METAL-ON-METAL HIP LITIGATION

GOOD NEWS FOR MANUFACTURERS; BAD NEWS FOR CLAIMANTS

***Gee v DePuy International Limited* [2018] EWHC 1208 (QB)** **May 2018**

Andrews J has today handed down judgment in *Gee v. DePuy International Limited* [2018] EWHC 1208 (QB), in what is an important decision for product liability practitioners. The claim related to the Pinnacle Total Hip Replacement manufactured by DePuy. Andrews J gave judgment on the following preliminary issue: "*whether or not the defendant is liable to the claimant, subject to any development risk defence*".

There have been various concerns as to the association of metal-on-metal hip implants with certain patients developing adverse reactions to metal debris (ARMD). The claimants, who alleged that they had suffered ARMD, put their case on two bases. First, that the product's alleged inherent propensity to shed metal debris that could cause an immunological reaction rendered it defective. Second, that the product had an abnormal "*potential for damage*", as against comparator implants, so as to be defective. Andrews J rejected both arguments. Whilst this important judgment warrants a close reading, the following points stand out:

1. In assessing defectiveness under the CPA, Andrews J strongly favoured the approach of Hickinbottom J (as he then was) in *Wilkes v. Depuy International Ltd* [2018] 2 WLR 531 to that of Burton J in *A v. National Blood Authority* [2001] 3 All ER 289. In particular, the judge agreed that proof of a causal connection between defect and injury cannot be attempted before determining whether there is a defect or what that defect might be. Further, Andrews J favoured a flexible approach to the assessment safety, rather than excluding certain considerations (such as avoidability of harm or a risk/ benefit analysis) as a matter of law. She accepted that safety was inherently a relative concept.

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2. The judgment considers the CJEU decision of *Boston Scientific Medizintechnik GMbH v. AOK Sachesn-Anhanlt-Die Gesundheitkasse* [2015] 3 CMLR 173. The CJEU found that where a group of defibrillators and pacemakers had a significantly elevated risk of failure that could lead to death (which could not be determined without removing them), the entire group (and any product within it) was defective, without any need to identify that any given device in fact suffered from the identified fault. However, Andrews J found that this was as far as *Boston Scientific* went: it was not authority to suggest that normal risks inherent in a product can constitute a defect. *Boston Scientific* was a case about abnormal potential for damage.

3. Given the findings on breach, it was unnecessary to deal with causation. However, Andrews J made some brief obiter comments. The judge set out that the claimants had to prove that they would not have suffered injury if the product had not carried with it the increased risk of early failure (i.e. the defect). However, Her Ladyship held that whilst the claimants would succeed by showing the defect doubled the risk of early failure, it was not necessarily the only way they could prove causation.

4. Andrews J adopted a cautious approach to the statistical evidence, which underlines the difficulties a claimant may face in establishing defect where the claim depends on such evidence. In particular, she found the National Joint Registry data an insufficiently reliable basis to draw proper conclusions as to the comparative performance and safety of hip implants because of confounding and other factors (including the effect of adverse media reports).

In summary, this is a highly significant judgment that merits careful reading. It has favoured *Wilkes* over *A v National Blood Authority* on the approach to assessing defectiveness. However, important issues remain for another day, such as the importance of the doubling of risk test and the scope of the development risks defence.