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CAUSATION IN HEPATITIS B VACCINATION LITIGATION IN FRANCE: BREAKING THROUGH SCIENTIFIC UNCERTAINTY?

JEAN-SÉBASTIEN BORGHETTI¹

Since the 1990s, significant litigation has developed in France in connection with hepatitis B vaccines. Plaintiffs claim compensation for damage resulting from demyelinating diseases, such as multiple sclerosis, allegedly caused or exacerbated by these vaccines. These cases are particularly complex, due to the state of continuing scientific uncertainty as to the possible link between the hepatitis B vaccination and the appearance or development of demyelinating diseases.

Problems raised by scientific uncertainty are rather new to lawyers, at least in France and in the context of tort law. Traditional rules, especially those contained in the Civil code (*Code civil*), the *Magna Carta* of French law drafted in 1804, have not been devised to deal with such problems, and judges, like legal academics, are ill at ease. They lack the conceptual tools that could help them apprehend and categorize the complex issues at stake in these situations of scientific uncertainty. Yet, French courts, true to their traditional plaintiff-friendly approach,² have done their best efforts to grant compensation to plaintiffs in hepatitis B vaccine cases. In order to do so, they have in effect broken through, or at least bypassed, scientific uncertainty, using various, more or less subtle, mechanisms. The development of hepatitis B vaccine litigation in France, discussed in Part I of this article, has led to a bypassing of scientific uncertainty. Part II examines why the current state of French law on this issue is not convincing and what the paths are for improvement.

I. THE DEVELOPMENT OF HEPATITIS B VACCINE LITIGATION IN FRANCE

The solutions reached by French courts in hepatitis B vaccine cases are better understood against the context in which this litigation developed.

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2. See S. Whittaker, *La responsabilité pour fait personnel dans l'Avant-projet de réforme du droit de la responsabilité: donner voix aux silences du Code civil*, in *REVUE DES CONTRATS* 89, 99 (2007); Jean-Sébastien Borghetti, *The Culture of Tort Law in France*, 3 *J. EUR. TORT L.* 158 (2012).

A. The Context of Hepatitis B Vaccine Litigation

Section 1 discusses how hepatitis B vaccine cases first appeared in a specific medical and scientific context. Section 2 examines how such cases have been dealt with in France's specific legal context.

1. The Medical and Scientific Context

Hepatitis B is an extremely common viral pathology affecting the liver. According to some estimations, between 3% and 6% of the world's population are currently carrying the hepatitis B virus, and about one in three human beings have been infected by the virus at some point in their lives.³ Most adults affected by hepatitis B get rid of the virus spontaneously. However, around 10% become chronic carriers.⁴ This represents an estimated 240 million people worldwide.⁵ Chronic carriers are exposed to a high risk of cirrhosis and liver cancer. Some medical treatments against chronic hepatitis B provide good results, but no drug is currently able to eradicate the disease. Moreover, chronic carriers are more likely to pass the virus on to other persons. Transmission of the virus results from exposure to infectious blood or body fluids containing blood. Possible forms of transmission include sexual contact, blood transfusions, reuse of contaminated needles and syringes, as well as vertical *in utero* transmission from mother to child. According to the World Health Organization (WHO), approximately 780,000 people die globally of hepatitis B each year.⁶ Therefore, fighting this disease is a serious public health issue.

The vaccination against hepatitis B has been available since 1982 and is advocated by the WHO as an efficient means to prevent the disease and fight against its extension. It was made compulsory in France for health care professionals (*professionnels de santé*) in 1991.⁷ Three years later, in

3. *Hepatitis B*, WORLD HEALTH ORG. (WHO), <http://www.who.int/mediacentre/factsheets/fs204/en/index.html> (last updated July 2015).

4. *Id.*

5. *Id.*

6. *Id.*

7. Loi 91-73 du 18 janvier 1991 portant dispositions relatives à la santé publique et aux assurances sociales [Law 91-73 of January 18, 1991 on the Provisions Relating to Public Health and Social Insurance], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE],

July 1994, the French Ministry of Health launched a mass immunization campaign against hepatitis B, especially targeting teenagers. The vaccination was not made compulsory, however. In the following years, cases were reported in which persons manifested symptoms of demyelinating diseases, such as multiple sclerosis or Guillain-Barré syndrome, after they had received the vaccine. The idea then spread that the hepatitis B vaccination could cause such diseases. This led the Minister of Health in 1998 to call a suspension of the vaccination campaign launched a few years before. The campaign never resumed. In the meantime, the debate on the advisability and possible side effects of the hepatitis B vaccination has been ongoing, even though the WHO,⁸ the French Medical Academy,⁹ and the French High Council for Public Health¹⁰ continue to recommend the vaccination.

Demyelination is the loss of the myelin sheath, which insulates the nerves. It is the source of neurodegenerative autoimmune diseases, including multiple sclerosis and Guillain-Barré syndrome. The etiology of these demyelinating diseases is still a matter of debate. It is believed that such diseases result from some combination of genetic, environmental, and infectious factors, but no definitive explanation has been found.¹¹ Yet, several epidemiological studies investigating the relationship between hepatitis B vaccinations and demyelinating diseases have been carried out since the end of the 1990s.

Until 2004, none of the published studies had found a significant statistical association between hepatitis B vaccinations and the occurrence of a demyelinating disease.¹² During that year, however, the Hernán et al. study,

Jan. 20, 1991, p. 1048 (now CODE DE LA SANTÉ PUBLIQUE [C. PUB. H.] [CODE OF PUBLIC HEALTH] art. L3111-4.

8. See WORLD HEALTH ORG., TABLE 1: SUMMARY OF WHO POSITION PAPERS – RECOMMENDATIONS FOR ROUTINE IMMUNIZATION, http://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1 (last updated Feb. 27, 2015).

9. NAT'L ACAD. OF MED., VACCINATION AGAINST HEPATITIS B IN FRANCE: MAINTENANCE RECOMMENDATIONS AND STRENGTHENING OF IMMUNIZATION COVERAGE 1495–96 (2008).

10. *Calendrier vaccinal 2008 – Avis du Haut conseil de la sante publique*, BULL. ÉPIDÉMIOLOGIQUE HEBDOMADAIRE § 2.5 (Apr. 22, 2008), http://www.invs.sante.fr/beh/2008/16_17/beh_16_17_2008.pdf.

11. See Bernard Zalc, *Multiple Sclerosis (MS)*, INST. NAT'L DE LA SANTE ET DE LA RECHERCHE MÉDICALE, <http://www.inserm.fr/thematiques/neurosciences-sciences-cognitives-neurologie-psychiatrie/dossiers-d-information/sclerose-en-plaques-sep> (last visited Nov. 19, 2015).

12. See Alberto Ascherio et al., *Hepatitis B Vaccination and the Risk of Multiple Sclerosis*, 344 NEW ENG. J. MED. 327, 327–32 (2001); Christian Confavreux et al., *Vaccinations and the Risk of Relapse in Multiple Sclerosis*, 344 NEW ENG. J. MED. 319, 319–26 (2001); F. De Stefano et al., *Vaccinations and Hepatitis B Vaccine Central Nervous System Demyelinating Disease in Adults*, 60 NEUROLOGY 504–09 (2003); A. Dessa Sadovnick & David. W. Scheifele, *School-Based Hepatitis B Vaccination Programme and Adolescent Multiple Sclerosis*, 355 LANCET 549, 549–50 (2000); M. Stur-

titled *Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis*, was published, which concluded that there was a significant association between the vaccination of adults and the occurrence of demyelinating diseases within three years.¹³ The Global Advisory Committee on Vaccine Safety (“GACVS”) of the WHO quickly took a stand against this study, criticizing its methodology, and stating, “the evidence and argument submitted by Hernán et al. are insufficient to support the hypothesis of a link between the hepatitis B vaccination and multiple sclerosis.”¹⁴ Since that date, there has been no new study supporting the hypothesis of a link between hepatitis B vaccinations and demyelinating diseases. In fact, studies conducted on children and teenagers have concluded to the contrary.¹⁵ Therefore, in the current state of things, there is only one (criticized) epidemiological study supporting the hypothesis of a link between hepatitis B vaccinations and demyelinating diseases,¹⁶ whereas the other studies available apparently point to the absence of such a link, but do not allow a definitive conclusion that no such link exists. Thus, the issue is still open for epidemiologists and scientists.

kenboom et al., *Vaccinations, Demyelination and Multiple Sclerosis Study (VDAMS): A Population-based Study in the UK*, 8 PHARMACOEPIDEMOLOGY & DRUG SAFETY S170–71 (1999); E. Touze et al., *Hepatitis B Vaccination and First Central Nervous System Demyelinating Event: A Case-control Study*, 21 NEUROEPIDEMIOLOGY 180, 180–86 (2002); Frauke Zipp et al., *No Increase in Demyelinating Diseases After Hepatitis B Vaccination*, 5 NATURE MED. 964, 964–65 (1999).

13. M. A. Hernán et al., *Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis: A Prospective Study*, 63 NEUROLOGY 838, 838–41 (2004).

14. *Global Vaccine Safety*, WORLD HEALTH ORG., http://www.who.int/vaccine_safety/topics/hepatitisb/multiple_sclerosis/sep_04/en/index.html (last visited Nov. 28, 2015).

15. Yann Mikaeloff et al., *Hepatitis B Vaccine and Risk of Relapse After a First Childhood Episode of CNS Inflammatory Demyelination*, 130 BRAIN 1105, 1105–10 (2007); Yann Mikaeloff et al., *Hepatitis B Vaccination and the Risk of Childhood-Onset Multiple Sclerosis*, 161 ARCH. PEDIATR. ADOLESC. MED. 1176, 1176–81 (2007).

16. Another study concluded that there is no link between the hepatitis B vaccination and acute demyelinating episodes, but a statistically significant connection was nevertheless observed for one of the samples under scrutiny. Yann Mikaeloff et al., *Hepatitis B Vaccine and the Risk of CNS Inflammatory Demyelination in Childhood*, 72 NEUROLOGY 873, 873–79 (2009). However, this has been considered a fortuitous result by the authors of the study, and by the French Commission nationale de la pharmacovigilance and the National Academy of Medicine. See BULL. ÉPIDÉMIOLOGIQUE HEBDOMADAIRE, *supra* note 10, at 139.

2. The Legal Context

In order to better understand the solutions given by French courts in hepatitis B vaccine cases, Part (a) describes French court institutions, while Part (b) discusses the basic rules on proof and evidence in such cases.¹⁷

a. The French Court System

In France, there is a sharp divide between private law and public law. Substantive law, including rules on liability, normally varies according to whether the defendant is a private or a public person. Moreover, civil courts, which have jurisdiction in private law matters, are distinct from administrative courts, which deal with questions pertaining to public law.

The civil court system is a three-degree one, with courts of first instance,¹⁸ appellate courts (*cours d'appel*), and a unique *Cour de cassation* at the top. The *Cour de cassation* is not an appeal court.¹⁹ It does not appraise facts or consider evidence. Its task is to check that rules of law have been correctly applied. It therefore only deals with 'questions of law,' as opposed to 'questions of fact,'—the latter being dealt with exclusively by first- and second-instance courts. The *Cour de cassation* is thus called '*juge du droit*,' as opposed to lower courts, which are called '*juges du fond*' (i.e., judges ruling on the merits of the case). Rulings by appellate courts containing errors of law²⁰ are quashed, and the case is then submitted to another appellate court in order to be decided anew. If the appellate court's decision is found to contain no error of law, it is confirmed and cannot be further contested. The *Cour de cassation* is unique, but has several chambers. Although the chambers normally deal with different types of litigation, it may happen that two or more chambers will address the same legal issue. This can be a source of discrepancies. If a discrepancy persists on a given issue, and if a new case arises in connection with it, a plenary assembly (*assemblée plénière*) may be called, in which members of all chambers

17. For an excellent presentation of French law in English, see generally JOHN. BELL ET AL., *PRINCIPLES OF FRENCH LAW* (2d ed. 2008).

18. The name of the courts of first instance may vary depending on the field of private law in which they have jurisdiction.

19. See J. Bell & S. Whittaker, *The Spirit of French Law*, and J. Bell, *Court Institutions*, in BELL ET AL., *supra* note 17, at 1–2, 37.

20. The *Cour de cassation* only considers those aspects of the appellate court's ruling, which are discussed by the claimant.

sit. The *assemblée plénière* will take a common position on the disputed issue, which the various chambers will normally follow, even though they are not legally bound to do so (as there is no such thing as binding precedent in French law).

No leave to appeal is required in order to bring a case before the *Cour de cassation*. Any appellate court ruling may be submitted to the *Cour de cassation*. This explains why the latter issues approximately 9,000 decisions each year (not counting criminal cases).²¹ These decisions are usually very terse (not more than a page). The court sticks to a formal reasoning and does not give the reasons underlying its choices. It will say if a provision has been correctly interpreted by the lower court or not, but it will not explain the reasons why this interpretation is correct or incorrect. Some explanations can sometimes be found in the reports of the magistrates who have prepared the court's decision, but these reports are only occasionally made public and have no authority per se. Because they are so terse, decisions by the *Cour de cassation* usually leave great room for interpretation—if not divination.²²

The administrative court system is to a large extent analogous to the civil courts. Courts of first instance (*tribunaux administratifs*) and appellate courts (*cours administratives d'appel*) are topped by the *Conseil d'État*. Although the attributions of the latter may vary depending on the type of litigation, its role is normally the same as the *Cour de cassation*'s. It does not appraise facts or evidence and only quashes appellate courts' rulings for errors of law. The *Conseil d'État*'s decisions are also quite terse, but the preparatory reports are often more easily available than with the *Cour de cassation*.²³

b. Rules of Evidence

Evidence rules in French law are not as developed as they are in other legal systems—especially common law systems. Facts may normally be

21. FRENCH MINISTRY OF JUSTICE, ANNUAIRE STATISTIQUE DE LA JUSTICE, ÉDITION 2011-2012, 27 (2012), http://www.justice.gouv.fr/art_pix/stat_annuaire_2011-2012.pdf.

22. All decisions by the *Cour de cassation* can be found on the judicial case law page of the official French law website Légifrance by simply indicating the decision's number. LÉGIFRANCE, <http://www.legifrance.gouv.fr/initRechJuriJudi.do> (last visited Feb. 20, 2016).

23. All decisions by the *Conseil d'État* can be found on the administrative case law page of the official French law website Légifrance by simply indicating the decision's number. LÉGIFRANCE, <http://www.legifrance.gouv.fr/initRechJuriAdmin.do> (last visited Feb. 20, 2016).

proven by any means.²⁴ Additionally, there is no official standard of proof. Facts do not have to be established ‘on the balance of probabilities,’ or ‘beyond a reasonable doubt’. First- and second-instance judges freely decide if evidence is enough to consider a fact as established. Their appreciation is a matter of ‘*intime conviction*’ (firm personal conviction) and may not be challenged before the *Cour de cassation* or the *Conseil d’État*.²⁵

When a fact cannot be directly established, its existence may be deduced from another fact or from a set of facts. This mechanism is called a presumption. Article 1353 of the *Code civil* provides that presumptions are normally “left to the learning and wisdom of the judges, who shall only admit serious, precise, and consistent presumptions.”²⁶

The parties may of course bring evidence to the court, which will then freely appraise the value of it. However, there are no expert witnesses in French procedure.²⁷ French courts do not hear evidence on technical matters. When a court needs clarification on a technical point, it will usually commission an expert. The expert must be independent from the parties and is normally required to draft a report for the court. In theory, the expert must report on purely factual matters and may not make any assessments of legal nature. This last rule, however, is difficult to apply. The court is not bound to follow the expert’s conclusions. Though in practice, it is only very seldom that a court will reject them.

B. The Solutions Reached by the Courts

It is in this general context, and also in an atmosphere of growing mistrust vis-à-vis vaccinations in general, that the claims regarding hepatitis B vaccines and their possible link with the occurrence of demyelinating dis-

24. There are some exceptions, especially in regards to contracts, but they are not relevant in the context of hepatitis B vaccine litigation.

25. See S. Whittaker, *Legal Procedure*, in BELL ET AL., *supra* note 17, at 85–87.

26. CODE CIVIL [C. CIV.] [CIVIL CODE] art. 1353. All citations of the French *Code civil* in English are borrowed from the English translation accessible on the French law official website Légifrance, and are written by David W. Grunning. LÉGIFRANCE, www.legifrance.gouv.fr (last visited Feb. 20, 2016). A reform of French contracts law, which also encompasses rules on the proof of obligations, was adopted in February 2016: Ordonnance 2016-131 du 10 février 2016 portant réforme du droit des contrats, du régime général et de la preuve des obligations [Statute 2016-131 of February 10, 2016 Laying Down Reform of Contracts Law, the General Rules on Obligations and Proof of Obligations], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], Feb. 11, 2016, text no. 26. The reform will come into force on October 1, 2016. It maintains the substance of the rule now found at art. 1353, but shifts it to art. 1382 of the upcoming version of the *Code civil*.

27. See Whittaker, *supra* note 25, at 85, 106–08.

eases have been raised and adjudicated since the 1990s. These claims come in significant numbers and have been brought on at least four different legal bases. Only two of those will be addressed here, as they are by far the most important in practice.²⁸ Part 1 discusses the compulsory vaccinations compensation scheme, while Part 2 analyzes the product liability legislation.

1. The Compulsory Vaccinations Compensation Scheme

A 1964 statute created a special compensation scheme for injuries resulting from compulsory vaccinations.²⁹ This scheme is now regulated by article L. 3111–9 of the *code de la santé publique* (the Code of Public Health). A special compensation fund, ONIAM (*Office national d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales*), is in charge of fully compensating any damage directly imputable (*directement imputable*) to a compulsory vaccination. Compensation is due as soon as the plaintiff proves that damage is directly imputable to the compulsory vaccination. No other condition, such as negligence or the vaccine's defectiveness, is required. Cases of compulsory vaccination include compulsory hepatitis B vaccinations for health care professionals under article L. 3111–4 of the *code de la santé publique*³⁰; but article L. 3111–9 does not apply to non-compulsory vaccinations, even if they were recommended, encouraged, or subsidized by the government. Claims based on this special compensation scheme must be brought before the ONIAM. The latter decides whether the conditions set by the law are met, and if so, offers a certain amount of damages. If a plaintiff is unsatis-

28. The two other legal bases are: CODE DE LA SÉCURITÉ [C. SOC. SEC.] [CODE OF SOCIAL SECURITY] art. L411-1 (work accidents (*accidents du travail*) legislation for private sector workers), and Loi 86-33 du 9 janvier 1986 portant dispositions statutaires relatives à la fonction publique hospitalière [Law 86-33 of January 9, 1986 Laying Down Statutory Provisions Concerning the Public Hospital], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], Jan. 11, 1986, p. 535 (service accidents (*accidents de service*) legislation for public sector employees).

29. Loi 64-643 du 1^{er} juillet 1964 relative à la vaccination antipoliomyélitique obligatoire et à la répression des infractions à certaines dispositions du code de la santé publique [Law 64-643 of July 1, 1964 on compulsory polio immunization and suppression of violations of certain provisions of the Code of Public Health], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], July 2, 1964, p. 5762.

30. Loi 91-73 du 18 janvier 1991 portant dispositions relatives à la santé publique et aux assurances sociales [Law 91-73 of January 18, 1991 on the Provisions Relating to Public Health and Social Insurance], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], Jan. 20, 1991, p.1048 (now CODE DE LA SANTÉ PUBLIQUE [C. PUB. H.] [CODE OF PUBLIC HEALTH] art. L3111-4).

fied with the ONIAM's appraisal of the situation or its compensation proposal, he can appeal to an administrative court.

At the end of the 1990s, litigants began filing claims with administrative courts, based on article L. 3111-9, regarding damage allegedly caused by hepatitis B vaccinations.³¹ Due to the state of scientific uncertainty, judges initially took diverging positions on the issue of the link between hepatitis B vaccinations and the occurrence of demyelinating diseases.³² Things were then clarified by the *Conseil d'État* in four decisions handed down in March 2007.³³ On that occasion, the court followed the opinion of Thierry Olson, the magistrate in charge of preparing the cases.³⁴

In his preliminary report, Judge Olson described the (rather uncertain) state of the lower administrative courts' (and of the *Cour de cassation*'s) case law on the subject at the time. He also explained the state of scientific uncertainty on the issue of the relationship between the hepatitis B vaccination and the occurrence of demyelinating diseases. He concluded that it was not possible to answer 'yes' or 'no' to the question whether the vaccination could cause such diseases. Yet, having said that, he went on to declare that vaccinations can be regarded as a factor that may trigger the appearance of a demyelinating disease if the subject has certain predispositions. However, he added, such a link between the vaccination and the occurrence of the disease can only be regarded as established if the first symptoms of the disease appear in the three months following the vaccination. He gave no precise scientific reason for this three-month delay.

31. "Sans préjudice des actions qui pourraient être exercées conformément au droit commun, la réparation d'un dommage imputable directement à une vaccination obligatoire pratiquée dans les conditions mentionnées au présent chapitre, est supportée par l'État." Until 2000, the rule now contained in this article was found at CODE DE LA SANTÉ PUBLIQUE [C. PUB. H.] [CODE OF PUBLIC HEALTH] art. L3111-9.

32. For cases negating the link, see *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Douai, June 21, 2005, 03DA01306; *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Bordeaux, Dec. 6, 2005, 03BX00793; *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Nantes, Oct. 13, 2005, 04NT01007; *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Douai, Oct. 17, 2006, 05DA00803; *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Paris, May 15, 2006, 04PA01401. For cases affirming the link, see *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Paris, Nov. 5, 2002; *Cour administrative d'appel* [CAA] [regional administrative courts of appeal] Paris, civ., May 16, 2006, 02PA03495.

33. *Conseil d'État* [CE] [Council of State] Mar. 9, 2007, 267635; *Conseil d'État* [CE] [Council of State] Mar. 9, 2007, 278665; *Conseil d'État* [CE] [Council of State] Mar. 9, 2007, 283067; *Conseil d'État* [CE] [Council of State] Mar. 9, 2007, 285288. Three of these cases were actually grounded on service accidents legislation and only one on compulsory vaccinations compensation rules. In all four cases, the *Conseil* addressed the issue of the link between the hepatitis B vaccination and the occurrence of a demyelinating disease exactly the same way.

34. Thierry Olson, Conclusions under *Conseil d'État* (CE), No. 285288, Mar. 9, 2007.

Unsubstantiated though it may be from a scientific point of view, Judge Olson's position was endorsed by the *Conseil d'État*.³⁵ The court affirmed two lower court decisions, which had rejected the plaintiffs' claims. In one case the delay between the last injection of the vaccine and the first symptoms of multiple sclerosis (ten months) did not support the existence of a causal link between the vaccination and the disease. In the second case, the first symptoms of the disease had appeared before the vaccination and could therefore not be regarded as a consequence of the latter. The *Conseil d'État* quashed the two other lower court decisions, which had rejected the claims for lack of causation, on the ground that the short delay between the vaccination and the first symptoms of the disease (a couple of months in both cases) should have been regarded as establishing causation.

Since 2007, the *Conseil d'État* has stuck to this position and has confirmed in several decisions the rule according to which a short (*bref*) delay (three months at most) between receiving the vaccination and the occurrence of the first symptoms establishes causation, if no other cause for the disease can be identified.³⁶ In practice, the court has thus broken through the veil of scientific uncertainty, establishing a new legal rule, whereby causation must be presumed in certain circumstances. What is striking, though, is that no scientific reason, nor actually any reason at all, was put forward by the court to justify the short delay criterion, which is a major condition of application of this rule.

2. Product Liability Legislation

The European Union, of which France is a member, has set up common rules on product liability for its Member States through *Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Li-*

35. See *supra* note 32.

36. Conseil d'État [CE] [Council of State] July 25, 2007, 288052; Conseil d'État [CE] [Council of State] July 4, 2008, 299832; Conseil d'État [CE] [Council of State] July 11, 2008, 289763; Conseil d'État [CE] [Council of State] Feb. 18, 2009, 305810; Conseil d'État [CE] [Council of State] Apr. 10, 2009, 296630; Conseil d'État [CE] [Council of State] July 24, 2009, 308876; Conseil d'État [CE] [Council of State] July 24, 2009, 304325; Conseil d'État [CE] [Council of State] Feb. 9, 2011, 319497; Conseil d'État [CE] [Council of State] Feb. 25, 2011, 324051; Conseil d'État [CE] [Council of State] Mar. 4, 2011, 313369; Conseil d'État [CE] [Council of State] July 28, 2011, 318466; Conseil d'État [CE] [Council of State] Feb. 13, 2012, 331348; Conseil d'État [CE] [Council of State] Feb. 17, 2012, 331277; Conseil d'État [CE] [Council of State] Nov. 8, 2012, 350886; Conseil d'État [CE] [Council of State] Nov. 6, 2013, 345696; Conseil d'État [CE] [Council of State] Dec. 13, 2013, 352460; Conseil d'État [CE] [Council of State] Apr. 30, 2014, 357696; Conseil d'État [CE] [Council of State] Nov. 5, 2014, 363036.

*ability for Defective Products.*³⁷ These rules apply in France to all products put into circulation as of July 31, 1988.³⁸ They make the producer liable for damage caused by a defect in his product.³⁹ The producer is defined as the manufacturer of the product or any person who, by putting his name, trademark, or other distinguishing feature on the product presents himself as its producer.⁴⁰ It is of course the injured person who must prove damage, the defect, and the causal relationship between defect and damage.⁴¹ The Directive regards a product as defective when it does not provide the safety a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation.⁴² The producer can escape liability if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.⁴³ Claims based on product liability may in theory be brought before either civil or administrative courts, depending on the status (private or public) of the producer. However, there are only two producers marketing vaccines against hepatitis B in France, both of which are commercial companies, and claims against them are to be brought before civil courts.

The first reported product liability cases related to hepatitis B vaccinations are two rulings by the Nanterre⁴⁴ court of first instance on June 5,

37. Council Directive 85/374/EEC, 1985 O.J. (L 210) (EU). The rules contained in a directive generally need to be transposed to apply in a Member State. Transposition of Directive 85/374 was supposed to take place before the end of July 1988, but France waited until May 1998 before it complied with its obligations. The rules set by the Directive are found in articles 1386-1 to 1386-18 of the French *Code civil* (and will be shifted to articles 1245–1245-17 when the reform of French contracts law, on which see *supra* note 26, comes into force on Oct. 1, 2016). CODE CIVIL [C. CIV.] [CIVIL CODE] arts. 1386-1–1386-18. On the rather hectic transposition process of the Directive in France, see GENEVIÈVE VINEY & PATRICE JOURDAIN, *LES CONDITIONS DE LA RESPONSABILITÉ* ¶ 771–76 (3d ed. 1996).

38. July 31, 1998 marked the end of the delay set for the transposition of the Directive. The current *Code civil* provisions on product liability only apply to products put into circulation after May, 21 1998. Products put into circulation before that date are subject to judge-made rules, but these have been modified or interpreted to match exactly those of the Directive. See Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., May 15, 2007, 05-17947, Bull. civ. I, No. 186.

39. Council Directive 85/374/EEC, art. 1, 1985 O.J. (L 210) (EU).

40. *Id.* art. 3.

41. *Id.* art. 4.

42. *Id.* art. 6.

43. *Id.* art. 7(e). For a general analysis of the Directive, its origins, and its regime, see JANE STAPLETON, *PRODUCT LIABILITY* (1994).

44. Most pharmaceutical firms in France have their headquarters in Paris and its vicinity. Hence, a majority of product liability cases concerning pharmaceuticals are brought before the Parisian courts or neighbouring ones (Nanterre court of first instance and Versailles appellate court).

1998.⁴⁵ The court of first instance allowed the claims and the producer appealed to the Versailles appellate court. The latter acknowledged the state of scientific uncertainty and stated that “the existence of a link between the vaccination and the occurrence of the disease cannot be scientifically proven”; but it went on to say that scientific evidence did not exclude the existence of such a link.⁴⁶ It then concluded that, in the cases under scrutiny, the time coincidence between the vaccination and the occurrence of the first symptoms of the disease, as well as the absence of another identified cause for multiple sclerosis, allowed a presumption that the vaccination had actually caused the disease.⁴⁷ The appellate court thus confirmed the court of first instance’s rulings.⁴⁸ The cases were subsequently brought before the *Cour de cassation*. In two 2003 rulings, the first civil chamber of the higher court quashed the appellate court’s decisions, on the ground that the lower judges could not regard causation between the vaccination and the disease as established, given the absence of scientific certainty on the possible link between hepatitis B vaccinations and multiple sclerosis.⁴⁹

These rulings by the *Cour de cassation* have been interpreted as follows: the state of scientific uncertainty regarding the effects of hepatitis B vaccinations forbids that a causal link be established between a vaccination and the appearance of a demyelinating disease in a given case. This position was followed by lower courts⁵⁰ and, on at least one occasion, the first civil chamber of the *Cour de cassation* confirmed a lower court’s decision that had rejected a claim related to a hepatitis B vaccine for lack of proven

45. Tribunal de grande instance [TGI] [ordinary court of original jurisdiction] Nanterre, June 5, 1998, D. 1999, 246.

46. Cour d’appel [CA] [regional court of appeal] Versailles, civ., May 2, 2001, 98/06839, D. 2001, 1592.

47. *Id.* The court also considered, on very shallow grounds, that the vaccine could be regarded as defective. The issue of defectiveness will be dealt with *infra*.

48. Cour d’appel [CA] [regional court of appeal] Versailles, civ., May 2, 2001, 98/06839, D. 2001, 1592. For a detailed study of this decision, see Sophie Gromb & MG Kirman, *Vaccination contre l’hépatite B et sclérose en plaques*, 51 MÉDECINE ET DROIT 22 (2001); JEAN-SÉBASTIEN BORGHETTI, *LA RESPONSABILITÉ DU FAIT DES PRODUITS, ÉTUDE DE DROIT COMPARÉ* ¶ 376 (2004).

49. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., Sept. 23, 2003, 01-13063 and 01-13064, Bull. civ. I, No. 188.

50. Cour d’appel [CA] [regional court of appeal] Versailles, civ., Nov. 25, 2005, 04/03953; Cour d’appel [CA] [regional court of appeal] Paris, civ., June 2, 2006, 03/17991; Cour d’appel [CA] [regional court of appeal] Lyon, civ., Nov. 22 2007, 06/02450; Cour d’appel [CA] [regional court of appeal] Lyon, civ., Feb. 12 2008, 06/01764. Before the 2003 *Cour de cassation*’s rulings, the Versailles appellate court recognized a causal link between the hepatitis B vaccination and the occurrence of a demyelinating disease in another case. Cour d’appel [CA] [regional court of appeal] Versailles, Sept. 12, 2003, 97/04862. However, this decision was later quashed by the *Cour de cassation* on the issue of the product’s defectiveness. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., Jan. 24, 2006, 03-19534, Bull. civ. I, No. 33.

causation between the vaccination and the occurrence of the disease.⁵¹ Plaintiffs and part of academia were very critical of this position, however. Many described it as unfair and found it shocking that ‘victims’ could get no compensation.⁵² Critics also pointed to the position adopted by the *Conseil d’État* in 2007 to support their argument: how could the two higher courts take a different stance on the same important issue and create such inequality among plaintiffs?⁵³

This debate apparently had an impact on the *Cour de cassation*. The court changed its position in two rulings issued on May 22, 2008. In both cases, the appellate courts had followed the rule established by the first civil chamber in 2003 and rejected compensation claims on the ground that scientific uncertainty did not permit the recognition of a causal link between the hepatitis B vaccination and the occurrence of a demyelinating disease. Yet, the same chamber of the *Cour de cassation* quashed these two decisions. It held that the lower courts had violated the law because they had followed “a probabilistic approach based exclusively on the lack of scientific and statistical link between vaccination and the development of the disease” (“*une approche probabiliste déduite exclusivement de l’absence de lien scientifique et statistique entre vaccination et développement de la maladie*”), whereas they should have considered whether the facts of the case allowed for a presumption that the vaccine caused the plaintiff’s disease.⁵⁴ These decisions must be well understood. They have not affirmed that there was a causal relationship between the vaccination and the disease in the cases under scrutiny; but they have repudiated the former approach, which regarded the state of scientific uncertainty as a bar to product liability claims involving hepatitis B vaccines. As the *Cour de cassation* later put it in a 2009 decision, lower judges cannot require an “unquestionable scientific proof” (“*une preuve scientifique certaine*”).⁵⁵ Furthermore, the 2008 rulings did not follow the *Conseil d’État*’s solution. According to the latter, causation must be presumed if the disease appeared

51. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., Feb. 27, 2007, 06-10063.

52. See, e.g., Cour d’appel [CA] [regional court of appeal] Paris, 2 June 2006, RCA 2006, comm. 306, note Christophe Radé.

53. In a work accident case, the second civil chamber of the *Cour de cassation* confirmed a lower court decision which had recognized causation between a vaccination and multiple sclerosis. Cour de cassation [Cass.] [supreme court for judicial matters] 2e civ., May 25, 2004, 02-30981, Bull. civ. II, No. 237 (ruling on Cour d’appel (CA) Metz, June 11, 2002, 99/02280).

54. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., May 22, 2008, 06-10967, 05-20317, 06-18848, 06-14952, Bull. civ. I, No. 148-149.

55. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., June 25, 2009, 08-12781, Bull. civ. I, No. 141.

in the three months following the vaccination and no other cause for the disease is identified. The *Cour de cassation* did not set such a rule, but only required lower courts to decide, on the facts of the case, if a presumption of causation may be retained.

The position adopted by the *Cour de cassation* in effect grants lower courts full freedom in assessing the existence of causation between a vaccination and a demyelinating disease. Acknowledging such causation has become a matter of presumption “on the facts,” over which the *Cour de cassation* exerts no control. As subsequent cases have shown, this inevitably leads to diverging approaches by lower courts. Very similar circumstances can lead to different rulings on the issue of causation, depending on the lower judges’ conception of the etiology of demyelinating diseases.⁵⁶ It seems as though scientific truth varies from one local jurisdiction to the other. Typically, the Paris appellate court seems to be very open to the epidemiologists’ argument, and usually decides that the facts of the case do not allow a presumption that the vaccination caused the demyelinating disease, whatever the delay between the former and the outbreak of the latter. Quite to the contrary, the Versailles appellate court (located only 20 km away!) readily accepts time proximity between the vaccination and the first symptoms of the disease as proof of causation, when no other factors explaining the disease can be found in the plaintiff or his family.⁵⁷ For many French judges, the state of scientific uncertainty regarding the relationship between the hepatitis B vaccination and demyelinating disease is thus not an obstacle to legal causation being established between the two. This bypassing of scientific uncertainty is worth investigating.

56. For cases in which lower judges considered causation as established on the facts of the case, see *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., July 9, 2009, 08-11073, Bull. civ. I, No. 176; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., July 10, 2013, 12-21314, Bull. civ. I, No. 157. For cases where lower judges have refused to acknowledge causation, see *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., Sept. 24 2009, 08-16097; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., Nov. 25 2010, 09-16556, 09-71013, Bull. civ. I, No. 245; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., Apr. 28, 2011, 10-15289; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., Jan. 26, 2012, 10-28195; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., June 28, 2012, 11-14287; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., May 29, 2013, 12-20.903, Bull. civ. I, No. 116.

57. On this issue, see Jean-Sébastien Borghetti, *Contentieux du vaccin contre l’hépatite B : en route vers Luxembourg!*, in RECUEIL DALLOZ 2602 (2015).

II. THE BYPASSING OF SCIENTIFIC UNCERTAINTY

The solutions reached by French courts, and which have just been described, are hardly satisfying. The position adopted by the *Conseil d'État* lacks any explicit justification, whereas the *Cour de cassation's* position results in considerable legal disorder and unpredictability. Part A examines how, more generally, the desire to grant compensation to plaintiffs, while pretending to abide with existing legal rules, leads judges to rely on pseudo-scientific reasoning. Part B suggests that clearer conceptual distinctions are needed, especially on the issue of causation, in order to reach better, or at least more convincing, solutions.

A. Pseudo-Scientific Reasoning

The majority of academia approved of those cases in which judges ruled that scientific uncertainty did not bar the establishment of causation between a hepatitis B vaccination and the outbreak of a demyelinating disease—at least in so far as those cases are favorable to plaintiffs.⁵⁸ On a more technical ground, some authors try to justify those decisions by the simple idea that legal causation is not scientific causation.⁵⁹ Even if this

58. Of course, establishing causation is not always enough for a compensation claim to succeed. When the claim is grounded on the compulsory vaccinations compensation scheme, causation between the vaccination and the disease is indeed sufficient. Most claims, however, are based on product liability and directed at the producer. In these claims, the plaintiff must also prove the defect in the product, and this may be even harder than proving causation. In its latest rulings, however, the *Cour de cassation* tried to go over this obstacle, just as it went over the causation obstacle. On two occasions, the Court quashed lower court decisions, which had recognized the existence of causation between a vaccination and multiple sclerosis on the facts of the case, but had nevertheless rejected the plaintiff's claim on the ground that the risk/benefit ratio of the vaccine was positive, and the vaccine therefore not defective. *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., July 10, 2013, 12-21314, Bull. civ. I, No. 157; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., Sept. 26, 2012, 11-17738, Bull. civ. I, No. 187. In both cases, the *Cour de cassation* ruled that the lower courts could not rely only on the risk/benefit ratio to rule out defectiveness and that they should have considered if the elements that were used to presume causation could also justify a presumption that the vaccine doses used were defective. By doing so, the *Cour de cassation* did not say that hepatitis B vaccines are defective, but it allowed lower courts to reach this conclusion on a case-by-case basis. The approach is therefore exactly the same as the one taken on causation in 2008, and the result will also be the same. This means that the hepatitis B vaccine will most likely be regarded as defective by some French lower courts, but not by others. This, obviously, is neither convincing nor satisfying.

59. See Philippe Brun, *Raffinements ou faux-fuyants ? Pour sortir de l'ambiguïté dans le contentieux du vaccin contre le virus de l'hépatite B*, in RECUEIL DALLOZ 316 (2011).

distinction is to be accepted, however, this justification is hardly convincing, as judges tend to put forward arguments, which they present as scientific, in order to justify the solutions they reach. French courts therefore do not make a clear distinction between scientific causation and legal causation. Quite to the contrary—they very often mix up the two.

A 2009 case decided by the *Cour de cassation* offers a good illustration of this. The case involved all the elements that are commonly put forward to justify the recognition of a causal relationship between a vaccination and the outbreak of a demyelinating disease, be it before administrative or civil courts.⁶⁰ Mrs. X, a young woman, developed the first symptoms of multiple sclerosis a few weeks after she received a hepatitis B vaccine. The first instance court of Lyons rejected her product liability claim against the producer of the vaccine on the ground that “mere chronology” cannot suffice to establish a link between a vaccination and the disease (“*la seule chronologie ne peut suffire à imputer la survenue de la sclérose en plaques à la vaccination*”).⁶¹ The appellate court of Lyons later reversed this judgment, and ruled that the connection between the vaccination and the disease could be presumed on the facts of the case.⁶² This new decision was then challenged before the *Cour de cassation*, and was confirmed. The justification given by the *Cour de cassation* for the rejection of the challenge was as follows: “having noted, first of all, that if scientific studies produced by [the vaccine manufacturer] do not establish a significant increase of the relative risk of multiple sclerosis or demyelination after a vaccination against hepatitis B, yet they do not exclude a possible link between this vaccination and the outbreak of a multiple-sclerosis-like demyelination; having also noted that the first symptoms of multiple sclerosis appeared less than two months after the last injection of the product; [and having noted] that neither Mrs X nor any member of her family had previous neurological history, and, thus, that no other cause could explain this disease, whose link with the vaccination was regarded as evident by Mrs X’s practitioner; the appellate court, which was sovereign in deciding that these facts amounted to serious, precise, and consistent

60. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., July 9, 2009, 08-11073, Bull. civ. I, No. 176.

61. Tribunal de grande instance [TGI] [ordinary court of original jurisdiction] Lyons, Mar. 27, 2006, 05/10454.

62. Cour d’appel [CA] [regional court of appeal] Lyons, civ., Nov. 22, 2007, 06/02450.

presumptions,⁶³ could come to the conclusion that there was a causal connection between Mrs X's vaccination and her injury."⁶⁴

It can be deduced from this statement by the *Cour de cassation* that, as long as science does not exclude the existence of a causal connection, the finding that there is such a connection is possible. Legal causation is thus not totally independent from scientific causation, or at least cannot contradict it openly.⁶⁵ With this requirement that there be no contradiction with formal scientific findings, the elements which have been retained by lower judges to regard causation as established, and which the *Cour de cassation* has accepted, are the following: 1) time proximity between the last injection of the vaccine and the first symptoms of the disease; 2) absence of neurological history and, more generally, of any other cause that could explain the outbreak of the disease; and 3) the intimate belief of the plaintiff's practitioner. These elements must be considered in turn.

First of all, the practitioner's conclusion that his patient's disease had been caused by the vaccination, is certainly worth considering. Yet, it is rather surprising that it is given the same weight as the above-mentioned scientific studies, especially as nothing indicates that this practitioner had special expertise in the field of multiple sclerosis or neurological diseases. It is therefore not very surprising that this element is not frequently relied on.

Quite to the contrary, the second element (that there was no other cause than the vaccination that could explain the outbreak of the disease) is very often put forward. It may be formulated in slightly different ways, and courts sometimes underline, like the *Conseil d'État*⁶⁶ or the appellate court in Mrs. X's case, that there was no history of the disease in the plaintiff or his family. It is true that, generally speaking, eliminating alternative causes

63. This is a reference to article 1353 of the *Code civil*. See *supra* Part I(A)(2)(b).

64. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., July 9, 2009, 08-11073, Bull. civ. I, No. 176. "Ayant relevé, d'abord, que si les études scientifiques versées aux débats par [le fabricant du vaccin] n'ont pas permis de mettre en évidence une augmentation statistiquement significative du risque relatif de sclérose en plaques ou de démyélinisation après une vaccination contre l'hépatite B, elles n'excluent pas, pour autant, un lien possible entre cette vaccination et la survenance d'une démyélinisation de type sclérose en plaques ; qu'ayant, ensuite, relevé que les premières manifestations de la sclérose en plaques avaient eu lieu moins de deux mois après la dernière injection du produit ; que ni Mme X... ni aucun membre de sa famille n'avaient souffert d'antécédents neurologiques, et que dès lors aucune autre cause ne pouvait expliquer cette maladie, dont le lien avec la vaccination relevait de l'évidence selon le médecin traitant de Mme X... , la cour d'appel, qui a souverainement estimé que ces faits constituaient des présomptions graves, précises et concordantes, a pu en déduire un lien causal entre la vaccination de Mme X... et le préjudice". *Id.* (the French translation).

65. See *infra* Part II(B).

66. See *supra* Part I(B)(1).

can prove the causal link between two events.⁶⁷ For such reasoning to be valid, however, it is necessary that all possible causes of the event whose origin is under investigation be identified. The problem with multiple sclerosis is that its etiology is not yet fully known.⁶⁸ In this context, how is it possible for judges to assert that, in any given case, there could be no other cause than the vaccination to account for the outbreak of the disease? In particular, the fact that there was no history of the disease in the plaintiff's family can be regarded as convincing only if it is assumed that multiple sclerosis normally develops out of internal or genetic factors; but the courts give no justification for this assumption.

The major element put forward to establish causation is the proximity in time between the vaccination and the onset of the first symptoms of the disease. It seems as though for many judges, as well as for many in academia, this proximity is the ultimate proof of causation. The importance of this element is especially clear in the decisions of the *Conseil d'État*.⁶⁹ Undoubtedly, such a time coincidence between the vaccination and the appearance of the first symptoms of a demyelinating disease is disturbing, and it is not surprising if some plaintiffs are convinced that this is more than a coincidence. One can regard such a coincidence as proof of causation, however, only if one implicitly assumes that the vaccination can cause a demyelinating disease and that the disease will then occur in a very short time after the vaccination. Without such an underlying theory, the mere coincidence of two facts does not bear any significance. Viewing the coincidence of time as proof of causation therefore amounts to holding true the theory that should have been demonstrated in the first place. A French author has put it very clearly:

“Does one not see that this proximity in time is significant only if one holds as true precisely what calls for a demonstration? Indeed, absent the presupposition, in one way or the other, that the injection of the vaccine and the disease are linked to one another, the near concomitance of these two events would not have any particular meaning, and would hardly be worth mentioning. This is made all the clearer by the fact that, to this day, the time needed for the said disease to develop its effects is not known. In such a context of ignorance, the proximity in time between the two events does not hint unambiguously to anything in particular. As a matter of fact, should it appear in the future that multiple sclerosis remains latent in the body for several years before the onset of the first

67. For examples in French law, see G. VINEY ET AL., *LES CONDITIONS DE LA RESPONSABILITÉ* ¶ 382 (4th ed. 2013).

68. See *supra* Part I(A)(1).

69. See *supra* Part I(B)(1).

symptoms, the near concomitance of the two events would appear as the sign of the absence of causation between them!”⁷⁰

Scientists have of course investigated the disturbing fact that the first symptoms of a demyelinating disease sometimes appear shortly after a hepatitis B vaccination. Most of their studies conclude, however, that such a coincidence cannot be regarded as significant from a statistical point of view. In other words, given the overall number of people who receive a vaccination against hepatitis B and the overall number of people who develop a demyelinating disease, the number of cases in which such a disease appears shortly after a vaccination, appears to be in line with what statistics would predict in the absence of any causal relationship between the vaccination and the occurrence of a demyelinating disease. In fact, some studies even seem to suggest that, given the development pattern of demyelinating diseases, if the vaccination can cause a demyelinating disease, then the first symptoms of the disease should probably appear several years after the vaccination.⁷¹ If this were true, the time coincidence between the vaccination and the first symptoms of the disease would become proof that the former did *not* cause the latter.

As a result, the elements most commonly put forward to justify a presumption that the plaintiff’s demyelinating disease was caused by a vaccination against hepatitis B are not really convincing. Judges pretend not to be tied by science and do not want to consider the state of scientific uncertainty resulting from existing epidemiological studies as an obstacle, but the arguments and reasoning they use to find causation are also of scientific nature—or at least pretend to be. When a court regards the concomitance in time to find that there is indeed causation, it relies implicitly on a pseudo-scientific general rule, whereby the negative side effects of the vaccination, if any, must appear very quickly. By doing so, judges actually replace causation, as understood by scientists and epidemiologists, with their own brand of “scientific causation”. It is as though they implicitly concluded

70. G. Canselier, *De l'explication causale en droit de la responsabilité civile délictuelle*, 41 REVUE TRIMESTRIELLE DE DROIT CIVIL 41, ¶ 20. (2010). “*Ne voit-on pas que cette proximité temporelle n'est significative que si l'on tient pour acquis précisément ce qui appelle démonstration ? En effet, si l'on ne présupposait pas, d'une manière ou d'une autre, que l'injection du vaccin et l'apparition de la maladie sont reliées l'une à l'autre, la quasi-concomitance de ces deux événements n'aurait pas de signification particulière et mériterait à peine d'être relevée. Ceci apparaît d'autant plus clairement que l'on ne connaît pas aujourd'hui le temps nécessaire pour que la maladie en question manifeste ses effets. Dans un tel contexte d'ignorance, la proximité temporelle des deux événements n'est l'indice univoque de rien. En effet, s'il devait apparaître à l'avenir que la sclérose reste latente dans l'organisme plusieurs années avant son déclenchement, la quasi-simultanéité des deux événements apparaîtrait finalement comme le signe d'une absence de lien causal entre eux !*” *Id.* (the French translation).

71. C. Confavreux, *Vaccination Contre L'hépatite B et Sclérose en Plaques*, 34 LA PRESSE MÉDICALE 1205–08 (2005).

that they know better than scientists: “Scientists may well tell us that time coincidence is no proof of causation, but we know that it is!” Presuming causation on the facts of the case, despite the state of scientific uncertainty, is thus not substituting legal causation for scientific causation, but rather substituting scientific causation as understood by (some) lawyers for scientific causation as understood by scientists. This is hardly satisfying. A change in the French courts’ position could more easily be made, however, if new concepts and distinctions were made available to judges in order for them to better address the questions with which they are faced.

B. Distinguishing Different Types of Causation

The traditional distinction between scientific and legal causation cannot provide a solid justification for the solutions currently given by French courts in the field of hepatitis B vaccination litigation. Admittedly, scientific causation and legal causation are distinct, but the fact that they should be distinguished does not mean that they are totally independent from one another, or that they can be at odds. Indeed, if it were to be scientifically proven that a vaccination against hepatitis B *does not* cause demyelinating diseases, it is quite likely that the *Cour de cassation* and the *Conseil d’État* would change their position, since their rulings suggest that causation may be found in certain circumstances—despite the state of scientific uncertainty—only because existing epidemiological studies do not formally exclude the existence of causation, even if they do not support it.

Putting forward the distinction between scientific causation and legal causation is just a way to bypass the obstacle of scientific uncertainty. It would be much better to face it openly. But this is made more difficult by the fact that French tort law lacks the conceptual tools needed to address and overcome this obstacle. The section of the French *Code civil* devoted to tort law only consists of five articles, three of them being either redundant or of very limited scope. The fundamental provision is article 1382,⁷² which states: “Every act whatever of man that causes damage to another, obliges him by whose fault it occurred to repair it.”⁷³ The very general character of this principle has given French tort law distinctive flexibility.

72. This provision will remain unchanged but will be shifted to article 1240 when the reform of French contracts law (on which see *supra* note 26) comes into force on Oct. 1, 2016.

73. CODE CIVIL [C. CIV.] [CIVIL CODE] art. 1382. “*Tout fait quelconque de l’homme, qui cause à autrui un dommage, oblige celui par la faute duquel il est arrivé à le réparer.*” *Id.* (the French translation).

The courts, and especially the *Cour de cassation*, have made extensive use of this flexibility, with a view towards fostering compensation. Accordingly, they have always refused to give precise definitions of the key concepts contained in the articles of the *Code civil*. The result of this is that French tort law is structured around a limited number of ill-defined concepts, the three basic ones being fault, damage and causation.⁷⁴ This, obviously, does not provide many tools to address the issue of scientific uncertainty in hepatitis B vaccination litigation. Causation is a pertinent concept in this context, but French law does not have a clear definition of it. Besides, French law usually views causation as only the link between fault and damage; but this fails to capture the fact that tort cases can actually involve different types of causal relationships.⁷⁵ It is suggested that at least two distinctions should be established in that respect.

First of all, the relationship existing between the *use* of the product and damage should be distinguished from the connection that may exist between the product's *defect* and damage. Product liability regimes like the one established by the European Directive only mention the second connection, which they call causation. For example, article 1 of the Directive provides that "the producer shall be liable for damage caused by a defect in his product."⁷⁶ Yet, although the relationship existing between the *use* of the product and damage is not mentioned, and thus receives no distinct name, it is an implicit prerequisite of liability.⁷⁷ When French courts talk of causation in hepatitis B vaccination cases, and more generally in product liability cases involving pharmaceuticals, they usually have in mind the first relationship, i.e. the one between the *use* of the product and damage, and not the second one between *defect* and damage.

The second distinction that could and should be made is quite familiar to many American lawyers, and has an even closer connection to the issue of scientific uncertainty. It is the distinction between general causation and

74. *Id.*

75. The distinction between cause in fact and cause in law, which many legal systems have adopted, though under different guises, is not officially recognized in French law.

76. Council Directive 85/374/EEC, art. 1, 1985 O.J. (L 210) (EU). This text has been implemented at article 1386-1 of the *Code civil*: "*Le producteur est responsable du dommage causé par un défaut de son produit, qu'il soit ou non lié par un contrat avec la victime.*" CODE CIVIL [C. CIV.] [CIVIL CODE] art. 1386-1 ("A producer is liable for the damage caused by a defect in his product, whether he was bound to the victim by a contract or not.")

77. This has been acknowledged by the *Cour de cassation* in a couple of decisions. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., Feb. 27, 2007, 06-10063; Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., May 29, 2013, 12-20.903, Bull. civ. I, No. 116. Some authors, however, are very critical of this solution, arguing that it creates a new hurdle on the path to compensation. See Brun, *supra* note 59.

specific (or individual) causation.⁷⁸ General causation deals with the issue of whether a substance is capable of causing a particular injury or condition in the general population, whereas specific causation has to do with whether a substance caused a particular individual's injury. This distinction may seem basic to some common lawyers who have some expertise in the field of toxic torts, but it is totally absent from French law.

French lawyers should adopt this distinction. An immediate benefit would be a better identification of the core difficulty in the hepatitis B vaccination cases. The problem in those cases is determining not only if the vaccine caused the plaintiff's disease (specific causation), but also whether this product is generally capable of causing such a disease, independently from the case under discussion (general causation). In light of this distinction, the question, which French courts and lawyers have been grappling with for more than a decade, can be formulated very simply: should the proof of general causation be a prerequisite for the possibility, or even the admissibility, of the proof of specific causation?

American law generally seems to answer this question in the affirmative. This is also substantially the position that the *Cour de cassation* adopted in 2003,⁷⁹ even if it did not use the concepts of general and specific causation. Today, however, both the *Cour de cassation* and the *Conseil d'État* implicitly accept that specific causation can be established even though general causation has not been proven. There seems to be a logical problem there. Admittedly, the prerequisite of general causation could be set aside if the plaintiff's injury were attributable to some specific characteristics of the vaccine doses he received, and not to the vaccine's general characteristics. But the plaintiffs in the hepatitis B vaccine litigation cases have never seemed to suggest this.⁸⁰

Distinguishing general causation and specific causation thus more plainly exposes the contradiction in the position adopted by (some) French

78. See, e.g., *Baxter v. Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005); *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1129 (9th Cir. 2002) ("'Generic causation' has typically been understood to mean the capacity of a toxic agent, such as radiation, to cause the illnesses complained of by plaintiffs. If such capacity is established, 'individual causation' answers whether that toxic agent actually caused a particular plaintiff's illness."); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 402 (S.D. N.Y. 2005); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 524–25 (W.D. Pa. 2003); *Burton v. R.J. Reynolds Tobacco Co.*, 181 F. Supp. 2d 1256, 1266–67 (D. Kan. 2002); see also RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 28 cmt. c (AM. LAW INST. 2010).

79. See *supra* Part I(B)(2).

80. On the other hand, the *Cour de cassation* has done so in two decisions, but in a rather unconvincing way, which is essentially an implicit recognition that its current position is not convincing. See *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., July 10, 2013, 12-21314, Bull. civ. I, No. 157; *Cour de cassation* [Cass.] [supreme court for judicial matters] 1e civ., Jan. 26, 2012, 10-28195.

courts. They pretend to apply tort law rules and to appraise causation on the basis of objective elements and scientific reasoning, but they actually resort to a biased logic, and use tort law as a smoke-screen to try and grant compensation, whose real justification does not lie in the application of tort law rules, but in the desire to help plaintiffs attracting their compassion.

This actually illustrates two distinctive traits of French case law in the field of tort law. The first one is the tendency to take an instrumentalist approach to the law and to twist, or bend, tort law rules in order to foster compensation. This might seem surprising, especially in a legal system based on written provisions, where the judge's role is traditionally understood as being only to apply the law, and not to create it. In the field of torts, however, the lack of guidance offered by the *Code civil*, combined with the necessity to answer society's changing needs, has created an incitation for the courts to take a more proactive role. They started to do so at the end of the 19th century,⁸¹ and have progressively set themselves free from the legislature—at least in the fields the legislature has left untouched since 1804.⁸² More recently, French courts have tended to set themselves free from mere logic, especially on the issue of causation—and hepatitis B vaccination litigation offers a topical, but by no way unique, example of this trend.⁸³ This of course raises many questions, the most notable one being: what, if any, is the limit on judges' discretion?

The other distinctive trait of French case law in the field of torts is that, despite their having gained so much freedom and discretion, higher judges, and especially the *Cour de cassation*, still pretend to be following the legalist model and applying the law, without creating it. As a result, they continue handing down decisions, which are very short, that contain very little motivation, and give no indication of the policy considerations underlying the positions or rules that are adopted. This is partly due to the technicalities of the procedure before the *Cour de cassation*, but the result of it is a striking paradox: The *Cour de cassation* is a major source of tort

81. The seminal case is *Teffaine*, in which the *Cour de cassation* created a new strict liability regime on the basis of a provision of the Civil code which was intended to serve as an introduction, and not to state a rule. *Cour de cassation* [Cass.] [supreme court for judicial matters] civ., June 18, 1896, S. Jur. 1897, 1, 17.

82. On several occasions, the French legislature adopted special liability rules applicable to specific types of accidents. The most famous piece of legislation in that respect is a 1985 statute on traffic accidents, which imposes extra strict liability on drivers. See S. Whittaker, *The Law of Obligations*, in BELL ET AL., *supra* note 17, at 400–02. Courts are normally much more respectful of the provisions contained in those special statutes than they are of the traditional *Code civil* provisions.

83. For another striking example in a wrongful death case, see *Cour de cassation* [Cass.] [supreme court for judicial matters], ass. plén., Nov. 17, 2000, 99-13701, Perruche, Bull civ, No. 9.

law, but its power is to a large extent unchecked, and it does not even have to give its reasoning when it creates the law.

In this context, it is not surprising that French courts, and especially the *Cour de cassation*, should not be fond of new concepts or conceptual distinctions. To define more precisely some basic notions, like causation, or to distinguish explicitly between different types of causation—like courts in other countries commonly do—would restrict the discretion and the freedom they have been enjoying for so long. If French judges were constrained by hard concepts and precise distinctions, they could not regard causation as established rather offhandedly, or on the basis of dubious reasoning, as they do now. And this is precisely why French law needs those definitions and distinctions! In the particular case of hepatitis B vaccination litigation, adopting the distinction between general causation and specific causation would make it more difficult for judges to hide behind pseudo-scientific arguments or reasoning in order to (try and) grant compensation to plaintiffs, despite the prevailing state of scientific uncertainty. They would have to either change their position concerning the proof of causation, or make their policy choices explicit by openly acknowledging that they believe that some plaintiffs must be granted compensation, even though they *cannot* demonstrate causation. Whether judges should be allowed to opt for the latter option is debatable, but French courts could likely do it by changing the burden of proof of causation in hepatitis B vaccine cases.⁸⁴ This, it is suggested, would not be a good solution, but if judges are to bend the law, let them at least do so frankly.

84. French courts have already done this in other types of litigation involving medical products, but never when there were doubts on general causation. See, e.g., Conseil d'État [CE] [Council of State] Jan. 15, 2001, 208958 and Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., May 9, 2001, 99-18161, 99-18514, Bull civ, No. 130 on the issue of hepatitis contamination through blood transfusions.