High Court Rejects Claims on Metal on Metal (MoM) Implants

Michael A Foy

The judgement on Gee and others v DePuy International Ltd was published on the 21st May 2018 by the Honourable Mrs Justice Andrews DBE and runs to 170 pages. The hearing ran from 16th October 2017 until 26th January 2018. Over 40 witnesses were called. In 2016, the Daily Telegraph published an article headlined, "I used to swim and run and then a metal hip crucified me."

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In the article one of the claimants in this case said that the MoM hip had "blighted" his life. It recorded that in another patient the MoM implant had caused "such a mess to flesh" in his hip and he later developed "pseudotumours and part of his hip socket had been eaten away." It is interesting to note, in light of comments such as these, that in her judgment, Mrs Andrews referred to, "the panic about MoM hips that was engendered in consequence of the increasingly hysterical media reporting", which typically contained no scientific research to support it, together with "alarmist contentions" which may have led patients to seek revision surgery and may have influenced surgeons' willingness to revise. She also described, "increasingly hysterical" reporting on BBCs Newsnight and the BMJ who described, "poorly regulated and potentially dangerous" hip devices and also suggested that the wear debris may be carcinogenic.

The claim involved a Group Litigation by 312 individual patients (claimants) in respect of 341 MoM hip replacements carried out using the Pinnacle/ Ultamet System manufactured by DePuy (the Defendant). There was no allegation of substandard practice brought against any of the orthopaedic surgeons involved in the management of these patients. The Pinnacle system was introduced into the UK in 2002. The acetabular liner could be cross-linked polyethylene, ceramic or metal. All the claims related to MoM (Ultamet) procedures. All of the claimants alleged that they had suffered an adverse reaction to metal wear debris (ARMD) generated by the MoM articulation leading to a requirement for revision arthroplasty. Six lead claims were selected, three by the claimants' legal representatives and three by DePuys legal representatives.

The claims were brought under Part 1 of the Consumer Protection Act (1987). The primary allegation was that the Pinnacle/Ultamet MoM system was defective because it had a tendency to produce ARMD which caused them personal injury for which DePuy should provide compensation. Under the Act a product is "defective" when it fails to meet the standard of safety that the public is generally entitled to expect at the time that it was introduced to the market. An additional argument was also introduced by the claimants' legal representatives that the Pinnacle system had an "abnormal propensity" to produce ARMD.

At the trial it was argued that:

The Pinnacle MoMs tendency to cause ARMD was itself the defect under the 1987 Act despite the fact that ARMD is a recognised risk of such procedures and that particulate debris from polyethylene is recognised to cause osteolysis in metal on polyethylene articulations.

The failure rate of the Pinnacle MoM system was higher because of the above alleged defect. Statistics from the National Joint Registry (NJR) were used in support of this allegation.

The court heard a wide range of expert evidence in disciplines ranging from orthopaedics, mechanical engineering, statistics and histopathology. Five of the six lead claimants

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gave evidence either directly or via video link. Four of the orthopaedic surgeons carrying out the revision procedures gave evidence. Initially there was expert engineering evidence criticising various design features of components within the Pinnacle/Ultamet system. Many of these criticisms were made on the basis of incorrect factual evidence and were withdrawn. Those that were persisted with did not help or advance the claimants case. At the time that the Pinnacle/Ultamet system was introduced there were many other companies that had introduced MoM systems. Legal proceedings had been commenced against most if not all of these companies. All these other actions were stayed pending the outcome of this case. Mrs Justice Andrews indicated that although her Judgement was not binding she hoped that her interpretation and reasoning would provide suitable guidance in deciding the way forward in the other claims.

Although the case was brought under the Consumer Protection Act, there was rigorous analysis through expert evidence and statistical analysis on the data contained in the NJR and its use in support of the claimants pleaded cases. The claimants' representatives argued that the cumulative revision rate (CRR) for the Ultamet MoM liner was materially higher than for comparable implants. The evidence presented led the Court to take the view that when it was introduced in 2002 the CRR for the existing generation of hip implants was 10-14% at 10 years. The NICE guidelines from 2000 were said to suggest that better performing prostheses would have a revision rate of around 10% at 10 years. The Court decided that at the time of its introduction the public was entitled to expect that the Pinnacle/Ultamet MoM system (irrespective of which stem was used) would not have a greater risk of failure in the first 10 years after implantation than the expected failure rate of the product that it was intended to improve upon, i.e. metal on polyethylene. As far as the need for an actual comparator was concerned, that is the implant they would have received had they not received Pinnacle/ Ultamet, the Court decided that this would be metal on polyethylene and not other bearing surfaces within the Pinnacle system.

After careful consideration of the NJR statistics, Mrs Justice Andrews drew the following conclusions:

- The NJR did not record data on levels of post-surgery activity which she believed was a major variable affecting implant survival
- The data relied upon had a systemic bias in the reporting of body mass index which had the potential to be a confounding factor
- The Pinnacle/Ultamet data had a small number of outlying surgeons with a very high revision rate who had a significant effect on the overall statistics
- The NJR data on the Pinnacle/ Ultamet (and in general) was incomplete which affected the reliability of the statistics
- The NJR data combined results from older polyethylene bearing surfaces with newer cross linked polyethylene liners
- A different type of MoM implant (ASR) had been withdrawn in 2010 following which guidance was given by the Medicines and Healthcare products Regulatory Agency (MHRA) leading to enhanced surveillance of MoM hips compared to other bearing surfaces
- A panic fuelled by sensationalist media reporting had an impact on revision rates.

On the basis of her interpretation of the NJR statistical data, she decided that she could not safely rely on the CRR of 13.98% as being representative of the performance of the Pinnacle/Ultamet system over 10 years. She believed that there were too many potentially confounding factors, arguing that the outlier effect alone would suggest that a CRR of 10/11% was more accurate.

The preliminary issues were tried with the six lead cases. In two of these cases, DePuy admitted that the claimant had suffered ARMD while denying that this was because their implants were defective. In the other four cases, they disputed the diagnosis of ARMD. The Court took evidence from the claimants themselves and the revision surgeons to matters of fact and from experts in the fields of orthopaedics, radiology and histopathology. In each of the four disputed cases the Court found in DePuys' favour.

Mrs Justice Andrews concluded that the claimants pleaded case was untenable because the "inherent propensity" of MoM hips to shed metal debris through normal use, to which some patients may suffer an adverse immunological reaction is not a defect in the product within the meaning of the CPA. She did not believe that it subsequently became a defect because of the recorded incidence of such adverse reactions or the calculated risk of revision caused by such reactions. On the alternative case she opined that the claimants had failed to prove that the Pinnacle/ Ultamet MoM prosthesis did not meet the level of safety that the public were entitled to expect at the time of its introduction to the market in 2002. On this basis she found that DePuy were not liable to the claimants.

The team at Crown Office Chambers who represented DePuy were obviously delighted at and supportive of the decision reporting that, "The Court's discussion of the factors to be taken into account when deciding whether or not a product is defective under the CPA is likely to become the definitive judgment in the field of Product Liability law. Producers are likely to welcome the Court's acknowledgment that factors such as risk-benefit and avoidability are relevant in deciding whether or not a product met the level of safety that the public generally is entitled to expect. The judge's endorsement of *"a flexible approach to the assessment of the appropriate level of safety"* is expected to give producers greater scope for defending product liability actions. Producers will also appreciate the court's endorsement of DePuy's submission that where a product includes a feature which gives it a potential functional advantage, or eliminates a perceived deficiency in design, but by doing so necessarily introduces a risk, the Court should not be prevented from considering the actual or potential benefit when assessing whether the product is defective. The safety risk may be one that, objectively, the public would be expected to accept, bearing in mind the benefits that the product would confer."

The claimants' solicitors were not (as one might expect) so supportive of the Judgement with the Association of Personal Injury Lawyers (APIL) describing in its June 2018 issue of PI Focus how the four firms representing the claimants (Corries, Leigh Day, Hugh James and Irwin Mitchell) had issued a joint statement to express their concerns that "a product group that the orthopaedic profession has rejected for the serious harm that it can cause has been deemed safe by the Judgement." It is not clear at the present time whether there will be any appeal against this Judgement. The claimants were particularly surprised that Mrs Justice Andrews found the NJR data unreliable as it is, "the largest and one of the most respected registries in the world." They were also concerned by comments in the Judgement relating to the National Institute for Clinical Excellence (NICE),

accepting that whilst NICE guidelines were relevant, they did not determine what level of safety patients were entitled to expect. The claimants solicitors felt that the judgment was a retrograde step for consumer protection, and therefore were not surprised that the manufacturers and their legal teams were happy with it.

Whilst this judgement is not directly applicable to our day to day clinical practice we do have a certain amount of input and responsibility in the decision making process for selection of the type of implants that we use in a great variety of operative procedures. Against the background of this case, it is interesting to reflect how the interpretation of the CPA by the Courts has metamorphosed over the last 20 years. In 2001, in the case of A v National Blood Authority a patient contracted Hepatitis C after blood transfusion following which the Court found in the claimants favour. In 2016, in the case of Wilkes v DePuy where there was a femoral stem fracture three years after a total hip replacement the Court found in favour of DePuy. While these cases are very different they were held as landmark judgements in medical product liability litigation in 2001 and 2016 until the case of Gee v DePuy. The Judges in the NBA and Wilkes cases used very different methods to analyse and define the meaning of "defect". Under the CPA there is a defect in a product if its safety is, "not such as persons are generally entitled to expect" taking into account "all the circumstances". In the 2001 case, the claimant had described this as a requirement for a "legitimate expectation" of safety from a product. However, the judge in the 2016 case described this as "unnecessary and unhelpful". He went on to emphasise that safety is "inherently and necessarily" a relative concept and there cannot be a "sensible expectation that any medicine or medicinal product is entirely risk free." In the Pinnacle/Ultamet case, Mrs Justice Andrews adopted the more flexible approach to the interpretation of the CPA (in similar fashion to the Wilkes case) concerning the definition of defect and what in the circumstances a patient is entitled to expect. It will be interesting to see if the case goes to appeal and how the situation evolves in the future. ■

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References

References can be found online at *www.boa.ac.uk/publications/JTO* or by scanning the QR Code.