https://doi.org/10.22364/iscflul.8.2.32

Philippe Pierre, *Professor*
Rennes University, France[1]

PATIENT PROTECTION UNDER FRENCH LAW: THE EXAMPLE OF MEDICAL INFORMATION

Keywords: medical liability, physicians, medical establishments, patient's information duty, ethical fault, proof, compensation

Summary

The duty of physicians and health institutions to inform patients about medical risks is a much-debated source of liability in French law. Ethical misconduct resulting from breaches of these obligations is likely to call into question the balance of relations between health professionals and patients. Case law, and then the French law of 4 March 2002, have constantly improved the possibilities of action for victims of incomplete or imperfect information, by making it easier for them to prove the lack of information and by establishing the compensable damages, which are distinct from bodily injuries. However, one may wonder whether this increased protection of patients is not now excessive, by transferring the burden of the medical decision and the related risks onto them, once they have been fully informed.

Introduction

French medical liability law was deeply reformed by a law on the rights of users of the health system, the "Kouchner Law" of 4 March 2002[2], so named because it was inspired by our then Minister of Health, Bernard Kouchner, who is well known for having founded the association "Médecins sans frontières".

To sum up, this law separates the damages caused by the liability of physicians and health establishments, which can be compensated by private insurers, and

[1] The theme of this presentation was discussed with Mustapha Mekki, Professor at the University of Paris 1, Panthéon-Sorbonne.

[2] Loi No. 2002-303 du 4 mars 2002 "Relative aux droits des malades et à la qualité du système de santé" [Law No. 2002-303 of 4 March 2002 "On the rights of patients and the quality of the health system"].

the consequences of the most serious medical hazards, which are compensated by a public guarantee fund (ONIAM[3]).

Regarding liability, French law envisages a different treatment of technical misconduct, such as diagnostic errors or negligence during operations, and so-called ethical misconduct, which affects the information and consent of the patient. Indeed, medical information is at the junction of ethical values and of the legal standard. Whereas ethics tends to define a base of commonly accepted values, their positivity, postulates a conjunction with the legal rule, which is defined by its compulsory nature: the principle and amount of the damages that can be compensated are hardly debated, because they guarantee the effectiveness of the legal rule.

In this case, patients can claim compensation for a breach of their right to be informed, in violation of our Public Health Code, which manages the protection of persons in contact with the French health system. Thus, health rules now provide that information belongs to the "rights" of the person, and that it should regard "frequent risks or normally predictable serious risks" [4] of the treatments prescribed. These ethical faults have caused significant litigation, which is in continuous development for approximately twenty years, and the subject is yet not completely controlled by the supreme French courts, the "Court of Cassation" and the "Conseil d'État"[5]. For example, the issue of patient information and consent has become particularly relevant since the COVID health crisis[6], as it also concerns the administration of health products such as vaccines, which currently raise medical questions about the extent of the risks involved.

A good medical information appears to be the key to the trust relationship between the physician and the patient. More importantly, it allows to obtain the informed consent of the patient, while being appropriate, adapted to his understanding and to his sensitivity. Litigation in this area is extensively publicised due to its ethical dimension, rebalancing relationship between the medical sphere and patients, insofar as they were until recently too opaque. We may, however, wonder if the increased repression of ethical faults, intended to protect health users, will not be Pyrrhus victory, by transferring on the latter the weight of medical and technical decisions. This paradox emerges with the debate on the proof of medical information (viewed in Section 1 below), but also with the issue of compensation of insufficient information, which enables ethical principles to find their legal sanction (considered in Section 2 below).

---

[3] Office National d'Indemnisation des Accidents Médicaux, des Affections Iatrogènes et des Infections Nosocomiales [National Compensation Office for Medical Accidents, Iatrogenic Diseases and Nosocomial Infections].

[4] Code de la Santé publique [Public Health Code], Art. L. 1111-2

[5] The jurisdiction of these supreme Courts depends on whether the dispute is public or private.

[6] See Pierre P. Le risque médical au temps du COVID 19 [Medical risk at the time of COVID 19]. Resp. civ. et ass. oct. 2020, Etude 9.

1. Proof of medical information: A new balance between physicians and patients

1.1. The way to achieving this new balance

The world of providing information to the patient has been totally transformed when, in the beginning of 1997, our Court of Cassation changed the principles it had applied for decades, stating "that the person who is legally or contractually bound to a specific obligation to inform should give evidence of the enforcement of the obligation thereof"[7]. In this case, it concerned a colonoscopy which had led to an intestinal perforation – a risk concerning which the patient pretended that he had not been informed by the surgeon. Until then, it was up to the victims to prove the inaccuracy or the lack of information about the risks incurred, which posed two series of difficulties to them.

Firstly, they came up against difficulties of access to medical documentation, even against a tacit solidarity of practitioners, since many experts were themselves practitioners who were likely to be personally sued in other litigation[8].

Secondly, the evidence to be provided was a *probatio diabolica*, the proof of negative fact – failure to inform – was much more difficult to report than a positive fact such as a technical mistake, the slip of a knife, etc.

Due to these difficulties, the Court of Cassation completely changed its mind, a change, for all that, applicable to all professionals, whatever their specialty, such as notaries, lawyers, bankers, but also – to return to the sphere of medicine –to the laboratories producing vaccines, and the practitioners injecting them[9]. Anyway, the "Kouchner Law" approved the solution, since the Art. L. 1111-2 of Public Health Code provides that the evidence of the information release is incumbent upon "the professional or the medical institution". Moreover, the law provides for everyone the right to have direct access to one's medical record,[10] whereas previously it was necessary to obtain a doctor's approval. This certainly facilitates a lot the evidence of medical malfunctioning.

---

[7] Cass. 1ère civ., 25 fév. 1997, n° 94-19.685. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

[8] Cayol J. Réflexion sur la responsabilité médicale à la suite de l'introduction du dossier médical personnel [Thoughts on medical liability following the introduction of the personal medical file]. Médecine et Droit, 2006, No. 78, p. 85.

[9] Cass. 1re civ., 23 janv. 2014, Resp. civ. et assur. 2014, comm. 116, note Hocquet-Berg S. No. 12–22.123. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

[10] Code de la Santé publique [Public Health Code]. Art. L. 1111-7 : "Any person shall have access to all information concerning his or her health held, in whatever capacity, by health professionals, by health establishments, by health centres, by the armed forces health service or by the National Invalids Institution, which is formalised or has been the subject of written exchanges between health professionals, in particular examination results, consultation, intervention, exploration or hospitalisation reports, protocols and therapeutic prescriptions implemented, monitoring sheets, correspondence between health professionals, with the exception of information mentioning that it has been collected from or concerning a third party not involved in the therapeutic management. She may access this information directly or through a doctor she designates…".

1.2. Assessment of such an evolution

At a first glance, this sounds like a victory for the patients. Nevertheless, the practice of medical information which has entirely changed within duration of almost twenty years, leads to relativization of those advances in the patients' rights.

Thus, the precautions taken by physicians and medical institutions to escape legal sanctions have significantly increased. This led to a profusion of informative documents signed by patients, such as extremely detailed "consent forms", which at the beginning gave rise to a very lucrative market, as they were sold by companies. The problem arose from the reach of information which has to be passed on to health users. Our rules impose that all serious risks must be specified, including the most exceptional ones, such as a death risk following a general anaesthesia, a blood contamination by the AIDS virus during a skin transplant, which, statistically, only represents a "chance" in several millions… Because of this defensive medicine, which protects itself by pointing out risks which hitherto were not mentioned in the patient's interest, a shift progressively appeared: the purely medical choice – such as the decision of a treatment, or getting a vaccine – which was previously refereed by professionals who mastered the advantage/cost ratio, is most often transferred to the patients, naturally in a weakened state and lacking a sufficient background in medicine. So much so that some medically appropriate decisions have been wrongly postponed, since the patient's consent could not, in principle, be ignored.

Fortunately, public authorities have now taken over the control of informational documents by publishing official guidelines about good practices expected[11]. However, there is an "ethical valve" considering the patient's will to be informed[12]. In other words, the patient retains control regarding obtaining of information he wishes to receive, and nothing may stop him, once access is opened by the doctor or the medical institution, from being fully informed about all the risks incurred. To put it simply, it will be up to him to make it known to the health professional, by way of a document clearly expressing his will, to keep something in the dark…

[11] Regarding Haute Autorité de Santé [HAS – the High Authority for Health] guidelines, see: https://www.has-sante.fr.

[12] Code de la Santé Publique [Public Health Code]. Art. L 1111-4 al. 3, art. R. 4127-36: "Any physician has the duty to respect the person's wishes after having informed him or her of the consequences of his or her choices and of their seriousness. If the person's decision to refuse or interrupt any treatment puts his/her life in danger, he/she must reiterate his/her decision within a reasonable time. He or she may call on another member of the medical profession. The entire procedure is recorded in the patient's medical file…".

2. Compensation for the lack of medical information: Which positivity?

2.1. An ethical dimension or a classical compensation for personal injury?

Any lack of information compromises the relationship between the physician and his patient, especially the trust that the latter has placed in the former. Does this loss of trust, even this feeling of betrayal suffered by the patient, not account for the non-pecuniary damage that can be compensated as such, regardless of the evolution of the patient's physical condition? Accordingly, all things considered, it would not matter much that the unreported or poorly reported medical risk has occurred or not, the compensation being based on finding out the latter, afterwards, and the resulting anxiety and fright. Conceived like that, the compensation of the lack of information would then take on all its ethical dimension, but also threaten to aggravate the paralysis of the medical profession.

However, another reasoning would link up the compensation of the lack of information to the bodily harm that the patient actually suffered. Following this inclination, the risk has occurred after the victim was deprived of a choice between running this risk or choosing another treatment. Adequately informed, the patient might – or might not – have declined the treatment or the operation, which eventually were to turn out to be damaging. Consequently, the compensation of the poor information will go through the calculation of the chances of avoiding this risk, had the patient been well informed… How far, up to which percentage, the latter would have behaved differently and been medically satisfied? This probability theory leads to compensate only a "loss of chance" – the paradise of irresolute judges, assessed by applying a percentage to the amount of money that compensate bodily harms: 10% of the disability compensation, 10% of the *pretium doloris*, etc... [13].

2.2. The jurisprudence positions

To begin with, it should be noted that the "Kouchner Law", which is very detailed concerning the purpose and proof of medical information, remains silent regarding the terms of compensation, if not complied with. This question has therefore been left exclusively to the French jurisprudence. The Court of Cassation had a lot of hesitation facing a hard doctrinal controversy[14]. Firstly, our Highest Jurisdiction has stated that "the only principle that can be compensated following

[13] On this calculation method, concerning the loss of chance: Cass. 1ère civ., 7 déc. 2004, No. 02-10.10-957; CE 20 nov. 2020, No. 419778. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

[14] Feu l'arrêt Mercier ? Revue Des Contrats 2011, p. 335, débats, par M. Bacache, F. Leduc, Ph. Pierre [Late stoplight Mercier? Review of Contracts 2011, p. 335, debates by M. Bacache, F. Leduc, Ph. Pierre].

the non-observance by the doctor of the obligation to inform, obligation in view of obtaining the patient's consent, is the loss of chance of avoiding the risk which eventually occurred"[15]. This was the end of the non-pecuniary damage, replaced by a "corporalization" of the compensation of lack of information.

However, this position was only a step toward the actual solution. In fact, jurisprudence has since qualified its approach, distinguishing between two main hypotheses. Either, as we have seen, the patient has been deprived of a real choice between two treatments or a therapeutic abstention, and the compensation for the loss of a chance remains relevant, as previously exposed. Or, and this is the novelty since a few years, the patient, had he been correctly informed, would still have chosen to run the risk that was not pointed out to him. In retrospect, he would certainly have preferred to expose himself to a risk of nosocomial infection, for example, in order to put an end to the unbearable pain caused by a herniated disc. In this case, the Court of Cassation now states that "the failure of a health professional to comply with his duty to inform causes the person to whom the information was owed, when this risk occurs, to suffer moral prejudice resulting from a failure to prepare for the consequences of such a risk, which, once it is invoked, must be compensated"[16]. Notably, in this case, the damage is purely moral, it results from the psychological shock suffered by the patient, it is not a percentage of the bodily injury like the loss of chance. On the other hand, the case law requires that the bodily risk must have actually occurred. In other words, even if the Court of Cassation formally targets the right to the patient's dignity in its decisions, the current solution does not go as far as proposing compensation for ethical fault, including the cases when the silence has had no consequences because the unreported risk did not appear.

Conclusion

This case law is certainly subtle and complex in relation to the sometimes-low financial stakes, as compensation for moral prejudice is often limited to a few hundred or a few thousand euros. However, it increases the protection of the patient, as he will win the case on a symbolic level, and even on an economic level, as the loser will have to reimburse the costs of the trial, which are often very high in medical matters, much more than the compensation for the moral shock itself.

[15] Cass. 1ère civ., 6 déc. 2007, No. 06-19.301. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

[16] Cass. 1re civ., 23 janv. 2014, No. 12-22.123. Available: https://www.legifrance.gouv.fr, Cass. 1ère civ, 9 déc. 2020, No. 19-22.055. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

BIBLIOGRAPHY

Literature

1. Bacache M., Leduc F., Pierre Ph. Feu l'arrêt Mercier [Late Stoplight Mercier]? Revue Des Contrats, 2011, débats.
2. Cayol J. Réflexion sur la responsabilité médicale à la suite de l'introduction du dossier médical personnel [Reflection on medical responsibility following the introduction of the personal medical record]. Médecine et Droit, 2006, No. 78, p. 85
3. Hocquet-Berg S. Note under Cass. 1re civ., 23 janv. 2014, Revue Responsabilité civile et assurances [Review Civil liability and insurance]. 2014, comm. 116.
4. Pierre Ph. Le risque médical au temps du COVID 19 [Medical risk at the time of COVID 19]. Revue Responsabilité civile et assurances, 2020, Etude 9.

Legal acts

5. Loi No. 2002-303 du 4 mars 2002 "Relative aux droits des malades et à la qualité du système de santé" [Law "On rights of patients and the quality of the health system"]. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

Court practice

6. Cour de cassation, 1ère civ., 25 fév. 1997, No. 94-19.685. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].
7. Cour de cassation, 1ère civ., 7 déc. 2004, No. 02-10.10-957. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].
8. Cour de cassation, 1ère civ., 6 déc. 2007, No. 06-19.301. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].
9. Cour de cassation, 1re civ., 23 janv. 2014, No. 12-22.123. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].
10. Cour de cassation, 1ère civ., 9 déc. 2020, No. 19-22.055. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].
11. Conseil d'État, 20 nov. 2020, No. 419778. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].

Other materials

12. Haute Autorité de santé (HAS): French National Authority for Health. Available: https://www.has-sante.fr [viewed 15.11.2021.].
13. Légifrance: the official website of the French government for the publication of legislation, regulations, and legal information. Available: https://www.legifrance.gouv.fr [viewed 15.11.2021.].