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Medico-legal issues relating to metal-on-metal hip devices

With the worldwide recall of the DePuy ASR and field safety notices about other devices, together with articles in mainstream media, there has been a significant rise in compensation claims concerning the early failure of metal-on-metal (MOM) hip replacements and hip resurfacings.

Readers with a MOM revision practice are likely to have patients already bringing legal action, or considering doing so, and they might also have an interest in medico-legal reporting in these cases.

However, while some solicitors have regarded such cases as simple and straightforward, the cases can be very technically demanding and complex, with numerous pitfalls along the way. This paper seeks to discuss the different types of potential legal claims that can arise from failed MOM hips and considers some of the difficult issues that can arise.

GROUP LITIGATION ORDERS

Where many people wish to sue the same defendant, regarding the same issue, the Court can issue a Group Litigation Order (GLO), which determines that all similar cases be run in parallel, with a lead firm of solicitors and a steering committee dealing with the common issues. This is to prevent the waste of legal costs and potential inconsistency that could arise if many law firms were dealing with the cases separately, in different ways, in different courts.

At the time of writing, there are two such Orders: one relates to the DePuy Pinnacle MOM device, and the other to the Zimmer Durom/Metasul device. It is likely that there will be others in due course.

Even where there is no GLO, law firms are likely to work together on similar cases, to share the workload of the common issues and to ensure a consistency of approach.

MANUFACTURER CLAIMS

Given that this is a class of products that is believed to have performed poorly, and there are publicised settlement schemes in the USA in relation to some devices, it can be tempting to think that cases against the manufacturers, brought under the strict liability regime of the Consumer Protection Act 1987 (CPA), will necessarily be strong and will be settled readily. While it is correct that the CPA does not require a claimant to point to fault, to prove negligence or to identify a specific error made by the manufacturer, such claims are very far from straightforward.

It is of course not the case that any product that causes injury is defective. Whether a medical product is or is not defective is determined by assessing whether it has met the patient's reasonable or legitimate expectation of safety. The question the court must consider is, "what level of safety can patients expect from a device of this sort?"

In A *vs* National Blood Authority (2001), it was found that patients were entitled to expect that there was no risk whatsoever of the blood they received being contaminated with hepatitis C. It is unlikely that a court would find that a patient would be entitled to expect that there would be no risk at all of the early failure of a hip product. After all, the patient's natural hip had already failed and it is likely that the patient was specifically warned of the risk of early failure of the artificial one, whether by dislocation, infection, loosening or a reaction to the wear debris produced by such a device.

Instead, one must look at failure rates of the device, and also the way in which it fails. When reviewing the failure rate, one must consider a number of issues.

QUALITY OF DATA

When looking at data, the solicitor and the appointed expert must understand the limitations of the various sources of information.

Joint registries can be useful, but some have only ten years of data, and small numbers of cases beyond five years. Others have 30 years of data but are taken from different patient groups that might not be analogous to England and Wales. Also, when one looks at longer-term data, it must be borne in mind that devices and techniques will have changed over the years, hopefully, but not necessarily, for the better.

Surgeons often publish their own results, but some of these surgeons are designers of the devices or consultants to the manufacturers. The results achieved by these surgeons are

often far better than can reasonably be expected from all hip surgeons. Equally, some surgeons will publish their own poor results with a particular device, perhaps advising that it be used no longer. Again, these reports can be biased and one must consider whether other centres have reported similar results. If not, why not? Might there be an issue regarding technique, or patient selection? Or might it be that they adopted the device first and are ahead of the revision curve?

COMPARATORS

Before the court can establish whether the particular device has met the patient's expectations of safety, it must determine against which alternate device it should be compared.

Should it be compared with hip arthroplasties generally? The best hip on the market at the time of primary surgery? The next best MOM hip? MOM hips generally? Was the particular patient destined to have a particular device? Determining the proper comparator is crucial to establishing liability.

If the case is brought under the CPA, then it would seem that the comparator should be based on what a hypothetical patient would have been entitled to expect, given all the available knowledge at the time that they received the device.

Would it be reasonable for that patient to expect that the new device would be at least as safe as that which was already on the market? If not, why would they have agreed to have the new device? Why would their surgeon have recommended it? To what extent can the company's marketing claims be considered relevant? Would they have influenced the advice a surgeon would have given to the hypothetical patient?

If the comparator is found to be another MOM device, should its safety or longevity be based on what patients would have been entitled to expect at the time of their surgery, or should the court consider only the results that have actually been achieved? This is rather a question as to whether the patient should assume any of the risk of a new class of devices, to which the answer would seem, from the perspective of this patient's lawyer at least, to be a clear 'no'.

MODE OF FAILURE

The comparator question is also vital when considering the way in which a device fails. One might argue that, even if the failure rate is not significantly higher than the comparator product, the way in which the device fails is significantly more damaging than that of the comparator, and that this renders the device unsafe or defective within the terms of the CPA. If a lightbulb lasts as long as other lightbulbs on the market, but burns the house down when it eventually fails, then that is certainly an unsafe product. Is a hip product unsafe because when it fails it causes the death of muscle and bone, and leads to worse outcomes after revision surgery?

TIME LIMITS

The CPA carries with it a ten-year cut-off period, in addition to the usual three-year limitation period in which court proceedings must be started. If the claim is not issued within ten years of the date of supply of the device, the claim is extinguished. The date of supply is not the date on which the consumer received the device, nor is it the date of primary surgery. It is the date on which the device left the custody of the defendant company, perhaps going directly to a hospital or NHS Trust, but could arguably run from the date on which it was supplied to a distribution company with a very similar name, within the same group of companies. It is also important to note that the ten-year period cannot be extended by the court or by the parties. It does not depend on the claimant's knowledge or mental capacity. It is absolute.

WHO IS THE DEFENDANT?

The orthopaedic industry is relatively fluid, with companies merging and being bought and sold quite frequently. It can sometimes be difficult to determine the identity of the 'producer' for CPA purposes. Does the company that originally manufactured the device still exist? Has it been bought by another company? If so, did its liabilities pass to the new company or did they go elsewhere? Did all product lines transfer to the new company? Where was the device manufactured? Was it manufactured within the EU? Was it manufactured outside the EU and imported? This can be difficult to determine as many orthopaedic groups have companies and manufacturing plants both in the EU and outside. Some product lines will have their place of manufacture moved during the life of the product. If the device was made in the USA but imported through a company in the UK, then the UK-based company is the defendant. However, the device might have been manufactured in France and imported through a UK distributor, in which case the French company would be the defendant.

DEVELOPMENT RISKS DEFENCE

If a court determines that a product is unsafe or defective within the terms of the CPA, a defendant can still escape liability if it can show that the state of scientific knowledge at the time the device was placed on the market was not sufficiently advanced that the defect or hazard could have been discovered. This test does not incorporate any question as to what other companies were doing at the time, in respect of safety testing: it is not sufficient for a manufacturer to argue that the particular tests that would have discovered the problem were not routine, common practice or were not performed by other companies in the industry. It will not matter whether the tests would have been expensive or would have delayed the product launch. The only question is whether the defect *could* have been discovered.

For example, if the discovery of the defect could only have been achieved by the use of technology that was not available at the time the product was first put on the market, then the manufacturer might avoid liability for any defects in that device, at least until that technology became commercially available. Once it is *possible* to discover the hazard, then the defence evaporates, even if the technology required to do so is very expensive or not universally adopted.

It is, therefore, important for solicitors to consider the mechanism of failure and obtain evidence from surgeons and engineers as to how this problem might have been detected earlier. Was there sufficient knowledge in the wider industry to raise the suspicion of the hazard? What equipment or techniques would be required to discover it? Was that available at the time the product was launched?

MANUFACTURER NEGLIGENCE

One should consider the possibility of a negligence claim against the manufacturer. In drug cases, such claims are thought to be almost impossible, which was one of the reasons behind the creation of the Product Liability Directive, which led to the CPA. However, in some MOM cases, this might be possible and might represent the only hope for a claimant whose device was supplied more than ten years ago.

Examples might include a manufacturer failing to perform what could be considered obvious and simple *in-vitro* testing, giving poor or incorrect advice in surgical technique documents, orerrors in manufacturing or quality control.

The significant difference between a CPA claim and a negligence claim is that, with the latter, one must point to a single specific failing,

which can be very difficult indeed, particularly when one is without all the documents regarding the development, testing and manufacturing process.

SURGICAL NEGLIGENCE

MOM cases need not proceed only against the manufacturer. Before embarking on a product liability claim, solicitors would be wise to establish whether a clinical negligence claim might be a better option.

Was the device suitable for the patient? Did the surgeon properly consider the patient's age, gender and anatomy? If they were fitted with a resurfacing, was this appropriate? Should they have had a total hip arthroplasty instead? Was the surgery performed to an acceptable standard? Were the components properly sized and positioned? At what point does poor fitting of components become negligent fitting of components? What was known, or should have been known, about these issues at the time? Was the patient given adequate warnings, in light of the knowledge of MOM devices at the time? Should surgeons discuss with their patients the track record and Orthopaedic Data Evaluation Panel (ODEP) rating of a device? What if the device is not rated or has a very limited history? To what extent should a patient be involved in the decision about which device is to be used?

The law on consent has changed very dramatically since the Supreme Court's decision in the Scottish case of Montgomery *vs* Lanarkshire Health Board earlier this year. Prior to this case, the Bolam principle applied to the warning of risk: a doctor would be negligent in failing to warn of a risk only if there was no reasonable body of practitioners who would consider it acceptable to withhold such information from the patient. The test turned on what the doctor thought the patient *should* know. Montgomery reverses this; the test now focuses on what information the patient might be expected to *want* to know. A doctor is negligent if he fails to tell the patient of all material risks, all risks that a reasonable patient would consider significant, and if he fails to tell the patient of all alternatives to the proposed treatment.

MISMATCH AND OFF-LABEL USE

As readers will know only too well, a hip arthroplasty can consist of as many as six separate components. There is, therefore, a risk that some surgeons will use a combination of components from different companies.

There can be mismatches between head and stem and between head and cup. There can be a mismatch between brands, though some different-brand pairings were officially approved such as a Finsbury Mitch head on the Stryker Accolade stem. Others might not have been approved, but now have excellent long-term performance data, such as the DePuy Ogee cup with the Stryker Exeter head.

The combining of components not intended by the manufacturers to be used together would be regarded as off-label use. This can create unknown risks, as the combination will not have been subjected to any testing, and post-market surveillance will be left to the individual surgeon who uses them.

If a surgeon creates a new combination of components, unapproved and untested by any manufacturer, does he become a producer, strictly liable for his own hip replacement product, under the CPA? This was the view of the Medical & Healthcare Products Regulatory Agency (MHRA) when it issued a Medical Device Alert on the matter in February 2004. It warned that such use of devices may put patients at risk of injury, may amount to a breach of a doctor's duty of care, and may possibly render the doctor strictly liable as though he were the manufacturer of the device.

If this were not so, the patient would be deprived of the protection that was meant to be provided by the CPA, as the manufacturing companies would escape liability if the individual parts were used in breach of their advice. It would seem likely that, in this situation, the court would regard the surgeon as a producer for the purposes of the CPA.

Of course, the off-label use of devices makes the proper warning of risks even more important. Even before Montgomery, it would probably be regarded as substandard care to fail to warn a patient that the particular combination of components was unapproved by any company and that properly tested and approved combinations were available. While it might be argued, on a Bolam basis, that some surgeons would not consider it necessary to provide such information, that is no longer the test for establishing liability. Since Montgomery, the issue is whether a reasonable patient might consider it important to know that the device had not been tested or approved. It seems very likely indeed that the courts would consider it so.

PROGNOSIS

Surgeons will sometimes be asked to provide expert evidence as to a patient's course to date, their current condition, and their likely prognosis. The purpose of such a report is to assist the lawyers in determining whether the future is sufficiently predictable that it is safe to try to resolve the case at that stage and, if so, the proper level of compensation that should be awarded.

The surgeon would inevitably be asked how long a revision is likely to last. When will the next operation be required? How does this compare with what the patient would have been entitled to expect from the comparator device? Does the patient face an increased risk of complications at future surgery? Is the claimant likely to have impaired function after future revisions? Are they at risk of requiring a Girdlestone arthroplasty at some point in their life? Might future revision surgery have been brought forward from retirement into their working life? Is it likely to lead to early retirement?

Lawyers ought to appreciate that these are very difficult questions to answer, but surgeons should be advised that they are asked merely for an opinion, not a certain and definitive answer. The opinion should be based on published data and literature where possible, but experience and instinct are also valid bases for opinion.

Hopefully this paper has explained some of the different legal avenues open to patients and their solicitors when a MOM device has failed and caused injury. The issues faced by lawyers are complex, and the nature of cases can vary significantly. It is a rare case where there is a 'clear cut' claim against the manufacturer. Where one alleges that a product is fundamentally flawed in its design, the stakes are very high indeed, with a manufacturer facing the risk of thousands of claims around the world. These tend to become hard fought and technically challenging legal cases.

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