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Medical Implants and Product Liability: What is a "Defect" in terms of the Consumer Protection Act 1987

ROBERT MILLIGAN QC & CLARE CONNELLY

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HIP IMPLANTS

- Prosthetic hip replacement surgery is a successful reproducible operation
- It is used to treat those who suffer from hip joint disease, including osteoarthritis and following hip fracture
- Such surgery has clear and well substantiated benefits

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Total Hip Replacement (THR)

- A THR generally involves implantation of three parts/components:-
- The cup or socket (acetabular component), which replaces the worn out hip socket;
- The ball or femoral head, which replaces the head of the femur (thigh bone).
- The stem (femoral component), which fits into the femur.

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Hip Resurfacing

- Femoral Head is not removed
- Femoral head is trimmed and capped with a smooth metal covering, like a mushroom
- The damaged bone and cartilage within the socket is removed and replaced with a metal shell
- The recovery time from this surgery is shorter than THR.

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Component Combinations

- The most common is metal-on-plastic (a metal ball with a polythene socket).
- The other standard combinations are ceramic-on-plastic (a ceramic ball with a polythene socket) or ceramic-on-ceramic (where both parts are ceramic).
- Metal-on-metal (MOM) combines a metal ball with a metal socket and is now very uncommon.
- Many MOM components have been discontinued and withdrawn from the market

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REGULATION OF MEDICAL IMPLANTS

- Is testing as rigorous as for drugs?
- How is approval or CE marking secured?

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TESTING MEDICAL DEVICES

- Different from drug testing
- Drugs require a phase 1, 2 and 3 randomised human trial to establish benefits and harms.
- device trials may initially be conducted in a smaller “pilot” population. The total number of subjects needed to show safety and effectiveness is often only one or two hundred, rather than thousands needed for drug trials.

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DEVICES HAVE 3 PHASE TESTING

1. Pilot

- Smaller population with disease or condition (10-30 subjects)

- Determine preliminary safety and performance information

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2. Pivotal

- Larger population with disease or condition
- (150-300 subjects)

- Determine effectiveness and adverse effects

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- 3. Post Approval
- Post approval study
- Collect long-term data and adverse effects

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HOW TO GET A PRODUCT APPROVED

- What is needed for CE Marking?

- A producer can go to any notifying body across Europe and be given a Conformite Europeene ("CE") accreditation.

- Once the device is approved in one member state, it is automatically approved across all of them.

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HOW LONG SHOULD A HIP PROTHESIS LAST

- In 2000, the National Institute for Health and Clinical Excellence (NICE) guidance on selection of prostheses for primary hip replacement set a benchmark revision rate for conventional hip replacement of 10% or less at 10 years.

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WHAT IS THE PROBLEM WITH MOM HIPS

- National Joint Registry (NJR) research in 2012 reported MOM required revision due to failure more quickly than other implants.

- NJR reported MOM implants should no longer be used.

- All recipients should be carefully monitored.

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THAT'S NOT ALL – METAL DEBRIS

- Adverse Reactions to Metal Debris (ARMD) is an umbrella term used to describe a number of soft tissue inflammatory reactions to metal debris.

- ARMD covers a wide spectrum of reactions from small asymptomatic cyst to large soft tissue masses – pseudo tumours.

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EFFECTS OF METAL DEBRIS

- Can cause soft tissue injury in the form of a condition known as Aseptic Lymphocyte-Dominated Vasculitis Associated Lesion (ALVAL),
- Can cause the development of pseudotumour
- Can cause Metallosis
- Trunion disease - metal wear particles generated at the junction of the large metal head with the uncemented femoral neck taper(trunion surface)

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BY 2015

- The number of MOM prosthesis fell drastically from their peak use in 2008
- By 2015 < 1% of all THR in Australia and the UK were MOM
- Now not used by NHS in Scotland

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- Is a MOM Hip Prosthesis a defective product?

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“Mass tort” litigation

- Driven by experience in US
- All decided by jury trials
- “Bellweather” trials
- Vioxx – after 20 jury awards, defence costs $1.8B
- Not recoverable
- Settlement of 67,000 claims $4.8B
- Lawyers took 40%

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US litigation

- Partly due to sums involved, far more cut throat
- John Grisham novels unexpectedly realistic
- Volume of Documents – discovery as opposed to recovery
- Greater specialisation
- All parties "lawyered up" to the hilt
- Role of experts

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Inequality of arms

- The manufacturer has, or should have, complete knowledge of its product.
- There should have been extensive testing before it was placed on the market.
- The manufacturer has complete control over what information is or is not provided together with the product.
- The manufacturer has complete control over what claims are made in relation to the product's performance, including its safety
- Commercial confidentiality

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Richards v Pharmacia Ltd 2018 SLT 492

- Debate in relation to Celebrex
- In relation to complaint of lack of specification:
- "[48] in considering… submissions that the defenders have not been given fair notice of the case against them, the identity of the defenders and the nature of the activity with which the actions are concerned, provides the context in which [the defenders'] submissions have to be considered… they may be taken to know all that is known about Celebrex and its effects."

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Australia

- Vioxx – *Peterson v Merck Sharp & Dohme* [2010] FCA 180
- Court addressed a list of agreed questions and issues
- Ultimately settled on appeal (once defendants had won first appeal)
- Mesh
- Decision awaited
- Johnson & Johnson have already withdrawn mesh products from Australian market

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Product recall

- What is significance of product being recalled?
- Manufacturers prefer to talk of product no longer being available
- Vioxx – product withdrawn
- Celebrex – very similar product left on market with greater warnings

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European litigation before the Directive

- Burden of proof on manufacturers: Germany, Italy, Netherlands, France
- Germany already had statutory provisions in relation to pharmaceutical products in the Medicines Act 1976 (*Arzneimittelgesetz* 1976). Extend to causation as well as liability
- UK litigants dependant on common law
- Directive designed to harmonise law across the EC

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Directive 85/374 on Liability for Defective Products

- Implemented 25/7/85
- Allows member state to exclude "development risks" or "state of the art" defence
- Liability based on consideration of the product, not the conduct of the producer
- Single most difficult issue in the context of medical devices is what makes the product defective

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Definition of defect
Article 6

1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

(a) The presentation of the product;

(b) The use to which it could reasonably be expeccted that the product would be put

(c) The time when the product was put into circulation.

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation

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Consumer Protection Act 1987

- **3.— Meaning of *"defect"*.**
- (1) Subject to the following provisions of this section, there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes *"safety"*, in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury.

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General expectation of safety

- (2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including—
- (a) the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;
- (b) what might reasonably be expected to be done with or in relation to the product; and
- (c) the time when the product was supplied by its producer to another;
- and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question.

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A v National Blood Authority [2001] 3 All ER 289

- Long, complicated and controversial decision
- Blood transfusions infected with Hepatitis C
- Dichotomy between "standard" and "non standard" products
- Emphasis on "legitimate expectation" of the public
- Considerations appropriate to common law negligence, such as the avoidability of the harmful characteristic, the impracticability of precautions and the utility of the product to society were all irrelevant.
- Product defective if it was nonstandard in a harmful way and the public did not accept that a proportion of such products would be defective.

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Wilkes v Depuy International Ltd [2018] QB 627

- Metal hip stem fractured
- Judge disapproved approach in *A* and instead took holistic approach.
- Particular reference to (1) the balance of benefits and risks involved in the production and marketing of the product; (2) regulatory approval or compliance with appropriate mandatory standards.
- However, it should not involve considering the safety expectations of a particular patient or of the general public.

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The role of the regulator

- *Wilkes v Depuy International Ltd* [2018] QB 627
- Regulatory approval very important
- However, very little regulation of medical devices (as opposed to pharmaceuticals). No clinical testing of metal on metal hips
- *Pollard v Tesco Stores Ltd* [2006] EWCA Civ 393 – fact that a supposedly child resistant bottle top did not comply with British Standard did not mean that it was defective, so long as it was harder to open than normal

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Gee v DePuy International Ltd [2018] Med LR 347

- "…whilst the effective protection of consumers is a key objective of the Directive, it is not the main or overriding objective. It has equal status with the other objectives. It is important to bear this in mind."
- Is this an unreasonable statement?

Product Liability Poll 1: "...whilst the effective protection of consumers is a key objective of the Directive, it is not the main or overriding objective. It has equal status with the other objectives. It is important to bear this in mind." Do you agree with this statement?

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Really?

- "…whilst the effective protection of consumers is a key objective of the Consumer Protection Act, it is not the main or overriding objective. It has equal status with the other objectives. It is important to bear this in mind."
- In other words, the main or overriding objective of the Consumer Protection Act is not effective protection of consumers.

Product Liability Poll 2: "…whilst the effective protection of consumers is a key objective of the Consumer Protection Act, it is not the main or overriding objective. It has equal status with the other objectives. It is important to bear this in mind." Do you agree with this statement?

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Regulatory disapproval

- If approval is important (*Wilkes*), why is disapproval not equally significant?
- Several Medical Device Alerts have been issued in relation to Metal on Metal hips
- Most devices have been withdrawn from the market
- What is difference between lack of safety and "clinical inefficiancy" (see para 257)?

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Types of defect

- In manufacture – relatively straightforward e.g. *Donoghue v Stevenson*
- In design – very difficult
- In warnings and instructions – also extends to positive claims. The most commonly successful
- Marketing brochures tend to be in significantly larger print than warnings
- See Instructions for Use

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Instructions for use

- See handout

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Development Risks Defence

- A strict approach to "defect" does not necessarily impose unreasonable restriction on manufacturers
- Strong financial incentives to develop new products
- Vaginal mesh products cost about $20 to make and retail at $1,200.
- More importantly, state of the art defence
- Manufacturers perfectly placed to show why defect was not discoverable at the time of supply

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Contact

Compass Chambers
Parliament House
Edinburgh
EH1 1RF
DX 549302, Edinburgh 36
LP 3, Edinburgh 10
www.compasschambers.com

Robert Milligan QC

Clare Connelly
Advocate
Mobile: 07957 113 833
Clare.connelly@compasschambers.com

Gavin Herd
Practice Manager
Phone: 0131 260 5648
Fax: 0131 225 3642
gavin.herd@compasschambers.com