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Remedies for Damage Caused by Vaccines: A Comparative Study of Four European Legal Systems*

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Abstract: Compensation for damage caused to patients by vaccination is an increasingly prominent issue given the important public health consideration of ensuring the highest possible take-up of vaccination. This study explores the approach to vaccine damage cases in four different European countries (France, Germany, Italy and the UK), examining the variety of different mechanisms for providing redress, including specific compensation funds, social security systems, the operation of orthodox regimes of tort law and product liability, as well as in certain jurisdictions bespoke legislation for healthcare products or pharmaceuticals. The authors then go on to examine the recent case law on this topic at a Member State and European level, focussing particularly on issues relating to the notion of defect and that of causation in vaccine damage cases.

***Zusammenfassung*:** Der Ersatz von Impfschäden gewinnt angesichts des Bestrebens, zur Sicherung der Volksgesundheit eine möglichst hohe Impfdichte zu erreichen, ständig an Bedeutung. Diese Studie untersucht die Herangehensweise an Impfschäden in vier EU-Mitgliedstaaten (Deutschland, Frankreich, Großbritannien und Italien), indem sie die verschiedenen Mechanismen, den Geschädigten Ersatz zu verschaffen, analysiert, darunter spezielle Entschädigungsfonds, sozialrechtliche Instrumente, klassisches Delikts- und Produkthaftungsrecht und schließlich sektorspezifische Gesetzgebung. Zudem erörtern die Autoren die jüngste Rechtsprechung auf mitgliedstaatlicher wie auf EU-Ebene, unter besonderer Berücksichtigung des Fehlerbegriffs und der Kausalität in Impfschadensfällen.

***Résumé*:** La réparation des dommages causés par les vaccins est une question majeure, compte tenu notamment de l'objectif de santé publique visant à obtenir une couverture vaccinale aussi large que possible de la population. Cette étude s'intéresse à la manière dont sont appréhendés les dommages imputés aux vaccins dans quatre pays européens (l'Allemagne, la France, la Grande-Bretagne et l'Italie) et envisage différents mécanismes d'indemnisation, en particulier les fonds d'indemnisation, la sécurité sociale, les règles de droit commun de la responsabilité civile ainsi que les règles spéciales applicables aux produits de santé et aux médicaments dans certains pays. Les auteurs se penchent

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également sur la jurisprudence en la matière, au niveau national et européen, s'intéressant particulièrement à la notion de défaut et à la caractérisation du lien de causalité dans les affaires relatives aux dommages attribués aux vaccins.

KeyWords: Vaccination - product liability - burden of proof - defectiveness - causation

1. Introduction (*Eleonora Rajneri*)

1 Within the spectrum of potential claims for loss caused by defective products, the question of vaccine damage is of a very particular nature. The objective of vaccinations is to induce immunity to disease by administering killed or attenuated pathogens, thereby leading to the creation of antibodies in the immunized person which protect against the disease. It is accepted that there are risks associated with vaccinations, such as the limited possibility of adverse reactions. The great majority of those who suffer adverse reactions are simply afflicted by mild, transient illness. In some other cases, a small number of those who are vaccinated suffer adverse reactions which can lead to severe disability.

Given the public health desire in ensuring the highest take-up of vaccination, there is a strong argument that special considerations should apply to those who have been injured following immunization. Indeed, compensation for injuries caused by vaccines is a particularly sensitive topic in Europe because it involves important public health issues going beyond the individual interests of the parties. First, it concerns the consideration of social solidarity in favour of those families that are suddenly facing a serious and unpredictable disease affecting (generally) their children. Second, there is the need to reduce as much as possible the distrust of vaccines, which is the cause of a worrying decrease in voluntary vaccinations and the consequent return of some endemic diseases.[1] There is also the additional factor that excessive litigation might result in an inhibition of the investment in research and development by pharmaceutical manufacturers.[2]

National judges solving these cases deal with the uncertain notion of causality and the ambiguous notion of defectiveness, in the lack of unequivocal scientific evidences.

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1 Under this concern, the Italian Parliament has recently passed a controversial law that increases the compulsory vaccines from 4 to 10 (gratuitously provided by the State) in addition to 4 vaccines strongly recommended (L. n. 119/2017). In May 2012, the 194 Member States of the World Health Assembly endorsed the global vaccination action plan (http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/).

2 Although the vaccine market is a global oligopoly controlled by four major manufacturers insulated from the constraints of a competitive market, as it is shown in the detailed studies on vaccines market recently conducted by the Italian Antitrust Authority (*Autorità Garante*) (http://www.agcm.it/component/joomdoc/allegati-news/IC50_testo.pdf/download.html).

2 This article explores the approach to vaccine damage cases in four different European countries, taking into account that all legal systems provide different mechanism of redress, each of them having its own purpose complementary to the others and differently interacting with one another.[3]

Firstly, there is the regulatory system that aims at the prevention of mass torts. The regulator authorizes the distribution of the vaccine if the benefits for the community outweigh the costs, even though the vaccine may have collateral effects in some cases.

Second, as a counterbalance, there is the public or private compensation fund, which undertakes a solidarity function by awarding redress to the unlucky victims of the unavoidable side effects of a vaccine. The underlying idea is that, whenever an individual has to suffer a sacrifice for the benefit of the community, then the community has the duty to compensate him. This principle is generally accepted whenever the vaccine is compulsory; it is questioned when the vaccine is not compulsory, though strongly recommended by the Government.

In between these two approaches, there is tort law (and specifically product liability law), which has both the function of compensation in favour of the victims and of deterrence towards the one responsible for the damage, i.e. the party which could possibly have avoided the damage at the lower cost than the other could. However, when the risk of damage is unavoidable by both parties and therefore none of the two can be blamed, the judge has to make a policy decision. Either he implements the social solidarity issue by charging the manufacturer with the obligation to compensate the damages caused by his product, irrespectively of fault; or he exempts the manufacturer from liability, for the reason that his product is not defective since it is beneficial for the entire community following a general cost/benefit analysis.

3 The pertinence of this enquiry is reinforced by the fact that vaccine damage has been the subject of litigation to the highest level, with a preliminary reference from France to the European Court of Justice (ECJ) in the recent case of *Sanofi Pasteur* concerning the long-running litigation in France for hepatitis B vaccination giving rise to demyelinating disease.[4] In that case, the French judge asked whether Article 4

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3 F. Cafaggi, 'A Coordinated Approach to Regulation and Civil Liability in European law', in F. Cafaggi (ed.), *The Institutional Framework of European Private Law* (Oxford: Oxford University Press 2006), XV/2.

4 The first case decided by the French Cour de cassation dates back to 2003: Cour de cassation, première chambre civile (Cass civ 1re), 23 September 2003, nos 01-13063 and 01-13064, *D (Dalloz)* 2003, p 2579, note L. Neyret = *D* 2004, p 898, note Y.M. Serinet & R. Mislawski = *D.* 2004, 1344, obs. D. Mazeaud = *JCP G (La Semaine Juridique - Edition Générale)* 2003, II, p 10179, note N. Jonquet et al = *JCP* 2004, I, 101, no 23, obs. G. Viney = *Resp civ assur (Responsabilité civil et assurances)* 2003, chron 28, note C. Radé = *RTD civ* (*Revue trimestrielle de droit civil)* 2004, 101, obs. P. Jourdain. Since that date, at least a dozen cases have come before the higher court.

of Directive 85/374/EEC on product liability should be interpreted as precluding national judges from assessing causation through presumptions. The reply of the ECJ is interesting from the perspectives of both causation and the notion of defect.[5] The ECJ held that since Directive 85/374/EEC does not contain any definition of the concept of 'causal relationship' within the meaning of Articles 1 and 4, the ECJ leaves its ascertainment to the individual Member States, following the principle of procedural autonomy. Consequently, the ECJ affirms that whenever the national judge ascertains the causal link among the vaccine and the disease following its own procedural rules, then 'the vaccine therefore does not offer the safety that one is entitled to expect, taking all circumstances into account, as provided for in Article 6 of that directive, because it causes abnormal and particularly serious damage to the patient who, in the light of the nature and function of the product, is entitled to expect a particularly high level of safety' (paragraph 41). Indeed, it is striking that the Court does not mention at all the general cost benefit analysis, which is applied in some jurisdictions, like Germany. Since this point of the judgment is just an *obiter dictum*, it might not have a direct influence to future decisions on the matter. However, it is extremely relevant because the application or the disapplication of the benefit cost analysis raises two opposite solutions of the very same case.

2. The Vaccines Case Law in the Italian Legal System (*Eleonora Rajneri*)

2.1. The Public Compensation Fund

4 In Italy, the bulk of cases on vaccines are brought before the judge under the Law N°210/92, which set up a public compensation fund to provide redress for side effects caused by compulsory vaccinations, and loss deriving from infected blood transfusions. Following the intervention of the Italian Constitutional Court, the fund awards redress also in cases where a vaccination is not compulsory, but is merely recommended by the Government.[6] The redress provided by the fund is an 'indemnity' and is lower than full compensation.[7] In order to be entitled to get the indemnity, the claimant has the burden of proving causation.

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5 ECJ 21 June 2017, C-621/15 *N. W and Others* v. *Sanofi Pasteur MSD SNC and Others.*

6 Corte Cost. 23-26 February 1998, n. 27; Corte Cost. 9-16 October 2000, n. 417 (R. Caranta, 'Danni da vaccinazione e responsabilità dello Stato', *Resp. civ. e prev. (Responsibilità Civile e Previdenza)*, fasc. 6, 1998, p 1352).

7 The indemnity awarded could be approximately between € 750 and 850 a month, according to the specific disease. In case of more than one disease a further indemnity could be awarded *una tantum.* In case of death, the more close relatives are awarded € 150.000,00 in total (although they were not financially dependent from the deceased).

2.2. The Proof of Causation Before an Italian Civil Court

5 The legal concept of causation is not defined by the legislator, despite the fact that causation is, according to the comparatist *Gino Gorla*, 'a function of our minds and not a *quid in rerum natura*'.[8] The statutory provisions on causation are very limited. The two main ones are in the criminal code (Arts 40 and 41 c.p.),[9] while the civil code simply states that the victim should be compensated for those damages which are 'immediate and direct consequences' of a wrongful act (Art. 1223 c.c.).[10]

Even though civil courts usually refer to the criminal law provisions, the Italian Supreme court has made it clear that the proof required in order to ascertain causation is not the same in a criminal or in a civil case.[11] In criminal cases, the proof has to reach a degree of certainty close to 100%, while in civil claims, it is sufficient to prove that the cause alleged by the claimant is the most probable one, compared to the other possible causes brought to the attention of the court.[12] Italian civil courts do not

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8 G. Gorla, 'Sulla cosiddetta causalità giuridica: "fatto danno e conseguenza"', *Riv. Dir. Comm. (Rivista del Diritto Commerciale)* 1951, I, p 405. Among the vast Italian literature on causation, see: F. Antolisei, *Il rapporto di causalità nel diritto penale* (Torino: Giappichelli 1960) p 105; M. Capecchi, *Il nesso di causalità* (Padova: CEDAM 2002); P. Forchielli, *Il rapporto di causalità nell'illecito civile* (Padova: CEDAM 1960); M. Infantino, *La causalità nella responsabilità extra-contrattuale* (Naples: Edizioni Scientifiche Italiane 2012); P.G. Monateri, *La responsabilità civile* (Torino: UTET 1998); G.E. Napoli, *Il nesso causale come elemento costitutivo del fatto illecito* (Naples: Edizioni Scientifiche Italiane 2012); P. Trimarchi, *Causalità e danno* (Milano: Giuffrè 1967). For the latest updated comparative analysis on causation: M. Infantino & E. Zervogianni, *Causation in European Tort Law* (Cambridge: Cambridge University Press 2017).

9 Art. 40 c.p.: 'No one may be punished for an act foreseen by the law as a crime, if the harmful event, which integrates the crime, is not the consequence of his action or omission.

Not preventing an event, which someone has the legal duty to prevent, is equivalent to causing it.'

Art. 41 c.p.: 'The concurrence of preexisting or simultaneous or supervening causes, even if independent from the action or omission of the person at fault, does not rule out the causal relationship between the act or omission and the event.

The supervening causes exclude the causality link when they were in themselves sufficient to determine the event. In this case, if the act or omission previously committed is in itself an offense, it will be punished.

The same shall apply even when the preexisting or simultaneous or supervening cause is due to somebody else's tort.'

10 *Gorla* explained that the legal provision on the immediate and direct consequences has the function not to put at the charge of the wrongdoer all the consequences of his action. '(T)he *ratio* is to avoid making unbearable the risk of action', since every action implies some risks. See G. Gorla, *Riv. Dir. Comm.* 1951, p 405.

11 Cass. civ., 16 October 2007, n. 21619, *Corriere giuridico* 2008, p 35.

12 The reason for this difference of approach is because the aims of the two procedures are not the same and therefore the attention of the respective courts is not equally focused on the same matter. In a criminal court, the attention is given in priority to the defendant (which should not be

measure the degree of probability necessary to satisfy the burden of proof in respect of causation. It is a question of comparison with the other possible causes in order to assess which one of them is the most likely. Therefore, if the other possible causes are more than one, causation may be established with a degree of probability even less than 50%.[13] On the contrary, when it is impossible to establish with a certain degree of probability, which one among the others is the cause of the damage, then none will be responsible for the damage (the all or nothing rule). This is also the case when it is impossible to prove which one among several producers put on the market the vaccine specifically assumed by the victim. In fact, in Italy the apportionment of liability according to the percentage of probability (so-called proportional liability) is not allowed, nor is the market share approach.[14]

It is usually argued that the ascertainment of causation has to be undertaken in accordance with a general scientific rule explaining the phenomenon in statistical terms. However, the judge is allowed to decide the specific case according to a logical inference that deviates from the scientific rule, or that takes the place of a scientific rule.[15] In fact, there might be circumstances in the specific case other than the scientific rule, which are able to justify (legally) the decision of the court, taking also into consideration the aim of the applicable law to that case, i.e. the policy choices underlying the legal system.[16] In other words, legal concepts (such as causation) are

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punished unless it is certainly proven that he is the wrongdoer), while in a civil court the attention is focused on the need of the victim claiming for a compensation.

13 E.g. in a case where it wasn't possible to determine for sure which one of four possible events was the one which put the house on fire, the Corte di Cassazione held liable the producer of the defective gas bottle because this cause of damage 'is in the first place according to a descending order of four chances' (Cass. civ., 26 July 2012, n. 13214). The causality is sometimes presumed by the fact that there is no other possible cause of the damage (see e.g.: Cass. civ., 29 October 1980, n. 5795, *Resp. civ. e prev.* 1981, p 302).

14 This doctrine on apportionment has been affirmed just in one case on medical malpractice decided by the Corte di Cassazione: being impossible to ascertain if the death of the patient was caused by the proven negligent action of the doctor or by the pre-existing fragile condition of the patient, the Court condemned the doctor to compensate just a percentage of the damage according to the percentage of probability that his action was actually the cause of the death (Cass. civ., 16 January 2009, n. 975, *Giust. Civ. (Giustizia civile)* 2010, I, p 2927). This decision has been radically and explicitly rejected in subsequent decisions for the reason that the proof of causation, already uncertain, would have become totally dependent on speculations about probabilities and eventualities (Cass. Civ., 21 July 2011, n. 15991, *Diritto di famiglia e delle persone* 2012, p 576). Analogously, in the UK the doctrine on proportionate liability affirmed by the House of Lord in *Barker* v *Corus* [2006] UKHL 20 was immediately after rejected by the Compensation Act 2006.

15 See e.g.: Cass. Pen S.U., 10 July 2002, n. 30328. See M. Bona, 'Causalità materiale, causalità scientifica e causalità giuridica a confronto: quale ruolo ai consulenti tecnici nell'accertamento del nesso di causa?' in M. Bona et al. (eds), *Il nesso di causa nel danno alla persona*, (Milano: IPSOA 2005) p 147 ff.

16 This doctrine is exposed in P. Trimarchi, *Causalità e danno.* Following this doctrine, in order to ascertain the legal causation, the court should take into consideration what is intended to be

tools in the hands of the judge that the judge can soften or strengthen according to the aims he wants to achieve and to the policy factors underpinning the system.

2.3. Case Law on the Public Compensation Fund

6 Given that unequivocal scientific evidence on vaccine cases does not exist, the ascertainment of causation in this sphere is by its very nature controversial and has thus given rise to contradictory judgments.

In particular, there are some courts of first instance in Italy, which consider that circumstantial evidence is enough to infer causation.[17] On the contrary, the few cases brought in front of the Courts of Appeals and the Supreme Court have ruled against the claimant for the reason that circumstantial evidence represented merely a possibility, rather than a serious probability of a causal link between the vaccination and the disease.[18]

Among the decisions given in favour of the claimant, there is the case brought before the Tribunal of Milan by the parents of a child who received (when he was a few months born) the injection of three doses of the compulsory vaccine Infanrix Hexa SK. Four years after the injections, following the appearance of different symptoms, the child was diagnosed with autism. Because their application for the indemnity provided by the public compensation fund was rejected, they filed a lawsuit against the Ministry of Health before the Tribunal of Milan.[19] As the resolution of the issue of causation requires specific knowledge of medical science, an expert was appointed by the court, as provided by Italian law in such circumstances.[20] The parties however did not appoint their own experts, even though this opportunity is provided for under Italian civil procedure. This case is of particular interest because the proof of the causation was inferred by the expert, among other circumstances, also from the internal data of the clinical trials carried out by the producer, i.e. the data that must be mandatorily published since January 2015, under Regulation (EU) No. 536/2014

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protected and to what extent by the legal provision that has been infringed by the wrongdoer. If the damage alleged by the claimant is not included into the protection sphere insured by the infringed legal provision, than there is no causation between the wrongful act and the damage.

17 E.g.: Trib. Rimini, 15 March 2012; Trib. Milano, 14 December 2012; Trib. Pesaro, 11 November 2013; Trib. Milano, 24 September 2014.

18 E.g.: Cass. civ., 16 June 2016, n. 12427; Cass. civ., 18 March 2014, n. 6266; App. Bologna, 13 February 2015 n. 1767.

19 Since the case concerns the legal right of an individual, the civil court is competent, while the administrative court is competent just in case of individual legitimate interests jeopardized by the public administration (with the exception of specific competences related to legal rights).

20 The relevance of the expert opinion in the judgment was emphasized in a comment on an analogous case concerning vaccine and autism, where the judge, on the contrary, did not consider proven the causal link among the two (S. D'Errico, 'Autismo e vaccinazioni: la buona scienza nelle giuste mani. un primo passo verso la "certificazione" dell'expert witness?', *Resp. civ. e prev.*, fasc. 5, 2015, p 1747).

on clinical trials on medicinal products for human use.[21] In fact, the court-appointed expert considered that it was more probable that the autism had been caused by the vaccine than by any other plausible cause, due to three specific circumstances. First, according to the internal document of the vaccine producer, batches of this vaccine seemed to have contained mercury, which has a toxic effect particularly on young children. Secondly, the internal document revealed that two cases of autism had been reported out of more than 6 million persons exposed to the vaccine within a period of 24 months. Lastly, the Tribunal noted that there was a temporal correlation between the vaccination undertaken on the child in 2006 and the diagnosis of autism in 2010, following the appearance of different symptoms. The expert rejected the genetic cause of the autism alleged by the defendant because of the lack of 'a specific constant alteration of chromosomal material transmissible to the others'. Therefore, the expert affirmed that it was more likely than not that the autism had been caused by the vaccine than by other causes alleged by the defendant, and despite the fact that the likelihood of the causal relationship with the vaccine had not been proven to a high degree of certainty.

In Italy, the courts usually follow their expert's opinion, and this case was no exception. So the Tribunal decided the case in favour of the claimant pointing out that the two cases of autism reported in the trial prove that there is a serious probability (rather than a mere possibility) that the vaccination was the cause of the autism.

2.4. Case Law on Tort Law for Dangerous Activities

7 Having been awarded redress by the public compensation fund, since the amount of the indemnity covers just a part of the damage, the victim may claim for the residual compensation from the producer. One claim does not preclude the other. Nevertheless just one case against a vaccine's manufacturer has been reported.[22] The claim was brought under Article 2050 c.c. which states that the person who carries on a dangerous activity is responsible for the damages caused by this activity, unless he is able to prove that he used all the suitable measures to avoid the damage.[23] Although the notion of dangerous activity has been interpreted

21 See Arts 80, 81 of EU Reg. 536/2014, OJ 2014 L 158/1. The Regulation's purpose is the growth acceleration of pharmaceutical research via clinical trials in the European Union. This process will be assisted through a new Clinical Trial Data Portal Gateway, with the cooperation of the European Medicines Agency and the European Commission. The new policy, entered into force on 1 January 2015, applies to clinical reports contained in all applications for centralized marketing authorizations submitted after that date. The sponsor of the authorized clinical trial must report to the database all information on 'serious and unexpected adverse reactions'.

22 Cass. civ., 13 February 2015, n. 2875.

23 This legal provision appeared for the first time in the 1942 Italian Codice civile and it deals with the problems generated by the new industrial society. The legal provision regulates those activities

narrowly, the legal provision has been applied in regard of pharmaceutical manufacturers;[24] and it is still applied, disregarding the implementation of the European directive on product liability.[25] In general, Italian tort law provisions are preferred to product liability discipline for several reasons.[26] Among others, they have a longer time limit (five years instead of three), they do not have a foreclosure period, there is no limitation on the recoverable damages and more importantly, they do not require the claimant to prove the defectiveness of the product (see below). He has the burden to prove just the causal link and, in this case, the causal link was already ascertained in the decision against the public fund. However, the producer may still escape from liability by proving that he did his best to avoid the damage. This is exactly what happened in the reported case. The judge considered that the vaccine producer could not have done more to avoid the damage since the vaccine had been authorized by the Regulator, knowing that there was a certain percentage of risk of side effects that has been considered unavoidable.

The next point examines what could possibly have happened if the same case was brought before the court under the product liability law.

2.5. Product Liability in Vaccine Cases

8 Unlike in other countries, no product liability claims against vaccine manufacturers have been reported thus far in Italy. Among the other reasons, under product liability law the victim has the burden to prove the defectiveness of the product, and the ambiguous definition of defectiveness given by the European Directive makes the result of such lawsuits highly uncertain.[27]

The assessment of defectiveness is indeed the key issue for the attribution of the responsibility among the parties. In theory the judge, in order to implement the deterrence function, should place liability upon the party who was in the best position to avoid it at the lowest cost, considering their respective position and their respective information at the moment when the damage occurred.[28] The problem arises when, like in vaccines cases, the damage is unavoidable by both

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which, although they imply a great risk of injury, cannot be prohibited since they are beneficial to community.

24 E.g.: Cass. civ., 20 July 1993, n. 8069, *Giust. Civ.* 1994, I, p 1037.

25 Tribunale di Roma, 20 April 2002, *Resp. civ. e prev.* 2002, p 1112.

26 E. Rajneri, 'Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy', in D. Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge: Cambridge University Press 2005) p 67.

27 E. Rajneri, 'La notion de défectuosité du produit dans les jurisprudences des pays Européens', *RIDC (Revue Internationale de Droit Comparé)* 2015, p 186 ff.

28 There are several cases where the judge have affirmed that the damage could have been easier avoided by a more careful user rather than by the manufacturer. As example see: Cass. civ., 15 March. 2007, n. 6007/2007 in Italy; OLG Düsseldorf, 20 December 2002, 14 U 99/02, *VersR (Versicherungsrecht)* 2003, p 912, in Germany, and recently *Wilkes* v *De Puy* [2016] EWHC 3096.

parties (except the choice not to use the product), though statistically foreseeable in percentage.[29] When the unavoidable damage is caused by a manufacturing defect, a strict liability rule is generally applied against the manufacturer, even though he has taken all possible precautions.[30] It is assumed that the manufacturer, having statistically calculated the risk of damage caused by the manufacturing defects, has consciously accepted this risk because the expected profit of his activity outweighs its costs, including the costs of damages to third parties.[31] After all, he can easily manage this measurable cost, either with an insurance or with a proportional increase of the product price. Furthermore, the strict liability rule may incentivize the manufacturer to finance research in order to find a way to eliminate the side effects of his product, rather than waiting for someone else's research on solving the problem.[32] In other terms, the strict liability rule for manufacturing defects represents an application of the 'enterprise liability' doctrine that was in circulation in Europe in the 1960s, though never made explicit by lawmakers.[33]

9 The question is what happens when the damage has been allegedly caused by a design defect, rather than by a manufacturing defect. Manufacturing defects are

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29 If the risk of the specific unavoidable damage was unforeseeable, then the manufacturer will be exempt from all responsibility applying the development risk defence, that has been put into force almost everywhere in Europe.

30 The strict liability rule for manufacturing defects has been made explicit by the Italian and the Spanish legislator (Art. 117 para. 3 of the Italian consumer code states: 'a product is defective if it does not offer the same safety offered by the other products of same series'), while in other Member States it has been implemented by judges (see e.g. BGH, 9 May 1995, *NJW (Neue Juristische Wochenschrift)* 1995, p 2162).

31 The strict liability rule on manufacturing defect cases was at first advocated by W.L. Prosser, 'The Assault upon the Citadel (Strict Liability to the Consumer)', 69 *Yale Law Journal* 7 (1960), p 1099. In Italy: U. Carnevali, *La responsabilità del produttore* (Milano: Giuffrè 1974).

32 The reasoning is exposed in W.M. Landes & R. Posner, 'A Positive Economic Analysis of Product Liability', *J. Legal Stud (Journal of Legal Studies)* XIV (1985), p 555.

33 In Italy, the doctrine has been exposed in a perspective of social solidarity in S. Rodotà, *Il problema della responsabilità civile* (Milano: Giuffrè 1964); in an economic perspective in P. Trimarchi, *Rischio e responsabilità oggettiva* (Milano: Giuffrè 1961). The doctrine emerged first in France, at the end of the 19th century, following the industrial revolution, as a way to award compensation for workers injuries (P. Josserand, *La responsabilité du fait des choses inanimées* (Paris: Rousseau 1897). In the US as well the first studies on the enterprise liability doctrine start from the workers compensation statutes at the beginning of 20th century (cfr. F.H. Bohlen, 'The Basis of Affirmative Obligation in the Law of Tort', 53. *Am. L. Reg. (American Law Register)* 209 (1905), p (273) at 337. The doctrine then evolved with the works of *Fleming James* on strict liability as an instrument of distribution of risks, followed by a very well-known article of *Prosser* which is considered the complete formulation of the doctrine (W.L. Prosser, 69 *Yale Law Journal* (1960), p 1099). These first studies were further developed under the economic analysis perspective. For an historical study on the enterprise liability doctrine: G.L. Priest, 'The Invention of Enterprise Liability: a Critical History of the Intellectual Foundations of Modern Tort Law', *J. Legal Stud* XIV (1985), p 461.

easily detectable because the product which caused the damage does not perform as the others of the same series. On the contrary, when the design of an entire series of product is questioned, the detection of a product's defectiveness becomes much more complex since a completely safe product cannot exist. Following the American third Restatement on torts, in order to prove a design defect, the claimant has to demonstrate that an alternative design of the product would have avoided the damage and would have been cheaper than the overall costs of damages foreseeable at the time when the product has been put into circulation.[34] When an alternative design does not exist, then the risk/utility test becomes an assessment of the benefit of a type of product for the community. Therefore, a civil law court duplicates the function of the regulatory authority, taking into account the general interest within a trial among individual interests.[35] Briefly, because the product is beneficial to the entire community, the manufacturer is immune from liability in the individual case where the product is the cause of a side effect.[36] This output is justified by arguing that the user has consciously accepted that risk, at the condition that the producer has adequately warned the user about it (this explains why these cases are usually brought in front of the court claiming a warning defect rather than a design defect). This reasoning, based on the principle of free will of the victim, might be acceptable as regards hedonistic products, such as cigarettes or alcoholic drinks. In contrast, when it is the case of a vaccine or a drug that is necessary to treat or to prevent a disease, it is more difficult to argue that the user has the free choice not to use the product if he prefers to avoid its inherent risk of damage. Furthermore, this argument does not work for compulsory vaccines.

My point is that the cases on design defects present the very same factors that justify the application of a strict liability rule in manufacturing defect

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34 The risk/utility test reintroduces the concept of fault in the design defects cases, since it gives relevance to the foreseeability and the avoidability of the damage in order to attribute the responsibility to the manufacturer. The risk utility test is mentioned in the 3rd Restatement of torts: Product Liability. A.D. Twerski, 'From Risk-utility to Consumer Expectation: Enhancing the Role of Judicial Screening in Product Liability Litigation', 11 *Hofstra Law Review* (1983), p 861. For a critical analysis of the test: D.G. Owen, 'Risk-Utility Balancing in Design Defect Cases', 30 *U. Mich. J.L. Reform (University of Michigan Journal of Law Reform)* (1996–1997), p 239 ff.; J. Stapleton, 'Restatement (Third) of Torts: Product Liability, an Anglo-Australian Perspective', 39 *Washburn Law Journal* (2000), p 379 ff.

35 W.K. Viscusi, *Reforming Products Liability* (Cambridge, Mass.: Harvard University Press 1991), p 2.

36 Paradoxically, the vaccine would be considered defective when the magnitude of the side effect happens to overcome the benefit, contrary to what expected, making the manufacturer liable for the unforeseeable costs (see e.g. the *Trilergan* case). Unless the judge exempts the producer from liability because the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the magnitude of the known risk (in this sense: C. Cass., 28 July 2015, n. 15851). Following this reasoning straightforward, what makes the product defective is the magnitude of the risk for the entire community and not just the simple existence of the risk in the specific case.

cases.[37] These factors are, on the one hand, that the risk of damage caused by a known side effect has been foreseen by the manufacturer who has consciously accepted it, since it does not exceed the expected benefits of his activity (otherwise the vaccine would not have been authorized). On the other hand, although the user is aware of the risk of damage, he does not have any way to avoid it except the decision not to use the product. It also has to be pointed out that the European directive does not make any reference to the risk/utility test or to a benefit/cost analysis as a way to detect the defectiveness of the product.

10 Nevertheless, the benefit/cost analysis has penetrated also into Europe and is applied so far to cases of side effects caused by the authorized vaccine, making the producer immune from the strict liability regime. This solution obviously underlies a political choice justified by the fear to inhibit the vaccine production and innovation. However, this fear does not take into account the fact that the peculiarities of the vaccines market already guarantee a high level of protection to manufacturers. A recent detailed study, conducted by the Italian antitrust authority, shows that the vaccines market is a global oligopoly controlled to 80% by four major manufacturers.[38] This market represents the most profitable activity within the pharmaceutical production.[39] Moreover, the high complexity of new generation vaccines, combined with a long-lasting patent system,[40] gives to the manufacturer the opportunity to fix the price of his vaccines without the constraint of a competitive market.[41]

From this perspective, the aforementioned recent decision of the ECJ is extremely relevant since it explicitly affirms that the vaccine is defective when it causes abnormal and particularly serious damage to the patient, and therefore the producer is liable not taking into any consideration the global benefit/cost analysis. Though expressed in an obiter dictum of the decision, this statement will not be

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37 E. Rajneri, 'The threat of collective redress in product liability cases', in E. Lein, D. Fairgrieve & M. Otero Crespo (eds), *Collective Redress in Europe - Why and How?* (London: BIICL 2015), p 317 ff.

38 http://www.agcm.it/component/joomdoc/allegati-news/IC50_testo.pdf/download.html. The four manufacturers are: GlaxoSmithKline, Merck Sharp & Dohme, Sanofi Pasteur and Pfizer.

39 'In 2014, the global vaccines market increased 6% to around $25 billion. The market is expected to continue growing and represent around $38 billion by 2020', see GSK Annual Report 2014, February 2015, 8, https://www.gsk.com/media/603031/annual-report-2014.pdf. Considerably higher estimates are reported, up to € 60 billion by 2019 (see Reuters, *Global Vaccine Market 2014–2019: Technology Analysis – Live Attenuated, Toxoid, Conjugate, Subunit, Synthetic, Dendritic Cell & Inactivated* (18 February 2015), (http://www.reuters.com/article/idUSnGNX7V5hbv+1d0+GNW20150218).

40 G. Pitruzzella & G. Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector* (Alphen aan den Rijn: Kluwer 2016); M. Friede, *Patent Landscaping for Vaccines: Patent Information, Tools and Methodologies*, WHO/WIPO/WTO Symposium, Geneva, February 2011 (http://www.who.int/phi/Martin_Friede.pdf).

41 G. Pitruzzella & L. Arnaudo, 'Vaccini, mercati farmaceutici e concorrenza, in una prospettiva (anche) di diritti umani vaccines – Pharmaceutical Markets and Antitrust: A Human Rights Perspective', *Rivista Italiana di Medicina Legale* 2017, p 1.

without consequences. However, at this stage, considering the ongoing uncertainties of the legal scenario, it is still difficult to predict what would be the rule applied by the Italian judge to a vaccine case under product liability law.

3. Vaccines in Germany – Social Security Law Solutions Substitute Product Liability (*Peter Rott*)

3.1. Introduction

11 The issue of damages stemming from vaccines has not been dealt with in great detail in German product liability case law. Two main problems arise for a claimant who suffers damage that he or she believes to have been caused by vaccinations: the proof of the defectiveness of the vaccine, and the causation between the vaccine and the damage. In the area of pharmaceuticals, which includes vaccines, the German legislator has created a special liability regime which is slightly more consumer friendly than the system envisaged by the Product Liability Directive. Its features shall be examined first (3.2.). That special regime is complemented by regular tort law, which may be more beneficial to the claimant in particular cases (3.3.), and by a social security law regime that applies to vaccinations that have been recommended by public authorities (3.4.). Finally, the picture of German legal reality would be incomplete if one did not take into account the potential liability of the doctor who performs the vaccination (3.5.).

3.2. Product Liability Law Under the Pharmaceuticals Act

12 The Pharmaceuticals Act (*Arzneimittelgesetz*; AMG)[42] is the encompassing legal regime for pharmaceuticals, and vaccines are, of course, pharmaceuticals within the meaning of the AMG.[43] In §§ 84 ff. AMG, it contains special strict liability rules that prevail over the general strict liability regime of the Product Liability Act (*Produkthaftungsgesetz*; ProdHaftG) of 1990, which implements the Product Liability Directive 85/374/EEC.[44] Historically, that special regime was introduced mainly as a reaction to the difficulties that victims of the Contergan

42 An English translation of the Act is available at http://www.gesetze-im-internet.de/englisch_amg/index.html.

43 See § 4 para. 4 AMG.

44 See explicitly, § 15 ProdHaftG and the explanations of the German government, *Bundestags-Drucksache* (Printed Matters of the German Bundestag; BT-Drs.) 11/5520, p 17. Some authors argue that the inapplicability of the Product Liability Act is in breach of Art. 13 of the Product Liability Directive. For an account of the debate, see G. Wagner, in *Münchener Kommentar zum Bürgerlichen Gesetzbuch* (München: C.H. Beck, 7th edn 2017), § 15 ProdHaftG, margin n. 8. The ProdHaftG definitely applies to pharmaceuticals *outside* the scope of application of the AMG. E.g. the AMG does not apply to pharmaceuticals that the consumer has bought abroad and imported to Germany by himself, see § 73 para. 3 AMG.

(Thalidomide) scandal experienced when they tried to obtain compensation for the damage caused by that drug.[45] The previous regime of regular contract and tort law proved to be insufficient to that effect, in particular due to the requirement of negligence. The Act applies to medical products that are intended for human use and that are subject to market authorization or that would, in principle, be subject to market authorization but have been exempted by special ordinance.

Liability under §§ 84 ff. AMG complements claims stemming from contract or tort law.[46] Its main special features are (1) a special definition of the grounds for liability, (2) a right of disclosure and (3) special rules on causation. Moreover, contrary to general product liability law, the development risk defence does not apply.

3.2.1. Grounds of Liability

13 Under § 84 paragraph 1 AMG, the producer is liable if (1) when used in accordance with its intended purpose, the medicinal product has harmful effects which exceed the limits considered tolerable in the light of current medical knowledge, or (2) the damage has occurred as a result of labelling, expert information or instructions for use which do not comply with current medical knowledge. With this definition, the provision expressly takes into account that many pharmaceuticals have side effects. Thus, the producer is held liable for design defects, manufacturing defects and warning defects.

Damage according to § 84 paragraph 1 AMG means the death or significant personal injury or damage to health of the vaccinated person. Personal injury and damage to health are insignificant if there is no need of treatment and if it does not impact seriously on physical well-being.[47] Since the reform of the law of damages of 2001, the victim can also claim damages for pain and suffering, which had previously been excluded under the strict liability regime of the AMG.

14 The risk/benefit balance follows the same rules as under the provision of § 25 paragraph 2 no. 5 AMG relating to grounds for the denial of admission of a pharmaceutical product.[48] Thus, once a pharmaceutical has been admitted, due to its benefits that outweigh the risk, it cannot normally have a design defect. The risk/benefit balance is defined in § 4 no. 28 AMG in line with Article 1 no. 28a of Directive 2001/83/EC as an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28, first indent. Those

45 See G. Wagner, in *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, § 15 ProdHaftG, margin n. 1 with further references.

46 See § 91 AMG.

47 A. Kloesel & W. Cyran, *Arzneimittelrecht* (München: C.H. Beck, 130th del. 2016), § 84 AMG, margin n. 20.

48 See *also* OLG Hamm, 18 June 2003, *NJW-RR (Neue Juristische Wochenschrift – Rechtsprechungsreport)* 2003, p 1382.

risks are defined in § 4 no. 27 AMG in line with Article 1 no. 28 of Directive 2001/83/EC as any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health. Thus, the balance requires three steps: the assessment of the positive therapeutic effects, the assessment of the risks, and the balancing between them.[49]

Of primary importance for the benefit assessment is the therapeutic usefulness of the pharmaceutical product:[50] The more serious the indication is, and the less available alternative treatment is, the more severe side effects must the consumer tolerate.[51] The risks to be considered include the side effects but also the risk of insufficient quality and effectiveness of the pharmaceutical product. On balance, even serious side effects usually do not trigger the liability of the pharmaceutical company.

In an administrative procedure concerning the admission of a pharmaceutical product, the burden of proof for an unfavourable risk/benefit balance is on the authority. It suffices, however, if the authority can show scientific findings from which one can derive serious concerns that the pharmaceutical may be intolerably risky.[52]

In that respect, academic authors have discussed controversially whether tolerability is to be assessed under consideration of the state of the science at the time when the pharmaceutical was put into circulation,[53] or at the time when the claim is brought.[54] The latter opinion seems preferable with the view to the fact that § 84 AMG establishes a strict liability regime. As to warning defects in the terms of § 84 paragraph 1 sentence 2 no. 2 AMG, the relevant question is whether the labelling and the instructions of use reflect the state of science and art.

15 The damage must arise despite the correct use of the pharmaceutical product, which is determined by the package insert that must be comprehensible not only for experts but also for laymen. The victim must provide full evidence for the fulfilment of the requirements of § 84 paragraph 1 AMG. Thus, he or she does not only have to prove harmful effects but also that those harmful effects and their frequency are intolerable when compared to the benefits of the pharmaceutical.

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49 See D. Hart, 'Die Nutzen/Risikoabwägung im Arzneimittelrecht', *Bundesgesundheitsblatt* 2005, p 204.

50 M. Hielscher, 'Zulassung von Phytopharmaka – Wirksamkeitsnachweis – Risiko-Nutzen-Abschätzung', *PharmR (Pharma Recht)* 1984, p 4.

51 W.A. Rehmann, *Arzneimittelgesetz* (München: C.H. Beck, 4th edn 2014), § 4, margin n. 30, with reference to OVG Berlin, 26 July 1983, 7 S 312.83.

52 See OVG Northrhine-Westphalia, 17 September 2009, 31 A 1428/08, *PharmR* 2010, p 85.

53 A. Sander, *Arzneimittelgesetz* (Stuttgart: Kohlhammer, 1st edn 2015), § 84, margin n. 14; P. von Czettritz and T. Strelow, 'Die Haftung für Impfschäden und die Verwirrung um die Schweinegrippe', *PharmR* 2010, p 163.

54 E. Deutsch, *Medizinrecht* (Berlin et al.: Springer, 7th edn 2014), margin n. 423.

3.2.2. Right of Disclosure

16 For the claimant who has no insights in the development and the manufacturing of the pharmaceutical product, it is very difficult to prove the existence of a design defect or a manufacturing defect in the terms of § 84 paragraph 1 AMG.[55] Therefore, in order to improve the claimant's procedural position[56] and to re-establish equal terms between the parties,[57] a special right of disclosure was introduced in 2002. According to § 84a AMG, the victim can request information related to effects, side effects and interaction of medical products that are known to the producer and to suspected effects, side effects and interaction of medical products that were brought to the producer's attention and all further knowledge which could be of significance in assessing the justifiability of harmful effects, provided that facts exist that justify the assumption that a medical product has caused the damage in question. Courts have placed the full burden of proof on the claimant relating to those facts,[58] whereas the causation between the medical product and the damage must only be plausible.[59] § 84a paragraph 2 AMG grants the same disclosure right as regards authorities that are responsible for the approval or supervision of the medical product. Exceptions apply on the grounds of secrecy laws and overriding secrecy interests of the producer and third parties.

The disclosure right is in compliance with Article 13 of the Product Liability Directive 85/374/EEC. Most authors had argued that § 84a AMG did not change the substantive liability rules in pharmaceutical liability cases but merely facilitates the procedural enforcement of the claim.[60] On reference by the Bundesgerichtshof,[61] the Court of Justice confirmed that view.[62]

3.2.3. Causation

17 Under the original version of § 84 paragraph 1 AMG, the victim had to provide full evidence of the causal link between the defectiveness of the pharmaceutical and the damage.[63] This heavy burden was alleviated with an amendment of 2001. Under the then

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55 For an example, see LG Traunstein, 29 September 1994, 1 O 1742/93, *MedR (Medizinrecht)* 1995, p 242.

56 BGH, 12 May 2015, VI ZR 328/11, *NJW (Neue Juristische Wochenschrift)* 2015, p 2502. On the procedural relationship between the disclosure claim and the claim for damages, see BGH, 29 March 2011, VI ZR 117/10, *NJW* 2011, p 1815.

57 A. Spickhoff, *Medizinrecht* (München: C.H. Beck, 2nd edn 2014), § 84a AMG, margin n. 1.

58 See LG Berlin, 18 October 2006, 22 O 75/06, *NJW* 2007, p 3584 - Vioxx.

59 For detailed analysis, see BGH, 12 May 2015, VI ZR 328/11, *NJW* 2015, p 2502 – Levemir. See also OLG Cologne, 26 January 2011, 5 U 81/10, *NJW-RR* 2011, p 1319.

60 See the references in BGH, 6 May 2013, VI ZR 328/11, *PharmR* 2013, p 459.

61 BGH, 6 May 2013, VI ZR 328/11, *PharmR* 2013, p 459.

62 ECJ, 20 November 2014, Case C-310/13 *Novo Nordisk Pharma GmbH* v. *S.*

63 E. Reinelt, 'Zur Haftung des Arzneimittelherstellers für die Übertragung von Viren durch Blutprodukte', *ZRP (Zeitschrift für Rechtspolitik)* 1994, p 333 ff.

new § 84 paragraph 2 AMG, the damage will be presumed to have been caused by the medicinal product administered if that medicinal product is capable of causing the damage, in the circumstances pertaining to the individual case. The capability in the individual case will be determined according to the composition and the dosage of the administered medicinal product, the manner and duration of its administration when used as intended, the temporal relationship to the occurrence of the damage, the damage symptoms and the person's state of health at the time of the administration as well as all other circumstances which, in the individual case, speak for or against the causation of damage.

In contrast, the presumption of causation does not apply if, in the light of the circumstances pertaining to the individual case, another fact is capable of causing the damage. However, the administration of additional medicinal products which, in the circumstances pertaining to the individual case, are capable of causing the damage shall not be considered as another fact unless, owing to the administration of these medicinal products, claims for reasons other than the lack of causality for the damage, do not exist under this provision.

Thus, the victim must (only) prove the damage, the application of the concrete pharmaceutical and the possibility of the pharmaceutical causing the damage,[64] or, in the case of warning defects, that the damage was caused by the vaccination and the consequence of missing or incorrect instruction.[65] In this regard, no full proof is necessary but the victim must only prove that the medicinal product is capable of causing the damage. It is then for the producer to show that the damaging effects of the medical product do not have their cause in the areas of design and manufacturing.

3.2.4. Various Other Rules

18 Under § 88 AMG, liability caps apply. Liability is limited to € 600,000 for the death of or injury to a person, or an annuity of € 36,000 per year. The total liability for the deaths or injuries of several persons arising from the same medical product is limited to € 120 million or annuities of € 7.2 million per year. If the sum of the individual damages exceeds that total liability, individual compensation is reduced pro rata.

Several producers that have caused the same damage are jointly and severally liable, and as in general product liability law, a slight modification to the general rules on recourse of § 426 BGB applies in that apportionment with a view to the particular circumstances of the individual case (rather than per capita) is the rule, § 93 AMG.

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64 W.A. Rehmann, *Arzneimittelgesetz*, § 84, margin n. 9.

65 G. Wagner, 'Das Zweite Schadensänderungsgesetz', *NJW* 2002, p 2049.

Under § 94 AMG, the producer has to provide financial coverage for potential damage; which can be arranged by way of insurance or a bank guarantee. That type of compulsory insurance is missing in general product liability law.

§ 94a AMG has introduced special jurisdiction of the court where the victim has his or her domicile at the time of the filing of the action (rather than the place where the damage occurred).

3.2.5. Case Law

19 The defectiveness of vaccinations in terms of § 84 paragraph 1 AMG appears to have only been discussed in very few cases. In 2007, a claimant failed to show, to the satisfaction of the court, that a vaccination against tick-borne encephalitis (TBE) was defective because she developed a Chronic Fatigue Syndrome.[66] In the case of a child who turned blind after vaccination against hepatitis B, the court held that the risk/benefit balance clearly was in favour of the vaccine so that the vaccine was not defective. Moreover, no warning defect was present as the package insert mentioned the risk of damage to the visual nerve, and finally the court also rejected causation between the vaccination and the blindness, arguing that blindness could also have been caused by a bacterial or viral infection.[67]

Cases on Infanrix Hexa do not seem to have been brought under § 84 AMG.

3.3. General Tort Law

20 Claims can, in principle, also be brought under the general tort law provision of § 823 of the German Civil Code (Bürgerliches Gesetzbuch; BGB). The advantages compared to liability under § 84 AMG are the following: § 823 paragraph 1 BGB does not only cover design defects, manufacturing defects and warning defects but also imposes liability on a producer who does not observe his product after he has put it into circulation and who fails to take precautions, in particular by way of recalls, if the defectiveness of the product becomes apparent at a later stage.[68] Tort liability can also arise in case of a vaccine that fails to have the desired protective effect.[69]

A disadvantage as compared to the strict liability regime of § 84 paragraph 1 AMG is, in particular, that liability under § 823 paragraph 1 BGB is fault based. Moreover, the special rules on the victim's disclosure right and the slight facilitation of the proof of causation do not apply to claims under general tort law. Quite

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66 See LG München, 12 January 2007, 6 O 23277/04, *ZMGR (Zeitschrift für das gesamte Medizin- und Gesundheitsrecht)* 2009, p 105.

67 See OLG Hamm, 18 June 2003, 3 U 99/02, *NJW-RR* 2003, p 1382.

68 See BGH, 24 January 1989, VI ZR 112/88, *NJW* 1989, p 1542; OLG Frankfurt, 11 November 1993, 1 U 254/88, *NJW-RR* 1995, p 406.

69 See BGH, 17 March 1981, VI ZR 191/79, *NJW* 1981, p 1603 (concerning a plant protection product).

obviously, the claim is even more difficult to establish than the claim under § 84 AMG.

3.4. Social Security Law

3.4.1. The Act on Protection Against Infections

21 Typically, vaccines are not defective in the terms of § 84 paragraph 1 AMG.[70] In order to close that gap and to support persons who suffer damage from a vaccination despite of the lack of defectiveness in terms of the AMG, § 60 of the Act on Protection against Infections (*Infektionsschutzgesetz*; IfSG) of 2001 provides for a special compensation regime under social security law. If the requirements are met, the claimant can obtain, for example, medical treatment, sickness benefits, rehabilitation measures, an economic rent or compensation for the inability to exercise his or her profession further.[71]

The claim requires 'vaccination damage', which is defined by § 2 no. 11 IfSG as the health-related and economic consequence of damage to health that exceeds the normal reaction to a vaccination. The basic idea is that vaccination is not only meant to protect the individual but also serves the public good of avoiding the spread of diseases.[72] Thus, the individual who obtains the vaccination also acts in the public interest and shall not bear the risk of suffering damage from this.[73]

§ 60 IfSG, however, only applies if the vaccination had been 'publicly recommended', that recommendation confirming the public interest in the vaccination. This means, according to the case law of the Federal Social Court (*Bundessozialgericht*; BSG), that the competent public authority must have recommended the vaccination.[74]

The claimant must prove that the vaccination caused an unusual reaction, and that that reaction caused adverse consequences. Whereas the vaccination as such, the reaction and the adverse consequences must be fully proven, the claimant must only demonstrate reasonable likelihood of causation between them.[75] According to the BSG, the causal link is present if under consideration of the

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70 See the explicit statement in BSG (Federal Social Court), 20 July 2005, B 9a – 9 VJ 2/04 R, *BSGE (Entscheidungen des Bundessozialgerichts)* 95, 66, at para. 32.

71 S. Knickrehm, *Gesamtes Soziales Entschädigungsrecht* (Baden-Baden: Nomos 2012), § 60 IfSG, margin n. 11.

72 H.G. Ritz, 'Impfentschädigung', in O. Deinert & F. Welti (eds), *Stichwortkommentar Behindertenrecht* (Baden-Baden: Nomos, 2nd edn 2014), margin n. 1.

73 See BSG, 20 July 2005, B 9a – 9 VJ 2/04 R, *BSGE* 95, 66; P. von Czettritz & T. Strelow, *PharmR* 2010, p (163), at 166.

74 For a case where a vaccine was used in clinical trials but had not yet been admitted to the market, and therefore the claim under § 60 IfSG failed, see BSG, 20 July 2005, B 9a – 9 VJ 2/04 R, *BSGE* 95, 66.

75 § 61 IfSG.

leading medical opinion it is more likely than not that the vaccination was the cause of the permanent damage.[76] Hereby, the court will consider the state of scientific knowledge at the time of the court decision even if the vaccination had been many years ago. Where the origins of a particular disease are unclear, that causal link will not normally be established.[77]

3.4.2. Case Law

22 Cases under § 60 IfSG are much more frequent than cases under product liability law. Examples of successful litigation include claims relating to a polio vaccination, followed by encephalitis.[78] In many cases, however, the claims failed because the courts saw no sufficient evidence of the causation between the vaccination and the damage. This applies, in particular but not exclusively, to vaccinations with Infanrix Hexa.

In 2015, the LSG Hamburg dealt with a case of autism. Here, the court decided that with regard to 750,000 vaccinations in Germany and several million vaccinations worldwide with the vaccine Infanrix Hexa, the few cases of brain damage that are claimed to have been caused by Infanrix Hexa could not be connected with that vaccine with sufficient probability. The mere theoretical possibility that the vaccination might have caused brain damage was not enough to trigger a claim under § 60 IfSG.[79] Thus, the claim failed. Appeal against that decision was not allowed by the BSG.[80]

Courts have also denied sufficient likelihood of a causal link between vaccinations with Infanrix Hexa and diabetes mellutis type 1.[81] A likely causal link between an Infanrix Hexa vaccination and a seizure disorder was denied in a case where such disorders had occurred in the wider family of the child.[82] In contrast, a child who developed a seizure disorder and had shown relevant symptoms on the day of the vaccination was successful in court.[83]

Beyond Infanrix Hexa, courts have rejected the likelihood of a causal link between an influenza vaccination and the development of a Chronic Fatigue Syndrome[84] as well as between a vaccination against mumps, measles and rubella

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76 See e.g. BSG, 19 March 1986, 9a RVi 2/84, *BSGE* 60, 58.
77 See LSG Berlin-Brandenburg, 8 July 2016, L 13 VJ 16/12, *BeckRS* 2016, 73023.
78 See LSG Berlin-Brandenburg, 16 March 2016, L 13 VJ 59/14 WA, *BeckRS* 2016, 69718.
79 LSG Hamburg, 29 September 2015, L 3 VE 9 13, *BeckRS* 2016, 70836.
80 See BSG, 27 April 2016, B 9 V 73/15 B, *BeckRS* 2016, 69521.
81 See LSG Berlin-Brandenburg, 8 July 2016, L 13 VJ 16/12, *BeckRS* 2015, 112974.
82 See LSG Sachsen-Anhalt, 8 July 2015, L 13 VJ 16/12, *BeckRS* 2014, 68871.
83 See SG München, 3 December 2015, S 9 VJ 2/06, *BeckRS* 2016, 70604. See also LSG Bayern, 15 December 2015, L 15 VJ 4/12, *BeckRS* 2016, 67978 (on Hexavac).
84 LSG Nordrhein-Westfalen, 15 January 2016, L 13 VJ 27/13, *BeckRS* 2016, 68405.

(MMR) and severe brain damage.[85] Time seems to be of the essence: Where the problem does not become apparent close to the vaccination, courts tend to reject the likelihood of a causal link.[86]

3.5. Medical Liability

23 The previous analysis has demonstrated the difficulties in obtaining compensation for vaccination under product liability law as well as under social security law, and the limitations of compensation under social security law, which does not provide damages for pain and suffering. It is before that background that victims of vaccination damages have resorted to suing the doctor who administered the vaccination, or the hospital, under tort law. That route is facilitated by the fact that every vaccination, at least by way of injection, is per se a physical injury under German law, which requires justification through the consent of the victim. That consent must be given under full information on the risks of the vaccination as well as of the omission of a vaccination.[87] Thus, victims have argued that they had not been fully informed of these risks and that therefore their consent had been invalid.

The extent of the duty to inform the patient has been concretized by the permanent vaccination commission of the Robert Koch Institute (*Ständige Impfkommission beim Robert-Koch-Institut*), which is an expert commission that is entrusted to advise the German government in vaccination matters. According to the vaccination recommendations of the StIKO, the doctor must inform the patient, amongst others, on the disease to be prevented, treatment of that disease, the usefulness of the vaccination for the individual patient and for public health, the vaccine itself, the vaccination, the duration of the protection achieved, required behaviour after the vaccination, contraindications, side effects and complications regardless of their frequency and the necessity of booster injections.[88] According to the BGH, the doctor has to inform the patient in person, whereas it is normally insufficient to merely hand out an information sheet to the patient.[89] Quite obviously, the medical profession has reacted by drafting comprehensive information sheets and by making the patient sign that he or she was fully informed on all the above-mentioned issues.

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85 LSG Baden-Württemberg, 21 April 2015, L 6 VJ 1460/13, *BeckRS* 2015, 69463.

86 *Ibid.*

87 For details, see E. Deutsch, 'Aufklärung und Einwilligung vor Impfungen', *VersR* 1998, p 1053 ff.

88 J. Bütikofer, 'Schutzimpfungen: Aufklärungspflicht aus juristischer Sicht', *Ärzteblatt* 1997; 94, p A-1794-1796.

89 BGH, 15 February 2000, VI ZR 48/99, *NJW* 2000, p 1784.

3.6. Conclusions

24 Under German law, the defectiveness of pharmaceuticals under product liability law is assessed with the same risk/benefits balance test that is also used for the admission of pharmaceuticals. Thus, where a pharmaceutical has passed that test in the admission procedure, it is quite unlikely that courts will consider it defective in the terms of product liability law. The additional measures of a disclosure right and the facilitation of the proof of causation have therefore not produced significant effects in practice.

There are two ways, by which vaccination victims can still obtain compensation for the damage they suffer. The route that was designed by the legislator under the Act on Protection against Infections (IfSG), which belongs to the sphere of social security law, is to compensate victims of side effects that are generally tolerable (in the sense of the risk/benefits balance) but materialize in an unusual manner in the individual case. The alternative route, under medical liability law, is to sue the doctor who administered the vaccine, or the hospital, in the case of insufficient information concerning the disease to be prevented, treatment of that disease, the usefulness of the vaccination for the individual patient and for public health, the vaccine itself, the vaccination, the duration of the protection achieved, required behaviour after the vaccination, contraindications, side effects and complications regardless of their frequency and the necessity of booster injections. The advantage of that latter route is that the victim can obtain damages for pain and suffering, which are not part of the claim under social security law.

Still, even under social security law, causation between a (publicly recommended) vaccination and the damage must at least be more likely than not, and that test may well fail in cases where a reaction to the vaccination was not immediate and where the causes of diseases are not sufficiently researched. With regard to Inferix Hexa, German courts were not convinced that autism could be caused by that vaccine. Therefore, claims failed even under social security law.

4. The Vaccines issue in France (*Jean-Sébastien Borghetti*)

4.1. Introduction

25 Many cases concerning damage allegedly caused by vaccines have reached French superior courts over the last decade. Vaccine-linked litigation is actually quite diverse, with different types of vaccines being concerned, but the most significant part of it has to do with vaccines against hepatitis B. This contribution will therefore focus on hepatitis B vaccination litigation.

Hepatitis B is a viral pathology affecting the liver.[90] Vaccination against is has been available since 1982. It was made compulsory in France for health care

90 For detailed fact-sheet on the disease by the World Health Organization (WHO), see http://www.who.int/mediacentre/factsheets/fs204/en/index.html.

professionals in 1991.[91] Three years later, in July 1994, the French Ministry of Health launched a mass immunization campaign against hepatitis B, targeting especially teenagers. Vaccination was however not made compulsory. In the following years, cases were reported in which persons had showed symptoms of demyelinating diseases after they had received the vaccine. The idea spread that hepatitis B vaccination could cause such diseases. This led the Minister of Health in 1998 to call a suspension of the vaccination campaign, which has never resumed. In the meantime, the debate on the opportunity and possible side effects of hepatitis B vaccination has been going on, even though the World Health Organization (WHO),[92] the French Medical Academy,[93] and the French High Council for Public Health[94] keep recommending this 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 aetiology of these demyelinating diseases is still a matter of debate. It is believed that they result from some combination of genetic, environmental, and infectious factors, but no definitive explanation has been found so far.[95] Several epidemiological studies investigating the relationship between hepatitis B vaccination and the occurrence of a demyelinating disease have been carried out.[96] All of them, except one, which was later criticized for its methodology,[97] have failed to find a significant statistical association between the two. To this day, there is therefore no scientific evidence that a vaccination against hepatitis B can cause a demyelinating disease; but there is no definitive evidence to the contrary either. The existence of a connection between hepatitis B vaccination

91 Art. 1 of loi no 91-73 of 18 January 1991, now Art L 3111-4 code de la santé public (public health code).

92 See the WHO Recommendations for Routine Immunization (updated September 2016), http://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1.

93 Communiqué de l'Académie nationale de médecine, 14 October 2008, http://www.academie-medecine.fr/publication100035919/.

94 Avis relatif à la vaccination contre l'hépatite B, 2 October 2008, http://www.hcsp.fr/Explore.cgi/avisrapportsdomaine?clefr=41.

95 See the factsheet (October 2014) of the French National Institute for Health and Medical Research (INSERM), http://www.inserm.fr/thematiques/neurosciences-sciences-cognitives-neurologie-psychiatrie/dossiers-d-information/sclerose-en-plaques-sep.

96 For more details on these scientific studies, see J.-S. Borghetti, 'Litigation on Hepatitis B Vaccination and Demyelinating Diseases in France: Breaking Through Scientific Uncertainty?', in M. Martín-Casals & D.M. Papayannis (eds), *Uncertain Causation in Tort Law* (Cambridge: Cambridge University Press 2015) p (11) at 13 f.

97 WHO Global Advisory Committee on Vaccine Safety, Response to the paper by M.A. Hernán and others titled Recombinant hepatitis B vaccine and the risk of multiple sclerosis, *Neurology* September 2004, http://www.who.int/vaccine_safety/topics/hepatitisb/multiple_sclerosis/sep_04/en/index.html.

and the development of demyelinating diseases is thus still an open issue for epidemiologists and scientists.

It is in this context that French courts have been faced with compensation claims brought by plaintiffs who have allegedly developed a demyelinating disease due to their having been vaccinated against hepatitis B. Judges have been surprisingly favourable to these claims. This is illustrated by the way in which they have handled proof of causation (4.2.) and of defectiveness (4.3.).

4.2. Causation

26 A majority of claims in relation with hepatitis B vaccination have been brought on one of two legal bases.[98] The first one is a special compensation scheme for injuries caused by compulsory vaccinations.[99] This scheme is now regulated by Article L 3111-9 *code de la santé publique* (public health code).[100] Compensation is due as soon as the plaintiff proves that his damage is directly imputable to a compulsory vaccination. No other condition, such as negligence or the vaccine's defectiveness, is required. Article L 3111-9 obviously applies to compulsory hepatitis B vaccination for health care professionals; but it 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 a special compensation fund, ONIAM (*Office national d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales*). The fund decides whether the conditions set by the law are met, and, if so, offers a certain amount of damages. If a plaintiff is not satisfied with the ONIAM's appraisal of the situation or its compensation proposal, he can appeal to an administrative court.[101]

27 The second legal basis for claims in relation with hepatitis B vaccination is of course the product liability regime derived from the Product Liability

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98 On the other possible legal bases for such compensation claims in French law, see J.-S. Borghetti, in *Uncertain Causation in Tort Law*, p 16.

99 Loi no 64-643 of 1 July 1964.

100 This text provides: 'Sans préjudice des actions qui pourraient être exercées conformément au droit commun, la réparation intégrale des préjudices directement imputables à une vaccination obligatoire pratiquée dans les conditions mentionnées au présent chapitre, est assurée par l'Office national d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales institué à l'article L. 1142-22, au titre de la solidarité nationale.'

101 In France, there exists a sharp divide between private and public law. Substantive law normally varies according to whether the defendant is a private or a public person. Besides, civil courts, which have jurisdiction in private law matters, are distinct from administrative courts, which deal with questions pertaining to public law. ONIAM is a public person and any claim against it must therefore be brought before an administrative court.

Directive 85/374/EEC.[102] As is well known, the Directive makes the producer liable for damage caused by a defect in his product (Article 1), if the plaintiff proves damage, the defect, and the causal relationship between defect and damage (Article 4). 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; (c) the time when the product was put into circulation (Article 6). Claims based on product liability legislation and directed against hepatitis B vaccine producers,[103] which are commercial companies, are brought before civil courts (as opposed to administrative courts).

28 Whatever the basis of his claim, the plaintiff must demonstrate that the vaccine he took caused his disease.[104] But how is that possible, when there is no scientific or epidemiological evidence that hepatitis B vaccination can actually cause a demyelinating disease? French courts, both administrative and civil, have helped plaintiffs to overcome this obstacle by accepting, or even requiring, the use of presumptions.

As far as claims based on L 3111-9 *code de la santé publique* are concerned, the *Conseil d'État*, the supreme French administrative court, set a rule in four 2007 decisions, whereby causation between the vaccination and the demyelinating disease must be regarded as established, if the first symptoms of the disease appear within a short ('*bref*') delay after the vaccination,[105] and no other cause for the disease can be identified.[106] The

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102 Transposition of Directive 85/374/EEC was 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 now to be found at Arts 1245–1245-17 (formerly Arts 1386-1–1386-18) of the French Code civil. On the rather hectic transposition process of the directive in France, see S. Whittaker, *Liability for Products: English Law, French Law, and European Harmonization* (Oxford: Oxford University Press 2005) p 450.

103 Two different pharmaceutical companies have marketed Hepatitis B vaccines in France. No differences between these two vaccines have been alleged, as far as a possible side effects are concerned.

104 Art L 3111-9 code de la santé publique requires that damage be 'imputable' to a compulsory vaccination, but this is just another way of requiring a causal relationship between the two. As to the Directive, it only mentions the causal relationship between the product's defect and damage (Art. 4), but it is quite obvious that this relationship cannot exist if damage was not a consequence of the product's use. The existence of a causal relationship between the vaccination and the disease therefore appears as a fundamental requirement under both regimes.

105 Subsequent cases have shown that, for the Conseil d'État, the delay must be regarded as short if it is not longer than three months.

106 Conseil d'État (CE), 9 March 2007, nos 267635, 278665, 283067 and 285288, *AJDA (Actualité Juridique Droit Administratif)* 2007, p 861, concl. T. Olson, *D* 2007, p 2204, note L. Neyret, and p 2900, obs. P. Brun, *JCP G* 2007, II, p 10142, note A. Laude.

Conseil d'État therefore considers that, absent identified possible other causes for the disease, a short delay between the vaccination and the appearance of the disease creates a presumption that the former caused the latter.[107] No scientific reason was given for the adoption of this rule, however, which thus appears as arbitrary.[108]

Civil courts faced with claims based on product liability rules have adopted a slightly different approach on causation, but are also willing to allow the bypassing of scientific uncertainty. France's highest civil court, the *Cour de cassation*, actually started by adopting a rather strict view on the issue. In 2003, it ruled that lower judges could not regard causation between vaccination and the plaintiff's disease as established, given the absence of scientific certainty on the possible link between hepatitis B vaccination and multiple sclerosis.[109] Five years later, however, partly under the pressure of the academia,[110] the *Cour de cassation* changed its position. It quashed two decisions by appellate courts, which had rejected compensation claims on the ground that the state of scientific uncertainty did not allow the admission of a causal link between hepatitis B vaccination and the occurrence of a demyelinating disease. The *Cour de cassation*, on that occasion, 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

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107 For other applications of this rule, see CE, 25 July 2007, no 288052; 4 July 2008, no 299832; 11 July 2008, no 289763; 18 February 2009, no 305810; 10 April 2009, no 296630; 24 July 2009, nos 308876 and 304325, *JCP G* 2009, p 223, obs M.-C. Rouault, *RDC* (*Revue des Contrats*) 2010, p 79, obs J.-S. Borghetti; 9 February 2011, no 319497; 25 February 2011, no 324051; 4 March 2011, no 313369; 28 July 2011, no 318466; 13 February 2012, no 331348; 17 February 2012, no 331277, *AJDA* 2012, p 1244, note C. Lantero; 8 November 2012, no 350886; 6 November 2013, no 345696; 13 December 2013, no 352460; 30 April 2014, no 357696; 5 November 2014, no 363036; 27 May 2015, no 369142.

108 Decisions by French supreme courts are usually very terse and stick to a formal mode of reasoning. They do not give the substantive reasons underlying the choices made by judges; but these reasons can sometimes be found in the reports of the magistrates who have prepared the decisions, even if these reports are only occasionally made public and have no authority *per se.* However, the preliminary report to the 2007 decisions which established the short-delay rule does not give any justification for it (even though it explains the state of scientific uncertainty on the issue of the relationship between vaccination against hepatitis B and the occurrence of demyelinating diseases): see T. Olson, conclusions on CE, 9 March 2007, *AJDA* 2007, p 861.

109 Cass civ 1re, 23 September 2003, nos 01-13063 and 01-13064, *D* 2003, p 2579, note L. Neyret, *D* 2004, p 898, note Y.M. Serinet & R. Mislawski, 1344, obs. D. Mazeaud, *JCP G* 2003, II, p 10179, note N. Jonquet et al, 2004, I, 101, no 23, obs. G. Viney, *Resp civ assur* 2003, chron 28, note C. Radé, *RTD civ* 2004, p 101, obs. P. Jourdain.

110 Tort scholars in France are traditionally quite plaintiff-oriented, and so are the courts. Many scholars criticized the position adopted by the Cour de cassation in 2003 as too harsh for plaintiffs (and also pointed to the discrepancy between the Cour de cassation's position and that of the *Conseil d'État* after the latter's 2007 decisions); see e.g. C. Radé, note on Cour d'appel (CA) Paris, 2 June 2006, *Resp civ assur* 2006, comm 306.

vaccination and the development of the disease',[111] whereas they should have considered whether the facts of the case did not allow for a presumption that the vaccine had caused the plaintiff's disease.[112]

29 These decisions must be well understood. They have not affirmed the existence of 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 vaccines against hepatitis B. These 2008 decisions have not followed the *Conseil d'État*'s solution, either. According to the latter, causation *must be* presumed if the disease appeared in the three months that follow the vaccination, and no other cause for the disease is identified. The *Cour de cassation* did not set such a rule, but only requires lower courts to decide, on the facts of the case, whether 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', on which the *Cour de cassation* exerts no control. This inevitably leads to diverging approaches by lower courts, as subsequent cases have shown.[113] Very similar circumstances can lead to diverging rulings on the issue of causation, depending on the lower judges' conception of the aetiology of demyelinating diseases.[114] Some courts are quite willing to regard causation as

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111 'Une approche probabiliste déduite exclusivement de l'absence de lien scientifique et statistique entre vaccination et développement de la maladie'.

112 Cass civ 1re, 22 May 2008, *Bull civ (Bulletin des arrêts de la Cour de cassation, Chambres civiles)* I, nos 148 and 149, *D* 2008, p 2894, obs. P. Jourdain, *JCP G* 2008, II, p 10131, note L. Grynbaum, I, 186, no 3, obs. P. Stoffel-Munck, *Resp civ assur* 2008, Étude 8, note C. Radé, *RTD civ* 2008, p 492, obs. P. Jourdain, *RDC* 2008, p 1186, obs. J.-S. Borghetti.

113 For cases in which lower judges considered causation as established on the facts of the case, see Cass civ 1re, 9 July 2009, no 08-11073, *Bull civ* I, no 176, *D* 2010, p 49, obs. P. Brun, *JCP G* 2009, p 308, note P. Sargos, *RTD civ* 2009, p 735, obs. P. Jourdain, *RDC* 2010, p 79, obs. J.-S. Borghetti; 26 September 2012, no 11-17738, *D* 2012, p 2853, note J.-S. Borghetti and obs. C. Radé, 2013, p 40, obs. P. Brun; 10 July 2013, no 12-21314, *D* 2013, p 2306 avis C. Mellottée, p 2312, note P. Brun, p 2315, note J.-S. Borghetti. For cases where lower judges have refused to acknowledge causation, see Cass civ 1re, 24 September 2009, no 08-16097; 25 November 2010, no 09-16556, Bull civ I, no 245, *JCP G* 2011, p 79, note J.-S. Borghetti, *Resp civ assur* 2011, comm. 24, note C. Radé, *RTD civ* 2011, p 134, obs. P. Jourdain; 25 November 2010, no 09-71013; 28 April 2011, no 10-15289; 26 January 2012, no 10-28195; 28 June 2012, no 11-14287; 29 May 2013, no 12-20.903, *D* 2013, p 1717, note J.-S. Borghetti, p 1723, note P. Brun.

114 The best example is a case in which an appellate court had regarded causation as established on the facts of the case (CA Versailles, 10 February 2011, no 09/07555); this decision was later quashed on the issue of defectiveness (Cass civ 1re, 26 September 2012, no 11-17738) and submitted to the Paris appellate court to be decided anew. The Paris court then ruled that the facts put forward by the plaintiff were not sufficient to establish causation (CA Paris, 7 March 2014, no 13/01546).

established, if (1) the demyelinating disease appeared shortly after the vaccination, and (2) no other cause than the vaccination can be found to explain the outbreak of the disease. These elements are the same as those which are used by the *Conseil d'État* to presume causation, but the difference is that lower civil courts are free to regard them as convincing or not, and to decide what is the maximum length of the delay within which the appearance of the symptoms can be regarded as conclusive of causation. Other lower civil courts, on the other hand, are much stricter in their assessment of causation and tend to regard the same elements as inconclusive, given the state of scientific uncertainty as to the links between hepatitis B vaccination and demyelinating diseases.

30 This divergence among lower courts is of course hardly satisfying. Apart from giving the impression that scientific truth varies from one local jurisdiction to the other, it creates obvious inequalities among plaintiffs, depending on the court before which they bring their case, and encourages forum shopping. Some authors are therefore of the opinion that the *Cour de cassation* should follow the *Conseil d'État*'s path and regard causation as established, if certain conditions are met. Others, including the author of this contribution, believe that there is in the first place a problem with the elements, which are used by the courts to presume causation.[115]

The first element, i.e. the absence of another cause than the vaccination to explain the outbreak of the disease, is not really convincing. It is true that, generally speaking, eliminating alternative causes can establish the causal connection between two events. 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, as has been said before, is that its aetiology is not yet fully known. 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, a factor often put forward by the *Conseil d'État*, 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 second and main element put forward by the courts 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 the 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.* Undoubtedly,

115 For a presentation of the debate and the various positions advocated by French authors, see F. Leduc, S. Carval. J.-S. Borghetti, G. Mor & J. Vogel, 'Discussion sur la causalité en matière de responsabilité du fait des produits de santé', *Resp civ assur* 2016, dossier 11-15.

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 a proof of causation, however, only if one implicitly assumes that 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 time coincidence as a proof of causation therefore amounts to holding true the theory that should have been demonstrated in the first place, but which is not supported by existing epidemiological studies.[116]

31 Yet, in its recent *Sanofi Pasteur* decision,[117] the ECJ has expressly validated both the *Cour de cassation*'s approach to proving causation and the elements that are taken into account by lower courts to establish causation. Asked whether causation could be established on the facts of the case, notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, the Court of Justice ruled that this does not run contrary to Article 4 of the Product Liability Directive 85/374/EEC, since this provision only sets the burden on proof, and not the means through which proof can be established. But the Court even went beyond answering the question that had been referred to it, and expressly endorsed, although *obiter*, the above mentioned criteria that are commonly used by French lower courts to establish causation i.e. temporal proximity between the administering of a vaccine and the occurrence of a disease, the lack of personal and familial history of that disease, together with the existence of a significant number of reported cases of the disease occurring following such vaccines being administered).

The *Cour de cassation's* position, however debatable, has thus been anointed by the ECJ. The latter, though, has also made it impossible for the French higher court to go a step further and to follow the *Conseil d'État*'s path, by establishing a legal rule whereby causation *must* be regarded as established, if certain items of factual evidence are presented. In effect, this means that the *Cour de cassation* is now stuck in the situation it has created by its 2008 decisions: in hepatitis B vaccination cases, lower courts are free to decide the existence of causation on the facts of the case, and their potentially contradicting rulings cannot be harmonized by the higher court.

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116 See G. Canselier, 'De l'explication causale en droit de la responsabilité civile délictuelle', *RTD civ* 2010, p 41, no 20.

117 ECJ, 21 June 2017, C-621/15 *N. W and Others v. Sanofi Pasteur MSD SNC and Others*. For French views on this decision, see e.g. *D.* 2017, p 1807, note J.-S. Borghetti, *JCP G* 2017, p 1533, note G. Viney.

32 How unsatisfying this situation is has just been illustrated by the final decision of the *Cour de cassation* in the very case that was the occasion of the *Sanofi Pasteur* ruling of the ECJ. The claimant in this case argued that the hepatitis B vaccine was defective and that this was the cause of his multiple sclerosis, whose first symptoms had been diagnosed a short time after he had received the vaccine. He had won in the first instance, but the Versailles appellate court had ruled that, even though causation could be established on the facts of the case, the vaccine's producer was not liable, since the vaccine, even assuming that it could cause demyelinating diseases, still had a positive risk/benefit balance, and was thus not defective.[118] This decision was quashed by the *Cour de cassation*, on the issue of defectiveness, and the case was sent back to the Paris appellate court to be decided anew.[119] But the Parisian judges, ruling on the same facts as their Versailles colleagues, took a different view on causation, and decided that these facts did not allow the conclusion that the vaccine had caused the claimant's disease in the first case.[120] The case was then brought before the *Cour de cassation* for the second time, and it was then that the higher decided to make a reference to the ECJ.[121] Based on the latter's decision, the *Cour de cassation* has recently rejected the challenge against the Paris appellate court's ruling, since it is for the lower judges to decide, on the facts of the case, if causation is to be regarded as established. In practice, the *Sanofi Pasteur* ruling of the ECJ results in French law being locked in a stalemate of contradicting lower courts' decisions as far as the assessment of causation in hepatitis B vaccination cases is concerned.

4.3. Defectiveness

33 In order to succeed, claims based on Article L 3111-9 code de la santé publique only require that causation between the vaccination and the disease be proven. Product liability claims, on the other hand, also require proof of the vaccine's defectiveness. This is another major hurdle for plaintiffs. As a matter of fact, even assuming that hepatitis B vaccination can cause demyelinating diseases, this negative side effect cannot be considered independently from the vaccination's efficiency in preventing the transmission and spreading of hepatitis B.

Some French courts helped plaintiffs go around this hurdle by deciding that hepatitis B vaccines' producers[122] had been in breach of their duty to warn and were therefore liable for damage caused by their product, since they had not informed the users that the vaccine could cause a demyelinating disease as a side

118 CA Versailles, 10 February 2011, no 09/07555.

119 Cass civ 1re, 26 September 2012, no 11-17738.

120 CA Paris, 7 March 2014, no 13/01546.

121 Cass civ 1re, 12 November 2015, no 14-18.118, *D.* 2015, p 2602, note J.-S. Borghetti, and 2016, p 2535, obs. J.-D. Bretzner, *JCP G* 2016, p 8, note G. Viney.

122 Vaccines against hepatitis B have been commercialized by two different producers in France.

effect.[123] Whatever the merits of this solution,[124] however, it will seldom apply in future cases, since the notices of vaccines against hepatitis B have now been mentioning this alleged risk for some years.

In most cases, therefore, courts have had to take a stand on the hepatitis B vaccine's *intrinsic* defectiveness. The 1985 Directive gives little indication on how this defectiveness should be assessed, as the standard set by Article 6 ('a product is defective when it does not provide the safety a person is entitled to expect') is extremely vague. There is a broad scholarly consensus in France that the legitimate expectations test should be interpreted as meaning that a product is defective if it is abnormally dangerous.[125] The (ab)normality of a product's danger will normally be assessed through a comparison with other products.[126] The problem with pharmaceuticals, however, is that they often lack comparables. It has therefore been suggested[127] that the defectiveness of pharmaceuticals should be assessed using a risk/benefit ratio.[128] Several French appellate courts have endorsed this suggestion,[129] including in hepatitis B vaccination cases.[130]

All of them have concluded that the vaccine against hepatitis B could not be regarded as defective, since, even assuming that it may in certain cases cause demyelinating diseases, its benefits to the community greatly outweigh its potential negative side effects.[131] It therefore seemed that the efforts to establish causation

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123 The Cour de cassation accepted this reasoning in one case at least: Cass civ 1re, 9 July 2009, no 08-11073.

124 This solution is actually quite debatable, for at least two reasons. First of all, it is not at all obvious why producers should warn against side effects that are not proven, and are even extremely doubtful. Besides, the courts in those cases did not check that the producer's breach of duty had had an impact on the patient's decision to be vaccinated.

125 See e.g. J.-S. Borghetti, *La responsabilité du fait des produits. Étude de droit comparé* (Paris: L.G.D.J. 2004) no 294; G. Viney & P. Jourdain, *Les conditions de la responsabilité* (Paris: L.G.D.J., 3rd edn 2006), no 774.

126 J.-S. Borghetti, *La responsabilité du fait des produits. Étude de droit comparé*, nos 331–334.

127 *See* e.g. G. Viney, observations on Cass civ 1re, 23 September 2003, nos 01-13063 and 01-13064; L. Clerc-Renaud, 'Quelle responsabilité en cas de dommages causés par des produits de santé?', *Revue Lamy droit civil* 2007, p 34, no 14; J.-S. Borghetti, 'Quelles responsabilités pour les laboratoires fabricants de médicaments dangereux?', *Revue générale de droit médical, special issue 'Les responsabilités du fait des médicaments dangereux. Perspectives nationales et transfrontalières'*, 2012, (p) 19 at 25.

128 This test obviously raises a 'pre-emption' problem, since it is substantially the same as the one used by sanitary authorities before they authorize the putting into circulation of pharmaceuticals. Proving that an authorized pharmaceutical is defective thus amounts, in most cases, to proving that sanitary authorities have made a mistake when authorizing the product. It is difficult, however, to find another test to assess a pharmaceutical's defectiveness.

129 See e.g. CA Versailles, 17 March 2006, no 04/08435; CA Paris, 19 June 2009, no 06/13741.

130 See e.g. CA Versailles, 16 March 2007, no 05/09525; 29 March 2007, no 06/00496; 5 November 2007, no 06/06435.

131 See e.g. CA Versailles, 5 April 2012, no. 09/05661.

in product liability cases were bound to remain fruitless, as even the most plaintiff-friendly appellate courts refused to regard the vaccine against hepatitis B as inherently defective.

34 In two cases at least, however, the *Cour de cassation* tried to go over this obstacle as it has gone over the causation obstacle. On these two occasions, the Court quashed lower courts 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 was therefore not defective.[132] 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 whether the elements that had been used to presume causation could not also justify a presumption that the vaccine doses used in the case were defective. By so doing, the *Cour de cassation* did not say that vaccines against hepatitis B *are* defective, but it allowed lower courts to reach this conclusion on a case-by-case basis.[133] The approach is exactly the same as the one taken on causation in 2008, and the result will also be the same. The vaccine against hepatitis B will most likely be regarded as defective by some French lower courts, but not by others. This is of course quite absurd, especially considering that the vaccine's fitness for purpose is undisputed and that its use is recommended in many countries (including France).

Yet, the ECJ, in its *Sanofi Pasteur* decision, has also validated this approach. It ruled that national courts may, on the facts of the case, use the same evidence to conclude that there is a defect in the vaccine as they do to conclude that there is a causal link between that defect and the claimant's disease. In effect, this seems to open the door to lower courts' decisions that would regard the hepatitis B vaccine as defective because this product has been presumed to cause a severe demyelinating disease in one given case, even though its global risk/benefit ratio remains positive, and there is no evidence that there was something wrong specifically in those doses of the vaccine that were used by the claimant. This, it is suggested, would be a deplorable result. It must be said, however, that no appellate court seems to have reached it so far.

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132 Cass civ 1re, 26 September 2012, no 11-17738; 10 July 2013, no 12-21314.

133 The language of the two decisions suggests that the lower courts were criticized for having considered only the possibility of a design defect of the vaccine, and not that of a manufacturing defect in the doses used by the plaintiffs. However, the general context of the cases, as well as the report of a higher magistrate in the second case (C. Mellottée, *D* 2013, p 2306), make it clear that, in both cases, the plaintiffs alleged the existence of a design defect.

5. The Vaccine Issue in the United Kingdom (*Duncan Fairgrieve*)

5.1. The Statutory Fund for Vaccine Damage

35 Realization of the potentiality of vaccine damage occurred relatively early in the United Kingdom. As early as 1930, a report recorded adverse reactions to a smallpox vaccination.[134] Responses to that in terms of compensation were however long time in coming.

It was not until the 1970s that there was an organized campaign in favour of the granting of compensation for vaccine damage. Initially, through individual initiatives, a parliamentary campaign,[135] and even an Ombudsman inquiry.-[136] The turning point came with the establishment in December 1972 of a Royal Commission on Civil Liability and Compensation for Personal Injury under the chairmanship of Lord Pearson with a remit to examine to what extent, and by what means, compensation should be payable in respect of death or personal injury. In the ultimate report, the Pearson Royal Commission[137] recommended the introduction of strict liability for defective products. Although this general recommendation was not put into effect,[138] the more specific recommendation to create a bespoke statutory fund for vaccine damage was followed, with the creation of a statutory fund by virtue of the Vaccine Damage Payments Act 1979.[139]

The Vaccine Damage Payments Act 1979, and the accompanying Regulations,[140] came into force in early 1979, and allow for the provision of a lump-sum payment for persons who are severely disabled as a result of vaccination against specified diseases. These initially covered diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, tuberculosis and smallpox,[141] and have been extended to cover mumps, *haemophilus influenza* type b, meningitis C, pneumococcal infection and human papillomavirus, pandemic influenza A (H1N1),[142]

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134 Further Report on Post-vaccinal Nervous Disease (Cmd 3738, 1930).

135 Jack Ashley MP attempted to raise the issue of compensation for vaccine-damaged children in Parliament in 1974: HC Deb, 31 January 1974, Vol 868, Col. 718–730.

136 Parliamentary Commission for Administration, *Sixth Report for Session 1976–77, Whooping Cough Vaccination*, 26 October 1977.

137 Royal Commission on Civil Liability and Compensation for Personal Injury (Cmnd 7054, 1974).

138 See further S. Whittaker, *Liability for Products* (Oxford: Oxford University Press 2005), p 432.

139 Interestingly, on a direct comparative note, a British government Minister explained the basis of the English fund in terms reminiscent of the French principle of *égalité devant les charges publiques :* 'the community as a whole has sought to share a responsibility for the hardship that has fallen upon [the victims]' (cited by C. Harlow, *Administrative Liability: A Comparative Study of French and English Law* (Thesis, University of London 1979), p 317).

140 Vaccine Damage Payments Regulations 1979.

141 S. 1(2) of the Vaccine Damage Payments Act 1979.

142 Up to 31 August 2010.

rotavirus, influenza,[143] meningitis W and meningitis B.[144] In the UK, there are no mandatory vaccines.

Under this scheme, the vaccination must have occurred in the UK,[145] and (with some exceptions),[146] the vaccination must have occurred when the claimant was either under eighteen or during an outbreak of the disease in the UK or the Isle of Man.[147] It extends also to unborn children whose mother was vaccinated for one of those diseases.[148] The scheme is premised on no-fault liability so there is no requirement to show negligence or any other type of fault on the part of the authorities.[149] The original sum under the Act of £10,000 has been increased over the years to an amount of now £120,000.[150]

5.2. The Proof of Causation

36 The issue of causation has for a long time been a thorny one.[151] As *Richard Goldberg* has noted, the failure rates, for lack of the requisite causal link, are high.[152] Following a recent Freedom of Information Request made by the author, the Department for Work & Pensions indicated that since 1979, there had been 6,196 claims, of which 936 resulted in awards.[153] There have been 4,177 rejections on the basis that 'causation due to vaccination has not been accepted', and 125 where 'causation [is] accepted but resulting disablement [is] not severe (less than 60%).'[154] The other main reason for rejection was that claims were received outside the statutory time limit for making a claim,[155] with 587 thereby rejected.

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143 Except for influenza caused by a pandemic influenza virus: Vaccine Damage Payments (Specified Disease) Ord. 2015, s. 2 (2015, No 47).

144 Vaccine Damage Payments (Specified Disease) Ord. 2016, s. 2 (2016, No 454).

145 Or to serving members of the armed forces, their spouse and their dependent children who were vaccinated elsewhere as part of armed service medical facilities.

146 Poliomyelitis, rubella, meningitis C, human papillomavirus, pandemic influenza A (H1N1), and meningitis W (before 26th birthday).

147 S. 2(1) of the Vaccine Damage Payments Act 1979.

148 S. 1(3) of the Vaccine Damage Payments Act 1979.

149 For discussion of such statutory schemes, see D. Fairgrieve, *State Liability in Tort: A Comparative Law Study* (Oxford: Oxford University Press 2003), Ch. 8.

150 Vaccine Damage Payments Act 1979 Statutory Sum Ord. 2007.

151 R. Goldberg, *Medicinal Product Liability and Regulation* (Oxford: Hart Publishing 2013), p 11.

152 *Ibid.*

153 FOI 2141 dated 31 May 2017.

154 FOI 2141 dated 31 May 2017.

155 I.e. the later of: the date on which the disabled person attains the age of 21; and the end of the period of six years beginning with the date of the vaccination to which the claim relates (Vaccine Damage Payments Act 1979, S. 3(1)(c).)

5.3. The Defectiveness of the Vaccine

37 Rather than pursuing a claim under the statutory scheme, those affected can of course bring an action against the manufacturer of the vaccine. Such litigation faces significant obstacles in the law, in particular in terms of showing that the vaccine caused the loss,[156] and that the product in question was defective (for claims brought under the Consumer Protection Act 1987). As for defectiveness, the practical test laid down in the Directive of whether a product 'does not provide the safety which a person is entitled to expect' has raised difficulties,[157] and the case law that there has been at a European level has left many questions unanswered.[158] One recurrent issue is whether within this entitled expectations test there is a role for considerations of risk/utility. In the US, the risk/utility test has played a prominent role, involving the balancing of the probability and seriousness of harm against the cost of taking precautions. As explained by Owen, in the US, 'a product is considered "defective" under a risk-utility test if the costs of eliminating a particular hazard are less than the resulting safety benefits.'[159]

38 The relevance of such considerations in a European context is the subject of some debate. From one perspective, the opportunities for the deployment of risk-utility considerations would seem quite limited: it is quite difficult to see how the utility of a product is a relevant consideration when assessing defectiveness within the meaning of Article 6 of the Product Liability Directive. Moreover, the recitals of the Directive give a centrality to the notion of a 'fair apportionment of risks',[160] as has been underlined in the case law,[161] rather than the cold calculation of costs and benefits enshrined in the US risk/utility calculus. Indeed, the American experience shows that once risk/utility is adopted, the ultimate test inevitably becomes close to that of a negligence-style analysis. That would be problematic in a European

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156 See e.g. *Bonthrone* v. *Millan*, Scottish Court of Session, 10 October 1981, unreported (claim by child with serious brain damage failed); *Loveday* v. *Renton (No 1)* (1989) 1 Med LR 117, QBD (judge held that the plaintiff had failed to prove on the balance of probability that pertussis vaccine can cause permanent brain damage in young children). See analysis of these cases in R. Lee, 'Vaccine Damage: Adjudicating Scientific Dispute', in G. Howells (ed.), *Product Liability, Insurance and the Pharmaceutical Industry* (Manchester University Press, Fulbright Papers, Vol 9, 1990) p 52 ff. Causation issues also proved fatal to the MMR litigation in the late 1990s/2000s.

157 Indeed, the European Commission has admitted in its Third Report on the Directive that '[t]he subjective nature of the "expectations" test means that this principle is incapable of precise definition', see COM(2006) 496, p 10.

158 ECJ, 5 March 2015, joined Cases C-503/13 and C-504/13 *Boston Scientific Medizintechnik GmbH* v. *AOK Sachsen-Anhalt - Die Gesundheitskasse.*

159 D.G. Owen, *Products Liability Law* (3rd edn, St. Paul: Thomson/West 2014) p 301.

160 See Recitals 2 and 7.

161 ECJ, 5 March 2015, joined Cases C-503/13 and C-504/13 *Boston Scientific Medizintechnik GmbH* v. *AOK Sachsen-Anhalt - Die Gesundheitskasse*, at para. 42.

context, given that the standard of defect in the Directive should not require proof of fault.[162] On the other hand, it has been argued that it is difficult to exclude risk-utility factors entirely, particularly in pharma cases.[163] It should also not be forgotten that members of the English judiciary have been reared on the traditional common law diet of cost-benefit analyses in negligence, and this was perhaps reflected in the recent decision of *Wilkes* v. *Depuy International*,[164] in which the Court departed from the approach in earlier cases[165] and endorsed a role for risk/benefit analysis amongst the basket of factors considered within the defectiveness standard,[166] at least in a *standard* case.[167]

39 From the perspective of causation, it is difficult to speculate on the exact approach of the courts in vaccine cases in the absence of any recent case law on the issue. However, *Richard Goldberg* has argued that the US case law is useful in determining the relevant standards for showing general and specific causation in vaccine cases:[168]

'This legal standard of proof for causation in fact under the Program was elaborated on in the leading case of Althen v. Secretary of Health & Human Services.[169] There, the Federal Circuit established three factors which had to be satisfied to overcome the burden of proof, viz: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury.'

In the United Kingdom, the most high-profile vaccination litigation brought in recent times was the ill-fated MMR vaccination claims, arising out of the alleged link between the administering of the MMR vaccine and the subsequent development of autism and gastrointestinal problems in children.[170] After the scientific basis for the link was discredited, the public funding of the claims was withdrawn

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162 There is clear textual evidence in favour of the creation of a no-fault liability regime: this may be inferred from Arts 1 and 6 of the Directive. The Recitals confirm this fact explicitly.

163 M. Mildred, 'Pharmaceutical Products: The Relationship between Regulatory Approval and the Existence of a Defect', *EBLR (European Business Law Review)* 2007, p 1267.

164 *Wilkes* v. *Depuy International Limited* [2016] EWHC 3096 (QBD).

165 *A* v. *National Blood Authority and another* [2001] 3 All ER 289 (QBD), in which Burton J held that along with avoidability and the impracticability of taking precautionary measures, the benefit to society or the utility of the product was not legally relevant.

166 See *Wilkes* v. *Depuy International Limited* [2016] EWHC 3096 at paras 65–67, 82, 93–96.

167 At para. 96, the Judge remarked that in a 'non-standard' (out of specification) case, the risk-benefit of an in-specification product is unlikely to have much if any weight. He did not, however, advocate a rule of law that it should have none.

168 R. Goldberg, 'Vaccine Damage and Causation: Franco-American comparaison', 1 *Journal de Droit de la Santé & de l'assurance Maladie* (2014), p (134) at 135.

169 *Althen* v. *Secretary of Health & Human Services* 418 F 3d 1274 (Fed Cir 2005).

170 For a detailed appraisal, see R. Goldberg, *Medicinal Product Liability and Regulation*, Ch. 6.

on the basis that the litigation had no reasonable prospect of success, and the status as group litigation was brought to an end in June 2007.[171]

6. Conclusion (*Duncan Fairgrieve*)

40 It will be readily apparent from the foregoing that the initial hypothesis provided at the start of this article has been confirmed in the sense that in all the systems studied, there are a plurality of routes to a remedy in case of vaccine damage. These moreover seem to follow quite a similar typology in all the systems: over and above the orthodox regimes of tort law and product liability (and in Germany the Pharmaceuticals Act), a bespoke (and often) statutory compensation scheme is available, whereby compensation is provided by a scheme which is subject to procedural and substantive rules which are more flexible than under the orthodox civil law approach. The procedural rules under such a scheme generally allow victims to gain compensation direct from the relevant fund rather than having to suffer the litigant's lot of fighting litigation through the courts. Importantly, the substantive rules are often more accommodating for the claimants so that typically all that needs to be shown is a vaccination, subsequent injury and the causal link between the two. This is all underpinned, as noted at the outset, by reasons of social solidarity according to which the fact that an individual has to suffer a sacrifice (vaccine damage) for the benefit of the community (reduction in serious disease due to public programme of immunization), then the public purse should provide compensation to him or her.

41 The second area of importance identified at the outset of this article would also seem to have been confirmed by the research results presented above, namely the pertinence of analysing vaccine cases from an orthodox tort/product liability perspective. Such cases pose particular challenges for the ordinary civil law rules, concentrating within this sphere some of the most critical issues facing products claims, namely the composite elements of defectiveness and the difficulties of proving causation in healthcare cases, where many competing factors are necessarily involved.

42 In terms of defect, the correct interpretation of the relevant test is of crucial importance. As ever in medicinal cases, a key parameter is how far that global risk/utility considerations are relevant to the test under the Directive. Views have already been expressed on this issue in all of the systems studied above, showing a variety of perspectives albeit that English, French and German case law seemingly take into account such considerations. This approach was however strongly challenged by *Eleonora Rajneri* in her section on Italian law above, in which she argues that, though it might be understandable to avoid inhibiting innovation in the

171 Sayers v. Smithkline Beecham Plc [2007] EWHC 1335. For a detailed appraisal, see R. Goldberg, *Medicinal Product Liability and Regulation* Ch. 6.

vaccine sphere, it is also important to take account of the fact that manufacturers are in a highly protected position due to the specific market conditions relating to vaccines, which are favourable to producers. Therefore there are neither economical or legal reasons to insulate the vaccines producer from the strict liability regime put in place by the European directive, through a duplication of the same risk/utility test already applied by the Regulator. Certainly, it would seem that manufacturers are in a position to be able to factor into the price of the product the costs of compensating the limited number of vaccine damage cases. In such conditions, it is not necessarily evident that that loss should be automatically shifted to the public purse by means of the statutory schemes mentioned above.

The arguments protecting the producers are perhaps finely balanced but it does seem that the law, particularly at an EU level, is moving in the direction of *Eleonora Rajneri's* position. In the *Boston Scientific* decision, the ECJ took the position that the particular products implanted (pacemaker and ICD) had an *'abnormal potential for damage'* and were defective because they belonged to a group or production series of products which had been shown to have a significantly higher than normal risk of such a fault. Though it thus conceptualized the defect standard *in terms of risk*, the Court did not seem to consider it necessary to weigh that risk up against the product's benefits or wider societal utility of the product. Whilst it might be said that *Boston Scientific* concerned a very different fact pattern, the recent ECJ decision in *Sanofi Pasteur* is, as has already been seen, specifically concerned with this issue.[172] In that case, the Advocate General specifically examined the argument (on the part of Sanofi) that the test of defectiveness required a broad assessment of the cost/benefits of the product, going beyond the concrete case.[173] The Advocate General explicitly said that he disagreed with that proposition opining that the test of defectiveness 'essentially refers to baseline expectations of the product under normal conditions of use. It does not mean that where the product is used normally and causes serious harm in an individual case, that a conclusion of defectiveness necessarily requires a balancing of the costs and benefits of the product.'[174] Such an approach would result in the court 'creating (or at least boldly deducing) new conditions of liability.'[175]

The indications are that the Court followed this analysis of defect. In defining what it is necessary for the claimant to show in proving defect in the context of a vaccine case, the ECJ states that this requires that the vaccine 'causes abnormal and particularly serious damage to the patient who, in the light of the nature and function of the product, is entitled to expect a particularly high level of safety.'[176]

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172 ECJ, 21 June 2017, Case C-621/15 v. *N. W and Others v. Sanofi Pasteur MSD SNC and Others.*
173 *Ibid.*, para. 85.
174 *Ibid.*, para. 87.
175 *Ibid.*, para. 88.
176 *Ibid.*, para. 41.

There is no reference to a weighing of risk with a wider societal benefit, and thus the Court seems to apply the defect notion in a way which excludes the risk/benefit equation.

43 Similarly, in respect of causation the sphere of vaccine damages poses some challenges, since very often there is not unequivocal scientifical evidence of the fact that the vaccine was the cause of the disease. The vaccine could be at the most one plausible cause among several others. Questioned about the definition of causality and its proof, the recent decision of the ECJ leaves its ascertainment to the individual Member States, following the principle of procedural autonomy. Because none of the legal systems taken into account allows the apportionment of the liability according to the percentage of probability that the vaccine was actually the cause of the disease, it is required to prove that the vaccine was the most probable cause compared to the others, in order to hold the producer liable. In all the systems, proof can be given through presumptions and the presumptions are everywhere inferred from the absence of any other probable cause of the disease and from the temporal proximity between the vaccination and the emergence of the symptoms. However, while in France and Germany the temporal proximity is about three months, in Italy a lapse of time of three years was considered relevant. This anomaly may be explained by the fact that in the Italian case there was one further element supporting the presumption that the vaccine was the most probable cause of the disease. In fact, the internal document of the vaccine producer shows that batches of this vaccine contained mercury, which is a toxic substance particularly in respect of young children. Further, the Italian decision concerned a claim for redress provided by the public compensation fund, i.e. a claim where the social solidarity issues are very prominent. In conclusion, the comparative studies show that the elasticity and the ambiguity of the notion of causality allows the courts to adapt it according to the peculiar issues that are the guidelines in the different type of claims.