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Editorial

Lisa O'Dwyer
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Lenin once said, *"There are decades when nothing happens; and weeks where decades happen"*. The weeks since the last LS Newsletter almost certainly demonstrate the truth of that statement.

NHS Resolution's *"The second report: The evolution of the Early Notification Scheme"* published on 29th September, confirms that factors impacting neonatal outcomes remain consistent, problems with fetal monitoring, especially incorrect interpretation of CTG traces, remain top of the list. Other headline points include average defence costs for ENS (£11,738) representing approximately one-third of the non ENS claims (£34,219). Speedier resolution, under ENS, total time taken from birth to admission of liability is 18 months, contrast average time of 7 years in non ENS cases – note, these figures are based on an analysis of 10 ENS claims. The introduction of a new system of reviewing ENS cases using a Liability Protocol, a key element of which is the Expert Summit.

The Kirkup report into the Independent Investigation of East Kent, maternity and neonatal unit was published in October 2022, shortly after service failures found in the maternity unit at Shrewsbury and Telford Hospital, another inquiry is underway into Nottingham maternity services. The East Kent Report is a familiarly depressing read, with Dr Kirkup conceding that making policy changes based on these type of inquiries *"does not work in preventing the recurrence of remarkably similar sets of problems in other places"* he goes on to say *"...unless these difficult areas are tackled, we will surely see the same failures arise somewhere else."* The problems are embedded and deep rooted.

Dr Kirkup has identified core themes which need to be tackled, these include giving care with compassion and kindness; teamworking with a common purpose; responding to challenge with honesty; improving early identification of poorly performing units. There is a need to properly measure outcomes in maternity services.

However, it is highly unlikely that themes will be exclusive to maternity and neonatal services. Indeed, the theme of responding to a challenge with honesty is one which will resonate with all claimant focused clinical negligence lawyers. The point is well illustrated in the article ***"Acting***

for a client following an accusation of fundamental dishonesty" written by **Bernadette McGhie** and **Grant Incles** both of Russell-Cooke LLP. The article walks us through the background to the unreported but nonetheless important case of *Karen Preater v Betsi Cadwalladr University Health Board* (2022), where the claimant was wrongly accused of fundamental dishonesty. The accusation resulted in Karen losing her legal representation, leaving her a litigant in person until Russell-Cooke took the case on. Thankfully, expertise and experience triumphed, and the Claimant had a successful outcome.

"Patient fault and contributory negligence in clinical negligence" by **Matthew Stockwell**, barrister at Exchange Chambers is an excellent practical guide for managing allegations of contributory negligence. It reminds us that the burden of proof in contributory negligence claims rests with the defendants throughout.

Increasingly, the NHS is looking to tackle its excessive waiting lists by spending public money on purchasing healthcare services from the independent sector. The question of who becomes responsible in clinical negligence when subcontracted care is shown to be substandard can be complicated. In recent years, there have been a number of cases considering the issues of non-delegable duties and vicarious liability. The most recent clinical negligence case is the Court of Appeal case of *Iris Hughes v Rajendra Rattan* (2022) 1 WLR 1680. ***"Vicarious Liability and Non delegable Duties in the wake of Hughes v Rattan"*** by **Bella Webb**, barrister at Old Square Chambers, explores the far-reaching implications of *Hughes*, helpfully reminding us of the criteria for establishing a non-delegable duty.

Lawyers who have acted for clients whose care was provided privately, will be familiar with the need to recover the cost of private treatment required to treat the injuries arising because of negligent care. Claimants are typically obliged to recover these costs under the terms of their policy. It is also often the case, that the Claimant's private health insurance premiums increase because of the additional medical costs incurred to manage the consequential injury. During AvMA's recent discussions with Bupa they made clear that in some circumstances *"customers"* premiums can be remediated, **Bupa** has helpfully provided case examples to illustrate how this can work in practice in ***"Subrogated claims and the benefits to Bupa health insurance customers"***

We are pleased to include **Christopher Johnson KC** of Serjeants' Inn Chambers, comprehensive article on ***"Implants and Product Liability"***. Unfortunately, because of illness, Christopher was unable to present on this topic in person at AvMA's Annual Clinical Negligence Conference (March 2022), we were fortunate to have Eloise Power also of Serjeants' Inn stand in for him on the day. Christopher has kindly given permission for us to publish key points intended for his presentation, starting with how to assess what constitutes a defect for the purposes of the Product Liability Directive 1985/374 to considering the appropriate level of safety of the product and a reminder of the relevant limitation periods.

November, the month for men to grow moustaches, hence *"Movember"*, is an opportunity to raise awareness of male related illness such as prostate and testicular cancer. **Arran Macleod**, Senior Associate at Pennington Manches Cooper LLP (Guildford Office) contribution ***"Prostate Cancer Awareness Month 2022 – why early detection can be the difference between life and death"*** calls us to become more familiar with the signs and symptoms of the disease and encourages men to visit their doctors early. Arran reminds us that early diagnosis is key, there is a good prognosis for early-stage disease.

The inquest into the death of Katie Horne was case managed by Dr Charlotte Connor of AvMA with pro bono representation and support from counsel, **Thomas Beamont** at 1 Crown Office Row. Katie was a 21-year-old woman who lost the opportunity to have potentially lifesaving treatment due to a series of inexplicable delays, especially a delay in considering her viral tests and a delayed gastroenterologist review. By the time Katie was referred to Kings College Hospital, she had developed covid, it was not possible to proceed with a much-needed liver transplant and tragically, Katie died. The Coroner's PFD was of particular interest as he wrote *"...Although it was suggested that these failures in care were associated with the capacity of the hospital to deliver services in the first wave of the pandemic, there was little evidence to support or refute that"*

We regret to advise of the recent death of Tim Wright, Senior Associate at Pennington Manches Cooper LLP. Tim was a well-respected, and liked lawyer, a long-standing supporter of AvMA, he will be known to many of you. A short obituary is included in the Newsletter.

We look forward to seeing you at the AvMA panel meeting and/or the 40th Anniversary Gala Dinner.

Best wishes

Acting for a client following an accusation of fundamental dishonesty


BERNADETTE MCGHIE, CONSULTANT SOLICITOR
& GRANT INCLES, PARTNER. RUSSELL-COOKE LLP

When Karen Preater first contacted me in 2021 having been referred by AvMA, she was in a desperate situation. She had undergone surgery for urinary incontinence involving a vaginal mesh procedure in 2014. The surgery had clearly gone wrong resulting in her needing to self-catheterise in order to pass urine and leaving her in such chronic pain that she had been unable to return to the job that she loved. Consequently, she became very depressed.

Initially when she had contacted the Betsi Cadwalladr University Health Board, she simply wanted to know what had happened but after making a formal complaint it transpired that the medical records associated with the procedure were *'missing'*. She had therefore instructed solicitors to bring a claim and all went well, proceedings were served and after some negotiation judgment was entered in her favour and the matter proceeded on the basis of quantum only.

Karen had been seen by her own and the defendant's medical experts and a JSM was planned for January 2021. However, in December 2020 the defendant had served video surveillance evidence and a *'cyber report'* having trawled through her social media. It was alleged she had lied about the extent to which she was able to work and needed care and that instead she was running a *'thriving'* and *'successful'* beauty therapy business. Prior to the surgery, Karen lived in North Wales had been earning over £40,000 per year as a professional in sales and marketing. As a result of the problems following the mesh surgery she was unable to return to paid employment. She did attempt various initiatives from her home, including beauty treatments to friends and contacts via social media. In the face of the Defendant's allegations this omission showed her to be dishonest, her evidence was that she never thought of the activity as 'work' compared to what she did previously, that she saw it as therapeutic, and that she had never made any profit from any of the various enterprises when costs of equipment, product and training courses were taken into account. Moreover, in every special damages schedule she had submitted, she gave credit for future earnings of £6-8,000 (net) per annum.

The JSM at the start of 2021 went ahead but the Defendant refuted that Karen had suffered a chronic pain condition as pleaded and disclosed at the JSM damning, previously undisclosed, evidence from their experts. The allegation of fundamental dishonesty (FD) was made at the same time under s.57 Criminal Justice and Courts Act 2015. Despite Karen's solicitors at that time asking for, and receiving, reassurance from the Defendant about its good intentions to settle the claim at the meeting, it was clear no such intention existed. In the light of this evidence and the accusation of FD, her legal team declined to represent her further. They had been acting under a CFA with ATE insurance and in the light of an allegation of FD, that insurance was voided.

Karen was left alone to act as a litigant in person with no means of funding her claim and a trial fixed for June/July 2022 at Wrexham County Court. Not only was she fighting for reasonable compensation for her injuries but she was also defending herself against the accusation of FD. On the other hand, the Health Board had the benefit of a legal team including their barrister and was determined to show that that she was dishonest and not entitled to any compensation. The court showed some sympathy for her position as a litigant in person but she was ordered to provide confirmation from her experts that they would continue to act.

However without the benefit of insurance and no funds to pay them, this seemed impossible. Everything was loaded against her despite the fact that she had clearly suffered injury as a consequence of the defendant's negligence and her life had been significantly altered. She had been the major earner and her family were struggling financially without her income, she was accruing debts and had judgment debts against her. She was in despair.

When I first spoke with Karen, by video call due to covid restrictions, she freely accepted that she had not helped herself by failing to mention the beauty treatments. In common with many people with chronic pain, she explained that she had good days and bad days and when she had a better day she pushed herself hard to try and do something even if she paid for it the next day. No one wants to present a gloomy picture of their life on social media but even so the extracts that the defendant was relying upon were selective, they did not include any entries where she described her pain. I considered that her explanations were entirely plausible but I was concerned that she had failed to correct information in expert reports that she should have known was misleading. She already knew that her situation was extremely difficult and that should the court find with the defendant that she had been fundamentally dishonest, then she also faced the possibility of a prison sentence. I agreed to look at the evidence against her and to consider whether Russell-Cooke could help. It was important to be completely honest with her and not to give her false hope.

After reviewing the video surveillance and social media evidence, whilst still having faith in Karen I knew that we had a difficult task ahead of us. Firstly I needed to carry out an internal risk assessment and to decide whether as a firm we could accept the risk of taking the case on under a CFA. Would we be able to secure insurance? We would clearly need a very experienced barrister to provide a formal advice before any insurer would consider cover. I therefore approached several leading counsel who were sympathetic but mindful of the likely work and time that would be involved, and so reluctant to commit. Our first barrister was able to assist with a helpful advice for the risk assessment setting out the challenges ahead and recommended keeping the current trial listing in Wrexham rather than transferring the case to the RCJ as I had originally proposed. He advised that at best based on the information he had available at that time, the prospects were finely balanced in Karen's favour. Attempts to secure insurance failed but on the basis of this advice Russell-Cooke agreed to enter into a CFA with Karen in November 2021. This meant that Russell-Cooke was accepting a huge risk on costs to take this case to trial but all agreed that this was *'the right thing to do'*. Karen was fully aware of this and the need for a high success fee that she was willing to accept. It was important to keep her updated on the costs situation throughout and for us a firm to constantly reassess risk.

From the outset, the defendant's stance was particularly aggressive. It appeared that every single point was taken where other defendants are likely to have taken a more reasonable approach. Requests were made for excessive amounts of social media disclosure going back to before the injury. Karen had been extremely active on social media and the disclosure involved trawling through many years of WhatsApp, Facebook and Instagram. This took disproportionate amounts of fee-earner and admin time as well as IT resource. It was clear that the defendant was determined to push this allegation at trial and as a firm we had to consider what resources we had available. Having committed to taking the case on it was essential that we ran it as effectively as possible if Karen was to have any chance of success. We also had to consider our own risk and the possibility of losing a very large amount of fees and having to pay large disbursements and counsel. I already had a very full caseload and needed to work out how I could manage this case so close to trial with all the added complexities.

At about this time Grant Incles joined the team as partner at Russell-Cooke. Although allegations of fundamental dishonesty are still relatively unusual in clinical negligence claims, they are much more common in PI claims. Grant had considerable PI experience including experience of running cases where FD accusations had been made. Grant therefore joined me dealing particularly with the FD issues. We worked well together but realised that having two leading solicitors on the case could lead to overlap on the approach to large trial. As the main issues in contention related to the FD rather than the clinical negligence and he had greater experience of FD, it made sense for Grant to take over the case heading the team of fee-earners and admin staff working towards trial. Our original barrister was unavailable for trial and so we instructed James Arney KC who Grant had worked successfully with in the case of *Swift v Carpenter*. James took an extremely systematic and thorough approach to all of the evidence. In a case involving allegations of FD and reams of social media evidence this proved to be key to undermining all of the Defendant's allegations. Nothing was overlooked and James worked with us as part of the team. He was honest in his assessments at every stage, made it clear where he had any concerns and involved Karen in those discussions so that she knew what to expect. Had the case not succeeded then she would know that everything possible that could be done for her had been done.

The Defendant from early 2021 onwards adopted an *'all or nothing'* approach. It refused to engage in any negotiations at the JSM. It refused the Claimant's offer to mediate in February 2022. Even after closing submissions on the 7th day of trial, when given ample opportunity by the Court, the Defendant declined to offer anything substantive to

the Court on quantum to assist it in making the obligatory assessment of damages where fundamental dishonesty has been alleged. A counter schedule with all heads of loss submitted with *'nil'* had been served.

This refusal to engage was accompanied by a failure to provide anything more than generic allegations of *'lying in respect of every aspect of the case'*. The allegations were vaguely particularised. The extracts from the social media were selective, taken on face value only, and completely ignored an equal, if not more substantial, amount of material which supported Karen's evidence. Five out of six of the Defendant's expert witnesses were found to have been unbalanced (or worse) in consideration of the Claimant's evidence. The surveillance footage had no *'silver bullets'* for the Defendant and arguably was favourable to the Claimant's case.

Overall, the Defendant's evidence did not satisfy the requirement to present *'cogent'* dishonesty evidence to the Court, let alone dishonesty which went to the core of the claim. Whilst the legislation indicates the evidential burden on the Defendant to sustain an FD allegation is on the balance of probabilities, the use of the word *"cogent"* means the lower threshold is not the usual 51%, but something significantly higher than that. The Defendant's presentation of this Defence appeared to get nowhere near it and the court found in her favour. Karen recovered over £970,000 after taking into account additional sums payable for beating her own P36 offer as well as an indemnity costs order.

Whilst there does seem to be a trend for defendants to try to raise allegations of fundamental dishonesty, and sadly at times that is appropriate, the impact on claimants' access to legal representation and therefore justice can be disproportionate. Claimants are often left fighting these allegations on their own because understandably there are not many firms who have appetite to accept such a significant risk on costs. From my own enquiries, there is also no appetite for insurers to provide any form of insurance and even if they did so, the premiums would be so excessive they would intolerably deplete the damages. If a claimant is unable to contest the allegation for lack of legal representation or funds, then they are left with the stigma of an allegation of fundamental dishonesty. This cannot be fair when, as in this case, the accusation is unfounded.

If a solicitor is accepting instructions in a fundamental dishonesty claim then my advice is to keep a cool head and to be sure that you have sufficient resources to carry out due diligence. It is essential to ensure that you look at the make up of your team and allocate the work to those who have the most appropriate experience and available time regardless of who the case was referred to. Witness statements must be extremely thorough and address all of the allegations made. It is also essential that the medical experts are clear in what they have asked the claimant, and in particular in cases of chronic pain that they have established the range of function on good and bad days. In our case, all of the experts instructed by the Claimant's previous solicitors and by the Defendant had failed to do this, taking a more general approach. When instructing experts this should be specifically requested; a client should be aware that they should make it clear where there is a range in their ability to carry out activities of daily function.

It is always better not to find your client in a situation where such allegations have been made. When assessing new cases at the outset and entering into funding agreements, you should be as confident as you possibly can be that you know your client. A face-to-face meeting is always preferable but where this is not possible then a video call is generally better in my view. Clients should also be advised that defendants can and will scrutinise their social media and will draw whatever conclusions they wish which could be used against them. This may feel like an infringement on personal freedoms but this information is of its nature in the public domain. Clients should also be warned of the use of video surveillance and the need to let their solicitor know about any changes in their condition or any attempts to carry out any form of work even if they do not consider it to equate with their usual employment.

Patient Fault and Contributory Negligence in Clinical Negligence

MATTHEW STOCKWELL, BARRISTER
EXCHANGE CHAMBERS

EXCHANGE CHAMBERS

Background

One of my first clinical negligence cases involved a young man who had driven carelessly into a wall whilst showing off in a car. Administrative error led to delay in reporting and review of medical imaging, which in turn led to delay in treatment of the fractured forearm he suffered in the collision. Proceedings were commenced and, whilst breach of duty and causation were admitted, a plea of contributory negligence was raised, the first such allegation I had seen.

It took a considerable amount of time, not to mention additional cost, for the defendant to grudgingly accept that my client was 100% responsible for his self-inflicted injury, but it was 100% responsible for the additional suffering and sub-optimal recovery he had made by reason of the delay in his treatment. Contributory negligence had no application here.

Since that early experience, I have seen sporadic attempts to raise contributory negligence allegations in clinical negligence cases. Enthusiasm for such arguments appears to wax and wane. This article is intended as an aid memoir of the relevant principles and cases, and a practical guide for when you next encounter one.

Breach, Causation and Contributory Negligence – intertwined

Professional experience and the reported cases (considered below) suggest issues of breach, causation and contributory negligence are invariably intertwined. The advisor's role is to carefully unpick the strands. Whilst there is a factual and legal overlap, the issues need to be considered separately on their individual merits. When undertaking this exercise, it is useful to go back to first principles:

'Joint' & *'Several'* liability

Where damage is caused as the result of torts committed by two or more defendants, these may be: (1) joint tortfeasors; (2) several tortfeasors causing the same damage; or (3) several tortfeasors causing different damage.

Defendants are said to be *'joint tortfeasors'* where the cause of action, damage and evidence required in support is the same in each case. Joint tortfeasors may be working jointly towards a common purpose. Some legal relationships give rise to joint liability (employment, partnership and agency etc). If a joint or several tortfeasor who has caused the same damage is sued alone, that person is liable for the whole damage, even if only contributing to a small degree. In the case of several tortfeasors causing different damage, each is liable only for the discrete damage which he or she has caused.

Where two or more defendants cause different damage to the same claimant, the causes of action against each tortfeasor are entirely distinct from one another and the claimant can recover from each tortfeasor only that part of his or her damage for which the tortfeasor is responsible (*Holtby v Brigham & Cowan (Hull) Ltd*).

'Divisible' or *'Indivisible'* injury

'Indivisible' injury is harm of the same kind caused by an unbroken chain. Any tortfeasor will be liable to compensate for all the damage caused. A *'divisible'* injury is one where the type of harm is discrete, or the extent of the tortfeasors' contribution can be determined (e.g. in NIHL). In clinical negligence, a claim may arise where an injury or illness (or its effects or consequences) have been made worse by negligence. There are cases where the tort or the harm are coextensive (e.g. suicide prevention claims).

Supervening Events

Often *'contributory negligence'* and *'chain of causation'* arguments are rolled-up together, but how do they differ? A novus actus interveniens or supervening event is (a) an intervening act or occurrence, (b) which may or may not be tortious that (c) breaks the chain of causation, i.e. brings the liability of the first or primary defendant to an end.

In the leading case of *Webb v Barclays Bank plc* [2001] EWCA Civ 1141, C had mobility problems associated with polio. C tripped and fell at work suffering injury to the left knee and then sued her employer. Unfortunately for C, she was then negligently advised to undergo an above knee amputation by an orthopaedic surgeon, who was joined as second defendant to the claim. The Court held that the latter's negligence did not *'eclipse the original wrong-doing'* and liability was apportioned between the employer and the surgeon.

The Court of Appeal expressly approved the editorial in *Clerk & Lindsell* at [55]: *"Moreover, it is submitted that only medical treatment so grossly negligent as to be a completely inappropriate response to the injury inflicted by the defendant should operate to break the chain of causation"* (18th ed., 2-55). Logically then, only *"a completely inappropriate response"* by a patient would operate to break the chain of causation in a clinical negligence claim.

Most cases will, instead, be concerned with whether apportionment is appropriate with reference to general principles. For example, two or more parties may be responsible for an accident giving rise to a need for treatment. C may receive negligent treatment from one or more party. Negligent treatment may worsen C's outcome from the injuries sustained or cause discreet injury (e.g. a surgical error or hypoxic event). C's own actions (e.g. failing to seek prompt treatment or to follow advice) may prolong recovery or worsen the outcome. If you can separate out responsibility and outcome in such cases you do. If not, you are more likely to be looking at apportionment or contributory negligence as appropriate.

Patient Fault (or shared responsibility)

This is a hugely important and far reaching issue in healthcare. One study suggests that the relative contribution made to our health and wellbeing by access to and the quality of healthcare received is only up to 15%, whereas health behaviours or lifestyle factors (40%) and social circumstances and environmental factors (45%) have a much more substantial role (McGinnis et al, 2002).

Background factors commonly arising in clinical negligence claims include: illicit drug use, smoking, alcohol, obesity, inactivity, long term conditions (e.g. diabetes, mental health). Successful medical treatment frequently depends upon cooperation or compliance by patients, and health providers place ever increasing emphasis on engagement, prevention and health surveillance.

Experience would suggest these factors introduce a danger of subconscious or cognitive bias. Every seasoned clinical negligence lawyer will have come across examples where, it might reasonably be inferred, a patient's lifestyle or comorbidities have influenced the timeliness and standard of care the patient received.

Adverse lifestyle factors (or poor patient compliance) are potentially both a sword and shield. It is a general principle of both medicine and law that you take a patient or person as you find them. The risk profile of a patient may be highly relevant to breach. It will also commonly have implications for causation (for example, the likely *'but for'* outcome or prognosis of the patient), condition and prognosis (especially future morbidity and life expectancy). Against this background, an obvious question for a Defendant is whether fault arguments are more effectively deployed in a different way.

Contributory Negligence: General Principles

There is no special rule for clinical negligence. The three essential ingredients for any allegation in this context are:

- Was there fault on the part of the patient?
- If so, was this causative of damage; and
- If so, to what extent would it be just and equitable to reduce damages (apportionment).

It is always necessary to prove all three ingredients and the burden of proof remains with the Defendant throughout.

The apportionment is a balancing or comparative exercise between *'blameworthiness'* v. *'causal potency'*. Likewise, there are three stages:

- Stage 1 (often missed) – consider the relative blameworthiness of defendant and patient.
- Stage 2 – consider the effect that each party's actions have had on the patient's outcome.
- Stage 3 – conduct a balancing exercise based on the outcome of Stages 1 and 2.

Relevant factors specific to assessment of contributory negligence in a clinical negligence context include:

- Paternalism and imbalance of relationship (cf. employees, children, pedestrians etc) – these factors tend to militate against findings of responsibility and inform the relative blameworthiness of the parties.
- *Bolam* / *Bolitho* – in keeping with employers' liability claims, the Courts will not readily exculpate defendants for fear of emasculating the standard of care (and patients

having to overcome a relatively high hurdle to establish negligence in the first place).

• Patient specific behaviours and characteristics (stoicism, gender, age, education, anxiety etc) – these can operate both ways.

• Principles underpinning access to healthcare and patient fault – the notion that you take your patient as you find them, where appropriate.

• Knowledge and appreciation of harm on the part of the patient – this is key, particularly against a background of inadequate advice.

Clinical Negligence: The Cases

Contributory negligence has been consider in the following judgments. Each case turns on its own facts, they span a period of over three decades in which treatments have changed and the relationship between doctor and patient has evolved, but the following themes can be gleaned:

• Allegations of this nature are relatively rare.

• Judicial disinclination to arguments of this nature is clear.

• Allegations of contributory negligence tend to be combined with arguments over breach of duty and causation.

• Contributory negligence allegations are time consuming and costly to deal with.

• Allegations of this type invariably anger or upset clients (especially in bereavement claims).

***Pidgeon v Doncaster Health Authority* [2002] Lloyd's Rep. Med. 130**

This case involved a cervical smear test wrongly evaluated in 1988. In 1997, following gynaecological referral, an ovarian carcinoma was discovered. Between 1991 and 1997, C rejected the urgings of her GPs to have further smear tests on seven occasions and ignored two letters from a screening programme. The Judge rejected argument that C's actions broke the chain of causation. However, damages were reduced for contributory negligence by two thirds, a deduction having been accepted in principle by her representatives. This seems an exceptionally harsh result. C had explained she found the smear test very painful and embarrassing, and that she had already been traumatised by a miscarriage at full term in December 1987. Moreover, the Judge accepted that at no point had a GP explored the reasons for her ongoing reluctance. Notwithstanding, the Judge felt able to substitute his own assessment, in the apparent absence of direct expert evidence on this issue, about her likely embarrassment and anxiety regarding intimate examination.

***P (Deceased), Re* [2011] EWHC 1266 (QB)**

P visited her GP in Jan 1999 with a mass in her breast. No abnormality was detected on referral to a breast clinic. P visited her GP again in Jan 2000 and was again referred to a breast clinic. P was sent two appointments, which she failed to attend and her GP was advised. Unbeknown to anyone, the appointment letters had been sent to the wrong address. P moved house and saw her new GP in Jan 2001, and was then referred to hospital. In the meantime, bone metastases had occurred and P died in 2003. Causation was established in favour of P's estate. Allegations of contributory negligence were dismissed, having been based on P's alleged failure to follow up about appointments. In so doing, the Judge described the facts in *Pidgeon* as *"extreme"*.

***Spencer v Hillingdon Hospital NHS Trust* [2015] EWHC 1058 (QB)**

C underwent surgery for repair of an inguinal hernia. He subsequently suffered a deep vein thrombosis, followed by a pulmonary emboli on each lung. The Hospital had not advised of this risk and he had not been made aware of the associated signs and symptoms (a good example of the *'safety netting'* duty). Breach of duty and causation were established. Contributory negligence was alleged on the basis C failed to seek advice in connection with calf pain, which arose a few days later. The Judge held C reasonably attributed his pain to immobility, given surgery to other body parts, temporal delay and having regard to the Hospital's own advisory failings.

***Darnley v Croydon Health Services NHS Trust* [2015] EWHC 2301 (QB)**

The facts here should need little or no introduction. This is the leading case (following successful appeal to the Supreme Court) establishing that Trusts have a duty to take reasonable care not to provide misleading information (in this case, regarding waiting times), C having left A&E without being seen in ignorance as to the severity of his head injury. Contributory negligence was alleged as a fallback position to the Trust's primary case that no duty was owed and C's actions broke chain of causation. This allegation was not dealt with by the Judge given his finding on causation. In the Court of Appeal, the Trust effectively conceded that this allegation stood or

fell with its causation argument. As with *Spencer* above, C's actions were intertwined with the Trust's failure.

***Sims v MacLennan* [2015] EWHC 2739 (QB)**

This was another fatal claim involving S who suffered a stroke in 2011. S underwent a private medical examination in 2002, where his blood pressure was raised. There was a factual dispute as to whether the doctor advised S to consult his own GP for follow-up. Breach of duty and causation were disputed. Contributory negligence was alleged on the basis that S's own GP had advised him to have a BP check in 2007. The case failed on both breach of duty and causation. If the claim had succeeded, the Judge indicated he would have reduced damages by 25%.

***Spearman v Royal United Bath Hospitals NHS Foundation Trust* [2017] EWHC 3027 (QB)**

In this case, the Hospital had breached its duty to take reasonable steps to keep a vulnerable patient reasonably safe whilst on its premises, when he fell from a roof terrace after gaining access to it via an unsecured fire door. The Trust pursued four allegations on contributory negligence. The first three allegations fell away with the Judge's findings of fact. The fourth allegation, relying on the patient's own actions in climbing on to the roof terrace, failed owing to his state of mind at the time. The Judge accepted that the law does not *"penalise a person for being ill or of unsound mind"* and here the duty, breach and patient's actions were coextensive.

***Dalton v Southend University Hospital NHS Foundation Trust* [2019] EWHC 832 (QB)**

This was another case involving alleged delayed diagnosis and management of breast cancer. Breach of duty and causation were disputed. Contributory negligence was originally pleaded based on C's alleged failure to seek earlier re-referral, but the allegation was abandoned at trial. Whilst the case failed on breach of duty and causation, the Trust's original plea of contributory negligence attracted criticism from the Judge, Yip J at [33]:

"I consider that the circumstances in which a finding of contributory negligence can properly be made in a clinical negligence claim will be rare. Certainly, they do not arise here. I imagine that the allegation was a difficult one for Mrs Dalton to read (particularly at a time when the prognosis was less optimistic than it is now). I am not entirely sure that there was a sufficient evidential basis for it to be made. However, I commend Mr Kennedy for not persisting with it and make it clear that I find Mrs Dalton blameless."

***Plant v El-Amir* [2020] EWHC 2902 (QB)**

This case involved eye surgery performed on a 79-year-old patient, who was partially sighted and whose vision was worse in her left eye. Breach of duty and causation were disputed. The Judge held the surgeon had failed to explain that surgery on C's right eye would not achieve her aim of reading again and carried a risk of complications, hence liability was established. The Judge rejected various allegations that C had been non-compliant with medication or acted against advice.

***Otu v Datta* [2022] EWHC 2388 (KB)**

This was another fatal claim by the wife of O, who died of colon cancer diagnosed in 2016. There was an admitted breach in failing to arrange a colonoscopy in 2014, but a dispute about whether earlier diagnosis would have altered O's outcome. Causation was established in favour of O's estate. In like manner to *P (Deceased), Re* above, contributory negligence allegations based on O's alleged failure to follow up about a colonoscopy appointment were dismissed. The Judge held O had reasonably understood the investigation to be precautionary, not urgent or particularly important. The possibility of cancer had not been mentioned to O and administrative responsibility for follow-up had been that of the Defendant alone in all the circumstances.

The Defendant had emphasised that medical treatment is not a matter for the doctor alone and prayed in aid the concept of patient autonomy. A handful of commentators have suggested the latter should weigh more heavily in a post-*Montgomery* world, inviting more regular consideration of contributory negligence. The logic of this argument is unclear. It appears to conflate the concepts of negligence and informed consent, and it is difficult to identify a single example where *Montgomery* has or might affect the determination of an allegation of contributory negligence one way or the other.

Practical Considerations

What might practitioners do when considering contributory negligence in a clinical negligence claim? Here are a few pointers:

- Investigate allegations early and thoroughly.
- Chronologies and timelines are key (to assist with the unpicking exercise outlined above).
- Obtain and scrutinise every potential document at the earliest opportunity (as contributory negligence

allegations may arise from material that is not directly related to breach of duty and causation).

• Proofing of the client and other witnesses should cover this ground (and involve gentle, but firm challenge of people's actions and understanding).

• Make sure experts (as to breach of duty, causation and quantum) cover the relevant issues.

• Respond robustly and promptly to contributory negligence allegations.

• Make effective use of Part 36 offers.

• Make sure contributory negligence is reflected in budgeting and case plans.

• Reassure and support clients throughout, anticipating that additional upset is likely.

• If acting for a Defendant, raise allegations sparingly, only in clear cut cases, and think about the wider implications for litigation of a claim (e.g. effect on cooperation, settlement and judicial impression).

There will be cases in which patients reasonably attract criticism for failing to take reasonable care for their own safety, but these cases will be rare and deductions should only be agreed or imposed on a principled and properly evidenced basis.

Vicarious Liability and Non delegable Duties in the wake of *Hughes v Rattan*

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In the much-debated case of *Iris Hughes v Rajendra Rattan* (2022) 1 WLR 1680, the Court of Appeal, comprised of Bean LJ, Nicola Davies LJ and Simler LJ, considered the question of whether dental practices which service NHS General Dental services Contracts were liable for negligence on the part of associate dentists engaged by them. The Court of Appeal considered that they were in a judgment which has potentially far wider reaching implications.

The Factual Background

Dr Rattan was both the owner and sole principal dentist at the practice at which Mrs Hughes received dental care. Mrs Hughes was, however, treated by a number of dentists other than Dr Rattan, three of whom were categorised as self-employed Associate dentists and one trainee dentist. It was accepted that the latter was an employee, for whom the practice was uncontroversially vicariously liable. Mrs Hughes alleged that her treatment had been negligent on a variety of occasions between August 2009 and December 2015. The specifics of her claim in negligence need not be considered for present purposes.

Notably, the treating dentists had been identified and apparently remained willing to respond to the claim but both the Practice and Mrs Hughes declined to engage with them and instead continued to pursue Mr Rattan as practice owner.

The facts were largely agreed. Dr Rattan contracted with the Primary Care Trust under a General Dental Services Contract (GDS). That contract itself derived from the NHS (General Dental Services Contracts) Regulations 2005. Under that contract Dr Rattan's practice provided dental services to patients and was entitled to sub-contract his obligations to Associates in order to deliver those services, so long as he took reasonable care to ensure that they had the requisite clinical experience, training and arrangements for appraisal and CPD.

The Associate contracts were based upon the British Dental Association standard contract. They were engaged as independent contractors and tax, sickness absence and pension provisions reflected that position but there was also provision for parental leave, maximum holiday, restrictive covenants to protect the goodwill of patients for the benefit of the Practice and notice of termination. Dr Rattan received a *"licence fee"* from the Associates and fees received under the GDS, together with private and laboratory fees, expenses, NHS charges and bad debts were split 50/50 between the Practice and the Associates, the latter of whom also held insurance and provided an indemnity to Dr Rattan in respect of claims in negligence. Appointments were arranged by the Practice who held all patient records centrally. Mrs Hughes (and other such patients) could express their preference to see a particular dentist but were not entitled to be treated by that individual and in respect of each course of treatment, a Personal Dental Treatment Plan was signed by the patient, and which referred to Dr Rattan as the provider of services. Nonetheless, the Associates had complete freedom and responsibility in respect of their clinical decision making and treatment.

The High Court

Before the High Court, Heather Williams QC as she then was, held that Dr Rattan did owe a non-delegable duty to Mrs Hughes following the test set out by Lord Sumption in *Woodland v Swimming Teachers Association and others* [2014] AC 537. In that case it was held that a non-delegable duty will arise if the following criteria are met:

1. The claimant is a patient or a child, or is especially vulnerable or dependent on the protection of the Defendant against the risk of injury.

2. There is an antecedent relationship between the Claimant and the Defendant, independent of the negligent act or omission itself, (i) which places the claimant in the actual custody, charge or care of the defendant, and (ii) from which it is possible to impute to the defendant the assumption of a positive duty to protect the claimant from harm, and not just a duty to refrain from conduct which will foreseeably damage the claimant. Such relationships have an element of control over the Claimant.

3. The claimant has no control over how the Defendant chooses to perform those obligations, i.e. whether personally or through employees or through third parties.

4. The Defendant has delegated to a third party some function which is an integral part of the positive duty which he has assumed towards the Claimant.

5. The third party has been negligent not in some collateral respect but in the performance of the very function assumed by the Defendant and delegated by the Defendant to him.

However, the judge also found that Dr Rattan was vicariously liable for any negligence on the part of the Associates, concluding that his relationship with them was akin to one of employment in the sense considered in *Various Claimants v Barclays Bank Plc* (2020) UKSC 13 and most importantly, that the Associates were carrying on tasks as an integral part of the business' activities of Dr Rattan (further to *Cox v MOJ* (2016) UKSC 10 and *Various Claimants v Catholic Child Welfare Society* (2012) UKSC 56.) It was critical to the decision that Dr Rattan bore the majority of the business risk and the Associates enabled him to meet his GDS contractual obligations. The defendant conceded that if the relationship criterion was met then the second limb of the test, namely the closeness of connection between the relationship and alleged wrongdoing, was satisfied.

Dr Rattan appealed both aspects of that judgement.

Court of Appeal

Bean LJ, giving the judgement of the court held that Dr Rattan was under a non – delegable duty to Mrs Hughes but was not vicariously liable for the actions of the Associate dentists.

Addressing the five criteria set out in the *Woodland* case (above), it was held that:

1. The Claimant was a patient (which must include anyone receiving treatment from a dentist) and therefore vulnerable or otherwise dependent upon the Defendant's protection against the risk of injury. There was no requirement that she should be within a subset of especially vulnerable patients in order to qualify.

2. An antecedent relationship was established between the Claimant and Defendant on each occasion on which the Claimant signed the Personal Dental Treatment Plan and which she had to do before NHS treatment was undertaken. That placed her in the defendant's care as he was the Practice owner. The plan stated that *"the dentist named on this form is providing you with a course of treatment"* and named only Dr Rattan – which was in accordance with the GDS contract and Associate agreements which sought to prevent Associates from soliciting patients away from the Practice. That relationship involved an element of control over the patient.

3. The Claimant had no control over how the defendant performed his obligations. Any preference she expressed as to choice of practitioner was no more than a preference and did not amount to an entitlement.

4. Criteria 4 and 5 were not in issue. The defendant had delegated to a third party a function that was integral to the positive duty owed and that party had been negligent in performing that function.

As such, the issue of vicarious liability did not strictly arise but the court nonetheless expressed its obiter conclusions upon the issue given that the case was viewed as a test case.

Bean LJ considered that where primary facts are largely agreed and the preliminary issue is one of law, reduced deference is accorded to the evaluation of the trial judge. It was accepted that the Associates were carrying on activities as an integral part of Dr Rattan's business and for its benefit and were not conducting independent businesses of their own. However, it was noted by Baroness Hale in *Barclays* that the concept of business integration in *Cox* had not eroded the classic test for vicarious liability which was found in the distinction between relationships akin to employment and relationships with independent contractors.

The Court considered that in the present case, those criteria were not met for a range of reasons including:

(a) Associates were free to work at the Practice for as many hours as they liked and for other Practices;

(b) The Defendant had right to control and nor did he seek to control the way in which treatment was undertaken nor the clinical decision making of the Associates;

(c) Associates were responsible for their own tax and NI and were treated as independent contractors by HMRC;

(d) The defendant took most of the financial risk although the Associates shared the risk of bad debts;

(e) Associates were required to indemnify the defendant against any claims made against him in respect of their treatment of patients.

Whilst there were some factors pointing in the other directions such as the Defendant being responsible for deciding opening hours and providing equipment and facilities, the requirement of Associates to follow the Practice's policies and procedures and with some control by means of the NHS duty to ensure the completion of courses of treatment within a reasonable period of, they were not considered to outweigh those against a finding of vicarious liability.

Comment

The judgement provides much needed clarity in respect of the liability of dental practices and specifically the ruling that whether treatment is provided by employees or independent Associates, the practice continues to owe a non-delegable duty to patients whose treatment is provided pursuant to NHS contracts. For Claimants the long-established requirement/tendency to sue a multiplicity of practitioners in order to bring claims which are often of limited value and extent, can be put to bed with a single, simpler, quicker and more cost-effective claim pursued solely against the practice especially where has been a course of treatment of various dates by various different practitioners or where associate dentists may have insufficient or non-existent insurance cover.

Where there is no written Associate agreement, it now seems likely that one will be implied based upon the standard template BDA associate agreement. The Claimant will nonetheless still need to consider carefully the factual matrix in any particular case, by reference to the *Woodland* criteria as interpreted by the Court of Appeal in the index case and the terms of the contractual agreements in place if and to the extent that they differ from the standard form contracts.

The judgement should also be read alongside the Court of Appeal's decision in *Pawley v Whitecross Dental Care Ltd* (2021) 1 WLR 2577 which prevents practices from requiring Claimants to join associates to the claim against their wishes.

The judgement also upholds the application of Baroness Hale's judgement in *Barclays*, albeit obiter and is as such a reinforcement of the principle that the classic distinction between employee and independent contractor remains key, overriding policy considerations for business integration. It further illustrates that the concepts of non-delegable duty and vicarious liability remain distinct legal questions based upon separate tests. The decision does not necessarily mean that all such claims of vicarious liability in cases relating to dental (or other) practitioners will now fail, but that much will depend upon the precise circumstances of the case by reference to the factors considered by Bean LJ. For example, vicarious liability may yet be found in cases where the Associate Dentists are prevented from working at other practices and/or are required to work a set number of hours.

For clinical negligence practitioners generally, the case provides useful guidance as to where the line can be drawn between a duty to arrange and a duty to perform which is particularly relevant in cases where aspects of NHS medical care are subcontracted or outsourced to third party providers.

It should nonetheless be noted that there is a distinction between NHS dental treatment and private dental treatment. It is clear from the judgment that the fact the Claimant received NHS dental treatment was of critical importance to the judgment on non-delegable duty. It seems less likely that the decision would have been the same if treatment had been provided privately, although of course, although there would of course need to be careful consideration of the facts and agreements in place should such a claim arise.

It should also be noted that, where the duty is statutory rather than under common law, the issue of delegability will be determined by analysis of the statute and not by the *Woodland* criteria.

Furthermore, it remains unclear whether the judgement will apply (and to what extent) to an NHS patient undergoing a purely private course of treatment like adult orthodontics, implants or facial aesthetics. There are of course also some NHS treatments which are combined with elements of private care. That clarity is ultimately only likely to be determined by the courts in due course.

In the writer's view, the most interesting aspect of the judgement is the potential wider reach of the principles espoused and which it seems likely may reach beyond that of the dental sphere. On the issue of non-delegable duty, Bean LJ would, it seems, have considered the Claimant to have been in the Defendant's care had the practise been run by a company or a partnership. How might that translate to other providers in the wider healthcare sector? In particular, cases where a hospital providing facilities is the only legal body with sufficient insurance cover (ie: where the surgeon's cover is inadequate or non-existent) could be brought into focus again as in the *Spire v RSA /*

Patterson litigation. Moreover, the Privy Council is shortly due to consider the issue in the case of *Gulf View Medical Centre Ltd v Tesheira* which it is hoped will provide further analysis.

In the meantime at least, healthcare organisations providing such work and engaging independent contractors, and on either side of the contract should take great care to consider the terms of any contracts and indemnity provisions, especially where there is any variation to the NHS standard terms.

Subrogated claims and the benefits to Bupa health insurance customers

MICHAEL HOLLAND, SUBROGATION CASE HANDLER, BUPA UK INSURANCE

Bupa health insurance customers have obligations under the terms of their policy to recover treatment costs incurred resulting from both clinal negligence and personal injury claims. Bupa's experienced third-party team supports both customers and their acting solicitors with the subrogation process.

When a Bupa health insurance customer considers pursuing a clinical negligence claim, Bupa signposts them to Action against Medical Accidents (AvMA) where they can find information and support.

Bupa helps customers and acting solicitors by providing details of relevant treatment costs to be included in a clinical negligence claim. This includes details of any excess and payments paid by the customer if they've used up their health insurance policy benefits.

Premium remediation

Claims history is one of the factors Bupa considers when calculating customers' premiums. Following a successful recoup of treatment costs resulting from a clinical negligence claim, Bupa can potentially remediate customers if their clinical negligence related treatment claims have impacted their premium, potentially over several years.

Here are some examples where Bupa has successfully recouped treatment costs via a subrogated claim and remediated customers' premiums.

Case study A – A 65-year-old lady who had a hip operation

Due to ongoing pain and discomfort, this customer had numerous consultations, x-rays and injections. Four years later, she had to have a hip replacement revision operation and physiotherapy for almost a year afterwards as a result of clinical negligence during the initial operation.

She pursued a clinical negligence claim against the consultant for £72,000 which included her £11,396.57 treatment costs which were paid by Bupa because these were covered by her health insurance policy. She also claimed for the £3,042.61 additional treatment costs she incurred because they weren't covered by her policy.

Following her successful claim, Bupa recalculated her low claims bonus which resulted in a reduction in her monthly premium and a £2,561.61 refund.

Case study B – a 77 year-old gentleman whose prostate cancer diagnosis was delayed

This customer pursued a clinical negligence claim against the consultant for the delay in diagnosing his prostate cancer which led to it spreading to other areas. He also suffered heart problems due to the medication he'd been prescribed.

He incurred £435.85 costs for treatment which wasn't covered by his health insurance and his policy excess. He claimed this back from the defendant. Bupa recovered £104,105.84 for treatment costs which were covered by his policy and paid for by Bupa.

Following this, Bupa recalculated the customer's premium to remove the impact on his premium of the treatment he needed as a result of the negligence. This meant he was due a £2,986.20 refund and his monthly premium payments were also reduced following the recalculation of his low claims bonus.

Bupa offers a dedicated contact to assist customers and solicitors. The third-party team can be contacted on 0800 028 6850 between 9am and 5pm Monday to Friday or by email: infothirdparty@bupa.com

Implants and Product Liability

SERJEANTS' INN

CHRISTOPHER JOHNSTON QC
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Context: Product Liability Law : "No fault" in theory

The Product Liability Directive 1985/374 (*"the Directive"*) was (purportedly) brought into English law by the Consumer Protection Act 1987 (*"CPA"*). The approach of the European Court in **European Commission v UK** was to say that the UK Courts would have to interpret the CPA in line with the Directive:

"the statute must be interpreted in the light of the wording and the purpose of the Directive so as to achieve the result which it has in view." (*Case C-300/95* [1997] AER (EC) 481, §38).

The driver behind the Directive was the *"Thalidomide scandal"* (*"Distaval"* in the UK). The aim was to give greater consumer protection by making it easier to bring and prove cases by removing the requirement to prove fault on the part of European manufacturers.

Also uniformity of basic standards was the price for European manufacturers to enter a vast consumer market. The Directive *"aims not only to avoid differences in levels of consumer protection, but also to ensure undistorted competition between traders and to facilitate the free movement of goods."* (*Somer v Dalkia France* Case C-285/08, paragraph 29). See also:

Commission of the European Communities v France *Case C-52/00* [2002] ECR I-3827;

Commission v Greece *Case C-154/00* [2002] ECR I-3879 and

González Sánchez *Case C-183/00* [2002] ECR I-39

The introduction of *"no fault"* was seen as a *"fair apportionment of the risk"* between consumers and manufacturers.

"Liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality of a fair apportionment of the risks inherent in our modern technological processes." [2nd preamble to **the Directive**]

Underpinning that thinking was that manufacturers could insure, consumers could not. The aim was to simplify recovery for consumers as it was almost impossible for them to determine what had gone *"wrong"* or who was at *"fault"* when a product was defective. *"Simply"* consumers have to prove that assessed objectively the safety of the product is not such as persons generally are entitled to expect. Nevertheless the burden of proof was left on claimants to establish defect in the product and the causation that flowed from that defect.

The Directive provided no separate regime for pharmaceuticals or medical devices. UK litigation in these fields has not proved easier for consumers as a result of the Directive.

The Directive provides no particular regime for pre-birth injury and this has been left to domestic law. This is a startling omission given the Thalidomide experience drove the need for the Directive.

The standard applied: *"Defect"*

Article 6 of the Directive sets out the test for *"defect"*:

"a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account..."

The Sixth Recital of the Directive states that

"to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect".

The Directive makes clear that:

"A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."

The CPA (unhelpfully) sets out a more complicated two-stage definition for *"defect"*:

3(1): *"there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect"*

3(2): *"in determining for the purpose of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account..."*

Key European case law in this area includes:

Boston Scientific Medizintechnik GmbH v AOK Sachesn-Anhanlt-Die Gesundheitskasse (Case C-503/13, C-504/13) [2015] 3 CMLR 173 ("**Boston Scientific**").

NW v Sanofi Pasteur (Case C-621/15) (2017) ECLI:EU:C:2017:484 ("**Sanofi Pasteur**")

The Court of Appeal is clear that if a claimant proves that a product has a *"defect"* there is no requirement on the claimant to go further and prove the mechanism of that defect.

Ide v ATB Sales Ltd [2008] EWCA Civ 424: Thomas LJ: it was *"unnecessary to ascertain the cause of the defect"* (defective mountain bike handlebar)

Baker v KTM Sportmotorcycle UK Ltd [2017] EWCA Civ 378: *"there may be a defect within the meaning of section 3 of the CPA, even though the precise mechanism by which that defect arose is not proven"* (failed motorcycle brakes).

But what is a *"defect"* under the Directive and CPA? There is a schism in the first instance English case law which has yet to be resolved at appellate level between the older *A v NBA* (2001) and the newer hip implant cases in particular *Gee* (2018) and the earlier *Wilkes* (2016). In Scotland in the case of *Hastings* both the first instance court and the inner house on appeal adopted the approach in *Gee*.

A v National Blood Authority [2001] Lloyd's Rep Med 187, Burton J ("**A v NBA**")

Wilkes v DePuy International Ltd [2016] EWHC 3096 (QB), [2017] 3 All ER 589 ("**Wilkes**")

Gee v DePuy [2018] EWHC 1208 (QB) ("**Gee**")

Hastings v Finsbury Orthopaedics Ltd **[2021] CSIH 6** and **[2019] CSOH 96** ("*Hastings*")

A v NBA

Many manufacturers – particularly in the pharmaceutical and medical device context – have vast resources to throw at litigation challenging their products. Consumers are not so well placed and often need to resort to group actions in order to have the legal firepower sufficient to bring a claim. However, this is difficult when the application of the law is uncertain and when there is no limit placed on the manufacturers' ability to run defences and canvass wide ranging evidence encompassing such things as *"avoidability", "risk/ultility", "learned intermediary defences", "regulatory compliance"* and the statutory *"development risks defence"*. A v NBA attempted to restrict the scope of the areas to be considered in a product liability hearing in order to give effect to the intent and meaning of the Directive.

No *"avoidability":* Burton J determined that the correct question to be posed was whether the product in question met the *"legitimate expectation of safety"* for that product. This was the consumer expectation of safety as objectively interpreted by the court under article 6 of the Directive. Relying on the *German bottle case*, Burton J concluded that it was not necessary for a claimant to prove that a defect could have been avoided. To permit an assessment of whether the defect was avoidable in his opinion was to introduce a fault standard by the back door. Thus whether or not it was technically feasible to detect or avoid the defect was neither here nor there. What mattered in the assessment of defect was the *"legitimate expectation of safety of the product"* and what was therefore required evidentially was a description of the *"composition or construction of the product"* and its *"effect and consequence in use"* but it was not appropriate in this context to *"consider what could or should have been done, whether in respect of its design or manufacture, to avoid the problem"*. Thus the claimant did not have to prove that there was some hypothetical alternative universe in which the defect could have been avoided. Avoidability was irrelevant when assessing defect.

The **German bottle case**: Bundesgerichtsgof, 9/5/1995 - VI ZR 158/94 (Sparkling Water Bottle) in which the German Federal Supreme Court held that it was correct to determine that a consumer expected a mineral water bottle to have no obvious or even microscopic damage which might lead it to explode. Importantly they stressed that: *"The fact that it is not technically possible to detect and repair such defects in the bottle does not alter the consumer's expectations."*

"Risk/utility": An important concept relied upon in US product liability law was *"risk/utility"*: i.e. the assessment of whether a product was defective had to consider whether the benefits of the use of the product outweighed the risks. Burton J in *A v NBA* again was clear the introduction of risk/utility was anathema to a *"no fault"* Product Liability Directive assessment: that approach had been expressly

rejected in the drafting of the Directive; it formed no part of the Article 6 test. **A v NBA** §35.i

Wilkes

The *A v NBA* approach gave hope to claimants that the evidence to be adduced at a product liability trial could be restricted simply to focus on Burton J's formulation of legitimate expectation of safety. However, the approach in *A v NBA* has been decisively and comprehensively rejected in recent English first instance cases involving hip implants, *Wilkes* and *Gee*.

In *Wilkes v DePuy International Limited* the claimant sued in negligence and under the CPA following the failure after three years of a component – a C-Stem – within the defendant's hip implant. The claimant alleged the implant was defective in that the grooved area of the neck of the C-Stem created an excessive stress at its neck. The defendant contended the C-Stem was not defective, arguing that the groove was a beneficial feature, because it allowed the C-Stem to be used with both metal and ceramic femoral heads. Hickinbottom J concluded there was no defect in the product: there was no manufacturing defect and no evidence of it being outside its design specification.

Further, the design was not defective in that other possible designs had other disadvantages, other manufacturers had adopted the same approach, the device surpassed the material British regulatory standards, there was no evidence the C-Stem carried a higher risk of failure and there were adequate warnings given about the risk of fracture (the consequence of which fracture were relatively limited). In so ruling, the judge rejected the approach taken in A v NBA (as discussed further below).

Wilkes v DePuy International Ltd [2016] EWHC 3096 (QB) [2017] 3 All ER 589 ("**Wilkes**")

Gee v DePuy

"All the circumstances": Andrews J in Gee also expressly rejected the *A v NBA* approach which sought to restrict the circumstances which could be considered by the court, instead endorsing Hickinbottom J's approach in *Wilkes*, which required a *"flexible approach to the assessment of the appropriate level of safety"* with the factors to be considered *"being quintessentially dependent"* upon the particular facts of any case. [§143] The Court is entitled to take into account *"all circumstances which may have a bearing on the assessment of the safety of the product"* with the Court simply needing to be *"vigilant not to let notions of negligence or other irrelevant considerations creep into that assessment."* [§160]

"Abnormal harm": In *Gee* there was a debate between the parties about the formulation of the harmful characteristic of the hip implants under consideration. For Andrews J in looking at harm the focus must be on whether the outcome should be considered *"abnormal"*:

"However, if the incidence of that harm, either in nature or degree, is abnormal, then the product may be regarded as falling below the standard of safety that persons generally are entitled to expect. If that is the case, the defect is not the inherently harmful characteristic which is part of the normal behaviour of the product, for so to characterise it would be to make all products of that type 'defective,' *as they all bear that characteristic. That is the fundamental flaw in the claimants' original formulation."* [§112]

In *Gee* the defect was determined to be *"the abnormal potential for harm", "i.e. whatever it is about the condition or character of the product that elevates the underlying risk beyond the level of safety that the public is entitled to expect; it is identifying what it is about the condition or state of the product that makes it unsafe by the objective yardstick set out in s.3 of the Act."* [§112]

***"Risk/utility"*:** In accepting that risk/utility must form part of the assessment of a medical implant, Andrews J stated the position succinctly as follows:

"As Hickinbottom J pointed out in Wilkes, safety is inherently and necessarily a relative concept, because no product, and particularly a medicinal product, if effective, can be absolutely safe. Even such commonly prescribed medicines as penicillin or aspirin can cause a hypersensitive response in certain patients which, in an extreme case, can prove fatal. The public is not entitled to expect that a product which is known to have an inherently harmful or potentially harmful characteristic will not cause that harm, especially if (as in the present case) the product cannot be used for its intended purpose without incurring the risk of that harm materialising." [§100]

In assessing the question of defect, risk/utility was relevant:

"It would be wrong in principle to exclude from consideration of what level of safety the public is entitled to expect, the benefits that the product could confer, or to confine the relevant benefits to safety benefits, in cases in which those wider benefits might properly have a bearing on that assessment. " [§161]

"If the use to which the product can reasonably be expected to be put is a relevant consideration, as it undoubtedly is, then it cannot be objectionable for the Court to consider

the benefits likely to arise from its contemplated use as part and parcel of the circumstances that have a bearing on the evaluation of the level of safety that the public generally is entitled to expect. In the example given, the additional benefit conferred by the new chemotherapy drug is plainly a relevant circumstance that would assist in the evaluation of its safety by reference to the test set out in s.3 of the Act." [§164]

"Avoidability": On *"avoidability"*, Andrews J agreed that there would be many cases in which avoidability would be irrelevant such as when a drug caused an *"unpredictable and unavoidable side-effect which causes brain damage"* [§148] or the faulty pacemakers under consideration in *Boston Scientific* with their 17- to 20-fold increase in risk of cardiac arrest. Further, *A v NBA* was reasonably a case in which avoidability was irrelevant. Where she departed from Burton J's approach was in her rejection of the contention that avoidability was always irrelevant. To do so would undermine the *"flexibility of the Act"*. Whilst avoidability should never be the core determinant, Andrews J concluded that:

"...in an appropriate case and without inappropriately moving the focus of the exercise, the ease and extent to which a risk can be eliminated or mitigated may be a circumstance that bears upon the issue of the level of safety that the public generally is entitled to expect." [§166]

"Learned intermediaries": Further, it was important in Andrews J's view to consider what information had been conveyed to doctors (to *"learned intermediaries"*):

"... the existence of a learned intermediary and the information and warnings provided to that intermediary are plainly relevant circumstances... ; however, the weight to be given to the existence of a learned intermediary and the information, including warnings, passed on to such intermediary, in the evaluation of whether the product met the entitled expectation of safety will depend on the circumstances of the individual case. I agree with the claimants that in assessing safety, the focus must be on what the public generally are entitled to expect, not what clinicians are entitled to expect, but the latter may have a considerable bearing on the former. I also agree ... that where a product is not defective, the regime is not designed to classify it as defective because of some fault or failing on the part of the intermediary (for example, a failure to pass on warnings or obtain properly informed consent)." [§169]

And: *"A producer of a new hip prosthesis would expect a learned intermediary to inform himself of any risks contained in the IFUs and technical monographs pertaining to that product and to give the patient sufficient information about them to obtain informed consent to the operation. If, in an individual case, the surgeon did not inform himself of the risks or discuss the risks with a patient, his failure to do so cannot have an adverse impact on the assessment of the objective safety of the product"* [§490]

"Regulatory compliance": Andrews J in *Gee* [§176] agreed with Hickinbottom J in *Wilkes* that in an appropriate case, compliance with regulatory standards will have *"considerable weight, because they have been set at a level which the appropriate regulatory authority has determined is appropriate for safety purposes."* It was stressed, nevertheless, that the standards must have a relevance to the defect that is alleged. On the facts of *Gee* it was concluded that the state of science was not such that any product specifications would have had a direct impact on the incidence of *"Adverse Reaction to Metal Debris"* [§178] and that *"the achievement of regulatory approval, whilst a positive factor, is therefore of limited assistance in the overall evaluation of the entitled expectation of safety in this case."* [§489]

Pinnacle *"not defective":* The focus in the Pinnacle trial was on the survivorship of the Pinnacle Ultamet Metal-on-Metal prosthesis. Andrews J's ultimate conclusion was that the public were entitled to expect that the prosthesis would not have:

"a much greater risk of failure in the first 10 years after implantation than the expected failure rate over that period for the product it was designed to improve upon, namely, an uncemented metal on conventional plastic prosthesis. At that time, the expected failure rate of such a comparator was, on a conservative basis, around 15%." [§494]

Applying that standard – or even applying the standard of the actual performance of the comparator – there was *"insufficient evidence"* from which to conclude that the Pinnacle revision rates were *"materially worse"*. [§496]

Hastings

The Scottish courts in *Hastings* were invited to consider whether *"the admitted inherent propensity of metal- on-metal hip prostheses to shed metal debris through wear in use"* and the *"admitted risk that some patients may suffer an adverse reaction to such metal debris that may necessitate early revision"*, rendered the MITCH/Accolade hip product less safe than persons generally were entitled to expect and thus defective within the meaning of the CPA, taking account of all of the circumstances. Lord

Tyre at first instance found for the Defendant but noted a possible difference with the approach outlined in *Gee* by stating he did not see *"any persuasive reason"* why a total hip replacement patient should have to establish *"that revision rates were* 'very much' *higher in order to establish that the product had a defect"*. The threshold required was that: *"subject to de minimis considerations, its level of safety would not be worse, when measured by appropriate criteria, than existing non-[metal- on-metal] products that would otherwise have been used."*

[**Hastings v Finsbury Orthopaedics Ltd** [2019] CSOH 96 at §119]

It was agreed that – in contrast to *Gee* – the assessment to be made was at the time of supply of the hip product. [§91] Lord Tyre concluded that the MITCH-Accolade prosthesis was not defective. All prostheses have a propensity to create debris:

"That could not thus be regarded as a defect as it was an inevitable, and, at the time of the supply to the pursuer, recognised problem. The finite life of a [total hip replacement] was well known and had to be balanced against the benefits which a [total hip replacement] would bring The evidence did not establish that its revision rate was worse than alternative non-metal-on-metal prostheses or that it gave rise to an increased risk of an unsatisfactory revision." [2021] CSOH 96 §71-72

Lord Tyre's determinations were upheld on appeal.

Hastings v Finsbury Orthopaedics Ltd [2021] CSIH 6

"Development Risks Defence"

Even if defect is established, a defendant may have a *"development risks defence"* (*"DRD"*). Article 7(e) of the Directive provides a defence for manufacturers that:

"The producer shall not be liable … if he proves that the state of scientific and technical knowledge at the time when he put his product into circulation was not such as to enable the existence of the defect to be discovered."

Not all EU countries chose to include DRD in their national legislation as it was not mandatory to do so. The UK, however, did – and translated it into the CPA at section 4(e): it shall be a defence for a manufacturer to show: *"that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control."*

The Directive is looking at the most advanced state of knowledge available to a manufacturer at the time and does not require that the manufacturer in fact had that knowledge. As stated by the Advocate-General in **Commission v United Kingdom**:

"…the 'state of knowledge' *must be construed so as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of a reasonableness test the actual opportunities for the information to circulate."* (Case C-300/95 [1997] ECR I-2649)

The example was given that knowledge would not be assumed if the defect in question had only been discovered by a researcher in Manchuria whose work had not been promulgated to the wider world. (This leads to - yet another - product liability label: *"non-Manchurianly accessible knowledge"*). There is a discussion in Miller & Goldberg §13.89 - §13.90 on the question of whether the development risks defence would have applied to thalidomide.

Australian Transvaginal Mesh Litigation: *Gill v Ethicon Sàrl Litigation*

Claimants in Australia successfully sued Ethicon, a manufacturer of transvaginal mesh products which had caused them significant injury. The claims were brought under common law negligence and under Australian product liability legislation – the Trade Practices Act 1974 (TPA) and the Competition and Consumer Act 2010 (ACL) – so care needs to be taken in translating the legal determinations to the UK context, although the TPA adopts a similar test to the CPA in that products have a defect if their safety is *"not such as persons generally are entitled to expect"*.

Katzmann J stated:

"Unless a manufacturer provides frank warnings about the risks associated with the use of its products, medical devices included, persons generally are entitled to expect that the product does not carry those risks. It is no answer to say that the risk is rare, since the rarer the risk, the greater the chance that neither the patient nor the doctor will know about it. Nor is it an answer to say that other products or other procedures carry the same or similar risks." [§3376]

Gill v Ethicon Sàrl (No 5) [2019] FCA 1905 (Katzmann J) (21 November 2019) (Federal Court of Australia)

On the facts the judge concluded that all the Ethicon devices carried risks of complications which were

admitted to be clinically significant and against which no adequate warnings were given, and about which doctors and patients alike could have been misled. The key determinations made by the Court were:

The only person to give evidence who worked for (or had worked) for any of the respondents admitted that Ethicon knew their devices could cause each of the pleaded complications at the time of their supply.

The manufacturer had failed to conduct pre-market evaluation of the Ethicon devices, failed to address all known hazards and failed to warn of them.

Ethicon did not define the physiological forces at work in the female pelvis or incorporate these considerations into the development of the Ethicon devices.

Ethicon's clinical evaluation reports were manifestly inadequate, and it had no cohesive risk management system and its design control and validation processes were flawed.

No or adequate clinical trials were undertaken before taking the devices to market. There was widespread regulatory non-compliance by Ethicon.

Few of the pleaded complications or the inadequacies of Ethicon's clinical evaluations were disclosed in the instructions for use issued with the devices or in any of the promotional material that was tendered in evidence.

They did not inform doctors or patients of the limitations of the available information, all the risks that could eventuate, how they could be effectively managed, or how they could be remedied. They introduced changes to their devices which they believed or hoped would reduce the risk of injury. But they continued to promote and sell the older devices after the new and *"improved"* versions were introduced and they remained publicly coy about what they knew and did not know about all of them.

Ethicon represented that the mesh elicited a minimal to slight inflammatory reaction which was *"transient"* or *"transitory"* when they knew that the reaction was not invariably minimal to slight and that it was never transient or transitory. The first version of the instructions for use issued did not warn of the risk of mesh erosion. Although later versions did list erosion and extrusion as potential adverse reactions, they did so in a way that was misleading or deceptive. It was not until April 2015, and then only after the intervention of the regulators, that Ethicon first warned that any of the devices could cause infection.

On DRD, the Court rejected the defence that the state of scientific or technical knowledge at the time the Ethicon devices were supplied was not such as to enable the defects to be discovered: in fact before the devices were supplied, the respondents were admittedly aware of the relevant risks.

Boston Scientific – devices which might place lives at risk

The Court of Justice of the European Union in *Boston Scientific* considered faulty pacemakers and cardioverter defibrillators and whether it was necessary for claimants who had the particular devices in question fitted needed to prove that in fact their devices were faulty. The Court held that given the function and the life-threatening nature of a malfunction, patients were entitled to expect a high level of safety and that for such products, if it is found that products belonging to the same group or forming part of the same production series have a potential defect, it may exceptionally be possible to classify other products in the same group or series as defective without having to prove that the particular product in question had the defect.

Boston Scientific Medizintechnik GMbH v AOK Sachesn-Anhanlt-Die Gesundheitskasse (Case C-503/13, 504/13) [2015] 3 CMLR 173 ("**Boston Scientific**").

Andrews J in *Gee* stressed that *Boston Scientific* was not a case about the natural risks inherent in the use of the product, but was concerned with an unusual situation in which any one of a group of implants had a significantly elevated risk of failure which if it occurred could result in a patient dying. That increased risk was sufficient to render all products in the group defective because of the serious consequences if the risk materialised. [§126 - 127] She contended *Boston Scientific* was not a case which assisted in defining what was meant by *"defect"* as the *"defect"* had already been identified. [§120]

Limitation and Longstop

Never forget that the claims are subject, first, to the usual 3 year limitation period from injury or date of knowledge that applies to personal injury claims under the Limitation Act 1980 §11A(4). Section 33 provides a discretion to disapply that limitation period.

Second, all claims are subject to a 10 year *'longstop'* under the Limitation Act 1980 section 11A. Claims brought more than 10 years after the date of the supply of the product by the producer to another are extinguished unless proceedings have already been instituted against the producer. It is important to note that – whilst there are potential arguments against this – practitioners need to work on the basis that *"supply"* means the date the

product leaves the factory rather than the date the device was implanted in the patient. Vitally, there is no discretion to set that *"longstop period"* aside.

For a very helpful limitation overview: see Mark Harvey's article on Lauren Sutherland QC's blog at **https://laurensutherlandqc-lawandethics.com/product-liability/product-liability-limitation/**

Causation & Practical Focus on Outcomes

The CPA requires that liability arises *"where any damage is caused wholly or partly by a defect in a product."* Sometimes the *"or partly"* portion of the formulation is forgotten.

Generally when assessing the merits of cases, it is helpful to jump to the end and carefully consider causation. If the patient has had a wholly unexpected outcome – that is, not one generally associated with or warned about with that particular medical implant – one may be looking at straightforward product liability case in terms of both defect and causation of injury.

For example the pacemakers in *Boston Scientific* or the Australian Ethicon transvaginal mesh product.

If however one is dealing with an outcome which is known to occur as a complication with a particular implant and is warned about by manufacturers – either to surgeons or to the patients directly – then one will need carefully to assess whether causation can be established and whether a defect argument is viable. The simplest way of looking at it is if the particular implant in question more than doubled risk of the particular complication/condition which eventuated that looks like a stronger claim. If not, it will be a more difficult – but not impossible claim.

XYZ v Schering Health Care Ltd [2002] EWHC 1420 (QB)

Novartis Grimsby v Cookson [2007] EWCA Civ 1261

Jones v Secretary of State for Energy and Climate Change [2012] EWHC 2936 (QB)

In *Gee*, Andrews J did not have to determine causation but stated that she was *"not persuaded"* that doubling the risk was the only way in which causation could be established, or that *"more than double the risk"* should be adopted as *"a bright-line test in a case such as this"*.

Remember the Courts will focus intently on the particularisation of the defect by the Claimant – so intensive consideration of the question of what makes the product defective must drive all preliminary investigations.

"There must be absolute clarity in the Claimants' case on defect. It is that defect which must cause the injury. It is in respect of that defect that the Defendant is entitled to raise its development risk defence. The Claimants' case on defect drives the scope of the expert evidence and the focus of the trial." [**Bailey v Glaxosmithkline (Seroxat litigation)** [2019] EWHC 337 (QB), Lambert J at §11].

Can information be a product?

The ECJ in *Krone-Verlag* Case C-65/20 (10 June 2021) was asked to determine the following question:

Where a daily newspaper publishes inaccurate health advice in a daily column written by an independent newspaper columnist, can that newspaper be sued on the basis that it has distributed a defective product within the meaning of Council Directive 85/374/EEC (2) ('the Product Liability Directive') when a reader of the newspaper subsequently claims that she has suffered physical injury as a result of following that advice? **Krone-Verlag** Case C-65/20 (10 June 2021)

The short answer was *"no"*. The newspaper was not a defective product – the product was *"merely the medium"*; the service of providing information was not part of the *"inherent characteristics of the printed newspaper"*. Thus *"faulty information"* did not make the newspaper a defective product.

Consider also **St Alban's City & District Council v International Computers Ltd** [1996] 4 All ER 481

Consider other remedies

Check in any given case whether there is a contract between the parties:

The *"PIP Breast implant group action"* considered *"any of the implied terms pursuant to Supply of Goods and Services Act and/or Sale of Goods Act regarding description, satisfactory quality and fitness for purpose were breached."*

Also: consider if there any third party rights based on a contract. Contract (Rights of Third Parties) Act 1999

Is there greater scope for the NHS to sue in contract in relation to failed devices?

Never forget negligence: this goes back to the *Donoghue v Stevenson* ginger beer bottle.

Most importantly in the medical context – consider *Montgomery* consent – and hence carefully review and consider the surgeon's pre-operative advice.

Also consider *Montgomery* and whether it can be used as a basis for informing the standard to be applied to the manufacturer's provision of information.

Note that in **Wilson v Beko Plc** [2019] EWHC 3362 (QB) consideration was given as to whether it was possible for consumers to circumvent the limitations of Part I of the CPA by bringing a claim under Part V of the CPA for breach of statutory duty of safety regulations made under Part II. It was determined that they could not: Part I provided an exhaustive system of liability, preventing any other form of strict liability claim by consumers.

Conclusion: Cumberlege Review

The Cumberlege Review reported in July 2020:

www.immdsreview.org.uk/

Campaigners have recently written to the Health Secretary warning that the failure to implement the review recommendations was *"causing pain and destroying lives"*: see **https://bit.ly/Sky-News-17-Feb-22**

The Product Liability Directive is currently the subject of an impact study assessment which may lead to it being revised: see **https://bit.ly/PD-impact-assessment**. The focus of the assessment is on whether there is a need for reform to take into account modern digital products but it may also look into more general areas of concern about the limits on consumer protection in reality afforded by the Directive. Whether the UK government would implement any consequent changes to the Directive by amending the CPA is open to question.

With thanks to Emily Campbell of Serjeants' Inn Chambers for her assistance with researching this paper.

Prostate Cancer Awareness Month 2022

ARRAN MACLEOD, SENIOR ASSOCIATE
PENNINGTONS MANCHES COOPER

Why early detection can be the difference between life and death

Globally, 1.4 million men are diagnosed with prostate cancer each year. Across the UK, it is the most commonly diagnosed cancer and more than 395,000 men are currently living with the disease. Over 52,000 men are diagnosed here annually, and 12,000 men will die. One in eight men will get prostate cancer during their lifetime.

November is Prostate Cancer Awareness Month, also known as *'Movember'*. The charity, Movember, was established to raise awareness of prostate cancer, its signs and symptoms, and to encourage men to see their doctors early. The overall objective is to increase the number of patients cured of their prostate cancer, and to reduce the number of prostate cancer related deaths.

Prostate cancer occurs when some of the cells in the prostate, the gland in the male body used to help make semen, reproduce more rapidly than normal, resulting in a tumour. It is not always life threatening. In many cases, the tumour grows slowly and may never cause any life-threatening problems. However, some men develop a cancer that is more likely to spread and cause secondary tumours. Therefore, if a person exhibits signs or symptoms of prostate cancer, it is very important to find out whether the cancer is likely to be serious or not. If it is, the earlier the diagnosis, the more likely it is to be cured.

There is no national screening programme for prostate cancer, like, for example, there is for breast cancer. This makes early detection and diagnosis more difficult and relies upon men presenting to their doctors when signs and symptoms that could indicate prostate cancer become apparent.

On the Movember website, the very first objective listed is to help men understand and realise the signs, symptoms and risk factors of prostate cancer. Despite the disease being the most common cancer in men in the UK, awareness of signs and symptoms that might indicate cancer is still lacking across the population. Early detection is key and, as the Movember charity puts it, *'the difference between early detection and late detection can be life and death'*.

The signs and symptoms commonly associated with prostate cancer include:

- a need to urinate frequently, especially at night;
- difficulty starting urination or holding back urine;
- weak or interrupted flow of urine;
- painful or burning urination;
- difficulty in having an erection;
- painful ejaculation;
- blood in urine or semen; and
- frequent pain or stiffness in the lower back, hips or upper thighs.

The Movember charity encourages men aged 50 – even those without symptoms – to seek a PSA test from their GP. Black men, or men with a history of prostate cancer, have a higher risk of developing the disease. They are encouraged to see their GP when they are 45 years old.

Once prostate cancer is suspected, most commonly in the first instance by a GP (if, for example, a patient has a PSA level over four, or if the doctor has detected an abnormality on examination of the prostate), the patient will be referred urgently (to be seen within two weeks) to the urology department of the local NHS hospital. At the urology appointment, the patient is likely to undergo a further examination of the prostate and, if suspicions of a possible malignancy persist, the patient is likely to be referred for an MRI scan of their prostate.

That scan will give the doctors sufficient information to determine whether or not a cancer is present and, if so, the size and aggressiveness of the disease. If a patient is diagnosed with prostate cancer, they will then be advised on their options for treatment, which will be tailored to them depending on the nature of their cancer. They could be advised to watch and wait, if the cancer is small or not aggressive, or they may be offered treatments including

surgery, radiotherapy or chemotherapy. Many patients who are diagnosed when their cancer is at an early stage will have a good outcome from treatment. However, as is the case with many cancers, the later the diagnosis, the worse the outcome tends to be.

Arran Macleod, senior associate in the clinical negligence team at Penningtons Manches Cooper, comments: *"Prostate cancer affects thousands of men in the UK every year. It is important that men reaching middle age are not afraid to pay attention to their bodies and seek medical advice from their doctor if it is appropriate to do so. Without a national screening programme for detection of prostate cancer, the only way that the number of prostate cancer related deaths will fall is from patient self-referral.*

"Prostate cancer can have devastating consequences on men and their families and, sadly, things don't always go right even when early medical help is sought. I am, sadly, instructed in a number of cases brought by the wife or children of their husband/father who feel aggrieved at delays in diagnosis and treatment, despite the deceased presenting to their doctor early. As a medical negligence solicitor this is, unfortunately, a frailty in the system that I see, and which occasionally undermines the good work of charities such as Movember."

Inquest into the death of Katie Horne

THOMAS BEAMONT, BARRISTER
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1 CROWN OFFICE ROW

In August 2022 HM Senior Coroner for Inner South London, Andrew Harris, concluded an inquest which considered hospital delays in the diagnosis and treatment of autoimmune hepatitis.

Background

Katie Horne was a fit and healthy 21 year-old woman. She worked in a children's nursery.

In later February 2020, Katie became concerned that her eyes had yellowed. After contacting her GP, a pharmacist, and the NHS 111 helpline, she was advised to attend E&E.

On 1st March 2020, Katie attended A&E at the Princess Royal Hospital, with worsening jaundice symptoms. Blood tests were taken which showed elevated bilirubin levels, and an inflamed liver. Katie's family were specifically concerned about hepatitis, but were reassured by doctors who said that viral tests would be returned in due course. It was decided on 1st March that Katie should see a specialist Gastroenterologist.

Katie returned to the hospital's Rapid Assessment Medical Unit very regularly over the course of the next fortnight for blood tests. However, viral tests which had been returned on 9th March were only considered by doctors until 16th March. Further, and despite that the treatment plan included Gastroenterology review, there was an extended delay and Katie was reviewed by a Gastroenterologist for the first time on 16th March 2020. In that time, Katie's INR had elevated, and her liver function tests had worsened.

Katie was referred to the King's College Hospital (KCH) liver unit on 18th March 2020, who advised that liver biopsy at that stage was not possible in view of Katie's presentation. Katie was transferred to KCH for consideration of liver transplant on 24th March 2020, but by 30th March she was found to be Covid-positive, which was treated as a contraindication for transplant. It was also discovered that Katie was steroid-resistant, which complicated treatment for her auto-immune hepatitis.

Katie developed Covid pneumonitis, and died on 11th April 2020.

AvMA instructed Tom Beamont, of 1 Crown Office Row, to represent Katie's family.

The hearing

The inquest heard evidence from several witnesses from Princess Royal Hospital. The Consultant Gastroenterologist who reviewed Katie on 16th March was unable to explain why there had been a delay of around two weeks in reviewing Katie; he was asked for the first time on that date. He said he would have hoped to have been involved significantly earlier.

The inquest also heard from a Consultant in General Medicine, who had reviewed Katie in the course of Katie's visits to RAMU. She explained that she could not answer why there had been a delay, nor why she had arranged for Katie to attend on days when a gastroenterologist was not present. She explained it may have been because she was busy.

Finally, the inquest heard evidence from a Consultant Hepatologist at KCH, who gave evidence as to the likely treatment outcome for Katie in the event that he had seen her earlier. The Hepatologist could not say that the delays in referring Katie contributed to her death, given the difficulties posed by Covid infection to transplant at the time, and the fact that Katie was steroid-resistant.

The Coroner found that a biopsy had been rendered impossible, and referral for transplant delayed, by the delays in obtaining gastroenterologist review, and that there was no evidence of doctors chasing up missing results.

The Coroner returned a conclusion of natural causes.

Prevention of future deaths

Following the inquest, the Coroner wrote a Prevention of Future Death Report to the Chief Executive of the Princess Royal Hospital, raising the following matters of concern:

"Despite multiple attendances as an outpatient with deteriorating hepatitis, it took 15 days for crucial blood test results to be seen by the doctors (in part due to lab backlog but there was no evidence of any doctor prioritising or chasing the results) or for a gastroenterologist to be consulted on care. This led to a liver biopsy not being possible (in part as her blood clotting had deteriorated) and later than necessary commencement of steroid therapy and consequent later referral for liver transplantation at Kings College Hospital.

Although it was suggested that these failures in care were associated with the capacity of the hospital to deliver services in the first wave of the pandemic, there was little evidence to support or refute that"

In response, Princess Royal Hospital have set out a series of changes which it is claimed will render it *"extremely unlikely that there would be a similar delay in the future"*.

In Memoriam: Tim Wright

PENNINGTONS MANCHES COOPER

We are sad to note the passing of Tim Wright, a Senior Associate at Penningtons Manches Cooper LLP, who passed away recently having been diagnosed with cancer earlier this year.

Tim was a key member of the Clinical Negligence Team at Penningtons Manches Cooper, who was based in their Basingstoke office, having joined the firm from DAC Beachcroft in April 1999.

Tim will be remembered for his wealth of knowledge, particularly in the areas of Human Rights and Coronial Law in the context of clinical negligence claims, as well as for his love of opera and boating. He will be greatly missed.

Forthcoming conferences and events from AvMA

For full programme and registration details, go to www.avma.org.uk/events or email conferences@avma.org.uk

AvMA Specialist Clinical Negligence Meeting

Afternoon of 2 December 2022, Leonardo Royal London St Paul's Hotel

The annual meeting for AvMA Specialist Clinical Negligence Panel members provides the opportunity to meet, network and discuss the latest key developments and issues facing clinical negligence law. Registration and a networking lunch will commence at 12.30, with the meeting starting at 13.30 and closing at 17.00.

AvMA 40th Anniversary Gala Celebration

Evening of 2 December 2022, Leonardo Royal London St Paul's Hotel

Join us to celebrate 40 years of the great work that AvMA has achieved in striving to improve patient safety and justice for people affected by medical accidents. The evening will commence with a drinks reception followed by a fantastic three-course meal with wine, live entertainment and dancing. It will be the perfect event to entertain clients and/or reward staff, on an evening that will bring together the key people from the medico-legal and patient safety worlds.

Cerebral Palsy & Brain Injury Cases – Ensuring you do the best for your client

19 January 2023, Crowne Plaza Liverpool City Centre

We are delighted to announce that this popular AvMA conference is returning on 19 January 2023 in Liverpool. The programme of excellent speakers will discuss and analyse the key areas currently under the spotlight in Cerebral Palsy and Brain Injury Cases so that lawyers are aware of the challenges required to best represent their clients.

Court of Protection conference

2 February 2023, Hilton Leeds City Hotel

AvMA's Court of Protection conference returns on 2 February 2023 to examine the current state of litigation and the challenges and responsibilities facing those who work in this important area. The programme will be available and booking will open in November 2022.

33rd Annual Clinical Negligence Conference (ACNC)

23-24 March 2023 (Golf Day & Welcome Event 22 March) 2023, Bournemouth International Centre

Join us in Bournemouth on 23-24 March 2023 for the 33rd AvMA Annual Clinical Negligence Conference (ACNC), the event for clinical negligence specialists! The very best medical and legal experts will ensure that you stay up to date with all the key issues, developments and policies in clinical negligence and medical law. Early bird booking opens in October, with the full conference programme available in December.

Representing Families at Inquests: A Practical Guide

26-27 April 2023, Gatehouse Chambers, London

This conference returns to London after a three year hiatus and will present a comprehensive guide to the practice and procedures when representing a family at an inquest. You will hear from an excellent programme of speakers, all experienced in their involvement in inquests, who will provide you with case examples to help you to put the theory into practice. You will also learn more about AvMA's important role in representing families.

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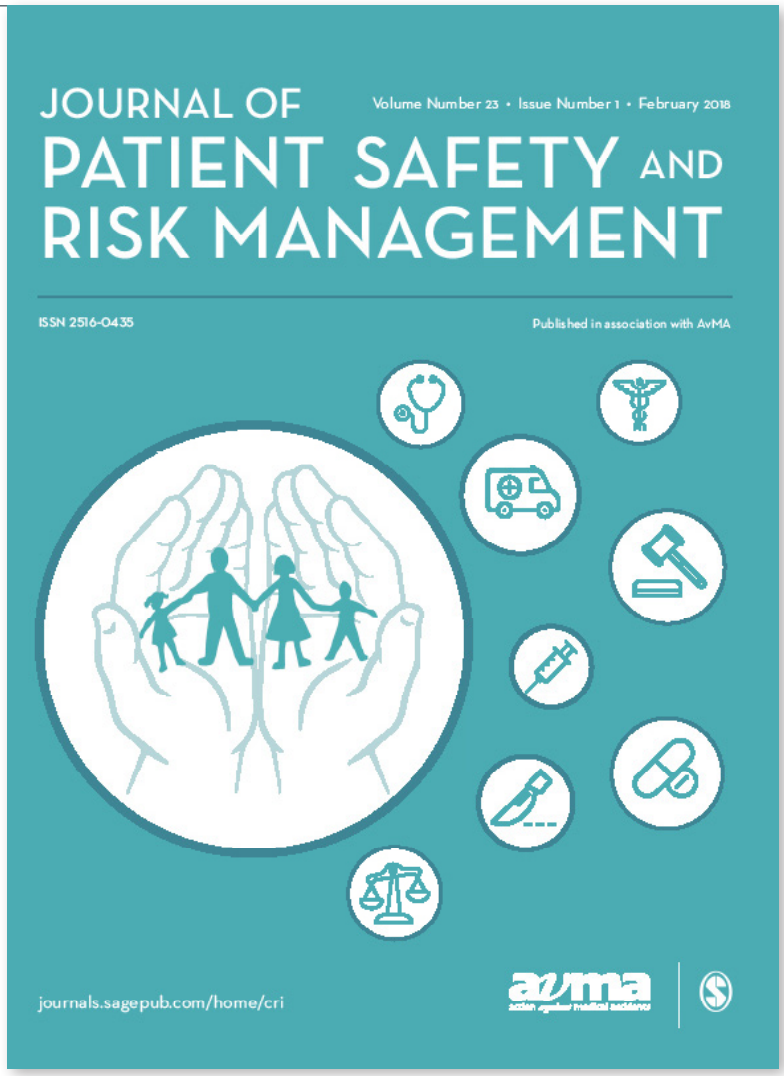

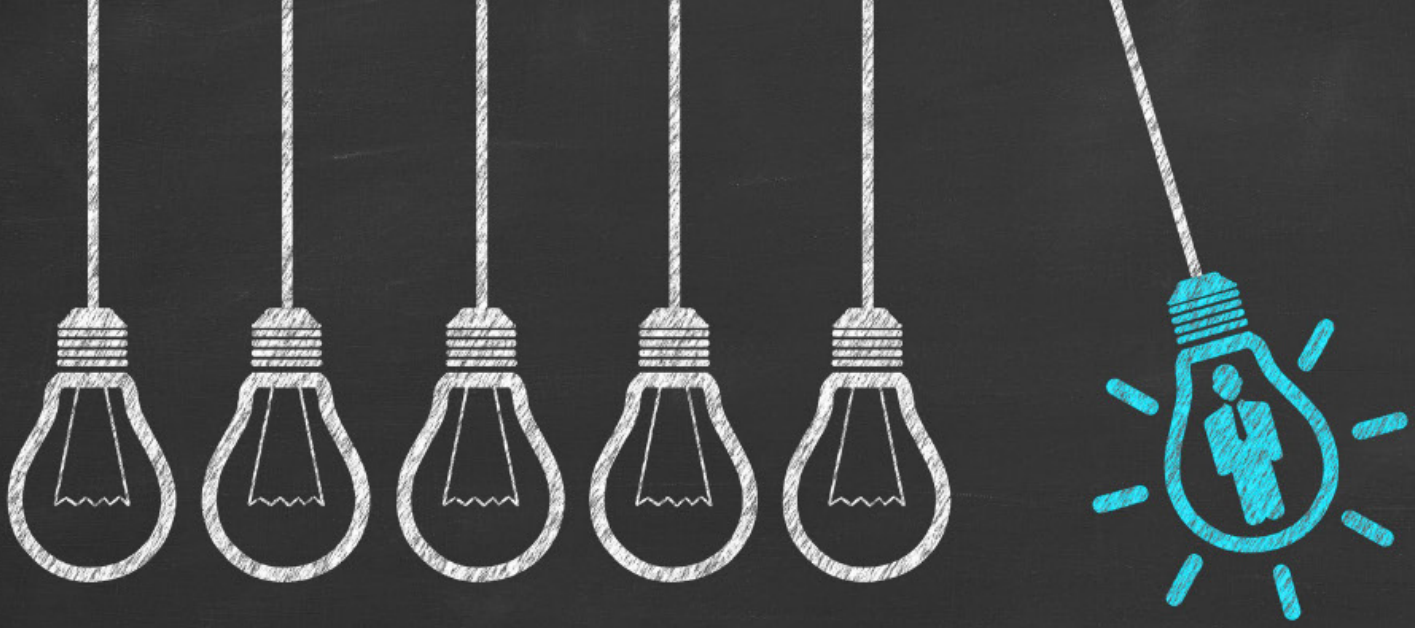

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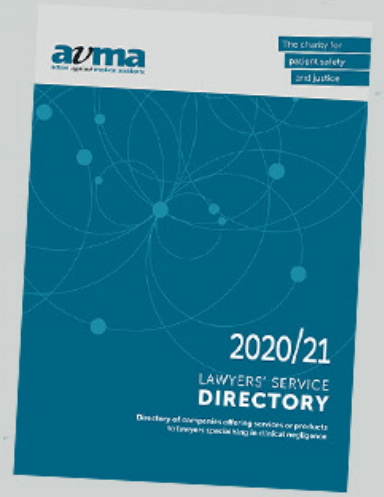

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