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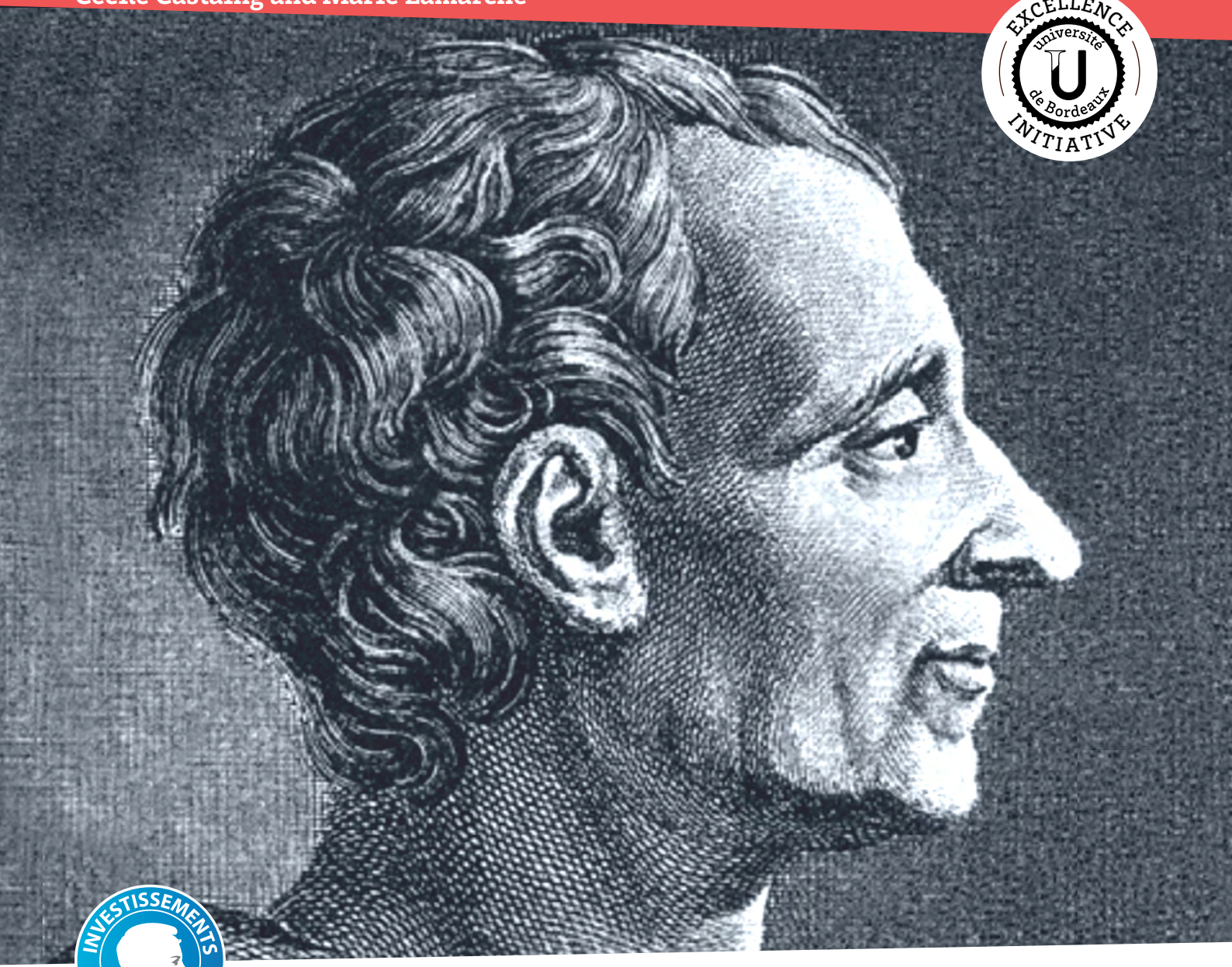

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Civil Law:

Patients at end of life

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Amongst the issues raised by health law, end of life is one of the specific because it touches on each person's beliefs, the choices of society, public order and individual human rights.

The Law of 22 April 2005 on patients' rights and the end of life (1) was an important step in France in supporting patients at end of life, the prohibition of unreasonable obstinacy and the legal regulation of end-of-life decisions. Now the prohibition on causing the death of another, the Law set down a number of essentially procedural rules, incumbent on physicians making decisions as to whether or not to withdraw or undertake treatment or care. The particular nature of the issues surrounding end of life manifests itself especially in the perpetual claim of new rights to be secured, and so the social debate continues to rage. Discussions began on the need to complement/supplement the existing system and were reiterated by the then presidential candidate, François Hollande, who had committed to propose, if elected, that "any person of legal age, at an advanced or terminal stage of an incurable illness, causing unbearable physical or psychological suffering, under clear and strict circumstances, benefit from medical assistance in ending their life with dignity" (2). Once elected, and in accordance with this commitment, the President set up a mission concerning the end of life, entrusted to Professor Didier Sicard, who presented his report *Penser solidairement la fin de vie* 18 December 2012. Other reports followed (3) and a Citizens' Conference was launched in mid-November 2013 to reflect on end of life (4). Several unanimous findings emerged from this work: poor knowledge of the Law of 22 April 2005; the failure of existing measures, ignorance of palliative care and the existence of exceptional circumstances not considered/covered by current legislation. All of these reflections were turned on their heads by the Vincent Lambert "case" and the trial of Nicolas Bonnemaison between 2013 and 2015, having been widely reported in the media, helped fuel the debate surrounding the law on end of life.

A lengthy process then began and, after many months of parliamentary work, exchanges between the French National Assembly and the Senate, the Law creating new rights for patients and persons at end of life was adopted and promulgated on 2 February 2016 (5). The Law states or strengthens a number of fundamental human rights and provides clarification on procedures to be followed in withdrawing treatment. It explicitly provides that artificial nutrition and hydration constitute treatment and affirms the right of any person throughout French national territory to receive the treatment and care best suited to easing patient suffering. The most significant changes are the recognition of a right to continuous deep sedation and the right to respect for advance directives. The Law has put people back at the heart of measures for withdrawing treatment and end of life, where the Law of 22 April 2005 had been heavily criticised as being a procedural law designed to provide a framework for the decisions made by doctors. However, just as it does not legalise new medical practices, it does not really alter the balance in decisions relative to patients at end of life, whether it is a decision to withdraw treatment or an end-of-life decision.

I. Decisions to withdraw treatment

In 2002, the French legislature codified the patient's right to consent to treatment and, further, made patients real players in the care relationship as they are now fully involved in decisions about their health (6). This assertion holds true only as long as patient are able to express themselves; the law is less clear as to the consequences to be drawn in particular when a patient refuses treatment. The 2005 Law established a procedure for withdrawing treatment but did little to dispel the ambiguity, and the question is really one of who decides on the withdrawal of treatment.

A distinction must therefore be made between two situations, depending on whether the patient is able to express himself. This distinction is crucial because, at least until the 2016 Law, physicians held all the decision-making power when the person was no longer able to speak. However, a question has already arisen as to identifying a person "unable to express their will," as the legislature has not specified such a situation. An amendment was put before the National Assembly during debates on the bill that would become the Law of 4 March 2002, indicating that the fact of being unable to express their will "must be due to an altered state of consciousness" to prevent doctors from omitting to secure consent from those patients affected by paralysis or dysarthria (7). The amendment was not adopted. It would appear that the legislature's intention was indeed to equate a person unable to express their will to an unconscious person. The first sign of this is included in a parenthesis in the information report on the 2002 Law, which gives a non-exhaustive list of three situations that describe the position of a person unable to express their will: coma, unconsciousness, mental disability (8). Another sign is in the explanatory memorandum to the draft 2005 Law (9) in which the authors distinguish between the "conscious" and "unconscious" patient. The wording used by the 2016 Law remains the same and contrasts with the very specific legal consequences of that state.

A. The decision to withdraw treatment when the patient is able to express their wishes

The corollary to the right to consent to treatment is necessarily the right to refuse it. The physician will respect this as long as that refusal is not life-threatening for the person who expresses it. In the event that the patient's will to stop or not to begin treatment places his life in danger, the law prior to 2016 only established that the physician should make every effort to persuade the patient to accept essential treatment/care. It is by exploiting this deficiency on the part of the legislature that the courts could confer only relative value to the right to refuse care. The administrative courts in particular have accepted, on grounds of the sanctity of life, a physicians who overrides the refusal of treatment expressed by the patient in order to save the latter's life is not at fault (10). Whilst refusing to give precedence generally to the medical duty to safeguard human life over the respect for the will of the patient, the *Conseil d'Etat* has invited medical practitioners to act according to their conscience and on a case-by-case basis. This precedent was retained after the adoption of the Law of 4 March 2002, and after that of 22 April 2005 (11).

The Law of 2 February 2016 has strengthened the recognition of the patient's wishes to refuse treatment, specifying the legal consequences of the right of consent: it is now expressly provided that *"everyone has the right to refuse or not receive treatment* "and that the doctor "*is under an obligation to respect* " the patient's wishes once the latter has been informed of the consequences and seriousness of their choice (12). Following the same line of greater autonomy of the person, the Law removes the provision requiring the doctor to make every effort to convince the patient to accept essential treatment. If the Law was intended to improve the consideration of the wishes of a patient who refuses treatment, even when those wishes are life-threatening, the question of the

court's interpretation or application arises. It would seem particularly difficult to imagine that the court would reverse existing case law and consider that the doctor who provides essential care to a patient with the sole aim of saving their live would thus commit an act of negligence incurring the doctor's liability; the contribution made by the new Law is thus to be gauged in terms of legal disclosure rather than greater autonomy.

B. The decision to stop treatment when the patient is not able to express their wishes

In such cases and until the 2016 Law, the patient was not an actor in their own health, and the wishes they could express prior to that state were by no means binding on the doctor. Some saw this as a relic of medical paternalism; others as a way to protect the family from sometimes difficult decisions or to protect the patient from decisions that would be guided more by family interests than the patient's own. Pursuing its intention to strengthen the consideration of the patient's wishes, the 2016 Law contains a number of provisions in that vein, even when those wishes are expressed prior to the patient's state of unconsciousness. It is only when those wishes are not known that the doctor may decide, after complying with the requirements of the collegiate procedure, to withdraw treatment where this reflects unreasonable obstinacy.

The person of trust, like family members or relatives, no longer expresses an "opinion" but rather gives a "witness statement". The position thus expressed is therefore deemed to be that of the patient himself. The Law also confirms that "[the] *testimony* [of the person of trust] *supersedes any other testimony*", thus indicating that the patient has exercised their right to appoint a person of trust to whom they have entrusted their wishes if they were no longer able to express themselves: the exercise of this right justifies the prevalence of this evidence over that of other members of the patient's entourage. But the Law does not transfer the responsibility for the decision which, in the absence of any advance directives, falls to the doctor subject to compliance with the collegiate procedure. It is only when advance directives are drafted that the Law gives binding effect to the wishes thus expressed, thereby enhancing the measures still further. The Law now states that advance directives *"are binding on the doctor for any decision to investigate, intervene or treat"* (13). There is no consensus in Europe on the binding nature of advance directives and the legal frameworks in those countries that have adopted regulations are highly heterogeneous (14). The choice made by the French legislature in 2016 was to strengthen the scope of advance directives and to make them "*enforceable under certain conditions*" (15). They do not indicate a desire that may or may not be satisfied, but reflect the wishes of a person who can no longer be ignored. The Law, however, attaches certain exceptions to this rule. An overly general and systematic approach to the binding nature of advance directives carried with it certain risks, especially if the patient's clinical situation were not the same as that described in the advance directive; this freed the doctor of any liability, since they would not have had to assess the patient's medical condition. The Law thus provides for two cases in which advance directives are not binding. The first is "*life-threatening emergency*". In this case, the doctor must be free from any advance directives *"for the time necessary to assess the situation fully ".* The second case is one in which the advance directive would appear to be *"clearly inappropriate"* or *"not in accordance with the medical situation":* the doctor may decide to ignore the directive, provided that this decision is taken at the end of the collegiate procedure. Whatever the applicable case, life-threatening emergency or the manifestly inappropriate nature or non-compliance of the directive with regard to the medical situation, the assessment falls within the sole remit of the medical authority. Thus the principle of the binding or enforceable nature of advance directives is ultimately, if not an illusion or mere wishful thinking, at least dependent on the discretion of the physician, which does not

fundamentally change the former scenario whereby the doctor had to "take account" of advance directives in decisions to withdraw treatment.

II. The end of life

While the Law of 2 February 2016 created "*new rights for patients and persons at end of life*," the French legislature has not taken the step that some expected. These rights include the right not to die: the advocates of any assisted suicide or euthanasia exception have not been successful (16). However, the implementation of "*continuous deep sedation causing altered consciousness maintained until death*" is now possible under Article 1110-5-2 of the Public Health Code. What may have been seen as a compromise in relation to the rejection of euthanasia or assisted suicide was presented as genuine progress in terms of patient autonomy. The qualification of "*the right to continuous deep sedation*", a "*new and major right*" (17), has often allowed it to be believed the goal of "guaranteeing all patients at end of life the certainty of benefitting from such sedation" (18) had been attained.

However, it is through the conditions imposed for use of continuous deep sedation that one can perceive the situations in which the decision can be taken. The autonomy of the individual in relation to end of life appears very limited in reality. There is no question for the person to impose a true "end of life decision" but simply to request or "benefit" from conditions of continuous deep sedation at end of life. Too quick a shortcut could lead one to believe that the deep and continuous sedation brings about the end of life, when the reasoning is in fact the reverse: end of life must first be established before the sedation decision can be made. The new legislation therefore undertakes to retain a more objective and more restrictive definition of end of life: end of life is not caused; it is very limited and uncertain life. The Law's requirements in order to determine an end of life situation likely to give rise to continuous deep sedation, however, can only be fulfilled within a relatively short period of time between the sedation decision and death. End of life becomes a limited period of time, and death may consequently appear to be planned.

A. Sedation subject to end of life

Article 1110-5-2 of the Public Health Code, which governs the administration of continuous deep sedation, distinguishes between two scenarios. The first seems to give way to the patient's wishes since it is "*the patient's request*"; in the second, "*the patient cannot express their wishes*" (19).

The very end of life does not depend here on the patient's wishes, but rather on a condition that strikes the patient. In order to request (not decide upon) continuous deep sedation, the patient must first be suffering from a serious and incurable disease. The patient's life must be threatened in the short term (either directly because of the condition, or due to a withdrawal of treatment decided by the patient) (20); this ultimately corresponds to an imminent end of life. Lastly, the patient must demonstrate "*pain resistant to treatment*" (in the case of a life-threatening condition in the short term due to a serious or incurable disease) or that the decision to halt treatment will "*likely cause unbearable suffering*". The request for continuous deep sedation combined with an analgesic is considered by the medical team through a collegiate process which ensures that the above conditions are met. The assessment of the conditions (disease; life-threatening short-term condition; suffering) is therefore a genuine medical decision and not that of the patient who cannot impose their wishes on the physician. This excludes people suffering from a serious and incurable disease who are not at end of life (their condition is not life-threatening in the short term or who are not suffering (even if they are at end of life) because such suffering can be eased.

Induced end of life is the second case provided by the 2016 Law. When the patient cannot express their wishes and doctors withdraw life-support treatment on grounds of unreasonable obstinacy, (21) end of life is then somehow induced. The patient is not necessarily suffering from a serious or terminal illness which has become life-threatening in the short-term, as in the previous case; but their life depends on a treatment that is halted. The use of continuous deep sedation then appears to be necessary ("[the physician] *administers sedation*" (22)), which stems from the decision to halt life-support treatment, taken in theory in the course of a single collegiate procedure. Note that the legislation provides for sedation "causing an altered state of consciousness maintained until death, associated with analgesia," which shows that the Law of 2 February 2016 of course distinguishes between the patient who cannot express their wishes (objective criterion of the situation) and impaired consciousness (under the effect of sedation). It should also be stressed that advance directives are ignored here. This seems logical since they have been considered *ab initio* for the decision to stop life-support treatment. This may seem less obvious if we consider that to refuse artificial life support does not necessarily imply the wish to benefit from an automatic continuous deep sedation. The patient's wishes do not appear to be more respected here and the doctor's legal obligation to use sedation cannot be described as "*patient's rights*". It is a restrictive view of the duration of end of life that is actually adopted here and, in that sense, the 2016 Law seems to provide a more precise definition for end of life. However, continuous deep sedation does not end life. It is only a "development" in the conditions of end of life. Death may however seem "planned".

B. Sedation in the context of a "planned" end of life

Since sedation can occur only within a very limited timeframe (short-term life-threatening prognosis or withdrawal of life support), it is tempting to believe that the choice of this sedation overcomes the hazard of death, allowing patients to choose when their life will end, which would constitute progress for self-determination of the individual. In fact, it seems as if the end of life, the meaning of death, can be planned or scheduled; it is essentially the doctor who can determine a more or less precise date. The decision to withdraw life-support treatment (particularly artificial nutrition and hydration) allows the doctor to know that death is now close.

This may be related to the issue of organ extraction and the criteria for death as determined by law. It should be recalled that the extraction of organs from deceased patients has forced lawmakers to narrow the criteria for death and, more specifically, so-called brain death (23). The problem of the lack of "donors" (i.e. tissue for transplants) raises questions abroad and in France as to the criteria to be applied. Medics have worked since 1995 at the University Hospital of Maastricht, to begin transplants using organs taken from patients who have died of irreversible cardiac arrests (also known as cadaveric or "non heart-beating" donors). The result of these studies is four categories (Maastricht I to IV) which correspond to cardiac arrest situations, controlled or otherwise. Category III is cardiac arrest of a hospitalised person, resulting from the decision to halt treatment. The extraction of organs from patients who have died from circulatory arrest as a result of the withdrawal of treatment is already effective in several European countries (including the UK and the Netherlands) and is the subject in France of an experimental protocol in force at a number of pilot hospitals, supervised by the *Agence de Biomédecine* (Biomedicine Agency), under the stewardship of the *Office parlementaire d'évaluation des choix scientifiques et technologiques* (Parliamentary Office for the Evaluation of Scientific and Technological Options) (24).

If one juxtaposes the announced amendment to the criteria for death in order to proceed with organ extraction and planned death with the withdrawal of life support and the use continuous deep sedation, one might just begin to wonder. Should we fear that the organ extraction process may begin for a patient who is not yet dead but from whom treatment has been withdrawn whilst under continuous deep sedation? This fear can , with a great deal of caution, be put into perspective with the 2016 Law, the *loi Touraine*, which amended Article L1231-1 of the Public Health Code concerning organ extraction (25). The goal of increasing the number of transplants has driven lawmakers to strengthen the "*presumption of consent to donation*": the doctor may only be bound by a refusal expressed by the patient whilst still alive and not by statements given by relatives of the deceased who, since 1 January 2017, are merely informed of the decision (26). It should not be the case that some people, particularly the vulnerable, agree in advance to organ extraction in order to qualify for the withdrawal of treatment and continuous deep sedation (27). The question arises in Belgium with access to euthanasia. The right to die (unrecognised in France) cannot be haggled over and obtained for the price of the organs which are lacking for the living. The progress heralded by the Law of 2 February 2016 on patient autonomy can quickly become illusory, if not dangerous.

Notes:

(1) *Loi n° 2005-370, JORF n°95 du 23 avril 2005 p. 7089*.

(2) Proposal 21 by presidential candidate François Hollande, during the 2012 election.

(3) Conseil national de l'Ordre des médecins, 8 février 2013 ; Comité national de suivi du développement des soins palliatifs, Bilan du plan « Soins palliatifs » 2008-2012, juin 2013 ; Comité consultatif national d'éthique, 13 juin 2013.

(4) Opinion submitted on 14 December 2013.

(5) *Loi n° 2016-87 du 2 février 2016 créant de nouveaux droits en faveur des malades et des personnes en fin de vie, JORF n° 0028 du 3 février 2016* (Law No. 2016-87 of 2 February 2016 creating new rights for patients and persons at end of life, *JORF* No. 0028 of 3 February 2016).

(6) *Loi n° 2002-303 du 4 mars 2002 relative au droit des malades et à la qualité du système de santé, JORF du 5 mars 2002, p. 4118* (Law No. 2002-303 of 4 March 2002 on patients' rights and the quality of the health system, JORF of 5 March 2002, p. 4118). Art. L 1111-4 Public Health Code.

(7) *Assemblée nationale (AN), Discussion en séance publique, 2ème séance du 3 octobre 2001, Compte-rendu analytique. Amendement 128.*

(8) *Rapport d'information, AN n° 3688, 11 avril 2002.*

(9) *AN n° 1882, 26 octobre 2004.*

(10) CE 26 October 2001, *Mme. Senanayake,* No. 198546.

(11) TA Lille, 25 August 2002, No. 02-3138; CAA Nantes, 20 April 2006 No. 04NT00534.

(12) Art. L. 1111-4 Public Health Code, paragraphs 2 and 3.

(13) Art. L. 1111-1 Public Health Code.

(14) See methodological note and documentary summary titled « Pourquoi et comment rédiger ses directives anticipées ? », HAS, April 2016.

(15) *Rapport sur la proposition de loi créant de nouveaux droits en faveur des malades et des personnes en fin de vie, AN n° 2585, 17 février 2015.*

(16) It should be recalled that neither the Sicard Report (cited above) nor the CCNE's Opinion 121 submitted on 1 July 2013, « Fin de vie, autonomie de la personne, volonté de mourir » had made such recommendations. As part of the *Conférence des citoyens sur la fin de vie* (14 December 2013), however, some expressed support for these solutions. Later in the

legislative debate, amendments to authorise "active medical assistance to die" or assisted suicide were successively rejected.

(17) See e.g. C. Bergoignan Esper, « La loi du 2 février 2016 : quels nouveaux droits pour les personnes malades en fin de vie , », *RDSS* 2016, p 296 et s.

(18) *Ibid.* It should be recalled that the doctor could already implement treatments including analgesics and sedatives to "accompany the dying until his final moments" (Article R. 4137-37, last paragraph, Public Health Code).

(19) On persons "unable to express their wishes", see above.

(20) The two scenarios are envisaged at points 1 and 2 of Article L. 1110-5-2, Public Health Code.

(21) See above, Part I.

(22) Article L. 1110-5-2, para. 4, Public Health Code.

(23) A decree of December 31, 1941 had set the criterion of stopping the blood flow and a circular of 24 April 1968 had substituted the criterion of stopping the circulation of the brain death and according to a decree of December 2, 1996 - Article R. 1232-1 to 4 CSP - the finding of death, in the case of people with persistent cardiac and respiratory arrest, should be based on three clinical criteria simultaneously present (total lack of conscience and spontaneous motor activity, abolition of all brainstem reflexes, abolition of spontaneous breathing). Clinical examination attesting to the irreversible destruction brain (brain death) should be performed if the person died clinically but is assisted by mechanical ventilation and maintains hemodynamic function (cardiovascular circulation).

(24) On all these issues, see http://www.agence-biomedecine.fr/Arret-circulatoire-suite-a-un , the protocol guide and an instructional guide.

(25) *Loi n° 2016-41 du 26 janvier 2016 de modernisation de notre système de santé* (Law No. 2016-41 26 January 2016 modernising the French health system)

(26) Article 192 of the Law of 26 January 2016 refers to orders made by the *Conseil d'Etat*, the question of the conditions under which the finding of death is established and "the prohibition or suspension of protocols mentioned at Article 1232-3 by the Minister for research and arrangements for the transmission by the *Agence de biomédecine* of information available to it on the protocols.

(27) On the behavioural analysis of law, see A. Alemanno, G. Hellinger, A.-L. Sibony, « Brève introduction à l'analyse comportementale du droit », *Dalloz* 2016, p. 911