

**CAUSAL EFFECT RELATIONSHIP IN MEDICAL CASES.
AN OLD PROBLEM IN A NEW SCENARIO.
COMMENTARY TO CJEU JUDGMENT (SECOND CHAMBER)
OF 21 JUNE 2017, N.W. & OTHERS V. SANOFI PASTEUR
MSD & OTHERS, CASE C-621/15, EU:C:2017:484
*APPROBATIVE GLOSS***

*Agata Wnukiewicz-Kozłowska**
*Urszula Drozdowska***

ABSTRACT

This commentary evaluates the problem in assessing the role of a causal connection between damage and the use of a defective medical product, specifically a vaccine. The judgment of the Court of Justice of the European Union (CJEU) in the Sanofi Pasteur Case, which allowed the possibility of recognizing damage claims, even in cases where the prevailing scientific theory claims that there is no scientific evidence of a causal link between a vaccination and the disease, became a base for consideration. Consequently, procedural solutions (such as the standard of proof required, the admissibility of *prima facie* evidence reasoning and other solutions in cases of an uncertain causation) remain to be decided by national law. The authors assessed two legal systems: the French and Polish legal systems in the context of how to resolve these dilemmas and to describe the impact of the above-mentioned

* Dr. habil. Agata Wnukiewicz-Kozłowska, Assistant Professor, Faculty of Law, Administration and Economics, University of Wrocław; correspondence address: ul. Uniwersytecka 22–26, 50-145 Wrocław, Poland; e-mail: agata.wnukiewicz-kozłowska@uwr.edu.pl; <https://orcid.org/0000-0002-4872-3852>.

** Dr. Urszula Drozdowska, Assistant Professor, Faculty of Law, University of Białystok; correspondence address: ul. Mickiewicza 1, 15-213 Białystok, Poland; e-mail: drozdowska@uwb.edu.pl; <https://orcid.org/0000-0002-7663-1904>.

judgment on the case-law of French and Polish courts as regards the application of Directive 85/374/EEC. As a result, they concluded that the most important interpretative motive has become the individual interest of the vaccination's victim as a consumer of medical services. It seems to be in accordance with Directive 85/374/EEC, which is motivated by the necessity of approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products. However, since the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property, in countries belonging to the European Union, the authors wonder how the commented judgment will affect the further development of consumers protection against defective vaccines.

Keywords: uncertain causation, standard of proof, vaccine, damage, defective medical product

1. INTRODUCTION

It is common knowledge that the paper by Andrew Wakefield and 11 other colleagues, then of the Royal Free Hospital in London, from 1998 published in the *Lancet* (now retracted)¹ which suggested that measles, mumps, and rubella (MMR) vaccine may predispose to autism spectrum disorders (ASD) and gastrointestinal problems in children, was not confirmed in other scientific studies². Although, no epidemiological studies, published later in respected and recognised medical journals

¹ Andrew J. Wakefield et al., "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children," *Lancet* 351 (1998): 637. Retracted: The Editors of The Lancet, "Retraction-Ileal-lymphoidnodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children," *Lancet* 375 (2010): 445.

² Kreesten Meldgaard Madsen et al., "A population-based study of measles, mumps, and rubella vaccination and autism," *New England Journal of Medicine* 347 (2002): 1477–82; Corri Black, James A. Kaye, and Hershel Jick, "Relation of childhood gastrointestinal disorders to autism: nested case control study using data from the UK General Practice Research Database," *British Medical Journal* 325 (2002): 419–421; Brent Taylor et al., "Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study," *British Medical Journal* 324 (2002): 393–396.

(among others the BMJ, Lancet and the New England Journal of Medicine)³ confirmed the existence of a causation between the vaccine and ASD⁴, it is possible to indicate court decisions, in which the courts recognized the existence of this type of causal link⁵.

Does this mean there is a conflict between law and science? Or do court decisions – as some authors note⁶ - distort scientific knowledge and point out an improper indifference to the legitimate methods by which scientific knowledge is generated in the context of vaccines?

Undoubtedly, in the collective consciousness, the thoughts expressed in the jurisprudence are of great importance and their misinterpretation attracts the attention of the media, which may lead to a widespread fear of

³ Fiona Godlee, Jane Smith, and Harvey Marcovitch, “Wakefield’s article linking MMR vaccine and autism was fraudulent,” *British Medical Journal* 342 (2011): 64–65; T.S. Sathyanarayana Rao and Chittaranjan Andrade, “The MMR vaccine and autism: sensation, refutation, retraction, and fraud,” *Indian Journal of Psychiatry* 53 (2011): 95–96; Brian Deer, “How the Case Against the MMR Vaccine Was Fixed,” *British Medical Journal* 342 (2011): 77.

⁴ Current knowledge on the etiology of ASD does not provide full insight into the issue. The academic literature suggests it can be caused by genetic factors or environmental factors (so called ‘triggered factors’), which include: drugs taken by pregnant women, infections, inflammations and increased testosterone levels during pregnancy, as well as allergies and any severe reactions (including post-vaccination) observed in a child (see: Amy E. Kalkbrenner, Rebecca J. Schmidt, and Annie C. Penlesky, “Environmental chemical exposures and autism spectrum disorders: a review of the epidemiological evidence,” *Current Problems in Pediatric Adolescent Health Care* 44 (2014): 277–318; Ousseny Zerbo, Ana-Maria Iosif, Cheryl Walker et al., “Is Maternal Influenza or Fever During Pregnancy Associated with Autism or Developmental Delays? Results from the CHARGE (Childhood Autism Risks from Genetics and Environment) study,” *Journal of Autism Developmental Disorders* 43, no. 1 (2013): 25–33.

⁵ So e.g. The Tribunale of Rimini, Judgment of the of 15 March 2012, ref. n° 148/2010. The similarly in the judgment of the Tribunale of Milano, of 23 Sept. 2014, ref. n° 14276/13. These judgments were made on the basis of Law n° 210 of 25 Feb.1992. However, it is important to bear in mind the inconsistency of Italian case law and the frequent disregard of claims, c.f. The Italian Supreme Court (sez. lavoro), Judgment of 23 Oct. 2017 (ordinanza n° 24959).

⁶ Laura R. Smillie, Marc R. Eccleston-Turner, and Sarah L. Cooper, “C-621/15 – W. and others v Sanofi Pasteur: an exemple of judicial distortion and indifference to science,” *Medical Law Review* 26 (1) (2018): 134–145.

vaccination⁷. The truth is that such a phenomenon poses a very real and serious threat not only to those members of society who remain unvaccinated, but also in terms of undermining the confidence of those who, relying on scientifically proven advice, start to doubt mass immunisation.

On the other hand, the public has the right to expect the safety of the medicinal products placed on the market, so when an ‘adverse event’ occurs, a fair and impartial verdict is expected with regard to all the circumstances of the case.

The role of jurisprudence in society can by no means be ignored. Courts and their judgments are seen as merely a forum for resolving disputes but also an important social institution. Courts often shape the life of a community through their judgments or advisory opinions⁸.

In this context, the ruling of the CJEU in the case of the N.W. and others v. Sanofi Pasteur on the relationship between hepatitis B vaccine and Multiple Sclerosis (MS), takes on great importance. It reveals the tension described above between, on the one hand, objective scientific evidence and, on the other hand, the need to deal with the case in its entire complex context. This ruling is described in numerous articles and comments⁹. Interestingly, in French legal doctrine it is perceived positively, in

⁷ Philip J. Smith et al., “Parental delay or refusal of vaccine doses, childhood vaccination coverage at 24 months of age, and the Health Belief Model,” *Public Health Reports* 126 (suppl 2) (2011): 135–146; Mariam Siddiqui, Daniel A. Salmon, and Saad B. Omer, “Epidemiology of vaccine hesitancy in the United States,” *Human Vaccines & Immunotherapeutics* 9 (2013): 2643–8.

⁸ Shimon Shetreet, “On Assessing the Role of Courts in Society,” *Manitoba Law Journal* 10 (1980): 357–414.

⁹ E.g., Ruiz Cairó, “The Lack of Medical Research Does Not Prevent an Injured Person from Proving the Defect of a Product and the Causal Link between the Defect and the Damage,” *European Journal of Risk Regulation* 4 (2017): 798–803; Estelle Brosset and Elsa Supiot, “Le vaccin contre l’hépatite B: l’autonomie de la preuve juridique en l’absence de consensus scientifique devant la Cour de justice de l’Union européenne,” *Revue des contrats* 4 (2017): 662–668; Estelle Brosset, “Distinguishing between law and science in terms of causation and the hepatitis B vaccine: W. v. Sanofi Pasteur,” *Common Market Law Review* 55 (2018): 1899–1916; Smillie, Eccleston-Turner, and Cooper, “C-621/15 – W. and others v Sanofi Pasteur,” 134–145; Marco Rizzi, “A Dangerous Method: Correlations and Proof of Causation in Vaccine Related Injuries,” *Journal of European Tort Law* 9 (2018): 289–307; Erdem Büyüksagis, “Arrêt “Sanofi”: la responsabilité du fait

a foreign one rather negatively¹⁰. In the Polish legal literature it has not yet been commented on in detail, but as it seems in the context of current dilemmas related to the need to administer the vaccine to the largest possible number of people against COVID-19 with simultaneous concerns about its safety, it is worth recalling the motivation of the Sanofi Pasteur Case and describing its impact on national legal orders.

The purpose of this commentary is to address its main theses and also to show its broader context in relation to the settlement of cases of damage caused by medicinal products by civil courts. In particular, the reasoning of the courts is presented - how these bodies have examined the basic premise of the manufacturer's liability: the causal link between the use of the medicinal product and the patient's injury. Comparative information is contained in the judgments of French and Polish courts. In both cases, it is a matter of civil law systems, which makes it possible to overcome the difficulties linked to the differences in the systemic order: common law and civil law¹¹.

2. THE FACTUAL CONTEXT AND THE COURT'S RULING

On 21 June 2017, the Court of Justice of the European Union (CJEU) passed judgment (a preliminary ruling) in the case of *N. W. and others v. Sanofi-Pasteur* (C-621/15), a dispute in which the family of the deceased N.W., asked a French court for compensation. The patient was vaccinated against Hepatitis B with three injections of a vaccine produced by Sanofi Pasteur, administered on 26 December 1998, 29 January 1999 and 8 July 1999. From August 1999, N.W. began to display various symptoms which, in November 2000, led to the diagnosis of Multiple Sclerosis disease (MS). The patient died on 30 October 2011.

des produits défectueux appliquée aux vaccins, une responsabilité objective basée sur des présomptions," *Journal de droit européen* 244 (2017): 395–397.

¹⁰ Compare f.e.: Brosset, "Distinguishing between law and science," *passim* and Smillie, Eccleston-Turner, and Cooper, "C-621/15 – W. and others v Sanofi Pasteur," *passim*.

¹¹ In particular as regards the specificity of the legal solutions concerning the standard of proof adopted by the courts.

Referencing Article 4 of Council Directive 85/374/EEC of 24 July 1985, on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective product¹², the CJEU had to answer three questions put to it by the French Supreme Court:

- 1) Does the Article 4 Directive prevent a court from relying upon the evidence presented by W when determining liability, what constitutes ‘serious, specific and consistent presumptions’ to show a defect and causal relationship, notwithstanding that medical research does not establish a ‘causal relationship’ between a vaccine and the injury (i.e. there is no scientific consensus)?
- 2) Does the Directive prevent Member States from creating a system of ‘presumptions’ with respect to vaccine injuries, where, if certain ‘indications of causation’ are found, liability always follows (regardless of ‘scientific consensus’)?
- 3) Does the Directive require that a victim must adduce evidence that a ‘causal relationship’ between the vaccine and the injury is scientifically established?

The CJEU made rulings with respect to questions one and two and found it unnecessary to consider the third.

The sentence of the Court assumed that: “when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, 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

¹² Article 4: “The injured person shall be required to prove the damage, the defect and the causal relationship between the defect and the damage”, Article 1: “The producer shall be liable for the damage caused by a defect in his product”, Article 2: “For the purpose of this Directive ‘product’ means all movables, with the exception of primary agricultural products and game, even when incorporated into another movable or into an immovable”, Article 3: “‘Producer’ means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part or any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer”. O.J. 1985, L 210/29, modified by Directive 1999/34/EEC of 10 May 1999, O.J. 1999, L 141/20.

of the victim's disease, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease. National courts must, however, ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by Article 4 being disregarded or the effectiveness of the system of liability introduced by that Directive being undermined¹³.

Certainly, the CJEU judgement is not a very revolutionary one, in regards to the legal interpretation of Article 4 of Directive 85/374 based on the formula that an injured person will be required to prove damage, the defect and the causal relationship between the defect and the damage. As it is clear from the case-law of the CJEU to date, the Court has accepted the practice of taking evidence, e.g. in establishing the product defect and in the existence of a causal link between the defect and the damage¹⁴. However, these improvements must not lead to a reversal of the burden of proof, and thus to a denial of the legal formula on which Article 4 of the Directive is based.

What is really new is the way in which national courts can - within the framework of their procedural autonomy - rule on disputes regarding the establishment of a causal link between damage and vaccination and the defectiveness of a medicinal product. Of particular interest here is the statement of the court that: "In the present case, evidence such as that relied on in the main proceedings relating to the temporal proximity between the administering of a vaccine and the occurrence of a disease and 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, appears on the face of it to constitute evidence which, taken together where applicable, may lead a national court to consider that a victim has discharged his burden of proof under Article 4 of Directive 85/374".

¹³ *N. W. and others v. Sanofi Pasteur*, Case C-621/15.

¹⁴ CJEU: *Novo Nordisk Pharma*, Case C-310/13, EU:C:2014:2385; *Gonzales Sanchez*, Case C-183/00, EU:C:2002:255; *Nike European Operations Netherlands*, Case C-310/14, EU:C:2015:690; *Eturas and others*, Case C-74/14, EU:C:206:42.

Doubts came from the possible acceptance of the link between the vaccination and the disease, which could become overly automatic and lacking in objectivity from a scientific point of view. It should be emphasized that such a point of view is by itself contradictory to the well-established principle of evidence-based medicine which is the ‘emerging clinical discipline that brings the best evidence from clinical and health care research to the bedside, to the surgery or clinic, and to the community’¹⁵. Naturally, the sophisticated language used by the judges to express their findings does not imply that this link is established by default. This case has been greatly simplified in some communications¹⁶. Meanwhile, it follows the grounds for the ruling that the judges did not dismiss the possibility of proving a link between a defective medicinal product (e.g. vaccine) and a patient’s disease in a special situation, when there is no scientific consensus to establish such a causal link but the circumstances of the particular case may support it.

With reference to the literature on the subject, it is worth noting that the CJEU recognizes the difficulties in proving both general causation (whether the product was capable of causing the damage alleged) and specific causation (whether the product did so in the individual case)¹⁷. The judgment of the CJEU allows us to “slip through” the often insoluble problem of establishing the first general causation and only answer the second question.

¹⁵ David L. Sackett and Brian R. Haynes, “On the need for evidence-based medicine. EBM Notebook,” *Evidence-Based Medicine* 1 (1995): 5–6, <https://ebm.bmj.com/content/ebmed/1/1/5.full.pdf>, accessed February 13, 2021.

¹⁶ But while such an interpretation will be easily understood by lawyers and practitioners in this field, it is more likely to be interpreted literally by the by the anti-vaccine lobby. Thus, using the media as an example, it was simply reported that: “The highest court of the European Union ruled Wednesday that courts can consider whether a vaccination led to someone developing an illness even when there is no scientific proof”, see: <https://www.cbsnews.com/news/eu-court-vaccines-can-be-blamed-for-illnesses-without-proof>, accessed February 19, 2020. (First published on June 21, 2017/10:27AM).

¹⁷ Richard Goldberg, “Vaccine damage and causation: a Franco-American comparison,” *Journal de Droit de la Santé et de l’Assurance Maladie* 1 (2014): 134–137.

It's hard not to agree with this claim if one considers the specificity of the medicinal product, which is dangerous *per se*¹⁸. The active ingredients used in it, in addition to their therapeutic effects, may also have harmful side effects. However, their use is justified by the fact that the benefits outweigh the risks of complications. With this in mind, first of all, the problem is to determine what the level of safety for people being vaccinated in light of the provisions of the Directive can reasonably be expected, given that a vaccine, like any other medicine, may be inherently dangerous¹⁹.

It should be taken into account that the patient is not a 'normal' user of the product. The decision to vaccinate is linked to a belief in the indications given by the manufacturer which suggest an increase in the patient's health safety.

In this context, it cannot be said that the product is certainly safe on the sole basis that it has undergone all necessary clinical trials and has been authorised. As it is known, clinical trials on a medical product are conducted on a specific population group. It may be that, compared to the target population to which the drug was applied, the group of people on which the drug was tested was too small to discover a specific causation. Therefore, on the basis of the results of clinical trials that did not detect a given causation, it cannot be assumed in advance that a causal link between the medicine and the adverse event is definitely not involved. Even the European Medicine Agency (EMA) explains that: "All medicines have benefits as well as risks. While the authorisation of a medicine is based on an overall positive balance between the benefits and risks at population level, each patient is different and before a medicine is used, doctors and their patient should judge whether this is the right treatment option for them

¹⁸ It is important to distinguish between a simple defectiveness of the product and a defect that causes danger. A defective product might not pose a risk of harm, while a non-defective product might be harmful, see more: Monika Jagielska, "Odpowiedzialność za produkt," in *System Prawa Prywatnego*, t. 6, ed. Adam Olejniczak (Warsaw: C.H. Beck, 2009), 907 (our translation).

¹⁹ CJEU: *Boston Scientific Medizintechnik GmbH*, joined Cases C-504/13 and C-504/13, EU:C:2015:148. The EU Court considered that the safety that could reasonably be expected should be assessed in particular in light of the intended use, the characteristics and objective characteristics of the product concerned and the specificity of the user group for which the product is intended.

based on the information available on the medicine and on the patient's specific situation"²⁰.

In conclusion, the specificity of drugs (including vaccines) requires a different definition of safety, i.e. the determination of a higher level of safety that one can expect from a given drug. Referencing Article 6 of Directive 85/374, the assessment must be taken in light of the legitimate expectations of the general public. A product which, given its function, on the basis of an assessment of its objective properties, can be assumed to pose a threat to life and health, becomes a dangerous product²¹.

For these reasons, the judges also concluded that exclusion of the possibility to prove the relationship between the medical product's (a vaccine) defectiveness and a disease (patient's damage) on evidence not necessarily connected with scientifically proved product's properties, would contradict the assumptions of the Directive 85/374.

It seems that this concept expresses the requirement to share the risks associated with modern technical production fairly between the injured party and the producer and to protect the safety and health of consumers²². On the other hand, it must not be forgotten that Directive 85/374, by harmonising legal solutions concerning a producer's liability in the EU market, should lead to the unification of case law in this area²³. As the following considerations will show, this effect will not necessarily be achieved.

²⁰ From laboratory to patient: the journey of a medicine assessed by EMA, https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorized-medicine_en.pdf.

²¹ CJEU: *Boston Scientific Medizintechnik GmbH*, joined Cases C-504/13 and C-504/13, EU:C:2015:148, paras 37, 38. See more: Richard Goldberg, *Medical Product Liability and Regulation* (Oxford: Hart Publishing, 2013), *passim*.

²² See point 2 of the preamble to the Directive 85/374/EEC: The position of the victim would have to be strengthened.

²³ As Brosset rightly points out: '... the ECJ's ruling does nothing to unify this case law, despite pointing out that national courts must take into account the principle of legal certainty, whose corollary is the principle of protection of legitimate expectations', Brosset, "Distinguishing between law and science," 1915.

3. COMMENTARY IN THE CONTEXT OF CIVIL LIABILITY FOR VACCINE DAMAGE IN FRENCH LAW

The problem of compensation for post-vaccination damage is regulated specifically within the French legal system, mainly due to the separation of types of vaccinations into those which are compulsory and those which are non-compulsory²⁴. Damages resulting from compulsory vaccination are controlled by a special compensation process²⁵, while liability for damages resulting from non-compulsory vaccination are mainly regulated under civil liability laws for defective products.

In the French legal system, as in the legal orders of other EU Member States (including Poland), the latter liability is based on risk, and the burden of responsibility is usually placed on the producer and sometimes also certain other operators²⁶. The manufacturer shall be liable if damage to

²⁴ The creation of specific liability rules is limited by Article 13 of Directive 85/374/EEC, according to which: ‘This Directive shall be without prejudice to the rights of the injured party under the contractual or non-contractual liability or special liability regime existing at the time of notification of the Directive. The case law of the CJEU has recognised that a competitive system regulating liability for damage caused by defective products can function alongside the system introduced by a Directive if: it existed already before its entry into force, and its application is limited to a specific sector of production, e.g. medical products (this was the case in France and Germany) or if its liability is based on a different principle than the regime introduced by the Directive and is therefore dependent on fault or constitutes contractual liability (e.g. warranty for hidden defects of goods). See CJEU: *González Sánchez*, Case C-183/00 EU:C:2002:255; *Novo Nordisk Pharma GmbH*, Case C-310/13. ECLI:EU:C:2014:2385.

²⁵ In cases where the hepatitis B vaccination was compulsory, e.g. in the course of a professional activity, compensation was paid under the Code de la Santé Publique rules (L. 3111–9 CSP), see French Conseil État, Judgment of 9 March 2007, *Recueil Dalloz* (2007): 2204.

²⁶ In addition to the manufacturer, the seller of the product, the manufacturer of the raw material used, the person claiming to be the producer and any other professional supplier of the product (wholesaler) may be responsible. See. Article 3 of the Directive 85/374 and the national solutions based on its provisions.

person²⁷ or property (intended and used for private purposes) is caused by a defective product placed on the market by him²⁸.

Pursuant to the provisions of this directive, the manufacturer bears responsibility for introducing into the market a product which is potentially hazardous and might prove harmful as a result of its use. In the case of vaccines, there is no typical defective product. The manufacturers of such products, knowing the potential risk factors, have the responsibility to disclose information related to this, while providing proper guidance and warnings as to its use²⁹. It is necessary to monitor the use of the product as soon as it is placed on the market³⁰.

The provision of Article 1245–8 of the French Civil Code³¹, similarly to the aforementioned article 4 of the Directive 85/374, has made the person seeking damages responsible for providing evidence of the defect and proving the causal relationship between defect and damage. However, in practice, the rules described above concerning the distribution of the burden of proof are not treated too strictly, in particular they are mitigated by presumptions leading to a reduction the ‘standard of proof’ in court proceedings³².

²⁷ Personal injury is subject to compensation if it is pecuniary loss, regulations on compensation for non-pecuniary loss, the Directive leaves it up to the national regulations.

²⁸ The responsibility for the introduction a defective product into the market according to the principles adopted in the Directive was introduced by the French legislature with a 13-year delay (therefore, France was responsible for non-implementation of the Directive). Finally, after long discussions, the act of 19 May 1998 (loi n° 98–389) was adopted and its content was incorporated into the French Civil Code.

²⁹ See also The Spanish Supreme Court, Judgment of 10 July 2014, *RJ* (2014): 4318.

³⁰ See also comparative studies: Duncan Fairgrieve et al., “Product Liability Directive,” in *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies*, ed. Piotr Machnikowski (Cambridge–Antwerp–Portland: Intersentia, 2016), 17–108.

³¹ Previously, Articles 1386–9 French Civil Code, changed by the ordinance n° 2016–131 of 10 Feb. 2016 (Art. 2).

³² In the French judiciary the presumption of a causal relation is assumed, especially in medical compensation cases. See: Yvonne Lambert-Faivre and Stéphanie Porchy-Simon, *Droit du dommage corporel. Systèmes d’indemnisation* (Paris: Dalloz, 2012), 489; Geneviève Viney, “La responsabilité des fabricants de médicaments et de vaccins: les affaire de la preve,” *Receuil Dalloz* 7 (2010): 391–396.

The notion of the “burden of proof” (*onus probandi*) belongs to the basic canon of legal concepts and denotes which party will suffer the negative consequences of not proving a given fact in a court dispute, while the concept of ‘standard of proof’ is much less clear for lawyers educated in countries whose legal systems are part of civil law orders (like France or Poland)³³. In general, the ‘standard of proof’ is assumed to mean the extent or degree of certainty (probability) of the truthfulness of the facts presented, which must be apparent from the evidence presented in the case, leading to the assumption that the fact is proven. This definition makes it possible to distinguish between ‘the burden of proof’ and ‘the standard of proof’. In the commented judgment, the Court confirmed this distinction by considering that, the principle of procedural autonomy granted to each Member State implies the possibility of laying down a set of detailed conditions for the taking of evidence and the evidential value of that evidence before the competent court³⁴. While this court is bound by the burden of proof rule established in law, the required standard of proof is seated in the internal legal order of each Member State.

Thus, in its judgement, the Court of Justice did not prejudice the existence of a causal link between vaccination and Multiple Sclerosis disease (MS); it merely sanctioned the practice of state courts by adopting the evidentiary rules established in case law concerning the possibility of considering the version presented by the plaintiff. To clarify, it is worth noting that, in Advocate General Bobek’s view, the French term “présomption” does not mean a legal presumption but rather should refer to what he calls circumstantial evidence or indirect evidence³⁵, i.e. a situation where a fact

³³ It is indicated that this concept derives from common law systems. See: Ewa Bagińska, *Odpowiedzialność deliktowa w razie niepewności związku przyczynowego. Studium prawnoporównawcze* (Toruń: TNOiK, 2013), 44.

³⁴ The verdict was widely commented in the French literature, see: Béatrice Espesson-Vergeat and Pierre. A. Morgon, “A propos de la preuve de la défectuosité du vaccin. Regards sur la position de la Cour de Justice de l’Union européenne dans un contexte de la politique vaccinale en pleine ébullition,” *Revue générale de droit médical* 64 (2017): 123–137; Paul Véron and François Violla, “Contentieux du vaccin contre l’hépatite B : l’autonomie de la causalité juridique validée par la Cour de Justice de l’Union européenne,” *Revue générale de droit médical* 65 (2017): 223–233.

³⁵ See also explanations Brossset, “Distinguishing between law and science,” 1904.

or set of facts is established, and from it is inferred the likelihood of occurrence of another fact or set of facts”³⁶.

French courts have for years been confronted with the problem of liability claims for post-vaccination damages³⁷. The surge of such complaints into the courts was linked to widespread rumours among the French public, connecting the Hepatitis B vaccination of a large part of the adult population (around 20 mln.) in the mid-1990s, with an almost near two-fold increase in the number of newly confirmed cases of MS disease that later followed³⁸.

In its judgement of 2 May 2001, the Court of Appeal in Versailles became the first to adopt the presumption of defectiveness of the product (vaccine) and causal link between the vaccine and the plaintiff’s injury.³⁹ The argument expressed by the Court for taking on evidence regarding post-vaccination damages, was subsequently applied by the French Court of Cassation and used in verdicts that it handed down on 23 Sept. 2003⁴⁰ and 27 Feb. 2007⁴¹.

³⁶ The opinion of Advocate General Bobek, delivered on 7 March 2017; EU:C:2017:176 (para 32).

³⁷ See also the jurisprudence of administrative courts at that time. In the judgement of the French Conseil d’Etat of 9 March 2007, ref. n° 267635, ref. n° 278665, ref. n° 285288, ref. n° 283067 (cases were joined for recognition), *Recueil Dalloz* (2007): 943 and 2204. The Court indicated that having taken into consideration the short period of time elapsed between injection (vaccination) in March 1991 and emergence of the symptoms leading to a clinical diagnosis indicating Multiple Sclerosis on the one hand, and the patient’s previous state of good health and absence of any features indicative of the development of this disease on the other, the adoption of a relationship between the two events is possible.

³⁸ See: Dominique Le Houézec, “Evolution of multiple sclerosis in France. B vaccination,” *Immunologic Research* 60 (2014): 219–225; <https://doi.org/10.1007/s12026-014-8574-4>. See also: Critical reports, accusing the author of the wrong methodology of the study, i.e. not taking into account other factors that may have influenced the increase in morbidity, Rodolfo E. Bégué, “Critical reports,” *Immunologic Research* 5 (2015).

³⁹ See: Faivre-Lambert and Porchy-Simon, *Droit du dommage corporel*, 38, 822.

⁴⁰ The French Court of Cassation, Judgment of 23 Sept. 2003, ref. n° 188, *Recueil Dalloz* (2004): 898.

⁴¹ The French Court of Cassation, Judgment from 27 Feb. 2007, ref. n° 06–10.063, *Recueil Dalloz* (2007): 2899 (note Philippe Brun).

As it seems, the most representative judgement for such cases falling under civil jurisdiction, was that rendered by the French Court of Cassation on 22 May 2008⁴² in which the court accepted that "...if an action for damages due to a defective product requires proof of damage, product defect and causal relation between defect and damage, such evidence may be an outcome of presumption, if the evidence presented is serious, consistent and accurate"⁴³. The French Court of Cassation in this case ruled that the mere reliance by the court on the first instance where the lack of certain statistical and scientific evidence as to the existence of a causal link between the vaccination and sudden development of the disease, is not sufficient to dismiss the action. The court hearing the case should take into account all of the circumstances of the case, and may use in the process of proving the presumption of fact. In light of this ruling, meeting the standard of proof requires the plaintiff to prove that the following circumstances took place: temporal compliance between the time inoculation took place and appearance of the first symptoms of the disease (the time of coincidence)⁴⁴, no other risk factors (good state of health and lack of predispositions of the plaintiff - also defined as the lack of personal and family history of such illness), or the absence of other, unexplainable, causes leading to development of such illness⁴⁵. This judgment of the French Court of Cassation was part of a trend which clearly separates two con-

⁴² The French Court of Cassation, Judgment of 22 May 2008, *Receuil Dalloz* (2008): 1544; *Revue trimestrielle de droit civil* (2008): 492.

⁴³ Our translation. Text in french: "Si l'action en responsabilité du fait d'un produit défectueux exige la preuve du dommage, du défaut et du lien de causalité entre le défaut et le dommage, une telle preuve peut résulter de présomptions, pourvu qu'elles soient graves, précises et concordantes".

⁴⁴ In Polish law, time coincidence is also accepted if an adverse post-vaccination reaction occurs after vaccination; it does not directly mean that we are dealing with a causal relationship and consequently with liability for damage. There is no special policy in compensation for post-vaccine damage in Polish law although discussions on the subject are ongoing.

⁴⁵ The CJEU also suggests taking into account the existence of a significant number of reported cases of the disease which occurred following such vaccines being administered, which, in light of existing statistical studies, may give rise to doubts. These premises are also extensively discussed in the medical perspective: Espesson-Vergeat, Morgon, "A propos de la prevue," 128–131.

cepts: scientific causality (also known as material causality) from the causal connection of the juridical nature⁴⁶. Therefore, if there is a state of scientific uncertainty in the assessment of the causes of damage, the court should examine whether a causal link of a juridical nature (between the event and the damage) could have occurred, while the material links described by experts on the basis of current medical knowledge may be of auxiliary importance, without yet determining the existence or absence of a juridical link. In this context, the question arises as to what rank should be given to ‘the auxiliary importance of scientific evidence’. For example, in its judgement of 27 Feb. 2007, the French Court of Cassation qualified that: “... scientific uncertainty is not allowing to carry a causal relationship between the vaccination preventing Hepatitis B virus and the onset of multiple sclerosis from being recognized”.

In its judgement of 24 Sept. 2009⁴⁷, the French Court of Cassation ruled that primacy had to be given to the scientific data available, stating that presumptions by themselves could not meet the burden of proof in establishing a causal relationship between Hepatitis B vaccine and the development of MS disease at that time, thus dismissing the case against the vaccine’s manufacturer. Similarly, in a judgement handed down on 25 Nov. 2011,⁴⁸ the Court of Cassation ruled that the circumstances of the case did not allow the court to assign responsibility to the vaccine manufacturer.

Finally, it should be noted that also in the case commented on, on the basis of which the ruling of the CJEU judgment of 21 June 2017 was issued, the claims were not finally recognised by the French Court. The assessment of the facts by the judge on the basis of serious, specific and con-

⁴⁶ See: Grégory Maitre, “L’intercitude sur la causalité scientifique est indifférente à l’appréciation de la causalité juridique,” *Receuil Dalloz* 15 (2010): 947.

⁴⁷ The French Court of Cassation, Judgment of 24 Sept. 2009, ref. n° 08–16097, *Receuil Dalloz* (2009): 2426. Similarly, in the judgments of 25 Nov. 2010 and 28 April 2011, ref. n° 10–15289.

⁴⁸ The French Court of Cassation, Judgment of 25 Nov. 2011, ref. n° 09–16556, *JCP* (2011): 79. See: Philippe Brun, “Raffinements ou faux-fuyants? Pour sortir de l’ambiguïté dans le contentieux du vaccin contre le virus de l’hépatite B (à propos d’un arrêt de la Cour de Cassation du 25 novembre 2010),” *Receuil Dalloz* 5 (2011): 316–322.

sistent presumptions did not lead to the conclusion that the damage could be attributed to the use of a defective medical product⁴⁹.

4. COMMENTARY IN THE CONTEXT OF CIVIL LIABILITY FOR VACCINE DAMAGE IN POLISH LAW

Polish law does not provide for a special compensation procedure, as in French law, in cases involving losses following mandatory vaccinations⁵⁰. Both in the case of mandatory and optional vaccinations, the rules of liability for damages, set out in the Polish Civil Code, apply⁵¹. They al-

⁴⁹ Let us note the far-reaching discrepancies between the judgments of the courts of particular instances in case *W. and others v. Sanofi Pasteur*. In the verdict of the First Instance Court in Nanterre of 4 Sept. 2009, the action of the deceased's family was included, while the Court of Second Instance (Appellate Court in Versailles, Judgment of 10 Feb. 2011) did not agree with the plaintiffs' argument because they did not show product defects (vaccines). The French Court of Cassation passed the case for re-examination by its verdict of 26 Sept. 2012 to investigate whether the circumstances that determined the existence of a causal link did not support the defective nature of the product. As a result, the Paris Court of Appeal in its judgment of 7 March 2014, on hearing the case, stated that the evidence provided could not constitute, jointly or separately, serious, precise and consistent presumptions that would allow the recognition of the existence of a relationship. A cassation appeal was lodged against that judgment, which ended with the suspension of the proceedings and the court referred the prejudicial question to the CJEU (French Court of Cassation, Judgement of 2 Nov. 2015). Finally, the claim was dismissed. See: French Court of Cassation, Judgment of 18 Oct. 2017, ref. n° 14–18118, ref. n°15–20791, *Recueil Dalloz* (2017): 2096, *RTD civ.* (2018): 140–144 (note Patrice Jourdain). See also: Stéphane Prieur, "Défaut et causalité dans la contentieux de la vaccination contre l'hépatite B : suite, mais (probablement) pas fin," *Gazette du Palais*, November 21, 2017, 23–25.

⁵⁰ The special compensation procedure provided for in the Act of 6 Nov. 2008 on the Patients' Rights and the Patient's Ombudsman (consolidated text: Journal of Laws of 2019 r., item 1127 as amended) applies to the so-called 'medical events', which also include the use of medicinal products. The provisions of the Act provide for the possibility of establishing the existence of a 'medical event' only in relation to hospitals, which at the outset excludes the possibility of applying them to ambulatory vaccinations (in Poland within the framework of basic health care). This means that this mode can be used for post-vaccine damage to a very limited extent.

⁵¹ The Polish Civil Code (Act of 23 April 1964, Journal of Laws of 1964, No° 210, item 2135 as amended). In short: Pol.Civ.Code. See more: Ewa Bagińska, "Poland," in

low, depending on the actual state of affairs, the patient to sue the medical establishment (medicinal entity)⁵² or vaccine manufacturer.

The vaccine manufacturer's liability is based on the provisions of Articles 4491–44911 Pol.Civ.Code, introduced into the Code as a result of the implementation of the European Directive 85/374. The similarities between Polish and French law regulations result from the implementation of Directive 85/374.

Pursuant to Article 4491§1 of the Pol.Civ.Code.: “Anyone who manufactures a dangerous product within the scope of his business activity is liable for damage caused to anyone by that product”⁵³. That procedure may be applied both when a vaccination was compulsory and when it was optional, if the claimant proves: firstly, that the vaccine was a dangerous product within the meaning of Article 4491§3 Pol.Civ.Code; secondly, that damage was caused, and thirdly that there is an adequate causal link between the vaccination and the damage suffered by the claimant⁵⁴.

European Tort Law: Basic Texts, eds. Ken Oliphant, and Barbara Steininger (Vienna: Jan Sramek Verlag, 2011), 231.

⁵² The medical establishment is responsible if the vaccination has been carried out contrary to current medical knowledge and without due diligence, In this case, we are dealing with a classic fault-based liability, whose rules are set out in Articles 415, 416, 430 of the Pol.Civ.Code. See more: Kinga Bączyk-Rozwadowska, “Medical malpractice and compensation in Poland,” *Chicago-Kent Law Review* 86, Issue 3 (2011): 1227. In recent years the question of the responsible entity has become the subject of discussion. It has been proposed to introduce the responsibility of the State, as the entity which has decided in statutory provisions that certain types of vaccination are obligatory. See f.e. Mirosław Nesterowicz, “Glosa do wyroku Sądu Okręgowego w Lublinie z 4.07.2002, I C 656/99,” *Prawo i Medycyna* 3 (2004): 128; Urszula Drozdowska, “Odpowiedzialność odszkodowawcza za niezawinione skutki szczepień ochronnych – uwagi de lege lata i de lege ferenda,” *Białystok Legal Studies* 17 (2017): 99.

⁵³ See more: Ewa Bagińska, “Poland,” in *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies*, ed. Piotr Machnikowski (Cambridge-Antwerp-Portland: Intersentia, 2016), 377–406.

⁵⁴ To establish causal effect, in the first instance it is imperative to prove the occurrence of harm in relation to an event within an agreed factual state *conditio sine qua non*. It is equally important to establish that the harm caused was a ‘natural’ consequence of an event, according to ‘selection by consequences’ (Article 361 § 1 Pol.Civ.Code). Obviously, the course here is to evaluate a causal relationship, thus allowing the establishment of the proper liability of the defendant. It is worth noting that, unlike Polish law, French law

The standard of proof of these circumstances is treated rigorously in the case law of Polish courts⁵⁵, but Polish civil procedure allows for the use of *prima facie* evidence, as well as the use of factual presumptions to establish the causal link and product defectiveness.

Let's start with *prima facie* evidence. The inference of *prima facie* evidence (at first sight)⁵⁶ is the result of the concept of representatives of the legal doctrine, who recognized that in some cases the statement of the dependence between facts arises "by itself", which means that the court bases its findings on the typical, most likely course of events. Applying this reasoning to vaccination, the question must be asked: Is it possible to deduce from the mere fact that the patient has been given a vaccine (and therefore a substance that may cause side effects) that there is a causal link between the injury and the vaccination?

The answer to this question must be in the negative. The opposite view seems far too far-reaching and unjustified even in the face of the directive's demand for far-reaching protection for victims from dangerous products. However, if the question were to be whether a causal link could be deduced from the mere fact that a defective vaccine has been administered to a patient? This, given the definition of a defect in a product as a non-safety product that can be expected, given the normal use of the product, the use of this design could not be excluded. From the point of view of liability, it is therefore important to determine the safety of the product from the point of view of medical knowledge. As the French cases show, the evidence that the product has passed clinical trials is not always sufficient. In the case of adverse events which are not detected in clinical trials, a legal procedure must be initiated. In the Polish legal system, both the doctor

applies both the theory of equivalence of conditions and the theory of adequate causation. Without going into the differences between the two theories, from the point of view of the issue under consideration the results of the findings of the *sine qua non* test are the most important. This is applied in both theories.

⁵⁵ As a rule, the burden of proof for these circumstances lies with the patient (Article 6 Pol.Civ.Code). Unfortunately, Polish civil law does not apply in civil cases the test known in common law systems: the evidence prevalence test (probability balance). This test as opposed to the 'beyond all doubt' test makes it possible to establish causal regularity in a less stringent manner.

⁵⁶ In *common law* it is the doctrine of *res ipsa loquitur* – "the thing speaks for itself".

and the patient have the right to report undesirable effects of medicinal products. Although the probability of the existence of a defect itself should not lead to a reversal of the burden of proof (proof of the defect lies with the victim), information on the probability of the existence of a defect in case-law leads to a ‘specific reverse’ of the burden of proof. A presumption of a causal link is then raised which the defendant can deny by showing that the damage could have arisen for other reasons for which he is not responsible.

In other words, it must be shown in the proceeding that whether a substance is capable of causing a particular injury or condition in the general population and that whether it actually caused a particular individual’s injury⁵⁷.

This may be demonstrated by way of factual presumptions, which consist in the court inferring other facts from certain established facts, e.g. concerning the probability that a specific disease relied on by the claimant may be caused by the application of a defective medicinal product. The basis for the application of the presumptions is Article 231 of the Polish Civil Procedure Code⁵⁸ allows a court to consider presumptive facts derived from known facts, provided that such presumptions are always relevant to the case, sound in argument and believable in terms of evidentiary value. While such actual pre-accumulation simplifies the proof of facts process, it requires the recognition that if the presumption derived from certain facts is uncertain (e.g. because a different version of events is also possible) it cannot constitute the basis for making factual findings relevant to the resolution of the dispute⁵⁹.

This is exemplified by a case pending before the District Court in Warsaw⁶⁰, in which the patient, a person suffering from rheumatoid arthritis for years, was given a drug called Vioxx (active substance: rofecoxib),

⁵⁷ Similarly, in line with the principles adopted in *common law* systems in the context of medicinal product liability, see: Richard Goldberg, “Epidemiological uncertainty, causation, and drug product liability,” *McGill Law Journal* 4 (2014): 781–782.

⁵⁸ Act of 17 Nov. 1964 – Polish Civil Procedure Code (consolidated text: Journal of Laws of 2019, item 1460 as amended).

⁵⁹ Beata Janiszewska, “Dowodzenie w procesach lekarskich (domniemania faktyczne i reguły wnioskowania prima facie),” *Prawo i Medycyna* 2 (2004): 110.

⁶⁰ Provincial Court in Warsaw, Judgment of 12 Feb. 2016, ref. n° II C 1215/06.

manufactured by the defendant. In 2005, the patient underwent an acute myocardial infarction, which - in her opinion - resulted from the use of the aforementioned medicine. The Court found that the use of medicinal product Vioxx after 18 months increased the risk of myocardial infarction, which moreover was the basis for its withdrawal from the market in September 2004. Previously, scientific research had shown that there was a link between drugs from the group of selective cyclooxygenase-2 inhibitors (e.g. drug Vioxx) and the occurrence of cardiovascular incidents in patients. According to the Court, the withdrawal of the drug from the world market and the discontinuation of clinical trials following analysis of results indicating an increased risk of thrombotic complications, including heart attacks and strokes in patients taking this medicine, could have established that the product was dangerous and that its use could have caused the indicated diseases. However, this belief could not have led to producer liability in this particular case because of the lack of a causal link between the patient's use of the medicine and the myocardial infarction suffered and the consequent permanent disorder of health⁶¹.

Although the case presented does not concern the use of a vaccine but a medicine, this may be an example of how to establish a causal link in cases under the rules on liability for dangerous products. In this case, as in other medical cases, the courts are forced to use the knowledge of professional experts. Since in life sciences it is not possible to predict with certainty whether a given cause led to specific effects, in medical disputes

⁶¹ The Court, based on expert opinions, found that therapy with the drug rofecoxib was not the cause of myocardial infarction due to the significant time lag between the time it was used and the failure of the claimant's health. At the same time, it pointed to the existence of a number of other risk factors of myocardial infarction in the claimant. According to the court, even if the use of the medicine could have accelerated myocardial infarction, that fact does not lead to the conclusion that the use of the medicine was a *sine qua non* condition giving rise to harm. Therefore, the Court did not find a factual basis for a causation between the plaintiff's injury and the use of a dangerous medicine. A similar verdict was passed in a case decided by The Federal Full Court of Australia (decision in Peterson's case, see: The Australian Federal Court, Judgment of 12 Oct. 2011, case *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson: Heart Risk and Vioxx*). This Court concluded that while the epidemiological evidence meant that it was possible Vioxx had caused Peterson's myocardial infarction, there were other strong potential causes, such as "age, gender, hypertension, hyperlipidaemia, obesity, left ventricular hypertrophy and history of smoking".

the cause-and-effect relationship does not have to be established categorically (with 100% certainty). After numerous considerations, the jurisprudence has determined that this should be a high level of probability⁶². This case does not allow the problem of grading the level of probability to be presented because the court found that there is no specific causation, despite the fact that the experts did not rule out the possibility of accelerating the disease process, which resulted in myocardial infarction, as a result of taking a drug. In this case, the lack of causation was determined by a different - in the court's opinion - more probable course of events which had nothing to do with the use of the medicine.

The problem of determining the level of probability of a causal relationship can be found in other cases settled by courts of appeal in recent years⁶³. Although these were post-vaccination cases involving hospital liability, the problem of establishing a causation between vaccination and injury was similar. The characteristic of these cases is that expert testimonies are often not strong enough. They are seen as insufficient because they cannot prove or exclude the possibility of disease development as a result of the use of a vaccine. It is worth noting that even in cases where a vaccination could be shown to have acted as a 'trigger agent', the courts had doubts as to whether other factors could not have influenced the promotion of the disease.

In the judgment of the Court of Appeal in Łódź of 30 November 2012⁶⁴, the Court indicated that the occurrence of such additional circumstances as: complicated pregnancy and foetal growth disorders may constitute an additional risk factor for complications after vaccination. However, immediately after the admission of the claimant's minor to hospital, the doctor entered the following into the medical records: post-vaccination complication. This entry became the reason for the presumption that there is a causal link between the occurrence of the disease and vaccination.

⁶² Appellate Court in Kraków, Judgment of 8 Jul. 2016, ref. n° I ACa 360/16; Appellate Court in Katowice, Judgment of 5 May 2016, ref. n° I ACa 431/15.

⁶³ Appellate Court in Poznań, Judgment of 22 Jan. 2013, ref. n° I ACa 1160/12, Appellate Court in Łódź, Judgment of 30 Nov. 2012 r., ref. n° I ACa 1140/12; Appellate Court in Kraków of 4 Sept. 2012, ref. n° I ACa 676/12, I ACz 1011/12.

⁶⁴ Appellate Court in Łódź, Judgment of 30 Nov. 2012, ref. n° I ACa 1140/12.

Otherwise, in the judgment of the Court of Appeal in Poznań of 22 January 2013⁶⁵, the Court found no causal link between the disease and vaccination. The Court concluded that the causes of cerebral infirmity should be attributed to premature childbirth and immaturity of the foetus and probably to latent intracranial bleeding. The medical experts pointed that cerebral palsy in the child developed independently of the vaccine injection, probably the vaccine was like a 'trigger mechanism' and revealed symptoms of paralysis, which would also reveal itself later.

Reading the case law on post-vaccination injuries issued by Polish courts, it can be concluded that it is difficult for the claimant to meet the standard of proof. Claims are recognised, when the court - taking into account the expert opinion - has no doubts as to the high degree of probability that there is a causal link between the damage and the vaccine injection. Therefore, post-vaccine damage cases are characterised by a high degree of uncertainty as to the outcome of the case.

5. CONCLUSION

The European Court of Justice has opened the possibility for a compensation claim, even in cases where a dominant scientific theory claims that there is no scientific evidence of a link between vaccination and illness. As a result, procedural solutions (such as the required standard of proof, the admissibility of *prima facie* evidence reasoning and other solutions to cases of an uncertain causation) remain matters for national law to resolve.

Respect for procedural autonomy leads to the conclusion that, where the conditions led the court to consider: first, that the administration of the vaccine is the most reliable explanation for the outbreak of the disease, and, second, that the vaccine does not provide a level of protection which can reasonably be expected in light of all the circumstances of the case, the manufacturer may be held liable for damages.

The question arises as to whether this is in accordance with the spirit of Directive 85/374/EEC?

⁶⁵ Appellate Court in Poznań, Judgment of 22 Jan. 2013, ref. n° I ACa 1160/12.

One of the most important objectives, in the essence of European Union law, is to protect and promote the development of the single market in accordance with its four fundamental freedoms: the free movement of goods, capital, services and labour. In the context of consumer protection (an important element of the functioning of the single market), Directive 85/374 emphasises that ‘...the liability of a producer for damage caused by defectiveness of his products is necessary because existing divergences may distort competition and affect the movement of goods within the single market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property’.

The conclusion of the CJEU case law, including the Sanofi Pasteur judgment, is clear and appears to fully achieve the purpose outlined in Directive 85/374, which is to ensure consumer safety. The concern for consumer protection is clearly expressed in the preamble to the Directive in the following terms: “to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect”.

The analysis of the current CJEU case law indicates that it is the individual interests of the vaccination victim as a consumer of medical services that have become the most important interpretative motive for Directive 85/374. They are undoubtedly interpreted as one of the overriding interests and the protection provided by EU law, in particular the provisions of Directive 85/374 and actions such as the decision taken by the Court of Justice of the European Union, serve to support this idea. However, the Court does not seem to have noticed that the adoption of the latter principle may lead to significant differences in the scope of judgments in similar cases in European countries that are members of the EU. The above presented jurisprudence of Poland (as opposed to some French rulings) indicates that it would be rather unacceptable to claim that the uncertainty of causation with regard to whether a given medicinal substance is at all capable of causing a specific disease is legally indifferent to the assessment of legal causality.

It is certainly worth noting that human health is regarded as a highly ranked value in the hierarchy of individual rights. As far as consumer attitudes are concerned, there is a certain trend towards increasing levels

of entitlement in health-related situations and, at the same time, towards patients seeking alternative methods of treatment.

There is an interesting preliminary ruling currently pending before the CJEU in which the national court asks: “Where a daily newspaper publishes inaccurate health advice in a daily column written by an independent newspaper columnist, can that newspaper be sued on the basis that it has distributed a defective product within the meaning of Council Directive 85/374/EEC (2) (‘the Product Liability Directive’) when a reader of the newspaper subsequently claims that she has suffered physical injury as a result of following that advice?”⁶⁶. This case concerned the publication in a newspaper of advice, signed by a herbalist, according to which fresh, coarsely grated horseradish could help relieve the pain caused by rheumatism. Painful areas should first be rubbed with thick vegetable oil or pork lard, then a layer of grated horseradish should be applied and pressed. This compress can be left on for two to five hours and then removed. Its application has a positive draining effect. The confusion concerned the time-period of action of such a compress. The correct value is two to five minutes. According to the Advocate General, the answer should be negative, mainly because a claim of this kind falls outside the scope of the Product Liability Directive. It is essentially an action in relation to the provision of a service – advice to consumers contained in a newspaper column – which does not concern a newspaper qua physical product. It cannot therefore be said that any physical injuries which the applicant suffered were the result of a defect in a product as those terms are used in the Product Liability Directive⁶⁷.

However, it should be noted that in the era of “Dr. Google”, which means free access to unverified and often questionable sources of medical knowledge, the patient is exposed to the danger of using various methods of treatment that are not scientifically recognised or evidenced.

It will therefore be interesting to observe further rulings on compensation for damage caused by medical products, including vaccines. Once

⁶⁶ Request for a preliminary ruling from the Oberster Gerichtshof (Austria) lodged on Feb. 2020, VI v. Krone-Verlag Gesellschaft mbH & Co KG (Case C-65/20).

⁶⁷ Opinion of Advocate General Hogan delivered on 15 April 2021(1). Case C65/20, VI v. Krone-Verlag Gesellschaft mbH & Co KG, ECLI:EU:C:2021:298.

the window is opened, it can be closed again and may also cause a strong draught. The future will show.

REFERENCES

- Bagińska, Ewa. "Poland." In *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies*, edited by Piotr Machnikowski, 377–406. Cambridge-Antwerp-Portland: Intersentia, 2016.
- Bagińska, Ewa. "Poland." In *European Tort Law: Basic Texts*, edited by Ken Oliphant, and Barbara Steininger, 191–200. Vienna: Jan Sramek Verlag, 2011.
- Bagińska, Ewa. *Odpowiedzialność deliktowa w razie niepewności związku przyczynowego. Studium prawnoporównawcze*. Toruń: TNOiK, 2013.
- Bączyk-Rozwadowska, Kinga. "Medical malpractice and compensation in Poland." *Chicago-Kent Law Review* 86, Issue 3 (2011): 1217–1261.
- Black Corri, Kaye James A., and Jick Hershel. "Relation of childhood gastrointestinal disorders to autism: nested case control study using data from the UK General Practice Research Database." *British Medical Journal* 325 (2002): 419–421.
- Brosset, Estelle. "Distinguishing between law and science in terms of causation and the hepatitis B vaccine: *W. v. Sanofi Pasteur*." *Common Market Law Review* 55 (2018): 1899–1915.
- Brosset, Estelle, and Elsa Supiot. "Le vaccin contre l'hépatite B: l'autonomie de la preuve juridique en l'absence de consensus scientifique devant la Cour de justice de l'Union européenne." *Revue des contrats* 4 (2017): 662–668.
- Brun, Philippe. "Raffinements ou faux-fuyants? Pour sortir de l'ambiguïté dans le contentieux du vaccin contre le virus de l'hépatite B (à propos d'un arrêt de la Cour de Cassation du 25 novembre 2010)." *Receuil Dalloz* 5 (2011): 316–322.
- Büyüksagis, Erdem. "Arrêt 'Sanofi': la responsabilité du fait des produits défectueux appliquée aux vaccins, une responsabilité objective basée sur des présomptions." *Journal de droit européen* 244 (2017): 395–397.
- Cairó, Ruiz. "The Lack of Medical Research Does Not Prevent an Injured Person from Proving the Defect of a Product and the Causal Link between the Defect and the Damage." *European Journal of Risk Regulation* 4 (2017): 798–803.
- Deer, Brian. "How the Case Against the MMR Vaccine Was Fixed." *British Medical Journal* 342 (2011): 77–82.
- Drozdzowska, Urszula. "Odpowiedzialność odszkodowawcza za niezawinione skutki szczepień ochronnych – uwagi de lege lata i de lege ferenda." *Białystok Legal Studies* 17 (2017): 99–112.

- Duncan, Fairgrieve, Geraint Howells, Peter Møgelvang-Hansen, Gert Straetmans, Dimitri Verhoeven, Piotr Machnikowski, André Janssen, and Reiner Schulze. "Product Liability Directive." In *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies*, edited by Piotr Machnikowski, 17–108. Cambridge–Antwerp–Portland: Intersentia, 2016.
- Espesson-Vergeat Béatrice, and Pierre A. Morgon. "A propos de la preuve de la défec-tuosité du vaccin. Regards sur la position de la Cour de Justice de l'Union européenne dans un contexte de la politique vaccinale en pleine ébullition." *Revue générale de droit médical* 64 (2017): 123–137.
- Godlee, Fiona, Jane Smith, and Harvey Marcovitch. "Wakefield's article linking MMR vaccine and autism was fraudulent." *British Medical Journal* 342 (2011): 64–66.
- Goldberg, Richard. "Epidemiological uncertainty, causation, and drug product liability." *McGill Law Journal* 4 (2014): 777–818.
- Goldberg, Richard. "Vaccine damage and causation: a Franco-American comparison." *Journal de Droit de la Santé et de l'Assurance Maladie* 1 (2014): 134–137.
- Houézec, Dominique Le. "Evolution of multiple sclerosis in France. B vaccination." *Immunologic Research* 60 (2014): 219–225.
- Jagielska, Monika. "Odpowiedzialność za produkt." In *System Prawa Prywatnego*, t. 6, edited by Adam Olejniczak, 869–934. Warsaw: C.H. Beck, 2009.
- Janiszewska, Beata. "Dowodzenie w procesach lekarskich (domniemania faktyczne i reguły wnioskowania prima facie)." *Prawo i Medycyna* 2 (2004): 104–129.
- Kalkbrenner, Amy E., Rebecca J. Schmidt, and Annie C. Penlesky. "Environmental chemical exposures and autism spectrum disorders: a review of the epidemiological evidence." *Current Problems in Pediatric and Adolescent Health Care* 44 (2014): 277–318.
- Lambert-Faivre, Yvonne, and Stéphanie Porchy-Simon. *Droit du dommage corporel. Systèmes d'indemnisation*. Paris: Dalloz, 2012.
- Madsen, Kresten Meldgaard, Andres Hviid, Mogens Vestergaard, Diana Schendel, Jan Wohlfahrt, Poul Thorsen, Jørn Olsen, and Mads Melbye. "A population-based study of measles, mumps, and rubella vaccination and autism." *New England Journal of Medicine* 347 (2002): 1477–1482.
- Maitre, Grégory. "L'intercitude sur la causalité scientifique est indifférente à l'ap-préciation de la causalité juridique." *Receuil Dalloz* 15 (2010): 947–951.
- Nesterowicz, Mirosław. "Glosa do wyroku Sądu Okręgowego w Lublinie z 4.07.2002, I C 656/99." *Prawo i Medycyna* 3 (2004): 122–130.
- Prieur, Stéphane. "Défaut et causalité dans la contentieux de la vaccination contre l'hépatite B : suite, mais (probablement) pas fin." *Gazette du Palais*, November 21, 2017, 23–25.

- Rao, T.S. Sathyanarayana, and Chittaranjan Andrade. "The MMR vaccine and autism: sensation, refutation, retraction, and fraud." *Indian Journal of Psychiatry* 53 (2011): 95–96.
- Rizzi, Marco. "A Dangerous Method: Correlations and Proof of Causation in Vaccine Related Injuries." *Journal of European Tort Law* 9 (2018): 289–307.
- Sackett David L., and Brian R. Haynes. "On the need for evidence-based medicine. EBM Notebook." *Evidence-Based Medicine* 1 (1995): 5–6.
- Shetreet, Shimon. "On Assessing the Role of Courts in Society." *Manitoba Law Journal* 10 (1980): 357–414.
- Siddiqui, Mariam, Daniel A. Salmon, and Omer B. Saad. "Epidemiology of vaccine hesitancy in the United States." *Human Vaccines & Immunotherapeutics* 9 (2013): 2643–2648.
- Smillie, Laura R., Marc R. Eccleston-Turner, and Sarah L. Cooper. "C-621/15 – W. and others v Sanofi Pasteur: an exemple of judicial distortion and indifference to science." *Medical Law Review* 26 (1) (2018): 134–145.
- Smith, Philip J., Sharon G. Humiston, Edgard K. Marcuse. "Parental delay or refusal of vaccine doses, childhood vaccination coverage at 24 months of age, and the Health Belief Model." *Public Health Reports* 126 (suppl 2) (2011): 135–146.
- Taylor, Brent, Elizabeth Miller, Raghu Lingam, Nick Andrews, Andrea Simmons, and Julia Stowe. "Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study." *British Medical Journal* 324 (2002): 393–396.
- Véron, Paul, and François Vialla. "Contentieux du vaccin contre l'hépatite B : l'autonomie de la causalité juridique validée par la Cour de Justice de l'Union européenne." *Revue générale de droit médical* 65 (2017): 223–233.
- Viney, Geneviève. "La responsabilité des fabricants de médicaments et de vaccins: les affaire de la prevue." *Receuil Dalloz* 7 (2010): 391–396.
- Wakefield, Andrew J., S. H. Murch, A. Anthony, J. Linnell, D. M. Casson, M. Malik, M. Berelowitz, A. P. Dhillon, M. A. Thomson, P. Harvey, A. Valentine, S. E. Davies, and J. A. Walker-Smith. "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children." *Lancet* 351 (1998): 637–641.
- Zerbo, Ousseny, Ana-Maria Iosif, Cheryl Walker, Sally Ozonoff, Robin L. Hansen, and Irva Hertz-Picciotto. "Is Maternal Influenza or Fever During Pregnancy Associated with Autism or Developmental Delays? Results from the CHARGE (Childhood Autism Risks from Genetics and Environment) study." *Journal of Autism Developmental Disorders* 43, no. 1 (2013): 25–33.