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## ***HEPATITIS B VACCINATION AND THE RISK OF DEMYELINATING DISEASE IN FRANCE***

by

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# ***HEPATITIS B VACCINATION AND THE RISK OF DEMYELINATING DISEASE IN FRANCE***

by

Isabelle Chivoret<sup>♦</sup>

## **Abstract:**

The difficult determinations of causation that arise in tort cases are particularly troublesome to the courts and lawyers when plaintiffs claim that the use of a defendant's product caused their injuries or disease. A perfect illustration of this issue is the concern that hepatitis B vaccine may cause or exacerbate a demyelinating disease in exceptional cases, in particular multiple sclerosis and Guillain-Barré syndrome. Indeed, scientific available data does not support such a suggestion, but French judgments specify circumstances under which the causal relationship between these vaccines and these diseases may be proven by presumptions of fact. In these cases, the opportunity to use presumptions for proving such a link does not seem to be justified.

*Key words:* Product liability, Pharmaceutical product, Hepatitis B vaccine, Demyelinating disease, Multiple sclerosis, Guillain-Barré syndrome, Causality, Causation, Imputability, Presumptions, Risk-benefit ratio.

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## **Introduction**

All vaccines and drugs may cause side effects. It is the role of drug safety monitoring and epidemiological studies to identify and monitor these possible side effects, which must further be described in the various information documents that come along with any pharmaceutical product legally marketed in the European Union. Nonetheless, the evidence of an unquestionable causal link between an adverse effect and a substance is made difficult in the presence of scientific uncertainty. A perfect illustration of this issue is the concern that hepatitis B vaccine may cause or exacerbate a demyelinating disease in exceptional cases, in particular multiple sclerosis and Guillain-Barré syndrome<sup>1</sup>.

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<sup>1</sup> A demyelinating diseases is a nervous system disease. The primary demyelinating disease is multiple sclerosis (MS), “an inflammatory autoimmune disorder of the central nervous system with destruction of the myelin sheath surrounding neurons” (VIAL T, DESCOTES J. Autoimmune diseases and vaccinations. *European Journal of Dermatology* 2005;14;2:86-90). Guillain-Barré syndrome (GBS) is a type of demyelinating disease of the peripheral nervous system. It is “an acute inflammatory autoimmune demyelinating polyradiculoneuritis that results in progressive paralysis” (*ibid*). Rheumatoid arthritis is a chronic (long-standing) joint disease that damages the joints of the body.

Since hepatitis B vaccination began in 1982, different hepatitis B vaccines have been administered to over a 1 billion people around the world<sup>2</sup>. In France, the legislation requires health professionals to be immunized against hepatitis B virus since 1991<sup>3</sup>. A mass immunization campaign against hepatitis B has been initiated by France's health minister Mr Douste-Blazy in 1994. One year later, the possibility that the vaccination may be linked to demyelinating diseases originated from cases reports describing the onset or recurrence of demyelination symptoms shortly after the vaccination. Therefore, the possibility of an association between the vaccination and such sides effects has received wide coverage in the French media. However, what do we know exactly about the risk to contract a demyelinating disease after the vaccination against hepatitis B?

The possibility of a link between the vaccination and demyelination events has been evaluated in several studies. Yet, so far, the weight of the available scientific evidence does not support the suggestion that the vaccination may cause or exacerbate demyelinating diseases<sup>4</sup>. Only the Hernán *et al.* study<sup>5</sup> which have investigated this issue some years ago admitted a link between the recombinant hepatitis B vaccine and an increased risk of multiple sclerosis. This study was published in the journal *Neurology* in September 2004 and has encouraged the World Health Organization (WHO) to take a stand on this controversial question. The Global Advisory Committee on Vaccine Safety (GACVS) of the WHO has thus carefully reviewed the scientific evidence on whether hepatitis B vaccine can cause demyelinating diseases and has decided that available scientific data does not demonstrate a causal relationship between hepatitis B vaccination and such diseases. Concerning especially the so mediated Hernán *et al.* study, the GACVS has decided that the evidence and argument submitted by the researchers were “insufficient to support the hypothesis of a link between hepatitis B vaccination and multiple sclerosis”

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<sup>2</sup> KANE M. Global programme for control of hepatitis B infection. *Vaccine* 1995;13 Suppl 1:S47-S49.

<sup>3</sup> Act n° 91-73 of 18 January 1991. Article L. 3111-4 of the French Public Health Code.

<sup>4</sup> ASCHERIO A, ZHANG SM, HERNAN MA, OLEK MJ, COPLAN PM, BRODOVICZ K, WALKER AM. Hepatitis B vaccination and the risk of multiple sclerosis. *New Eng J Med* 2001;344:327-32. CONFAVREUX C, SUISSA S, SADDIER P, BOURDES V, VUKUSIC S, for the vaccines in multiple sclerosis study group. Vaccinations and the risk of relapse in multiple sclerosis. *New Eng J Med* 2001;344:319-26. DE STEFANO F, VERSTRAETEN T, JACKSON LA, OKORO CA, BENSON P, BLACK SB, SHINEFIELD HR, MULLOOLY JP, LIKOSKY W, CHEN RT. Vaccinations and Hepatitis B vaccine central nervous system demyelinating disease in adults. *Arch Neurol* 2003;60:504-9. SADOVNICK AD, SCHEIFELE DW. School-based hepatitis B vaccination programme ad adolescent multiple sclerosis *Lancet* 2000;355:549-50; STURKENBOOM M, ABENHAIM L, WOLFSON C, ROULLET E, HEINZLEF O, GOUT O. Vaccinations, demyelination and multiple sclerosis study (VDAMS): a population-based study in the UK. *Pharmacoepidemiol Drug Safety* 1999;8:S170-S171. TOUZE E, FOURRIER A, RUE-FENOUCHE C, RONDE-OUSTAU V, JEANTAUD I, BEGAUD B, ALPÉROVITCH A. Hepatitis B vaccination and first central nervous system demyelinating event: a case-control study. *Neuroepidemiology* 2002;21:180-6. WEIL JG, EINHAUPL KM. No increase in demyelinating diseases after hepatitis B vaccination. *Nature Med* 1999;5:964-5. ZIPP F, WEIL JG, EINHAUPL KM. No increase in demyelinating diseases after hepatitis B vaccination. *Nature Med* 1999;5:964-5.

<sup>5</sup> HERNÁN MA, JICK SS, OLEK MJ, JICK H. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. *Neurology* 2004;63:838-42.

and did “not justify discontinuation or modification of immunization programs with HBV”<sup>6</sup>. Given that the benefits of the vaccination have never been questioned, the risk-benefit *ratio* of the vaccination remains favorable. For this reason, national programmes of hepatitis B vaccination are still recommended by the WHO for all countries.

In spite of the lack of scientific data supporting a causal link between hepatitis B vaccination and the development or the exacerbation of demyelinating diseases, patients who developed such diseases after having received the vaccine claimed since the end of the 1990's that the latter has been the cause of their injury and asked for damages. To determinate whether these patients are entitled to receive compensation, judges have to decide whether the plaintiff has adequately proven that the injury was caused by the vaccine. In these circumstances, the dispute raises the question of the judicial treatment of scientific uncertainty in judgments involving pharmaceutical products. The specific question is: Can judges establish a causal relationship between a product (such a vaccine) and a damage (such a nervous system disease) despite the lack of scientific evidence of the causal link between the two? If so, in what circumstances?

Judges don't often have the opportunity to answer the question of this link. This relationship is indeed generally not disputable. For instance, people with hemophilia should not take aspirin because aspirin increases the risk of bleeding. Nonetheless, cases involving pharmaceutical products and scientific uncertainty usually present courts with a difficult causation issue and plaintiffs can be easily placed in the position of being unable to prove that the product has caused their injury. In the dispute of people who developed serious nervous system diseases shortly after receiving the hepatitis B vaccine, French administrative and judicial courts finally decided to establish in certain circumstances a causal link between vaccination and demyelinating diseases since the end of the 2000's (I). For reasons which will appear evident in the discussion that follows, the decisions of the courts of justice were viewed as a progress for followers of the compensation of “victims” of the vaccination<sup>7</sup>. However, these decisions were criticized in the medical world because it is not biologically plausible that the hepatitis B vaccine can cause or exacerbate demyelination. Besides, such decisions were not unanimously approved in the

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<sup>6</sup> World Health Organization Global Advisory Committee on Vaccine Safety: Response to the paper by MA Hernán and others in *Neurology* 14th September 2004 issue entitled “Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis”.

<sup>7</sup> See for instance GRYNBAUM L. Produits de santé défectueux: la Cour de cassation s'affranchit des doutes scientifiques. *Gaz. Pal.* 2009;328:47. LEGOUX A. Avis de l'avocat général. *Gaz. Pal.* 2009;225:9. MAURY F. Victimes du VHB (vaccin contre l'hépatite B): faut-il attendre une certitude scientifique pour les indemniser? *Médecine & Droit*, 2004;125. MAZEAUD D. La distension du lien de causalité à des limites. *Dalloz* 2004;1344. MISLAWSKI R. Vaccin contre l'hépatite B et scléroses en plaques; retour sur la causalité. *Médecine & Droit* 2010. RADÉ C. Vaccination anti-hépatite B et sclérose en plaques: première condamnation d'un laboratoire. *RCA* 2009;13. SARGOS P. Les effets indésirables du droit des produits défectueux en matière de dommages causés par des médicaments, et notamment des vaccins. *JCP G* 2009;41:308.

judicial world<sup>8</sup>. The establishment by judges of a causal link between hepatitis B vaccination and demyelinating diseases may indeed be criticized (II).

## **I - The establishment of a causal link between hepatitis B vaccination and demyelinating diseases**

In cases related to the hepatitis B vaccination, facts are relatively easy to understand. The plaintiff who has contracted a demyelinating disease after being injected with an hepatitis B vaccine claims that the vaccine caused the disease and asks for compensation. In principle, the claimant has to prove that the damage is attributable to the product and courts must decide whether the claimant has adequately proven that the alleged injury has been caused by the product. In France, judges have answered the question of this causal link between the hepatitis B vaccine and demyelinating diseases in the legal framework of three kinds of liabilities: the liability of the French State for damages resulting from compulsory vaccinations, the employer's liability for damages resulting from work-related accidents, and the product liability<sup>9</sup>. Over the last 13 years<sup>10</sup>, there has been an ambivalence towards the way post-vaccination events are viewed by courts. The causal issue was different according to the context of the vaccination. Nowadays, the case law seems stabilized and admits the establishment of a causal link between the hepatitis B vaccination and demyelinating diseases, despite the lack of scientific evidence data supporting such a relationship. The case law considers that this relationship may be presumed under certain circumstances. The cases related to compulsory vaccination and work-related accidents

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<sup>8</sup> See notably BORGHETTI J-S. Vaccinations contre l'hépatite B et scléroses en plaques: en cas de doute scientifique persistant, prière de s'adresser à la juridiction la plus proche! RDC 2010;1:79. JOURDAIN P. Lien de causalité entre vaccination et maladie apparaissant ultérieurement: la jurisprudence s'affine. RTD civ. 2009:723. SERINET Y-M, MISLAWSKI R. Vaccination contre l'hépatite B: les conditions de la responsabilité du fait des produits défectueux. Dalloz 2004:898.

<sup>9</sup> The resort to precautionary principle seems not convincing to admit the manufacturer's liability. According to this principle, which applies in the context of scientific uncertainty, "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" (Wingspread Statement on the Precautionary Principle, 1998). Then the question should be: Should the precautionary principle justify precautionary measures, as the prohibition or the restriction of the hepatitis B vaccine, in the presence of the lack of scientific data supporting a causal link between hepatitis B vaccination and the development or the exacerbation of demyelinating diseases? It seems difficult to respond to this question with a positive answer, and thus to admit the manufacturer's liability because he did not take such measures. Indeed, the precautionary principle must apply to the proved benefits, not only to the presumed side effects, and for the moment the risk-benefit ratio of the vaccine remains favorable.

<sup>10</sup> The first decisions concerning the hepatitis B vaccination have been rendered in 1997 and 1998: Court of First Instance of Nanterre, 4 April 1997: *Nouv. Pharm.* 2000;367:257. Court of First Instance of Nanterre, 5 June 1998: REVEL J. Les risques de la vaccination: rôle causal du produit ou prédisposition du patient? *Dalloz somm.* 1999:246. GALLOUX J-C. Obligation de sécurité du fabricant de vaccins. *Dalloz somm.* 2009:336. MONTEYNE P, ANDRÉ FE. Is there a causal link between hepatitis B vaccination and multiple sclerosis? See also GIRARD M. Questions et... réponses sur l'imputabilité médicamenteuse. *Dalloz* 2001:1251.

(A) and the cases related to products liability will be explained separately (B). Indeed, French judges apply special texts which take into account the compulsory character of the vaccination for certain employees.

*A - The cases related to compulsory vaccinations and work-related accidents*

The first judgments rendered in “the hepatitis B vaccination affair” have been delivered by both administrative and judicial courts in relation to compulsory vaccination and work-related accidents. In this legal framework, persons who have contracted demyelinating diseases following after the hepatitis B vaccination have different legal means to claim compensation for their injuries (1). Nevertheless, whatever the legal means chosen by claimants to ask for compensation, judges admit that the causal relationship between the vaccination and their diseases may be presumed under certain conditions (2).

1 - The law

A system of compensation was established for injury resulting from compulsory vaccination by the Act n° 64-643 of the first July 1964<sup>11</sup>. The Act introduced a no-fault and non-contractual liability of the French State. Such a liability is justified because the authority to enact rules relevant to the protection of the public health, like mandatory vaccination rules, derives from the State's general police powers. Vaccination against hepatitis B is imposed since 1991<sup>12</sup>. Nowadays, the Article L. 3111-4 of the French Public Health Code requires such an immunization for all persons exposed as a result of their professional activity in a public or private health care or medical prevention establishment to the risk of contamination, as well as all medical students<sup>13</sup>. The compensation procedure concerning compulsory vaccination is notably governing by the Article L. 3111-9 of the French Public Health Code. The article specifies that the compensation requires a damage directly imputable to the compulsory vaccination. Then, the imputability of the damage to the vaccination is explicitly required. Administrative judges are

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<sup>11</sup> See concerning the accidents related to the compulsory vaccination: MODERNE F. La responsabilité administrative en cas d'accidents de vaccination. R. 1974;65; La responsabilité généralisée de l'État à raison des accidents causés par les vaccinations obligatoires. Dalloz chron. 1975:161; Un nouveau progrès législatif dans la réparation des conséquences dommageables des vaccinations obligatoires. R. 1986:583. The Act of 1964 was modified by the Act of 26 May 1975 and by the Act of 3 January 1985. See the decision of the Conseil d'État of 7 March 1958, which consecrated French State's presumed fault liability: Rec. CE 1958:153.

<sup>12</sup> Act n° 91-73 of 18 January 1991. Article L. 3111-4 of the French Public Health Code.

<sup>13</sup> See the Order of 6 February 1991 which establishes the conditions of immunization of persons covered by Article L.10 of the French Public Health Code, and the Order of 15 March 1991 which establishes a list of public or private health care or public health establishments in which exposed personnel must be vaccinated. See also the Act n° 2002-303 of 4 March 2002 which extends the protection regime to people who were vaccinated against hepatitis B before the enforcement of the law of the 18 January 1991.

competent for cases related to the French State liability for damages resulting from mandatory vaccination<sup>14</sup>. Pursuant to Article L. 3111-9 of the French Public Health Code, the application of the French State's no-fault liability regime, concerning compulsory vaccination, does not exclude the application of the work-related accidents or accident de service legislation<sup>15</sup>.

A system of compensation was established for injury resulting from work-related accidents at the close of the nineteenth century<sup>16</sup>. Both administrative and judicial courts are competent to render judgments in the context of work-related accidents. If the employee work in the public sector, administrative judges are competent. If the employee work in the private sector, judicial judges are competent. Besides, it should be noted that in France the work-related accident is differently called when the employee work in the public sector. The term is accident de service. Furthermore, that is not only a terminological distinction because judges do not apply the same texts and thus the compensation proceedings concerning the work-related accident and the accident de service are different, especially as regards the link between the work and the accident, *i.e.* the recognition of the professional character of the accident.

On the one hand, judicial judges apply the Article L. 411-1 of the French Social Security Code. The Article defines the notion of work-related accident. A work-related accident is the accident, whatever is its cause, which arises out of or in the course of work and causes personal injury to any person employed by one or more employers or entrepreneurs. The case law establishes a rebuttable presumption of the link between the accident and the work, and thus of the professional character of the accident, when the accident occurred during working hours and at the place of work<sup>17</sup>. Such a presumption can be overturned if the accident was not sudden and if the employee was not subordinate to his employer<sup>18</sup>. Besides, the employer or the Caisse de sécurité sociale<sup>19</sup> can contest the professional

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<sup>14</sup> Since recent French health system reforms (Act n° 2002-303 of 4 March 2002 and Act n° 2004-810 of 13 August 2004), claims shall be submitted to the office of National Indemnification for accidents of a medical nature, for nosocomial infections and for iatrogenic infections (ONIAM).

<sup>15</sup> The Article considers that this liability regime should apply “without prejudice” to the application of another regimes. That is mean that, even though the liability of the French State is recognized, work-related accidents regulations or accidents de service regulations shall apply. See for a consecration of this solution: Second Civil Law Chamber of the Cour de cassation: 22 March 2005, n° 03-30551, Bull. civ. 2005;II;75:68: OLIVE P. Gaz. Pal. 2005;181:28; Conseil d'État, 9 mars 2007, n° 278665, 267635, and Conseil d'État, 10 April 2009, n° 296630, *op. cit.*

<sup>16</sup> By instituting the employer's no-fault liability, the Act of 9 April 1898 has allowed victims of work-related accidents to obtain compensation under conditions more advantageous than these offered by tort rules. The Act was modified at several occasions. See Act of 29 October 1919, Act of 27 January 1993, Act of 30 October 1945 and Act of 30 October 1946. Since these two last Acts, the Sécurité Sociale compensate the employees victims.

<sup>17</sup> See Social Law Chamber of the Cour de cassation, 28 March 1973, n° 72-10435, Bull. soc. 1973;194. The link is presumed because the accident provoked personal injury and arose suddenly at work.

<sup>18</sup> See recently Social Law Chamber of the Cour de cassation, 23 May 2002, n° 00-14154, Bull. soc. 2002;V;178: PRÉTOT X. TPS 2002;268.



character of the accident. They can prove that the accident has no link with the work. The absence of any contestation during a limited-time leads to an implicit and definitive establishment of the causal relationship between the accident and the work (and thus, for instance, between a vaccination and the work which requires the vaccination). On the other hand, administrative judges apply the Act n° 84-53 of 26 January 1984 and the French Civil and Military Pensions Code. According to these texts, the relationship between the work and the accident de service has to be proven by the claimant. It does not exist in this legal framework such an automatic recognition of the link. This is a fundamental difference.

## 2 - Establishing of the law

The Cour de cassation has rendered several decisions relating to work-related accidents (Article L. 411-1 of the French Social Security Code) which are compensated if the presumption of the link link between the accident and the work is not overturned. On 11 May 2000<sup>20</sup>, the court decided that the development of osseous disorders could not be considered as a work-related accident because the vaccination was not mandatory for the employee. Indeed, the employee decided to receive the vaccination (whatever if the vaccination was recommended by the occupational health physician). The employee was thus not under the authority of the employer. On 13 February 2003<sup>21</sup>, the Cour de cassation decided that the incidence of a rheumatoid arthritis which occurred following a vaccination against hepatitis B could be considered, though, as a work-related accident, even though the vaccination was not imposed to the employee. Indeed, the employer asked the employee to be vaccinated. Then, the employee was under the authority of the employer. In the case under consideration, it is important to notice that the court also took into account the evidence of the link between the vaccination and the disease, but the proof of this link was not really relevant. The medical certificate of the employee's general practitioner attested indeed an unquestionable link between the disease and the vaccine, but was in complete contradiction with available scientific data. Moreover, the accident was not sudden.

An important decision rendered on 2 April 2003<sup>22</sup> by the Social Law Chamber of the Cour de cassation admitted that a multiple sclerosis could be considered as a work-related accident. The court delivered a ruling which clearly overturned the whole system of compensation for work-related accidents. In this

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<sup>19</sup> In France, the employer have to take out insurance for its employees covering work-related accidents. The insurance (Caisse de sécurité sociale) covers compensation. For this reason, the Caisse de sécurité sociale can contest the professional character of the accident. See Articles 413-1 *et seq.* of the French Social Security Code.

<sup>20</sup> Social Chamber of the Cour de cassation, 11 May 2000, n° 98-15632.

<sup>21</sup> Social Chamber of the Cour de cassation, 13 February 2003, n° 01-20972.

<sup>22</sup> Social Chamber of the Cour de cassation, 2 April 2003, n° 00-21768, Bull. civ. 2003;V;132: KOBINA-GABA H. Abandon du critère de souveraineté et confirmation du critère de la subordination. Dalloz jur. 2003:1724. VERKINDT P-Y. Accident du travail et vaccination. RDSS 2003:439.

new case, judges considered that the disease following a vaccination imposed by employer and carried out for work-related purposes can be considered as a work-related accident, whatever the cause of the disease or the date of the incidence of the disease. In the instant case, judges explicitly admitted that a work-related accident does not have to be sudden for being compensated and implicitly presumed the imputability of the disease to the vaccination<sup>23</sup>. On 25 May 2004<sup>24</sup>, the Civil Law Chamber of the Cour de cassation rendered a decision concerning the following facts: an occupational health physician recommends the vaccination to an employee for whom the vaccination was not required for work-related purposes; the employee's general practitioner vaccinated the patient outside the place and the working time. In this case, the plaintiff contracted a multiple sclerosis after being injected by the hepatitis B vaccine and alleged that the incidence of the disease was a work-related accident. The court answered the question of the professional character of the accident, deciding that the vaccination was a compulsory medical act because it was asked by the occupational health physician<sup>25</sup>. Concerning a healthcare student for whom the vaccination was mandatory, the same solution was rendered by the Cour de cassation on 22 March 2005<sup>26</sup>. The court held that the causal link between the disease and the vaccination was adequately proved by a plaintiff's medical certificate. This decision was confirmed by a decision on 14 September 2006<sup>27</sup>.

So the most that can be said is that judicial judges always discussed the justification or the professional character of the vaccination. Indeed, texts and the law case require such a link between the work and the accident. However, judges more rarely discussed the question of the causal link between the vaccination and the injury, even though they never affirmed the absence of any link between the disease and the vaccination. Indeed, this link is not explicitly required by texts and the law case. When judges analyze this link, it was very easily established by judges (proved by a plaintiff's medical certificate<sup>28</sup>). Finally, one element is really relevant to define a work-related accident in the framework of hepatitis B

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<sup>23</sup> Even though such a presumption usually requires a time proximity between the vaccination and the first symptoms of the disease. See Chambres réunies. 7 April 1921: S. 1922;1:81. This is a constant case law. See for instance Social Chamber of the Cour de cassation: 8 June 1995, Bull. civ., 1995;V; 351 and 4 December 1997.

<sup>24</sup> Second Civil Law Chamber of the Cour de cassation, 25 May 2004, n° 02-30981, Bull. civ. 2004;II;237: L'affection résultant d'une vaccination imposée par l'emploi constitue un accident du travail. TPS 2004;266. ROUGÉ-MAILLART C, JOUSSET N, GUILLAUME N, PENNEAU M. Complications neurologiques et vaccination contre l'hépatite B: l'impossible conciliation entre la preuve scientifique et la preuve judiciaire. Conséquences sur la pratique expertale. Médecine & Droit. 2005:89.

<sup>25</sup> See contrarily: Social Chamber Law of the Cour of cassation, 11 May 2000, *op. cit.*

<sup>26</sup> Second Civil Law Chamber of the Cour de cassation, 22 March 2005, n° 03-30551, *op. cit.* See *ibid* at 11.

<sup>27</sup> Second Civil Law Chamber of the Cour de cassation, 14 September 2006, n° 04-30642: JCP 2006:1852: FANTONI-QUINTON S. RDSS. 2007:281.

<sup>28</sup>

vaccination: the mandatory character of the vaccination, whatever the vaccination was required by employer or prescribed by the occupational health physician.

Administrative courts rendered numerous judgments in the legal framework of accidents de service<sup>29</sup>. In this framework, the relationship between the work and the accident de service has to be proven by the claimant. Originally, most of administrative courts were hostile to admit such a link<sup>30</sup>. Then, an employee submitted to a mandatory vaccination against hepatitis B could obtain compensation if the judge was judicial and not administrative. Such a solution was not easily comprehensive. The same reticence could be initially observed in compulsory vaccination cases involving the liability of the French State<sup>31</sup>. However, administrative courts finally admit the compensation of demyelinating diseases contracted after hepatitis B vaccination<sup>32</sup>.

The Conseil d'État, the French Supreme Court in administrative matters, ruled for the first time in the dispute of hepatitis B vaccination on 9 March 2007<sup>33</sup>. The court admitted that the imputability of demyelinating diseases to the vaccination may not be inferred from the lack of conclusive scientific evidence and could be presumptively proved<sup>34</sup>. In one of this case, an employee, who was submitted to a compulsory vaccination, was vaccinated and developed a multiple sclerosis shortly after received the

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<sup>29</sup> Act n° 84-53 of 26 January 1984 and the French Civil and Military Pensions Code.

<sup>30</sup> Administrative Court of Appeal of Douai, 21 June 2005, n° 03DA01306: MICHEL J. Le juge, l'Engerix B, la sclérose en plaques et les données actuelles de la science. AJDA 2005:1945. See also Administrative Court of Appeal of Bordeaux, 6 December 2005, n° 03BX00793.

<sup>31</sup> Administrative Court of Appeal of Nantes, 13 October 2005, n° 04NT01007. Administrative Court of Appeal of Douai, 17 October 2006, n° 05DA00803. Administrative Court of Appeal of Paris, 15 May 2006, n° 04PA01401. See *contra*: Administrative Court of Appeal, 16 May 2006, n° 02PA03495. This decision appears like an exception.

<sup>32</sup> Administrative Court of Paris, 5 November 2002: BONNEAU J. Janus ou la double responsabilité (sclérose en plaques imputable à la vaccination contre l'hépatite B). Gaz. Pal. 2003:11. PAUVERT B. Responsabilité de l'État pour le développement d'une sclérose en plaques après une vaccination contre l'hépatite B. AJDA 2003:1502. The court recognized a certain and direct link between the vaccine and a demyelinating disease. See also Administrative Court of Appeal of Rennes, 18 February 2004.

<sup>33</sup> Conseil d'État, 9 mars 2007, n° 267635, n° 278665, n° 283067, n° 285288: BRUN P, JOURDAIN P. Lien de causalité. In Responsabilité civile. Dalloz. 2007:2897. CARPI-PETIT S. Considérations sur la causalité entre la vaccination contre l'hépatite B et la sclérose en plaques JCP A 2007:2277. CRISTOL D. Responsabilité du fait d'une vaccination obligatoire contre l'hépatite B. RDSS 2007;543. DEFOORT B. Incertitude scientifique et causalité: la preuve par présomption. RFDA 2008:549. DIEU F. La responsabilité de l'État du fait des vaccinations obligatoires: la jurisprudence sur la vaccination contre le virus de l'hépatite B (à propos des décisions du Conseil d'État du 9 mars 2007, « Schwartz » et « Commune de Grenoble »). RDP 2008;4:1193. DIEU F. L'indemnisation des personnes atteintes de sclérose en plaques suite à leur vaccination contre le virus de l'hépatite B. Gaz. Pal. 2007;287:2. DAILLE-DUCLOS B. Responsabilité du fait des produits défectueux: la fin justifie-t-elle les moyens? JCP E 2009:2113. GROMB S, BENALI L, BÉRANGER B. Journal de médecine légale, Droit médical, Victimologie, Dommage corporel. 2008;2:101. HOCQUET-BERG S. Gaz. Pal. 2007;157:47-49; SPORTES C., RAVIT V. Décideurs Juridiques et Financiers 2009;103-104:82-83. JEAN-PIERRE D. Sclérose en plaques et imputabilité au service liée à la vaccination obligatoire contre l'hépatite B: les conditions posées par le Conseil d'État. JCP A 2007;19:2108. LAUDE A. Reconnaissance de l'imputabilité au service de la sclérose en plaques due à la vaccination obligatoire contre l'hépatite B. JCP G 2007;II:10142. NEYRET L. L'imputabilité de la sclérose en plaques au vaccin contre l'hépatite B. Dalloz. 2007;2204. OLSON T. Conclusions du commissaire du gouvernement. Lien de causalité reconnu entre une maladie et le vaccin contre l'hépatite B. AJDA 2007:861.

<sup>34</sup> Conseil d'État, 9 mars 2007, n° 267635 and n° 278665.

vaccine injections. This employee received a compensation from the French State on the ground of the Article L. 3111-9 of the French Public Health Code but asked for a compensation on the ground of the legislation concerning the accident de service. The Conseil d'État held that the imputability of the disease to the service could be presumed because the scientific available data does not indicate a link between the vaccination and the nervous system diseases, but does not exclude such a link, and thus considered that this imputability have to be based on a case-by-case analysis of three factual elements: first, the temporal relationship between the vaccination and the onset of the first symptoms of the disease, second, an absence of patient history, third, an absence of evidence of other causes of the disease<sup>35</sup>. In 2007, the solutions consecrated by the Conseil d'État were remarkable because, at the same time, the Cour de cassation refused to admit such a causal link between the vaccination and similar diseases in cases related to products liability. Indeed, compulsory vaccination and work-related accidents concern only a part of the people who developed demyelinating diseases after hepatitis B vaccination. For persons whose vaccination is not compulsory or when one or several requests have been rejected, the recourse to the common law is possible; it is the products liability.

#### *B - The cases related to products liability*

French product liability law can be divided into three main systems: contractual liability, tort liability, and defective product liability. The contractual liability does not concern lawsuits involving hepatitis B vaccine manufacturers because of the French prohibition for pharmaceutical products manufacturers to contract with users of these products<sup>36</sup>. However, in lawsuits involving these manufacturers, the Council Directive 85/374/EEC of 25 July 1985<sup>37</sup> and the tort liability have been applied (1). The most that can be said is that the establishment of the causal link between demyelination and vaccination was controversial (2).

#### 1 - The law

“The producer shall be liable for damage caused by a defect in his product”<sup>38</sup>. The Product Liability Directive of 1985 introduced a strict liability of manufacturer for damages caused by a defect in the product. The Directive shall apply to pharmaceutical products, ignoring the specificity of these

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<sup>35</sup> In this case, the fact that the compensation was accorded before by the French State was relevant.

<sup>36</sup> Article R. 5124-42 of the French Public health Code.

<sup>37</sup> EEC Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Liability for Defective Products. O.J. L 210/29. France enacted the Directive into national law ten years after the deadline for transposition, on 19 May 1998.

<sup>38</sup> First Article of the Directive of 25 July 1985.

products<sup>39</sup>. The Directive requires the injured person to prove, the damage, the defect, and, the causal relationship between the damage and the defect<sup>40</sup>. Pursuant to the Article 6.1 of the Directive<sup>41</sup>, “a product is considered to be defective “when it does not provide the safety which a person is entitled legitimately to expect”. The Directive shall not apply to products put into circulation before the date on which the act implement the directive enter into force<sup>42</sup>. In France, the Directive was only implemented in France by Act n° 98-389 of 19 May 1998, entered in force on 21 May 1998<sup>43</sup>. This system applies to products put into circulation after the 21 May 1998 and is without the prejudice to other pre-existing contractual, non-contractual, or special liability systems. Nevertheless, the two hepatitis B vaccines commercialized in France<sup>44</sup> were put into circulation at the end of the 1990's. As a consequence, the Directive has never been directly applied in the context of hepatitis B vaccination. However, the Directive shall indirectly apply to such products. Indeed, the European Court of Justice (ECJ) required national courts, when applying national law, whether adopted prior to or after the Directive, to interpret that law in the light of the wording and purpose of the directive since the *Marleasing* case<sup>45</sup>. Then, Members State which have not implement the Directive in the three years from the date of the notification of the Directive, *i.e.* before the 30 July 1988<sup>46</sup>, must apply their intern law in the light of the

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<sup>39</sup> See concerning the application of the products liability Directive to health products: BLOCH L. Pour une autre présentation de la responsabilité du fait des produits de santé. *RCA* 2009;16. FOUASSIER E, VAN DEN BRINK H. Produits de santé défectueux: premières applications des articles 1386-1 et suivants du Code civil. *Gaz. Pal.* 2002;171:11. LAUDE A. La responsabilité des produits de santé. *Dalloz* 1999:189. LAUDE A. Aperçu de la jurisprudence nationale en matière de responsabilité du fait des médicaments défectueux. *RDSS* 2005:743. CLERC-RENAUD L. Quelle responsabilité en cas de dommages causés par des produits de santé? *RLDC* 2007:11. OUDOT P. L'application et le fondement de la loi du 19 mai 1998 instituant la responsabilité du fait des produits défectueux: les leçons du temps. *Gaz. Pal.* 2008;320:6. See also “La responsabilité du fait des produits de santé défectueux”, *RDSS* 2008;6:1005.

<sup>40</sup> Article 4 of the Directive of 25 July 1985. Article 1386-9 of the French Civil Code.

<sup>41</sup> Article 1386-4 of the French Civil Code.

<sup>42</sup> Article 17 of the Directive of 25 July 1985.

<sup>43</sup> Act n° 98-389 of 19 May 1998 sur la responsabilité du fait des produits défectueux: JO of 21 May 1998, Articles 1386-1 *et seq.* 1386-18 of the French Civil Code. See notably concerning the adoption of the act: GHESTIN J. Le nouveau titre IV du Livre III du Code civil. “De la responsabilité du fait des produits défectueux”. L'application en France de la directive sur la responsabilité du fait des produits défectueux après l'adoption en France de la directive sur la responsabilité du fait des produits défectueux après l'adoption de la loi n° 98-389 du 19 mai 1998. *JCP* 1998;I;148. JOURDAIN P. Commentaire de la loi n° 98-389 du 19 mai 1998 sur la responsabilité du fait des produits défectueux. *RCA chron.* 1998;16. LARROUMET C. La responsabilité du fait des produits défectueux après la loi du 19 mai 1998. *Dalloz chron.* 1998:311. VINEY G. L'introduction en droit français de la directive européenne du 25 juillet 1985 relative à la responsabilité du fait des produits défectueux. *Dalloz chron.* 1998:291. See concerning the condemnation of the French State: European Court of Justice (ECJ), 25 April 2002, Commission des Communautés européennes c/ France, aff. C-52/00.

<sup>44</sup> GlaxoSmithKline (now GSK) and Aventis Pasteur-MSD (now Sanofi Pasteur-MSD, the vaccines division of Sanofi-Aventis Group) are the pharmaceutical companies involving in marketing hepatitis B vaccines in France. GSK involves in marketing Engerix B® and Sanofi-Pasteur MSD involves in marketing the GenHevac® B.

<sup>45</sup> The ECJ has called in those circumstances national judges to interpret the national law in accordance with the provisions of EC legislation. See Case 106/89 *Marleasing SA v La Comercial Internacional de Alimentacion SA* [1990] ECR 1839: the ECJ reiterated that under Article 249 EC, it “lies on all elements of the state, including the courts, and required national courts, when applying national law, whether adopted prior to or after the Directive, to interpret that law in the light of the wording and purpose of the directive”.

<sup>46</sup> The Directive was notified to Members State the 30 July 1985. Then, Members State had three years for implement the Directive before the 30 July 1988.

wording and purpose of the directive when the products were put into circulation after this day and before the coming into force of the legislation implementing the Directive.

Applying the intern law to the light of the wording and purpose of the directive, French judges developed a strict liability regime (l'obligation de sécurité de résultat) on the ground of the Articles 1147 (contractual liability)<sup>47</sup>, 1382, 1383<sup>48</sup> (fault liability), and 1384<sup>49</sup> of the French Civil Code (the liability for damages caused by things)<sup>50</sup>. This strict liability regime applies to manufacturers require the same conditions which are consecrated by the Product Liability Directive: the injured person must prove the damage, the defect, and the causal relationship between the damage and the defect but there is no mention of the causal relationship which could normally exists between the use of the product and the damage, neither in the Directive, nor in the strict safety liability regime. Nonetheless, in products liability cases involving hepatitis B vaccine, the question is not to know whether the product defect cause the damage, but to know whether the product itself cause the damage (the imputability of the damage to the product). In all the products liability cases involving hepatitis B vaccine, the main question at which judges must answer is to know whether the alleged damage is imputable to the hepatitis B vaccine.

## 2 - Establishing of the law

In the very first products liability cases involving hepatitis B vaccine, judges were not hostile to award compensation to plaintiffs who developed demyelinating diseases after an hepatitis B vaccination and who sued pharmaceutical manufacturers of vaccines<sup>51</sup>. The Court of appeal of Versailles notably

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<sup>47</sup> The regime were initially consecrated in contractual relationships.

<sup>48</sup> Pursuant to Article 1382 of the French Civil Code: "any act whatever of man, which causes damage to another, obliges the one by whose fault it occurred, to compensate it." Pursuant to Article 1383 of the French Civil Code: "everyone is liable for the damage he causes not only by his intentional act, but also by his negligent conduct or by his imprudence." Three elements are required to prove the fault liability: a fault, a damage, and a causal link between the two.

<sup>49</sup> Pursuant the Article 1384 of the French Civil Code: "a person is liable not only for the damages he causes by his own act, but also for that which is caused by the acts of persons for whom he is responsible, or by things which are in his custody."

<sup>50</sup> All studied courts' decisions in the following applied in general these articles (separately or together), interpreting these rules in the light of the wording and purpose of the directive. Exceptionally, courts' decisions mentioned the Article L. 221-1 of the French Consumer Code. Pursuant to article, "products and services must, under normal conditions of use or under other circumstances that may reasonably be foreseen by the professional, offer the safety that can legitimately be expected and must not be a danger to public health."

<sup>51</sup> Court of First Instance of Nanterre, 4 April 1997, *op. cit.* at 9: the court ruled in favor of patient who have claimed compensation and sued the vaccine manufacturer. Surprisingly, the court mentioned the Article 1384 of the French Civil Code. In appeal: Court of Appeal of Versailles, 12 September 2003: RADÉ C. Preuve du lien de causalité entre l'injection à une patiente du vaccin anti-hépatite B Genhevac B et un syndrome de Guillain-Barré. RCA 2004;344. See also First Instance Court of General Jurisdiction of Nanterre, 5 June 1998, *op. cit.* at 9: the court applied the national law (Article L. 221-1 of the French Consumer Code), interpreting that law in the light of the wording and purpose of the directive. In appeal: Court of Appeal of Versailles: 2 May 2001: BYK C. Responsabilité médicale. *In* Bioéthique. Législation, jurisprudence et avis des

accepted to presume the imputability of a multiple sclerosis to the vaccination because of the temporal relationship between the injection of the vaccine and the onset of the first symptoms of the disease, the absence of patient history and the absence of evidence of other causes of the disease<sup>52</sup>. Judges applied the Article 1353 of the French Civil Code, which allows them to use presumptions<sup>53</sup>. Nevertheless, on 23 September 2003<sup>54</sup>, a decision of the Cour de cassation overturned that decision and held that patients had not indeed developed diseases as a consequence of the vaccination and had not to be compensated by pharmaceutical companies manufacturing the vaccine. The Cour de cassation considered that judges of the Court of Appeal had based their decision on an hypothetical causal relationship. However, the court did not close the door at any compensation to plaintiffs who suffered demyelinating diseases. According to some commentators of the decision, the three factual elements retained by judges were not definitely condemned<sup>55</sup>. The Cour de cassation only overturned the decision because of the contradictory elements on which judges had based their presumptions: judges mentioned that both medical expert's opinion and available scientific data do not indicate the existence of an association between the vaccination and the disease, but they admitted the link between the two because of the existence of the three aforementioned elements. They should probably mention that the scientific available data does not exclude such a link. For other commentators of the decision, the court decided that presumptions of fact could not be used for proving the imputability of the disease to the

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instances d'éthique. JCP G 2002;I;146. GROMB S, KIRMAN M-G. Vaccination contre l'hépatite B et sclérose en plaques. *Médecine & Droit* 2001;51:22. JOURDAIN P. Causalité juridique et incertitude scientifique. À propos du lien de causalité entre le vaccin contre l'hépatite B et l'apparition de la sclérose en plaques. *RTD civ.* 2001:891 and 896.

<sup>52</sup> Court of Appeal of Versailles: 2 May 2001, *op. cit.*

<sup>53</sup> Pursuant to Article 1349 of the French Civil Code, "presumptions are the consequences that a statute or the court draws from a known fact to an unknown fact". Pursuant to Article 1353 of the French Civil Code: "the presumptions which are not established by a statute are left to the insight and carefulness of the judges, who shall only admit serious, precise and concurrent presumptions, and in the cases only where statutes admit oral evidence, unless a transaction is attacked for reason of fraud or deception."

<sup>54</sup> First Civil Law Chamber of the Cour de cassation, 23 September 2003, n° 01-13063 and n° 01-13064, *Bull. civ.* 2003;I;188: FAICT O, MISTRETTA P. Responsabilité du fait des produits défectueux: présumer n'est pas démontrer. *JCP E* 2003;I;1749. GOSSEMENT A. L'administration de la preuve en situation d'incertitude scientifique: la position attendue de la Cour de cassation dans l'affaire de l'hépatite B. *LPA* 2004;12:14. JONQUET N, MAILLOLS A-C, MAINGUY D, TERRIER E. Conditions de la responsabilité d'un fabricant de vaccin à raison d'une sclérose en plaques faisant suite à des injections d'un vaccin contre l'hépatite B. *JCP G* 2003;II;10179. JOURDAIN P. L'incertitude scientifique empêche de reconnaître un lien de causalité entre le vaccin contre l'hépatite B et l'apparition de la sclérose en plaques. *RTD civ.* 2004:101-103. LEVENEUR L. *CCC* 2003;12:19. MERCIER C, SICOT I. Le rappel à la rigueur de la Cour de cassation en matière de responsabilité du fait des produits défectueux. *Médecine & Droit* 2004:50-53. MAURY F, *supra* at 7. MÉMETEAU G. Vaccination préventive de l'hépatite B et sclérose en plaques: être médecin ou être juriste? *LPA* 2004;81:9. NEYRET L. Vaccination contre l'hépatite B: fin du débat judiciaire? *Dalloz* 2003;2579. SERINET Y-M, MISLAWSKI R. *Supra* at 8. MAZEAUD D. La distension du lien de causalité a des limites. *Dalloz* 2004;1344. STOFFEL-MUNCK P. Responsabilité civile. N° 2. La causalité. *JCP G* 2006;I;111. VINEY G. La responsabilité du fait des produits défectueux. *In* Responsabilité civile (Étude). *JCP G* 2004;I;101. The court applied the Articles 1147 and 1382 of the French Civil Code, interpreting these articles in the light of the wording and purpose of the directive.

<sup>55</sup> NEYRET L. *Supra* at 56.

vaccine in presence of scientific uncertainty<sup>56</sup>. Since 2003, the link was never considered as established in the products liability context<sup>57</sup>.

On 22 May 2008<sup>58</sup>, the Cour de cassation rendered several controversial decisions, which were let us presume that the solution of the Conseil d'État will be probably consecrated later. The court held that the damage, the product defect and the causal link between the two could be establish by presumptions of fact, in the framework of products liability legislation, according to the Article 1353 of the French Civil Code. However, the decision did not mention that the imputability of the damage to the product could be proved by presumptions, so fundamental in the cases which concern us. Nevertheless, the recourse by judges to presumptions for proving the imputability of the damage to the product was effectively validated in two decisions of the Cour de cassation rendered in 2009.

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<sup>56</sup> GOSSEMENT A. *Supra* at 56.

<sup>57</sup> Court of Appeal of Versailles, 25 November 2005: HÉNIN C. La responsabilité du fait des médicaments: de quelques rappels nécessaires sur ses fondements et ses conditions. LPA 2006;100:6. First Civil Law Chamber of the Cour de cassation, 24 January 2006, n° 03-19534, Bull. civ. 2006;I;33: GRYNBAUM L. Conditions d'application du régime des produits défectueux. JCP G 2006;II;10082. LEVENEUR L. La sécurité à laquelle on peut légitimement s'attendre n'est pas absolue. CCC 2006;5;77. RADÉ C. Le "syndrome de Guillain-Barré". RCA 2006;3;91. ZARKA J-C. Responsabilité civile. Conditions d'application du régime des produits défectueux. JCP G 2006;I;10082:1055-64. NEYRET L. La défectuosité: nouvel enjeu du contentieux du vaccin contre l'hépatite B. Dalloz 2006:1273. SARCELET J-D. Responsabilité du fait des produits défectueux: le moment de la mise en circulation dans l'appréciation du caractère défectueux. LPA 2006;45:6. Court of Appeal of Montpellier, 4 April 2006. Court of Appeal of Paris, 2 June 2006: GIZARDIN B. Observations du ministère public. Gaz. Pal. 2006;229:32. ONAT A. Pharmacie. Gaz. Pal. 2006;343:58. RADÉ C. Laboratoires pharmaceutiques (vaccin anti-hépatite B). RCA 2006;10;306. Court of Appeal of Lyon, 22 November 2007, n° 06/02450: ONAT A. Responsabilité du producteur de vaccin: résistance ou dissonance à la Cour d'appel de Lyon? Gaz. Pal. 2008;159:52. Court of Appeal of Lyon, 12 February 2008, n° 06/01764.

<sup>58</sup> First Civil Law Chamber of the Cour de cassation, 22 May 2008, n° 06-10967, Bull. civ. 2008;I;159, n° 06-14952, Bull. civ. 2008;I;147: BRUN P, Quézel-Ambrunaz C. Vaccination contre l'hépatite B et sclérose en plaques: ombres et lumières sur une jurisprudence instable. Revue Droit Civil 2008. BRUN P, JOURDAIN P. Préjudices causés par le vaccin contre l'hépatite B. In Responsabilité civile. Dalloz 2008:2894. BORGHETTI J-S. Retour sur le rapport de causalité entre la vaccination contre l'hépatite B et la survenance de la sclérose en plaques. RDC 2008:1186. DAILLE-DUCLOS B. Vaccin contre l'hépatite B et sclérose en plaques: appréciation du lien de causalité et du défaut du produit en cas d'incertitude sur l'origine du dommage. JCP E 2008:2137. GALLMEISTER I. Lien de causalité entre la sclérose en plaques et le vaccin contre l'hépatite B. Dalloz 2008:1544. GRYNBAUM L. La certitude du lien de causalité en matière de responsabilité est-elle un leurre dans le contexte d'incertitude de la médecine? Le lien de causalité en matière de santé: un élément de la vérité judiciaire. Dalloz 2008:1928. GRYNBAUM L. Vaccins contre l'hépatite B et produits défectueux: les présomptions constituent un mode de preuve du lien de causalité et du défaut. JCP G 2008;II;10131. JOURDAIN P. Lien de causalité entre la vaccination contre l'hépatite B et la sclérose en plaques: la Cour de cassation assouplit sa jurisprudence. RTD civ. 2008:492. JULIEN J. De la responsabilité des fabricants de vaccin (ou du réveil de la causalité). Dr. de la famille 2008;7;17. PEIGNÉ J. Lien de causalité entre la sclérose en plaques et le vaccin contre l'hépatite B. RDSS 2008;578. PIERROUX E. Vaccination contre l'hépatite B et sclérose en plaques: vers l'admission judiciaire d'un lien de causalité. Gaz. Pal. 2008;176:19. RADÉ C. Vaccination anti-hépatite B et sclérose en plaques: le tournant? RCA 2008;8. ROUYÈRE A. Questions de méthode. RFDA 2008:1011. SINTEZ C. Responsabilité du fait des médicaments défectueux: trois arrêts attendus pour un revirement mesuré. LPA 2008;169:6. STOFFEL-MUNCK P. Certitude du lien de causalité. In Responsabilité civile. JCP G 2008;I:186.



On 22 January 2009<sup>59</sup>, the court held that the Court of Appeal had correctly researched whether the factual elements of the case were sufficient for presume the causal link between the disease and the vaccination but decided that judges correctly excluded this link because there existed another causes of the disease<sup>60</sup>. On 9 July 2009, two decisions were rendered by the Cour de cassation<sup>61</sup>. In the first decision<sup>62</sup>, the court overturned the decision rendered by the Court of Appeal because judges did not research, despite the lack of scientific evidence of the link between the disease and the vaccination, whether the factual elements of the case were sufficient for presume the causal link between the disease and the vaccination. In the second decision<sup>63</sup>, the Cour de cassation approved the decision rendered by the Court of Appeal, considering that the link between the disease and the vaccine could be presumed, despite of scientific uncertainty, because of the temporal relationship between the vaccination and the onset of the first symptoms of the disease the absence of patient history and the absence of evidence of other causes of the disease. Then, the Cour de cassation adopted the reasoning of the Conseil d'État in decisions aforementioned of 9 March 2007. The judicial case law accepts thus to consider certain circumstances under which the link between a demyelinating disease and a vaccination against hepatitis B may be presumed<sup>64</sup>.

## **Part II - Critiques of the establishment of a causal link between hepatitis B vaccination and demyelinating diseases**

Any judgments involving pharmaceutical products involves science and any tort case involving science involves scientific uncertainty. Scientific uncertainty can concern both the etiology of a disease

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<sup>59</sup> First Civil Law Chamber of the Cour de cassation, 22 January 2009, n° 07-16449, Bull. civ. 2009;I;11: DESHAYES O. Causalité. RDC 2009;3:1028. KOUCHNER C. Responsabilité en matière de recherche sur la personne. Gaz. Pal. 2009;143:33. SARGOS P. L'importance de la distinction entre l'origine et la causalité amplifiée. JCP G 2009;II;10031.

<sup>60</sup> Such a genetic predisposition. See for an absence of consideration of such an element: Conseil d'État, 4<sup>e</sup> et 5<sup>e</sup> sous-sec., 24 July 2009, n° 308876: BORGHETTI J-S. *Supra* at 8.

<sup>61</sup> Second Civil Law Chamber of the Cour de cassation, 9 July 2009, n° 08-14493, n° 08-11073, Bull. civil, 2009;I; 176: BORGHETTI J-S. *Supra* at 8. GALLMEISTER I. Vaccination contre l'hépatite B: responsabilité du laboratoire. Dalloz 2009:1968. BRUN P. Responsabilité civile. Dalloz 2010:49. GRYNBAUM L. *Supra* at 7. LEGOUX A. *Supra* at 7. RADÉ C. *Supra* at 7. SARGOS P. *Supra* at 7.

<sup>62</sup> Second Civil Law Chamber of the Cour de cassation, 9 July 2009, n° 08-14493. The court applied the Article 1353 of the French Civil Code and the Article L. 411-1 of the French Social Security Code, interpreting these articles in the light of the wording and purpose of the directive.

<sup>63</sup> Second Civil Law Chamber of the Cour de cassation, 9 July 2009, n° 08-11073. The court applied the Article 1147 of the French Civil Code because the strict safety obligation were originally contractual. Usually, the court applied the Article 1382, 1147 and 1384 of the French Civil Code.

<sup>64</sup> See *contra* First Civil Law Chamber of the Cour de cassation, 24 September 2009, n° 08-16097: GALLMEISTER I. Dalloz 2009:2426. The link was not established in this case. See also Court of Appeal of Paris, 8 January 2010, n° 07/03209 and n° 07/19039.

(objective) and the conditions of the transmission of a disease (subjective)<sup>65</sup>. In cases involving products such as hepatitis B vaccines, decisions of French courts are rendered in a context of objective scientific uncertainty. Indeed, the scientific evidence data does not really know the etiology of demyelinating diseases. Then, the causes of these diseases, especially multiple sclerosis, are largely unknown<sup>66</sup>. So, the question was: can judges establish a causal relationship between a product and a damage despite the lack of scientific evidence of the causal link between the two? If so, in what circumstances? As shown, the vast majority of French courts recently held that the relationship of demyelination and vaccination could be proved on a case by case basis though international scientific researches are unable to answer generally the question. Indeed, both civil and administrative judges used presumptions for proving this causal relationship. Then, judges clearly affirmed that Law does not have to confirm Science. Nevertheless, the possibility that judges can establish such a link on a case by case basis meanwhile scientific uncertainty related to the general imputability which could exist between the diseases and the vaccination is not acceptable. The principle of the establishment of the link itself should be denounced (**A**). The criteria elaborated in the method of the demonstration of the link are also not convincing and thus the conditions of the establishment of the link should be disapproved (**B**).

#### *A - Critiques of the principle of the establishment*

The question of the causal link between a damage and a product is a crucial question in all cases involving health products. However, this is a double-barreled question. The first question is to know whether in a general way a particular damage can be caused by a product (abstract or general causality). The second question is to know whether a specific damage was caused by a product in a particular case (specific or individual causality). General causality concerns the ability of a product to cause a kind of damage. Specific causality concerns the material link between a product and a damage in a particular case<sup>67</sup>. The general causality is never explicitly required by texts. Only the specific causality is required. Indeed, this is not the role of judges to establish a general and abstract link between a product and a damage. In the course of delivering reasons for judgment, judges must pay regard to the background in

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<sup>65</sup> See concerning the distinction: GHILHEM J. La réception juridique de l'incertitude médicale. *Médecine & Droit* 2009:131.

<sup>66</sup> See *ibid* at 4.

<sup>67</sup> See concerning the distinction: BORGHETTI J-S. Vers un régime spécial de responsabilité du fait des produits de santé? *RDC* 2007:1157. BORGHETTI J-S. La responsabilité du fait des produits. *Étude de droit comparé*. Préf. VINEY G. Paris. LGDJ. 2004, n° 268 *et seq.* NEYRET L. *Supra* at 34. ROUYÈRE A. *Supra* at 56. SARGOS P. La certitude du lien de causalité en matière de responsabilité est-elle un leurre dans le contexte d'incertitude de la médecine? La causalité en matière de responsabilité ou le « droit Schtroumpf ». *Dalloz* 2008:1935. SERINET Y-M, MISLAWSKI R. *Supra* at 8.

question and appreciate whether a product could cause or not a damage on a case by case analyze<sup>68</sup>. Nevertheless, judges always implicitly answer the first question of the general causality before answering the question of the specific causality. Generally, this first question is not problematic, but in cases involving health products, especially pharmaceutical products, this question is often problematic because we don't know if the product is able to cause a kind of damage. Then, the question is: Can judges answer the question of a specific link between a product and a damage, in a particular case, while this link is abstractly impossible to prove? In the hepatitis B vaccination affair, judges finally decided to answer the question of the specific causality by using presumptions to establish the specific causal link between a demyelinating disease and a vaccination against hepatitis B. Then, judges did not explicitly answer the question of the general causality but they implicitly recognize this causality. Nevertheless, Law should confirm Science when scientific uncertainty concerns this general link. For this reason, the impossibility to prove the link between hepatitis B vaccination and demyelinating diseases contracted by claimants should not be consecrated (2). On the contrary, when Science confirm an abstract causality which can exist between a kind of adverse effect and the use of a product, judges should have the possibility to prove this link in certain circumstances (1).

#### 1 - The possibility to prove the link in presence of scientific uncertainty

That is not the first time that French courts accept to presume the causal link between a product and a damage in presence of scientific uncertainty. These decisions have been held in the context of French contaminated blood affair and the hepatitis C affair. In these affairs, some persons who have received transfusion of blood or blood products became infected with the Human Immunodeficiency Virus (HIV) or the Hepatitis C Virus (HCV). These persons claimed for damages against blood transfusion centers, hospitals, clinics or French State but they were often unable to prove that the damage had caused their injury. Face at the victims' difficulty to prove this causal relationship between their contamination by the HIV or by the HCV and the transfusion of blood or blood products, judges have decided to consider that the causal link between the transfusion and the contamination could be considered as proved under certain conditions. As regards the Article 1353 of the French Civil Code and the adequate causation, judges presumed the link between transfusions and contaminations because of the absence of the contamination before the transfusion, the incidence of the contamination after the transfusion and the absence of other causes of the contamination<sup>69</sup>. Finally, lawmakers consecrated

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<sup>68</sup> Such a specific causality is explicitly required by the aforementioned Article L. 3111-9 of the French Public Health Code and implicitly by the work-related accidents legislation.

<sup>69</sup> First Civil Law Chamber of the Cour de cassation, 12 April 1995, n° 92-20747: Bull. civ. 1995;I;179, n° 92-11950 and n° 92-11975: Bull. civ. 1995;I;180: JOURDAIN P. La responsabilité civile des centres de transfusion sanguine et des

these presumptions of fact by the Act n° 91-1406 of 31 December 1991<sup>70</sup> and the Act n° 2002-303 of 4 March 2002<sup>71</sup>. In cases related to damages linked to HCV, to HIV, or to the hepatitis B vaccination, the elements which are able to presume a link between a damage and a product are similar. Recently, the Cour de cassation admit in another context the link between the incidence of a disease (Lyell syndrome) and the absorption of a drug (Zyloric®). On 5 April 2005<sup>72</sup>, judges retained very similar elements, such as the proximity time between the cessation of the treatment and the cessation of the trouble and the absence of another causes of the disease for presuming the link between the syndrome and the alleged damage.

Some authors wondered about the consecration of presumptions of law in the hepatitis B vaccination context. Nevertheless, it is fundamental to notice that in the precedent frameworks, there is no scientific uncertainty (or a very marginal scientific uncertainty) concerning the possibility of being contaminated by these virus or by this syndrome after the administration of the product. The causality was supported by scientific available data. In such a context, the consecration of presumptions were comprehensive. Judges based their presumptions on an established fact, according to the Article 1349 of the french Civil Code. The Article defines the presumptions in fact. It precises that “presumptions are the consequences that a statute or the court draws from a known fact to an unknown fact”<sup>73</sup>. The consecration of such presumptions is though not easily acceptable, in the context of the hepatitis B vaccination, because the link between the product and the damage is not scientifically proved. The resort to presumptions of fact for proving a causal link between a disease and a vaccination seems artificial because presumptions of fact do not have for purpose to answer a general question. Besides, what is the known fact in the context of persons who contracted demyelinating diseases after being

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cliniques en cas de contamination de transfusés par le VIH: la Cour de cassation prend position. JCP G 1995;II;22467. Conseil d'État ass., 26 May 1995: MOREAU J. SIDA transfusionnel: responsabilité sans faute des centres de transfusion sanguine intégrés à l'hôpital. JCP G 1995;II;22468. LEROY J. Responsabilité des cliniques en matière de transfusion sanguine. RDSS 1995:766.

<sup>70</sup> Article 119 of the Act n° 91-1406 of 31 December 1991. Article L. 3122-2, *al.* 1 of the French Public Health Code. The Act of 1991 established a compensation program for persons infected with HIV as a result of HIV-contaminated blood products.

<sup>71</sup> Article 102, *al.* 1 of the Act n° 2002-303 of 4 March 2002, concerning the HCV.

<sup>72</sup> First Civil Law Chamber of the Cour de cassation, 5 April 2005, n° 02-11947 and n° 02-12065, Bull. civ. 2005;I;173: BRUN P, JOURDAIN P. Responsabilité civile. Dalloz 2006:1929. CHABAS F. Responsabilité du fait des médicaments. Droit & Patrimoine 2005. HÉNIN C, MAILLOLS A-C. La responsabilité du fait des médicaments: à la recherche d'un équilibre entre rigueur et pragmatisme. LPA 2005;122:9. JOURDAIN P. Produit défectueux: ne pas confondre danger et défectuosité. RTD civ. 2005:607. JOURDAIN P. Défaut du produit de santé: mise en oeuvre des critères tirés de l'insuffisance d'information sur les risques et du bilan bénéfiques/risques. RTD civ. 2006:325. GORNY A. La causalité à nouveau en péril. Dalloz 2005:2256. GRYNBAUM L. Lien de causalité entre l'absorption d'un médicament et le dommage subi par le patient et appréciation du caractère défectueux du produit. JCP G 2005;I;10085. LAUDE A. *Supra* at 37. RADÉ C. Laboratoire pharmaceutique (Syndrome de Lyell). RCA 2005;189. REBEYROL V. Les effets secondaires des médicaments et la responsabilité des laboratoires producteurs. LPA 2005;137:16. VINEY G. Responsabilité civile. JCP G 2005;I;149. See also First Civil Law Chamber of the Cour de cassation, 22 May 2008, n° 07-17200.

<sup>73</sup> Article 1349 of the French Civil Code.

vaccinated? There is no such known fact in this context. Courts draw consequences from a negative fact (the risk is not excluded)<sup>74</sup>.

This consideration concerns especially the products liability law. The liability of the manufacturer is not governed by a logic of compensation. The products liability regime established by the Directive does not establish presumption concerning the causal relationship between the product and the damage. Furthermore, it seems illogical to research a causal link between the product defect and the damage in the case in which the product cannot cause the damage. The imputability of the damage to the product should be appreciate before the causal link between the eventually product defect and the damage. Moreover, this imputability should be studied before the product defect. Then, the establishment of such presumption seems not conform the Directive. The same observation should be considered in the context of work-related accidents and compulsory vaccination, even though the link between the accidental consequences of a compulsory vaccination and the vaccination itself is not required by texts. When this link is established by judges, the proof of this relationship is not persuasive. The link between the alleged injury and the incidence of the vaccination is only based on a coincidental temporal association between the two. In presence of scientific uncertainty related to the causes of the demyelinating diseases, judges should not admit the possibility to prove by presumptions the causal link between such diseases and the vaccination.

## 2 - The impossibility to prove the link in presence of scientific uncertainty

Scientific uncertainty is related to the possibility of being infected by a demyelinating disease after an hepatitis B vaccination, and thus to the general causality which could exist between the damage and the product. When scientific uncertainty concerning such a causality, Law should confirm Science. Indeed, the resort to presumptions of fact in such a situation has not solid basis. Causation in law need to be direct and certain. The causal relationship between the product and the damage which cannot be established by scientists have to reflect scientific knowledge and the dispute which interests us should stop as soon as the link cannot be proved by science because this link is the first and the most obvious condition of any product liability. Such a relationship between the product and the damage have ever been consecrated in the framework of products liability. In an interesting decision which have been rendered by the First Civil Law Chamber of the Cour de cassation on 27 February 2007<sup>75</sup>, the court

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<sup>74</sup> See ROUYÈRE A. *Supra* at 56.

<sup>75</sup> First Civil Law Chamber of the Cour de cassation, 27 February 2007, n° 06-10063: BORGHETTI J-S. Vers un régime spécial de responsabilité du fait des produits de santé? RDC 2007:1157. BRUN P, JOURDAIN P. Responsabilité civile. Dalloz 2007:2897. GOUTTENOIRE A, RADÉ C. Vaccin contre l'hépatite B et sclérose en plaques. RCA 2007;5:165.

refused to admit the link between a demyelination and a vaccination against hepatitis B. In consideration of scientific available data and medical expert's opinion, which do not indicate such a link, the court decided that this link could not be deduced from the hypothesis that the risk, not demonstrated, cannot be excluded. The court held that “health products liability requires the prove of the damage, the *imputability* of the damage to the *administration* of the product, the product defect, and the causal link between this product defect and the damage”. The Cour de cassation reaffirmed that the plaintiff must prove the three classical required elements (the damage, the product defect, and the causal link) but required a new one: the imputability of the damage to the administration of the product. For the first time, this condition was explicitly required, concerning health products liability.

The proof of the imputability of the damage to the use of the product is a constant and obvious condition in all liability products regimes. Even if texts do not mention this condition, the imputability of the damage to the product is usually required by judges. For this reason, the solution consecrated by the court should be approved, especially in the health products liability. The court limited the solution to health products liability. Thus, the Cour de cassation attributed to health products a certain specificity in the legal framework of products liability<sup>76</sup>. The court mentioned the imputability of the damage to the *administration* of the product and required the proof of this condition concerning health products. It appears evident that the administration of a product only concerns specific products which have to be administrated to the patient or ingested by the organism of the patient. The court probably wanted to remind judges which ruled in the hepatitis B vaccination framework of the necessity to prove both the link between the damage and the product and the link between the damage and the defect product. For this reason, the court's decision should also be approved. Since 2007, such a decision was regrettably never held and courts faced potentially difficult issues concerning the method for establishing the proof of the link between demyelination and vaccination.

### *B - Critiques of the conditions of the establishment*

The reasoning adopted by judges in the hepatitis B vaccination context can be divided in two main parts. Firstly, judges insist on the limits of the scientific truth and thus may consecrate the autonomy of the judicial truth (1). Secondly, judges use presumptions for establishing on a case by case basis a

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The decision applied the Articles 1147 and 1384 of the French Civil Code, interpreting these articles in the light of the wording and purpose of the directive.

<sup>76</sup> See notably BORGHETTI J-S. Thesis. *Supra* at 65.

specific imputability between the product and the damage (2). Nevertheless, the two parts of judges' reasoning are not convincing.

#### 1 - The non exclusion of the link by science

The vast majority of cases, administrative and judicial judges affirm the limits of the scientific truth and insist on these limits. Indeed, judges usually declare that scientific studies are not able to support a link between demyelinating diseases and hepatitis B vaccination but do not formally exclude such an association. Then, judges demonstrate that scientific available data is unable to answer the question. Above all, they demonstrate that science cannot formally exclude a causal link between the damage and the product. This element is very important. According to judges, the analysis of the eventual characterization of the link depends on the establishment of this requirement. Scientific non-exclusion of is a prerequisite which is required by the judicially research of such a link. This element shows a certain relationship of Law and Science. If scientific studies formally exclude the relationship of the damage and the product, judges will not be able to characterize the causal relationship. Law and Science become dependent. On the contrary, insofar as the link is not excluded, judges will be able to establish it. Law and science become independent. According to judges, Law does not have to confirm Science because Science does not exclude the general link which could exist between the damage and the product. The autonomy of Law at this level is clear. The main problem in the reasoning of judges is that the vast majority of scientific available data exclude this link: there is no association, no link, no relationship between vaccination and demyelination. Even if Science always involves a part of doubt, Science excludes the link.

#### 2 - The use of presumptions

Judges consider explicitly or not that they may use presumptions of fact for proving a link between a product and a damage though this link is not proved by scientific available data. By using presumptions, judges adopt an inductive reasoning. Administrative and judicial judges generally considered that three elements are able to constitute serious presumptions of the imputability of the damage to the vaccine: the time proximity between the incidence of the disease and the vaccination, the absence of patient's history, the absence of other causes capable to explain the disease. Although these criteria are far too complicated to be analyzed fully in the present context, it seems worthwhile to pay attention to these elements.

On the other hand, two elements are related to the absence of the other causes of the disease: the absence of patient's history and the absence of other causes which are able to explain the disease. By utilizing these two criteria, judges use a method which consists to eliminate the possible other causes of the damage (causation by exclusion). In this method, it appears that the answer derives from a deductive model (probably) of reasoning. The plaintiff have to prove, first, that he had no history of the disease before the vaccination. Nevertheless, this element seems not relevant because the causes of the disease are largely unknown. We do not identify in particular what could be genetic predispositions for such diseases. However, this solution does not conform the french case law related to the incidence of genetic predispositions in the establishment of causation. Indeed, French courts accept to compensate victims who had genetic predisposition to the damage suffered<sup>77</sup>. The rule which applied is: you take the victim as you find it. Besides, the plaintiff must prove the absence of other causes which are able to explain the disease. This criterion also appears not relevant because the etiology of demyelinating diseases, especially multiple sclerosis, is largely unknown.

On the other hand, judges consecrate a chronological element. This is the element related to the time proximity between the first onset of the disease and the vaccination. In the framework of work-related accidents, the link between the vaccination and the work is implicitly established because of the time proximity between the incidence of the disease and the vaccination even if judges do not mention it. In several decisions, administrative and judicial courts consider explicitly that the first onset of the disease must occur during the few months (often less than two months) following the vaccination<sup>78</sup>. This element perplex us. Judges put in place another apparent scientific element which is absolutely not proved by science. Obviously, this element does not sufficiently prove the link between the disease and the vaccine<sup>79</sup>. Indeed the most likely explanation of the scientific available data concerning the causal relationship between the two is a coincidental association. As precedent ones, this element is not

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<sup>77</sup> See for instance Second Civil Law of the Cour de cassation 15 December 1986, Bull. civ. 1986;II;193. 21 May 1990, Bull. civ. 1990;II;122. 28 October 1991, Bull. civ. 1991;II;259. 28 February 1996. 19 February 1997: RADÉ C. La consécration de la présomption d'imputabilité du dommage à l'accident et l'abandon du critère de l'implication du véhicule dans le dommage. See also MONTANIER J-C. L'incidence des prédispositions de la victime sur la causalité du dommage. Thesis. Préf. DEJEAN DE LA BÂTIE N. Grenoble II. 1981. HOCQUET-BERG S. Études offertes à Hubert Groutel Paris Litec 2006;8:173.

<sup>78</sup> See notably Conseil d'État, 4<sup>e</sup> and 5<sup>e</sup> sous-sect., 24 July 2009, *op. cit.* The Court decided that in reason to the long time which separates the first symptoms of the disease and the vaccination, the causal relationship between the two is not established. See decisions in which the imputability of the disease to the vaccine was not established: Conseil d'État, 9 March 2007, n° 285288 (ten months before the vaccine injections and the first onset of the disease) and n° 283067 (ten years). See Second Civil Law of the Cour de cassation, 14 September 2006, n° 04-30642, *op. cit.*

<sup>79</sup> See MAURY F. *Supra* at 7. ROUGÉ-MAILLART C, JOUSSET N, GUILLAUME N, PENNEAU M. *Supra* at 23.



conclusive. Finally, none of the three criteria retained by judges are appropriate for justifying presumptions of the imputability of a nervous system disease to an hepatitis B vaccine<sup>80</sup>.

## **Conclusion**

To conclude, the dispute of the persons who contracted demyelinating diseases after the hepatitis B vaccination shows the uneasy relationship between Science and Law. The analysis of the aforementioned decisions demonstrates that the legal truth does not always have to confirm the scientific truth. Indeed, French courts finally decide to establish in certain circumstances a causal link between hepatitis B vaccination and demyelinating diseases, while scientific available data does not support a relationship between the vaccination and demyelination events. Then, French courts allow plaintiffs to be compensated for their injury though all studies which analyze this issue demonstrate that administration of the hepatitis B vaccine and onset or relapse of demyelinating disease are not linked.

French judges finally recognize the causal relationship between demyelination events and hepatitis B vaccination on a case by case analysis, and specify circumstances under which this causal relationship may be proven by presumptions of fact. Rules which permit to establish such a link are different according to the context of the dispute (the liability of the French State for compulsory vaccination, the liability of the employer, the liability of the manufacturer), insofar as these rules contain certain criteria as the mandatory character of the vaccination which can make easier the proof of the link. Nonetheless, elements retained by judges for admit this link are similar (generally, the temporal relationship between the injection of the vaccine and the onset of the first symptoms of the disease, the absence of patient history and the absence of evidence of other causes of the disease).

In this complex legal framework, the use of presumptions of fact for proving such a link seems to be artificial. The Law should embrace Science when scientific available data does not support a link between a kind of injuries or diseases and the exposure to a product. Then, judges should not recognize the causal relationship between the use of the hepatitis B vaccine and the occurrence of a demyelinating disease. The institution of presumption of law can be imagined, but seems not to be justified in the hepatitis B vaccination affair. Such presumptions are indeed consecrated in the French law, but concern

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<sup>80</sup> See concerning another vaccine: First Civil Law Chamber of the Cour de cassation, 25 June 2009, n° 08-12781, Bull. civ. 2009;I;141: SARGOS P. *Supra* at 7. GRYNBAUM L. *Supra* at 7. JOURDAIN P. *Supra* at 7. The First Civil Law of the Cour de cassation held that an unquestionable scientific evidence of the causal relationship between a vaccine and a damage cannot be required but can result from presumptions which are sufficiently serious, precise and concordant to justify a conviction, according to the Article 1353 of the French Civil Code.

hypothesis in which scientific uncertainty is almost non-existent. Finally, the analysis of the decisions rendered in the dispute of the hepatitis B vaccination affair should not lead to the consideration that doubt have to benefit claimants. Indeed, the courts' decisions which condemn a person, whoever it is, to compensate a damage are not justified when no element proves or allows seriously to presume that the damage was caused by a defendant's conduct.