

CONSENT IN PRODUCT LIABILITY

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PRODUCT LIABILITY: AN INTRODUCTION

- Council Directive 85/374/EEC of 25 July 1985, the product liability Directive
- The Consumer Protection Act 1987
- What about Brexit?

WHAT IS A PRODUCT?

- Consumer Protection Act definition
- Example: human tissue/ organs?
- Concession in *A v The National Blood Authority*
- *Veedfald*

WHO IS A PRODUCER?

- Consumer Protection Act definition
- Medical Devices Regulations
- Can a surgeon be a producer?
- Example: The Combination Prosthesis Hip Litigation

DEFECT AND MEDICAL DEVICES

- Safety not such as persons generally are entitled to expect
- “Legitimate expectation of persons generally” (A v National Blood Authority)
- “Particularly high” safety requirements for medical devices such as pacemakers and ICDs (Boston Scientific)

DEVELOPMENT RISKS DEFENCE

- The most relevant defence in medical device cases
- Also called the “Discoverability” defence
- *Example: JJML Pelvic Organ Prolapse Litigation*

MONTGOMERY AND INFORMED CONSENT

- Landmark Supreme Court decision: informed consent
- *“It is not possible to consider a particular medical procedure in isolation from its alternatives”* (Baroness Hale)

INFORMED CONSENT AND CAUSATION

- “The question of causation must also be considered on the hypothesis of a discussion which is conducted without the patient’s being pressurised to accept her doctor’s recommendation” (*Montgomery*)
- *Chester v Afshar*

GRIMSTONE: MEDICAL DEVICES AND CONSENT

- Permission to appeal to CA granted on 6 June 2016; to be heard in Feb 2017
- Does a surgeon have a duty to inform patients of his/ her connections with medical device companies?
- Does a surgeon have a duty to inform patients that there is a lack of follow-up data for a new medical device?
- Does a surgeon have a duty to advise patients of the advantages and disadvantages of different medical devices?

THE ROLE OF THE MANUFACTURER

- Claims for contribution by surgeons/ Trusts against medical device companies:
 - defective instructions for users and technical advice?
 - defective product information leading to patients not being properly consented?

Thank you

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