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What Medical Risks Should Physicians Disclose to their Patients? Towards a Better Standard in American and French Medical Malpractice Law

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**WHAT MEDICAL RISKS SHOULD PHYSICIANS DISCLOSE
TO THEIR PATIENTS? TOWARDS A BETTER STANDARD IN
AMERICAN AND FRENCH MEDICAL MALPRACTICE LAW**

Alina-Emilia Ciortea*

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ABSTRACT

This essay discusses the historical and evolutionary background of the doctrine of informed consent in medical malpractice cases in order to provide the reader with a detailed and a unique comparative perspective of the law in the United States and in France, along with some cross-references to other legal systems across the globe.

In order to achieve the desired goal, this paper conducts the analysis based on a hypothetical situation. Starting from these facts, the paper shows how and if the American and the French standards addressing the scope of the physician's duty to disclose the risks intrinsic to the procedure draw a proper balance between the two conflicting interests (i.e., the patient and the physician).

Keeping in mind that the principles of medical ethics and human rights should guide the legal development of the doctrine of informed consent, it is proposed, in a non-exhaustive manner, that the addition of two alternative legal standards of disclosure: a "mixed standard" that should embrace into tort law the notion of error, as vice of consent, and the shared-medical decision-making, which involves engaging both the physician and the patient in the process of deciding on the medical treatment or procedure. These innovative solutions protect the patient's ability to obtain the information necessary for an intelligent decision and, at the same time, provide the physician with a clear understanding of what necessary information should be disclosed in order to avoid liability based on the doctrine of informed consent.

Keywords: medical malpractice, doctrine of informed consent, comparative law, information disclosure, American law, French law, shared medical decision-making, new standards of disclosure

INTRODUCTION

“Had I known about the risks, I would have made another choice, but nobody told me. How could I have guessed?” As frequent as this situation might be, it is undeniable that it can be a painful experience when connected to a medical choice.

Think of the following scenario: while cleaning his home on Saturday, Paul fell down and injured his right wrist. Though he is in pain, he is reluctant to run to the emergency room during the weekend. On Monday morning, he seeks medical assistance at the Municipal Hospital, where his arm is x-rayed. Dr. Medicus, the orthopedist, tells Paul that his wrist is broken. “You have two options,” he says. “We can put this hand on a splint or you can have surgery. If you choose not to have surgery, you must rest this hand in a horizontal position for at least four weeks.” Dr. Medicus explains that if Paul chooses surgery, the hand will cure faster, though it might be more painful. Paul does not worry about pain (there are painkillers) but cares about mobility. He decides to have the surgery. Dr. Medicus performs the surgery, apparently successfully, but Paul does not recover completely, even with physiotherapy, he keeps some stiffness in one finger. He goes back to Dr. Medicus, who admits that this is a rare outcome of the procedure but not a usual risk. “Still, you could have told me of the risk,” says Paul. “Well, this is such an unusual development. If I told my patients of all these unusual risks, they would grow such anxiety that they would not survive the anesthesia. I am afraid you will have to live with this finger stiffness, which should not bother you too much unless you are a pianist”

Dr. Medicus lost his good humor hearing Paul tell him that his second job was to play the piano in the local orchestra.

Should Dr. Medicus be held liable for failure to disclose the unusual risk? Should he have guessed that his patient might have been a pianist on the sole account of him having fine hands? As

part of the conversation, did the parties have an opportunity to properly discuss what was at stake, including lifestyle?

All western legal systems are facing these questions, whether they are civil law or common law jurisdictions. Some systems may have it as an issue of tort law; others may consider it under contract law. All of the above will be embraced in this paper.

The standard of disclosure will be explored in two leading common law and civil law jurisdictions: The United States (part I) and France (part II) in order to provide a broad understanding of the doctrine of informed consent¹ in a comparative manner.² One may wonder why the United States and France?

Firstly, in the United States, one of the leading jurisdictions of the common law world, several standards of disclosure have been identified. Some states³ give physicians large discretion in choosing the medical procedure, and as a result the patient's autonomy is severely diminished. In other states, even if the patient has a certain voice, his right of self-determination is not well-protected as it is generally assumed that all patients in similar circumstances assess identically the risks and benefits of a medical procedure. Whether the actual standards of disclosure respond to the needs of the contemporary American society is a dilemma that has its roots in a variety of frameworks, including the ethical and juridical underpinnings of the doctrine of informed consent.

Secondly, in France, a jurisdiction all too famous for its seminal Civil Code, the doctrine of informed consent has evolved gradually and consistently, though not by a Civil Code reform.

1. A definition of the doctrine of informed consent explains it as "a negligent concept predicated on the duty of the physician to disclose to a patient information that will enable him to 'evaluate knowledgeable the options available and the risks attendant upon each' before subjecting the patient to a course of treatment." *See Perna v. Pirozzi*, 457 A.2d 431, 438 (1983).

2. The following part will focus mainly on the development of the physician's duty to inform the patient in these two jurisdictions, but some references to other countries will be made as well in order to enhance the comparative approach.

3. For example, Arizona, Arkansas, Colorado, Florida, Indiana, Maine, Nevada, New York.

Courts had to step in: the *Cour de cassation* ruled, in 1998, that the physician must inform the patient about the serious risks of a medical procedure and the treatment proposed and that this duty exists even if the serious risks occur only in exceptional cases.⁴ What did lawmakers mean by “serious risks” in 1998? What is to be understood by that phrase nowadays? What are the differences and similarities between the French standard and the standards applied in the United States?

It is known that the duty to disclose, implicitly its scope, that rests upon the physician has developed gradually in the United States, as well as in France, in order to meet the evolution of society. This paper discusses the historical and evolutionary background in order to provide the reader with a detailed and unique comparative perspective of the doctrine of informed consent by highlighting that the current standards of disclosure might not be sufficiently evolved to meet the needs of contemporary society.

To achieve the desired goal, based on the hypothetical situation above-mentioned, this paper will show that as society has changed over the last few years in the United States, as well as in France, the patient’s autonomy has become a valuable health care resource. Therefore, the choice of treatment must be the result of a compromise between the patient’s autonomy and the physician’s obligation to act with beneficence toward the patient. The outcome consists of a communication in which the patient and the physician are directly and personally engaged. Hence, part III will focus mainly on discussing two alternative and innovative solutions in order to adequately protect the patient’s ability to obtain the information necessary for an intelligent decision and, at the same time, provide the physician with a clear understanding of what necessary infor-

4. Cass. Civ. 1, 7 October 1998, Bull. Civ. I, no. 287, at 291; JCP 1998, 11, 10179 (concl. J. Sainte-Rose, note P. Sargos).

mation should be disclosed in order to avoid liability based on the doctrine of informed consent.⁵

Though we are aware that the patient may also bring criminal or disciplinary actions against the physician, the paper will focus on civil liability. It will not address the issue of whether the hospital has a (non) duty to obtain the patient's consent. The focus will be on the duty that the physician has to the patient involved in a medical procedure. This paper will only refer to the informed consent of legally competent patients, in normal circumstances of clinical care and not in emergency situations.

I. THE STANDARD OF DISCLOSURE IN THE UNITED STATES

A. *Origins of the Doctrine of Informed Consent*

In the United States, two major legal adjustments have been made to meet the needs of an evolving medical system. In the past, a patient who had been the victim of injury by physicians could file a civil battery lawsuit.⁶ Battery is defined as “an intentional tort that protects a person's interest in being free from physical contact

5. We are not of the opinion that the physician should have indefinite discretion in making a choice for the patient's treatment (as it was considered under the traditional paternalistic approach. For instance, for a presentation of this approach in the Israeli legal system, see Yehiel S. Kaplan, *The right of a Minor in Israel to Participate in the Decision-Making Process Concerning His or Her Medical Treatment*, 25 *FORDHAM INT'L L.J.* 1085, 1086-87 (2002). Therefore, it is mandatory to impose a standard, whether a judicial or a legislative one, in order to consolidate the “partnership” between the physician and the patient. See Leonard J. Nelson III, in 5 *MEDICAL MALPRACTICE* § 22.04 (David W. Louisell & Harold Willians eds. 2016). The traditional paternalistic approach can be seen in Romanian law as well: see Emese Florian, *Discuții în legătură cu răspunderea civilă a personalului medical pentru neîndeplinirea obligației privitoare la consimțământul informat al pacientului*, 8 *DREPTUL* 30, 31 (2008) (Ro.).

6. See *Mohr v. Williams*, 104 N.W. 12, 14-16 (Minn. 1905). In this case, the patient consented to an operation on her right ear. During the surgery, the physician considered that the left ear should be the one operated because it was in a more serious condition and proceeded with the operation on the left ear only. The patient sued the surgeon for the tort of assault and battery based on the theory of lack of consent. The court awarded damages to the patient because she gave no consent to the surgery on the left ear, thus the operation was unlawful.

with his or her person.”⁷ Historically, this course of action was taken due to the fact that the physician failed to obtain the patient’s consent to an invasive course of treatment,⁸ because it was contended that “[t]he physician’s need to obtain the consent of the patient to surgery derived from the patient’s right to reject a nonconsensual touching.”⁹ Therefore, battery was the proper and the efficient cause of action for the protection of the patient’s interest in being free from unconsented touching.¹⁰ The real focus in these early cases was on the right to bodily integrity, rather than on self-determination.¹¹

To conclude, the common law world faced with practical situations in which the physician failed to inform the patient about the risks of a certain medical procedure, had to find an equitable solution for the innocent victim. Wisely using the juridical tools that were available at a certain point in the past, and with the awareness that the law evolves empirically in the United States, the courts decided that, for the time, battery was the appropriate cause of action.¹²

Judge Cardozo’s opinion in *Schloendorff v. Society of New York Hospitals*¹³ adopted a slightly different view and stated that: “[e]very human being of adult years and sound mind has the right to determine what shall be done with his own body.” Thus, the accent was not placed so much on the unwanted touching (meaning

7. FRANK L. MARAIST ET. AL., *TORT LAW: THE AMERICAN AND LOUISIANA PERSPECTIVES* 25 (2d ed. 2015). The United States maintains the old boundary between intentional torts and negligence. *See also id.* at 15. Battery, assault, false imprisonment, intentional infliction of emotional distress, trespass to land, trespass to chattel etc. are, in a common law jurisdiction, included in the category of intentional torts, viewed as a tort theory of recovery for the innocent plaintiff against the intentional tortfeasor.

8. *Matthies v. Mastromonaco*, 733 A.2d 456, 456 (1999).

9. *Id.* at 460.

10. *Id.*

11. Jaime S. King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J. L. & MED. 429, 438 (2006).

12. *Matthies*, 733 A.2d at 460.

13. *Schloendorff v. Society of New York Hospital*, 105 N.E. 92, 93 (N.Y. 1914) (surgeon performing an operation without the patient’s consent).

the lack of consent), which is the very essence of the battery, but rather on the violation of the bodily integrity.¹⁴ Courts noticed that equity requires imposing liability upon physicians, and because the doctrine of informed consent was not yet adopted, the cause of action of battery was a practical alternative. Moreover, generally, physicians did not have the requisite intention to harm patients; rather they failed to provide the necessary information “in the relatively good faith for the benefit of the patient.”¹⁵ Being so, a shift from battery to negligence standard was definitely needed.¹⁶

Later, under the theory of negligence, the doctrine of informed consent may hold the physician liable “regardless of whether the injuries were the consequence of negligence or otherwise.”¹⁷ Negligence is defined as follows: “a conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm. It does not include conduct recklessly disregarding of an interest of others.”¹⁸

The doctrine of informed consent requires that, in the absence of an emergency, the physician must inform the patient about: “(1)

14. *Id.*; the court, in this case, just wanted to impose an absolute duty on physicians to inform patients of what was going to be done. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 49, 52 (2002). This right was not broad enough as it encompassed only the right of refusal. However, the case “neither invited nor required a sophisticated examination of the relationship between disclosure and consent on one hand, and self-determination, on the other.” This approach was “still decades away.”

15. *Id.* at 68.

16. Courts have recognized that “the need for patient’s consent is better understood as deriving from the right of self-determination” rather than an unauthorized touching or bodily integrity. *See, e.g.*, Matthies, 733 A.2d at 460. *See also* KATZ, *supra* note 14, at 69. Jay Katz, an American physician and a law professor, stated a number of reasons why, ordinarily, judges have rejected the theory of battery. Firstly, the inexistence of many defences as a remedy to battery, which might put the physician in a vulnerable position. Secondly, actual medical practice, rather than a judicial theory, is taken into account by judges in order to form the legal standard. Thirdly, the theory of negligence will help physicians liable only for failure to disclose information that would have been provided by other physicians. Last, but not least, the patient in a negligence claim will have a higher burden of proof to make sure no frivolous claims are filed.

17. *Housh v. Morris*, 818 S.W.2d 39, 42 (Tenn. Ct. App. 1991).

18. RESTATEMENT (SECOND) OF TORTS § 282 (A.L.I. 1979) [hereinafter RESTATEMENT].

the diagnosis; (2) the general nature of the contemplated procedure; (3) the risks involved; (4) the prospects of success; (5) the prognosis if the procedure is not performed; and (6) alternative medical treatments.”¹⁹

These broad requirements do not offer a clear and certain standard as to what type of risks the duty to disclose extends. In the interest of finding out the sphere of coverage of this duty and accordingly the correlative interest of the patient to be informed, we will have to use the adjustable legal microscope and examine the “plate” consisting of case law and legislation from different states in the United States.

B. Contemporary Development: The Standard of Disclosure

Most states have generally adopted the negligence theory of the doctrine of informed consent.²⁰ Thus, the patient has a distinct cause of action²¹ under the doctrine of informed consent.²² Still, there are also states in which the action for lack of consent is treated as an action based on battery.²³

19. Nelson, *supra* note 5, at §22.04 (citing *Sherwood v. Danbury Hosp.*, 896 A.2d 777, 778 (2006)).

20. For details, see Nelson, *supra* note 5, at §22.11.

21. Swiss law is another example in which the action for failure to obtain informed consent is a distinct cause of action. See Corrine Widmer Lüchinger, *Medical Liability in Switzerland*, in *MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS* 547, 579 (Bernhard A. Koch ed. 2011).

22. See, e.g., *Willis v. Bender*, 596 F.3d 1244, 1254 (10th Cir. Wyo. 2010) (quoting *Roybal v. Bell*, 778 P.2d 108, 111 n.4 (Wyo. 1989)): “While battery still ‘remains applicable where a treatment or procedure was completely unauthorized . . . negligence principles [now] apply to the more often encountered situation where the treatment or procedure was authorized but the consent was uninformed.’”

23. Pennsylvania is an example of such a jurisdiction. See *Pomroy v. Hosp. of the Univ. of Pa.*, 105 A.3d 740 (Pa. Super. Ct. 2014). Courts decided that “[t]here is no cause of action in Pennsylvania for negligent failure to gain informed consent” by referring to *Kelly v. Methodist Hospital*, 664 A.2d 148, 150 (Pa. Super. 1995). It was also decided that “[l]ack of informed consent is the legal equivalent to no consent” (quoting *Montgomery v. Bazaz-Sehgal*, 798 A.2d 742, 748 (Pa. 2002)).

Without ignoring the states that treat lack of consent as a battery claim, the focus of this paper will be on the right of action for negligence.²⁴ Hence, liability will be imposed if, before engaging into a medical procedure, the physician fails to provide sufficient relevant information in order to enable the patient to give his “intelligent consent.”²⁵ In *Salgo*, a 55 year-old man consulted Dr. Gerbode, a specialist in the surgical treatment of arterial diseases, because he complained about severe cramping pains in his legs.²⁶ Dr. Gerbode told the patient that his circulatory situation was quite serious, but he did not explain to the plaintiff all of the various possibilities of the proposed procedures.²⁷ The physician performed an aortography procedure, which departed, at that time, from the standard of care.²⁸ The surgery went well, but on the following day, both of his legs were in an irreversible paralyzed condition.²⁹ The court in this case did not clarify the standard of care that should be imposed.³⁰ After ruling, Judge Bray stated that “a physician violates his duty to the patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment;”³¹ and he granted discretion to the physicians regarding the necessary facts about which proper information must be given.³²

What are the elements of a *prima facie* case in the common law negligence theory? The plaintiff, *i.e.*, the patient, is required to

24. The theory of battery applies nowadays to situations in which the medical procedure was performed without the consent of the patient. *See Pizzalotto v. Wilson*, 437 So. 2d 859, 863 (La. 1983): “Thus, an unauthorized operation that is skillfully performed still constitutes a battery.” *See also Cobbs v. Grant*, 502 P.2d 1, 8 (1972): “The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented.”

25. *Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170, 181 (1957).

26. *Id.* at 173.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.* at 181.

32. *Id.*

prove as part of the *prima facie* case: the existence of a duty, a breach of that duty, proximate cause or causation, and injury.³³ Regarding causation, the patient has to prove that the physician's failure to provide the requisite information was the proximate cause of the patient's injuries³⁴ and that the patient would have refused to undergo the medical procedure had the information been disclosed.³⁵

Without any intent of minimizing the importance of the other elements of a lawsuit based on lack of informed consent, this paper will focus on the criteria used to measure the physician's duty to disclose information to the patient.

Generally, the standard of care requires physicians to "inform a patient of the dangers of, possible negative consequences of, and alternatives to a proposed treatment or procedure."³⁶ However, how is this abstract standard measured *in concreto*?

In the United States, there are two major lines of cases addressing the scope of the physician's duty to disclose the risks inherent in medical procedures.³⁷

The traditional negligence standard, known also as the "professional standard,"³⁸ is mainly opened to the wisdom and the practical experience of the physicians. Hence, one may say that the patient's autonomy is not well protected. Are there valid arguments to contradict or sustain this statement? How did doctrinal criticism contribute to the development of the doctrine of informed consent?

In recent years, many states have alternatively adopted a new standard, known as the "prudent patient standard."³⁹ Does the new standard adequately protect the patient's interests? What are the predictions for the evolution of this saga? Does this new standard

33. 70 C.J.S. PHYSICIANS AND SURGEONS § 122, 1 (2015). *See also* RESTATEMENT, *supra* note 18, at § 281-282.

34. King & Moulton, *supra* note 11, at 440.

35. *Id.* at 441.

36. King & Moulton, *supra* note 11, at 440.

37. *Id.* at 439-45.

38. Nelson, *supra* note 5, at §22.05.

39. *Id.*

indicate the end of the old controversy or the beginning of a new paradigm?

1. *The Professional Standard*

The professional standard⁴⁰ states that the physician's duty is determined by the prevailing practice in the community. The question is as follows: what would a reasonable physician disclose to a patient under similar circumstances?⁴¹

This standard, also known as the "professional theory,"⁴² has been adopted in many states whether judicially (see for example: Arizona,⁴³ Arkansas,⁴⁴ Colorado,⁴⁵ Indiana,⁴⁶ Maine,⁴⁷ Nevada,⁴⁸ North Carolina,⁴⁹ Texas,⁵⁰ Virginia,⁵¹ Wyoming⁵²) or by statute⁵³ (see for instance: Florida,⁵⁴ Nebraska,⁵⁵ New York,⁵⁶ and Vermont⁵⁷).

When a patient files a lawsuit for breach of informed consent, as part of the *prima facie* case, the plaintiff has to establish the existence of a duty on the part of the physician. This can be achieved

40. Justice Schroeder expressed a rationale for this approach. *See* Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960).

41. Nelson, *supra* note 5, at §22.05.

42. Curran v. Buser, 271 Neb. 332, 711 N.W.2d 562 (2006).

43. McGrady v. Wright, 729 P.2d 338 (Ariz. Ct. App. 1986).

44. Brumley v. Naples, 896 S.W.2d 860, 864 (1995); Fuller v. Starnes, 597 S.W.2d 88 (1980).

45. Gorab v. Zook, 943 P.2d 423, 428 (Colo. 1997).

46. Spar v. Cha, 907 N.E.2d 974 (Ind. 2009).

47. Ouellette v. Mehalic, 534 A.2d 1331 (Me. 1988).

48. Bronneke v. Rutherford, 89 P.3d 40, 45-46 (Nev. 2004); Smith v. Cotter, 810 P.2d 1204 (1991).

49. Starnes v. Taylor, 158 S.E.2d 339 (1968).

50. Sherrill v. McBride, 603 S.W.2d 365 (Tex. App. 1980).

51. Tashman v. Gibbs, 556 S.E.2d 772, 778-779 (2001).

52. Roybal v. Bell, 778 P.2d 108 (Wyo. 1989); Willis v. Bender, 596 F.3d 1244, 1255 (10th Cir. 2010).

53. There are jurisdictions in which the legal requirements of the doctrine of informed consent have been developed in case law as well as in statute. *See, e.g.,* for Swedish law, Lüchinger, *supra* note 21, at 547, 579.

54. FLA. STAT. ANN. § 766.103 (West 2012).

55. NEB. REV. STAT. ANN. § 44-2816 (2014).

56. N.Y. Pub. Health L. § 2805-d(1) (2014).

57. VT. STAT. ANN. tit. 12, § 1909(a)(1) (2014).

by proof that a “reasonable prudent practitioner” acting in the physician’s position, would have provided additional information. As the physician failed to disclose sufficient relevant information to the patient, he breached his duty.

How the physician discharges his obligation to inform the patient is “primarily a question of medical judgment.”⁵⁸ Therefore, the courts held that the patient has to prove that a professional custom exists (hence, the defendant’s departure from that standard) by relying on medical expert testimony.⁵⁹ The rationale for this approach: establishing that a physician breached his duty is rarely “sufficiently obvious as to lie within common knowledge.”⁶⁰

The professional standard is said to have two main justifications.⁶¹ Firstly, because disclosure of the risks is regarded as a professional judgment, it is contended that the physician is in the best position to estimate the effects of the disclosure of certain risks on the patient.⁶² Secondly, the physician cannot afford to waste time in order to inform the patient about every possible risk to protect himself from liability.⁶³

Courts have criticized the professional standard because it provides unlimited discretion to the physician.⁶⁴ Furthermore, some object that the standard “undercuts the value of autonomy”⁶⁵ of the patient, which stands as one of the foundations of the doctrine of informed consent.⁶⁶

What would be the result if the professional standard was applied to the hypothetical case presented above? If the physician

58. Natanson v. Kline, 350 P.2d 1093, 1106 (1960).

59. See, e.g., Copenhaver v. Miller, 537 So.2d 198, 200 (Fla. Dist. Ct. App. 2d Dist. 1989) (citing Public Health Trust of Dade County v. Valcin, 507 So.2d 596 (Fla. 1987)).

60. Woolley v. Henderson, 418 A.2d 1123, 1130 (Me. 1980) (citing Cox v. Dela Cruz, 406 A.2d 620, 622 (Me. 1979)).

61. Nelson, *supra* note 5, at §22.04.

62. *Id.*

63. *Id.*

64. See Cobbs, 502 P.2d 1, 10.

65. Nelson, *supra* note 5, at §22.04.

66. *Id.*

does not have knowledge of the patient's preferences and lifestyle, then it is more probable than not, taking into consideration the cases discussed in this section, that the custom in the medical field would have dictated that the physician, Dr. Medicus, did not have the duty to disclose the risk of nerve damage. This is because it represented a minor risk to the medical community and it was too remote in regard to the medical procedure performed. For example, there are many serious risks associated with a medical invasive procedure that are required, by the medical custom, to be disclosed: infections, bleeding, side effects to anesthesia, etc. Disclosing every single risk of the procedure, regardless of how remote and unlikely it is to occur, would likely result in constant refusal of treatment. Such behavior of the patients is not desirable in a modern and developed society. However, in case the patient communicates his preferences and lifestyle, then the physician might be under customary obligation to disclose even the unusual risks associated with the information provided by the patient. Taking into account that Paul, due to anxiety and stress, might not have communicated efficiently his preferences, it is difficult to say whether Dr. Medicus would have disclosed the risk of stiffness of one finger. Whereas this standard protects the physician from liability, it does not provide an adequate tool for the respect of the patient's autonomy. However, even if Paul informed Dr. Medicus about his second job as a pianist, it would be very hard for the plaintiff to prove the existence of a professional custom (admitting that such custom exists), which would impose on the physician the disclosure of such risks. Should society, *i.e.*, the policy makers and the judges, allow such unfairness? Perhaps this was one of the reasons that the law evolved over time and a new standard was developed.

2. *The Prudent Patient Standard*

Under the prudent patient standard, the physician's duty to disclose is determined by the information needs of a prudent patient in similar circumstances.⁶⁷ The patient's needs are "the information material to his decision"⁶⁸ to undergo a proposed therapy.

The plaintiff is not required to present expert testimony in order to establish a professional standard⁶⁹ (under the duty element), as part of the *prima facie* case.⁷⁰ Consequently, the patient must show that "the probability of the type of harm is a risk which a reasonable person would consider in deciding on treatment"⁷¹ or the jury must determine, based on the "credibility of the plaintiff's testimony"⁷² whether he would have refused the treatment, had he been informed about the risks of the medical procedure.⁷³ Correspondingly, the determination of materiality is a question for the trier of fact and does not require expert testimony.⁷⁴

In order to determine whether particular information is material to the decision of the patient, the courts have utilized two standards: the objective or the subjective patient-based standard.⁷⁵

a. *The Objective Patient-Based Standard*

In 1972, the courts of the United States elaborated a new standard—the prudent patient objective standard—in two landmark cases.

67. Nelson, *supra* note 5, at §22.05.

68. Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cir. 1972).

69. For the need of the elimination of expert testimony with respect to the standard of care, see Canterbury, 464 F.2d at 783.

70. Nelson, *supra* note 5, at §22.04.

71. Britt v. Taylor, 852 So. 2d 1128, 1135 (La. Ct. App. 2003).

72. Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979).

73. *Id.*

74. Marsingill v. O'Malley, 128 P.3d 151, 158 (Alaska 2006). However, we have to stress that there is still a need for expert medical testimony with regard to the "existence and nature of the risk as well as the likelihood of its occurrence." See Nelson, *supra* note 5, at §22.04.

75. *Id.* at §22.05.

This approach was firstly adopted in *Canterbury v. Spence*.⁷⁶ The facts presented a nineteen-year old boy who had experienced severe pain between his shoulder blades.⁷⁷ The patient underwent surgery.⁷⁸ A day after the operation, the lower half of his body was paralyzed and he had to be operated.⁷⁹ However, he remained paralyzed in the bowel region and had urinal incontinence.⁸⁰ The plaintiff contended that the physician had failed to perform his duty to inform him about any risk of paralysis from the procedure.⁸¹ He brought a negligence suit, claiming that the physician failed to disclose the risks necessary to allow the patient to make an informed consent relating to the medical procedure.⁸² Judge Robinson questioned the feasibility of the professional standard, and reached the conclusion that it had to be replaced with another standard that will give patients a larger role in determining whether to undergo a certain medical procedure.⁸³

According to the objective patient-based standard, the scope of the standard is “not subjective as to either the physician or the patient.”⁸⁴ The test whether a particular risk must be disclosed to the patient is “its materiality to the patient’s decision,”⁸⁵ meaning that all risks that might influence the decision must be revealed.⁸⁶ The materiality of the standard is defined as what “a reasonable person, in what physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster the risks in deciding whether or not to forego the proposed therapy.”⁸⁷

76. *Canterbury*, 464 F.2d at 772.

77. *Id.* at 776.

78. *Id.* at 777.

79. *Id.*

80. *Id.*

81. *Id.* at 778.

82. *Id.*

83. *Id.* at 786.

84. *Id.* at 787.

85. *Id.* at 786.

86. King & Moulton, *supra* note 11, at 442.

87. *Canterbury*, 464 F.2d at 787 (quoting Jon R. Waltz & Tomas W. Scheuneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628, 639-40 (1970)).

The court in *Canterbury* expressed the need for a change with respect to the standard of disclosure. Firstly, it held that “the patient’s right of self-decision shapes the boundaries of the duty to reveal.”⁸⁸ Secondly, the court finds “formidable obstacles”⁸⁹ to accept that the duty to disclose is limited by the custom in the medical practice.⁹⁰ To sustain this statement, Judge Robinson contended that “a professional consensus on communication of option and risk information to patients is open to serious doubt.”⁹¹ Moreover, the court acknowledged the deficiency of the professional standard that “physicians may or may not impose upon themselves.”⁹² In conclusion, the court calls for a “standard set by law rather than one which physicians may or may not impose upon themselves”⁹³ in order to respect the patient’s right of self-determination.⁹⁴

Then, *Canterbury v. Spence* was followed by *Cobbs v. Grant*.⁹⁵ The facts in this case suggest that a patient had his spleen removed after it had been injured in a previous surgery that was performed because of the plaintiff’s duodenal ulcer.⁹⁶ The plaintiff filed a suit claiming that the physician failed to disclose the inherent risk of the initial surgery, which led the patient to give a “vitiating consent” to the procedure.⁹⁷ The court held that “an objective test is preferable: i.e., what would a prudent person in the patient’s position have decided if adequately informed of all significant perils.”⁹⁸

88. *Id.* at 786.

89. *Id.* at 783.

90. *Id.*

91. *Id.*

92. *Id.* at 784.

93. *Id.*

94. *Id.*

95. *Cobbs v. Grant*, 8 Cal. 3d 229 (1972).

96. *Id.* at 234.

97. *Id.* at 235.

98. *Id.* at 245.

This standard was aimed at protecting the patient's autonomy⁹⁹ and, at the same time, at assuring that physicians are not exposed to "the whims and idiosyncrasies of individual patients."¹⁰⁰ However, the objective patient-based standard assumes that all patients assess the risks and benefits of a medical procedure similarly,¹⁰¹ which is obviously far from true.¹⁰²

Moreover, in *Canterbury*, Judge Robinson distinguishes between "the special and general standard aspects of the physician-patient relationship"¹⁰³ for the purpose of the duty to disclose. On the one hand, when a physician has to make a medical judgment (in which case the special standard controls), the court in *Canterbury* gives "great deference to the physicians' decisions."¹⁰⁴ On the other hand, the court does not give further indication on how medical judgment is defined or what criteria should be used in order to distinguish between medical and non-medical judgments.¹⁰⁵ Then, we ask ourselves: did the law really get to the point where the self-determination of the patient is well protected and the physician is given rigorous standards to rely on in order to avoid medical liability? Maybe some more steps need to be taken.

Applying the objective patient-based standard to the hypothetical, the plaintiff will not be required to prove, by medical experts, the existence of a standard of care. However, even if the burden of proof seems to be lighter, a reasonable person would be unlikely to

99. However, there is also an opposite opinion expressed in the doctrine. See, e.g., KATZ, *supra* note 14, at 76.

100. See King & Moulton, *supra* note 11, at 443, 458. Although the physician might seem to be protected if the objective patient-based standard is applied, such a conclusion might be deceitful. There are some difficulties on the part of the physician to know *a priori* what does a reasonable patient expect to be informed about before he gives his consent to a medical procedure. Thus, "the idea that all physicians and patients drew the same bright lines distinguishing those 'material' risks from 'immaterial' risks is misleading."

101. *Id.* at 443.

102. See KATZ, *supra* note 14, at 76: "The belief that there is one 'reasonable' or 'prudent' response to every situation inviting medical intervention is nonsense, from the point of view of both the physician and the patient."

103. *Canterbury*, 464 F.2d at 785.

104. King & Moulton, *supra* note 11, at 443.

105. *Id.*

attach so much significance to the minor loss of the finger's mobility. For Paul, the patient who plays in the local orchestra, the unwanted outcome of the procedure affects his life, thus the risk of loss of mobility would have been, for him, a relevant one, that should have been disclosed by the physician prior to the procedure. Under these facts, if the patient would file a suit, it is likely that he would not receive compensation because the physician did not breach the standard of care established on the basis of a reasonable patient. A reasonable patient might have placed more importance on the element of fast recovery, rather than on the particular risk that was not disclosed. Hence, this example shows that there are no black or white risks, but in lieu that the "risks exist only in shades of grey."¹⁰⁶

b. The Subjective Patient-Based Standard

In 1979, in *Scott v. Bradford*,¹⁰⁷ Justice Doolin of the Oklahoma Supreme Court established a subjective patient-based standard, which was aimed at enhancing the patient's autonomy, as "the law does not permit a physician to substitute his judgment for that of the patient by any form of artifice."¹⁰⁸

Under a subjective patient-based standard, the physicians could be held negligent for failing to obtain an informed consent if the plaintiff is able to prove that knowing the material risks would have made him refuse to undergo the medical procedure.¹⁰⁹ Hence, the material risk is the one that would "be likely to affect a patient's decision."¹¹⁰

106. *Id.* at 449 (citing August Piper, Jr., *Truce on the Battlefield: A proposal for a Different Approach to Medical Informed Consent*, 22 J.L. MED. & ETHICS 301, 303).

107. *Scott v. Bradford*, 606 P.2d 554, 556 (Okla. 1979). The facts of the case state that the plaintiff's wife underwent surgery for removal of the uterine tumors that she had developed. The plaintiff contended that the physician did not disclose the risks involved or available alternatives to surgery.

108. *Id.*

109. King & Moulton, *supra* note 11, at 443.

110. *Scott*, 606 P.2d at 558.

The Oklahoma Supreme Court rejected the “reasonable patient standard” in favor of a subjective approach, in order to adequately protect the injured patient.¹¹¹ The objective patient-based standard, although it was at that time the rule of the majority, has been criticized by commentators arguing that a particular patient, after being given a proper disclosure of the risks, would have declined the therapy proposed, and a reasonable person in similar circumstances would have consented, then the patient’s right of self-determination is “irrevocably lost.”¹¹²

The merit of the subjective patient-based standard stands for the fact that it focuses on the particular needs of each patient, requiring the physician to disclose the peculiar risks which that patient, in that position, in that moment would consider “material” for his decision to undergo the therapy.

However, the subjective patient-base standard was criticized because it eliminated the protection (if any)¹¹³ that the physicians were benefiting from with regard to the objective standard, as the latter required them to disclose “only what a ‘reasonable’ patient would want to know.”¹¹⁴ Furthermore, it was contended that the subjective standard might preclude recovery for lack of proper disclosure if the patient died after the medical procedure was done.¹¹⁵ Moreover, even if the subjective standard best reflects “the ethical and legal foundation”¹¹⁶ of the doctrine of informed consent, it fails because it lacks the certainty that physicians need to properly perform their tasks regarding the disclosure of the material risks.¹¹⁷ How could the physician predict the information that the patient would consider relevant? However, because the physician is rarely able to anticipate the values and the preferences of the particular

111. King & Moulton, *supra* note 11, at 443-44.

112. Scott, 606 P.2d at 559.

113. For details, *see supra* note 100 and accompanying text.

114. King & Moulton, *supra* note 11, at 443.

115. *Id.* at 444 (*citing* *Ashe v. Radiation Oncology Assocs.*, 9 S.W.3d 119, 122 (Tenn. 1990)).

116. *Id.* at 445.

117. *Id.*

patient, the law should not put such a burden on the practitioners of Hippocratic medicine.

Does the subjective patient-based standard provide a better solution to the hypothetical case that was exposed previously? The risk of having the finger's mobility reduced, for Paul, a piano player at the orchestra, is definitely a relevant one to be taken into consideration when consent is given. Thus, under this standard, the patient would recover under the doctrine of informed consent for the physician's failure to disclose the risk. However, if the physician is new in town and does not know and has no reasons to know that Paul is a piano player (and therefore, the risk is deemed to be material for the patient), should the law impose an omniscient knowledge on Dr. Medicus in order to protect the patient's autonomy? We hold the opinion that the policy behind every law (where two different interests are conflicting) is to draw a proper balance in order to achieve a feasible solution. Nevertheless, how should this be done?

II. THE STANDARD OF DISCLOSURE IN FRANCE

Based on the ideas expressed by Portalis in a famous speech,¹¹⁸ one may argue that changes in society, *i.e.*, practice of medicine, should have an echo in the legal evolution and this should apply to the doctrine of informed consent.

This part will focus on the country of good pastries and delicious wine in order to illustrate how the "codified law"¹¹⁹ responds

118. Jean-Étienne-Marie Portalis, *Discours préliminaire du premier projet de Code civil* (2014), <https://perma.cc/E3WB-ER57> (last visited Feb. 9, 2016).

119. Even if Anglo-American private law shows some repugnance with respect to the concept of codification (*see, e.g.*, Robert A. Pascal, *A Summary Reflection on Legal Education*, 69 LA. L. REV. 125, 133 (2008)), Simon Taylor stresses that "[c]odification of the patient's rights to information in France should have a symbolic role in promoting the position of the patient in his relationship with the medical professional." *See also* Simon Taylor, *Cross-Border Patients and Informed Choices on Treatment in English and French Law and the Patient's Rights Directive*, 19 EUROPEAN JOURNAL OF HEALTH LAW 467, 474 (2012). On the other hand, the author mentions that this "symbolic and didactic role for the patients" is much more difficult to see in English case law.

(or not) to the needs of the contemporary society, *i.e.*, the special relationship between the physician and the patient with respect to the standard of disclosure present in the doctrine of informed consent.

One may feel the need to establish the type of liability that the physician is held to in case he fails to perform the duty to disclose the necessary information to the patient. Considering this issue, the French law had an interesting development.

To begin with, under French law, physicians were held liable under tort law (fault-based liability).¹²⁰ Then, after the 1936 ruling of the *Cour de Cassation* in the famous case, *Mercier*,¹²¹ the medical malpractice liability, in the private sector, was viewed as a “matter of contract law.”¹²² Under this theory, the physician’s obligation was “not described as an obligation of result (*obligation de résultat*),”¹²³ but as an obligation of means (*obligation de moyens*).¹²⁴ Thus, the physician had to comply with the *Mercier* test, which provides that the doctor must act with “attentive and conscientious care and, subject to exceptional circumstances, consistent with established scientific knowledge.”¹²⁵ The practical distinction between the obligations of result¹²⁶ and the obligation of means¹²⁷

120. Florence G’Sell-Macrez, *Medical Malpractice and Compensation in France. Part I: the French Rules of Medical Liability since the Patients’ Rights Law of March 4, 2002*, 86 CHI.-KENT L. REV. 1093, 1096 (2011). By that time, physician’s liability was based on article 1382 of the French Civil Code. Article 1382 is found in “Title IV. Obligations Arising Without Agreement, Chapter II. Delicts and Quasi-Delicts: Every act whatever of man that causes damage to another, obliges him by whose fault it occurred to repair it,” translated in Legifrance translations <https://perma.cc/G9VV-5NN8> (last visited Apr. 1, 2016).

121. Cass. Civ. 1, 20 May 1936, D.P. I 1936, 1, 88 (concl. Matter, rapp. L. Josserand); GAZ. PAL. 1936, 2, 41 (note A. Besson).

122. G’Sell-Macrez, *supra* note 120, at 1096.

123. Olivier Moréteau, *France*, in EUROPEAN TORT LAW 2010 175, 177 (Helmut Koziol & Barbara C. Steininger eds., de Gruyter 2010).

124. *Id.*

125. *Id.* This test was later enshrined in the Code de la Santé Publique [Public Health Code] (Fr.) arts. R 4127-32 by Decree no. 2004-802 of July 29, 2004.

126. An obligation of result exists “whenever the performance or object of the performance is so precisely determined as to amount to a definite result to be achieved.” ALAIN A. LEVASSEUR ET AL., LOUISIANA LAW OF OBLIGATIONS: A

is that, while in the first situation it suffices for the obligee (the patient) to prove that the result has not been attained, in the latter case, the patient has to show that the physician acted with negligence, which is a more difficult burden of proof.¹²⁸

The analysis of the physician's failure to inform the patient under contractual theory of liability is not unknown to United States law. However, the courts hold that it is unlikely that the physicians will guarantee a certain result of a medical procedure,¹²⁹ thus enter into a contract with the patients. Even so, there are cases in which the court found that a contractual link was created by the physician-patient relationship.¹³⁰ Hence, the breach of the physician's duty was treated as a breach of contract.¹³¹

In 2010, the *Cour de Cassation*¹³² held the physician liable for failure to inform the patient based on article 16, 16-3 paragraph 2, and article 1382 of the Civil Code.¹³³ Thus, it appears that the liability of the physician is based on tort law (article 1382, liability for fault), rather than on a contractual basis (which has been the rule since the *Mercier* case in 1936).¹³⁴

The impact of the 2010 *revirement de jurisprudence* (or overruling) was thought not to have "a major practical consequence."¹³⁵ In supporting this argument, it was contended that, except for the prescription issues regarding bodily injury that have

METHODOLOGICAL & COMPARATIVE PROSPECTIVE, CASES, TEXTS AND MATERIALS 41 (Carolina Acad. Press 2013).

127. *Id.* An obligation of means or diligence can be defined as a situation "when an obligor is expected to use the best possible means available to him, or to act with outmost care and diligence in the performance of his obligation but without guaranteeing a definite result."

128. HENRI MAZEAUD ET. AL., *LEÇONS DE DROIT CIVIL, OBLIGATIONS* 13-15 (9th ed., Montchrestien 1998).

129. *Sullivan v. O'Connor*, 296 N.E.2d 183, 186 (Mass. 1973).

130. *Hawkins v. McGee*, 146 A. 641, 643 (N.H. 1929).

131. *Id.*

132. Cass. Civ. 1, 3 June 2010, Bull. Civ. I, no. 573; D. 2010, 1522 (note P. Sargos).

133. See English version, available at <https://perma.cc/G9VV-5NN8> (last visited Apr. 1, 2016).

134. Moréteau, *supra* note 123, at 177.

135. *Id.* at 178.

already been eliminated under the Law of March 4, 2002 (also known as the Patients' Rights Law¹³⁶), the patient's burden of proof did not change. Thus, the plaintiff still has to provide evidence of the negligence on the part of the physician,¹³⁷ similar to the situation in which the patient has to prove that the physician did not execute his contractual obligation of means.¹³⁸

A. What is the Legal Basis for the Duty to Inform?

In France, the Civil Code "is phrased in the form of general rules"¹³⁹ and special provisions can be found in other codes, such as the Public Health Code (*Code de la santé publique*) or statutes that cover specific areas of law. The "positive law," meaning the law enacted by the legislature,¹⁴⁰ should be seen in the view of jurisprudence.

136. *Id.* Loi 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé [Law 2002-303 of March 4, 2002, on Patients' Rights and the Quality of the Health System], [hereinafter the Patients' Rights Law of March 4, 2002] which was incorporated into the Code de la Santé Publique [Public Health Code]. The law aimed at unifying the medical malpractice liability rules, regardless if one party belongs to the private or to the public sector.

137. The question of causation as an element of the *prima facie* case of negligence can be posed differently in distinct civil law jurisdictions. For example, in Austria, the patient cannot recover if the defendant can prove that he would have undergone the medical procedure had he known all possible risks and complications thereof. See Lüchinger, *supra* note 21, at 1, 29, 547, 579. This element is also known as "the hypothetical consent" in Swiss law. However, in France, the difficulty in establishing the causal link has been reduced by the French courts' adoption of the notion of "loss of chance." Taylor, *supra* note 119, at 477-78. Actually, French courts have changed the notion of the injury in order to meet the standard of causation. Commentators of the French case, Cass. Civ. 1, 3 June 2010, *supra* note 132, seem to be uncertain of the need for the Supreme Court to award compensation for any failure to inform the patient (See, e.g., Patrice Jourdain, *Le manquement au devoir d'information médicale cause un préjudice qui doit être réparé (revirement de jurisprudence)*, RTDCiv 2010, 571, 573).

138. See *supra* note 126 for the definition of the obligation of result; see also *supra* note 127 for the definition of the obligation of means.

139. Olivier Moréteau, *Codes as Straight-Jackets, Safeguards, and Alibis: The Experience of the French Civil Code*, 20 N.C.J. INT'L L. & COM. REG. 273, 274 (1995).

140. *Id.* at 276.

For the first time, the duty to inform was imposed on the physician by the *Cour de Cassation* in the *Teyssier* decision.¹⁴¹ The court stated that the physician has to, except for emergency cases, obtain an informed consent prior to the surgery.¹⁴² This duty is imposed in accordance with the respect given to the human being. If the physician violates the duty to disclose, he will be held liable.¹⁴³

In 2001, the *Cour de Cassation*¹⁴⁴ held that the duty to inform the patient has its fundament in the requirement to respect the constitutional principle of the human dignity.¹⁴⁵ Even though the French Constitution does not contain *expressis verbis* the physician's duty to disclosure, the principle of human dignity derives its constitutional value from the preamble's reference to the Declaration of the Rights of Man and the Citizen.¹⁴⁶

Moreover, article 16 of the Civil Code,¹⁴⁷ states that the law interdicts the infringement of the person's dignity and guarantees respect for the human being from the beginning of his life.¹⁴⁸

141. Cass. Civ. 1, 28 January 1942, D. 1942, 63. Teyssier, a professional driver, was injured in a car accident. At the hospital, he was diagnosed with a broken left hand. There were two surgical procedures to choose from: treatment by plaster cast and osteosynthesis. The latter operation was performed. The outcome was not favorable to the patient, as he developed high fever and other complications which imposed the amputation of the hand. There was no breach with respect to the standard of care for the performance of the surgery. However, the court held that the patient should have been informed about the consequences of the surgery in order for him to be able to give his consent. Thus, the physician was held liable for the failure to provide the information necessary to the patient.

142. *Id.*

143. *Id.*

144. Cass. Civ. 1, 9 October 2001, Bull. Civ. I, no. 252; D. 2001, 3470 (note D. Thouvenin).

145. Pierre Sargos, *Portée d'un revirement de jurisprudence au sujet de l'obligation d'information du médecin*, D. 2001, 3470.

146. The Preamble of the 1958 French Constitution states that: "The French people solemnly proclaim their attachment to the Rights of Man and the principles of national sovereignty as defined by the Declaration of 1789 . . ." *translated in* CONSTITUTION OF OCTOBER 4, 1958, <https://perma.cc/HG2X-9JNL> (*Conseil constitutionnel*) (last visited Mar. 6, 2016).

147. This article did not exist at the time of *Teyssier*, as it was first enacted in 1994.

148. C. Civ. art. 16 (Fr.), available at <https://perma.cc/2BSW-2CXN> (last visited Mar. 6, 2016). Article 16 is found in Book I of Persons, Title I of Civil Rights, Chapter II of the Respect of the Human Body and states the following:

Additionally, article 16-3 of the Civil Code¹⁴⁹ shows that the inviolability of the human body is not absolute. Thus, exceptions such as “in case of medical necessity for the person or exceptionally in the therapeutic interest of others” may be regarded as legitimate. However, because these are exceptions to the general rule presented in article 16, these situations have to be interpreted narrowly.

The presence of the people’s guarantees, both in the Constitution and in the Civil Code, shows the important role that the human being plays with respect to the legislation. Furthermore, it highlights that the physician cannot be confined to a technician role in which he just respects the rules of the medical field without any consideration regarding the patient.¹⁵⁰

B. The Patient’s Right to Information

Even before the enactment of the Patients’ Rights Law, there was a *jurisprudence constante*,¹⁵¹ which imposed on physicians a heavy duty to inform the patient.¹⁵² In France, the patient’s right to information was given legislative value by the enactment of the

“Legislation ensures the primacy of the person, prohibits any infringement of the latter’s dignity and safeguards the respect of the human being from the outset of life.”

149. C. CIV. art. 16-3 (Fr.), available at <https://perma.cc/2BSW-2CXN> (last visited Mar. 6, 2016). This article is found in Book I of Persons, Title I of Civil Rights, Chapter II of the Respect of the Human Body and states the following:

There may be no invasion of the integrity of the human body except in case of medical necessity for the person or exceptionally in the therapeutic interest of others (Act no. 2004-800, Aug. 6, 2004). The consent of the person concerned must be obtained previously except when his state necessitates a therapeutic intervention to which he is not able to assent.

150. François Villa, *Comparaison des jurisprudences rendues en matière de responsabilité pour défaut d’information*, MÉDECINE & DROIT 57, 60 (2013) (Fr.).

151. For a comparison between the doctrine of *stare decisis* and *jurisprudence constante*, see Robert L. Henry, *Jurisprudence Constante and Stare Decisis Contrasted*, 15 A.B.A.J. (1929).

152. Suzanne Carval & Ruth Sefton-Green, *Medical Liability in France*, in MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS, *supra* note 21, at 207, 213.

Law of March 4, 2002. The principal elements of the 2002 law have been incorporated into the French Public Health Code. Art. L1111-2 paragraph 1 of the Public Health Code states that:

Every person has the right to be informed of his state of health. This information relates to different investigations, treatment or preventive action which is proposed, its utility, possible urgency, the consequences, the frequent and serious risks that are normally foreseeable as well as other possible solutions and the foreseeable consequences in the event of refusal. Whenever new risks are identified, after the investigations, treatment or preventive actions have been carried out, the patient must be informed, except when it is impossible.¹⁵³

The Patients' Right Law was an important event in the French legal history. This law has unified the medical malpractice rules in a civil law system that can be "portrayed as a very positive and legicentrist"¹⁵⁴ one. To deeply understand the present law that is composed by multiple pieces that evolved over time, we have to take a careful look at the roots of the norms and the evolutionary background of the rules. One should not forget that the French tort law resides in the continual cooperation between scholars¹⁵⁵ and the judiciary.¹⁵⁶

How important was the promulgation of the Patients' Right Law? Did the law bring a totally new approach to the issue of informed consent in France or just local remedies for the deficiencies that were noticed? Hereinafter, we will focus our attention on analyzing the law that was in force prior to March 4, 2002 and afterwards.

153. See the following for the text in French, available at <https://perma.cc/6E6K-HJ5W> (last visited Mar. 6, 2016).

154. Olivier Moréteau, *Basic Questions in Tort Law from a French Perspective*, in BASIC QUESTIONS IN TORT LAW FROM A COMPARATIVE PERSPECTIVE 8 (Helmut Koziol ed., Jan Sramek Verlag 2015).

155. *Id.*, it is important to keep in mind that the French scholars are more pragmatic than dogmatic.

156. *Id.*

C. The Duty to Disclose Before the Patients' Rights Law of March 4, 2002

With regard to the means of presenting the information to the patient, the *Cour de Cassation*¹⁵⁷ held that the physicians must give “a loyal, clear and appropriate”¹⁵⁸ disclosure of the serious risks, in order to allow the patient to decide if he wants to undergo the medical procedure.¹⁵⁹

In 1998, the *Cour de Cassation*¹⁶⁰ defined the scope of the physician's duty to disclose. In that case, the person had a vertebral fracture caused by a fall.¹⁶¹ Because of the persistent pain, she underwent surgery, which should have been followed by another.¹⁶² In the afternoon, after the first surgery, the left eye had definitively lost its functionality.¹⁶³ This risk was known to be very rare, so the physician did not inform the patient about it prior to surgery.¹⁶⁴ The patient filed a suit claiming, among other things, the failure of the physician to inform her about the rare risk of a definitive loss of an eye's functionality.¹⁶⁵ The Appellate Court dismissed the suit holding that the physician only had to disclose the normally foreseeable risks, and because the risk that occurred in this case was a very rare risk, the physician did not breach his duty by failing to inform the patient.¹⁶⁶ However, the *Cour de Cassation* reversed this decision; it found that the physician did not meet his duty to disclose.¹⁶⁷ In order to reach this conclusion, the *Cour de Cassation* held that the physician must inform the patient about the seri-

157. Cass. Civ. 1, 27 May 1998, Bull. Civ. I, no. 187; D. 1998.530 (note F. Laroche-Gisserot).

158. *Id.*, the French reads: “une information loyale, claire et appropriée.”

159. See also Cass. Civ. 1, 14 October 1997, JCP 1997, 2, 22942.

160. Cass. Civ. 1, 7 October 1998, *supra* note 4.

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

167. Patrice Jourdain, *Obligation d'information du médecin: extension confirmée de l'obligation aux risques exceptionnels graves*, RTDCiv 1999, 111.

ous risks of the investigations and the treatment proposed and that this duty exists even if the serious risks occur only in exceptional cases.¹⁶⁸

This leaves the question of what is the definition of a “serious risk.” The *Cour de Cassation*¹⁶⁹ defined the serious risks¹⁷⁰ as “the risk that might cause death, invalidity or serious aesthetic consequences, considering their impact with respect to the physiological and social aspect of the patient’s life.”¹⁷¹ Moreover, if it is clear that a minor and exceptional risk is not required to be disclosed by the physician,¹⁷² one may wonder if there is a duty to disclose a minor risk that is foreseeable?

Patrice Jourdain explains that, according to the *Cour de Cassation*, one must distinguish the serious risks, which must be disclosed, from the simple “inconvenience” of a medical procedure, which is not required to be disclosed.¹⁷³ This is a fine line and Advocate General Sainte-Rose insisted that this theory of the exceptional risks must be reanalyzed.¹⁷⁴ Thus, in 2002, the standard of disclosure was (re)defined by the legislature and encompassed in the Public Health Code.

D. The Duty to Disclose After the Law of March 4, 2002

The Patients’ Rights Law of March 4, 2002 relaxed the previous jurisprudential standard of disclosure¹⁷⁵ in article L. 1111-2 paragraph 1, which does not require the physician to provide ex-

168. Cass. Civ. 1, 7 October 1998, *supra* note 4.

169. Cass. Civ. 1, 14 October 1997, *supra* note 159.

170. In French it is “risques graves.”

171. In French: “les risques de nature à avoir des conséquences mortelles, invalidantes, ou même esthétiques graves compte tenu de leurs répercussions psychologiques et sociales.” Cass. Civ. 1, 14 October 1997, *supra* note 159.

172. Jourdain, *supra* note 167, at 111.

173. *Id.*

174. *Id.*

175. The rule stated that the physician must inform the patient of the “all inconvenience that arise” and all risks, even if they are exceptional. G’Sell-Macrez, *supra* note 120, at 1101.

haustive information to the patient.¹⁷⁶ Article L. 1111-2 paragraph 1 imposes on the physician the obligation to inform the patient about the “frequent risks or the serious but normally predictable risks.”¹⁷⁷

With respect to the frequency of the risks, administrative courts in France held that even if a risk is not serious, if it can be regarded as frequent, then the physician has a duty to disclose it to the patient.¹⁷⁸ Furthermore, there are cases that state that the physician’s duty to inform is not discharged if the risk is serious, even if it is not frequent.¹⁷⁹

One may note that there is no legislative definition of what actually constitutes “serious risks.”¹⁸⁰ However, there are cases in which judges expressed their opinion on what constitutes a serious risk.¹⁸¹ A similar definition to the one adopted by the courts is given by the *Haute Autorité de santé*¹⁸² in its guide to physicians on what actually can be defined as serious risk¹⁸³—“a serious harm¹⁸⁴ is one which is ‘life-threatening or that alters a vital bodily function.’”¹⁸⁵

The definitions that were attributed by the courts and governmental entities to the serious risks would indicate that, in France, the standard of disclosure is an objective one. Compared to United States’ law, French law does not provide any solid indication whether the “seriousness” of the risk is to be treated from the viewpoint of a reasonable physician, a reasonable patient, or a par-

176. PHILIPPE LE TOURNEAU, *DROIT DE LA RESPONSABILITÉ ET DES CONTRATS* 722 (9th ed. 2012).

177. G’Sell-Macrez, *supra* note 120, at 1101.

178. C.A.A. (Cour administrative d’appel; intermediate court of appeal for administrative law cases) Paris, 12 November 2012, 11PA02031.

179. *See, e.g.*, C.A.A. Lyon, 7 April 2001, 09LY01837.

180. Taylor, *supra* note 119, at 475.

181. Cass. Civ. 1, 14 October 1997, *supra* note 159.

182. French National Authority for Health. For details about this entity, *see* <https://perma.cc/6T3S-2SE2> (last visited Mar. 6, 2016).

183. Taylor, *supra* note 119, at 475.

184. It is just a way to refer to the same serious risk of causing harm.

185. Taylor, *supra* note 119, at 475.

ticular patient.¹⁸⁶ It is thought that French lawyers feel more comfortable with the use of abstract principles than lawyers in common law.¹⁸⁷ Thus, French society is less concerned to engage in a more detailed discussion about the type of standard of care that is imposed upon physicians.¹⁸⁸

In accordance with the legislative requirement that the risk has to be normally foreseeable, courts in France have ruled that a risk is “*normalement prévisible*,”¹⁸⁹ even if it is exceptional, if it occurs in one case out of a thousand cases.¹⁹⁰ Thus, statistical data plays an important role in the establishment of the foreseeability. Moreover, another factor that courts seemed to have taken into consideration is the health antecedent of the patient.¹⁹¹

Going back to the hypothetical situation that was presented above, one may argue that the risk of loss of the finger’s mobility is not a serious risk from an objective point of view and, more probable than not, this risk is not frequent. However, if the physician had known about the pianistic activity of the patient (*i.e.*, he had attended the local orchestra in the past or the patient himself had disclosed this information to the health care provider), then it is likely that the risk of stiffness of the finger would be regarded as serious. This risk affects “the social aspect of the patient’s life.”¹⁹² Thus, more probable than not, the physician would be found liable for the failure to disclose this serious risk to the patient, as he had knowledge of the patient’s lifestyle and preferences.

A common law scholar may point a finger at the lack the foreseeability on what type of risks are serious and/or frequent and normally foreseeable. He might also object that decisions of

186. *Id.*

187. *Id.*

188. *Id.*

189. The English translation is “normally foreseeable.”

190. C.A.A. Lyon, 23 December 2010, 09LY01051. However, one may note that in Switzerland, “[i]n general, the statistical risk percentages are not used for determining the scope of the duty to inform.” Lüchinger, *supra* note 21, at 580.

191. C.A.A. Nancy, 9 April 2009, 07NC01468.

192. For details, *see* Cass. Civ. 1, 14 October 1997, *supra* note 159.

French courts use brief and cryptic language and it might be only after the work of a scholar that the entire decision is fully understood. Hence, the physician's duty and the extent of the patient's right to information may seem to him unclear and ambiguous.

III. SUGGESTED ALTERNATIVE STANDARDS

The legal standards in the United States and in France have undergone impressive improvements with respect to the patient's right to self-determination in the sphere of the doctrine of informed consent. However, there are still areas in which the solutions provided by the law do not correspond to the need of the parties involved, *i.e.*, the physician and the patient. For example, in most jurisdictions in the United States the standard of disclosure does not depend upon the lifestyle of the patient, though he is the one who has to consent to the medical procedure, unless the patient brings his preferences to the physician's knowledge. However, generally, the reasonable prudent practitioner or the reasonable patient is taken into consideration to establish the physician's duty to disclose.

A proper legal standard of informed consent should aim at protecting the patient's ability to obtain the information necessary for making an intelligent decision, to either decide for him or to defer the decision-making to the physician. Moreover, the ideal legal standard should provide the physician with a clear understanding of what necessary information should be disclosed to the particular patient in order to avoid liability based on the doctrine of informed consent. One may ask whether the law in the common law as well as in the civil law arena could achieve such goals. This part of the paper will prove that this desideratum is not utopic.

The next part will propose, without aiming to achieve an exhaustive analysis, two possible alternative solutions¹⁹³: the modifi-

193. These alternative solutions are applicable in the United States and in France.

cation of the substantive patient-based standard developed by the courts in the United States and the implementation of a new standard of care, known as the shared medical decision-making.

A. Injecting Objectiveness into the Substantive Patient-Based Standard

In the United States, the subjective patient-based standard¹⁹⁴ adopted by the court in *Scott v. Bradford*¹⁹⁵ has been vigorously criticized because, among other objections, it was contended that it eliminated the protection given by the objective standard to the physician, as the latter standard required the physician to disclose the information deemed relevant to a “reasonable patient.”¹⁹⁶ In order to overcome this criticism, one may ask whether, by fusing different legal concepts, the law might find a solution that will consist of the combination between the objective and the subjective standard. However, is it worth the effort? How many jurisdictions worldwide have implemented the subjective patient-based standard?

The United States subjective approach of the doctrine of informed consent can be identified, though under different names, in many other jurisdictions such as Belgium, Germany, or Switzerland.¹⁹⁷

In Belgium, the traditional standard of informed consent, which stated that the physician must inform the patient about the “normal

194. King & Moulton, *supra* note 11, at 443; under the subjective patient-based standard, the physician could be held negligent for failure to obtain an informed consent if the plaintiff proves that knowing the material risks would have made him refuse to undergo the medical procedure. Hence, the material risk is one that would “be likely to affect a patient’s decision.” *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979).

195. *Scott*, 606 P.2d. at 558.

196. King & Moulton, *supra* note 11, at 443.

197. There might be other jurisdictions in which the subjective patient-based standard is adopted, but this paper will limit the analysis to these three European countries.

and foreseeable”¹⁹⁸ risks, has been criticized for being “too vague and too abstract.”¹⁹⁹ The more modern standard, so-called the “relevant-risk”²⁰⁰ theory has been implicitly accepted by the *Cour de Cassation* of Belgium.²⁰¹ Under this theory, the physician has to disclose to the patient the risks that are considered relevant for “the patient in a particular case.”²⁰² Thus, in Belgium, the United States subjective patient-based standard has been implemented since 2009.

The law in Germany with respect to the standard of disclosure is based on the principle of full disclosure.²⁰³ German law emphasizes on the patient’s right to self-determination.²⁰⁴ Hence, it was stated that “the decisive element here is the view of the specific patient in the specific situation, not the view of a ‘reasonable patient.’”²⁰⁵ Therefore, it is evident that Germany has adopted the subjective patient-based standard without specifically naming it as such.

Switzerland is another example where in order for the patient to give his intelligent consent to a medical procedure, he should be provided with all the necessary information.²⁰⁶ With respect to the standard of disclosure, Swiss law emphasizes that the “individual patient’s information needs are decisive, not those of a ‘reasonable patient.’”²⁰⁷ Hence, Switzerland is an additional jurisdiction in which the subjective patient-based standard seems to be effective.

198. Herman Nys, *Medical Liability in Belgium*, in MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS, *supra* note 21, at 61, 80.

199. *Id.*

200. *Id.*

201. See Cour de Cassation [Cass.] [Court of Cassation], 26 June 2009, no. C070548N, <https://perma.cc/P2N4-Z4TY> (last visited Apr. 10, 2016).

202. Herman Nys, *Medical Liability in Belgium*, in MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS, *supra* note 21, at 80.

203. WALTER VAN GERVEN ET. AL., CASES, MATERIALS AND TEXT ON NATIONAL, SUPRANATIONAL AND INTERNATIONAL TORT LAW 319 (2000).

204. *Id.* at 318.

205. Franz Michael Petry, *Medical Liability in Germany*, in MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS, *supra* note 21, at 233, 265.

206. Lüchinger, *supra* note 21, at 547, 580.

207. *Id.*

It was contended, in France, that the standard of disclosure is more likely treated as objective. However, even though there may be no clear guidelines as to whether the standard of disclosure is treated from the viewpoint of a reasonable physician, a reasonable patient, or a particular patient,²⁰⁸ it is important to notice that, in 1997, the *Cour de Cassation* showed great concern for the patient's physiological and social aspects.²⁰⁹ Thus, from this point of view, the French standard of disclosure may be regarded as a fusion of the American objective and subjective standard. Therefore, important steps have been taken in order for the law to evolve accordingly to the changing needs of society. Are these steps enough? Does the law fully satisfy the evolutionary sociological aspects of life?

Taking into consideration the above-mentioned references to different jurisdictions that seem to have adopted the United States subjective patient-based standard and that major criticism that was brought to this standard (the elimination of the physician's protection given by the objective standard), one may argue that injecting some objectiveness into the subjective standard might be a solution to the issue. Essentially, this means that the new "mixed" standard should require the physician to disclose the relevant information to the particular patient (not to a reasonable patient, as the objective standard requires), if the obligor of the duty to inform (*i.e.*, the physician) knows or should have reasonably known that the special risk is important to the patient.

The structure of the "mixed" standard seems similar to the requirements of error, as a vice of consent.²¹⁰ For a definition of error, article 1949 of the Louisiana Civil Code states the following: "Error vitiates consent only when it concerns a cause without

208. Taylor, *supra* note 119, at 475.

209. For details, see Cass. Civ. 1, 14 October 1997, *supra* note 159.

210. For details, see LEVASSEUR ET. AL., *supra* note 126, at 186-87.

which the obligation would not have been incurred and that cause was known or should have been known to the other party.”²¹¹

In order to properly examine the issue of error, it is mandatory to determine the notion and the legal effects of consent: “[c]onsent, which is the concurrence of the declared will of parties to an agreement, constitutes an essential element of contract in both the civil and the common law.”²¹² Consent given in order to enter into a contract can be vitiated by error, thus the contract is annulable.²¹³ In the United States, as well as in France, the physician’s liability for failure to disclose the relevant information to the patient is based on tort law. Thus, the notion of error, as a vice of consent, is inapplicable. However, because we are discussing consent, the provisions of error can be implemented by analogy in the field of defining the duty to disclose in the doctrine of informed consent.

The “mixed” standard is not totally unknown to United States case law. For example, in 1980, a California court in *Truman v. Thomas*²¹⁴ held that “if the physician knows or should know of a patient’s unique concerns or lack of familiarity with medical procedures, this may expand the scope of required disclosure.”²¹⁵ However, by using the word “may,”²¹⁶ the court seemed to be reluctant to hold this as a mandatory requirement imposed upon the duty to disclose, but it shows that the idea of injecting subjectivity into the objective standard may be a practicable solution.²¹⁷

By adopting a “mixed” standard, both in the United States and in France or in any other jurisdiction that implemented the subjective patient-based standard, the goals of the doctrine of informed

211. LA. CIV. CODE art. 1949.

212. Herbert A. Holstein, *Vices of Consent in the Law of Contracts*, 13 TUL. L. REV. 362 (1938).

213. *Id.* at 364.

214. *Truman v. Thomas*, 611 P.2d 902 (Cal. 1980).

215. *Id.* at 906.

216. The use of the word “must,” for example, would have given a more authoritative tone to the rationale.

217. However, this case was decided by applying the objective standard.

consent are better achieved by applying the actual objective or subjective patient-based standard. Thus, the right of self-determination of the patient is well protected because he is given the information regarding the risk that he, as an individual, deems important. Moreover, the physician is protected by the law as, in case he does not know or has no reasonable reasons to know that the risk is important to the patient, he will not be held liable for the failure to disclose such risk. This might imply, on the part of the patient, a duty to communicate his preferences and values so that the physician is under the legal obligation to disclose the risks associated with the patient's lifestyle. However, no obligation to inform the physician should be imposed on the patient. It should be rather left at his discretion and if the patient chooses not to inform the physician about his preferences and values, then the consequence will be that the physician cannot be held liable under the doctrine of informed consent for the failure to disclose the peculiar risks associated with the medical procedure.

How does the "mixed" standard work in the hypothetical scenario previously mentioned? The discussion should start by analyzing whether the physician knew or had reasons to know the patient's values and preferences (*i.e.*, the fact that he plays the piano, hence his fingers' mobility is very important aspect of his lifestyle). If Dr. Medicus knew because the patient told him about his piano passion or had reasons to know because, for example, Paul is famous in town for his piano performances, then the risk of nerve damage should have been disclosed to the patient. In the event that Dr. Medicus does not disclose the material risk and if the other elements of the action under the doctrine of informed consent are met, then the physician will be held liable. If, under the circumstances, the physician was unaware of the values and preferences of the patient, then the physician is not going to be held liable for the failure to disclose the risk of nerve damage.

In conclusion, even if implementing the "mixed" standard requires more profound research and analysis, from a general point

of view, it seems to be a feasible standard that achieves the goals of the doctrine of informed consent better than the actual standards. Apart from the “mixed” standard of disclosure, recently, in the legal and medical field, a new standard of care started to evolve, in which both the physician and the patient are protagonists.

B. Shared Medical Decision-Making

The current legal standards of disclosure in the United States and in France can be visually associated to a one-way road, in which the physician provides the patient with the information that a reasonable physician would disclose,²¹⁸ or a reasonable patient would consider material,²¹⁹ or the particular patient would deem important²²⁰ in making the decision to undergo a medical procedure. Nevertheless, one may ask why does the information go just one way? Why should the patient be deprived of the possibility to provide the physician with individual concerns or questions,²²¹ or emotional preferences, if the patient desires to do so?²²² The theory that pleads for a two-way “alley” of exchanged information is known as the shared medical decision-making.²²³

A possible definition of the shared medical decision-making is described as followed: “a process in which the physician shares with the patient all relevant risk and benefit information on all treatment alternatives and the patient shares with the physician all relevant personal information that might make one treatment or

218. Under the objective patient-based standard.

219. *Id.*

220. As expressed by the subjective patient-based standard.

221. King & Moulton, *supra* note 11, at 466.

222. Ministry of Employment and Solidarity & High Committee on Public Health, *Health in France* 306, February 2002 [hereinafter *Health in France*].

223. Benjamin Moulton & Jaime S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J.L. MED. & ETHICS 85, 89 (2010).

side effect more or less tolerable than others.”²²⁴ Thereafter, both parties use the information gathered from the interaction to come to a mutual medical decision.²²⁵

According to the definition of informed consent, one may view the process as consisting of three main steps.²²⁶ Firstly, the physician provides accurate and useful information regarding the option of treatment to the patient and then, the latter shares his preferences and values.²²⁷ Secondly, the physician and the patient engage in a process of shared medical decision-making.²²⁸ Thirdly, the two parties involved in the medical relationship will decide together the best option that fits the needs of the patient.²²⁹

To begin with, as people differ in their level of medical literacy, level of risk aversion, values, and preferences, etc.,²³⁰ they have to be assisted in clearly identifying whether they deem a specific risk important, so they want that risk to be disclosed by the physician.

Two different methods—decision aids and decision coaches²³¹—have been proposed to assist the patients through the decision process by providing them with the adequate information and helping them discover their preferences and values.²³² Firstly, the purpose of a decision aid is to “analyze the latest clinical evidence regarding the risks and benefits of different treatment options and

224. Robert M. Kaplan, *Shared Medical Decision Making: A New Tool for Preventative Medicine*, 26 AM. J. PREV. MED. 81, 81 (2004).

225. *Id.*

226. *Health in France*, *supra* note 222, at 307.

227. *Id.*

228. King & Moulton, *supra* note 11, at 466.

229. *Id.*

230. Gil Siegal, Richard J. Bonnie & Paul S. Appelbaum, *Personalized Disclosure by Information-on-Demand: Attending to Patients' Needs in the Informed Consent process*, 40 J.L. MED. & ETHICS 359, 361 (2012).

231. Moulton & King, *supra* note 223, at 91; for example, the Dartmouth-Hitchcock Medical Center has created a Center for Shared Decision Making. The Dartmouth model includes: “(1) a video decision aid; (2) an online survey and written questionnaire; (3) optional additional resources to help in resolving decisional conflict; (4) shared decision-making communication process; and (5) post-treatment survey.”

232. King & Moulton, *supra* note 11, at 464.

then present the information in a manner patients understand.”²³³ Thus, the patient will be given the information regarding the advantages and disadvantages of each medical option that is available to him in an unbiased manner.²³⁴ Secondly, the patient might be assisted in making the medical decisions by decision coaches.²³⁵ These individuals help the patient identify the values and the preferences in the medical treatment, so that the patient will be able to have a meaningful conversation with the physician, later in the process.²³⁶ Thus, this phase takes place before the patient’s meeting with the physician.²³⁷

Not every medical institution has the financial means to resort to decision aids and decision coaches and that they are not available for every major medical decision.²³⁸ However, scholars have argued that, while preferable, decision aids are not essential to the implementation of shared medical decision-making, as there are other resources that provide physicians with the needed up-to-date information.²³⁹

The physician and the patient should together “construct a care space.”²⁴⁰ Hence, the two actors should engage in a consultation, during which the patient’s treatment preferences together with the physician’s medical opinion will be mutually exchanged. This interaction can be described as a two-way street, where the information flows from both the physician and the patient. For example, in the Netherlands, the patient has the duty to communicate his preferences and values to the physician, as he “‘needs to do the best to his knowledge’ to inform the practitioner and cooperate

233. *Id.* at 463-64.

234. *Id.* at 464.

235. *Id.*

236. *Id.*

237. Moulton & King, *supra* note 223, at 91.

238. King & Moulton, *supra* note 11, at 465.

239. *Id.*

240. *Health in France*, *supra* note 222, at 308.

with him in as far as is reasonable needed for his treatment.”²⁴¹ However, one may highlight that no obligation to disclose should be imposed to the patient, as the requirement to provide personal information conflicts with his right to privacy.²⁴² Hence, the patient’s rights to keep silence with respect to his preferences and values should be respected.²⁴³ Nonetheless, in case the patient’s desire is to communicate his particular situation to the physician, except for the fact that such possibility should be provided by the law, the patient should also be provided with aid²⁴⁴ in order to properly identify his preferences and values.

Generally, there is mistrust on the part of physicians because they fear that patients might feel anxious after the information is provided.²⁴⁵ Moreover, the literature contends that there is little in the physicians’ medical training and experience that could prepare them to “sense how patients will react to disclosures.”²⁴⁶ Thus, the summary report that is done after the first step of the process helps the physician to identify the suitable level of disclosure with respect to the patient’s needs and his physical comfort.²⁴⁷

There are four possible outcomes with respect to the possibility to reach an agreement between the physician and the patient regarding the medical procedure to be undertaken. First, the parties arrive at a mutual medical decision.²⁴⁸ Second, the patient chooses to undergo a specific procedure, with which the physician disagrees, but he will provide nonetheless.²⁴⁹ Third, no agreement is reached, so the patient seeks medical care elsewhere.²⁵⁰ Fourth, the

241. Ivo Giesen & Esther Engelhard, *Medical Liability in the Netherlands*, in *MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS*, *supra* note 21, at 361, 389-90.

242. KATZ, *supra* note 14, at 127.

243. *Id.*

244. *See* Siegal, Bonnie & Appelbaum, *supra* note 230.

245. *Health in France*, *supra* note 222, at 308.

246. KATZ, *supra* note 14, at 77.

247. Moulton & King, *supra* note 223, at 91.

248. *Id.* at 89.

249. *Id.*

250. *Id.*

patient can choose to differ the treatment choice to the physician.²⁵¹ Whichever conclusion is going to be drawn, it is more likely that the medical procedure chosen will be adequate for the patient's individual values and preferences and the physician will not be held liable for the failure to provide the relevant information in order to allow the patient to make an intelligent decision.

At the end of the discussion, the physician will provide a consent form for the patient to sign that acknowledges that the parties successfully engaged in shared medical decision-making and, finally, reached a conclusion regarding the medical procedure.²⁵²

The value of the consent form has been discussed in many jurisdictions. For example, in Italy, the jurisprudence held that the duty to inform is not "a mere 'bureaucratic step,'"²⁵³ as the patient's consent has to be expressed based on comprehensible information.²⁵⁴ Moreover, in England, the British Medical Association "tool kit" underlines the importance of the discussion with the patient and emphasizes that the written consent form should be seen as a supplement to rather than a substitute of the dialog.²⁵⁵

Scholars have identified a set of benefits of shared medical decision-making.²⁵⁶ Firstly, from the patient's standpoint, shared medical decision-making enhances his autonomy, as it satisfies the need for adequate information and engagement in the medical discussion.²⁵⁷ Studies have shown that "the vast majority of patients want to be informed and involved in medical decision-making."²⁵⁸ However, there is no evidence that the patient strongly desires to

251. *Id.*

252. King & Moulton, *supra* note 11, at 466.

253. Alessandro P. Scarso & Massimo Foglia, *Medical Liability in Italy*, in *MEDICAL LIABILITY IN EUROPE: A COMPARISON OF SELECTED JURISDICTIONS*, *supra* note 21, at 329, 346-47.

254. *Id.*

255. Taylor, *supra* note 119, at 473.

256. King & Moulton, *supra* note 11, at 468.

257. *Id.*

258. Moulton & King, *supra* note 223, at 89 (citing W. Levinson et al., *Not All Patients Want to Participate in Decision-Making: A National Study of Public Preferences*, 20 J. GEN. INTERN. MED. 531, 335 (2005)).

remove annihilate the physician's integral part of the medical decisions.²⁵⁹ Thus, after receiving the information that the patient wants, he has the possibility to determine whether he will defer the decision entirely to the physician or make a final determination with the collaboration of the physician.²⁶⁰ Moreover, various studies have shown that by increasing the patient's involvement in the medical decision-making, he will reach psychological comfort, which will contribute to the patient's well-being.²⁶¹ Furthermore, some studies have shown that the involvement of the patients in medical decisions has improved the treatment outcomes.²⁶²

Secondly, from the physician's point of view, shared medical decision-making will provide insights on what the patient's preferences and values need to be taken into consideration when the disclosure is given.²⁶³ Thus, the law will give a clearer standard of disclosure. In addition, the physician's medical liability should be heavily reduced because of the extensive communication with the patient and the better perception of goals.²⁶⁴ Moreover, the ample discussions in which the physician and the patient engage will tighten the bonds between them. Thus, less stress is placed on the medical professional when he performs the chosen procedure.²⁶⁵

Skeptics, who have spoken against the potential benefits of the shared medical decision-making, argue that the implementation of such standard raises important challenges.²⁶⁶

Firstly, the management of the physician's time seems to be one of the major concerns.²⁶⁷ It has been contended that physicians

259. *Id.*

260. King & Moulton, *supra* note 11, at 468.

261. For more details, *see id.* at 469.

262. Pamela J. Mendonca & Sharon S. Brehm, *Effects of Choice on Behavioral Treatment of Overweight Children*, 1 J. SOC. CLIN. PSYCHOL. 343, 343-358 (1983).

263. King & Moulton, *supra* note 11, at 471.

264. *Id.*

265. *Id.*

266. Moulton & King, *supra* note 223, at 90.

267. King & Moulton, *supra* note 11, at 473.

do not have the time to explain every detail to patients.²⁶⁸ These obstacles are not insurmountable.²⁶⁹ For example, by adopting decision aids, or other decision management tools, such as a decision coach, the physician will save a lot of time. Thus, the physician will not be required to gather and provide information to the patient, in order for the latter to be able to engage in a productive communication.²⁷⁰ Even if there is definitely an “initial time investment”²⁷¹ designed to favor the training of physicians to properly take part in shared medical decision-making, this investment will profit in the long run by reducing the overall time needed for the delivery of information.²⁷²

Secondly, it has been contended that even if physicians had the time to properly engage in shared medical decision-making, they are not paid for the time spent discussing the risks with patients.²⁷³ Moreover, implementing shared medical decision-making may result in “a reduction in medical services as many patients would forego care if they had all the facts.”²⁷⁴ Thus, physicians will be rewarded with less financial support because of fewer treatment requests.²⁷⁵ However, engaging in shared medical decision-making will potentially lower the number of malpractice claims, as it is more probable than not that this standard of disclosure will be a solution to the communication difficulties that physicians and patients face.²⁷⁶

In conclusion, despite the criticism that might be brought to the idea of adopting shared medical decision-making as a standard of disclosure in the United States and France, there is definitely a

268. *Id.*

269. *Id.*

270. King & Moulton, *supra* note 11, at 473.

271. *Id.*

272. *Id.*

273. Moulton & King, *supra* note 223, at 90.

274. King & Moulton, *supra* note 11, at 474.

275. *Id.*

276. The communication defects in the relationship between the physician and the patient are said to be among the most common complaints from patients who sue physicians for malpractice. *Id.*

need to adapt the actual legal standards of disclosure, in both jurisdictions, to meet society's demands. The robust mechanism of this innovative idea may be the best, if not perfect, compromise between the patient's autonomy²⁷⁷ and the physician's expertise and beneficence.²⁷⁸

Back to our leading hypothetical, under the shared medical decision-making, the patient would have had the opportunity to discuss the medical procedure in depth with the physician and ask questions relating to it during the first two steps of the process. Hence, Paul would have had the possibility to identify and share his values and preferences with Dr. Medicus (*i.e.*, the fact that he plays the piano, hence his finger's mobility is very important to his lifestyle). The risk of nerve damage would have ultimately been disclosed to the patient. Therefore, Paul would have been able to give a proper informed consent to the medical procedure (whether he ultimately decides to undergo surgery or not). Although, Paul's preferences are unlikely to be shared by other patients, it is not impossible that some of them feel the same way. Dr. Medicus should nevertheless express his opinion regarding the treatment that best fits with the personal values of the patient. If, for instance, the physician has a strong preference for a certain procedure (the surgery, for example), which is not consented by the patient, Dr. Medicus has no authority to force Paul to undergo treatment. On the other hand, if under the same scenario, Paul is aware of the possible risk of nerve damage and consents to the surgery, he would give an informed consent. He would be prepared psychologically for the unlikely result that might occur and could not claim damages for the physician's failure to inform him about the risk.

277. Respecting the patient's autonomy can be defined as recognizing their "wishes regarding what information is relevant to their decision and how much they want to participate" in the decision-making process. Moulton & King, *supra* note 223, at 89.

278. The ethical obligation of the physician to act with beneficence was expressed as his duty to assist the "patients to select both a decision-making pathway and a treatment option that best satisfies their personal and medical goals." *Id.*

To conclude, by implementing shared medical decision-making in the United States and France, the cases in which physicians would be held liable for failure to disclose risks to patients would be substantially reduced and the patient's autonomy would be protected against any illegal intrusion.

CONCLUSION

It takes a global view to properly understand the duty to disclose imposed on the physician by the doctrine of informed consent. This paper covers a common law jurisdiction, the United States, and a civil law jurisdiction, France, while offering cross-references to other jurisdictions.

Firstly, in the United States, in case the patient gives his consent to the medical procedure, but he is not sufficiently informed beforehand, there are two lines of cases addressing the scope of the physician's duty to disclose the risks intrinsic to the procedure: the professional standard and the prudent patient-based standard. The latter is divided into two sub standards: the objective and the subjective patient-based standard. The professional standard determines the physician's duty by asking: what would a reasonable physician disclose to a patient under similar circumstances? The approach differs under the patient-based standard that establishes the duty to disclose by referring to the needs of a reasonable patient (under the objective approach), or by referring to the individual patient (as the subjective substandard requires).

Secondly, in France, the *Cour de cassation* held that the duty to inform the patient has its fundament in the requirement to respect the constitutional principle of human dignity. Moreover, the patient's right to information was reinforced by the enactment of the Law of March 4, 2002. Thus, each individual has the right to be informed about "the frequent and serious risks"²⁷⁹ that are "nor-

279. CODE DE LA SANTÉ PUBLIQUE [PUBLIC HEALTH CODE] art. L1111-2 para. 1.

mally predictable.”²⁸⁰ With respect to the definition given by courts and governmental entities to the serious risks would indicate that, in France, the standard of disclosure is an objective one, although there is no profound analysis on this matter.²⁸¹ It was contended that French lawyers are more at ease with the use of abstract principles than common law lawyers.

Criticisms have been brought to the actual standards of disclosure. Skeptics claim that under the professional standard, the physician is given discretion as the information process is regarded as a question of professional judgment. Moreover, it was contemplated that the objective patient-based standard assumes that all patients assess similarly the risks and benefits of a medical procedure, thus the right to self-determination is not protected. Furthermore, critique was brought to the subjective patient-based standard because it eliminates the protection given to physicians by the objective standard. Hence, the general inference is that the standard of disclosure, *i.e.*, the duty to inform, does not respect the “modern medical practice”²⁸² and the “individual autonomy rights”²⁸³ of patients.

Keeping in mind that the principles of medical ethics (autonomy, beneficence, non-maleficence and justice)²⁸⁴ and human rights (patient’s ability to exercise self-determination) should guide the legal development of the doctrine of informed consent,²⁸⁵ this paper proposed, in a non-exhaustive manner, the addition of two alternative legal standards of disclosure.

Firstly, in order to overcome the criticism that the subjective patient-based standard does not adequately protect the physician from unwanted liability, embracing into tort law the content of the

280. G’Sell-Macrez, *supra* note 120, at 1101.

281. Taylor, *supra* note 119, at 475.

282. King & Moulton, *supra* note 11, at 480.

283. *Id.* at 490.

284. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 12 (5th ed. 2001).

285. King & Moulton, *supra* note 11, at 434.

notion of error, as a vice of consent, might be a feasible solution. Thus, the new “mixed” standard should require the physician to disclose the relevant information to the particular patient (not to a reasonable patient, as the objective standard requires), if the obligor of the duty to inform, *i.e.*, the physician, knows or should have reasonably known that the special risk is important to the patient. This standard has the advantage that the right of self-determination of the patient is respected, as he is given personalized information. Moreover, the law protects the physician: in case he does not know or has no reasonable reasons to know that the risk is important to the patient, he will not be held liable for the failure to disclose such risk.

Secondly, implementing a new standard, known as the shared medical decision-making, may be a key to achieve the goals of the doctrine of informed consent. The shared medical decision-making, by engaging both the physician and the patient in the process of deciding on the medical treatment or procedure, makes possible the communication of patient’s treatment preferences, on the one hand, and the physician’s medical opinion, on the other hand. Hence, from the patient’s standpoint, shared medical decision-making enhances his autonomy, satisfies his need of adequate information and engagement in the medical discussion. From the physician’s point of view, shared medical decision-making will provide an understanding on what are the values and the preferences of the patient. The physician will then be able to disclose the relevant information to the particular patient and avoid unlimited liability for the failure to disclose the material risks.

The deficiencies found in United States law and in French law may be solved by applying, as an incremental step towards reaching the goals of the doctrine of informed consent, the “mixed” standard of disclosure. Meanwhile, the legal and economic framework of the countries will be able to implement the medical and legal national infrastructure to adopt properly and successfully shared medical decision-making.

We hope that this analysis provides lawmakers the legal arena with useful insights. While being careful to not swing the pendulum too far in favor of either party (*i.e.*, the patient or the physician), we believe that more in depth research ought to be undertaken in order for the proposed alternative standards of disclosure to be integrated into different legal systems across the world.

