



Product Liability, the Right to Health and Effective Consumer Protection

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Outline

- › Introduction to CJEU case law
 - *NW and Others v Sanofi Pasteur*, C-621/15 (2017)
- › The Court's reasoning
 - The right to health
 - Effective (consumer) protection
- › Lessons from national case law
 - United Kingdom
- › Conclusions



NW and Others v Sanofi Pasteur, C-621/15 (2017)





Relevant EU law

Article 1 Directive 85/374

- Producer is liable for damage caused by a defect in their product.

Article 4 Directive 85/374

- Burden of proof is on claimant regarding: damage, defect and causal relationship

Article 35 CFREU

- High level of human health protection in the definition and implementation of all union policies and activities

Article 38 CFREU

- Right to consumer protection

Article 47 CFREU

- Right to an effective remedy and to a fair trial; effective protection



Key issues addressed by CJEU

- > **Proof** of a **causal link** between a defective product and damage suffered by an injured person
- > **Method of proof** whereby certain facts can lead to factual presumption of causation even where it is not established by medical research



Sanofi and the right to health

- > Right to health not explicitly mentioned
- > Protection of consumer health and safety: **key objective** of Directive 85/374
- > Requiring proof of a causal link based on **medical research: inconsistent** with objectives of protecting consumer health and safety and a fair apportionment of risks
 - **Balance:** risk to consumer's health vs risk of producer's liability
- > **Nature and function** of medical products → consumer especially vulnerable



Sanofi and effective consumer protection

- > National rules on how evidence is adduced and appraised must **not undermine effectiveness** of system of liability
- > Making it easier for victim to establish liability through a presumption based on **serious, specific and consistent evidence** is not precluded by Art. 4
- > High evidentiary burden making it **excessively difficult** or even **impossible** to establish producer liability could undermine effectiveness of Directive



Consumer protection and protection of health

- > Evidentiary rules that appear neutral vis-à-vis Art. 4 and Directive's objectives **cannot be applied** in a way that **undermines effectiveness**.
- > **Balance** between risks to consumer and producer → evidentiary rules cannot introduce **unjustified presumptions** against producer
 - Effective protection of producers as well as consumers' health



Lessons from UK case law

- > *John Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited* [2021]
- > Warned against evidentiary burdens undermining effectiveness of a provision both in the **rules and their application**
 - ‘Balance of probabilities’
 - Principle of proportionality
- > Directive seeks “**fair apportionment of risks** inherent in modern technology between the injured person and the producer” (para. 40)



Conclusions

Protection of right to health in product liability cases regardless of explicit mention

Protection of health contributes to protection of consumers (and vice versa)

Limitations to maintain effectiveness of Directive and fairly balance the interests of and risks to both consumers and producers

Higher impact of health vis-à-vis products with abnormally high risk to consumer's health