
**OUTER HOUSE, COURT OF SESSION**

**[2018] CSOH 57**

**A54/14, A821/15, A442/14 & A239/14**

OPINION OF LORD BOYD OF DUNCANSBY

In the cause

AH

Pursuer

against

(FIRST) GREATER GLASGOW HEALTH BOARD; and (SECOND) JOHNSON & JOHNSON MEDICAL LIMITED

Defenders

and

SR

Pursuer

against

(FIRST) JOHNSON & JOHNSON MEDICAL LIMITED; and (SECOND) LOTHIAN HEALTH BOARD

Defenders

and

YT

Pursuer

against

(FIRST) SPIRE HEALTHCARE LIMITED; (SECOND) DR ALASTAIR MILNE; and (THIRD) COUSIN BIOTECH SAS

Defenders

and

EN

Pursuer

against

(FIRST) GREATER GLASGOW HEALTH BOARD; (SECOND) AMERICAN MEDICAL SYSTEMS INC; and (THIRD) AMERICAN MEDICAL SYSTEMS UK LIMITED

Defenders

**AH v Greater Glasgow Health Board &Johnson and Johnson**

**Pursuer: Smith QC, Ms Bennett, Ms Toner, Ms Connolly; Drummond Miller LLP**
**First defenders: Primrose QC, Bowie QC, Mr Reid, Mr Campbell; NHS Scotland Central Legal Office**
**Second defenders: Currie QC, C Paterson, A Smart; Clyde & Co**

**SR v Johnson and Johnson & Lothian Health Board**

**Pursuer: Smith QC, Milligan QC, Ms Bennett, Ms Toner, Ms Connolly; Thompsons**
**First defenders: Currie QC, C Paterson, A Smart: Clyde & Co**
**Second defenders: Primrose QC, Bowie QC, Mr Reid, Mr Campbell; NHS Scotland Central Legal Office**

**YT v Spire Healthcare, Milne & Cousin Biotech**

**Pursuer: Smith QC, Milligan QC, Ms Bennett, Ms Toner, Ms Connolly: Lefevre Litigation**
**Second defender: Stephenson QC, Mr Dawson, Mr Pugh; MDDUS**
**Third defenders: Haldane QC, Mr Balfour; Dentons UKMEA LLP**

**EN v Greater Glasgow Health Board & American Medical Systems**

**Pursuer: Smith QC, Milligan QC, Ms Bennett, Ms Toner, Ms Connolly; Drummond Miller LLP**
**First defenders: Primrose QC, Bowie QC, Mr Reid, Mr Campbell; NHS Scotland Central Legal**
**Second defenders: Ellis QC; MacRoberts LLP**

1 June 2018

**Introduction**

[1] This opinion relates to four actions which arise out of the use of what are called vaginal mesh products in treatment of the pursuers. There are over 500 cases presently before the court arising out of the use of such products. All but 18, which have been selected as lead cases, are sisted pending the outcome of these cases. Following case management hearings held in terms of Rule of Court 42A.4 these four cases were selected for debate on the procedure roll.

[2] While the pursuers' pleadings all refer to pelvic mesh products as a generic term there are in fact two different types of products involved which treat different symptoms. These are a vaginal tape which is used to treat stress urinary incontinence (SUI) and a mesh used to treat pelvic organ prolapse (POP). The common feature is that they both use polypropylene or prolene. In this opinion I use the term "product" to refer to the tape or mesh used in the individual treatment.

[3] These cases were set down for an eight day hearing. However as a result of the comprehensive notes of argument and succinct submissions it was completed in five days. I am grateful to counsel for their written and oral submissions.

**The structure of this opinion**

[4] I have elected to issue one opinion dealing with the four cases. There are two reasons for this. First, as noted these are lead cases and it is hoped that the terms of this opinion can act as guidance for other cases. Secondly, inevitably there was considerable overlap between the submissions, even although different parties were represented. In consequence I have not sought to replicate all of the submissions but I have hopefully captured the main points. For

ease of reference I have referred to the Health Boards and Dr Milne, the third defender in EN, collectively as "the doctors" and the three manufacturers as "the manufacturers".

[5] For convenience I have divided the opinion into six chapters.

[6] In chapter 1 I set out the pertinent facts of the individual cases

1. AH
2. SR
3. YT
4. EN

[7] In chapter 2 I comment on the pursuers' approach to pleadings in this case, the submissions made by them and my approach in considering the submissions made by the defenders.

[8] Chapter 3 deals with the common law case against the doctors. All four actions have a common law case against the treating doctors in similar terms. Each of the pursuers allege that the doctor, either a consultant gynaecologist or consultant urological surgeon, failed in their duty of care by failing to advise them of the risks inherent in the use of the pelvic mesh product and of reasonable alternatives. The issues that arise are as follows:

1. The pursuers in the pleadings list a number of alternative treatments which they say should have been offered to the pursuers by the treating doctors but were not. Both the pursuers and the doctors agree that following *Montgomery* v *Lanarkshire Health Board* [2015] UKSC 11; 2015 SC(UKSC) 63 [2015] AC 1430 the alternatives to be offered must be reasonable. The doctors submit that what is reasonable is to be judged by the test in *Bolam* v *Friern Hospital Management Committee* [1957] 1 WLR 582 and *Hunter* v *Hanley* 1955 SC 200. The pursuers submit that what is reasonable is to be determined by reference to what a patient might find reasonable after a full

discussion of all the treatments whether or not these are available. I have referred to this as the *"Montgomery"* issue.

2. The second issue relates to the specification of the case against the doctors and in particular whether the pursuers have sufficiently averred the basis upon which the doctors knew of the defects in the product. I have referred to this as the "knowledge of the doctors."
3. Having found against the pursuers in respect of the first issue and defects in the specification of the case against the doctors I outlined the basis upon which the cases against the doctors might proceed to a proof before answer.
4. I then deal with another issue of specification in particular the acceptance of risk and causation.
5. Finally I set out my conclusions on the common law case against the doctors.

[9] Chapter 4 deals with the cases against the manufacturers. As pled the cases against the manufacturers are based on the common law and breach of the Consumer Protection Act 1989. In the course of the debate Mr Milligan informed me that the pursuers no longer insist on the common law case against the manufacturers. There are two sub- headings to this chapter:

1. The relevancy of the cases based on the Consumer Protection Act.
2. I deal with some common issues of specification that arise in all of the cases against the manufacturers.

[10] Chapter 5 concerns time-bar. The defenders plead that the cases are time barred under section 17 or 22B of the Prescription and Limitation (Scotland) Act 1973. The pursuers contest these pleas but in the alternative ask the court to exercise its discretion to allow the cases to proceed under sections 19A and 22B(6). I deal with these matters as follows:

1. Factual background in each case

2. The statutory framework
3. The parties submissions
4. Discussion of the applicable law – section 17 and 22B
5. Application of section 17 to the individual cases
6. Application of section 22B
7. Discussion of the applicable law to the exercise of the court's discretion under sections 19A and 22B(6)
8. Application of sections 19A and 22B(6)

It should be noted that Mr Ellis for the second and third defenders (the manufacturers) in EN reserved his time bar plea.

[11] Chapter 6 contains conclusions and directions for the By Order hearing to follow the issuing of this opinion.

**Chapter One: The facts of the individual cases**

***AH***

[12] AH suffered for some time with stress incontinence and a vault prolapse. She underwent a number of procedures. On 18 November 2008 she was seen by Dr Mahesh Perera, a consultant gynaecologist at Glasgow Royal Infirmary. He offered AH a surgical procedure for pelvic floor repair. AH avers that he did not explain to her that the procedure would involve the insertion of mesh or tape and was not made aware of the risks associated with such a procedure. AH consented to the operation. On 19 February 2009 Dr Perera performed an anterior prolift repair, a sacrospinous fixation with a capio suture and a posterior repair for her vault prolapse and cystocele. In the course of the operation Dr Perera implanted Gynecare Prolift Anterior Pelvic Floor Repair System manufactured by the second defenders (Johnson &

Johnson Medical Limited). AH says that had she been aware of the risks of the operation she would not have consented to it. She says that after the operation she continued to have pelvic pain. On 27 November 2009 she had an operation for the excision of protruding mesh. Following that operation she continued to have pelvic pain and vaginal discharge. Her prolapse has recurred.

[13] The action is directed against, first Greater Glasgow Health Board, as Dr Perera's employer, and secondly Johnson & Johnson Medical Limited (Johnson & Johnson), the manufacturer of the product.

***SR***

[14] Towards the end of 2004 SR was suffering from SUI with urge and urgency. She was referred to the department of gynaecology at the Royal Infirmary of Edinburgh. Following the birth of her second child she became progressively aware of symptoms of vaginal prolapse. On 10 August 2009 she had a consultation and examination with Dr Lucie Dolan. She was found to be suffering from pelvic organ prolapse (POP) insofar as she was suffering from first degree rectocele, first degree cystocele and second degree uterine descent. Dr Dolan recommended that SR undergo surgery in the form of vaginal hysterectomy, posterior and anterior colporrhapy and the implantation of a tension-free vaginal tape (TVT). SR alleges that Dr Dolan did not properly advise her of the risks or complications associated with a mesh implantation procedure. SR underwent the operation on 15 October 2009. She avers that she would not have undertaken the operation had she been properly advised of the risks. The implantation procedure involved the insertion of a TVT tape described as "Gynecare TVT Laser Tension Free Support" manufactured by the first defenders (Johnson & Johnson). Following the operation SR has suffered from pain in her vagina, groin, back and legs, pain during bowel

movements and pain and difficulty in voiding her bladder. She suffered from a sensation of jagging inside her. On self-examination she was aware that the mesh product was protruding from her vagina. On 1 June 2010 the pursuer underwent a further surgical procedure to excise protruding mesh. Following the procedure she continued to suffer pain and the mesh continued to protrude. On 29 July 2010 the mesh was found to be palpable. On 11 August 2010 she underwent a further excision procedure under general anaesthetic. The TVT implanted in her is rigid, tight and contracted, consistent with dense scarification of the mesh. Her quality of life has been adversely affected in a number of ways detailed in the pleadings.

[15] The action is directed against, first Johnson & Johnson Medical Limited, the manufacturer of the product, and secondly, Lothian Health Board as Dr Dolan's employer.

***YT***

[16] From about 2000 YT suffered from stress urinary incontinence and in March 2004 reported urinary urgency and frequency. She consulted her GP in 2007 and 2008 and was referred for private treatment at the Murrayfield Hospital with the second defender, Dr Alastair Milne. The referral letter stated that she suffered from "moderately severe stress urinary incontinence which is causing distress. She has heard about TVT taping and wonders if this would be appropriate for her". On 6 September 2008 she met Dr Milne. He discussed the options available to treat her symptoms. She avers that he told her that she was a suitable candidate for a surgical procedure involving the insertion of tension free trans vaginal tape. She says that she was not told of the possible disadvantages and the risks associated with such a procedure. On 23 September 2008 she was admitted to hospital. She again consulted with Dr Milne who again, she says, failed to tell her of the disadvantages or associated risks. Having apparently consented to the operation she underwent a cystoscopy and a surgical procedure

involving the insertion of a transvaginal tape. The TVT was a suburethal support tape manufactured and supplied by Cousin Biotech SAS. After the operation when the pursuer came round from the anaesthetic she was in excruciating pain and passed out. She had a period of time off work. She was problem free until about 2011/2012 when her stress urinary incontinence problems returned. In around 2013 she started to develop pelvic pain, groin pain, and difficulty in emptying her bladder which resulted in urinary tract infections. She was unable to sit up straight, developed incontinence, altered bowel habits, loss of libido and fatigue. She has developed allergies. On 12 May 2014 she underwent a transvaginal removal of the mid portion of the vaginal sling. Since then she has experienced a marked improvement and eventual resolution of her symptoms.

[17] The action was first directed against Spire Healthcare Limited who operate Murrayfield Hospital. However the action so far as directed against them has been settled and they are no longer in the process. The second defender is Dr Alastair Milne. The third defenders are Cousin Biotech SAS.

***EN***

[18] In about June 2006 EN attended her GP suffering from SUI. She was referred to the Department of Urology at the Southern General Hospital in Glasgow. She was reviewed in November 2006 by Mr Mir, consultant urological surgeon who prescribed Duloxetine and advised her to carry out pelvic floor exercises. She was seen again by Ms Granitsiotis, consultant urological surgeon on 20 April 2007. She recommended that EN undergo a transobturator tape (TOT) procedure involving the insertion of a sling to support her bladder. She was told that this was a popular procedure and that Ms Granitsiotis had carried out a number of similar procedures on other women, with successful outcomes. EN says that she was not told what the sling would

be made from. She was told that it was possible that the TOT procedure would not be successful. She says that she was not told of any specific risks or complications associated with the procedure. She was not advised of any alternative procedures or products. On 24 June 2007 EN underwent a TOT procedure during which a Monarc Subfascial Hammock, manufactured by Astoria Women's Health LLC was implanted in EN. In about June 2009 EN began to suffer from faecal incontinence and urgency. Her symptoms of stress urinary incontinence began to return. She developed urinary urge incontinence and detrusor instability. Symptoms of pain began to return. She suffered from incomplete voiding of her bladder and had frequent urinary tract infections. She developed kidney stones. In June 2011 she was referred by her GP to the Department of Urology at Ross Hall Hospital, Glasgow. She was reviewed by Mr Dunn, consultant urological surgeon who noted an ultrasound scan report which showed a smaller right kidney with some upper pole scarring and a small simple cyst. She was subsequently seen at the Southern General Hospital on 8 February 2012. Her abdomen was soft with some mild tenderness in the right loin. On 22 June 2012 Ms Granitsiotis wrote to EN's GP advising that she should remain on prophylactic antibiotic long term.

[19] The first defenders in this case are Greater Glasgow Health Board the employers of Ms Granitsiotis. The second defenders were originally American Medical Systems Inc, but now, as result of amendment, Astoria Women's Health LLC. The third defenders are American Medical Systems UK Limited. The second and third defenders are jointly represented.

**Chapter two: The pursuers' approach to pleadings**

[20] The purpose of written proceedings is to set out the case so that the defender and the court can understand the basis of the action. It is an exercise in written advocacy. The pleadings should disclose facts which, if proved, would amount in law to a substantive case and which at

the very least require to be answered. In cases such as these, involving medical treatment and the use of a medical product, one would expect to see a narration of the pre-existing condition, the treatment, the product used in the treatment, the subsequent injury, the duty of care owed by the treating doctor and how that duty of care was breached, the defect in the product used and how the breach of duty and product defect each caused or contributed to the injury. The pleadings need not, indeed should not, be elaborate but they should give fair notice to the defenders of the allegations made against them.

[21] The pursuers' pleadings are on the whole not an easy read. They are at times confused, lacking in clarity and contradictory. Some of the pleadings are clearly extraneous and irrelevant. Not surprisingly the defenders have criticised the specification in the pleadings and complained of lack of fair notice as well as the relevancy of the cases against them. The problem appears to stem from the pursuers' approach which focuses on the alleged defects in the mesh products as a generic issue rather than on the facts of the individual cases. There is also a tendency to conflate the cases against the doctors with those against the manufacturers as if the issues are the same. One example of this is the listing of numbers of journal and other articles seemingly on the basis that both the manufacturers and the doctors ought to have been equally aware of them. Often there is little attempt to match up the dates of the articles to the dates of the operation with the result that many articles and other sources of information are listed well after the date of the operation. There is a tendency to assume, without any supporting averments, that the treating doctors should have the same knowledge about the product as the manufacturer. Equally I have found it difficult to follow some aspects of the pleadings, in particular on causation.

[22] The Practice Direction No. 2 of 2015 sets out the requirements that were to be followed in these cases during the period of the sist. That included intimation in the pursuer's pack of adjustments to the summons where not already included specifying amongst other things "the

decision which the pursuer would have made had she been given advice, warnings and/or counselling in the terms (which she contends should have been given to her)". Generally the pursuers have not said what decisions they would have taken had they been given the correct advice or warnings.

[23] In answer to the defenders' notes of argument the pursuers' note of argument addresses the issues of relevancy and specification. So far as relevancy is concerned they submitted,

> "It is trite law that (1) a claim will only be dismissed on the grounds of relevancy if it is bound to fail even if all of the pursuer's averments are upheld; (2) the pursuer's averments are held *pro veritate* for the purposes of a debate and (3) it is unusual for a case based in negligence to be dismissed on the grounds of relevancy;. *Jamieson v Jamieson* 1952 SC(HL) 44 at 50 and 63; *Miller v SSEB* 1958 SC (HL) 20 at 32 and 33; *McArthur v Rayneway Plant Ltd* 1980 SLT 74; *Murray v Edinburgh DC* 1981 SLT 253 at 256; *McGeouch v Strathclyde RC* 1985 SLT 321; *Meechan v BRB* 1989 SCLR 772."

[24] On specification the pursuers' note of argument quotes from *MacPhail's Sheriff Court Practice (3rd edition)*, paragraph 9.29:

> "The degree of specification which will be deemed sufficient for fair notice depends on the particular circumstances of each case. Enough specification must be given to enable the other party to identify what is being alleged against him and to prepare his case.
>
> When deciding whether the defender has been given fair notice of the pursuer's case the court will consider the matter broadly, and will regard a complaint of lack of fair notice as justifiable only if it is likely to result in material prejudice to the defender."

[25] In response to the general criticisms the pursuers have made a number of points. First they urge that the court adopts a "modern" approach to pleadings. They should not be seen as a conveyancing document and the court should bear in mind its case management powers. These could be used to provide practical solutions to concerns regarding lack of notice by, for example requiring parties to produce affidavits or the hearing of evidence on commission. Secondly the pursuers say that they have been hampered by the lack of cooperation from the doctors in failing to provide precognition facilities or answer written questions. In particular

that has hampered their ability to state where the breakdown in communication between the manufacturers and the doctors has occurred. It has also affected the pursuers' ability to state what alternative treatment they may have followed. They cannot do so until they know what alternative treatment the treating doctor may have advised. Thirdly, insofar as the manufacturers are concerned these actions are only part of a large number of actions being pursued against them in various parts of the world. Accordingly they should be well aware of the alleged defects of their products from these other actions. In any event the manufacturers have vast resources unequal to those of the pursuers and the court should bear that in mind when considering issues of specification. As these are test or lead cases of a wider cohort the court should take a more relaxed view of the pleadings.

***Discussion***

[26] It may well be that this court will in due course need to give further consideration to how it deals with a large number of actions each alleging similar facts with common defenders and common legal issues. However I am bound by the rules and practice of the court. Any innovation on these should not be to the prejudice of the parties. I was shown the pleadings in the Australian case and the decision in *Huskey* v *Ethicon* United States District Court for the Southern District of West Virginia dated 19 August 2015 as examples of how it was done in these jurisdictions with an implicit invitation to follow their example.

[27] I accept that a record should not be seen as a conveyancing document. However the importance of written pleadings has recently been reiterated by an Extra Division in *Melville Dow* v *Amec Group Limited* [2017] CSIH 75 where the court rejected an argument that in a chapter 43 case it was not necessary to specify the ground of fault; see Lord Brodie at paragraph 91 and Lord Drummond Young at paragraph 139. Lord Glennie noted that while

elaborate pleading is discouraged and there is no need to set out full specification of everything that is sought to be proved, chapter 43 does not relieve a party from the requirement to give fair notice in his pleadings of the case which the other side requires to be met; paragraph 180. As to the case management powers open to the court in chapter 42A it is for the pursuer to plead a relevant case; not for the court to take over the role. Litigation under chapter 42A is still an adversarial not inquisitorial process.

[28] The pursuers complained about the lack of access to the doctors for the purpose of precognition or to answer written questions. It should be recorded that counsel for the doctors rejected the charge made by the pursuers. It is not necessary for me to adjudicate on this issue. For reasons I set out below I reject the suggestion that the pursuers have been seriously prejudiced by not having access to the doctors. In any event the answers for the doctors are full and detailed.

[29] Finally in relation to the cases in other jurisdictions if there is anything in this point it relates only to the manufacturers. And not to all of them; Miss Haldane advised me that so far as Cousin Biotech SAS was concerned this was the only jurisdiction in which they were involved in litigation about its pelvic mesh products. I do accept that the pursuers will not have the resources available to the defenders. I also accept that a certain amount of generic pleading is inevitable. But the relevancy of a case in this jurisdiction is judged by the pleadings and not by reference to what might be happening elsewhere.

[30] The principles I have followed in considering the issues are these. First I take the pursuer's pleadings as *pro veritate*. Secondly, I accept that a case should only be dismissed if it is bound to fail. I accept that it would be unusual to dismiss a personal injuries case based on negligence on the grounds of relevancy; *McArthur* v *Raynesway Plant Ltd* per Lord Stewart at 77. I can see no sound reason for adopting a different approach to a case under the

Consumer Protection Act 1987. Specification in an action of negligence is a species of relevancy. It would be an exceptional course to dismiss an action for want of specification. There are many issues of specification raised by the defenders. In general I take the approach that they are for consideration only where it is clear that the defenders would be materially prejudiced by want of fair notice.

[31] It is not usual to look at the defender's pleadings unless debating the pursuer's pleas. However in this case when considering the case against the doctors I have had regard to their pleadings in order to understand the nature of the factual dispute between the parties and the scope of the duties on the doctors. As I noted the pursuers have complained that they did not get access to the doctors for the purposes of precognition. Nor have they had sight of their statements. Mr Stephenson pointed out that in YT the statement of the second defender was to all intents and purposes contained in the defences. The answers for the doctors in all of the cases set out at some length the interaction between the pursuers and the treating doctors. In those circumstances it would be wholly artificial to ignore the defenders' pleadings. If the defenders' answer to the pursuers' claim of prejudice is to point to the fullness of the defences they cannot complain if the court then has regard to these pleadings. It is in any event not in accordance with the spirit of chapter 42A, where parties are encouraged to make early disclosure in order to narrow the issues between them, to ignore what is pleaded in defence. That is not to turn the debate into one on the scope of the defenders pleadings but to use them to help understand the conflict in the factual case and the consequent bearing on the issues for the court.

**Chapter Three: The common law case against the doctors**

***The "Montgomery" Issue***

*Submissions for the doctors*

[32] The doctors submitted that on a proper reading of *Montgomery* v *Lanarkshire Health Board* the clinical standard as set out in *Bolam* v *Friern Hospital Management Committee* and *Hunter* v *Hanley* continues to apply in relation to the question of what treatment options the doctor should present to the patient. Thus, so far as the pursuers offer to prove that certain alternative treatments were "reasonable treatment options", to instruct a case of negligence they require to show that no ordinarily competent clinician, exercising ordinary skill and care, would have failed to offer those alternatives. They have no averments to that effect. They have intimated no expert reports to that effect. That is not a case that they could make and insist upon in the absence of proper expert evidence.

[33] In any action based on an alleged failure to advise of reasonable alternative treatment options, a pursuer must specify, amongst other things: (i) the reasonable alternative treatment options of which the pursuer should have been advised; (ii) the treatment options of which she was in fact advised and; (iii) the alternative treatment which she would have elected to undergo, had she been so advised. In the absence of sufficient averments in relation to each of these matters, the pursuer's case is irrelevant because it fails to specify the facts which, if proved, would entitle her to seek a finding in relation to liability and causation.

[34] In an action of this kind it is not sufficient to simply list alternative treatment options which are, in the abstract or as a generality, available to treat the type of condition from which the purser was suffering. The assessment of available alternatives is fact sensitive; *Montgomery* paragraph 89. It is necessary to identify which alternative treatment options were reasonable in the particular case of the pursuer and why that is so.

[35] Although reference had been made in each of the cases to alternative treatments that should have been offered to the pursuer none of the pursuers say that they would have opted for any of the alternatives. Mr Stephenson submitted that there was a distinction to be drawn between a "no treatment" and an "other treatment" case. On the pleadings YT's case is therefore a "no treatment" case. The extensive averments about alternative treatments are thus irrelevant, being unconnected with any loss sustained, and should be excluded from probation.

*The pursuers' response*

[36] The pursuers respond that the court should bear in mind the simplicity of the pursuers' case on consent. Broadly speaking, the alternatives to treatment available were those using biological materials (autologous, porcine or cadaverous); or indeed in many cases not carrying out the surgery at all. It is not suggested by the doctors that these alternatives were not known to a surgeon practising in urogynaecology. The interpretation that the *Hunter* v *Hanley/Bolam* test was still appropriate in relation to the alternative treatments offered to the pursuers still applied following the decision in *Montgomery* was simply wrong; *Montgomery*, paragraph 83; *Webster* v *Burton Hospitals NHS Trust* (2017) 154 BMLR 129 at paragraph 31. That is supported by the GMC Guidelines entitled "Consent: patient and doctors making decisions together". As to what alternative treatments should be offered to a patient Mr Smith submitted that the test was whether a reasonable patient would want that treatment. That might include treatments which had been offered in the past but are no longer routinely offered or ones which the treating doctor did not or could not offer but which other doctors might offer. It would also include a treatment which might be offered to other patients but which a treating doctor would decide could not be offered to the particular patient because of some other medical condition

which would render it unsafe. In that event it is for the patient to decide the treatment and if the doctor felt he or she could not give that treatment a second opinion might be required.

[37] As a matter of law the pursuer does not have to plead which of a number of alternatives she would have chosen. It is a matter for the court to determine. The pursuer could succeed without even giving evidence: see *Webb* v *Barclays Bank and Anr* [2002] PIQR P61 at paragraph [42]. The pursuers have been prejudiced by the refusal of the doctors to provide precognitions or witness statements, despite the provision of a detailed list of written questions. A pursuer cannot be obliged to commit to one alternative over another when she does not know what advice she would have been given by the treating doctor. It will have to be determined by the court after the treating doctors have been led in evidence. The alternative treatments available were known to the doctors.

*Discussion*

[38] The decision of the Supreme Court in *Montgomery* is an evolution on the professional duty of care that a doctor owes to his patient. In *Montgomery* the issue was whether the mother was told of the risks of shoulder dystocia associated with vaginal birth. That was a known risk because of the mother's diabetes.

[39] The ratio of the decision is to be found in paragraph 87:

> "An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

The "reasonable alternative treatment" that was not offered to Mrs Montgomery was a caesarean section. The decision not to offer that treatment was made, not on clinical grounds, but in accordance with the doctors own beliefs. Clinically it was a reasonable alternative. In reality of course there were only two alternatives; do nothing was not an option and there is no other way to deliver a baby.

[40] The question which these cases raise is a little more complex. Clearly do nothing is an option; each of the pursuers could no doubt with varying levels of pain, distress and discomfort continue to live with the symptoms. There are also a range of alternative treatments. Mr Stephenson informed me that there are over one hundred but even looking at the pleadings there are a range of alternatives which are canvassed as possibilities.

[41] Mr Smith was somewhat expansive in explaining the range of alternative treatments about which a doctor may be obliged to advise the patient in fulfilling the duty imposed on him by *Montgomery*. These could include treatments which were no longer routinely used for that condition, ones which were only just emerging even if not widely accepted and ones which the advising doctor did not himself offer but which might be offered elsewhere. Nevertheless no one was suggesting that there was no limit on the number of alternative treatments that could or should be offered to a patient. The question is how in law that range could be sensibly defined.

[42] The pursuers argue that what is a reasonable alternative is to be defined by the patient. What the patient considered to be reasonable would emerge from the discussion that the doctor would be expected to have with the patient. The doctors on the other hand say that the range of alternatives are those that the doctor considers reasonable exercising his or her skill and expertise as a reasonably competent doctor (the *Hunter* v *Hanley*/*Bolam* test) and are available.

[43] In my opinion the submissions for the doctors are to be preferred. If the pursuers are right the doctor may well be obliged to advise the patient of alternative treatments which he or she as a doctor would not consider as clinically suitable for the patient. Take, for example, the case of a patient with a pre-existing condition who is being treated for another illness. There is common and available treatment which is usually available to a patient with this illness. However it is dangerous for those with the pre-existing condition. That may arise where, for example, the combination of drugs used by the patient to treat the pre-existing condition with those used to treat the illness gives rise to complications imposing unacceptable risks to the patient. According to Mr Smith the duty on the doctor is to advise the patient of the existence of the alternative remedy even if, in the particular case it is not considered to be a reasonable alternative by the doctors. The explanation for this approach is that the patient may wish to get a second opinion.

[44] That is not consistent with the approach in *Montgomery*. The submissions made by counsel for the appellant to the Supreme Court are recorded at [2015] AC 1430 at 1435:

> "Decisions about diagnosis and treatment must necessarily, and by definition, be made by the medical practitioner by reference to his special skill, learning and experience in an expert field which is not shared by the patient. By contrast decisions by the patient as to whether to submit to proposed treatment are his to make as of right, and his to make by giving whatever weight he thinks it right to put upon the risks and benefits which the options available bring."

This emphasises that the ratio of *Montgomery* is a limited, albeit important, innovation on the rule in *Bolam/ Hunter* v *Hanley*. (See also Badenoch, *Montgomery and patient consent: perceived problems addressed* (2016) 12 Clinical Risk 12 at page 14; *Clerk & Lindsell on Torts 21st edition* at paragraph 10-76)

[45] What the treating doctor cannot do is to withhold information about a reasonable alternative treatment and the risks associated with it on the basis of their own preferences. If a

treatment is reasonable and available it should be discussed with the patient. The Supreme Court (paragraph 90) emphasised the importance of dialogue. This allows the patient to discuss the proposed treatment, its risks and benefits and enable her to make an informed decision about treatment. It may well be that during that process the availability of other treatments may be discussed including those which the doctor may consider not clinically advisable. A good doctor will no doubt explain the reasons for not pursuing a particular alternative. However as a matter of law I do not consider that a doctor can be held to be in breach of a duty to the patient for failing to advise on an alternative treatment which if performed by the doctor would be a breach of their duty of care to the patient.

[46] The pursuers argue that they do not require to set out what alternative treatment the pursuer would have opted for were she to have been advised of the alternatives. They cite *Webb* v *Barclays Bank and Anr* as authority for the proposition that it is not necessary for the pursuer to give evidence, and by extension to say what alternative the pursuer would have taken. This misunderstands *Webb*. While it is clear that it is not necessary for the pursuer to give evidence, the court in *Webb* were able to draw an inference from other evidence as to the alternative that the claimant would have opted for.

[47] The pursuers also argue that they have been prejudiced by the failure of the doctors to submit to precognition or answer questions in writing. Until they do so the pursuers cannot know what alternatives were available and therefore cannot say what they would have done.

[48] I am not satisfied that the pursuers have been prejudiced in this case by any failure of the doctors to give an account or answer questions. In the first place the pursuers say that the alternative treatments were well known to doctors. If that is the case then there should be no difficulty in the pursuers telling the court whether they would have opted for an alternative treatment and if so which one. In any event if the pursuers had instructed an expert they

would have opinion evidence as to what alternative treatments were available for SUI and POP at the time of the operations. Finally the answers for the doctors give fairly full details of the interaction between the individual pursuers and the treating doctors.

[49] In each case the pursuers plead that the following alternatives were available; (i) use of a vaginal support pessary; (ii) surgery using organic tissue; (iii) an abdominal anterior colporrhaphy; (iv) a laparoscopic abdominal sacrocolcopexy; (v) having no treatment; or (vi) having physiotherapy. That sits rather oddly with the submission that broadly speaking the alternatives to treatment available were those using biological material or no surgery. It also highlights the difficulty the pursuers have given themselves in proceeding with generic averments which fail to address the specific medical condition which the individual pursuers presented to the treating doctors. In none of the cases does the pursuer specify which of the alternative treatments she would have opted for if she had been properly advised.

[50] Accordingly if the case for the pursuers is to the effect that the doctors failed to properly advise of risks associated with the use of the product and of reasonable alternatives and that if they had been properly advised they would have opted for one of the alternatives then they need to specify which option they would have taken. To leave it to the proof prejudices the defenders who will not know what case they require to meet. It follows that averments as to availability of alternative treatments should not be admitted to probation.

[51] There is still a duty on the doctors to advise the patient of risks associated with the proposed procedure. In the absence of averments as to reasonable alternatives it seems clear that these are "no treatment" cases; that is that had they been advised of the risks associated with the treatment ultimately undertaken by the pursuers in each case they would have opted for no treatment other than perhaps conservative management of their symptoms.

[52] It should be noted that in each case the doctors in their answers have averred that they did discuss alternative treatments with the pursuer. (In the case of SR whose medical condition was perhaps more complex the second defender says that Dr Dolan discussed options for treatment with the pursuer.) In some of the cases the doctors have given reasons why an alternative was rejected. However in the absence of averments from the pursuer saying that she would, had she been properly advised, have opted for one of the alternative treatments it seems to me that these show the scope of the discussions that the doctors say took place but do not assist the pursuers' cases.

[53] I should also record that in the course of the debate Mr Smith presented a minute of amendment in the case of SR in which the pursuer offers to prove the alternative treatment that she would have undergone had it been offered to her. That was opposed by the defender. I continued consideration of the amendment. Before determining the motion I have decided that I should give the pursuer an opportunity to consider whether she wishes to continue with her motion, drop it, or make another motion in the light of my findings.

[54] In conclusion subject to the discussion below I shall allow the actions against the doctors to proceed on the basis of an alleged breach of duty to advise of the risks associated with the procedure but not of alternative treatments.

***Specification issues: The knowledge of the doctors***

*Submissions for doctors*

[55] As a specification point Mr Stephenson submitted that in the case of YT the pursuer cites publications which post-date the surgery conducted by Dr Milne as the basis upon which the pursuer seeks to demonstrate Dr Milne's knowledge at the time of the discussion which preceded YT's consent. Mr Stephenson submitted that the general averments that there was

increasing concern regarding the use of mesh from 2002 onwards were irrelevant and lacking in specification. However he went on to make a broader point of significance to all of the cases against the doctors. A doctor cannot be held negligent for failing to make a disclosure of matters of which he had no knowledge, unless that knowledge can be imputed to him (ie, unless it can be concluded that these were matters he ought to have known about), as was the case in *Webster*. Therefore, a patient would have to set out to prove that a doctor knew or ought to have known of the existence of the undisclosed risk, or some aspect of it such as its magnitude or probability, before she can go on to argue that the doctor had a duty to disclose it. Whether a doctor knew, or ought to have known about a risk is a matter that falls to be judged against the usual *Hunter* v *Hanley*, or *Bolam* test. That is, it is a matter in the medical realm, and analytically precedes the question of obligation to disclose.

[56] The written submissions for the NHS doctors in the cases of AH, SR and EN all make similar specification points as to the knowledge of the doctors of the risks which the pursuers say should have been communicated to the pursuer. In AH the first defender, points out that there is a contradiction in the pursuer's averments. In Condescendence 6 the pursuer avers that she had a right to be advised by Dr Perera of the fact that there had been no testing of the product and that as from 2005 there had been increasing reports of significant problems with the product and increasing concerns about the safety and benefits of the product. She further avers that the second defenders (Johnson & Johnson) marketed and sold their pelvic mesh products as safe effective reliable medical devices and that they did not give adequate warning of the risks either to doctors or to patients. However the pursuer does not say how, despite the marketing of the product by the manufacturers, Dr Perera knew of the risks associated with the product. There is no notice of the reports referred to in Condescendence 5 or any other reports which would form the basis of Dr Perera's knowledge. Reference is made to articles published

between 2007 and 2016 many of which postdate the operation. The pursuer relies on articles in the American Congress of Obstetricians and Gynaecologists in February and September 2007 without any specification of why a doctor practising in a Scottish hospital should be aware of these reports. The same applies to averments about warnings by the Federal Drugs Administration (FDA).

[57] Similar points are made in both SR and EN.

*Pursuers' response*

[58] The pursuers' position appears to be this. They agree with the proposition that a doctor cannot advise a patient of that which he does not know and it is only if he is negligently unaware of the risk that he will be held liable. The pursuers lodged written notes of argument dealing with the position of the doctor in the cases of AH, SR and EN. They are in exactly the same terms (even to the point of criticising answers by the defenders relating to Dr Dolan, the treating doctor in SR). They do not engage with these specific criticisms. Mr Smith did produce a written response in the case of YT which he spoke to in the course of his response to Mr Stephenson.

*Discussion*

[59] A doctor cannot advise a patient about a risk if he is unaware of it. In cases such as these involving the use of a medical product it seems that there are potentially three sources for the doctor's knowledge. The first will be those which the manufacturer themselves bring to the attention of the doctor using the product. These will normally be contained in the Instruction for Use (IFU) but may be in other general or supplementary information addressed to treating doctors.

[60] The second source is that associated with the doctor's skill and expertise as a reasonably competent doctor. That knowledge may be actual or imputed. It may include an obligation to investigate where he is faced with a set of circumstances with which he is unfamiliar. In *Webster* the trial judge found that the consultant obstetrician attending a mother had failed to inform himself of the implications of the particular rare combination of features which she presented. That obligation to keep himself informed would extend to new treatments.

[61] Where the treatment involves a medical device there is a duty on the doctor to apprise themselves of the implications of the use of that device together with any risks associated with its use. That again is part of the clinician's duty to the patient but its importance is underlined by the doctor's role as a learned intermediary between the producer of the product and the patient. The producer has no relationship with the patient who relies on the doctor to advise them of the risks associated with it. As Hickenbottom J observed in *Wilkes* v *DePuy International Limited* [2017] EWHC 3096 (QB) (paragraph 107):

> "Parliament has determined that, in relation to such products, information about risks is best relayed to, considered by, and applied and passed on to the patient by the treating surgeon, who must advise that patient as to intervention choices, and seek and obtain that patient's informed consent to the particular chosen implant procedure."

The doctor is also under an obligation to keep abreast of developments in the field of medicine in which he practices by, for example, reading articles related to treatments which he uses in his practice. In these cases the pursuers list a number of articles in journals without focussing on which may be relevant to the particular case. It is trite to observe that the doctor's knowledge needs to be established as at the date of the treatment which was performed on the individual pursuer. Those that post-date the operation are irrelevant for the purposes of establishing the doctor's knowledge at the time and it is not clear why they are mentioned.

[62] But whether an article in a journal is relevant for these purposes will I think depend on the circumstances. Not all articles in professional journals would be accorded the same respect. In general whether an article in a professional journal should place a doctor on notice of issues or problems associated with a particular treatment should be judged on the *Hunter* v *Hanley/Bolam* test. There may however be situations where the warnings contained in the article are so clear and obvious that the court may say that any doctor should have been aware of the implications without recourse to *Hunter* v *Hanley*.

[63] The third source of knowledge may come from warnings from regulatory bodies such as the MHRA. It is not clear however why a doctor practising in the UK should have regard to warnings from the FDA, though that may be a matter for proof.

[64] Each of the cases include the following averments:

> "Accordingly, as from the date upon the surgery on the pursuer, the pursuer had the right to be advised: (i) that there had been no testing for the efficacy and safety of the mesh product; (ii) that as from 2005 onwards there had been increasing reports of significant problems with the product; and (iii) as from the dates of the various publications referred to above, there was increasing concern about the safety and benefits of the product. Had the pursuer been advised of these matters she would not have consented to undergo the operation".

In none of the cases are these and related averments anchored in specification as to how the treating doctor should have been aware of these facts. On their own they look mere assertions. The defenders are entitled to notice of what it is they should have known and why they should have that knowledge. I am satisfied that without further specification the defenders would be prejudiced. Accordingly these averments should be excluded from probation.

[65] So far as the other averments bearing on the knowledge of the doctors are concerned it is incumbent on the pursuer to identify the foundation of the knowledge which the pursuer avers that he should have. It may be that it was said to have been communicated in the IFU (as

is the case in AH), or it was knowledge that should be imputed to the doctor because of the skill and expertise which an ordinarily competent doctor should have.

[66] I shall invite parties to make further submissions on which averments are thus excluded from probation.

***The possible scope of the case against the doctors***

[67] I recognise that my conclusions take out a substantial part of the case as pled against the doctors. The issue is whether there is still a relevant case. However in each case there is a significant factual dispute between the pursuer and the doctors as to what she was told. In most of the cases as I note below the doctors have made fairly detailed averments about the scope of discussion and advice that was given to the pursuer. These include, again in most cases, fairly detailed averments by the doctor about advice given to the pursuer about specific risks associated with the procedure. It is arguable that the advice that was given to the pursuers in each case was given as part of the duty on the doctor to advise the patient of the risks associated with the procedure.

AH

[68] In AH the pursuer avers in condescendence 2:

> "It was supplied with Instructions for Use ('IFU') entitled 'Gynecare PROLIFT' lists the adverse reactions as including infection, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction and that punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during insertion. These were all material risks and were therefore known by Dr Perera and should have been communicated to the pursuer."

[69] The first defender's answers detail a number of meetings at which alternative treatments and risks were discussed. These averments include the following:

> "Dr Perera fully counselled the pursuer about the risks associated with the proposed surgery. This included a discussion about failure of the procedure, infection, bleeding, injury to organs such as bowel and bladder and problems with mesh erosion. Dr Perera also warned the pursuer of the risk of long-term pain arising from the procedure. He warned her of the risks of thrombo-embolism and of the risk of denovo bladder symptoms."

There then follows averments about her discussion with Dr Sircar on the day of the operation.

> "Dr Sircar documented his discussion of risks with the pursuer in the hospital records. The entry confirms that the operation was explained to the pursuer again that day. The pursuer indicated that she was aware of the risks associated with the operation, including bleeding, infection, rejection of mesh, bowel/bladder injury and recurrence. The surgery was performed that day, 10th February, 2009. The pursuer suffered a known complication of her surgery, namely mesh erosion or exposure. She had been counselled about this risk prior to surgery."

In reply the pursuer denies that she was told these things although she accepts that she was advised that there was a small risk of infection.

[70] It appears therefore that there is a significant factual dispute between the parties on the advice that she was given about the risks. These risks include the risks that Dr Perera was advised about in the IFU. I think it is clear that Dr Perera had a duty to communicate these known risks to the pursuer. The first defender through the answers says that he did. The pursuer disputes this. If the pursuer is correct and, despite the terms of the answers, Dr Perera is found not to have communicated these risks then there is a potential liability to the pursuer.

SR

[71] In SR the purser avers in condescendence 4 that Dr Dolan did not properly advise of any risks or complications of the mesh implementation procedure. In answer 4 the second defender avers:

> "Dr Dolan explained the risks associated with the procedure to the pursuer, including the high risk of recurrence due to the pursuer's relatively young age and the condition of her internal tissues. At the conclusion of the discussion, the pursuer agreed to be placed on the waiting list for surgery. The pursuer met with Dr Dolan on 15th October

> 2009 prior to her surgery. Dr Dolan discussed the nature and purpose of the procedure to the pursuer, as well as the attendant material risks, including dyspareunia, laparotomy, bleeding, infection, voiding difficulties, overactive bladder, failure to cure her SUI, mesh erosion and the absence of data in relation to long-term outcomes. At the conclusion of the discussion the pursuer signed the consent form confirming that she wished to proceed with surgery."

Accordingly there is a factual dispute about whether or not the pursuer was given the advice which Dr Dolan avers in the answers.

YT

[72] The pursuer avers that she was not informed of the risks associated with the procedure. In answer the second defender replies that:

> "The second defender advised the pursuer of the risks of the tension free mesh procedure including (a) the possibility that the procedure might not cure her SUI symptoms or might not relieve them completely (b) injury to other organs (in particular the bladder) (c) erosion of the mesh (d) voiding problems after the procedure (e) groin discomfort and (f) bleeding. He mentioned that there would be a low risk of infection. The second defender explained to the pursuer that the procedure involved the insertion of a tape product made from synthetic material, namely polypropylene. He mentioned to the pursuer that this was a more inert material than had been available previously and that in his experience it had therefore produced less problems. He mentioned that the product would not dissolve and that it would stay in the pursuer's body. He indicated using his fingers the rough width of the tape. He mentioned that the tape would hold the urethra up by forming scar tissue."

Again by reference to the second defender's pleadings it is clear that there is a factual dispute between the parties as to whether the pursuer was told of the risks set out in the second defender's pleadings.

EN

[73] The pursuer avers in condescendence 2 as follows:

> "Ms Granitsiotis recommended that the pursuer undergo a transobturator tape ('TOT') procedure. Ms Granitsiotis advised the pursuer that the procedure involved the insertion of a 'sling' as a support to her bladder. The pursuer was advised that this was a popular procedure and that Ms Granitsiotis had carried out a number of similar procedures on other women, with successful outcomes. Ms Granitsiotis did not advise

> the pursuer what any proposed sling would be made from. The pursuer was not shown any product. Ms Granitsiotis informed the pursuer that it was possible that the TOT procedure would not be successful in stopping her stress incontinence. The pursuer was advised that the TOT, once implanted, may not be tight enough and that, if that were the case, it may not be successful in alleviating her symptoms of SUI. No specific risks or complications relative to the use of pelvic mesh products as hereinafter condescended upon were discussed with the pursuer. No alternative procedures or products were discussed with the pursuer. In particular, the pursuer was not advised of the possibility of surgery using native tissue. She was not advised that the use of native or organic material in surgery had the advantage that, if the surgery were to fail, it could be repeated. She was not advised that the TOT was a permanent implant which would be difficult, if not impossible, to remove once inserted…..The pursuer was given written information in relation to post-operative advice following a TOT insertion procedure. She was given no written material in relation to what the procedure itself entailed, or the associated and potential complications as hereinafter condescended upon. She was not advised of the risks from the TOT surgery of chronic pain, infection, vaginal bleeding, sexual dysfunction, de novo urinary incontinence, the need for long-term catheterisation, the risk of injury to bowel, blood vessels, bladder and urethra or the risk of the need for repeated surgery. She was not advised of the risk of erosion, extrusion or exposure of the product"

In response the first defender makes the following averments:

> "Ms Granitsiotis discussed transobturator tape procedure ('TOT') with her. She discussed that a TOT was made from an artificial material. She discussed the risks of undergoing such a procedure fully with the pursuer. She warned her that she could have a number of complications following such an operation, including de novo detrusor over-activity, an inability to empty her bladder completely, giving rise to a need for intermittent catheterisation and post-operative pain at her exit wounds. Ms Granitsiotis also discussed the risks of infection, bleeding, failure of the procedure, erosion, sexual dysfunction, long-term pain, thigh pain and urinary urgency. Ms Granitsiotis explained to the pursuer that the TOT could be ineffective if it was too loose or too tight, the latter possibly leading to voiding difficulties. She also gave the pursuer a detailed leaflet about the TOT procedure. Ms Granitsiotis discussed urethral bulking agents and the risks and benefits associated with these. It was explained to the pursuer, amongst other things, that urethral bulking agents had a higher failure rate, were unlikely to be a permanent solution to her SUI and would likely require to be repeated. The pursuer wished to go ahead with the TOT procedure. The pursuer attended a pre assessment clinic on 14th June, 2007. The pursuer was noted as having been provided with a TVT leaflet, which was a leaflet that detailed both a TVT and TOT operation, including associated risks.

[74] Accordingly, having regard to the scope of the averments for the first defender it is clear that there is a real factual dispute between the pursuer and the first defender as to what advice was given to the pursuer.

[75] In each of these cases the doctors have made detailed averments which are, for the most part, disputed, as to advice and information they gave to the pursuers on the risks associated with the operation to implant the product. It is arguable that such advice was given by the doctor in implementation of his duty of care to the patient to advise her of the risks. If, despite the defenders averments, such advice was not given as the pursuers allege, then there is a potential breach of the duty of care to the pursuer.

***Specification issues: Risks and causation***

*Submissions for doctors*

[76] The doctors submitted that the pursuers in each case narrate a lengthy list of risks that they assert were material to them but make no attempt to connect those to the losses claimed. Furthermore, on the face of it most of the risks appear not to have materialised. Accordingly the claims are irrelevant. In general, there are three categories of risks: (a) those that the patient knew of and accepted; (b) those that the patient did not know about but should have been told of; and (c) those that the patient did not know about and there was no duty to inform them. It is only where a category (b) risk materialises that the clinician is liable in negligence and that liability is restricted to the loss caused by the materialisation of that category (b) risk. The correct analysis involves consideration of the principles of scope of duty and causation. The two concepts overlap. The scope of duty principle involves a distinction between a breach of duty which gives the occasion for loss (a factual question), and one which is the legally substantial cause of the loss (a normative question). Damages can only be awarded if the loss

which the claimant sustained was within the scope of the duty to take care; *Hughes-Holland* v *BPE Solicitors and another* [2017] UKSC 21; [2017] 2 WLR 1029 at paragraphs 20 and 23 the case law dealing specifically with the issue of negligent disclosure of multiple risks in a clinical context is limited. The High Court of Australia analysed the issues in depth in *Wallace* v *Kam* [2013] HCA 19; (2013) 250 CLR 375. In it a surgical procedure involved two distinct risks (A and B). The doctor negligently failed to mention risk B. The patient agreed to proceed with the operation and risk A materialised. The claimant argued he would not have gone ahead with the operation if he had been told about both risks – and would therefore not have suffered from the damage caused by the risk A materialising. The High Court held that the claim failed and the fact that the claimant would have declined the treatment was irrelevant. It held that the policy of the law was to protect the patient from the occurrence of physical injury, the risk of which is unacceptable to the patient; the policy was not to protect the right to choose or to protect the patient from all unacceptable risks. The alternative conclusion would lead to the result that the patient is compensated for the eventuation of a risk she was willing to accept. The court found support for its conclusion in the House of Lord's case of *Chester* v *Afshar* [2004] UKHL 41; [2005] 1 AC 134

[77] In *Montgomery* the court observed that the issue of causation, where an undisclosed risk has materialised, is closely tied to the identification of the particular risk which ought to have been disclosed; paragraph 98. In the present case, the purpose of the duty to take reasonable care to ensure that a patient is aware of material risks inherent in the treatment is to allow a patient to avoid a risk of injury that she would not be prepared to take and is the counterpart of her entitlement to decide whether or not to incur that risk; paragraph 82. These observations are consistent with the approach in *Wallace*.

[78] In *Moyes* v *Lothian Health Board* 1990 SLT 444 the Lord Ordinary (Caplan) observed, *obiter*, that in the event of a negligent failure to warn, it would not have mattered that the risk that materialised was not one that should have been warned about, provided that the patient would have refused to undergo the operative procedure. *Moyes*, however, is (a) distinguishable from the present case (and *Wallace*) on the ground that it involved a single physical injury to which there were a number of factors contributing to the risk of that physical injury occurring; (b) pre-dates cases like *Montgomery, Chester,* and *BPE/SAAMCO* and (c) appears to be considering the point under reference to the first, factual, question and did not consider the second, normative, question.

[79] In the context of liability under the Consumer Protection Act Mr Currie submitted that a claimant in a professional negligence action could only recover that part of the loss which was within the scope of the duty of care of the defendant. The issue had been considered by Lord Sumption in *Hughes-Holland* v *BPE Solicitors and another*. In his submission the manufacturers gave information to the treating doctor. They could not be described as advisors to the patient. Accordingly they could not be held responsible for losses flowing from the patient's decision to have the operation; they could only be held responsible for losses resulting from any alleged deficiencies in the information for use provided to the doctor with the product. The relevant risk was the one which the defender had to warn about, but failed to do so, and which materialised; *Wallace* v *Kam*, paragraph 24. In his submission the fundamental deficiency in the pursuers' pleadings was the failure to link the risk which the manufacturers negligently failed to advise to the damage to the pursuer.

*Pursuers response*

[80] In order to provide fully informed consent the patient must have notice of all of the relevant risks and not merely those which ultimately arise. For example, imagine an operation that carries a 50% risk of mortality and a 1% risk of blindness and the treating doctor only warns the patient of the 1% risk of blindness. If the patient consents to the operation and then goes blind, it is no defence to say that he was warned of that 1% risk. There was clearly a breach of duty at the point of warning. If the patient would have refused the operation on the basis of the high mortality risk, there is also a causal connection between that breach and the ultimate injury. Accordingly, the patient would have a valid claim against the treating doctor.

[81] The defenders' arguments on this point are based on a misunderstanding of *Hughes-Holland* v *BPE Solicitors*, which dealt with the situation of a professional advising on one of a series of broader risks, some of which were outwith the scope of his duty to advise on (the so-called "mountaineer's knee" principle). This is not such a situation. All of the risks were within the adviser's scope of duty. The pursuer was entirely reliant on the professional advice given to them in making their decision. In this situation the adviser is responsible for all losses, regardless of whether the risk negligently advised on eventuates. A product can be defective even where no risk at all eventuates; *Boston Scientific* [2015] 3 CMLR 6. In any event, the manufacturers and doctors between them are advisers, not merely providers of information, in terms of the analysis in *Hughes-Holland*. This is demonstrated by the learned intermediary defence. The pursuer avers that she was not given adequate advice by her doctor – she cannot know whether that is because the manufacturer failed to tell the doctor, or the doctor failed to pass on what he had been told by the manufacturer. It is clearly within the scope of the duty of both the manufacturer and the doctor to warn the pursuer of all material risks. In *Wallace* v *Kam*, the court approved of the reasoning of Lord Caplan in *Moyes* v *Lothian Health Board* but

then added a gloss that does not exist in the original reasoning. Even if that gloss is justified and is part of Scots law (which is not accepted), it does not apply in the present case. The risks here are all of one single physical injury, with the same cause (polypropylene) and damage to the same part of the body. At the very least, these very fine distinctions cannot be determined as a matter of pure relevancy. They are classic proof before answer points.

*Discussion*

[82] In *Moyes* v *Lothian Health Board* a patient suffered a stroke while undergoing an angiography. An angiography is an invasive diagnostic technique involving a degree of risk of symptoms including stroke amounting to between 0.2 and 0.3 percent in a healthy patient. There are special risks including a hypersensitivity to the contrast medium used in the angiography. Where that is present it may double the risk. The pursuer claimed that she had, on an earlier CT scan, suffered an allergic reaction to the contrast medium, that it had been observed by the junior doctor who had given her anti-histamine tablets, and that it should have been noted in the medical records. There was a further issue as to whether a history of migraine presented a special risk.

[83] One of the issues in the proof was whether the treating doctor had warned the pursuer of the risks associated with the procedure. The doctor said that he had warned of the risk of a stroke but not of the special risks, in particular stemming from hypersensitivity. Lord Caplan found as a fact that she had not suffered a hypersensitive reaction on a previous occasion. He also found that the stroke had not been caused by an allergic reaction. However the pursuer's counsel had argued that even although the hypersensitivity had not caused the stroke it was an aggravating factor and the pursuer should have been warned about it. If the pursuer had been properly advised on the cumulative risks she would not have agreed to the angiography.

Accordingly failure to warn her that the allergy put her at added risk caused her loss in the sense that had she known of that risk along with the others she would not have agreed to the operative procedure. Lord Caplan dealt with this at page 447:

> "The ordinary person who has to consider whether or not to have an operation is not interested in the exact pathological genesis of the various complications which can occur but rather in the nature and extent of the risk. The patient would want to know what chance there was of the operation going wrong and if it did what would happen. If we were to suppose a situation where an operation would give rise to a 1 per cent risk of serious complication in the ordinary case but where there could be four other special factors each adding a further 1 per cent to the risk, a patient to whom all five factors applied might have a 5 per cent risk rather than the 1 per cent risk of the average person. It is perfectly conceivable that a patient might be prepared to accept the risk of one in 100 but not be prepared to face up to a risk of one in 20. If a doctor contrary to established practice failed to warn the patient of the four special risks but did warn the patient of the standard risk and then the patient suffered complication caused physiologically by the standard risk factor rather by one or other of the four special risks factors I do not think the doctor should escape the consequences of not having warned the patient of the added risks which that patient was exposed to. A patient might well with perfect reason consider that if there were five risk factors rather than one then the chance of one or other of these factors materialising was much greater. The coincidence that the damage which occurred was due to the particular factor in respect of which a warning was given does not alter the fact that the patient was not properly warned of the total risks inherent in the operation and thus could not make an informed decision as to whether or not to go through with it. In the example I give, by going through an operation with five risk factors rather than one the patient was exposed to a degree of risk materially in excess of what the patient had been warned about and was prepared to accept. If he had been given due warning he would have not risked suffering adverse complication from that particular operation and the fact that such complication occurred is causal connection enough to found a claim against the doctor."

[84] *Moyes* was considered by the High Court of Australia in *Wallace* v *Kam*. The claimant had sought medical assistance in relation to a condition of his lumbar spine. The surgical procedure had inherent risks. One was of temporary local damage to nerves within his thighs, described as "bilateral femoral neurapraxia" resulting from lying face down on the operating table for an extended period of time. Another distinct risk was a one in twenty risk of permanent and catastrophic paralysis resulting from damage to his spinal nerves. The surgical procedure was unsuccessful and his spine did not improve. The first risk of neurapraxia

materialised. The second of paralysis did not. The trial judge found that Dr Kam negligently failed to warn Mr Wallace of the risk of neurapraxia. But he also found that even if he had been told of the risk he would nevertheless have chosen to undergo the surgical procedure.

[85] The court said that Lord Caplan's approach in *Moyes* was entirely appropriate to a case that involves the coming home of a risk of a single physical injury to which there are several contributing factors the combination of which operate to increase the risk of that physical injury occurring. It was not however applicable to a situation which involved the materialisation of one of a number of distinct risks of different physical injuries. At paragraph 62 the court said this:

> "Consideration of a case involving the materialisation of one of a number of distinct risks of different physical injuries makes it necessary to return to the nature of the duty and the policy that underlies its imposition. The duty of a medical practitioner to warn the patient of material risks inherent in a proposed treatment is imposed by reference to the underlying common law right of the patient to choose whether or not to undergo a proposed treatment. However, the policy that underlies requiring the exercise of reasonable care and skill in the giving of that warning is neither to protect that right to choose nor to protect the patient from exposure to all unacceptable risks. The underlying policy is rather to protect the patient from the occurrence of physical injury the risk of which is unacceptable to the patient. It is appropriate that the scope of liability for breach of the duty reflect that underlying policy."

The underlying policy is that the pursuer should not be compensated for a risk that she was prepared to accept.

[86] In *Hughes-Holland* Lord Sumption draws a distinction between a professional person who supplies information and one who advises. The advisor becomes liable for risks of the whole decision – the person who gives information only for those risks covered by that information. Mr Bowie argued that in this case the doctors were in the position of information givers, not advisors. Accordingly they were only responsible for those risks covered by information given to the patient. Mr Currie submitted that so far as the manufacturers were concerned they were not advisors.

[87] I am not convinced of the applicability of the *Hughes-Holland* analysis to the clinical relationship between doctor and patient. It is true that *Hughes-Holland* dealt with the advice that a professional person may be expected to give to a client in respect of risk and his liability for losses occurring as a result of his failure to advise in accordance with that duty. However I note that neither *Montgomery* nor *Wallace* v *Kam* was cited to the court or referred to in the judgment of Lord Sumption. From the patient's perspective I doubt that they would regard the doctor as a mere giver of information. The doctor will usually have assumed a wider responsibility for the care of the patient which involves a diagnosis and treatment. The patient in these circumstances may have already relied on the doctor's diagnosis. I doubt that they would then see the doctor's discussion of proposed treatments and reasonable alternatives as anything other than advice.

[88] The key question is this; would the pursuer have been prepared to accept the risk which led to her loss and damage? If the answer is yes then even if there is a breach of duty in failing to communicate that risk to the pursuer she cannot succeed. That is because the causal link between the breach of duty and the loss is broken by the pursuer's willingness to accept the risk. As the court decided in *Wallace* v *Kam* a claimant should not be compensated for a physical injury the risk of which she was prepared to accept.

[89] It is clear that there are two possible approaches to assessing the issue of risk and its acceptance by the pursuer. The first is the one which was adopted by Lord Caplan in *Moyes* and sees the risk as cumulative. As Lord Caplan says:

> "The ordinary person who has to consider whether or not to have an operation is not interested in the exact pathological genesis of the various complications which can occur but rather in the nature and extent of the risk. The patient would want to know what chance there was of the operation going wrong and if it did what would happen."

That however does not answer the question as to whether she should be compensated.

[90] The second approach is that taken in *Wallace* v *Kam* where there were two distinct risks associated with the one operation.

[91] Both approaches have their merits but I am not clear that the circumstances of these cases neatly fit into either case. In all of the cases the outcome that the pursuers allege is not confined to one complication, such as the neurapraxia in *Wallace* v *Kam*. They aver that they have suffered pain, vaginal discharge, return of SUI or prolapse, extrusion of mesh as well as other symptoms. Nor do they occur at one time but often over a period of time. They do not fit into the neat boxes of risk A or risk B that forms the basis of *Wallace* v *Kam*.

[92] Whether a pursuer would have accepted a risk may be quite nuanced and will depend on the individual circumstances. That is particularly so when there are a range of injuries some more severe than others. Some may be acceptable and some not. It may be that in some cases it is the risk of a combination of potential injury that may be unacceptable.

[93] The decisions in *Moyes* and *Wallace* v *Kam* followed on a proof of the facts. At this stage it would be premature for me to say that the approach taken by either Lord Caplan or the High Court of Australia is to be preferred. Accordingly on this issue I agree with the pursuers that this is a matter for a proof before answer.

**Conclusions on the common law cases against the doctors**

[94] The pursuers' cases against the doctors are flawed in a number of respects. The approach appears to have been to start from the proposition that there was a fundamental problem with the use of vaginal mesh products and that there were quite a number of alternative treatments which would have been better. Having started from that proposition the pursuers then list all the alternative available treatments that should have been offered to the individual pursuer without analysing whether these were reasonable alternative treatments for

that particular pursuer. The pursuers then say that they were not offered alternatives. In most cases that is disputed by the doctors though it is true that they were not offered the full range of alternatives set out by the pursuers. In some cases the doctors give reasons why some alternatives were not available. However it seems to me that none of this matters since the pursuers (a) fail to identify what are the reasonable alternatives for that pursuer, and (b) with the possible exception of SR fail to say which alternative she would have taken.

[95] Having made those errors the pursuers then attempt to hold the doctors responsible for the alleged defects by building a case based on a negligent failure to warn of the risks associated with the product. In doing so they fail to identify how it is the doctors have, or should have, knowledge of these risks.

[96] The cases against the doctors can only rescued by holding, first, that these are 'no treatment' cases where it can be assumed that having had advice they would have opted not to have had any treatment, other than perhaps conservative management of their symptoms. That has an obvious problem for the pursuers in the damages that might be awarded. Secondly the cases rely on the detailed answers given by the doctors in setting out what advice they say was given to the pursuer. That will be a matter for proof and will depend on the credibility and reliability of the pursuer and the treating doctors. It appears that the averments in answer draw on the medical records, including the consent forms signed by the pursuer. The veracity of the records appear to have been put in dispute by the pursuers in some of the cases but given the lapse of time for reasons set out below when discussing time bar, it may be that the records take on greater significance. These are issues that the pursuers will have to face at proof.

[97] For completeness I should note that all of the cases against the doctors aver that had it not been for the doctor's breach of duty the pursuer would not have suffered loss and damage and breach of personal autonomy. The defenders submitted that this was irrelevant citing *Shaw*

v *Kovac* [2017] EWCA Civ 1028 and *Diamond* v *RDE NHS Foundation Trust* [2017] EWHC 1495 (QB). The pursuers informed me that they did not insist on that part of the claim and I shall exclude these averments from probation. I was nevertheless invited by the defenders to give my opinion on the matter for future reference. I decline to do that in the absence of full submissions.

[98] I shall invite further submissions from the parties on the scope of averments excluded from probation and whether there is then a relevant case on the basis I have set out above.

## Chapter 4: The case against the manufacturers

### *Relevancy of the cases under the Consumer Protection Act 1987*

*Submissions for manufacturers*

[99] Mr Currie, Ms Haldane and Mr Ellis all submitted detailed and helpful notes of argument supplements by oral submissions. What follows is a distillation of their submissions which all had similar features. All commended the approach of Hickinbottom J in *Wilkes* v *Depuy International Limited* [2016] EWHC 3096 (QB).

[100] In terms of section 3 of the 1987 Act there is a defect in a product if the safety of the product is not such as persons generally are entitled to expect. The pursuers had all failed to identify the defect that caused the damage. No explanation is given of the manner in which the particular product supplied to the pursuer is said to have been defective. It is not a standard of absolute safety. It is rather a relative standard related to what people are entitled to expect. It involves a consideration of the risks and benefits associated with the product. There is no recognition that a product may have side effects or indeed a complication risk. The fact that there is such a risk does not of itself infer that it is defective. The pursuers' fundamental error is to conflate risks with defects.

[101] Section 2(1) of the 1987 Act imposes liability "where any damage is caused wholly or partly by a defect in a product". The issue of damage being causally connected with a defect is therefore at the heart of the liability: *Wilkes* at paragraph 73.

[102] If the defect is alleged to be the use of polypropylene, then the pursuers require to address all these issues in that context. The pursuers fail to aver an injury caused by a defect. If it is the use of polypropylene, then they must aver a causal connection between that feature of the product and her subsequent condition.

[103] The pursuers say that the manufacturers failed to put out proper and reasonable warnings of the "very serious potential consequences that could occur in a recipient of a pelvic mesh product". It is not clear whether that is alleged to be part of the defect. However it is irrelevant because the pursuers fail to specify what the alleged risks are. The defenders are entitled to specification of these matters in order that they know the case they are required to meet and for the defence available under section 4(1)(e) of the 1987 Act.

[104] In determining what persons generally are entitled to expect in relation to a product, the court is required to take into account all the circumstances including the matters specified in subsections 3(2)(a), (b) and (c). It follows that in pleading her case the pursuer must make relevant and specific averments of the relevant circumstances including those specified in those subsections. Section 3(2)(a) specifies one circumstance as:

> "the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product."

Yet the pursuers failed to make relevant averments about the instructions for use (IFU's) issued with the products. Indeed they had somewhat contradictory approaches. In SR the pursuer simply denies the averments regarding the TVT IFU. In AH the pursuer admits the risks

specified in the Prolift IFU and maintains that Dr Perera did not communicate those to the pursuer.

[105] The position of a learned intermediary, such as a clinician is a relevant circumstance; *Wilkes* paragraphs 106 and 108. That was clearly relevant here where there is no direct relationship between manufacturer and the patient. Yet the pursuers do not address the issues which arise from the supply of a medical product to clinicians who will decide in the exercise of their clinical judgment whether or not to use that product.

[106] The date of supply is the date to test whether there is a defect - what were persons generally entitled to expect as at that date. That issue is not addressed. Many of the articles referred to postdate the date of supply. In EN they all do. The averments of knowledge of "lack of substantial benefit" and the averments of evidence of risks to patients are not supported by relevant or specific averment. The pursuer in EN makes no attempt to deal with the averments by the second and third defenders of general acceptance of similar products including by the NHS reviews in England and Wales and Scotland. To give fair notice the pursuer has to indicate her position about the available knowledge (for example Government reviews which conclude that similar products have acceptable risks). She needs to explain why she will say, notwithstanding such conclusions, the product when supplied was of a standard which is less than persons generally are entitled to expect.

*Pursuers' response*

[107] The pursuers' note of argument starts with a recital of the general law on the question of relevancy quoted above. It goes on to state that the pursuers criticise the products as having the following defects:

1. They are made from polypropylene which is not a suitable substance for a permanent prosthetic implant in the highly sensitive vaginal region, which cannot be completely sterilised, because (1) the pores are too small; (2) it is heavy weight mesh; (3) it degrades over time; (4) it causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, sharp edges, roping and curling of the mesh; (5) it deforms; (6) it is cytotoxic; and (7) the pores collapse with tension.
2. These features mean the products are likely to cause mesh erosion, mesh contractions, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and faecal incontinence and prolapse of organs.
3. Once implanted, the products are difficult and sometimes impossible to remove.
4. The products were supplied with inadequate warnings of the foregoing problems.

[108] The test of what amounts to a "defect" in terms of the Consumer Protection Act 1987 is unclear; see Goldberg, *Medicinal Product Liability and Regulation* (2013), pp 19-37; *Wilkes* v *Depuy* [2016] 3 All ER 589 and contrast the approach taken there with *A* v *National Blood Authority* [2001] 3 All ER 289. Even on the narrower approach taken in *Wilkes*, the judge was clear that a holistic approach was required, taking account of all of the relevant facts and circumstances; *Wilkes* paragraph 78.

[109] These allegations are common to all of the claims. More importantly, these allegations are common to claims made across the world, many of which have already been upheld; see *Huskey* v *Ethicon* United States District Court for the Southern District of West Virginia dated 19 August 2015. The test to be applied in such circumstances is set out at II A of the judgment

in *Huskey*. It is essentially the same as that applied by the courts in Scotland at the stage of a debate on relevancy. The judge dealt with all of the issues raised by the manufacturers in the current debate. He held that the evidence on the defective design claim is particularly strong. His reasoning is instructive and unimpeachable, both in relation to defect and causation. Even if this court does not agree with his reasoning it is significant that he deals with all of the questions of specification raised by the manufacturers in the present cases. There was also a group action against Ethicon in the Federal Court in Australia.

[110] In relation to the question of warnings, it is an essential requirement of any medical treatment that the patient has a proper understanding of the risks involved in order that they can provide fully informed consent. This requires the manufacturer to provide full information and then for the treating doctor to pass that information on. In the present cases, there is a failure in both respects. It is difficult for the pursuers to be precise about where the communication breakdown has occurred because none of the treating doctors has provided a statement or precognition facilities, despite being furnished with a list of questions by the pursuers.

[111] In oral submission I understood Mr Milligan to accept the submission of Mr Currie which rested on *Wilkes*.

*Discussion*

[112] While the pursuers made written submissions on the issue of relevancy they have not responded to the detailed analysis and criticisms of the pleadings outlined by the manufacturers and summarised above. That is unfortunate as it has made my task more difficult. Indeed the note of argument as to the alleged defects in the product is clearer than the pleadings. So far as the reference to *Huskey* is concerned I treat that with caution given that it is

dealing with an American statute though it is clear that many of the issues raised in these actions are dealt with in the American case.

[113] At this stage I consider that there are two questions for me to answer. First, are the pursuers bound to fail even if all of the averments on record are proved? Secondly, are the manufacturer defenders prejudiced by the lack of specification of a material nature?

[114] A defect is defined by reference to its safety. There is a defect "if the safety of the product is not such as persons generally are entitled to expect" (section 3(1)). Section 3(2) prescribes that in determining what persons generally are entitled to expect all of the circumstances are to be taken into account. I accept Mr Currie's submission that the use of the word "shall" makes it mandatory. There is then specification of three particular circumstances but I do not read these as exclusive. They are I think matters which must be taken into account along with any other relevant considerations; *Wilkes*, paragraph 77. What may be relevant will depend on the circumstances. As Hickinbottom J makes clear what is required is a holistic approach; paragraph 78.

[115] There must of course be some limits to the inquiry that a court embarks on in assessing whether there is a defect in terms of section 3(1). But at this stage the court should be wary of prescribing what may or may not be relevant, along with the circumstances narrated in section 3(2)(a), (b) and (c). Indeed as is pointed out in *Wilkes* (paragraph 78) what may or may not be relevant has been the issue of some debate. What may be relevant can only be addressed after proof when the court can make a proper assessment of the particular factor and the weight to be given to it.

[116] It is not necessary for the pursuers to show the cause of the lack of safety. If the product is not as safe as persons generally are entitled to expect then there is a defect for the purposes of

the Act whether or not the cause of the lack of safety has been proved. It is an objective test but a relative concept.

[117] The unifying feature of these cases is said to be the use of polypropylene. All the pleadings include the following averments:

> "Polypropylene is not a suitable substance for a permanent prosthetic implant in the pelvic region because: (1) the pores are too small; (2) it is heavy weight mesh; (3) it degrades over time; (4) it causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, sharp edges, roping and curling of the mesh; (5) it deforms; (6) it is cytotoxic; and (7) the pores collapse with tension."

[118] In EN the pleadings continue:

> "Transvaginal implantation carries a high risk of infection because the vagina cannot be sterilised. Polypropylene mesh becomes so firmly incorporated into body tissue that it is impossible to remove totally in the event that it causes problems.
>
> A study by Iakovlev, Mekel and Blaivas of explanted polypropylene monofilament transvaginal slings received between 2010 and 2014 concluded that "all specimens showed chronic and foreign body inflammation (which is not seen in mature scar from non-mesh surgeries), nerve ingrowth and mesh degradation. The findings suggest mesh is not inert, but rather degrades and elicits a continuous immune response. The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms. Polypropylene degradation needs to be studied further for its role in inflammation, mesh hardening and late deformation as well for (sic) the properties of chemical degradation products. This preliminary analysis also suggests that edge curling of the tapes contributes to mucosal exposure."

Similar, though not as extensive, averments can be seen in the other cases. However, while polypropylene is the starting point and the defining feature of these products it is not necessary to show a causal link between the use of polypropylene and the damage; the causal link is between the defect and the damage. Nevertheless there are in my opinion sufficient averments of a causal link between the use of polypropylene and the alleged damage to allow the cases to proceed to a proof before answer.

[119] The defenders submit that in each case the link between the damage which is averred on record and the defect is not sufficiently established and that the pursuers, for the most part,

simply narrate all the problems which they have experienced since the operation without bringing home which particular problem is linked to the defect. At this stage I do not think that is an issue. In the first place section 2(1) of the Act provides that the damage may be caused wholly or partly by the defect. Accordingly the pursuers do not have to prove that all of the problems they have encountered are necessarily the result of a defect. Secondly it is a matter for proof as to what damage, if any, has been caused by the defect assuming that is established. I do not consider that the defenders have been prejudiced by not having greater specification on this point. In any event the defenders have, in each case, had the pursuer medically examined and will no doubt have a report on their condition.

[120] The manufacturers submit that the pursuers have not recognised that a product may have side effects or risks of complications yet still be safe. Yet it was unclear to me what exactly was expected of the pursuers. There is in any event a comparison between the products and other procedures. In YT for example the pursuer avers in Condescendence 22 that these products create risks to the health and safety of the patients that are far more significant and devastating as persons generally are entitled to expect.

[121] One of the prescribed circumstances is "the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product"; section 3(2)(a). Mr Currie submitted that would include the IFU's. I agree. He also submitted that the failure by the pursuers to make relevant pleadings about the IFU's meant that the pursuers' cases in AH and SR were irrelevant.

[122] There is a degree of confusion about the IFU's in the pleadings. In AH reference is made to the IFU issued by the manufacturers in the case against Dr Perera. It is said that the IFU listed the adverse reactions associated with Gynecare PROLIFT but failed to communicate

these to the pursuer. It does not appear as part of the case against the manufacturer. There is no reference to the IFU in the pursuer's pleadings in SR, YT or EN.

[123] I do not accept that failure to mention the IFU's or other marketing material in the pleadings is fatal to the pursuers' cases for the following reasons. In the first place it is the manufacturers who know how the products were marketed and it is primarily for them to put the marketing material at issue. It is they who have access to the material not the pursuers. In YT in Answer 6 Cousin Biotech call on the pursuer to produce copies of all the marketing material on which she relies. It is of course for the pursuer to plead her case but the days in which a defender could sit back and call on the pursuer to produce material which is in their hands have long gone, if they ever existed.

[124] Secondly, in any event the issue of warnings is contained in the pursuers' pleadings in all the actions. The general tenor is that they were inadequate. The manufacturers question whether these warnings, or lack of them, are part of the defect relied on by the pursuers. But their relevance in establishing whether there is a defect is clear from the terms of section 3(2)(a) as the manufactures have themselves pointed out.

[125] It is of relevance that there is a learned intermediary in the shape of the treating doctors. There is no relationship between the manufacturer and the pursuer. I do not accept however that the pursuers do not address that issue. The position of the doctors is central to their cases. Part of the complaint against the manufacturers is a lack of appropriate warnings to the clinicians. In any event the court in determining whether there is a defect will have to address the presence of the treating doctor in the chain. It is not however a complete or automatic defence; *Wilkes* paragraph 108. It is merely another, though possibly important, circumstance.

[126] Another circumstance is the time when the product was supplied by its producer (section 3(2)(c)). The manufacturers have pointed to the number of articles relied on by the

pursuers in the pleadings that postdate the supply of the product and submit that reference to these articles is irrelevant. It is unsatisfactory that the pursuers have simply made generic averments about articles that clearly postdate supply without further demonstrating their significance. However at this stage I am not satisfied that reference to articles that postdate supply are necessarily irrelevant if they are able to demonstrate a defect which existed at the time of supply.

[127] The pursuers do not have to demonstrate the manufacturers' state of knowledge. The manufacturers have available a defence under section 4(1)(e) in the following terms:

> "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 relevant time must be the time that the product was supplied. Accordingly the manufacturers have the ability to lead evidence about the state of knowledge at the time of the supply as a defence. I reject the argument that the ability to lead such a defence is impaired by the quality of the pursuers' pleadings. The manufacturers know the date of supply and the state of knowledge at the relevant time. It is open to them to lead such evidence should they so wish.

[128] I have addressed the issue of causation in respect of assumption of risk under reference to the common law case against the doctors. The same considerations apply to the cases against the manufacturers and I adopt the reasoning there; I consider that this is a matter for proof.

[129] The pursuers' pleadings are not without difficulty. In particular in only one case have the pursuers made reference to the IFU though it is clear that it is a central feature of the factual matrix which the court will have to deal with. However the IFU's are clearly within the

knowledge of the defenders and it is at this stage difficult to see how they would be prejudiced if appropriate amendments were made.

*General specification points*

[130] All of the manufacturers have taken individual points of specification in respect of the pleadings in the individual cases. In general I am happy to accede to Mr Currie's suggestion that these be dealt with at the By Order hearing. Nevertheless there are a number of common themes and it might be helpful if I give my general views on these matters.

[131] In AH and SR the defenders (Johnson & Johnson) submit that averments regarding other vaginal mesh products marketed by the defenders are irrelevant. The pursuers submit that it is important to consider this product in the context of what else was available on the market. The pursuer identifies the risks associated with polypropylene which are applicable to all pelvic mesh cases.

[132] This is a lead case in a mass litigation. For the purposes of these cases the only product at issue is the one which the pursuer had implanted into her. No doubt other cases will deal with other products and in the course of a proof with a representative sample these other products will be dealt with. Accordingly while the relevance to these cases is questionable it may arise in other cases.

[133] The pursuers plead that the pore size of the mesh is too small. The defenders complain that they are entitled to notice as to the relevance of this point. The pursuers point out that in the case of *Huskey* v *Ethicon Ltd* Dr Guelcher, who is the pursuer's expert in this case, gave evidence that minimising the amount of polypropylene could reduce the foreign body reaction. One way of doing that is to increase the pore size. I agree with the pursuers that sufficient notice has been given of the evidence and its relevance.

[134] The defenders submit that averments to the effect that the manufacturers marketed the products without designing a safe and effective procedure for removal are irrelevant. These averments are not apparently founded on for the purposes of any of the pursuer's cases based on section 3 of the 1987 Act. There are no averments that would enable any of the pursuers to prove a causal link between the alleged injury in respect of which she sues and the fact that the manufacturers marketed the product without designing a safe and effective procedure for removal.

[135] The pursuers respond that these averments are relevant insofar as they relate to factors to be considered under section 3 of the 1987 Act and that these matters require consideration only after evidence at proof in determining whether there is a defect taking in to account "*all the circumstances.*" *Wilkes* (para 60 and 61).

[136] I consider that the pursuers may have a point. I note that section 3 requires all the circumstances to be taken into account and it may be after proof that this is one such factor. I note that in AH, for example it is said that the removal of the mesh is the only treatment that has a chance of resolving any of the pursuer's symptoms (article 20).

[137] The manufacturers submit that averments to the effect that they failed to advise physicians how to "tension" the product properly are irrelevant. The pursuers further aver that the manufacturers failed to advise physicians that if the product is not properly tensioned the pore size of the mesh is decreased which interferes with incorporation into body tissue. These averments are not founded on for the purposes of the claims based on section 3 of the 1987 Act. There are no averments that would enable the pursuers to prove a causal link with any injury.

[138] The pursuers respond that the manufacturers are aware that there are no instructions provided on how to tension their product properly. It is submitted that these averments are relevant for the same reasons as the averments regarding the removal of the mesh.

[139] On this matter I consider that the submissions of the defenders are well founded. It is not sufficient to say that this is a matter that can be dealt with after proof. Although there are references to the condition of the mesh in some of the pursuers following the operation in no case is it suggested that any of the pursuer's problems are as a result of a failure by any of the treating doctors to properly tension the mesh product and that such a failure was due to inadequate instructions. I consider these averments irrelevant and will not allow them to go to probation.

[140] There is a general complaint that the pursuers make serious allegations which lack essential specification either by specific averment or supporting documents. An example given is that the manufacturers have known of serious risks and defects since at least 1998.

[141] I am not sure where the date of 1998 comes from. I note that in relation to the case of YT Mr Smith made a motion at the bar to delete a similar averment which I granted. Without further specification it looks irrelevant. I am not clear why it is still in place in the other cases. So far as the pursuers' averments that the products had serious risks and defects are concerned the pursuers maintain that this is a matter for proof. In my view this is hyperbole. The product either has a defect or it does not. If it does have a defect and a causal link can be established it matters not whether it is characterised as serious.

[142] The defenders contend that averments regarding "injuries, conditions and complications suffered due to Pelvic Mesh Products" are irrelevant, in failing to provide any connection between the particular product and any loss alleged to have been sustained by the individual pursuer. They submit that the averments "women [who] have undergone intensive medical treatment, including but not limited to operations to locate and remove mesh. Women have required operations to repair pelvic organs. They have suffered tissue and nerve

damage." are prejudicial and irrelevant. The pursuers do not aver that they have had to undergo any such treatment or suffered tissue and nerve damage.

[143] The pursuers respond that these general averments are illustrative and support the pursuers' contention that pelvic mesh products are not safe for permanent implantation and are defective. In any event, some of the pursuers aver that they have had to undergo surgery to remove some of the mesh product and may require further surgery.

[144] I am prepared to allow these averments to go to probation. Although the issue in the individual cases relates to one product the complaint that is made by the pursuers is that the use of polypropylene is inappropriate. That is common to all the pelvic mesh products which are the subject of these litigations. In determining whether or not this product has a defect the risk benefit of the product will be an issue; *Wilkes* paragraph 65. In that analysis the fact that other women using similar products made from the same material suffered injury may be relevant.

[145] Each of the pursuers aver that:

> "In 2015 Professor Carl Heneghan produced a fake report for Jet Schouten, a journalist with Dutch consumer television programme *Radar*, seeking approval for netting used as a surgical aid. The netting was that used to carry oranges, and it was approved"

The defenders submit that this is wholly irrelevant. The pursuers contend that this averment shows the weakness of the regulatory regime in the UK and Europe.

[146] In my opinion this averment is irrelevant. It invites a proof on the manner in which this fake report was carried out, what product it related to and what precisely it showed. It is frankly collateral to the central issue as to whether the product was defective. The fact that the product had a CE marking is a factor, but only a factor, to be taken into account. It is not an automatic defence; *Wilkes* paragraph 101.

[147] I shall deal with any other points of specification that I may have missed or arise out this opinion at the By Order hearing.

**Chapter 5: Time bar**

[148] All the defenders, both doctors and manufacturers, have taken time bar pleas. All except Mr Ellis who appeared for Astoria Women's Health LLC in the EN case argued these pleas at procedure roll. Mr Ellis reserved his plea.

[149] The pursuers resist these pleas but submit that even if the triennium has expired it would be equitable for the court to allow the actions to proceed, in the actions against the doctors in terms of section 19A of the Prescription and Limitation (Scotland) Act 1973, and in the actions against the manufacturers in terms of section 22B(6) of that Act.

***Factual background***

*AH*

[150] The defenders aver that the action is time barred. They aver that by October or November 2009 at the latest (when the pursuer had an operation for the excision of the mesh) the pursuer had the requisite knowledge and knew that the injuries were serious enough to justify bringing an action for damages. The action was raised in about February 2014. The pursuer says that she first made the connection between her symptoms and the vaginal mesh when she read an article concerning the use of mesh or tape in the Sunday Mail in March 2013. She says that at no time prior to that date was she informed that her symptoms could be related to the product implanted in the operation.

*SR*

[151] The action in this case was raised in February 2015. The second defenders (the Health Board) aver in answer 23 that she should have been aware by, at the latest 1 June 2010 when she underwent the first excision procedure of the required facts. The pursuer says that she had no reason to believe that the symptoms were in consequence of the mesh implant prior to reading an article online in the Huffington Post, dated 11 March 2014. Up until then she had been consistently advised by her treating doctors that her symptoms were not attributable to the mesh implant and that her difficulties were psychological.

*YT*

[152] The action was raised in about July 2014. The defenders aver that the pursuer had the requisite knowledge shortly after having the surgery. The pursuer says that she did not appreciate that it was the mesh that was the cause of her difficulties until the surgery to partially remove the mesh on 11 May 2014. Up until then she had been repeatedly assured that the problems were not related to the mesh implant.

*EN*

[153] The summons in this action was served on 7 May 2014. The defenders aver that the action is time barred. EN says that she was not aware that she may have a cause of action until she read an article in a newspaper concerning the use of mesh and tape at the end of March 2013. She was advised by doctors that her symptoms were as a result of irritable bowel syndrome.

***Statutory background***

[154] Section 17 of the 1973 Act is in the following terms:

"(1) This section applies to an action of damages where the damages claimed consist of or include damages in respect of personal injuries, being an action (other than an action to which section 18 of this Act applies) brought by the person who sustained the injuries or any other person.

(2) Subject to subsection (3) below and section 19A of this Act, no action to which this section applies shall be brought unless it is commenced within a period of 3 years after—

(a) the date on which the injuries were sustained or, where the act or omission to which the injuries were attributable was a continuing one, that date or the date on which the act or omission ceased, whichever is the later; or

(b) the date (if later than any date mentioned in paragraph (a) above) on which the pursuer in the action became, or on which, in the opinion of the court, it would have been reasonably practicable for him in all the circumstances to become, aware of all the following facts—

(i) that the injuries in question were sufficiently serious to justify his bringing an action of damages on the assumption that the person against whom the action was brought did not dispute liability and was able to satisfy a decree;

(ii) that the injuries were attributable in whole or in part to an act or omission; and

(iii) that the defender was a person to whose act or omission the injuries were attributable in whole or in part or the employer or principal of such a person.

Section 19A (1)

(1) Where a person would be entitled, but for any of the provisions of section 17 , 18 , 18A or 18B of this Act, to bring an action, the court may, if it seems to it equitable to do so, allow him to bring the action notwithstanding that provision.

Section 22B

(1) This section shall apply to an action to enforce an obligation arising from liability under section 2 of the 1987 Act (to make reparation for damage caused wholly or partly by a defect in a product), except where section 22C of this Act applies.

(2) Subject to subsection (4) below, an action to which this section applies shall not be competent unless it is commenced within the period of 3 years after the earliest date on which the person seeking to bring (or a person who could at an earlier date have brought) the action was aware, or on which, in the opinion of the court, it was reasonably practicable for him in all the circumstances to become aware, of all the facts mentioned in subsection (3) below.

(3) The facts referred to in subsection (2) above are—

(a) that there was a defect in a product;

(b) that the damage was caused or partly caused by the defect;

(c) that the damage was sufficiently serious to justify the pursuer (or other person referred to in subsection (2) above) in bringing an action to which this section applies on the assumption that the defender did not dispute liability and was able to satisfy a decree;

(d) that the defender was a person liable for the damage under the said section 2.

(4) In the computation of the period of 3 years mentioned in subsection (2) above, there shall be disregarded any period during which the person seeking to bring the action was under legal disability by reason of nonage or unsoundness of mind.

(5) The facts mentioned in subsection (3) above do not include knowledge of whether particular facts and circumstances would or would not, as a matter of law, result in liability for damage under the said section 2.

(6) Where a person would be entitled, but for this section, to bring an action for reparation other than one in which the damages claimed are confined to damages for loss of or damage to property, the court may, if it seems to it equitable to do so, allow him to bring the action notwithstanding this section."

***Submissions for the parties***

*Submissions for the defenders*

[155] Mr Primrose began his submissions by referring to the policy behind limitation statutes. This is discussed comprehensively by Lord Drummond Young in *B* v *Murray (*No 2) 2005 SLT citing the judgement delivered by McHugh J in the High Court of Australia; *Brisbane South Regional Health Authority* v *Taylor* 186 CLR 541. As time goes by evidence is likely to be lost. The loss of evidence may be an actual loss, for example where a crucial witness dies or a

document is lost or it may be a decline in the quality of evidence available. The limitation period should not be seen as an arbitrary cut off point unrelated to the demands of justice or the general welfare of society. It represents rather the considered judgement of the legislature that the welfare of society is best served if causes of action are litigated within the specified time period, even if in consequence good causes of action may be defeated. It must accordingly be regarded as the general rule and the extension provision as an exception designed to deal with the justice of individual cases. Two important conclusions flow from this analysis: (a) the onus is on the prospective pursuer to establish that his or her case requires an extension and (b) in determining whether an extension should be granted, the court must evaluate the injustice or prejudice that either side may suffer by a reference to the rationales which underlie the limitation statute. An extension period, such as section 19A of the 1973 Act, reimposes a liability that the defender would otherwise have escaped. Because of that it is not material that the prejudice suffered by the defender is no worse than would have been the case had the action been raised towards the end of the limitation period. If a defender can show actual prejudice in defending the action or the real possibility of significant prejudice, it will normally not be appropriate to grant an extension.

[156] Fundamentally the pursuers' cases against the doctors are founded on an alleged failure to properly convey adequate information prior to their operations. In each case the pursuer contends that, had it been, she would not have agreed to the surgery proceeding as it did and that she would not have suffered the losses condescended upon. It is inherent in each of the cases that the breach of duty that is complained of is more than three years before the action was raised.

[157] In determining whether the action is barred by the passage of time three questions arise. First, when did the pursuer suffer the loss she now complains of? The answer to that question

will identify the presumptive start date of the triennium. Secondly, was the action commenced within the triennium? Thirdly, if not, is it equitable to relieve the pursuer of the consequences of limitation?

[158] The *injuria* was the failure to provide the proper information during the consent process. The *damnum* was the materialisation of the risks that it is said should have been warned of but, of which, she was not warned. There are two possible starting dates for the triennium: The date on which the injuries were sustained (section 17(2)(a)) or the date on which the pursuer became aware or on which it would have become reasonably practicable for her in all the circumstances to be aware of the following facts enumerated in section 17(2(b). Mr Primrose submitted that for the purposes of section 17(2)(b), knowledge that any act or omission was or was not, as a matter of law, actionable, is irrelevant section 22(3) of the 1973 Act; Johnston, *Prescription and Limitation* 2nd ed, paragraphs 10.36 – 10.37 and *McIntyre* v *Armitage Shanks* 1980 SC (HL) 46. Lack of awareness of actionability does not delay the start of the triennium. Whether an injury is sufficiently serious to justify raising proceedings is judged objectively: *CG* v *Glasgow City Council* [2011] SC 1 at paragraphs 18 and 21. Injuries which are not *de minimis* are sufficiently serious to justify bringing proceedings; *Mackie* v *Currie* 1991 SLT 407 at 409. The expression "attributable to" in section 17(2)(b)(ii) does not mean "caused by". Nor does it imply that before time starts to run the pursuer must have actual or constructive knowledge that the injuries are in fact attributable to the defenders' acts or omissions. It is enough that he has knowledge that they are capable of being attributed to them; Johnston, *Prescription and Limitation* at paragraph 10.57. In *Haward* v *Fawcetts (a firm)* [2006] 1 WLR 682 the House of Lords explained that the knowledge necessary in this context is knowledge in broad terms of the facts on which the claimant's complaint is based, of the defendant's acts or omissions, and that there is a real possibility that those acts or omissions were a cause of the claimant's loss

(see paragraph 90). The threshold of awareness is relatively modest. This is because the point of section 7(2)(b) is simply to fix the starting date for the limitation period, after which the pursuer has three years to carry out the necessary investigations; Johnston, *Prescription and Limitation* paragraph 10-24. The pursuer need not have knowledge of details that would be necessary to raise an action; *Murray* v *National Association of Round Tables* 2002 SLT 204 at paragraph 13. Where the pursuer has knowledge of the facts the question is whether that knowledge is sufficiently firm to make it reasonable for her to investigate whether there is a case against the defender, see: Johnston, paragraph 10-25. Reasonable practicability is not to be confused with reasonable excuse; *M* v *O'Neil* 2006 SLT 823 per Lord Glennie at paragraph 36; *Agnew* v *Scott Lithgow (No. 2)* 2003 SC 448. The pursuer's personal characteristics (eg embarrassment, reluctance or unwillingness to take action) are irrelevant; the question is objective and concerns the practicality of finding out. The pursuer's losses cannot be separated out so as to postpone the commencement of the triennium for particular injuries; *Aitchison* v *Glasgow City Council* 2010 SC 411 at paragraphs 34 to 41. The proper approach to constructive awareness is to consider the matter in three stages. First, what did the pursuer actually know? This is subjective. Secondly, what other facts would it have been reasonably practicable for her to know? Thirdly, taken together, did she know enough to investigate whether she had a claim against the defender? Mr Primrose referred to *A* v *Hoare* [2008] 1 AC 844 at paragraph 34. The salient question was formulated by Lord Glennie in *M* v *O'Neil* at paragraph 57 as follows:

> "The question to be asked is whether at some time more than three years before proceedings were commenced….the pursuer was aware of the statutory facts, or, if not, whether it was reasonably practicable for the pursuer to have become aware of those facts by that time"

[159] Mr Stephenson adopted the submissions made by Mr Primrose in respect of the case against Dr Milne.

[160] The note of argument for Johnson & Johnson submitted that absent specification of the alleged defect in the products, it is impossible to interrogate whether the pursuer can relevantly invoke the saving provisions on actions for personal injuries in section 17(2)(b) or section 22B(3) of the 1973 Act. Recital of the statutory facts does not relevantly invoke either section 17(2)(b) or section 22B(3). The pursuers in both AH and SR aver that they were not aware that the product was the cause of their symptoms and that they had a cause in action until they had each read a newspaper article. However, neither section 17(2)(b) nor section 22B(3) requires actual awareness. The test is whether the pursuer was aware or it was reasonably practicable for her to have become aware of the statutory facts, not of actionability. Indeed the Act specifies that awareness of actionability is irrelevant (sections 22(3) and 22B(5)). The pursuers require to aver why they could not, with reasonable practicality, have been aware of the statutory facts. In both cases the pursuer must have known that there was a real possibility that her injuries had been caused by the product; *Haward* v *Fawcetts (a firm)* at paragraph 90; *Nash* v *Eli Lilly & Co* [1993] 1 WLR 782).

[161] Ms Haldane adopted Mr Primrose's submissions in respect of sections 17 and 19A of the 1973 Act and Mr Currie's submissions on section 22B.

*Pursuers' response*

[162] The purpose of limitation is primarily to prevent stale claims. There are obvious policy reasons for such a rule, most importantly to avoid prejudice to defenders in investigating claims; *AS* v *Poor Sisters of Nazareth* 2008 SC(HL) 146 at paragraph 25. Where, however, the defenders are already investigating events for a whole series of other claims raising the same issues then that prejudice disappears. This consideration is most obviously relevant to the exercise of the court's discretion in terms of section 19A but it also impacts on the operation of

section 17 of the Prescription and Limitation (Scotland) Act 1973. The questions of what could have been known when and by whom are inextricably bound up with the merits of these claims. It is not possible for the court to say at this stage that it was reasonably practicable for the pursuers to know the necessary facts to raise a claim more than three years before the actions were raised. The date of actual knowledge is important and more readily ascertainable but the date of constructive knowledge is far more nebulous. The reality of the situation is that no solicitor in Scotland would have taken on the claims at an earlier date. The defenders – both manufacturers and doctors – have continued to maintain that there was nothing wrong with the product and it is difficult to ascertain at what stage any reasonable person would have felt able to seek legal advice in contradiction of that advice. Accordingly the pursuers submit that in all four cases the timebar pleas should be reserved at this stage. Applying the strict test of relevancy, it cannot be said that the pursuers will fail in their pleas if all of their averments are upheld.

[163] Mr Milligan submitted that a general feature of the pleadings was that the treating doctors, far from making the link between the pelvic mesh product and the injury suffered by the pursuers, specifically denied that such a link existed. In that event it could not be said that the pursuers had the relevant knowledge. In his submission the date on which the pursuers had the relevant knowledge was the date on which they became aware of the facts through the media. Knowledge involved a degree of certainty. For these purposes it was that which a particular pursuer would regard as sufficient to justify embarking upon the preliminaries to the making of a claim for compensation, such as taking legal advice. That would depend on the nature of the information received, the extent to which the pursuer paid attention to it and her capacity to understand it; *Nash* v *Eli Lilly & Co,* at p 792. These were subjective matters which could not be assessed on the pleadings alone. This was particularly true in the context of a case

where the background information is particularly confusing and conflicting. The position of the defenders amounted to one where every operation that did not go to plan would potentially give rise to a medical negligence claim. That was absurd. The claim against the manufacturers could not be progressed without expert advice. Until that was available there could not be a claim; *Nash*, p 799. Merely because the mesh had been excised did not mean that those pursuers would be put on notice that there was a defect in the product.

[164] Turning to section 19A Mr Milligan submitted that the claim against the manufacturers was a strong one given the success rate in the United States. That was a relevant factor; *Nash* pp 804 and 808. So too was the fact that the manufacturers had defended claims in the United States. They could not be said to be prejudiced; *Nash* p 805.

***Discussion of the applicable law - sections 17 and 22B***

[165] The pursuers have withdrawn the common law case against the manufacturers. Accordingly the cases against the doctors and the manufacturers require to be considered under different provisions of the 1973 Act. That said the approach should be consistent. So for example the significance of the injury to the pursuer should not depend on whether or not the case falls to be dealt with under section 17(2)(b)(i) or section 22B(3)(c).

[166] The defenders approach the position of the significance of the injury as an objective one citing the opinion of the court delivered by Lord Eassie in *CG* v *Glasgow City Council* in which the Extra Division affirmed the decision of the First Division in *AS* v *Poor Sisters of Nazareth*. Paragraph 26 of AS is in the following terms:

> "Whether the likely amount of damages would justify taking proceedings no doubt involves some element of judgment, particularly in marginal cases…It will also be the case that, as was observed in Carnegie v Lord Advocate (per Lord Johnston, p 812, para 16), some subjective, or perhaps more properly, individual personal features may enter into the assessment of quantum in that, by way of further exemplification of the

> instances mentioned by Lord Johnston, injury to a finger may be of much greater consequence to a concert pianist than to someone whose work and hobbies do not involve fine finger movements. But subject to those observations we consider that the statute can only be construed as intending sub-head (i) to be concerned with quantum, an objective assessment having to be made whether the gravity of the injury to the pursuer in question was such that it would have justified proceedings on the statutory assumptions of undisputed liability and a solvent defender. The sub-head is concerned with a single fact, namely the severity of the injury in so far as the pursuer was aware of it or could reasonably practicably have become aware of it."

The Extra Division in *CG* noted that this approach was consistent to the position in England under reference to the speech of Lord Hoffman in the House of Lords in *A* v *Hoare* at paragraph 34:

> "I respectfully think that the notion of the test being partly objective and partly subjective is somewhat confusing. Section 14(2) is a test for what counts as a significant injury. The material to which that test applies is generally subjective in the sense that it is applied to what the claimant knows of his injury rather than the injury as it actually was. Even then, his knowledge may have to be supplemented with imputed objective knowledge under section 14(3). But the test itself is an entirely impersonal standard: not whether the claimant himself would have considered the injury sufficiently serious to justify proceedings but whether he would reasonably have done so. You ask what the claimant knew about the injury he had suffered, you add any knowledge about the injury which may be imputed to him under section 14(3) and you then ask whether a reasonable person with that knowledge would have considered the injury sufficiently serious to justify his instituting proceedings for damages against a defendant who did not dispute liability and was able to satisfy a judgment."

[167] Mr Milligan relies on the English Court of Appeal case of *Nash* v *Eli Lilly* to argue that the test is a subjective one citing the passage at page 792:

> "whether or not a state of mind for this purpose is properly to be treated as knowledge seems to us to depend, in the first place, upon the nature of the information which the plaintiff has received, the extent to which he pays attention to the information as affecting him, and his capacity to understand it."

He submits that there are parallels between *Nash* and this case. In *Nash* v *Eli Lilly* the court was concerned with claims against a drug company arising from the use by the claimants of the drug Opren. The court noted that the provisions of section 14(3) of the Limitation Act 1980 were particularly relevant to the individual plaintiff's appreciation of his or her own condition

in relation to the question as to whether the effects from which he was suffering were acceptable side effects which can be expected from the use of any toxic drug or whether they have reached the intensity and persistence to be recognised as unacceptable and therefore significant injury; Purchas LJ at 799, 800.

[168] While this argument may be attractive it does not accord with the approach in Scotland. Nor is it consistent with the later English cases of *A* v *Hoare* and *B* v *Ministry of Defence* [2013] 1 AC 78 (a case not cited to me). In *B* v *Ministry of Defence* Lord Walker of Gestingthorpe, giving one of the majority judgements noted that there was a decisive shift away from the subjective approach. He said the notion "whether a claimant has knowledge depends both upon the information he has received and upon what he makes of it" expressed in *Nash* could no longer be accepted, at any rate without a lot qualification. The policy was for the date of knowledge to be ascertained in the same way for all claimants, without regard to their personal characteristics, which can be taken into account at the later stage of exercising discretion under section 33 of the 1980 Act; (paragraph 47).

[169] Accordingly the submissions of the defenders are to be preferred. Whether an injury is sufficiently serious to justify bringing an action of damages is an objective test whether one is looking at section 17(2)(b) or 22B(3).

[170] Turning to section 17(2)(b)(i) whether the injuries are attributable to an act or omission will depend on the facts. Where there is a medical procedure it might naturally be expected that one would experience pain and discomfort perhaps for some time after the event. The extent of such pain and discomfort may also differ from one patient to another. In these cases however the pursuers avers pain, discomfort and other symptoms which clearly go beyond the normal. More importantly they go beyond what they had been told by the treating doctors that they could expect to follow on the particular operation. Accordingly, if the injury is sufficiently

serious to justify the raising of an action then it should be reasonably practicable for the pursuer to be aware that the injury was attributable in whole or in part to an act or omission. At the very least the pursuer is put on notice that something is wrong and that there is a disconnect between what she has been told to expect and what has actually occurred. Accordingly I consider that *prima facie* an act or omission as defined in section 17(2)(b) may be discerned from looking at the difference between what the pursuer avers she was told about the risks and those symptoms which she says materialised. If there is a material difference then it ought to be reasonably practicable for the pursuer to appreciate that the injuries were attributable in whole or in part to an act or omission. It is not necessary for the pursuer to know precisely what that act or omission was. But it does form the starting point for the pursuer to make such investigations as may be required to bring an action of damages. Of course the pursuer may set out reasons why it was not practicable to be aware that the injuries were attributable to such an act or omission. However in an action against a doctor for a breach of duty in failing to advise of the risks associated with an operation it is not sufficient for her to say that she was never told by the doctors that the injuries could be attributable to the mesh product. That is not the issue. Something more is required. Liability for negligent advice does not depend on a defect in the product. There may be no defect but a doctor may fail in his duty to give advice because he failed to warn the patient of risks that he knew or should have known about. That is an important observation because the pursuers in all but one of the cases aver that they were not aware that their symptoms were associated with the mesh product until they read about it in a newspaper or online. Again the pursuers conflate the cases against the doctors with those against the manufacturer.

[171] Given that the name of the treating doctor was known to the pursuer in each case there can be no issue about attributing the act or omission to the particular defender in each case.

***Application of section 17 to individual cases***

*AH*

[172] The operation took place on 19 February 2009. The pursuer avers that after the operation, she experienced pelvic pain. She had a vaginal discharge. On 3 September, 2009, she was reviewed and put on a waiting list for removal of protruding vaginal mesh. Excision of the protruding mesh took place on 27 November, 2009, with release of the left arm of the mesh at the obturator foramen ("the excision operation"). Following the excision operation, she continued and continues to experience pelvic pain and vaginal discharge. Her prolapse has recurred.

[173] On these averments it is clear that the pursuer had sustained the injury no later than September 2009, when she was placed on the waiting list for the excision operation. That is the presumptive start of the triennium. The issue then is whether the factors listed in section 17(2)(b) of the 1973 Act can postpone the date to March 2013 when the pursuer read the article in the Sunday Mail. The onus is on the pursuer.

[174] The pursuer's engagement with the provisions of section 17(2)(b) is essentially formulaic. In relation to (2)(b)(i) the pursuer avers that it was not reasonably practicable for her to be aware "(d) that the damage was sufficiently serious to justify the pursuer in bringing an action…" It is difficult to understand that averment given that the damage that the pursuer was aware of in September 2009 is essentially the injuries for which she seeks compensation. Without further explanation it is irrelevant.

[175] Turning to (2)(b)(ii) the pursuer's position is that:

> "prior to undergoing the excision operation, Dr Perera advised the pursuer that he was going to loosen the tape because it was too tight and pulling her groin. She understood this to mean that the sling was too tight and needed to be loosened. There was no

> discussion about mesh erosion. Dr Perera did not inform her that the mesh product implanted in the operation had eroded. Accordingly, at the time that she underwent the excision operation she did not understand that the product implanted in the operation could be the cause of her symptoms. At no time since her operation in February 2009 was the pursuer informed that her symptoms could be related to the product implanted in the operation. The pursuer first made the connection between her symptoms and the implanted mesh product when she read an article concerning the use of mesh a tape in the Sunday Mail on or about March 2013."

[176] The first defender's answers detail interactions between the GP and the pursuer which appear to show an awareness by the pursuer that mesh was protruding into her vagina. If this is so then it is difficult to understand how she could come to the view that the operation was to "loosen the tape". Nevertheless the pursuer's position on record is that her awareness at the time of the second operation was limited as she describes.

[177] Whatever the pursuer's awareness what is beyond doubt is that she was suffering from pain and vaginal discharge serious enough to require corrective surgery. It cannot be suggested that this was not related to the mesh. Furthermore it was not something that she could have been expected to follow from the mesh implant given the advice that she was given on the risks associated with the operation. Indeed the problems went far beyond what she was told were the risks associated with the product.

[178] For these reasons I am satisfied that the case against the first defender is time barred in terms of section 17 of the 1973 Act.

*SR*

[179] The surgery took place on 15 October 2009. The action was raised in February 2015. The pursuer underwent the first corrective procedure to excise protruding mesh on 1 June 2010. A second corrective procedure followed on 11 August 2010. It is clear that the pursuer experienced pain and complications which went beyond what she could have expected given

what she says she was told about the risks associated with the operation. The pursuer has not engaged with the averments of the second defenders on time bar set out in answer 23. (There is however a passing reference to section 19A in condescendence 24.) Accordingly it is clear on the pursuer's own averments that it was reasonably practicable for her to become aware of the facts required in section 17(2)(b) by June 2010. That is the presumptive start of the triennium. There is nothing in the pursuer's averments that would postpone that date to a later time.

[180] I am satisfied that on the averments the case against the second defender is time barred in terms of section 17 of the 1973 Act.

*YT*

[181] The surgery took place on 23 September 2008. The summons was served on 30 July 2014. The second defender (Dr Milne) avers that she should have been aware of the necessary facts shortly after her surgery in 2008. The pursuer's position is that she was not aware that the mesh was the cause of her difficulties until the mesh was excised on 12 May 2014. In answer to the second defender's answer, she avers, at condescendence 24:

> "As the pursuer was not aware that her pain and discomfort were related to the mesh inserted during her SUI surgery she was similarly unaware that the consent process she had undergone with the second defender was negligent in that he had failed to advise the pursuer of the risks associated with TVT mesh and available alternative treatments as hereinbefore condescended upon. It was therefore not reasonably practicable for the pursuer to be aware that (a) the consent process she had undergone with the second defender was inadequate and negligent; (b) that the damage she had suffered was caused by a surgical process which she not been correctly consented for…."

[182] On the pursuer's pleadings it appears that apart from the pain and time off work immediately after the operation she was problem free until about 2011/2012 when the SUI returned. It was in 2013 that she began to experience further pain and other distressing symptoms. Mr Stephenson submitted that the excruciating pain that she experienced after she

came round from the operation, and which caused her to pass out, went beyond what could have been expected from a normal operation. Equally it would be unexpected for a person undergoing such an operation to be off work for a week or so after. Accordingly he submitted that it was reasonably practicable for her to become aware shortly after the operation of the necessary facts.

[183] Mr Stephenson may well be right. But in this case I am not convinced that the issue is quite as clear cut as it is in the other cases. The pain that the pursuer experienced on coming round from the operation was transitory in the sense that it eventually passed and she was pain free for a number of years. I do not think that I can say on the pleadings either that this pain or time off work was of such a nature that the court can be satisfied that it was reasonably practicable for the pursuer to be aware that the injuries were attributable in whole or in part to an act or omission.

[184] There may also be an argument that even if the immediate aftermath of the operation might have prompted questions in the pursuer's mind about whether there was a sufficiently serious injury the subsequent resolution of the problem, until they came back sometime between 2011 and 2013 has the effect of postponing the start date. At this stage I express no view on that issue.

[185] For these reasons I am not satisfied that I can sustain a plea of time bar in respect of the second defender at this stage. The issue should be resolved after proof.

*EN*

[186] The summons was served in this action on 7 May 2014. The operation was on 24 June 2007. The relevant averments of fact can be found in condescendence 2 as follows:

> "Following the operation, the pursuer suffered from pain in her hips, legs, back, abdomen, pelvis and vagina and down the lower right side of her body. She suffered from a sensation of painful pulsing and pressure inside her vagina. Her incontinence initially abated. The pain gradually began to subside. On or about June 2009, the pursuer began to suffer from faecal incontinence and urgency. Around this time, her symptoms of stress urinary incontinence had begun to gradually return. The pursuer developed urinary urge incontinence and detrusor instability. The pursuer's symptoms of pain had also begun to gradually return. Following the surgery, the pursuer suffered from difficulty in voiding her bladder. She required to strain to void her bladder. She suffered from incomplete emptying of her bladder. She suffered from frequent urinary tract infections. She required antibiotics. She developed from kidney stones. The pursuer was advised by her treating Doctors that the problem with her bowel and faecal incontinence was attributable to irritable bowel syndrome."

Subsequently an ultrasound scan report of 23 May 2011 showed a smaller right kidney with some upper pole cyst. On review in February 2012 her abdomen was soft with some mild tenderness in the right loin. She has been advised to remain on prophylactic antibiotic long term.

[187] It should be noted that on the pursuer's averments she had been advised that it was possible that the product once implanted might not be successful in alleviating her symptoms of SUI. However she says that she was not told of the other risks including chronic pain and *de novo* urinary incontinence. The question in this case is whether on the pleadings it is possible to conclude that it was not reasonably practicable for her to have become aware that the injuries, which were serious, were attributable in whole or in part to an act or omission?

[188] I am not satisfied that it is possible to come to that conclusion on the pleadings. So far as the problems that occurred after June 2009 are concerned it may not have been apparent that these were related to an act or omission rather than to natural causes. This view was reinforced by the suggestion from the doctors that the faecal incontinence was caused by irritable bowel syndrome. Immediately after the operation the pursuer did suffer from a range of symptoms which on the face of it were not expected on the basis of the advice that she had been given. But it is not entirely clear what the extent of these symptoms were and how long they lasted.

They clearly subsided as did the SUI. To that extent at least the pursuer may have been reassured that the operation was working. In contrast to the position in AH and SR the symptoms were not immediately attributable to problems with the mesh. She did not require to undergo any excision of the mesh. Some allowance should be given for the fact that there is always likely to be a degree of pain and discomfort associated with an operation and the extent of such post operational symptoms may differ from one person to another.

[189] Accordingly I have concluded that I cannot at this stage sustain a plea of time bar. It should be held over to after proof.

***Section 22B***

[190] There are four factors to be addressed under section 22B(3). As I have indicated the approach to 3(c) will be the same in both cases. I do not consider that there is an issue with regard to (3)(d). Once the other factors are in place I think it should be reasonably practicable to be aware of the identity of the defenders. The central issue in each case is when did the pursuer become aware or when was it reasonably practicable for her to become aware that there was a defect in the product? Unlike the case against the doctors where there was a clear mismatch between what the doctors said to each of the pursuers and what subsequently transpired, the fact that there was a defect in the product is less obvious. It is potentially masked by the fact that the product is one used by an apparently experienced and competent clinician. The products were approved for medical use. The doctors in each case told the pursuer that their problems were not attributable to the product and gave a variety of explanations. While it might be reasonably practicable for a pursuer to question the advice they got or the treatment they received finding out that there is a defect in the product, particularly

since it is now inside the body, is more difficult. Even if one embarks on an investigation it requires technical skill and expertise.

[191] In this case it is clear that concern about these products has built up gradually over the years. I am aware that there has been significant media interest welling over into the political sphere. Against that background it seems to me to be quite a leap to say that it would have been reasonably practicable shortly after the operation in each case for the pursuer to become aware that there was defect in the product. I cannot reach that conclusion in respect of any of the cases on a procedure roll debate.

[192] In the course of the debate I expressed the view that the time bar issue should be resolved in a preliminary proof. On further consideration it appears to me that the issues in respect of section 22B might only be resolved after a full proof. I invite further submissions on this point.

**Discussion of the applicable law: section 19A and section 22B(6)**

[193] The same principles apply to section 22B(6) as apply to section 19A. The following comments refer to both sections. The effect of section 19A is to reinstate a liability that has otherwise expired. It is a discretionary remedy to avoid injustice. The provisions of section 19A were considered in some detail by Lord Drummond Young in *B* v *Murray (no 2).* He analysed the authorities and drew heavily on the judgement of McHugh J in the High Court of Australia in *Brisbane Regional Authority* v *Taylor*. I do not consider it necessary for me to engage in a similar exercise.

[194] At paragraph 21 His Lordship sets out McHugh J's discussion of limitation statutes generally. He notes four broad rationales for the enactment of limitation periods. First, as time goes by evidence is likely to be lost. Second it is oppressive to a defendant to allow an action to

be brought long after the circumstances that give rise to it have passed. Third, people should be able to arrange their affairs and utilise their resources on the basis that claims can no longer be made against them. Even where the cause of action relates to personal injuries it will often be just as unfair to make the shareholders or taxpayers of today ultimately responsible for the wrongs of the distant past. Fourth the public interest requires that disputes be settled as quickly as possible.

[195] The principles which are pertinent to these cases are as follows. First, in multiple claims of this sort the court must exercise its discretion separately in relation to each claim; *B* v *Murray*, paragraph 33; *Nash* v *Eli Lilly*, per Purchas LJ 809 – 810. Second, the limitation period should be seen as the general rule. Accordingly the onus is on the pursuer to demonstrate that an extension should be granted; *B* v *Murray*, paragraph 25. Third, the question for the court is to evaluate the prejudice that may be caused to either party by either a grant or a refusal of an extension; paragraph 25. Another way of putting this may be to ask where the equities lie; paragraph 29 quoting *Forsyth* v *A F Stoddard & Co Ltd* 1985 SLT 51, per Lord Justice Clerk at p 55. Fourth, if a defender can show actual prejudice or the real possibility of significant prejudice it will not normally be appropriate to grant an extension; paragraph 27. Fifth, the conduct of the pursuer, and by extension her solicitor, since becoming aware of the circumstances giving rise to the action are factors to be taken into account by the court; paragraph 29. Sixth, in general ignorance of the legal right to claim damages is not to be taken into account; see the discussion in paragraph 30.

[196] The pursuers assert that the cases against both the doctors and the manufacturers are strong cases. Mr Milligan submitted that this was a relevant factor relying on *Nash* v *Eli Lilly* at pages 804 and 808. In summary what Purchas LJ says at page 808 is that a defendant should not be put to the trouble and expense of having to defend a poor claim with a low value which

would reflect as much or more the risk in costs as the fair value of the claim. That is a different to saying that it is a relevant factor that it is a strong case. In any event the pursuers in their pleadings make no distinction between the position of the doctors and the manufacturers. The case against the doctors is fact sensitive depending crucially on what may or may not have been said many years ago. In those circumstances I cannot see how a court can begin to establish that a claim against a doctor is a strong case. In oral submissions Mr Milligan made no attempt to persuade me that any of the claims against a doctor was a strong one having regard to the averments on record.

[197] A claimant has been successful in a jury trial in the United States against a manufacturer, Ethicon Ltd who are part of the Johnson & Johnson group of companies; *Huskey* v *Ethicon Ltd*. There is a reasoned judgement following on from the trial which will no doubt give comfort to the pursuers in these actions. I am nevertheless reluctant to conclude on the basis of that one action that there is a strong case against the manufacturers. For one thing the statutory basis is different. What may be of relevance is the fact that there are other actions against manufacturers in other jurisdictions. In a question of prejudice it may be significant that the same issues have been or are being investigated in other jurisdictions, though that may not apply to the third defenders in YT (Cousin Biotech). Nor does it apply to the doctors.

***Application of sections 19A and 22B(6)***

[198] It is convenient to deal with all of the section 19A issues that arise in the cases against the doctors together since the averments in each are much the same and there are common themes. With the exception of AH, the pursuer in each case deals with the issues under section 19A and 22B(6) together. That is inappropriate since the issues are different.

[199] All of the pursuers aver that the action is one of many raised against the defenders involving the same issues. In doing so, with the exception of AH there is no attempt to distinguish between the defenders. Thus in YT the second defender, Dr Milne responds that this is the only case in which he is a defender. All of the pursuers aver that the defenders will have to investigate all of these issues in any event. Again, that is not true of the second defender in YT. Nor does it take into account the realities of the case against the doctors. Accordingly while in AH, SR and EN the individual health boards are convened as defenders that is because they have vicarious responsibility for their employees. Each case will have to be separately investigated by these defenders.

[200] All of the pursuers aver that their medical conditions are well documented in the medical records. That is admitted in at least one case (YT). I have not examined the medical records but it does appear that the doctors have been able to make fairly full averments about the meetings they had with the pursuers in each case and the advice that they gave. I assume that this comes from the records. However in AH and EN the doctors point out that the pursuer does not accept the accuracy of the records (at least so far as consent is concerned). In EN it is averred that the pursuer has symptoms that she has never reported.

[201] In YT it is specifically averred that there are no issues that turn on individual recollections of events in relation to the claim against the second defender. There is a similar averment in relation to the doctors in EN. That is clearly incorrect and demonstrates a failure to appreciate the nature of the case against the individual doctors.

[202] As I indicated each of the pursuers avers that they have a strong case against the doctors. Having regard to the fact that there is in each case a very substantial dispute of fact I cannot accept that assertion. Each pursuer submits that in the event of the action being dismissed there is no reasonable prospect of success against their solicitor. In some of the cases

there is some explanation given for what the defenders submit are delays in consulting a solicitor and raising the action.

[203] I have considered what I should do in respect of the section 19A part of these claims. I gave consideration as to whether I should order a preliminary proof but in general I am not persuaded that is necessary or desirable. On the whole the pursuers' averments are sparse. Where there is a positive assertion of fact eg the account of the events prior to the raising of the action it may be that these matters can either be agreed or that the court proceed on the basis that they are taken as fact for the purposes of the debate. At this stage I am not persuaded that the delays are inordinate given the nature of the actions against a number of parties. Where there is an explanation involving the obtaining of medical records and the instruction of counsel it appears reasonable against the background of a very large number of similar actions being handled by a relatively small number of agents and counsel.

[204] The factor that I find most troubling is the possibility of prejudice to the doctors as a result of the long delay between the operation in each case and the raising of the action. On the authorities that may well prove fatal to the section 19A claims. The cases turn on the pre-operative consent process. That in turn will depend on the content of discussions, usually on a number of occasions leading up to the operation. In most cases there is more than one doctor involved in this process. Their memories may well be dimmed by the passing of time, as will that of the pursuer. The difference may be that a doctor will find it harder to recall the specifics of a conversation with a particular patient out of the many patients he or she may see in a particular period.

[205] However it is apparent that the doctors have been able to make fairly full averments as a result I assume of having detailed medical records. Putting to one side the issue of their accuracy for a moment it may be that the prejudice to the doctors will be substantially reduced

because of the existence of these records. This was a matter that I was not addressed on and I will therefore invite parties to make further submissions on this point.

[206] The position with regard to section 22B(6) will depend on the outcome of the time bar plea against the manufacturers.

**Chapter Seven: Conclusions**

[207] The common law case against the manufacturers has been withdrawn. Accordingly I shall sustain the relevant pleas in law to the extent of dismissing the common law case against the manufacturers.

[208] I hold that the cases of AH and SR are time barred in terms of section 17 of the 1973 Act.

[209] Subject to the issues of time bar I am prepared to grant a proof before answer in all cases. The scope of the proof is for further submission in the light of the views I have expressed in this opinion. In the case of AH and SR insofar as the case is directed against the doctors it is dependent on the court exercising its discretion under section 19A.

[210] I shall put the cases out By Order to deal with the following matters:

1. On time bar issues in the cases against the doctors I shall seek submissions from parties as to the best way of resolving the outstanding section 17 issues in respect of YT and EN and the exercise of discretion under section 19A in respect of all the cases.
2. On time bar in respect of the cases against the manufacturers I shall seek further submissions on whether the issues under section 22B, including the possible exercise of discretion under section 22B(6) should be dealt with at a preliminary proof or reserved to a proof before answer.

3. The matters to be excluded from probation in the cases against the doctors and the ensuing scope of any inquiry at a proof before answer.
4. The matters to be excluded from probation in the cases against the manufacturers.
5. Any other specification points not already dealt with.

[211] I would be grateful if parties would submit written proposals 7 days before the By Order Hearing.

[212] I reserve all matters of expenses.