Compensation for Vaccine Damage in the United Kingdom

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The issue of compensation for injury consequent to vaccination is again on the public agenda. In this piece, a review is undertaken of the position in the United Kingdom.

History

Although the recognition of vaccination damage occurred as early as the 1930s in the United Kingdom[1], it was not until much later, in the 1970s that there was an organised campaign in favour of publicly funded compensation for vaccine damage. The key moment 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 as an objective 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[2] recommended the introduction of strict liability for defective products. Although this general recommendation was not put into effect[3], 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[4].

Statutory Intervention

The Vaccine Damage Payments Act 1979, and accompanying Regulations[5], came into force in early 1979. This Act allows for the provision of a lump-sum payment for those who are severely disabled as a result of vaccination against specified diseases. The scheme initially covered diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, tuberculosis and smallpox[6]. It has more recently been extended to cover mumps, *haemophilus influenza* type b, meningitis C, pneumococcal infection and human papillomavirus, pandemic influenza A (H1N1)[7], rotavirus, influenza[8], meningitis W and meningitis B[9].

Under this scheme, the vaccination must have occurred in the UK[10], and (with some exceptions)[11], 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[12]. It extends also to unborn children whose mother was vaccinated for one of those diseases[13]. 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[14]. The original sum under the Act of the £10,000 has now been increased over the years to an amount of £120,000[15].

Proving causation

Within the context of vaccine damage, the issue of causation has for a long time been a thorny one[16]. As Richard Goldberg has noted, the failure rates, for lack of the requisite causal link, are high[17]. Following a recent Freedom of Information Request made by the author, the Department for Work & Pensions indicated that since 1979, there had been 6196 claims, of which 936 resulted in awards[18]. There have been 4177 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

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

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

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

4 - 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).

5 - Vaccine Damage Payments Regulations 1979.

6 - Section 1(2) of the Vaccine Damage Payments Act 1979.

7 - Up to 31 August 2010.

8 - Except for influenza caused by a pandemic influenza virus : Vaccine Damage Payments (Specified Disease) Order 2015, section 2 (2015, No 47).

9 - Vaccine Damage Payments (Specified Disease) Order 2016, section 2 (2016, No 454).

10 - 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. -

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

12 - Section 2(1) of the Vaccine Damage Payments Act 1979.

13 - Section 1(3) of the Vaccine Damage Payments Act 1979.

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

15 - Vaccine Damage Payments Act 1979 Statutory Sum Order 2007.

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

17 - Ibid.

18 - FOI 2141 dated 31 May 2017.

than 60 %)'[19]. The other main reason for rejection was claims were received outside the statutory time limit for making a claim[20], with 587 thereby rejected.

The defectiveness of the vaccine

An alternative route to compensation is bringing legal proceedings against the manufacturer of the vaccine. Such litigation faces significant obstacles however, in particular in terms of showing that the vaccine caused the loss[21], and, for claims brought under the Consumer Protection Act 1987, that the product in question was defective. 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[22], and the notion has always been shrouded by a degree of mystery and uncertainty due to its open-textured nature. Whilst the notion of defect has generated many cases at a national level[23], precious little case law had been handed down until recently at a European level. That has changed due to two recent decisions of the CJEU in *Boston Scientific GmbH v AOK Sachsen-Anhalt*[24], and *NW v Sanofi Pasteur MSD*[25].

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'[26].

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 PLD. Moreover, the Recitals of the Directive give a centrality to the notion of a 'fair apportionment of risks'[27], as has been underlined in the case law[28], 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 context, given that the standard of defect in the Directive should not require proof of fault[29]. On the other hand, it has been argued that it is difficult to exclude risk-utility factors entirely, particularly in pharma cases[30]. 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*[31], in which the Court departed from the approach in earlier cases[32] and endorsed a role for risk-benefit analysis amongst the basket of factors considered within the defectiveness standard[33], at least in a *standard* case[34]. On the other hand, different signals have emerged from the European decisions. In the *Sanofi* case, which concerned a preliminary reference from France to the ECJ concerning the French litigation concerning the claim that hepatitis B vaccination gives rise to demyelinating disease[35], the French judge asked whether Article 4 of Directive 85/374/EEC on product liability should be interpreted as precluding national judges from assessing causation through presumptions. The decision of the Court focussed mainly on the issue of proof, but the Court did seem to approve the standard referred to in the *Boston Scientific* decision[36]. In defining what it is necessary for the claimant to show in proving defect in the context of a vaccine case, it was stated that this requires that the vaccine 'causes abnormal and particularly serious damage to the patient who, in the

19 - FOI 2141 dated 31 May 2017.

20 - Ie 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, section 3(1)(c).)

21 - 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 (N° 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 *Product Liability, Insurance and the Pharmaceutical Industry* (Manchester University Press, Fulbright Papers, Vol 9, 1990). Causation issues also proved fatal to the MMR litigation in the late 1990s / 2000s.

22 - 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.

23 - For a recent example in the UK, see *Wilkes v De Puy* [2016] EWHC 3096.

24 - *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - Die Gesundheitskasse (Case C-503/13, 504/13)* [2015] 3 CMLR 173 (CJEU) AG§27.

25 - ECJ, 21 June 2017, C–621/15 *NW v Sanofi Pasteur MSD SNC*.

26 - D.G. Owen, *Products Liability Law* (St. Paul: Thomson/West 2005) p 303.

27 - See Recitals 2 and 7.

28 - 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.

29 - 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.

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

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

32 - ***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.

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

34 - At §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.

35 - On this generally, see J-S.Borghetti, « Causation in Hepatitis B Vaccination Litigation in France : Breaking Through Scientific Uncertainty ? » (2016) 91 Chicago-Kent Law Review.

36 - *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - Die Gesundheitskasse* (Case C-503/13, 504/13) [2015] 3 CMLR 173 (CJEU) AG§27.

light of the nature and function of the product, is entitled to expect a particularly high level of safety' [37]. It is to be noted that 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[38]. In response to this, the Advocate General explicitly said that he disagreed with that proposition: 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'[39]. Such an approach would result in the court 'creating (or at least boldly deducing) new conditions of liability'[40]. Although this issue was not broached specifically by the Court, it is possible to argue that -in reading between the lines- the Court followed this analysis. 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 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'[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.

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[42]:

> '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[43]. 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 measles, mumps, and rubella (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[44]. After the scientific basis for the link was discredited, the public funding of the claims was withdrawn 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[45].

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37 - ECJ, 21 June 2017, C–621/15 *NW v Sanofi Pasteur MSD SNC*, para. 41.

38 - ibid., para. 85.

39 - ibid., para. 87.

40 - ibid., para. 88.

41 - ibid., para. 41.

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

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

44 - For a detailed appraisal, see R. Goldberg; *Medicinal Product Liability and Regulation* (Oxford: Hart Publishing 2013), Chapter 6.

45 - *Sayers v Smithkline Beecham Plc* [2007] EWHC 1335. For a detailed appraisal, see R. Goldberg, ibid.