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Product liability in prosthetics: changes in the law 2016

The Consumer Protection Act (1987) (CPA) makes a producer strictly liable for personal injury, death or damage caused by a defective product. Although fault is not a requirement, the consumer (patient) must prove the defect, the injury and a causal link between them. This was tested in the medical field in the case of A *vs* National Blood Authority (NBA) in 2001.[1] A total of 117 claimants brought an action for damages under the Act arising from their infection with hepatitis C as a result of blood transfusions received after March 1988. It was claimed that the infected blood was a "defective" product within the meaning of the Act and that they were entitled to receive blood that was free from infection.

The NBA argued that as there was no test for hepatitis C until April 1991, the presence of the virus in the blood could not have been expected to be detected before that time. The court found in favour of the claimants in what was perceived to be a harsh decision at the time. In an 82-page judgement, it was argued under the Act and the European Union product liability safety directive, that the blood products were defective and that the public was entitled to expect that transfused blood should be free of infection, even though there was no reasonable means that the NBA could have used to identify the infection. After this case, it was generally accepted that it was much easier for patients to prove that a product was defective, and more difficult for manufacturers to escape liability by showing that they had done all that could be expected of them.

This brings us on to consideration of the case of Wilkes *vs* DePuy International Ltd,[2] a matter in the field of orthopaedics that has led to a significant change in the interpretation of the law on product liability. In January 2007 at the North Manchester General Hospital (NMGH), Mr Wilkes underwent a total hip arthroplasty. At that time he weighed 123 kg. The implants inserted were manufactured by DePuy International Limited. The procedure was a success and Mr Wilkes was able to return to work. However, on 5 January 2010, he felt his left hip "give way".[2] Subsequent investigations at the NMGH showed that the femoral component had fractured at the grooved area on the neck of the stem. Mr Wilkes was admitted to hospital and the C-Stem was revised. However, in August 2015 the revision stem once again fractured. Mr Wilkes brought a dual claim against De Puy, alleging that the fracture was caused by the negligence of the Defendant and also that there was a "defect" in the C-Stem, owing to the presence of the groove, as defined in the Consumer Protection Act 1987.[3] Mr Wilkes, through his legal team, sought damages from the Defendant. No expert orthopaedic evidence was submitted as the claim was made against the manufacturer and not the healthcare provider. However, in the judgement by Mr Justice Hickinbottom[2] there was some criticism/comment over the position of the treating orthopaedic surgeon in this case. The expert evidence for each side was provided by engineers.

Gordon Taylor was the Defendant's Complaints Manager. He said that the most recent sales information, to the end of June 2016, showed that nearly 133, 000 Mk II C-Stems had been implanted, of which 10, 275 were HO size 3 (the size inserted into Mr Wilkes). In respect of the 133, 000, there had been 26 reports of stem fracture, in six of which the complaint related to a fracture in the neck/taper region, one of which was the Claimant's case. That equates to a stem fracture failure rate of 0.0195%, and a stem neck fracture rate of 0.004%. Of the 26 cases, four related to HO size 3, one of which was again the Claimant's case. Two of these four cases concerned a fracture in the neck/taper region: the Claimant's case and one other.[2]

Mr Justice Hickinbottom was well aware that the National Joint Registry (NJR) publish an annual report on the data in relation to various joint procedures and reviewed the statistics from the relevant period in his judgement, pointing out that

"Although the release of data depends upon the patient's consent, the returns are high, e.g. at least 77% of all procedures in 2005, and 81% in 2006. The NJR's Third Report (for the year 2005), reported that, of a total of 5,348 recorded hip revision procedures that year, the indication for surgery in 88 cases (to the nearest round

number, 2%) was stem fracture. The Fourth Report (for the year 2006), reported that, of a total of 5,355 recorded hip revision procedures that year, the figure was 80 (1%). By far the highest number and percentage of cases gave an indication of failure of "aseptic loosening", i.e. loosening of the stem in the femoral bone (3352 (63%) and 3338 (60%) in 2005 and 2006 respectively".[2]

Therefore, it behoves us to keep abreast of NJR data as this may well be used in clinical negligence cases in addition to product liability claims.

The treating orthopaedic surgeon had not been invited to attend the trial until late in the day and was unable to do so because of pressing clinical commitments. His witness statement was available and referred to in the judgement. He had stated that "Between 2005 and 2007 there was no general awareness of fatigue fracturing risks affecting artificial hip products currently in circulation at that time. The expectations were that a specialist medical component like a femoral C-Stem would not fracture from metal fatigue." In this respect, Mr Justice Hickinbottom commented

"I do not understand why the surgeon says that there was at the relevant time no general awareness of the risk of stem fracture amongst orthopaedic surgeons who performed hip replacements. That risk was the subject of a specific warning in the instructions for use (IFU), which accompanied every C-Stem. It was also recorded in the NJR annual reports."

The view of Counsel and the Judge was that a surgeon carrying out this type of operation should be aware of such risks. Of course, whether this is considered to be a "material risk" under paragraph 87 of the Montgomery Judgement (2015)[4] is another matter. Mr Justice Hickinbottom did raise this issue

"It is also unclear on the evidence whether the surgeon took the view that it was unnecessary to give a specific warning about the risk of fracture – he appears to have discussed the risk of failure in other ways but, in any event, in my view, on the basis of the IFU, he was sufficiently well-informed as to the risk of stem fracture to give any specific warning to the Claimant that he considered appropriate."

I assume that this theme was not pursued as there was no suggestion that the orthopaedic care was in any way substandard.

The Judge discussed the fact that, "The Claimant was made expressly aware of other, much higher, risks of failure of the hip replacement, each of which, had it occurred, would have resulted in a revision procedure. It seems that he was not warned of this specific way in which failure might occur." This is an interesting observation as in clinical negligence claims (which this is not), it is surprisng how frequently it is argued by claimants and their legal teams that, although the risk of much more serious complications (including paralysis and death) have been accepted, the complication which occurred in their case would have prevented them from going ahead with the procedure had they been aware of it.

It is also of note that in the absence of expert orthopaedic evidence, there was reliance upon

"A statement of the Claimant's solicitor who had diligently performed a web-based search of the *Bone and Joint Journal* from 2003 to 2007 inclusive, which makes no mention of the phenomenon of stem fatigue fractures. However, given the low risk of such events, it is not necessarily surprising that researchers had not dedicated time and effort to them, particularly if the small risk was well-established."

In any event, the Judge dismissed this evidence, arguing that, "It provides no support of any substance to the Claimant's case."

In this case, the fundamental issue was whether the original C-Stem prosthesis contained a defect which caused it to fracture, and whether, therefore, De Puy had breached their responsibility under the CPA. The Judge believed that the definition of a 'defect' was the single most difficult part of the Act. He worked on the basis that for the purposes of the Act, there is a defect in a medicinal product if the safety of the product is "not such as persons generally are entitled to expect", taking into account "all the circumstances". It was clear from the expert engineers' evidence that the product design and testing for the C-Stem fulfilled, and indeed exceeded, the regulatory requirements.

The CPA applies to all products and takes an objective and flexible approach to the standard of safety. It takes into account all of the circumstances. The Judge believed that the focus must be on the appropriate level of safety, objectively assessed by the Court. However, safety is inherently and necessarily a relative concept, so it is not absolute as had been found in A *vs* National Blood Authority. Particularly in relation to medical products, in this case a femoral prosthesis, the Court emphasised that there cannot be a "sensible expectation that any medicine or medicinal product is entirely risk-free".

The Judge opined that as to the circumstances (and the weight attached to them), a "holistic approach" should be taken that would include looking at:

- Regulatory approval (requiring compliance with various standards);
- The warnings provided with the products as to the possibility of complications or injury (in this case warnings were provided to the surgeon, not directly to the patient);
- The risk-benefit analysis that must attach to certain products: do the benefits sufficiently outweigh the risks?

Kennedys Law in their case review (2017)[5] argued that

"The Court's decision provides clarity to producers and claimants as to the correct formulation of the question of defect under the CPA and should offer producers/manufacturers some comfort that courts will not impose strict liability where claimants sustain injury and/or damage in all circumstances. Strict liability will not apply where for example, as occurred here, a known but rare side-effect or complication from the use of a product occurs, but a warning was given as to the risk and the overall benefits outweigh the small risk."

They also believed that, "This decision also guides claimants to consider the merits of potential claims against manufacturers whose products have regulatory approval and meet appropriate standards that should reduce the numbers of speculative CPA claims."

In conclusion, although not a case directly focused on clinical competence, Wilkes *vs* DePuy gives some interesting insights into the workings of the legal and judicial mind in orthopaedic/medical cases. It is surprising to me that the case was allowed to proceed without the presence of the surgeon involved who would no doubt have been able to clarify a number of issues in the case. The Judge emphasised that the fact that there was no opportunity to cross-examine him meant that the weight he would give to the evidence from his witness statement would be affected. It is also interesting to note the importance given to the "small print" (IFU) in the prosthesis box and the NJR data as factors in the evaluation of the merits of the claim.

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