Claimants in the DePuy Pinnacle Metal on Metal group litigation fail to prove that metal on metal hip implant is defective under the Consumer Protection Act 1987

On 21st May, Andrews J in the High Court handed down her decision in *Colin Gee & ors v DePuy International Ltd* [2018] EWHC 1208 (QB). This significant judgment addresses the interpretation of "defect" in s. 3 of the Consumer Protection Act 1987. Andrews J found that the metal-on-metal hip prostheses manufactured by the Defendant for use in total hip arthroplasties were not defective under the Act.

Background

1. 312 Claimants brought a group action against DePuy International Ltd ("DePuy"), claiming under the Consumer Protection Act 1987 ("the CPA") that they had suffered damage due to defective metal on metal ("MoM") hip prostheses manufactured by the Defendant. This judgment was the trial of a common preliminary issue, namely whether or not the Defendant was liable to the Claimants, subject to any development risk defence.

2. This group action is one of several group actions brought against the manufacturers of MoM hip implants released in the 2000s. The other group actions were stayed pending the outcome of this trial.

3. The preliminary issues included the correct legal approach to the assessment of defect under the Consumer Protection Act 1987 and the Product Liability Directive 85/374/EEC. As the DePuy Pinnacle Metal on Metal group litigation was the first metal on metal group litigation to come to trial, the court gave permission for the parties in other metal on metal group litigation and managed litigation to make submissions on the

law. From Henderson Chambers, Malcolm Sheehan QC and James Purnell made submissions on behalf of Biomet UK Limited, Prashant Popat QC and Geraint Webb QC made submissions on behalf of Smith & Nephew Orthopaedics Limited and Oliver Campbell QC made submissions on behalf of Wright Medical Technology Inc.

The trial

4. The claims relate to prostheses belonging to the Defendant's Pinnacle Acetabular Cup System ("the Pinnacle System"), an uncemented hip prosthesis introduced into the UK market in 2002, and specifically those prostheses in which both the acetabular liner and the femoral head are made of metal ("the product"). The Claimants claimed that the product was defective, and that consequently they had suffered an Adverse Reaction to Metal Debris (ARMD), caused by the debris generated by the prosthesis, which necessitated revision surgery.

5. The Claimants' primary case was that the product's propensity to shed metal debris and consequently to require revision surgery constituted a "defect" under the CPA. Alternatively, the Claimants contended that the relevant defect was a materially increased risk of the prosthesis failing within 10 years, when compared to an appropriate comparator, also described as an abnormal risk of damage.

6. It was agreed that the product did have a propensity to shed metal debris and could cause ARMD in patients. It was disputed whether the product carried a materially increased risk of early failure compared to other prostheses available at the time. The Claimants sought to prove this aspect of their case through statistical comparisons and engineering evidence.

Summary of the judgment

7. As to the interpretation of "defect" in s. 3 of the CPA, Andrews J found:

    a. The CPA and the Product Liability Directive 1985 (85/374/EEC) ("the Directive"), on which it is based, balance the interests of consumers and producers by introducing a system of non-fault liability for products that fail to meet the standard of safety [66];

    b. The concept of 'defect' is defined in terms of failure to meet an objective standard of safety that the Court must evaluate [86-87];

    c. The Court must maintain a flexible approach to determining the appropriate standard of safety [143];

    d. The circumstances to be taken into account in determining the appropriate level of safety may include all those which have a bearing on the safety of the product, such as:

        i. the avoidability of the harmful characteristic;

        ii. the benefits provided by the product;

        iii. the existence of a learned intermediary and the information provided to said intermediary;

        iv. in certain cases, whether the product may be classified as standard or non-standard;

        v. compliance with any regulatory requirements; and

        vi. warnings provided with the product.

    e. As such, Andrews J preferred the approach taken by Hickinbottom J (as he then was) in Wilkes v DePuy International Ltd to that of Burton J in A v National Blood Authority (No 1) ("A v NBA").

8. Significantly, Andrews J rejected the Claimants' primary assertion that the product's propensity to cause harm in the form of ARMD and consequent revision surgery was a defect. In the context of hip prostheses she held that only an abnormal propensity to cause ARMD, otherwise expressed as a materially greater risk of the product failing within 10 years, would amount to a defect under the CPA.

9. The Claimants failed to prove that there was a materially increased risk of the product failing. The Court determined that:

    a. The level of safety should be measured by reference to what was known in terms of safety at the time the product was placed on the market. Accordingly, a comparison with the subsequent performance of other new products, such as other new articulations within the Pinnacle System, could not inform entitled expectations as to the level of safety [294];

    b. The correct comparator for the product was an uncemented metal on conventional polyethylene prosthesis, as such a product was the most likely to be offered to a patient undergoing a total hip arthroplasty at the date of the product's release (2002) [311];

    c. There is limited data on the likely survivorship to ten years of the comparator prosthesis implanted in a representative group of patients [318];

    d. The data in the National Joint Registry (NJR) is unreliable because of a number of potentially confounding factors [322, 417-455];

    e. The most reliable data for the comparator prosthesis is from the National Swedish Hip Arthroplasty Registry (SHAR) published in reports in 2000 and 2002 ("the 2000 Report" and "the 2002 Report"), in particular the former;

f. Based on the above SHAR reports, the cumulative risks of revision ("CRR") for an uncemented implant over ten years were at best around 15% [338-9];

g. There has been difficulty in assessing the CRR of the product. The only available figure, from the NJR, is 13.98%;

h. Accordingly, the Claimants failed to prove a materially increased risk of early failure.

Interpretation of "defect" in s. 3 of the CPA

10. The Claimants asserted that the Court, following the approach taken by Burton J in *A v NBA*, and in line with the Claimants' interpretation of the CJEU's approch in *NW and others v Sanofi Pasteur*[1] *("Sanofi Pasteur")* and *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse*[2] ("*Boston Scientific*"), should interpret "defect" within section 3 of the CPA as meaning the potential of a product to cause damage [101]. The allegedly high incidence of revision with the Pinnacle System was said by the Claimants to form part of the relevant circumstances to be taken into account by the Court when determining whether the product was in fact defective and, if the product is so found to be defective, that potential for damage becomes the defect [102]. Causation must then be established by asking whether, on the balance of probabilities, harm would have occurred had the product not been defective [102].

11. Further, the Claimants argued that avoidability, cost, and any benefits not specifically relating to safety must always be excluded from the circumstances to be taken into account when determining whether a

[1] (Case 621/15) (2017) ECLI:EU:C:2017:484
[2] (Case C/503/13, 504/13) [2015] 3 CMLR 173

product is defective, by seeking to extend the ratio of *A v NBA* to apply to standard as well as non-standard products [141]. Their basis was the concern that such considerations would risk introducing quasi-negligence concepts into an assessment intended to be non-fault-based; and that the balance of the CPA would be wrongfully shifted in favour of the producer [142].

12. The Court rejected both elements of the Claimants' argument. Essentially, the Court found that the Directive and the CPA had carefully balanced the interests of producers and consumers, providing for no-fault liability if a product does not meet the safety standard to which the public is entitled [66], but requiring the Claimant to prove defect, damage and causation. The Court determined that no-fault liability was the means by which the Directive achieved the aim of consumer protection and that neither the travaux préparatoires nor relevant decisions of the CJEU suggested that the other provisions of the Directive had to be interpreted as the Claimants alleged for the purpose of consumer protection [78].

13. As to the first element, the Court rejected the Claimants' interpretation, stating that it would have the effect of eliding proof of causation with proof of defect, and that it ignored the central question of the level of safety that persons are generally entitled to expect [106-107]. Andrews J preferred instead the approach of Hickinbottom J at paragraphs [60-65] of *Wilkes* – namely, that the hallmark of defect is a lack of safety, which is, in turn, inherently and necessarily a relative concept. There cannot be a sensible expectation that any medicine or medicinal product is entirely risk-free. The key question for defect is therefore not whether there is an inherent risk in the product, but whether the product demonstrates an *abnormal* susceptibility to cause damage.

14. As to the second element, the Court considered that a number of factors might be relevant to what level of safety persons are generally entitled to expect, including avoidability, risk/benefit analysis, the existence of a learned intermediary, compliance with regulatory requirements, and warnings provided with the product [156]. The Court would be willing to consider all those circumstances which have a bearing on the safety of the product [160].

15. The Court's interpretation of "defect" in s. 3 may be summarised as follows:

    a. A defect is to measured against an objective standard of safety, which will be determined by the Court having regard to all the circumstances;

    b. A harmful characteristic which is part of the normal behaviour of the product will not necessarily constitute a defect [112];

    c. An abnormal potential for harm may consititute a defect, dependent on the circumstances [112];

    d. A range of circumstances may be considered in determining the level of safety which the public is entitled to expect, so long as they are factually and legally relevant to the evaluation of safety [139].

Materially increased risk of harm may amount to a defect

16. The Court held, accepting the Claimants' uncontroversial alternative submission, that if the product carried a materially increased risk of early failure, in comparison with established hip prostheses, this could amount to a defect.

17. The steps to follow in determining this are [289]:

    a. First, to ascertain what the appropriate comparator product(s) should be;

b. Secondly, to carry out the comparison exercise, comparing the CRR for the product and the comparator;

c. Thirdly, to consider whether it can be reliably concluded that there was a materially increased risk of early revision;

d. If that can be reliably concluded, to consider whether in the light of said risk and all other relevant circumstances, the product fell below the level of safety which the public was generally entitled to expect.

18. In carrying out the comparison exercise, only information about the performance of a comparator product which was available at the date of release of the index product may be used [273].

19. No assumption can be made as to whether a product which is shown to be the worst in its class will be defective. *Gee v DePuy* states at [463]:

"In any event, the fact that there are or may be better products on the market used for the same purpose does not in itself make the product that is the "worst in class" unsafe. … [The fact of a better performing product] might well lead to prosthesis A being withdrawn from the market over time, because it was comprehensively out-performed by prosthesis B, which clinicians who became aware of the revision rates would plainly choose in preference; but it would not necessarily follow that prosthesis A was defective."

The Court's conclusions on defect

20. Pursuant to the principles set out above, the Court made the following findings as to the product having a materially increased risk of harm:

a. The appropriate comparator for the product was an uncemented metal on conventional polyethylene prosthesis;

b. A comparison with other new implants within the Pinnacle System was inapposite because reference should only be had to what was known in terms of safety at the time the product was released into the market (2002);

c. Ideally, comparative data would be on *"revisions or survivorship of an uncemented metal on conventional polyethylene prosthesis or prostheses implanted in a group of patients which would include a sufficient proportion of younger and more active patients to be representative of the cohort that was implanted with a Pinnacle Ultamet prosthesis."*[3]*;*

d. Such data does not exist, creating a major problem for the Claimants' case;

e. The NJR data contains a number of confounding factors, not least that it contains data relating to cross-linked and highly cross-linked polyethylene (HXLPE) articulations, and products introduced later than 2002, making it an unreliable comparator;

f. The NJR data suggested that the CRR of the product over ten years was 13.98%, but this was not reliable due to the many potentially confounding factors;

g. The most reliable data are the 2000 and 2002 SHAR reports, pursuant to which the CRR of the comparator prosthesis is between 7.5 – 15%;

h. On the available figures, there was no evidence that the product's CRR reflected a materially increased risk of failure.

21. The Claimants' argument on engineering issues did not succeed.

[3] *Gee v DePuy* at [318].

Comment

22. This is a significant decision on the interpretation of "defect" under the CPA. It is of particular relevance to the remaining group actions arising out of MoM hip prostheses, and to other medical device and pharmaceutical product liability claims, especially with regard to the approach taken to "materially increased risk of harm" in comparison to similar products.

23. The principles regarding materially increased risk of harm mean that there is no presumption that a product which is the worst in its class will be defective. Furthermore, the judgment demonstrates the difficulty which Claimants may have in using statistical evidence to prove a materially increased risk of harm.

24. Andrews J favoured the reasoning of *Wilkes v DePuy* over that in *A v NBA* and held that a defect should not be identified as a product's propensity to cause harm, but in relation to a product's failure to meet an objective standard of safety, to be assessed flexibly by the Court. Whilst questions remain as to how broadly "all the circumstances" in s.3 of the CPA will be interpreted following the judgment, this flexible approach is to be welcomed.

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