the halting of the lay standard in favour of the professional one; in Europe a defensive practice has come into being. This practice is based on complex risk management procedures and strict protocols consisting of many forms and very detailed information leaflets. Today, these two aspects - the preference of patients' right to self-determination and defensive practices - are the main reasons behind the physician-patient relationship transformation. Traditional one-way physician-patient communication is being replaced by dialogue. The move is one from information to counselling. The paternalistic approach of traditional medicine has already been replaced by the principle of physician-patient cooperation, which is a prelude to modern "talking medicine". This paper focuses on describing this medical approach change and the juridical and practical implications that come with it.

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I. INTRODUCTION

This paper shall attempt to show that the move from the physician's paternalism to the patient's self-determination is not yet complete, that consent is nothing but a formal act when it follows the delivery of strictly technical information, that there are cases (diagnostic evidence and/or therapeutic evidence) in which this is admissible within the economics of the physician-patient relationship and ensures

that the roles and interests of both parties are protected, but that there are other cases (diagnostic uncertainty and/or therapeutic uncertainty) in which such plain information is insufficient and requires that the physician's opinion be based on informational elements other than technical ones so that the patient is able to take independent and conscientious decisions relating to his/her health, is able to share the medical programme and cooperate towards its fulfilment, and is able to assume responsibility for unknown causes. Therefore, in order to properly approach this study, it is useful to start with an analysis of the historical development of medical law.

Starting from the second half of the twentieth century, western countries' focus on personal law has increased exponentially. This has obviously also been reflected on the law that governs medical care, which, in turn, has slowly but inexorably gone through a process of change. In the nineteenth century the physician-patient relationship was characterised by what sociologists call "professional dominance"¹. Law practitioners supported this transition and were aware of regulating their profession by governing the one of their fellow medical colleagues. Thus, the professional dominance of science and remedies, together with the principle of diligent service, came to favour the development of the concept of technical discretion. A type of aleatory contract came into being between the client and the professional, and the concept of professional responsibility was born.

However, the history of medicine did not come to a halt and has witnessed fundamental change over the last decades. This mainly relates to the technological revolution. The ever-broadening frontiers of science and medicine have introduced ethical, social, political and juridical debates on issues hitherto inexistent and on very sensitive questions. These essentially concern birth and death: genetic testing, medically assisted reproduction, premature birth, terminal illness, euthanasia, living wills.

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¹ For the theoretical support see Freidson, E. *Professional Dominance: The Social Structure of Medical Care*. New York: Aldine, 1970; Starr, P. *The Social Transformation of American Medicine*. New York: Basic Books, 1982.

More so, the above questions are strictly tied to medical and pharmacological experimentation: desperate cases and extreme situations legitimate and encourage recourse to non-standard techniques, drugs or procedures. Technological and scientific progress has de facto made the medical, health and pharmacological environment an inseparable one. The development of genetic medicine is also moving towards research of pharmacological therapies aimed at verifying genetic resistance to viruses.

Each area works in cooperation with other areas. When we give our authorisation for surgery, the informed consent includes the strictly medical service as well as hospital care and pharmacological services. If damage is suffered, some or all of these different players could be responsible.

From a comparative viewpoint we can observe how countries of the common law tradition have recognised, and progressively broadened, the independent nature of the subject-matter: Medical Law², Health Law³, Bioethology⁴.

In relation to European civil law systems, only German speaking countries - Germany and Austria - possess an autonomous law speciality: Medizinrecht⁵; in France, Belgium, Spain and Italy⁶, the tradition tied to the orthodox distinction

² Grubb, A. eds. *Principles of Medical Law*. 2nd ed. Oxford: Oxford University Press, 1998.

³ Furrow, B. R. eds. *Health law: cases, materials and problems*, 6th ed. St. Paul, MN: Thomson/West, 2008; Alexander, B. D. & Broccolo, B. M. eds. *Fundamentals of Health Law*. 4th ed. Washington D.C.: American Health Lawyers Association, 2008.

⁴ "Bioethology deals with a comprehensive aggregation of sources, turning them into one piece of law. It may comprise different trends, tendencies or views, which may be similar or contrasting each other, but all sharing the same ingredients of structure, scientific language, development and system." Carmi, A. "Ethical Issues and the Building of International Norms." *Asian Journal of WTO & International Health Law and Policy* 2 (2007): 5.

⁵ Deutsch, E. & Spickhoff A. *Medizinrecht*. 6th ed. Berlin: Springer Berlin, 2008; Höftberger, C. "Österreichische Rechtsprechung zur Arzthaftung." *MedR* (2000): 509 ff.; Kuhn, M. "Die Arzthaftung in der Schweiz", *MedR*. (1999): 250 ff.

⁶ For essential references on the evolutionary context of medical law in the continental Europe see on French law Savatier, E. "La responsabilité médicale en France" *Rev. int. dr. comp.* (1976): 493; Castelletta, A. *Responsabilité médicale. Droits des malade*. 2nd ed. Paris: Dalloz, 2004; on Spanish law see Gisbert Grifo, M. S. & Fiori, A. "Responsabilidad médica." Vallanueva Cañadas, E. & Gisbert Calabuig, J. A. eds. *Medicina legal y toxicología*. 6th ed. Barcelona: Masson, 2004, 112; Vázquez Barros, S. *Responsabilidad civil de los médicos*. Valencia: Tirant lo Blanch, 2009, 23 ff.; on Italian law see Princigalli, A. M. *La responsabilità del medico* Napoli: Jovene, 1983; Zeno-Zencovich, V. *La sorte del paziente. La responsabilità del medico per l'errore diagnostico*. Padova: Cedam, 1994; Stanzione, P. & Zambrano, V. *Attività sanitaria e responsabilità civile*. Milano: A. Giuffrè Editore, 1998.

between the obligation of skills and care and the obligation to achieve results⁷ has so far impeded that the law of medicine be independent from that of professional responsibility⁸, thus associating physicians to other professionals⁹. This is such a deep rooted distinction in European juridical culture that it has been adopted under the Common Frame of Reference¹⁰. In Italy the distinction has only recently been abandoned by the Courts¹¹.

In fact, the subject-matter is now delineated by such typified features that it is no longer possible to reason in terms of contract and professional responsibility. This is proven by the transformation of the concept of information and informed consent¹², which we shall address hereunder.

II. SALUS ET VOLUNTAS AEGROTI SECUNDA LEX

This legal principle states that ever since the beginning of medicine the patient has always assumed responsibility for his/her destiny: whether to seek a physician or not, which physician, but especially whether to follow a particular treatment, refuse one or suspend one. This principle has remained unchanged in

⁷ Demogue, R. *Traité des obligations en général. Effets des obligations*. vol. II, 6. Paris: Librairie A. Rousseau, 1932, 153 ff., 530 ff. and 597 ff. In recent French literature see Mèmeteau, G. *Le droit médical*. Paris: Litec, 1985, 419; Welsch, S. *Responsabilité du médecin*. 2nd ed. Paris: Litec, 2003, 167 f. In Spanish literature see Vázquez Barros, S. *Responsabilidad civil de los médicos*. *supra* note 6, at 38 ff. In Italian literature see Bilancetti, M. *La responsabilità penale e civile del medico*. 7th ed. Padova: Cedam, 2010, 1038 ff.

⁸ For a comparative approach see Gambaro, A. "La responsabilità medica nella prospettiva comparatistica." *La responsabilità medica*, Milano: A. Giuffrè, 1982, 25 ff.; Zambrano, V. *Interesse del paziente e responsabilità medica nel diritto civile italiano e comparato*. Napoli: Edizioni scientifiche italiane, 1993; Zeno-Zencovich, V. "Una commedia degli errori? La responsabilità medica tra illecito e inadempimento." *Riv. dir. civ.* (2008): 297 ff.

⁹ For an overview on Italian law see, among others, Cafaggi, F. "Responsabilità del professionista." *Digesto Disc. Priv. Sez. Civ.* vol. XVII. Torino: Utet, 1998, 137, 181 ff.; Fresa, R. *La colpa professionale in ambito sanitario*, Torino: Utet Giuridica, 2008.

¹⁰ Art. IV.C.-2:105, 106 DCFR. See Cascão, R. "Comment to Chapter 7." Barenbrecht, M. Jansen, C. Loos, M. Pinna, A. Cascão, R. & van Gulijk, S. eds. *Principles of European Law: Service Contracts*. München: Sellier, 2007, 787.

¹¹ Corte di Cassazione, Un. Sect., 11th january 2008, n° 577. *Nuova Giur. Civ. Comm.* (2008): I, 612 ff. Comment by De Matteis, R. "La responsabilità della struttura sanitaria per danno da emotrasfusione." at 616 ff.

¹² For a wide analysis of the historical implications of the principle see Faden, R. R. & Beauchamp, T. L. *A History and Theory of Informed Consent*. New York: Oxford Univ Press, 1986. Very useful is the historical synopsis from 18th centuries documents to the actual operational rules by Pasinelli, G. G. *Il consenso informato. Una svolta nell'etica medica*. Milano: F. Angeli, 2004.

spite of the revolutions which have forged the physiognomy of medicine over the centuries. In modern constitutional texts autonomous decisional power is among the fundamental human rights. However, it acquires different nuances at the time of applicative interpretation: at the extremes we have legal systems where will can prevail over health, and individuals are recognised the right of programmed suicide (Holland), or those which theoretically claim the right to self-determination but in practice subject the exercising of such a right to an individual's economic power (U.S.A.).

It is especially in legal systems that strongly emphasise the Constitution that the powers of civil freedom, personal law, and the principle of an individual's self-determination have strongly asserted themselves. A comparative analysis of medical law shows that in these countries the duty of informing plays a fundamental role (United States and Canada), whilst in countries where the Constitution is not so centre-stage, or is not formally set-out in a document (England), the situation is completely different¹³.

Courts, even more than the lawmaker, are sensitive to change. Case law has followed the history of medicine very closely, oftentimes finding solutions in order to adapt to change. It started, in the 19th Century, with conceiving damage as a violation of physical integrity - thus setting the legal grounds for a physician's requirement to provide information for prior consent - to reach, nowadays, the broader and all inclusive principle of personal integrity.

Civil liability has also changed: from 19th century liability-sanction, based on allocating fault on the person responsible for the damage, to 20th century liability-indemnity, based on risk and centred on the victim and on damage suffered. The 21st century is poised to be the one of *responsabilité-anticipation*¹⁴.

¹³ See Diurni, A. "Die Arzthaftung von gestern und das Medizinrecht von heute in rechtsvergleichender Perspektive." *Medizin und Haftung. Festschrift für Erwin Deutsch*. Ahrens, A. H. von Bar, C. Fischer, G. Spickhoff, A. & Taupitz, J. eds. Berlin/Heidelberg: Springer, 2009, 95.

¹⁴ See Thibierge, C. "Avenir de la responsabilité, responsabilité de l'avenir." *Recueil Dalloz* (2004): 581 ff.

In Holland, during the nineties, *responsabilité-anticipation* was codified in various forms in *Nieuw Burgerlijk Wetboek*¹⁵. In other countries of continental Europe - France, Spain, Italy, Germany, Austria and Switzerland – *responsabilité-anticipation* came into being with the slow but inexorable search for legal solutions favouring patients. In this regard, attention has focused on failure to fulfil informational requirements: courts have inverted the onus of proof given the patient's difficulty to provide evidence of non-information or on the basis of the evidence's proximity to the physician rather than the patient. Over the last years these countries have witnessed a significant increase in the number of cases centred around lack of information, including cases where the physician is at fault. For example, in France¹⁶ and in Italy¹⁷ this situation started in 1997, when courts radically changed their orientation, establishing that the onus of proof is on the party that has a specific informational requirement to meet. More so, in France, failure to provide the information means that the physician becomes fully liable for the damage he/she may cause unless the physician is able to prove fulfilment of his/her requirement¹⁸. The principle has been fixed at a legislative level too¹⁹.

In continental Europe, therefore, informed consent has become the centre of tort litigation in medical law. Conversely, in England, the duty of informing plays a somewhat marginal role: no information means no consent, and the consequence is the physician's potential liability under tort of battery. Jurisprudence in England is very reluctant to apply tort of battery in cases of a physicians' responsibility²⁰;

¹⁵ See Hartkamp, A. "Das neue niederländische Bürgerliche Gesetzbuch aus europäischer Sicht." *RabelsZ* 57 (1993): 672 and 679. For a comparative analysis between Netherlands, German and UK see Janssen, A. J. "Informing Patients about Small Risks: A Comparative Approach." *Eur. J. Health Law* 13 (2006): 159 ff.

¹⁶ Cour de Cassation, 25th february 1997. *Dalloz* (1997): IR, 81.

¹⁷ Corte di Cassazione, 24th september 1997, n° 9374, *Mass. Foro it.* (1997).

¹⁸ Cour de Cassation, 11th february 1986, mentioned by Castelletta, A. *Responsabilité médicale. Droits des malades. supra* note 6, at 71. See also Hocquet-Berg, S. "Les sanctions du défaut d'information en matière médical." *Gaz. Pal.* 1998, I doct.: 2 ff.

¹⁹ Art. L 1111-2 Cod. santé publ.

²⁰ *Hills v. Potter* (1983) 3 All ER 716, 728; *Chatterton v. Gerson* (1981) QB 432, 443; *Abbass v. Kenney* (1995) 31 BMLR 157, 163; *The Creutzfeldt-Jakob Disease Litigation, Plaintiffs v. United Kingdom Medical Research Council and another* (1996) 54 BMLR 1; *The Creutzfeldt-Jakob Disease Litigation Group B Plaintiffs v. The Medical Research Council* (2000) Lloyd's Rep Med 161.

damage claims moved against physicians for breach of duty are all actions of negligence²¹. In actions of negligence the onus of proof rests strictly with the claimant and, therefore, with the patient. Attempts to invert the onus of proof²² were strongly rebutted by the House of Lords²³. However, jurisprudence in England has also had to make concessions when faced by stronger request for patient protection: in cases of medical liability the traditional “but for test” was too rigid and led the House of Lords to introduce the criterion of “material contribution to the injury”²⁴. This new legal orientation was triggered by the Court’s will to infer fault from a few elements of fact in favour of the claimant.

Until the 1950s jurisprudence in the United States had closely followed the one in England²⁵. The 1960s witnessed consolidation of the principle of informed consent, as the physician’s diligent duty, breach of which led to liability for negligence²⁶. Under the new orientation, theorisation of the information obligation and search for criteria with which to judge diligence in fulfilling this obligation started. At first, the criterion was identified with compliance to the professional practice of the information provided by the physician in the case in question: this is the so-called professional standard²⁷. However, in the early 1970s a number of courts²⁸ started to give more and more importance to a patient’s autonomous right to decide, shifting the centre of the assessment of the information diligence from the physician to the patient: the lay standard criterion came into being. However, its diffusion and adoption came to a sudden halt with the advent of what is globally

²¹ Grubb, A. eds. *Principles of Medical Law*, *supra* note 2, at 316; *Pfizer Corporation v. Ministry of Health* (1965) AC 512 (HL).

²² *McGhee v. National Coal Board* (1973) 1 WLR 1.

²³ *Wilsher v. Essex AHA* (1986) 3 All ER 801.

²⁴ *Bomington Castings v. Warlow* (1956) AC 613; *Holtby v. Brigham & Cowan (Hill) Ltd* (2000) 3 All ER 421 (CA).

²⁵ *Mohr v. Williams*, 104 N.W., 12 (Minn. 1905); *Pratt v. Davis*, 79 N.E., 562 (Ill. App. 1906); *Schoendorff v. Society of New York Hospital*, 105 N.E., 92 (N.Y. 1914); *Hall v. United States*, 136 F.Supp., 187 and 193 (W.D.La.1955); *Woods v. Pommerening*, 271, P.2d, 705.

²⁶ *Salgo v. Leland Stanford Jr. Board of Trustees*, 317 P.2d, 170 and 181 (Cal. App. 1957); *Natanson v. Kline*, 350, P.2d, 1093 (Kan. 1960); *Mitchell v. Robinson*, 334 S.W.2d, 11 (Mo. 1960).

²⁷ See Prosser, W. & Keeton, W. *The Law of Torts*. 5th ed. St. Paul (Minn.): West publishing, 1984, 182.

²⁸ In this sense see *Canterbury v. Spence*, 464 F.2d, 772 (D.C.Cir. 1972); *Wilkinson v. Vesey*, 295 A.2d, 676 (R.I. 1972); *Cobbs v. Grant*, 502 P.2d, 1 (Cal. 1972).

known as medical malpractice crisis²⁹: between the 1970s and 1980s medical liability litigations increased dramatically, and with it soared the amounts for damages and, hence, the cost of insurance³⁰. Courts abandoned the lay standard, even in its milder reasonable patient standard form, and in many countries the lawmaker was required to intervene to halt the crisis³¹.

III. PROFESSIONAL STANDARD V. LAY STANDARD

The distinction between lay and professional standards is still a popular subject, and may be useful to look into in order to find effective rules to govern new medical law. It is however useful that the contents and limits of the same within the legal system that produced it be established before attempting any theoretical use. In particular, a definition of the two standards must take into consideration the American procedural system and especially the mechanism of interdependence between judge and jury in court decisions³², where the former decides on matters of law and the latter decides on matters of fact.

According to the professional standard the physician must inform the patient of all matters that any other physician with the same experience, skills, specialisations would inform the patient of under similar circumstances. The effect on legal proceedings is that the content of the duty of informing is considered a matter of fact to be determined through a professional opinion³³, which may be provided by a physician from the same medical community or possessing the same specialisation.

²⁹ See, among others, Reder, M. V. "Medical Malpractice: An Economist's Viewpoint." *Am. Bar Found. Res. J.* (1976): 513; Franzki, H. & Franzki, D. "Waffengleichheit im Arzthaftungsprozeß" *NJW* (1975): 2225; Danzon, P. M. "The Effects of Tort Reforms on the Frequency and Severity of Medical Malpractice Claims." *Ohio St. L.J.* 48 (1987): 413.

For a comparative perspective between USA, Canada and Great Britain see Dewees, D. N. Trebilcock, M. J. & Coyte, P. C. "The Medical Malpractice Crisis: A Comparative Empirical Perspective." *Law & Contemporary Problems* 54 (1991): 217 ff.

³⁰ See the reports by the U.S. Bureau of the Census. *Statistical Abstract of the United States*. From the 98th ed. to the 108th ed. Washington, 1977-1990.

³¹ Dobbs, D. B. *The Law of Torts*. St. Paul (MN): West Group, 2001, 631. For a comparative approach see Di Landro, A. R. *La colpa medica negli Stati Uniti e in Italia*, Torino: Giappichelli, 2009.

³² Weiner, S. A. "The Civil Jury Trial and the Law-Fact Distinction." *Cal. L. Rev.* 54 (1966): 1867 ff.; Hazard, G. & Taruffo, M. *American Civil Procedure*. New Haven (CT): Yale University Press, 1993, 72 ff.

³³ For a deeper analysis see Stansfield, M. P. "Malpractice: Toward a Viable Disclosure Standard for Informed Consent." *Okla. L. Rev.* 32 (1979): 868 ff.

In the former case, more than in the latter case, it is easy to suppose that physicians who practice the same medical profession in the same environment be somewhat reluctant to make statements against fellow colleagues, whilst in the second case the fear is that of being discredited before the jury by the defendant's lawyers.

The lay standard is based on accentuating the patient's right to self-determination within the physician-patient fiduciary relationship, which means that the physician must inform the patient so that the patient be put in a position to make a conscientious decision. On a procedural level this translates into an advantage for the claimant since the jury does not need an expert opinion to assess whether or not the physician fulfilled his duties: nobody can ascertain the physician's diligence or negligence and award the case better than a group of citizens³⁴. Clearly, the application of this standard takes power away from lawyers and decreases the physician's position of advantage, bringing uncertainty to the outcome of cases, which outcome, however, lies in the American procedural system, not in the choice of the standard³⁵.

Professional and lay standard criteria have been closely examined by continental European legal theory since the end of the 1980s. The classificatory nature of civil law tradition has carried out a further subdivision within the two standards, breaking each one down into subjective or objective terms³⁶. The outcome of this abstraction exercise is that the professional standard is subjective when, in the assessment of the information's diligence, reference is made to the individual physician; it is objective when the reasonable physician standard is used as an example and the content is generally compared to medical practice or protocols; the patient-oriented standard shall make reference to suitable information for a reasonable patient or for a specific individual patient. This progressive move (professional standard subjective-objective, lay standard objective-subjective),

³⁴ In this sense see Jaeckel, L. B. "New Trends in Informed Consent?" *Neb. L. Rev.* 54 (1975): 66 ff.; Stansfield, M. P. "Malpractice: Toward a Viable Disclosure Standard for Informed Consent." *supra* note 33, 882.

³⁵ Glatz, C. *Der Arzt zwischen Aufklärung und Beratung. Eine Untersuchung über ärztliche Hinweispflichten in Deutschland und den Vereinigten Staaten*. Berlin: Duncker & Humblot, 1998, 96.

³⁶ Giesen, D. *International Medical Malpractice Law*. Tübingen: MohrGiesen, 1988, 271 ff.

highlights the progressive increase in patient protection as the criteria based on professional know-how is weakened.

IV. THE RIGHT TO HEALTH V. THE RIGHT TO SELF-DETERMINATION

Working out a rule at a legislative or class level necessarily requires a choice be made between one of the following four variables, which needs to be taken into account in the confrontation between authorities: lawmaker and laws, medical associations and guidelines. The choice is a question of policy; it's a choice between which interests to protect and has effects on how medicine is conceived.

Whatever the choice, there can be no doubt it will pursue the objective of ensuring the patient has suitable legal protection; however, the objective may focus on the patient's health or on the patient's will. A decision in favour of the professional standard reflects the Hippocratic traditional and paternalistic idea that the physician knows what is best for the patient and that therefore the criteria for assessing his work should be based on the physician's professionalism. Conversely, preference for personal protection and an individual's right to self determination is reflected in the choice of an assessment standard which meets the patient's expectations. This last position has been expressed in three alternative models: the contractual one³⁷, the shared decision one³⁸, and the therapeutic alliance one³⁹.

The alternative conceals the dilemma between the right to health and the right to self determination, or, in other words - to speak in practical terms – between force-feeding and euthanasia. The issue is one of fundamental importance and has a broad spectrum. It encompasses the difficult balance between autonomy and heteronomy, between participation and paternalism. It involves the entire system and is symptomatic of the medical evolution which we mentioned earlier. More so, it would appear that the medical evolution has made this decision no longer deferrable, to the extent that in legal systems where the lawmaker fails to clarify policy in the

³⁷ Engelhardt Jr., H. T. *The Foundation of Bioethics*. 2nd ed. New York: Oxford University Press, 1995.

³⁸ Veatch, R. *The Basics of Bioethics*, 2nd ed. Upper Saddle River (NJ): Prentice-Hall, 2003.

³⁹ Pellegrino, E. D. & Thomasma, D. C. *The Virtues in Medical Practice*. Oxford: Oxford University Press, 1993.

medical sector - simply providing rules without determining the principle or criteria it intends to apply, limiting itself to settle individual questions - runs the risk of being incoherent.

The irresoluteness of lawmaking authorities triggers a system flaw which undermines the principle of legal certainty and weakens the physician-patient relationship, the validity of which becomes somewhat overly dependent on the reasonableness and cooperative will of the parties.

Whilst waiting for legislative interventions to be made, the judicial interpreter is tasked with ensuring clarity on a reconstructive level, searching for new possible intervention instruments that may be recommended to lawmakers.

V. THE EVOLUTION OF INFORMED CONSENT: FROM INFORMATION TO COUNSELLING

In summary, when it comes to medical responsibility, civil law legal systems have moved from tort to contract⁴⁰ and have moved the assessment criterion of medical practice from the professional standard to the lay standard. These changes are directly related to the abandonment of the absolute health concept, which has

⁴⁰ In common law systems the medical law's evolution is based on the reform of the tort law or on the introduction of a no-fault system. For a description of the contest see Harvard Medical Practice Study. *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation and Patient Compensation in New York*. The Report of the Harvard Medical Practice Study To the State of New York (1990).

In relation to the tort reform see Danzon, P. "Tort Reform: The Case of Medical Malpractice." *Oxford Rev. Ec. Pol.* 10 (1994): 84 ff.; McAfee, J. "Medical Malpractice Crisis Factional or Fictional?: An Overview of the Gao Report as Interpreted by the Proponents and Opponents of Tort Reform." *Mich. St. J. Med. & L.* 9 (2005): 161 ff.; but see Mello, M. M. & Brennan, T. A. "Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform." *Tex. L. Rev.* 80 (2002): 1606 f., who observe that "most defensive-medicine studies have failed to demonstrate any real impacts on medical practice arising from higher malpractice premiums," and that any defensive medicine "has diminished over time in response to the growing presence of managed care".

About the alternative solution of a no-fault system see Studdert, D. & Brennan, T. "No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention." *JAMA* 286 (2001): 217; Soleimani, F. "Learning from Mistakes in New Zealand Hospitals: What Else Do We Need Besides 'No-Fault'?" *J. New Zealand Med. Assoc.* 119 (2006): 1239; Hall, M. A., Bobinsky, M. A. & Orentlicher D. *Healthcare Law & Ethics*. 7th ed., New York: Aspen Law & Business, 2007, 379.

The suggestion of a no-fault compensation for medical injuries comes from studies on the New Zealand health system: see Gellhorn, W. "Medical Malpractice Litigation (U.S.)—Medical Mishap Compensation (N.Z.)" *Cornell L. Rev.* 73 (1988): 170 ff.; Davis, P. et al. "Compensation for Medical Injury in New Zealand." *J. Health Pol. Pol'Y L.* 27 (2002): 833 ff.

been replaced by the one of individual wellbeing⁴¹. Under a legal point of view this has taken place through the increasing prevalence of legislative and courts' interventions (and case law) that favour the safeguarding of an individual's right to self-determination over that of the individual's right to his/her health⁴². In the medical field, an individual is guaranteed his/her respect to the right of self-determination by his/her essential consent to receive treatment⁴³. For such consent to be valid the patient needs to be adequately informed⁴⁴. In the physician-patient relationship contracting process that we have witnessed over the last years, the physician's requirement to inform the patient has acquired extraordinary, though fatal, importance: in fact, the informational requirement is the condition for a valid consent, but becomes the instrument by which the risk of an unknown cause is transferred from the patient to the physician⁴⁵: if an unknown cause occurs and the physician has failed to inform the patient of this possible risk, the physician becomes liable for the consequences of non-fulfilment of the obligation to inform the patient,

⁴¹ At the end of the 20th centuries clinicians and policymakers began to recognize the importance of measuring health-related quality of life to inform patient management and policy decisions: see Guvatt, G. H. Feeny, D. H. & Patrick, D. L. "Measuring health-related quality of life." *Ann. Int. Med.* 118 (1993): 622 ff. For a detailed historic survey see Cosmacini, G. *L'arte lunga: storia della medicina dall'antichità ad oggi*. Roma/Bari: GLF editori Laterza, 2011; specific about the Italian history see ---, *Storia della medicina e della sanità in Italia*. Roma/Bari: GLF editori Laterza, 2010; Durante, V. "La salute come diritto della persona." Canestrari, S. *Il governo del corpo*. Milano: A. Giuffrè editore, 2011, 583 ff.

⁴² See Hoerni, B. & Saury, R. eds. *Le consentement, information, autonomie et decision en medicine*. Paris: Masson, 1998 ; Berthiau, D. "Comprendre le principe d'autonomie en droit de la santé." *Mèd. et droit* (2006): 53 ff.; Ferrando, G. "Consenso informato del paziente e responsabilità del medico. Principi, problemi e linee di tendenza." *Studi in onore di Pietro Rescigno*. vol. V. Milano: A. Giuffrè editore, 1998, 201 ff.

⁴³ For the analysis of the influence of the democratic and individualist approach on the concept of informed consent see Graziadei, M. "Il consenso informato e i suoi limiti." Lenti, L. Palermo Fabris, E. & Zatti, P. eds. *I diritti in medicina*. Milano: A. Giuffrè editore, 2010, 12 ff. In France the art. L. 1111-4, par. 3, Code de la Santé Publique codified the principle according to which "aucun acte medical ou aucun traitement ne peut être pratiqué sans le consentement libre et éclairé de la personne."

⁴⁴ To have a concise overview of informed consent from the combined perspectives of a physician, a lawyer, and a social scientist see Applebaum, P. S. Lidz, C. W. & Meisel, A. *Informed Consent: Legal Theory and Clinical Practice*. Fair Lawn (NJ): Oxford University Press, 1987. On this item see also Guige, J. & Esper, C. "Le juge judiciaire et le juge administratif se prononcent sur l'information médical du malade. Convergences ou divergences jurisprudentielles." *Gaz. Pal.* (1997): Doctr. 3 ff.; Todeschini, N. "Responsabilità professionale e dovere d'informazione: dal consenso dis informato al dovere contrattuale di informare." Loré, C. ed. *Tra scienza e società*. Milano: A. Giuffrè Editore, 2008, 295 ff.

⁴⁵ For considerations on the relationship between medical malpractice, risk and assurance see Comandè, G. & Turchetti, G. eds. *La responsabilità sanitaria. Valutazione del rischio e assicurazione*. Padova: Cedam, 2004.

regardless of the diligent fulfilment of the strictly medical activity⁴⁶. We therefore seem to be drifting towards automatic reimbursement for a breach of the right to self-determination, released from the proof of the concurrent harm to the right to health⁴⁷.

This leads to an excessive protection of the patient and to an undue penalisation of the professional, and has produced a harmful unbalance in the positions of the parties. This unbalance has in turn been exacerbated by the tendency of case law and legal theory to relate the physician-patient relationship to the professional-consumer relationship, with a depersonalisation of the interpersonal relationship and a consumerist view of medical services and treatment⁴⁸. The assimilation of the patient to a consumer is based on a recognition of their common asymmetric condition⁴⁹. However, the fact that the physician-patient relationship concerns the health of a human being implies a profound difference between medical services and consumer services. Moreover, a consumerist interpretation of the relationship has led to the following negative consequences⁵⁰: firstly, it has transformed what should be a therapeutic alliance into antagonism; secondly, according to recent studies⁵¹, it is the main cause of defensive medical practice⁵²;

⁴⁶ In this regard see Paradiso, M. "Il dovere del medico di informare il paziente. Consenso contrattuale e diritti della persona." *La responsabilità medica. supra* note 8, at 141; ---, "La responsabilità medica tra conferme giurisprudenziali e nuove aperture." *Danno e resp.* (2009): 712: "il consenso diviene propriamente contrattuale sia perché, quando sia debitamente "informato", diviene idoneo ad addossare (o a trasferire) al paziente il rischio di esiti infausti, sia perché concorre a definire l'oggetto delle obbligazioni del medico e della struttura sanitaria, contribuendo così a delineare l'ambito della responsabilità e gli interessi rilevanti al momento di definire tipo ed entità del risarcimento".

⁴⁷ In the United States some courts have taken a slightly broader view of liability imposing a duty of care where the doctor undertakes to advise the person of his condition and misrepresents or conceals the results [*Hoover v. Williamson* (1964) 203 A 2d 861 (Md CA)] and the advice is relied upon to his detriment [*Heller v. Community Hospital* (1993) 603 NYS 2d 548]. In England the courts are unwilling to shoulder a doctor with the burden of liability where he has not made the claimant's position worse and they may well insist that he has increased the risk of the intermediary harming the claimant: eg, *Hill v. Chief Constable of West Yorkshire* (1989) AC 53.

⁴⁸ Mazeaud, D. "L'attraction du droit de la consommation." *RTD* (1998): Com. 95 ff.

⁴⁹ In Italy the Supreme Court denied the application of the consumer rules in cases of medical malpractice: Corte di Cassazione, ord. 2nd april 2009, n° 8093. *Resp. civ.* (2009): 918 ff. comment by Nardi, S. "Il foro competente per la lite tra struttura sanitaria pubblica e paziente."

⁵⁰ For a deeper analysis see Rousset, G. *L'influence du droit de la consommation sur le droit de la santé*. Paris: Ed. Hospitalières, 2009.

⁵¹ See the report of Cuvette, M. *Il Sole 24 Ore. Sanità*, 22nd-28th march 2011.

finally, it has contributed over the last years to the important increase in medical malpractice disputes and to the huge increase in the costs of insurance.

From this point of view, the information requirement has become a contractual obligation based on detailed and standardised information protocols just like the information leaflets of pharmaceutical products and medicines and informed consent or liability discharge forms⁵³. The means – the requirement to inform – has caught up with and gone beyond the end – the patient’s protection – reaching a point where the trust and solidarity which are the foundations of a good physician-patient relationship are now undermined.

In point of fact, this situation⁵⁴ is explained by the confusion between two levels of reconstruction, a traditional one and a modern one, which in reality are alternatives to each other. To the extent that we subscribe to a paternalistic view, we justify that the physician control every phase of the medical activity⁵⁵, decide on the diagnostic and therapeutic activities and limit himself/herself to comprehensively informing the patient of his/her choices, in relation to which it is fair that under these circumstances he/she assumes all responsibility⁵⁶. In this case the patient’s informed consent is of an authorising nature and the physician’s actions are assessed according to the professional standard⁵⁷ in terms of the respect or violation of the

⁵² Lord Denning was particularly concerned about the risks of defensive medicine: *Roe v. Minister of Health* (1954) 2 QB 66, 86 f.; *Lim v. Camden and Islington AHA* (1979) 1 QB 196, 217; *Whitehouse v. Jordan* (1980) 1 All ER 650, 658. In Italy see the research of the Ordine provinciale di Roma dei Medici Chirurghi e degli Odontoiatri. *La medicina difensiva in Italia in un quadro comparato: problemi, evidenze e conseguenze*. Rome, 2008. U.S. literature distinguishes between the direct costs of the litigation and the indirect costs, such as those associated with the practice of defensive medicine: Studdert, D. M. et al. “Claims, Errors, and Compensation Payments in Medical Malpractice Litigation.” *N. Engl. J. Med.* 354 (2006): 2024 ff.; Sage, W. M. & Kersh, R. eds. *Medical Malpractice and the U.S. Health Care System*. Cambridge: Cambridge University Press, 2006. See also the report *Defensive Medicine and Medical Malpractice*. Washington: U.S. G.P.O., 1984.

⁵³ In Spain art. 4 of the Ley n° 41/2002 has reversed the burden of proof in case of oral information: “Cuando la información se da al paciente de forma oral, será el facultativo interviniente y, en su caso la Administración pública, la que deba acreditar convenientemente que la información recibida por el enfermo ha sido la adecuada, suficientemente clara y extensa” (Vázquez Barros, S. *supra* note 6, at 161).

⁵⁴ The situation is well described by Cathelineau, A. “La notion de consommateur en droit interne: à propos d’une dérive.” *CCC* (1999): 4 ff.

⁵⁵ See Roman, D. “Le respect de la volonté du malade: une obligation limitée?” *RDSS* (2005): 423 ff.

⁵⁶ See Laude, A. & Tabuteau, D. *De l’observance à la gouvernance de sa santé*. Paris: PUF, 2007.

⁵⁷ See Zatti, P. “Il diritto a scegliere la propria salute (in margine al caso S. Raffaele).” *Nuova Giur. Civ. Comm.* (2000): II, 1 ff.

right to health. If, conversely, we subscribe to the prevailing principle of self-determination, then we need to structure the physician-patient relationship in terms of bilateralism and solidarity. In this case, the informational requirement is reciprocal and functional to shared diagnostic and therapeutic decisions, for which each party assumes its relative share of responsibility: as patient (unknown risks related to one's health conditions) and as professional (professional risk). The consent is an act of decision, an expression of the right to self-determination. The physician's actions are assessed on the basis of whether they respect the choices of the patient for the patient's wellbeing according to the lay standard, whilst the actions of the patient are assessed according to his/her cooperation or not towards carrying out the shared treatment programme.

Since the radicalisation of the parties' positions is neither beneficial to one nor the other, and since the situation is disliked by both operators⁵⁸ and users⁵⁹, lawmakers have initiated studies and reforms to intervene on the situation of mounting disputes and the economic and social costs related to the same: effective from March last year, the Italian lawmaker has imposed mediation to resolve medical malpractice disputes⁶⁰; the German lawmaker has funded studies on Scandinavian health systems to try and find alternatives to its own expensive health system⁶¹; the French lawmaker has introduced a number of remedies and allocated the "*aléa thérapeutique*" (or medical risk) to the social budget⁶².

⁵⁸ See the criticising observations of Barni, M. "Sulle obbligazioni del medico: acrobazie e astrattezze giurisprudenziali." *Resp. civ. e prev.* (2007): 1986; and the report of the OTA. *Defensive Medicine: Definition and Causes*. Princeton University (1994): 31 f. http://www.princeton.edu/~ota/disk1/1994/9405_n.html

⁵⁹ See Guignard, L. "Les ambiguïtés du consentement à l'acte médical en droit civil." *RRJ* (2000): 45.

⁶⁰ D.lgs. 2010/n° 28 in force as of 21st march 2011.

⁶¹ Preusker, U. K. *Gesundheitssysteme in Skandinavien im Vergleich zu Deutschland*. Eschborn: Govi-Verlag, 1997; Deutscher Bundestag, *Drucksache* 17/4747, 2011, 7; Hart, D. "Zur Gestaltung einer Fondshaftung für Arzneimittelschäden als Alternative oder Ergänzung zur arzneimittelgesetzlichen Individualhaftung." *MedR* (1996).

⁶² The Loi, 4th march 2002, at the article. L. 1142-1. II, created a plan of amicable settlement and compensation in cases of unforeseeable medical complication: "Lorsque la responsabilité d'un professionnel, d'un établissement, service ou organisme mentionné au I ou d'un producteur de produits n'est pas engagée, un accident médical, une affection iatrogène ou une infection nosocomiale ouvre droit à la réparation des préjudices du patient au titre de la solidarité nationale, lorsqu'ils sont directement imputables à des actes de prévention, de diagnostic ou de soins et qu'ils ont eu pour le patient des conséquences anormales au regard de son état de santé comme de l'évolution prévisible de

Without dwelling upon the peculiarities of each legal system and on the dynamics of the law in practice, I believe that a standard solution to the question could be to recognise the bilateralism of the informational requirement from its contractual point of view and to complete the move from paternalism to the patient's right to self-determination. The instrument that could be used to support the completion of this move and renew the therapeutic alliance between physician and patient is counselling. Counselling is to be understood as a time of meeting and dialogue shared between the physician and the patient: during the counselling the physician explains the strictly technical information to the patient (which technical information should continue to be provided before the meeting in detailed hardcopy form), answers any questions and in turn asks questions⁶³, presents the diagnosis or possible diagnoses and the recommended treatment or treatments according to good medical practice, as well as any possible alternatives. In short, the physician should not only provide information, but should, rather, accompany the patient towards a comprehensive understanding of his/her clinical case and an awareness of the situation and the foreseeable development of the same, so that the patient may, independently, and under his/her own responsibility, make a decision (which may sometimes be restricted, if there are no alternatives, to whether intervene or not) and if the treatment is not successful – not due to a medical error – he/she may be better prepared to accept this is a fatal circumstance and not as a harmful event with a responsible party.

Counselling, however, is not only a pre-ordered way of exchanging information for the purpose of sharing a decision. If this were the case, then counselling would be comparable to the generic exchange of information that the

celui-ci et présentent un caractère de gravité, fixé par décret, apprécié au regard de la perte de capacités fonctionnelles et des conséquences sur la vie privée et professionnelle mesurées en tenant notamment compte du taux d'incapacité permanente ou de la durée de l'incapacité temporaire de travail. Ouvre droit à réparation des préjudices au titre de la solidarité nationale un taux d'incapacité permanente supérieur à un pourcentage d'un barème spécifique fixé par décret ; ce pourcentage, au plus égal à 25 %, est déterminé par ledit décret.”

⁶³ Hart, D. “Der mündige Patient. Patienten als kompetente Partner für die moderne Medizin.” *medgen* 15 (2003): 60 ff.

parties are mutually required to carry out in the pre-contractual phase⁶⁴: counselling falls within the contents of the health service that is provided, to the extent to which it proves helpful for an active and collaborative participation of the patient to the treatment, and is a necessary condition for a correct diagnosis (only patients who are aware of their clinical situation and of the intentions of their physician are able to help him/her in their anamnesis) and for the successful outcome of the treatment (only patients who are aware of the purpose, nature, and limits of a therapy can effectively contribute to its application). This is proven by the fact that information for consent purposes is required before the treatment⁶⁵ while counselling both precedes and follows treatment, accompanying the patient along every phase of it.

Replacing mere information with the more articulated instrument of counselling, which contains and enriches information, achieves a number of objectives concurrently: it preserves the patient's hard won independence, it supports the transposition of the concept of health to the more general concept of wellbeing, it reinforces the therapeutic principle of the physician-patient alliance, leaving the hermeneutic criterion based on the lay standard untouched.

Counselling prevents information and the relative informational requirement from being used in court to broaden the cases of objective liability in the medical field⁶⁶, which cases, in fact, should be confined to ones in the health field, where health services may indeed be treated somewhat like the consumption of goods and services⁶⁷.

A. When to provide information and when to provide counselling?

The fact that the information requirement has ended up going beyond its original purpose and now needs to be somewhat downscaled and fitted into a more

⁶⁴ In Italian literature see, in this sense, Princigalli, A. M. *La responsabilità del medico. supra* note 6, at 213; Bianca, C. M. *Diritto civile. Il contratto*. 2nd ed. Milano: A. Giuffrè editore, 2000, 166 ff.

⁶⁵ See the article L. 1111-2, par. 3, Code de la Santé Publique: "Cette information doit être délivrée au cours d'un entretien individuel."

⁶⁶ See the development of the obligation de sécurité de résultat en France: Laude, A. Mathieu, B. & Tabuteau, D. *Droit de la santé*. 2nd ed. Paris: PUF, 2007, 436 f.

⁶⁷ See Peccenini, F. ed. *La responsabilità sanitaria*. Bologna: Zanichelli, 2007; De Matteis, R. "La responsabilità in ambito sanitario." Visintini, G. ed. *Trattato della responsabilità contrattuale*. vol. II. Padova: Cedam, 2009; Balduzzi, R. *La responsabilità professionale in ambito sanitario*. Bologna: Il Mulino, 2010.

appropriate context, does not necessarily mean it always needs to be replaced by counselling. Let's proceed in an orderly fashion.

In cases that are characterised by diagnostic and therapeutic evidence or requiring a simple diagnosis, merely technical information shall be sufficient.

In cases that are difficult to treat, are incurable or are new under a diagnostic, prognostic or therapeutic point of view, where the risk of error is higher, law tends to relieve the physician from liability so as not to discourage medical intervention⁶⁸. However, it is only in cases of emergency that waiving the principle of informed consent and of the duty to inform the patient are accepted. Conversely, if the patient has an extremely serious clinical situation, is suffering from an irreversible pathologic condition, or has an unknown pathologic condition, then not only is the physician required to inform the patient, but such information should not be limited to communicating the technical-scientific information, but should rather extend to all additional information that the patient needs to have in order to make a conscientious and independent decision.

Ideally, the same should happen for clinical cases that can be treated, but which are characterised by a number of diagnostic and therapeutic alternatives. This exchange between the physician and patient is customary in aesthetic surgery⁶⁹, where the professional needs to clarify every aspect of the result that the customer wishes to obtain, accompanying and sharing with the patient the choice of the outcome itself, and inviting the patient to consider aspects beyond ones of a strictly aesthetic nature.

B. The genetic medicine example

In order to verify the feasibility - as well as the effectiveness - of counselling in the medical field, we need to better define its contours and observe how it is applied in practice. Paradoxically, counselling is governed and its importance has emerged in the regulating of diagnostic tests. Diagnostic tests are less invasive than therapeutic interventions which would suggest that a purely technical information for

⁶⁸ See Diurni, A. "Gli eventi dannosi." Belvedere, A. & Riondato, S. eds. *Le responsabilità in medicina*. Milano: A. Giuffrè editore, 2011, 321 f.

⁶⁹ For an essential reference, Diurni, A. "Gli eventi dannosi." *supra* note 68, at 337 ff.

the purpose of the informed consent would suffice for them. Diagnostic counselling has not, however, taken over for all testing; the counselling requirement only exists in the practice of genetic tests⁷⁰.

Genetic medicine has become particularly important in the medical field because of certain characteristics: these characteristics especially concern the extreme sensitivity of genetic data⁷¹ and the fact that genetic medicine has increased diagnostic possibilities without there having been a matching increase in therapeutic remedies. This means that genetic medicine often lacks the classic symptom-diagnosis-therapy-recovery sequence. Last but not least, there are certain genetic tests that fail to provide useful information or whose results may only be indicative of a predisposition to an illness (predictive tests)⁷², the actual onset of which may depend on unpredictable and uncontrollable factors⁷³. This is why we may compare the diagnosis that follows a predictive genetic test to a proper medical intervention, to the extent that as an “informational intervention” such test results can be psychologically devastating and damaging to the person in question, despite such person having voluntarily chosen to have the test and to be informed of the outcome of it. The uncertainty on the degree of severity of a genetic predisposition to an illness, associated with the impossibility of precisely quantifying the risk of its onset, are highly damaging to a person’s psychological stability. The attention of lawmakers and operators in the sector cannot therefore fail to take this aspect into consideration.

⁷⁰ See Rothman, D. *Strangers at the bedside. A history of how law and bioethics transformed medical decision making*. London: Basic Books, 1991; Macilotti, M. “Consenso informato e biobanche di ricerca.” *Nuova giur. comm.* (2009): 159 ff.; Villani, L. “Biobanche e test rivelatori di informazioni genetiche: spunti di riflessione per un nuovo consenso informato.” *Resp. civ.* (2010): 140 ff.

⁷¹ See, among others, Salter, B. & Jones, M. “Regulating human genetics: the changing politics of biotechnology governance in the European Union.” *Health, Risk and Society* 4 (2002): 325 ff.; Casabona, C. M. R. “La tutela del genoma umano.” Canestrari, S. et al. *Il governo del corpo*. *supra* note 41, at 249 ff.; Stefanini, E. *Dati genetici e diritti fondamentali: profili di diritto comparato ed europeo*, Padova: Cedam, 2008; Ferrando, G. “Il principio di gratuità, biotecnologie e atti di disposizione del proprio corpo.” *Europa dir. priv.* (2002): 761 ff.

⁷² See Memmo, D. “Test genetici, medicina predittiva, privacy.” Cicognani, A. & Pelotti, S. eds. *Il Dna nella società attuale: test genetici, disastri di massa, identificazione criminale*. Milano: A. Giuffrè Editore, 2006, 16 ff.

⁷³ See Dagna Bicarelli, F. “I test genetici.” Canestrari, S. et al. *Il governo del corpo*. *supra* note 41, at 371 ff.

It is precisely as a result of genetic findings that the so-called Personalised Medicine (P-Medicine)⁷⁴ is becoming popular. Personalised Medicine looks at molecular and genetic uniqueness, but also at the patient's individuality, requirements, social and family history, psychological characteristics and ethical and religious beliefs.

It is for these reasons that genetic medicine is at the forefront of a movement to modernise the physician-patient relationship setting, particularly in central Europe, with significant consequences on the concept of medicine. In fact, genetic medicine is the maximum expression of the principle of cooperation between physician and patient and, therefore, of so called modern "talking medicine"⁷⁵. This is proven by a worldwide procedure to access genetic tests, which European and international laws and practices have recognised to be of fundamental importance⁷⁶. Genetic counselling is considered a pre-test must, and post-test counselling is becoming indispensable too. From this perspective we may talk about a counselling-test-counselling procedure.

Under this point of view it would appear that counselling is at the centre of the physician-patient relationship for genetic medicine. In time, law has also come to believe that genetic counselling should play the main role⁷⁷. The most fitting solution, legally adopted by Austria⁷⁸, Switzerland⁷⁹, Spain⁸⁰, Portugal⁸¹, Norway⁸² and

⁷⁴ See Cohen, N. ed. *Pharmacogenomics and Personalized Medicine*. Totowa (NJ): Humana Press, 2008; Jain, K. K. *Textbook of Personalized Medicine*. New York: Springer, 2009.

⁷⁵ See O'Neill, O. "Informed consent and genetic information." *Studies in History and Philosophy of Biological and Biomedical Sciences* 32 (2001): 689 ff.

⁷⁶ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4th april 1997, and the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, Strasbourg, 27th november 2008.

⁷⁷ Conselho Nacional de Ética para as Ciências da Vida (CNECV), opinion n° 56 of the 8th june 2008 to read on page www.cneqv.pt/admin/files/data/docs/1273053928_P_056CNECV.pdf

⁷⁸ Bundesgesetz, mit dem Arbeiten mit gentechnisch veränderten Organismen, das Freisetzen und Inverkehrbringen von gentechnisch veränderten Organismen und die Anwendung von Genanalyse und Genterapie am Menschen geregelt werden (Gentechnikgesetz - GTG), n° 510/1994 http://bmg.gv.at/cms/home/attachments/7/8/8/CH1060/CMS1226929588865/gtg_i_d_g_f_ris.pdf

⁷⁹ Bundesgesetz über genetische Untersuchungen beim Menschen (GUMG) n° 810.12/2004 http://www.admin.ch/ch/d/sr/810_12/index.html

⁸⁰ Ley 14/2007, de 3 julio, de Investigación biomédica, BOE n° 159 (4th july 2007), 28826 ff.

Germany⁸³, would appear to be that of making genetic tests subject to genetic counselling.

1. German and Swiss statutes on genetic counselling

The contents of legislative solutions are however different and conceal different policies. Let's look at two legal systems that are somewhat associated by tradition and language: Germany and Switzerland⁸⁴.

Under the statute on genetic testing of 2004, which came into force in 2007 (Bundesgesetz über genetische Untersuchungen beim Menschen, GUMG), the Swiss lawmaker established that pre-birth and pre-symptomatic genetic tests and genetic tests for family planning must be preceded and followed by documented genetic counselling (art. 14 GUMG). Mandatory genetic counselling is counterbalanced by the law's express recognition of a person's right not to be informed of the result of the test (art. 6 GUMG). The strict nature of the Swiss lawmaker's decision suggests a belief that only providing for preventive genetic counselling as a requirement for genetic testing makes proper and full information to the patient possible, putting the latter in a condition to be aware of his/her right not to be informed of the tests' results and to conscientiously exercise such a right.

German law on genetic diagnosis, Gendiagnostikgesetz (GenDG), has only recently been finalised, with the lawmaker opting for a somewhat less strict procedure. The German lawmaker has differentiated between diagnostic genetic testing and predictive genetic testing. Pre and post genetic counselling is only prescribed for predictive genetic testing, with the patient having a right to expressly renounce to such counselling.

⁸¹ Lei n.º 12/2005, Informação genética pessoal e informação de saúde. Diário da República, I Série-A, n.º 18 (26th january 2005), 606.

⁸² Lov om humanmedisinsk bruk av bioteknologi (Bioteknologiloven) n.º 100/2003 <http://www.lovdata.no/all/hl-20031205-100.html>

⁸³ Gesetz über genetische Untersuchungen bei Menschen (Gendiagnostikgesetz–GenDG) 31st july 2009 www.bundesrat.de/cln_161/nn_8336/SharedDocs/Drucksachen/2009/0301-400/374-09,templateId=raw,property=publicationFile.pdf/374-09.pdf

⁸⁴ For a detailed comparative analysis see Diurni, A. "Esperienze di regolamentazione della diagnostica genetica." *Danno e resp.* (2010): 660 ff.

2. Genetic counselling in the statutes

Under both Swiss and German law, testing is subject to an adequate explanation of test contents, achievable objectives, methodology, and related risks. What is unclear is whether such content represents the information or the counselling.

Under German law the two concepts are separated with specific provisions for each (§ 9 GenDG information, *Aufklärung*; § 10 GenDG genetic counselling, *genetische Beratung*)⁸⁵. However, the legal distinction does not solve the dilemma: when reading the two provisions of law we infer that both relate to genetic testing; however, in the first case the content is explained on a point-by-point basis, whilst in the second case it is described in summary so as to also include the information. In any way, the law provides that the contents of each be documented (§ 9.3 and § 10. 4 GenDG).

Swiss law also does not help distinguish between the two concepts: on the one hand it establishes that the consent must follow sufficient information (art. 5 GUMG); on the other hand, in relation to genetic counselling in general, it lists a number of points that the patient needs to be informed of (art. 14. 3 GUMG), which more or less correspond to those that the German lawmaker had included in the *Aufklärung*.

Evidence of the quick evolution of the two concepts is provided by the first European law on the subject-matter, the Austria's Gentechnikgesetz (GTG) of 1994, which appears to make no significant distinction between the two concepts (§ 69. 1 and 3 GTG).

3. Genetic counselling in practice

Lack of a standardised legal definition of information and counselling means that we need to turn our attention to practice. Information forms, statistically⁸⁶

⁸⁵ Henn, W. "Der Diskussionsentwurf des Gendiagnostikgesetzes." *Ethik in der Medizin* (2005): 34: "Die genetische Beratung bei prädiktiven genetischen Untersuchungen verpflichtend durchzuführen, ist neben der Aufklärung Voraussetzung für die Ausübung des Selbstbestimmungsrechts. (...) Die Beratung geht über die für die Aufklärung erforderliche Vermittlung von Informationen."

⁸⁶ Kommission Qualitätssicherung Genetische Beratung, Berufsverbandes Deutscher Humangenetiker e.V. (BVDH). *medgen* (2006): 229 ff.

distributed or sent to interested parties before the genetic counselling appointment and generally downloadable via internet, provide information on genetic counselling creating a form of interdependence between the two phases: the *Aufklärung* phase is needed to give a general explanation on the nature, content and purposes of genetic testing, whilst the counselling that follows specifically informs the patient about genetic tests. In short, the forms are a type of *Beratungsaufklärung*⁸⁷, in which genetic counselling is defined as a communication process by which the patient who (potentially) is at risk of a genetic illness is informed about all aspects of genetic tests.

That said, in German the two terms *Beratung* and *Aufklärung* are used somewhat interchangeable in medical language, often to specify an aspect of the other term, with the inevitable outcome of creating a terminological confusion⁸⁸. It is unclear whether these are two historically different terms used to express the same concept or whether they are two distinct and autonomous forms of communication with the patient; the option gives rise to different consequences on a juridical level: in the first case we would have only one obligation, whilst in the second case the physician would have two distinct obligations.

A thorough analysis of the theoretical (*rectius*, legislative) and practical application of the terms *information* and *counselling* in the field of genetic testing would suggest a certain similarity in the contents of the two concepts, as well as certain significant differences, essentially relating to characteristics, context and purpose: information would appear to relate to an “ordinary” situation and to be of a somewhat approximate, general and objective nature: counselling would appear indispensable for situations that are uncertain and appears to be characterised by greater accuracy, details and a particular sensitiveness for the condition of the patient. Counselling includes information, but reaches beyond, to a broader and more personal communication setting⁸⁹, where the obligation to inform is bilateral and

⁸⁷ “Richtlinie GfH und BVDH.” *medgen* (2007): 452.

⁸⁸ Deutsch, E. & Spickhoff, A. *Medizinrecht*. *supra* note 5, at 175.

⁸⁹ See Goldim, J. R. “Doenças hereditárias exigem aconselhamento genético” 2010 downloadable www.cienciahoje.pt/index.php?oid=39767&op=all ; Hart, D. “Der mündige Patient. Patienten als kompetente Partner für die moderne Medizin.” *supra* note 63, at 62.

where choices are shared. Information has scientific content, counselling is modelled around the individual patient.

V. CONCLUSIONS

The historical process has already been described and we have also addressed the American crisis and the recent and ongoing increase in medical law litigations in central Europe. Case law – as we have seen – has been increasingly protective of patients, favouring patients by inverting the onus of proof, focusing attention on failure to fulfil the duty of informing, which often actually prevails over medical errors as the cause of medical liability⁹⁰.

However, this “socialisation” of risk runs the risk of bringing down the legal systems. Antidotes to these excesses have been generated more or less spontaneously. In the U.S. legal system the adoption of the professional standard over the lay standard has prevailed, and in certain U.S. states the lawmaker has actually intervened with provisions specifically designed to limit excessive litigation⁹¹. In Europe, starting with France and Germany⁹², a defensive practice has prevailed, centred on the introduction of complex risk management procedures and strict protocols, so that information provided to patients is very accurate, many forms and detailed information leaflets are handed over, and certain treatment⁹³ actually includes a contract accurately describing every step of the surgery, minimum expected results, possible risks etc.

⁹⁰ Santosuosso, A. ed. *Il consenso del paziente: tra giustificazione per il medico e diritto del paziente*. Milano: Raffaello Cortina Editore, 1996; Kuhn, M. “Die Arzthaftung in der Schweiz.” *supra* note 5, at 252; Höftberger, C. “Österreichische Rechtsprechung zur Arzthaftung.” *supra* note 5; Dreifuss-Netter, F. “Feue la responsabilité civile contractuelle du médecin?” *Resp. civ. ass.* 10 (2002): 4 ff.; Spickhoff, A. “Die Entwicklung des Arztrechts 2006/2007.” *NJW* (2007): 1632; Scalisi, A. “Professione medica: doveri, divieti e responsabilità.” *Danno e resp.* (2007): 965; Vázquez Barros, S. *Responsabilidad civil de los médicos*. *supra* note 6, at 119.

⁹¹ Code of Alabama, Title 6: Civil Practice, Sec. 6-5-540; The Alabama Medical Liability Act of 1987, n° 87-189, 261, §1.

⁹² See Nannini, U. G. *Il consenso al trattamento medico: presupposti teorici e applicazioni giurisprudenziali in Francia e Germania*. Milano: A. Giuffrè Editore, 1989.

⁹³ Such as aesthetic treatment. See Cour d’Appel de Paris, 16th june 1995. *Dalloz* (1995): IR, 194; Cour de Cassation, 14th january 1992 n° 90-10.870. *Bull. civ.* (1992): I, 16; Deutsch, E. & Geiger, M. “Medizinischer Behandlungsvertrag” Bundesminister der Justiz eds. *Gutachten und Vorschläge zur Überarbeitung des Schuldrechts*. Köln: Bundesanzeiger, 1982, 1049, 1095.

These efforts do not, however, appear to have improved the situation: on the one hand disputes and insurance costs continue to soar, the practice of defensive medicine is more and more widespread⁹⁴, and physicians and patients do not trust each other. On the other hand, alternative medicine is getting more and more popular, and some observers explain this popularity by the greater attention that alternative medicine gives to listening, to dialogue and to the individual personality of patients. Moreover, preferring alternative medicine to traditional medicine is a choice made by a patient who is fully aware of the higher economic costs and scientific approximation of the former and of the lower legal protection enjoyed by alternative medicine in light of the greater uncertainty of its results.

An alternative to these antidotes appears to be precisely that of turning to the concept of counselling. The exercise here is one of trying to understand the advantages of moving from information to counselling. I believe there are two advantages: one related to the dynamics of medical liability, and another one related to interpersonal dynamics.

Counselling falls within the scope of modernising the physician-patient setting, or the so called “talking medicine”. This medicine opts for a communicative approach and an active participation of the patient to the therapeutic and decision making process, thus moving beyond Evidence Based Medicine⁹⁵. Within this framework, we are able to better identify the legal value of the two terms, information and counselling: on the one hand information refers to the communication of medical data in order to fulfil a unilateral requirement and is the

⁹⁴ See, among others, Esposto, A. G. “Tort Reform, Defensive Medicine, and the Diffusion of Diagnostic Technologies.” *East. Ec. J.* 34 (2008): 141 ff.; Roati, A. *Medicina difensiva e colpa professionale medica in diritto penale: tra teoria e prassi giurisprudenziale*. Milano: A. Giuffrè Editore, 2012. In critic terms Barbot, J. & Fillion, E. “La « médecine défensive »: critique d’un concept à succès.” *Sc. Soc. et Santé* 24 (2006): 5 ff.

⁹⁵ Evidence-based medicine (EBM) has been defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” [Sackett, D.L. et al. “Evidence based medicine: what it is and what it isn’t” *BMJ* 71 (1996): 312]. Nevertheless many aspects of health care depend on individual factors such as quality- and value-of-life judgments, which are only partially subject to quantitative scientific methods. Application of EBM data therefore depends on patient circumstances and preferences, and medical treatment remains subject to input from personal, political, philosophical, ethical, economic, and esthetic values. See also Hart, D. “Evidenz-basierte Medizin und Gesundheitsrecht. Überlegungen zu rechtlichen Konsequenzen der Verwissenschaftlichung der Medizin.” *MedR* (2000): 1 ff.

basis for an informed consent with authorising value. It would thus appear reasonable that the standard to be adopted for the duty of informing be the professional standard. Counselling, on the other hand, applies to all elements – medical, social, ethical and psychological – the patient needs to be able to make a conscientious and responsible decision where several options exist. In this case consent takes on the form of an instruction, the exercising of one's right of self-determination, and therefore it is more reasonable that the lay standard be applied.

The advent of counselling in medical practice is fairly recent and has coincided with the diffusion of new medical practices which involve delicate aspects of human life and end-of-life⁹⁶: in addition to genetic tests, my thoughts go to medically assisted reproduction, organ transplants, and pharmacological and surgical experimentation on seriously ill or terminally ill patients. In fact, based on our observation, it emerges that the physician can limit himself/herself to providing information and acquiring the patient's authorising consent for the simplest diagnostic interventions or for medical situations that are characterised by diagnostic and therapeutic evidence. In these cases variables are fixed by statistical criteria and information can be technical and precise (Evidence Based Medicine)⁹⁷. Conversely, for situations that are new, uncertain and complex under a medical and/or personal point of view, physicians should prefer counselling. In these cases not all variables are controllable, there is more uncertainty and therefore a greater risk margin (P-Medicine).

In high-risk medical operation cases, uncertain and poorly understood situations, particularly difficult or delicate situations, or experimental testing cases, counselling is very important since it can frame the risk that comes with such circumstances within the legal dynamics of the physician-patient relationship,

⁹⁶ Crowley, M. ed. *From Birth to death and bench to Clinic: The Hastings Center Bioethics Briefing Book*. New York: Garrison, 2008: it's a book for journalists, policymakers and campaigns, contains overviews of issues in bioethics. See also Defanti, C. A. *Eugenetica. Un tabù contemporaneo*. Torino: Codice edizioni, 2012; Singer, P. *Practical Ethics*. 3rd ed. New York: Cambridge University Press, 2011; Knoepffler, N. Schipanski, D. & Sorgner S. L. eds. *Humanbiotechnology as Social Challenge. An Interdisciplinary Introduction to Bioethics*. Aldershot: Ashgate, 2007; Pessina, A. *Bioetica: l'uomo sperimentale*. Milano: Mondadori, 2006.

⁹⁷ Kistin, C. J. "Patient Health Literacy and the Practice of Evidence-based Medicine." *Evid Based Med* 17 (2012): 135 f.

balancing the distribution of risk factors between the patient, who takes on the risk of unknown causes, and the physician, who takes on professional risk.

In conclusion, we believe we may state that the difference between information and counselling is that information is aimed at an authorising consent whilst counselling is aimed at an instructing consent. The distinction conceals the conflict between two different medical concepts; it's not only a question of terminology, but rather the point where traditional medicine of information (Evidence Based Medicine) meets the future medicine of counselling (P-Medicine), where a patient's health (professional standard) meets the patient's wellbeing (lay standard), where the right to health meets the right to self-determination, and where the paternalistic approach meets the cooperative one.