Colin Gee and others -v- Depuy International Limited (The Depuy Pinnacle Metal on Metal Hip Litigation) Press Summary 21 May 2018

1. The Defendant ("DePuy") is the manufacturer of a hip prosthesis system for use in total hip replacement operations, known as the Pinnacle Acetabular Cup System ("the Pinnacle system") which was first introduced in the UK in 2002. The Pinnacle system is an uncemented modular system, within which different articulating surface combinations were available. Surgeons could select the materials from which the femoral head and liners to the acetabular cup were made, to produce the combination of materials which they thought best suited the patient.

2. The claims in this Group Litigation were brought against DePuy by 312 individual claimants who were implanted with one or more Pinnacle prostheses where both the acetabular liner and the femoral head were made of a metal alloy, giving a Metal on Metal ("MoM") articulation. In most cases the femoral head was 36mm in diameter. Each claimant claimed to have suffered an adverse immunological reaction to metal wear debris generated by their prosthesis, which brought about damage to the soft tissues around the prosthesis, necessitating revision surgery to replace some or all of the components. The claims were case managed together pursuant to a Group Litigation Order which was approved on 31 July 2014. There were six lead claims selected from among the claimants on the group register.

3. The claims were brought under Part 1 of the Consumer Protection Act 1987 ("the Act") which implements in England and Wales the Product Liability Directive 1985. ("the Directive") The claimants' case was that the prostheses supplied to them were defective within the meaning of s.3 of the Act and that this caused them personal injury for which DePuy is liable to compensate them. A product is "defective" when, in all the circumstances, it fails to meet the standard of safety that the public generally is entitled to expect at the time when it is introduced to the market.

4. Most, if not all, producers of hip prostheses manufactured MoM articulations during the 2000s. Legal proceedings have been commenced in this jurisdiction against all, or almost all, manufacturers of such prostheses. The other actions were stayed pending the outcome of this trial. Although the findings of the court are not binding on parties to those other proceedings, it is hoped that they will provide them with guidance. For that reason, and in order to ensure, so far as possible, that the relevant legal arguments were comprehensively addressed, permission was granted for interested parties to make additional written submissions on the law.

5. This is my judgment following the trial of a common preliminary issue, namely "*whether or not the defendant is liable to the claimant, subject to any development risk defence*." It encompassed any issues of causation.

6. The trial took four months. I heard evidence from a wide variety of experts in disciplines ranging from orthopaedics to mechanical engineering, from histopathology to statistics. I also heard evidence from five of the six lead claimants, and from the surgeons who carried out the revision operations on four of them. Apart from the excellent written and oral submissions of the teams of counsel representing the parties to this Group Litigation, I received extensive written submissions on the legal issues from six legal teams representing non-party claimants and non-party defendants. I am

very grateful to everyone concerned for their hard work and for the clarity and thoroughness with which they addressed the issues.

7. For the reasons more fully set out in my necessarily lengthy judgment, I have concluded that:

   i) The inherent propensity of a MoM hip 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 Act and the Directive. It did not become a "defect" by reason of the recorded incidence of such adverse reactions or the calculated risk of the probability of the revision of the prostheses on account of them.

   ii) On their alternative case, the Claimants failed to prove that the Pinnacle 36mm MoM prosthesis did not meet the level of safety that the public generally were entitled to expect at the time when it entered the market in 2002. I was unable to conclude on the balance of probabilities that there was a materially greater risk of a Pinnacle 36mm MoM prosthesis failing within the first 10 years after implant than a comparator prosthesis, and thus that the product carried with it an "abnormal risk" of damage as alleged.

   iii) Accordingly, DePuy is not liable to the Claimants.

   iv) In four out of the six lead claims, the Claimants did not suffer an adverse reaction to metal debris.

NOTE: This summary is provided to help in understanding the Court's decision. It does not form part of the reasons for the decision.