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MEDICAL MALPRACTICE AND COMPENSATION IN FRANCE

PART I: THE FRENCH RULES OF MEDICAL LIABILITY SINCE THE PATIENTS' RIGHTS LAW OF MARCH 4, 2002

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INTRODUCTION

The French law of medical malpractice must be understood within the context of a French health care system that is characterized by the division among the public sector, primarily public hospitals, and private practitioners or institutions, which may be either non-profit organizations or for-profit establishments that depend on their fees for funding. Indeed, 86 percent of the salaried health professionals work in the public sector, and 65 percent of the available beds are located in public hospitals. With regard to physicians, only 46.5 percent of physicians work independently in private practice, while 41.7 percent are employed by public or private hospitals, and 11.8 percent do both private practice and hospital work. The weight of the public sector is also palpable through the action of the Sécurité Sociale (Social Security), the public health insurance program that was established in 1945. The Social Security takes care of all health costs, though it does not fully cover these expenses since reimbursement is regulated through uniform rates and tariff references. About 75.5 percent of the total health expenditures are covered by the public health insurance system, whereas

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2. Id. at 122 tbl3.2.1.
4. Within the French context, the expression “Social Security” refers to the public social insurance system, which mostly covers health care, like Medicare or Medicaid in the United States, or retirement pensions.
9.4 percent are paid by patients and 13.4 percent by complementary insurance. Most practitioners conform to the Tarif de convention (tariff references), which stipulates the fixed rates to be charged by doctors set by the national convention for all health services. In principle, patients are free to choose their doctor, but this freedom of choice has been diminished by Law 2004-810 of August 13, 2004, for the “coordination of care,” which requires each insured individual to choose a “primary care physician” ("médecin traitant").

Since health is considered a matter of public policy, there is traditionally in France a ministry of public health that is in charge of conducting health policies. In addition, various public agencies are very active in the field, especially in prevention and deterrence of medical accidents. The High Council of Public Health (Haut Conseil de la Santé Publique [HCSP]) contributes to the definition of public health goals. The French Agency for Sanitary Safety of Health Products (Agence Française de Sécurité Sanitaire des Produits de Santé [AFSSAPS]) guarantees the efficiency, quality, and proper use of health products. The French National Authority for Health (Haute Autorité de Santé [HAS]) manages “a number of activities designed to improve the quality of patient care and to guarantee equity within the healthcare system.” The HAS activities “range from assessment of drugs, medical devices, and procedures to publication of guidelines to accreditation of healthcare organisations and certification of doctors.” The Regional Agencies for Health (Agences Régionales de Santé [ARS]), were created in 2010 and are responsible for safety, preventive actions, organizing the supply of care based on population needs, risk


7. CODE DE LA SECURITE SOCIALE [CSS] art. L. 162-5-3. The primary care physician is a general practitioner (or more rarely, a specialist) who may refer the patient, if necessary, to a particular specialist. The primary care physician manages the patient’s personal record, which contains all necessary information regarding the patient’s health.


11. Id.
management, control of management of health facilities, pilot programs to improve work practices, and collection and interpretation of health data. The Agencies also aim to foster cooperation between health professionals and health facilities to improve the care of patients. Despite the action of these various public institutions, the lack of sufficient prevention policies, especially in terms of “risk management,” is often highlighted. This is why recent texts were adopted concerning prevention policy.

In this context, Law 2002-303 of March 4, 2002, relative aux droits des malades et à la qualité du système de santé (hereinafter the Patients’ Rights Law) has unified medical malpractice liability rules, regardless of the actors involved—public or private. This Law defines patients’ rights and sets forth general principles regarding the responsibility of health professionals and health institutions, which are now in the Code of Public Health (CODE DE LA SANTÉ PUBLIQUE) [CSP]. However, despite the unification of medical malpractice rules, disputes still have to be brought before administrative or civil courts, according to whether the medical malpractice has occurred in a public hospital or in a private practice or institution. It should also be noted that victims may initiate prosecution before criminal courts against any health professional if it appears that he or she committed a criminal offense. And physicians may be brought before disciplinary courts in case of violation of the Code of Ethics (Code de déontologie médicale).


13. Id.


17. Id.
The Patients’ Rights Law of March 4, 2002, not only provides for new liability rules but also organizes the compensation of injuries that cannot be attributed to any misconduct.\textsuperscript{18} When the injury results from acts of prevention, diagnosis, or treatment, and when such injury is abnormal with respect to the patient’s previous health and its likely evolution,\textsuperscript{19} the victim’s claim may be brought before the National Fund for Compensation of Medical Accidents (Office National d’Indemnisation des Accidents Médicaux [ONIAM]).\textsuperscript{20} In addition, the ONIAM is in charge of compensating the victims who cannot get compensated by the health professional or his/her insurer, even if liability rules are applicable. The compensation schemes that complement civil liability in such cases are said to be based on the principle of “solidarité nationale” (national solidarity): the term reflects the idea that the whole community supports the cost of such risks. Finally, the Patients’ Rights Law of March 4, 2002 regulates the settlement of disputes between patients and health professionals.

This piece will focus on the cases where a medical accident is likely to justify the responsibility of the practitioner. We will first consider the general conditions of the health professional’s liability (Part I), before turning to the question of administration and adjudication of claims (Part II).

\section{General Conditions of Medical Liability}

Before the Patients’ Rights Law of March 4, 2002, medical malpractice liability in the private sector was viewed as a matter of contract law, due to a famous ruling of the \textit{Cour de cassation} in the \textit{Mercier} case.\textsuperscript{21} This case overruled previous decisions according to which physicians were liable under tort law.\textsuperscript{22} Since 1936, a contract was deemed to be formed be-

\begin{itemize}
  \item \textsuperscript{18} Id.
  \item \textsuperscript{19} CSP art. L. 1142-1.
  \item \textsuperscript{20} See Geneviève Helleringer, \textit{Medical Malpractice and Compensation in France. Part II: Compensation Based on National Solidarity}, 86 Chi.-Kent L. Rev. 1019, 1127 (2011).
\end{itemize}
between a doctor and a patient, thereby excluding the application of tort law principles. However, there was no deemed contract when the patient was unable to accept care (and his or her family, partner, or designated contacts could not be contacted), and the liability regime was then one based on tort law principles. The Patients' Rights Law of March 4, 2002, modifies the legal basis for medical liability, which is now regarded as a "legal regime" that is neither contractual nor tortious. This change has been very recently confirmed in an important decision of the Cour de cassation on January 28, 2010, which merely mentions Article L. 1142-1 of the CSP without referring to Article 1147 of the Civil Code like previous decisions usually did. However, in the case where the physician breaches his or her duty to inform, the applied provision is now Article 1382 of the Civil Code, which means that, in such case, the physician's responsibility is based on tort law.

There are traditionally three basic requirements to establish such liability. The first requirement is negligence or, in the case of a no-fault exception, any fact likely to justify civil liability. The second requirement is the victim's injury, which must warrant compensation and is often a loss of a chance, as we shall see. The third requirement is a causal link between the physician's negligence and the victim's harm. We will thus study those three conditions.

A. Facts Likely to Justify the Physician's Responsibility

The Patients' Rights Law of March 4, 2002, reaffirms the principle of fault-based liability in medical malpractice cases. However, it also admits the physician's strict liability in specific circumstances.

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23. For example, in the case where the patient was unconscious.
26. See Helleringer, supra note 20, at 1140.
1. Liability Based on Fault

a. Liability for Negligence

Since the Mercier decision of 1936, French Law has traditionally considered that the physician was under an obligation de moyen, which implies that the victim must establish the physician’s negligence, not merely the fact that the expected result (recovery) was not reached. Indeed, the contracting party who is under an obligation de moyen must strive to achieve the desired result by using reasonable diligence, whereas the obligation de résultat requires the defendant to achieve the promised result at any cost. Today, the physician’s negligence is a requirement clearly stated in the first paragraph of Article L. 1142-1 CSP. This provision also applies to public health services whose liability was admitted a long time ago by administrative courts for gross negligence (faute lourde), and then, since 1992, for simple negligence.

Traditionally, the contract of care was deemed to include the commitment of the practitioner to give his or her patient “conscientious and attentive care and, subject to exceptional circumstances, in line with what is known by science.” This formula appears, slightly modified, in the Code of Ethics, which is now part of the CSP. Article L. 1111-5 para. 1 CSP uses more modern language to express the same principle in terms of subjective rights of the patient:

Any person, given his health and the emergency response that it requires, is entitled to receive the most appropriate care and to receive treatment whose effectiveness is recognized and which guarantees the best safety in light of established medical knowledge. Acts of prevention, investigation, or treatment should not, in the state of medical knowledge, make him take risks that are disproportionate to the expected benefits.


The established standard of scientific knowledge to be considered is the one that existed when the physician performed the therapeutic act of care, not the one that existed at the time of the judgment. For example, it was recently decided that the use of an innovative treatment was not negligent in a case where there were no known adverse effects, where the usual medical treatment had failed, and where no surgical treatment was possible, even though the authorization for marketing the treatment had not been provided for this specific use.34

In general, French courts are not very demanding for negligence to be established so that the victims can be compensated. A simple mistake35 or clumsiness36 may be characterized as negligent. With regard to diagnosis, it should be noted that misdiagnosis is not a fault per se.37 The physician is considered negligent only if he or she failed to gather the necessary resources to complete his or her mission.38 Hence, the persistence of the doctor in his or her diagnosis, in spite of signs justifying a review of such diagnosis, is negligent39 and the physician is at fault if the misdiagnosis could have been avoided through further examination or by appealing to more specialized colleagues.40 Recently, the Conseil d'État sanctioned a hospital that did not proceed with the necessary investigations in order to verify the presence of a tumor: the patient's kidney had been removed when there was no tumor.41 Negligence has been retained in case of "unreasonable obstinacy in investigations or therapy" for the prolonged resuscitation of a child born in a state of apparent death.42

38. The CSP provides that the physician must always make his or her diagnosis with the utmost care and devote the necessary time to his or her analysis with the help of the best-suited scientific methods. CSP art. R. 4127-33; see Cass. le civ., Sept. 30, 2010, No. 09-68372.
requirement also applies to the case of the installation of a device in or on the patient or of an investigation that implies certain risks. Negligence can be committed in the context of the operation of a health service, for example, if certain elements are omitted in the patient's record or if a nurse did not contact in due course the physician responsible for the service.

In very few cases, negligence is assumed. Article L. 1121-10 CSP provides for a presumption of negligence that weighs on the shoulders of any laboratory conducting experiments. The laboratory compensates for damage arising from biomedical research, unless it is able to establish that the damage is not attributable to its negligence.

Finally, it should be noted that medical negligence may also amount to a criminal offense like unintentional manslaughter or involuntary harm to the integrity of the person. Physicians and health professionals are increasingly confronted with criminal proceedings for acts committed in the exercise of their functions. Criminal courts have the ability to award compensation to the victim through the "action civile," under which the health professional can be criminally convicted and the victim can obtain damages directly from the criminal court. Such a procedure is advantageous for the victims because they benefit from the evidence gathered by the penal judge. It should also be noted that under French Law, corporations ("personnes morales") can be criminally responsible. Criminal convictions concerning health professionals have been increasing in recent years, especially unintentional manslaughter and unintentional injuries.

Indeed, French courts appear to be relatively severe in medical malpractice cases. For example, the Criminal Division of the Cour de cassation has recently sentenced for manslaughter a physician who had supervised an intern for a coelioscopy, during which the intern provoked a hemorrhage that resulted in the patient's death.

46. See C. PEN. arts. 222-19, 222-20.
b. Liability for Breach of the Duty of Disclosure
("Obligation d’information")

In addition to the classic case where the physician commits negligence in performing his mission, the practitioner may also be liable for breach of his or her duty of disclosure. Indeed, the physician must disclose to his or her patient the risks of treatment or operation and obtain his or her well-informed consent. This duty was defined by case law before being reaffirmed by the Patients’ Rights Law of March 4, 2002 in Article L. 1111-2 CSP. The Cour de cassation states that such a duty of disclosure “is rooted in the requirement to respect the constitutional principle of safeguarding the human person.” The reference to the principle of human dignity explains that the decision condemning the practitioner who has failed to deliver complete information is based on Article 1382 of the Civil Code, which means that such responsibility is now a matter of tort law.

Previously, the doctor was not obliged to inform the patient of exceptional risks. However, the Cour de cassation ruled that the physician must inform the patient of all the “inconveniences that may arise” and all risks, even exceptional ones. Echoing civil courts, administrative courts adopted a similar position. The Patient’s Rights Law of March 4, 2002 relaxed the rule in Article L. 1111-2 para. 1 CSP that requires information on frequent risks or on serious but normally predictable risks. Thus the disclosed information relates to the various investigations, treatments, or

preventive measures that are proposed, their usefulness, their degree of urgency, their consequences, the frequent or serious risks that could be reasonably anticipated, the likely consequences of refusal, and other possible solutions.56

The mere fact that the intervention is medically necessary does not exclude the duty of disclosure.57 The practitioner also has a duty to advise for or against such treatment or operation and must make the patient aware of the consequences of his or her possible refusal or consent.58 However, there are exceptions to the duty of informing the patient. If the patient’s psychological condition does not allow an understanding of the medical advice or the consequences of his or her decision to accept or refuse the treatment or operation, the physician must keep the information to himself59 and reserve the truth for the family. These limits to informing the patient must be based on legitimate reasons and on the interest of the patient, which must be “assessed according to the nature of the pathology, its foreseeable evolution, and the personality of the patient.”60

In 1997, the Cour de cassation ruled that the burden of proving the performance of the duty of disclosure rests on the doctor.61 The Patients’ Rights Law of March 4, 2002, has confirmed this solution.62 Since performance of the duty is a fact, proof can be established by all means. Therefore, the doctor (especially surgeons) should pre-constitute evidence of the fulfillment of his or her duty to inform by preparing a document containing the information provided in the clearest possible manner that should be signed by the patient.

A physician who fails to disclose information “deprives the patient of an opportunity to escape, by a better decision, the risk that eventually realized,” and the patient’s harm then becomes a specific harm.63 The compensable damage is determined by measuring the lost opportunity of avoiding the treatment or operation.64 In other words, the non-compliance

56. Id.
59. CSP art. R. 4127-35.
with the obligation to inform the patient is the loss of chance ("perte de chance") to escape the risk that eventually realized. Therefore, the failure to disclose information should be without consequences when the medical treatment was indispensable, as the patient had no choice if he or she wanted to recover. Until very recently, the Cour de cassation rejected compensation for moral distress resulting from the fact that the patient had not obtained the relevant information. However, the Cour de cassation has overruled its previous decisions on the subject. On June 3, 2010, the court ruled that a patient who did not receive the complete and necessary information suffered a moral distress for which the patient should be compensated.

c. Vicarious Liability

A physician or a clinic may be vicariously liable in various circumstances. For example, in the case of surgery, a surgeon directs and coordinates the actions of the members of the team that he or she has formed. As team leader, the surgeon is responsible for all the members of the medical team (e.g., anesthesiologist, nurse, midwife) that he or she has chosen. Then he or she has a right of recourse against the negligent professional who caused the harm.

When the practitioner is employed by a private institution, the physician's independence does not preclude his or her subordination with respect to vicarious liability. Despite the fact that such independence belongs to "the general principles of law," it does not prevent a physician from being employed by a hospital or any private institution. Therefore, while, in principle, a clinic or private hospital should not be responsible for the actions of the physician or surgeon because of the independence of those


69. Tribunal des conflits [TC] [reconciles disputes between the Conseil d'État and the Cour de Cassation], Feb. 14, 2000, Bull. t. confl., No. 2; RFDA 2000, 1232, note D. Pouyaud. Indeed, the Code of Medical Ethics forbids the physician to "alienate" his or her independence. CSP art. R. 4127-5.

skilled in the art,\textsuperscript{71} the \textit{Cour de cassation} decides otherwise in cases where an employment contract has been signed.\textsuperscript{72} Thus, private clinics are liable for their salaried practitioners working as employees, including nurses or midwives.\textsuperscript{73} Hence, doctors and other private clinic employees shall not be personally liable when they do not exceed the limits of the mission assigned to them by their employer.\textsuperscript{74} On the contrary, when the physician is self-employed, he or she is responsible for his or her own acts. However, even when the doctor is personally liable, the clinic still is responsible for any breach of its own duty of care,\textsuperscript{75} which varies depending on the circumstances and the patient's condition.\textsuperscript{76}

For damage suffered by the patient of a public hospital, the personal responsibility of the practitioner is normally not likely to be engaged. The fault is covered by the service, unless it may be regarded as entirely separable from the service. Indeed, French administrative law draws a distinction between the public service's negligence (\textit{faute de service}) and the agent's personal fault, which is committed if the practitioner places himself or herself outside the normal scope of his or her mission in light of the seriousness of his or her misconduct. This might be so when a physician refuses to treat a patient\textsuperscript{77} or when a hospital physician does not reveal in due course an error in the injection administered to a patient.\textsuperscript{78} Except in such cases, the patient who suffers a harm that he or she finds to be attributable to the conditions under which he or she was treated should seek the responsibility of the public institution.

\textsuperscript{71} The situation is different for public hospitals.


2. Strict Liability

At the time when medical liability was based on contract law (i.e., before the 2002 Law), physicians or clinics were sometimes deemed to owe an “obligation de résultat” to their patient in certain very specific circumstances. In such cases, they were liable because the expected result (safety in conducting analyses, for example) was not reached, even though no negligence was established. Today, strict liability is provided for in various texts, especially in cases where the physician provides health products and when the patient gets infected with a hospital-acquired or nosocomial infection.

a. Strict Liability for Products Provided by Health Professionals

The CSP states that health professionals are strictly liable for any damage caused by the health products (produits de santé) provided to patients. Evidently, the law requires that the provided product be defective. Such products may be pharmaceuticals, cosmetics, poisonous substances and preparations, vaccines, contraceptives, insecticides, dietary foods for special medical purposes, or medical devices. In doing so, the law reaffirmed previous solutions developed by the courts. For example, physicians or dentists have long been strictly liable for the safety of supplied prostheses even though negligence must be established regarding the installation of prostheses even though negligence must be established regarding the installation of prostheses.

Moreover, the Cour de cassation has ruled that transfusion agencies are strictly liable for harm caused by the poor quality of the blood products.
that they provide. Such a strict obligation of safety ("obligation de sécurité de résultat") was extended to clinics in the case where they provide blood products. It should be noted here that compensation was made easier when the courts relaxed the causation requirement. Indeed, when the victim proves that his or her viral contamination followed a blood transfusion and that no other mode of contamination existed, the burden of proof is shifted to the defendant, who has to prove that the provided blood products were not defective. Such presumption is now provided by various provisions of the Code, which have even abandoned the requirement of the absence of another possible factor.

The Cour de cassation has also decided that health professionals owe an obligation of safety for the things they use in the course of any therapeutic act. However, physicians may be liable only when the thing they use is defective: for example, a physician’s liability was excluded in a case where the patient had an allergic reaction to the physician’s gloves.

In addition, the Conseil d’État decides that public health institutions are strictly liable for the defective products they supply or the materials they use. For contaminated transfusions (e.g., HIV, hepatitis), administrative courts have also granted compensation to victims without requiring proof of any negligence.


Finally, it should be noted that the provisions of Law 98-389 of May 19, 1998, on products liability may threaten the existing rules. This Law implemented in the Civil Code the provisions of the Directive of July 25, 1985, on products liability and established a strict liability of manufacturers (and providers) of defective products for harm caused by such products. Yet such a regime contains substantial differences from the provisions of the Code of Public Health. Under these rules, manufacturers are strictly liable for the defective products they put in circulation, but providers are liable only in the case where the manufacturer cannot be identified. In addition, the limitation period is shorter under the products liability regime. And the defendant is exempted from liability when it is established “that the state of scientific and technical knowledge when the product was put into circulation did not allow for the detection of the existence of the defect,” though such exemption is excluded for damage caused by a product or element of the human body. Since specific liability regimes are, in principle, excluded by the general regime of products liability, one could wonder if the provisions of the CSP still are applicable to defective health products.

*b. Strict Liability for Hospital-Acquired Infections ("Nosocomial Infections")*

With regard to nosocomial (hospital-acquired) infections, the *Cour de cassation* has ruled that physicians and private health institutions were under a “safety obligation of result.” In other words, anytime the infection may be attributable to medical care, clinics and physicians are strictly

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97. See C. civ. arts. 1386-1 to -18.
98. C. civ. arts. 1386-1, -7.
99. See C. civ. arts. 1386-16 to -17.
100. C. civ. art. 1386-11.
101. C. civ. art. 1386-12.
liable, unless they establish that the victim’s harm resulted from an external cause (cause étrangère). There is no presumption of causal link between care and infection, so it is for the patient to demonstrate that his or her infection was contracted in the hospital. Whereas this ruling concerned both private practitioners and health institutions, the Patients’ Rights Law of March 4, 2002 confirmed it only for health care institutions.103 Private practitioners are no longer under this rule. Thus, while clinics and health institutions are still strictly liable for hospital-acquired infections, physicians are liable only for negligence for all interventions that occurred after September 5, 2001.104 In cases where the physician’s civil liability is not incurred, the victim may still obtain compensation in the name of the welfare system (solidarité nationale): Law 2002-1577 of December 30, 2002 decided that the ONIAM bears the cost of compensating infections that result in death or in a permanent disability rate above 24%.105

In the public sector, hospitals’ liability was originally based on the notion of negligence in the organization and operation of the service. In this context, administrative courts created a presumption of negligence, according to which the accidental introduction into the patient’s body of a microbial organism during hospitalization revealed the hospital's negligence.106 However, the Conseil d’État had a rather strict interpretation of the rule and excluded, for example, endogenous infections, i.e., infections that resulted from bacteria that were already present in the body of the patient but appeared on the occasion of hospitalization.107 Now, public hospitals are strictly liable, and Article L. 1142-1 para. 2 CSP provides that health institutions are responsible for damages resulting from hospital-acquired infections, except in the case where they establish an external cause for the victim’s harm.

c. Strict Liability for Harm Resulting from Therapeutic Hazards ("Aléa Thérapeutique")

If an accident occurs in the course of medical care where no negligence was committed, the victim cannot be compensated. Before the Pa-
tients’ Rights Law of March 4, 2002, administrative judges established a compensation scheme guided by fairness for the benefit of patients of public hospitals. In the Bianchi decision in 1993, the Conseil d’État set out several requirements: therapeutic act necessary for the treatment or diagnosis of the patient, with an exceptional but known risk, absence of any predisposition of the patient to such risk, damage directly related to the achievement of hazard, and extremely serious injury. Compensation was to be granted only for disorders that presented an obvious abnormality that was out of proportion to those the patient suffered before care and did not constitute a reasonably foreseeable development of the patient’s previous state. The mechanism was defined narrowly, and the application of the rule was therefore limited. Since the Patients’ Rights Law of March 4, 2002 created a compensation scheme for medical hazards in cases where victims suffer serious harm (permanent disability of 24% or temporary incapacity of more than six months), this rule should henceforth concern a very small number of victims.


109. CE Ass., Apr. 9, 1993, Bianchi Rec. Lebon, 127 (“lorsqu’un acte médical nécessaire au diagnostic ou au traitement du malade présente un risque dont l’existence est connue mais dont la réalisation est exceptionnelle et dont aucune raison ne permet de penser que le patient y soit particulièremen exposé, la responsabilité du service public hospitalier est engagée si l’exécution de cet acte est la cause directe de dommages sans rapport avec l’état initial du patient comme avec l’évolution prévisible de cet état, et présentant un caractère d’extrême gravité”) (“when a medical act necessary for the diagnosis or treatment of the patient presents a risk whose existence is known but improbable, and there is no reason to believe that the patient is particularly predisposed, the public hospital is deemed liable if its execution of the act is the direct cause of injury unrelated to the initial state of the patient, and the injury is extremely serious”)

110. The fact that an accident is due to a risk that was unknown at the time of surgery can preclude compensation. CE, Oct. 24, 2008, No. 297994 M. et Mme Chottin; CE, July 7, 2006, No. 264217, Lagorio


115. See CSP art. L. 1142-1-1.
B. The Causal Link

1. Causation Criterion

The proof of causal link is required to compensate the consequences of any breach of contract or any tort, but the causation criterion is difficult to determine. The theory of the equivalence of conditions has commonly been applied in French civil law, so that a factor must be a but-for condition of the damage to qualify as a cause. This means that causation is not established unless it is shown that the damage would not have occurred absent the factor in question. For example, there is no causal link if it is established that, had the victim been fully informed of the risks of surgery, he or she still would have chosen to undergo it. The equivalence of conditions is also applied in cases where the patient shows pathological predispositions. Indeed, the peculiarities of the patient do not prevent the courts from judging that the physician’s misconduct caused the harm and justifies full compensation—for example, in cases where the medical malpractice had revealed a pre-existing and latent disease or where the patient had an allergic reaction to the gloves used by the surgeon.

However, the principle of equivalence is not always applied as such by the courts. The notions of direct link or adequate causation are sometimes invoked as well. For example, despite the earlier cases, the Cour de cassation has decided to ignore the victim’s contributory negligence to the accident in cases of blood contamination after a traffic accident. Similarly, the Criminal Division of the Cour de cassation has refused to link the death of the victim of a hospital-acquired infection to the accident that made hospitalization necessary. In certain medical malpractice cases, the Civil Chambers of the Cour de cassation have sometimes judged that the victim’s harm could not be considered as resulting from a previous accident.

122. Cass. crim., Oct. 5, 2004, Bull. crim., No. 230. It should be noted that this case applied the new provisions of the law of July 10, 2000, which require proof of serious misconduct if the causal link is indirect. Id.
dent\textsuperscript{123} or from earlier medical malpractice,\textsuperscript{124} even when such events had made the surgery necessary. Moreover, in French administrative law, most commentators have asserted that the requirement of causal link is expressed by the courts through the test of \emph{la théorie de la causalité adéquate},\textsuperscript{125} and there is a good deal of consensus on the use of this test by the administrative judiciary.\textsuperscript{126} Chapus asserts that the correct inquiry is whether the defendant’s act could ‘in the normal run of things’ be considered as having played a ‘particular’ role in causing the damage.\textsuperscript{127} Consequently, it is not possible to speak of a uniform application of the equivalence principle: it varies on a case-by-case basis.

2. Causation Proof

In principle, the burden of proof is upon the claimant to prove that the defendant’s wrongful act has generated his or her damage. In this context, causation is considered as a legal fact ("\emph{fait juridique}") that can be proved by all means ("\emph{par tous moyens}"). This implies that all types of evidence are admissible. Moreover, the assessment of the evidence submitted by the claimant falls within the sovereign appreciation of lower courts ("\emph{appreciation souveraine des juges du fond}"). However, the French Cour de cassation has the ability to review the grounds given by trial judges to justify their decisions. In many cases, judges resort to the use of presumptive evidence by basing their decision on Article 1349 of the Civil Code, which defines presumptions as "the consequences that a statute or the court draws from a known fact to an unknown fact." Specifically, Article 1353 C. civ. provides that presumptions "are left to the insight and carefulness of the judges, who shall only admit serious, precise, and concurrent presumptions." In this context, the Cour de cassation controls the arguments used by judges to justify the admission or rejection of a causal link.\textsuperscript{128} The for-

\textsuperscript{125} ‘Adequacy theory’ or ‘adequate cause theory.’ See JACQUES MOREAU, 2 DROIT PUBLIC: DROIT ADMINISTRATIF 598 (3d ed. 1995); see also WALTER VAN GERVEN, JEREMY LEVER & PIERRE LAROCHE, TORT LAW 421 (2000); Pierre Vialle, \emph{Lien de Causalité et Dommage Direct dans la Responsabilité Administrative [Causation and Damages in Direct Administrative Liability]}, 90 REVUE DE DROIT PUBLIC ET DE LA SCIENCE POLITIQUE EN FRANCE ET A L’ÉTRANGER [JOURNAL OF PUBLIC LAW AND POLITICAL SCIENCE IN FRANCE AND ABROAD] 1243, 1268 (1974).
\textsuperscript{127} RENE CHAPUS, 1 DROIT ADMINISTRATIF GENERAL ¶ 1413 (15th ed. 2001).
mula "serious, precise, and concurrent presumptions" is generally used.129 Here it should be noted that "evidence by exclusion" is a form of presumptive reasoning. If no other factors explain the occurrence of the damage, then the defendant’s behavior is deemed to be a cause—for example, if the patient’s hypertension cannot be explained by anything other than taking a specific drug.130

Whilst French courts generally try to assert their independence vis-à-vis the views of experts, experience shows that, in fact, the impact of science on the judicial determination of causation is significant.131 The French system is particularly marked by the judicial delegation of technical matters to a court-appointed expert. Nevertheless, the Cour de cassation has recently illustrated the willingness of the French judiciary not to follow systematically the view of appointed court-experts. Litigation concerning the Hepatitis B vaccine has given rise to important decisions of the Cour de cassation in a context where there is no tangible scientific evidence of the vaccine’s toxicity. Confronted with victims of neurological disorders such as multiple sclerosis, French judges have gradually changed their minds. In 2003, the Cour de cassation refused to accept the existence of a causal link between Hepatitis B vaccination and multiple sclerosis because of the scientific uncertainty of that link as highlighted by experts.132 However, in 2008, the Cour de cassation handed down six important decisions in which it was accepted that such a causal link could be established by “serious, precise, and concurrent” presumptions, notwithstanding scientific uncertainty and lack of conclusive statistical data.133 Since then, the Cour de cassation has had the opportunity to reaffirm its position on several occa-


131. Cass. le civ., Feb. 27, 2007, No. 06-10063, RCA 2007, No. 165 ("l’existence d’un lien causal ... ne pouvait se déduire du seul fait que l’hypothèse d’un risque vaccinal non démontrée ne pouvait être exclue") ("the existence of a causal link... could be inferred from the mere fact that the hypothesis of an unproven vaccine risk could not be excluded").


sions in cases concerning multiple sclerosis as well as other neurological disorders. In such cases, two considerations are taken into account by judges: first, the fact that no other factor could explain the disease (victim in good health, no medical history); second, the temporal proximity between the injection of the vaccine and the appearance of the first symptoms. It should also be mentioned here that the Conseil d'État has adopted a similar position and criteria in litigation arising from the compulsory vaccination against Hepatitis B. However, in other recent vaccine cases, French judges have denied the existence of a causal relationship when other factors could explain the disease or when the evidence brought by the claimants did not appear sufficient to constitute “serious, precise, and concurrent presumptions.”

“Serious, precise and concurrent presumptions” are “presumptions of fact,” which must be distinguished from “presumptions of law” (“prévomptions de droit”) that require the judge to assume a certain fact once another fact is established. Presumptions of law can be created by the legislature or by the judge. For instance, mandatory presumptions are prescribed by law for certain kind of injuries, especially diseases resulting from contaminated blood transfusions. When the legislator or the judge decides to reverse the burden of proof, this action amounts to a presumption of law. For instance, the Cour de cassation has recently decided to reverse the burden of


139. See supra text accompanying notes 85-89.
proof for the benefit of victims in cases where the defendant could not be identified,\textsuperscript{140} thus creating a new presumption of law in diethylstilbestrol (DES) litigation. More recently, in a case where the victim of a hospital-acquired infection had been treated in various institutions, it was decided that all institutions were jointly and severally liable unless they were able to establish that they did not cause the infection.\textsuperscript{141}

Finally, it should be emphasized that French courts tend to compensate the uncertainty of causal judgments by widely using the concept of loss of chance.\textsuperscript{142} In a seminal case, a doctor had committed an error of diagnosis on a child who remained crippled: the judges condemned the doctor to pay damages for the loss of "chances of cure."\textsuperscript{143} Since this decision, French courts often use the "loss of chance" concept in order to compensate the victims, even though the causal link is uncertain. It is often decided that, if the patient was not thoroughly informed, he or she should be compensated only for the loss of chance to escape the risk. Moreover, compensation is granted for loss of chance when the patient should have benefited from an earlier or better treatment, but it is impossible to determine whether the patient would have recovered if such treatment had been provided.\textsuperscript{144} Thus, the victim must establish that his or her chance of survival, recovery, or even fewer sequelae, would have been greater if the doctor had given a good diagnosis or appropriate care\textsuperscript{145} or if the decision to hospitalize the patient had been taken earlier.\textsuperscript{146} With regards to the public sector, it should be noted that before 2000, the \textit{Conseil d'État} did not apply the concept of loss of chance to hospital liability and decided cases


\textsuperscript{141} Cass. 1e civ., June 17, 2010, Bull. civ. I, No. 137.


\textsuperscript{144} See Cass. 1e civ., July 8, 1997, Bull. civ. I, No. 239.


on an all-or-nothing basis. Then two decisions ruled that the “loss of a chance to escape an event that finally occurred should correspond to a fraction of the various heads of damage sustained.” The Conseil d’État has recently extended compensation for loss of chance to malpractice cases. In addition, the Criminal Division of the Cour de cassation sometimes hands down convictions for manslaughter in cases where only a chance of survival was lost, i.e., where it could not be established with certainty that the patient would not have died if properly cared for. However, when healing, survival, or improving the patient’s condition remains highly speculative in the absence of medical malpractice, no legal remedy is possible because the fault did not cause the victim to lose a substantial chance.

Although the courts do not admit officially that compensation for loss of chance is a way to relax the causation requirement, they accept the principle of measuring compensation in reference to the extent of the lost opportunity. When the impact of the defendant’s action (or forbearance) is difficult to measure, the defendant’s liability is modulated according to the probability that he or she has caused the damage: thus the entire injury is not compensated.

Khoury has pointed out the extreme flexibility of French law on the subject and the proximity of the mechanism of compensation for missed opportunities with liability based on increased risk.

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C. The Victim’s Harm

Article 16-3 para. 1 of the Civil Code provides that the integrity of the human body cannot be impaired except in case of medical necessity for the person.\(^\text{155}\) However, in medical malpractice cases, the damage alleged by the victim often is a lost opportunity for an improvement in his or her condition, because it is difficult to assess what would have happened if the victim had been properly cared for. The \textit{Cour de cassation} has even admitted that the victim’s heirs could be compensated for the loss of a chance of survival.\(^\text{156}\) But there are other kinds of compensable harm. For instance, victims in a chronic vegetative state or who are unconscious can be compensated for moral distress insofar as compensation for damage does not depend on the victim’s subjective feeling, but its finding by the court and its objective evaluation.\(^\text{157}\) Moreover, being contaminated with HIV is compensable as such even if AIDS has not been triggered: the courts use the concept of “specific harm of contamination” ("préjudice spécifique de contamination") in order to compensate the fact of being contaminated.\(^\text{158}\)

Finally, when a child is born disabled or malformed, administrative and judicial courts do not preclude recognition of a parent’s right to compensation if, for example, the child was born disabled as a result of a failed abortion attempt.\(^\text{159}\) When a physician commits an error in prenatal diagnosis regarding the possibility of a genetic or congenital disability, the damage caused by the physician’s misconduct does not correspond to the

\(^{155}\) C. CIV. art. 16-3 ("Il ne peut être porté atteinte à l’intégrité du corps humain qu’en cas de nécessité médicale pour la personne").


\(^{158}\) Cass. 2e civ., Apr. 2, 1996, Bull. civ. II, No. 88; JCP 1996, I, 3985, no 12, obs. Viney ["ce préjudice comprend l’ensemble des préjudices de caractère personnel... tant physiques que psychiques et résultant, notamment, de la réduction de l’espérance de vie, des perturbations de la vie sociale, familiale et sexuelle ainsi que des souffrances et de leur crainte, du préjudice esthétique et d’agrement ainsi que de toutes les affections opportunistes consécutives à la déclaration de la maladie"] ("this harm includes all harms of a personal nature... both physical and psychological, resulting, particularly, in the reduction of life expectancy, disruption of social, family, and sexual life, as well as suffering and fear, disfigurement, loss of enjoyment, as well as all opportunistic infections resulting from the onset of the disease"); Cass. 2e civ., Sept. 24, 2009, Bull. civ. II, No. 226.

handicap, but to the birth of the child. Both the Conseil d'État and the Cour de Cassation have accepted the principle of compensating the parents in such a case. Moreover, in the notorious Perruche case, in 2000, the child himself won a claim for “wrongful life.” Since this latter decision generated much criticism and controversy in France, the Patients' Rights Law of March 4, 2002 has intended to break the trend initiated by the Perruche decision by stating that “no one can claim an injury solely because of his or her birth.” In addition, this Law provides that a person born with a disability due to medical negligence can obtain compensation for his or her damage only when the wrongful act was the direct cause of the disability, or worsened it, or when the practitioner wrongfully avoided taking the measures likely to lessen its impact. In other cases, disabled persons have the right to benefit from the solidarity of the entire national community, which is provided for in Law 2005-102 of February 11, 2005, which created a new “compensation benefit” in addition to the existing aids. In any case, since the provisions of the Patients' Rights Law of March 4, 2002 reduce the existing rights of the victims to obtain compensation, it has been decided that such provisions should be applied only to cases where the child was born after the Law entered into force.


163. Patients' Rights Law of March 4, 2002, supra note 16, at art. 1 ("Nul ne peut se privaloir d'un préjudice du seul fait de sa naissance.").

164. Id.


II. ADMINISTRATION AND ADJUDICATION OF CLAIMS BASED ON LIABILITY RULES

Since the Patients' Rights Law of March 4, 2002, all health professionals and health institutions are under the obligation to buy insurance against their own liability,167 except for public institutions, which are their own insurers.168 Articles L1142-25 and -26 CSP provide for criminal sanctions in the absence of insurance.169 In the case where the liable health professional is not covered (e.g., coverage elapsed or insurance limits are reached), or if the insurer's offer is insufficient, the victim can ask for compensation from the ONIAM.170 It should be emphasized that compensation through public welfare ("solidarité nationale") is subsidiary to compensation based on liability rules, which means that the ONIAM shall only compensate medical accidents when no health professional or institution may be held liable.171 However, the Cour de cassation has recently decided that the two systems shall complement each other when full compensation cannot be granted through liability.172

The Patients' Rights Law of March 4, 2002 has provided for a new procedure to the benefit of the victims, in order to promote simple and quick compensation. Today, the victims have two options: (1) they can...

\[\text{...}\]
bring their claim before a conciliation commission, or (2) they can file a lawsuit against the health professional.\textsuperscript{173}

\textbf{A. Adjudication Through Conciliation Commissions}

The Patients' Rights Law of March 4, 2002 and the Law of December 30, 2002\textsuperscript{174} provide for regional commissions of conciliation and compensation for medical accidents ("Commission Régionale de Conciliation et d'Indemnisation des accidents médicaux, affections iatrogènes et infections nosocomiales" [CRCI]) in each region.\textsuperscript{175} This new organization aims to provide new ways to solve disputes through amicable means and to help the victims obtain prompt compensation. CRCIs were created by the Decree of May 3, 2002\textsuperscript{176} and are meant to be an alternative to courts. CRCIs are chaired by a magistrate and composed of twenty persons, divided into six major categories of members representing patients, health professionals, hospital practitioners, health institutions and facilities, ONIAM, and insurers. The mission of CRCIs is twofold. The first is to promote, through conciliation, the resolution of disputes arising in connection with a medical treatment. The second function of CRCIs is to solve disputes in order to facilitate compensation for the victims of medical accidents who suffer from serious injuries.

As a conciliator, the CRCI seeks to reach a conciliation agreement between the victim and the health professional or the insurer of the liable health professional.\textsuperscript{177} It is possible to bring a request for conciliation before a CRCI when medical care was not satisfactory or in case of disagreement with a health professional or health institution. To be admissible before the commission, the dispute must have originated on a medical incident occurring on or after September 5, 2001. The claimant and the health professional are heard by the commission as a whole or by a single member of the commission, or by an independent mediator, depending on the will


\textsuperscript{175}. CSP art. L. 1142-5.


\textsuperscript{177}. CSP art. L. 1142-5.
of the complainant. The result of the conciliation is stated in a document signed by the claimant and the concerned health professional.

CRCIs also have a mission of dispute resolution in cases of injuries of some importance. To be admitted to this procedure, claims must be related to accidents that occurred after December 5, 2001, and caused serious injuries. In such a case, the victim can take the case to the competent Regional Commission, which has six months to give an opinion based on expertise (if necessary). At this stage, two solutions are possible. First, the commission can make a rejection notice, either because the damage is not attributable to medical care, or because no negligence was committed and the damage is not an abnormal result with regard to the patient's initial state.

Second, the commission may believe that the patient's harm can be compensated. Notice is then transmitted to the institutions responsible for the payment of compensation. It can be either the insurer of the health professional if such compensation can be based on liability rules, or the ONIAM if compensation can be granted on public welfare ("solidarité nationale") principles. In the first case, the insurer of the responsible health professional must make a compensation offer that provides full compensation to the victim within four months. If the victim accepts the offer, a settlement is concluded and payment must be made within one month. The concluded agreement is a "transaction," within the meaning of Article 1144 of the Civil Code which means it ends any possibility of litigation, except in cases where the victim's state has worsened after the settlement was concluded. In case of refusal of the insurer's offer, or if the period of four months is exceeded, the victim can bring the claim before the ONIAM, which then replaces the insurer and makes an offer under the same conditions as discussed previously. In such a case, the ONIAM has a right of recourse against the liable professional or institution insofar as civil liability rules may found such recourse. For its part, the insurer can also challenge the CRCI's opinion before the court.

178. A serious injury is defined as permanent partial disability of 24% or temporary incapacity of at least six consecutive months or six non-consecutive months in a period of twelve months or even, in exceptional cases, inability to carry on business or particularly serious disturbances in the conditions of existence. Décret 2003-314 du 4 avril 2003 relatif au caractère de gravité des accidents médicaux, des affections iatrogènes et des infections nosocomiales prévu à l'article L. 1142-1 du code de la santé publique (Decree 2003-314 of April 4, 2003 Concerning the Serious Nature of Medical Accidents and Iatrogenic and Nosocomial Infections Under Article L. 1142-1 of the Code of Public Health, J.O., Apr. 5, 2003, p. 6114; see CSP art. L. 1142-8.


180. See Helleringer, supra note 20, at 1135–36.
As of today, approximately 60 percent of claims are treated by a settlement concluded through CRCIs.\textsuperscript{181} However, the new system has not resulted in a reduction of the proceedings before the courts, which may be explained by the fact that CRCIs' decisions are often contested before the courts.\textsuperscript{182} The activity of CRCIs is presented in the report that the ONIAM publishes twice a year.\textsuperscript{183} The ONIAM also publishes an indicative scale of amounts to be awarded.\textsuperscript{184}

### B. Adjudication Through Courts

Victims are not obliged to enter into a conciliation procedure under the auspices of the Regional Commissions. They may also proceed against the liability insurer through direct action. Moreover, they can go to court if they are not satisfied with the opinion of the CRCI or with the compensation offer proposed by the insurer of the liable health professional or institution. A victim who has already started proceedings before a court may still bring the claim before the appropriate Regional Commission, as long as the court and the Commission are informed.\textsuperscript{185} With respect to fault-based medical liability, courts appear more severe than CRCIs: 66 percent of claims before courts end up in sanctions, whereas fault is characterized by CRCIs in only 33 percent of cases.\textsuperscript{186}

It should be noted that patients are not the only ones who can enter into proceedings against health professionals by basing their claims on liability rules. Social Security agencies also have a right of recourse against the responsible practitioner for everything they paid to the victim.


\textsuperscript{185} CSP art. 1142-7.

\textsuperscript{186} Courgeon & Letouzey, supra note 182, at 75–76. This aspect is explained by the fact that victims go to court only in cases where the practitioner’s misconduct is obvious.
The limitation period for actions relating to medical liability was reduced to ten years in 2002, then reduced again to five years, though the limitation period is still ten years for claims relating to personal injuries. However, the fact that the limitation period starts at the moment of "consolidation," i.e., the moment when the healing or permanent damage to the victim is stabilized, which may be difficult to determine, counteracts the recent reduction of such period.

Although the Patients’ Rights Law of March 4, 2002 unified the law of medical malpractice from a substantive perspective, the duality of jurisdiction remains. This means that the action shall be filed either in front of civil or administrative courts.

In 2005, the "Observatoire des risques médicaux" (Observatory of Medical Risks), created by Law 2004-810 of August 13, 2004 and attached to the ONIAM, started collecting and analyzing data on medical accidents in order to better understand the cost of claims and to identify the most avoidable accidents. In this respect, it is generally highlighted that the number of claims has significantly increased since the beginning of the 1990s and that the reform of 2002 did not reverse this trend, despite the creation of the new compensation scheme based on national solidarity.

In 2008, the number of claims concerned 2.5 percent of private practitioners. 44 percent of surgeons faced a claim, and 67 percent of the cases submitted to courts ended in liability. The awarded amounts have also increased: while the average cost of a claim was €120000 in 2002, it was €256000 in 2007. Observers agree on the fact that the medical liability insurance sector has been experiencing a major crisis over the past decade, which has led to a net increase in insurance premiums. Some proposals

189. C. CIV. art. 2226.
191. See CSP art. L. 1142-29; generally WANNEPAIN, supra note 181.
192. See generally Courgeon & Letouzey, supra note 182, at 75-81.
193. Id. at 75-82.
194. N. Gombaud, La situation de l’assurance de responsabilité médicale [The Situation of Medical Malpractice Insurance], RDSS 51 (2010); see also Courgeon & Letouzey, supra note 182, at 81 figs.12-13, 82 fig.14.
195. Gombaud, supra note 194, at 51; see also generally INSPECTION GÉNÉRALE DES FINANCES & INSPECTION GÉNÉRALE DES AFFAIRES SOCIALES [INSPECTORATE GENERAL OF FINANCE & INSPECTORATE GENERAL OF SOCIAL AFFAIRS], CONCLUSIONS DU RAPPORT D’ENQUÊTE SUR L’ASSURANCE DE RESPONSABILITÉ CIVILE MÉDICALE [CONCLUSIONS OF THE INQUIRY ON MEDICAL
have thus been made in order to limit the number of trials, like forcing the victims to first bring their claims before CRCIs or creating a procedure of selection of cases by the competent court. But such reforms remain to be done.
