Neutral Citation Number: [2024] EWHC 1688 (KB)

Case No: QB-2019-004130

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 2 July 2024

Before:

HER HONOUR JUDGE CARMEL WALL SITTING AS A JUDGE OF THE HIGH COURT

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Between:

DEBORAH BIGGADIKE	**Claimant**
- and –	
KAMILIA EL FARRA	**First Defendant**
-and-	
SOHIER EL-NEIL	**Second Defendant**

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Ms Eloise Power (instructed by **Pennington Manches Cooper LLP**) for the **claimant**
Mr Andrew Kennedy KC (instructed by **Hempsons Solicitors**) for the **first defendant**
Mr Andrew Perfect (instructed by **Weightmans LLP**) for the **second defendant**

Hearing dates: 12-20 March 2024

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APPROVED JUDGMENT

Her Honour Judge Carmel Wall:

Introduction

1. The claimant, Deborah Biggadike, ("the claimant") represented by Ms Power, was born on 26 November 1964. Between 2016 and 2017 she was a patient of Ms Kamilia El Farra, a consultant urogynaecologist and surgeon ("the first defendant"), represented by Mr Kennedy KC. In 2018 the claimant was the patient of Professor Sohier El-Neil, another consultant urogynaecologist and surgeon ("the second defendant"). She is represented by Mr Perfect. I am grateful to all counsel for their careful and focussed cross-examination and clear written and oral submissions.

2. The first defendant performed surgery on the claimant on 14 January 2017. This included the implantation of TVT-Abbrevo ("TVT-A") tape to treat urinary stress incontinence, and a posterior prolapse repair. The claimant alleges that the first defendant negligently managed her pre-operative care by failing to offer conservative treatment for her symptoms in the form of pelvic floor exercises (her primary case); and in failing to arrange urodynamic studies ("UDS") before the decision was made to proceed to surgery to treat stress urinary incontinence (her secondary case). The claimant further alleges that there was a failure to obtain her informed consent to the implantation of the TVT-A tape and to the posterior prolapse repair (her tertiary case).

3. In consequence of these breaches of duty, either individually or in combination, the claimant alleges that she underwent a TVT-A tape implantation procedure that would otherwise have been avoided, at least until the national pause in TVT-A tape implantation which applied from July 2018.

4. The first defendant denies each allegation of breach of duty.

5. The second defendant performed mesh excision procedures, initially on 20 March 2018 when the central part of the tape was removed, and then again on 28 July 2018 when further flecks of tape were excised. As part of the operation performed on 28 July 2018, the second defendant performed a colposuspension procedure.

6. The claimant and first defendant allege that the mesh excision in March 2018 was in breach of duty because it was without clinical justification.

7. The claimant and first defendant further allege that the colposuspension was an unjustified procedure. She alleges it was not clinically indicated and so should not have been performed. Further, had she been informed that this procedure lacked clinical justification, she would not have agreed to it. Hence, she further alleges it was performed in the absence of informed consent.

8. The second defendant denies each of these allegations.

9. The claimant suffered personal injury, loss and damage as the result of the various procedures she underwent. It is not disputed that the cause of a significant element of her ongoing symptoms is multi-factorial.

10. By the end of the trial, quantum was agreed as between the claimant and first defendant, subject to liability and issues of apportionment (if applicable), in the total sum of £500,000. This sum has been broken down into a schedule, agreed as between the claimant and first defendant, and which is annexed to this judgment as Appendix A. The second defendant has not given agreement to the total figure or to the breakdown, but has raised no objection to either through submissions, and has not called evidence to suggest any different figure or figures for either the total figure or the figures comprising the breakdown. Like the first defendant, she disputes liability and apportionment (if applicable).

11. It is the claimant who bears the burden of proof. The standard she must meet to discharge this burden is that of the balance of probabilities. Where allegations of fraud or dishonest conduct are made (as against the second defendant), cogent evidence is needed to prove them to the required standard.

The Issues

The First Defendant

12. The claimant makes three distinct allegations of breach of duty against the first defendant.

13. The first is that contrary to NICE Guideline CG 171, the first defendant failed to offer the claimant conservative treatment by way of a trial of supervised pelvic floor physiotherapy. The claimant argues that had she been offered such a trial, she would have accepted it and avoided the TVT-A tape implantation; or at least deferred this treatment until after there was a national pause in offering this treatment in July 2018.

14. There is no dispute that NICE Guideline CG 171 applied to the claimant's circumstances and that a trial of supervised pelvic floor exercises should have been offered to the claimant. The issue between the claimant and first defendant is whether, as a matter of fact, it was.

15. The second allegation is that in not arranging for the claimant to undergo UDS before the decision to undergo surgery was taken, the first defendant was in breach of duty. There is no dispute that the first defendant did not arrange for UDS. The issue between the claimant and first defendant is whether this was a breach of duty having regard to the relevant terms of NICE Guideline CG 171 and the "professional practice" test.

16. The third allegation is that the first defendant failed to obtain *Montgomery* compliant consent from the claimant to each and every procedure undertaken in surgery. The

claimant makes this allegation with respect to both the posterior prolapse repair and the implantation of the TVT-A tape; but it is the latter that is principally relied on as having led to surgery with problematic consequences that she says she would have chosen to avoid if the consenting process had been *Montgomery* compliant.

17. Resolving this issue between the claimant and first defendant depends in part on determining what was said and done prior to surgery as a matter of fact; and also whether the admitted lack of discussion about UDS renders the consenting process defective.

18. The claimant does not suggest that the surgery itself was performed negligently.

The Second Defendant

19. There is no dispute that the second defendant removed approximately 8cm of the central portion of the implanted TVT-A tape during a first surgical procedure on 20 March 2018; and removed further flecks of mesh during a second operation on 17 July 2018. The first limb of the claimant's case against the second defendant (following a late re-amendment of her claim) and the position taken by the first defendant, is that the decision to excise the mesh was not justified and failed the "professional practice" test.

20. The second defendant stands by her decision to excise the mesh and maintains it was justified. She further asserts that in fact the mesh ought to have been excised by the first defendant at a much earlier stage. She maintains that in any event, had she undertaken a less invasive procedure and not excised the mesh when she did, the claimant's symptoms and anxieties were such that the claimant would have sought and undergone mesh excision very shortly thereafter.

21. The claimant does not allege any defect in the consenting process for these procedures; or that the mesh excision procedures themselves were negligently performed.

22. The second limb of the claimant's case against the second defendant concerns the colposuspension procedure undertaken as part of the surgery on 17 July 2018.

23. The claimant's primary allegation is that the colposuspension was not clinically justified and therefore in breach of duty. Resolution of this issue depends on issues of fact and expert opinion.

24. The claimant further alleges that the consenting process for the colposuspension procedure was defective. This is on the principal ground that the second defendant did not report to the claimant the results of UDS which showed no evidence of stress incontinence. The claimant's case is that had the consenting procedure been *Montgomery* compliant, she would not have agreed to a colposuspension procedure.

25. There is no dispute that each of the surgical procedures has had some impact on the claimant. There are issues between all parties as to causation and how attribution of that injury, loss and damage should be approached.

The Legal Framework

26. There has been no dispute about the relevant legal principles when considering breach of duty and so I address these below briefly.

27. Causation was initially contentious, because the first defendant alleged that the actions of the second defendant broke the chain of causation of injury and damage that began with the TVT-A implantation. The first defendant ultimately abandoned this argument in favour of an apportionment approach which was the same approach adopted by the other parties. In the event, I have had to assess damages on the basis there is only one liable defendant and so issues of apportionment have not arisen.

The professional practice test

28. The Supreme Court in *McCulloch and Others v Forth Valley Health Board* [2023] UKSC 26 recently confirmed that:

> *The legal test for establishing negligence by a doctor in diagnosis or treatment is whether the doctor has acted in accordance with a practice accepted as proper by a responsible body of medical opinion.*

29. The Supreme Court confirmed in its judgment the well-known exposition of the test for medical negligence set out in *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 with the qualification that "as recognised in *Bolitho v City and Hackney Health Authority* [1998] AC 232 the court may, in a rare case, reject the professional opinion if it is incapable of withstanding logical analysis."

The approach to NICE Guidelines

30. NICE guidelines do not have the force of law, but they do carry some authority. In *Price v Cwm Taf University Health Board* [2019] EWHC 938 (QB) Birss J (as he then was) said, "… what must be right is that a clinical decision which departs from the NICE Guidelines is likely to call for an explanation of some sort. The nature and degree of detail required will depend on all the circumstances." On the facts of that case, it was held that the departure from the guideline was not prima facie evidence of negligence.

Informed consent

31. The scope and extent of the duty to obtain informed consent is commonly described as the *Montgomery* duty after the decision of the Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11:

> *The doctor is … 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. [para 87]*
>
> *… The assessment [of whether a risk is material] is therefore fact sensitive, and sensitive also to the characteristics of the patient. [para 89]*

The causation of damage

32. In approaching causation of damage, and where there are two potential tortfeasors, all parties have addressed me on the approach to apportionment. In the event I have concluded there is only one liable tortfeasor and so I have focussed on the particular damage caused by her proven breaches of duty.

Chronology

33. The Claimant first presented with symptoms of urinary incontinence after the birth of her second child in 2000. She was referred for physiotherapy (pelvic floor exercises) which she undertook.

34. Her next complaint of symptoms of incontinence was during a consultation with the claimant's General Practitioner ("GP"), Dr Glynn, on 8 August 2016. Dr Glynn's note of that consultation is as follows:

    History: since having children slight continence issues

    History: more recently feels like a prolapse

    History: one episode of vaginal bleeding while on holiday but does not fall into the fast track category

    History: advised her if any more bleeding she must come back and let us know

    History: the gynae team will investigate this bleeding through the referral

    Comment: refer to gynae for further investigation and query TVT or vaginal pessary

    Comment: private letter done and given to the patient

    Comment: if she is not covered by her private insurance then will refer NHS

35. Dr Glynn referred the claimant to the first defendant. The referral letter written on the same day as the consultation said this:

Thank you for seeing this 51 year old lady who is complaining of prolapse of the uterus and continence issues.

She feels like the uterus is coming down her vagina. She has problems with coughing and passing a small amount of urine at the same time.

She has had a small bleed whilst on holiday recently even though she has not had a period for about a year. She is not on any HRT.

I would be grateful for your expert opinion and advice.

36. The first defendant had a first consultation with the claimant on 15 August 2016. She had not met the claimant before. The relevant notes from this consultation include the following:

51 ys P2+0. NSVD. Fast birth 2nd child

c/o – feels a prolapse +/- 1m ago

- *S.I. [stress incontinence] on cough & laughing not very bad. Avoids jogging …*
- *[no] urgency – Nocturia occ [occasionally]*
- *Bowel function NAD*

Menopause +/- 1 year not on HRT

Went on HRT +/- 2 ys ago headaches no major issues now

Had one episode of PMB [post-menopausal bleeding] a week ago

Cx smear 2016 NAD

PMH Asthma on R/

Surgical H lumps removed from R breast NAD

[No] Allergies. [No] smoking. Alcohol mod/more than 14/week.

Social H Self employed. Charity fundraising. Lots of heavy lifting

O/E:

P/A [examination of abdomen]. NAD

P/V [examination vaginally] v. atrophic V & V [vulva and vagina]

Mild/mod rectocele. No obvious cystocele. No uterine prolapse

Plan:

- *Uss [pelvic ultrasound scan] to check endometrial thickness*
- *PFE [pelvic floor exercises]*
- *HRT*
- *Review in 2 – 3 months if not better for ? surgical treatment/exam again*

37. On the same day as the appointment, the first defendant wrote to Dr Glynn, reporting her findings and plan. The material parts of that letter are:

She felt a prolapse for the last month with stress incontinence on coughing and laughing, she has been avoiding jogging and external exercise due to that. She has no urgency but she wakes up at night occasionally to empty her bladder…

On examination of her abdomen no abnormality was detected. Vaginal examination revealed very atrophic vulva and vagina. It was uncomfortable for Deborah to have the internal examination. She had a mild rectocele, no obvious cystocele and no obvious uterine prolapse in the lithotomy position.

I reassured her about these findings. I requested a pelvic ultrasound to exclude any reasons for the post-menopausal bleeding. I also will refer her for pelvic floor exercises with our bowel and bladder nurse specialist Nora Roberts. I also will discuss Hormonal Replacement therapy once the ultrasound scan results are available to try to strengthen the collagen in the area and reduce the atrophy of the vaginal walls. I advised Deborah to book another appointment if she feels the prolapse much worse than it is today so that I can examine her again to see if the prolapse is worse.

38. The letter was copied to the claimant.

39. On 17 August 2016 the claimant underwent a pelvic ultrasound scan. This revealed a thickened endometrium with no evidence of fibroids and normal ovaries. The plan was to admit her for examination under anaesthetic for hysteroscopy and endometrial biopsy. The first defendant wrote again to Dr Glynn:

I will take the opportunity to assess her prolapse further while she is under general anaesthetic and I will keep you informed of her progress.

40. This too was copied to the claimant.

41. The claimant's next appointment was on 10 September 2016 when she underwent a hysteroscopy, curettage, cervical biopsy and cautery procedure. The relevant findings from the examination were recorded on the clinical notes as "large cystocele, 2nd degree uterine prolapse, mild/moderate rectocele. Cx [cervical] -ectropion bled ++ on

touch …" Those findings were reported by letter dated 13 September 2016 to Dr Glynn. The curetting and cervical biopsies were sent for histopathological analysis.

42. The biopsy results were, very fortunately, unremarkable; and not indicative of any cancer. This was reported directly to the claimant by letter dated 21 September 2016.

43. The next appointment the claimant attended was on 19 October 2016. The clinical notes include the following:

p/v bl.

Vag hyst +Repair ant. + TVT-A [because] leaks on jogging, sneezing fit

- *Eido [ticked]*

- *Risks and Benefits [ticked]*

44. "Eido" is a reference to a series of patient information leaflets. It is not disputed that they are considered authoritative and a "gold standard" for leaflets of their type.

45. The clinical notes also contain a sketched diagram of the sideways view of the relevant part of the female anatomy.

46. The reporting letter from this consultation is dated 19 October 2016. It was addressed to Dr Glynn and once again copied to the claimant:

I am pleased to see her cervical biopsies and endometrial biopsies did not show any abnormality. She feels uncomfortable with the prolapse and would like something done about it and so I booked her for vaginal hysterectomy and repair together with tension free tape as she does have stress incontinence on jogging and sneezing. She suffers with asthma and will go and review her asthma medications prior to surgery to try to maximise the success rate of her surgery…

47. The surgery was due to be performed in November 2016 but there is no dispute that this date was moved at the claimant's request.

48. On 20 December 2016 the claimant attended her pre-admission assessment appointment when she was seen by a nurse. The nurse recorded that the claimant was provided with "EIDO", "VTE" [venous thrombosis] and "Anaesthetic" patient information leaflets.

49. On 14 January 2017 the claimant attended for surgery. The consent form is dated 11 January but it is common ground that it was not signed until the day of surgery. The proposed procedure was recorded as "Vaginal hysterectomy, repair and tension free tape (TVT-A)." The "intended benefits" were recorded as "To correct prolapse & stress incontinence".

50. The "Significant, unavoidable or frequently occurring risks" were recorded as "Infection, Bleeding, deep vein thrombosis, injury to surrounding structures, Mesh erosion, urinary retention Bladder instability."

51. The consent form is counter-signed by a nurse.

52. The operation note records that the first defendant performed a vaginal hysterectomy, anterior and posterior repair and implanted tension free tape (TVT-A). The description of the clinical findings includes "Moderate rectocele, large cystocele. 2nd degree uterine prolapse."

53. It was anticipated that the claimant would remain in hospital for two to three days and would attend a follow up appointment with the first defendant after six weeks.

54. The contemporaneous nursing records of the claimant's immediate post-operative condition are as follows:

15.01.17

1220 Pain appears well controlled on IV paracetamol + oral ibuprofen

1840 Settled afternoon, no complaints voiced. Visited by family

2300 Medication given as charted settle and slept well.

Pain assessed by patient as within acceptable range according to pain scale (0 – 3 on 0 -10 scale)

16.01.17

0845 Pain improved this morning

1200 Mobilising independently, self caring with hygiene needs

1600 Pt complaining of pain. Offered heat pad which settled the pain, Pt did not want to take any tablets

2015 Mobilised around room, helped with back stiffness.

2300 Settled down well after analgesia was given.

0015 c/o not have been able to sleep as she can feel her catheter and pain as a result of the operation. Oramorph given as per request.

0300 Fees much better trying to sleep

Pain assessed by patient as within acceptable range according to pain scale 0 – 3 on 0 – 10 scale).

17.01.17

Independent with ADLS [activities of daily living]

55. On 23 January 2017 the claimant returned to see the first defendant. This was earlier than had been expected. The notes of that consultation record "bad pain in abdomen related to going to toilet". The reporting letter to Dr Glynn reports that the claimant was "finding it very difficult to have efficient pain relief while at home. She contacted the ward over the weekend and as advised to use (sic) codeine at night and I am pleased to see her pain control is a little bit better." The claimant was also reporting "severe menopausal symptoms in the form of night sweats".

56. The claimant attended a further appointment on 1 February 2017. The first defendant reported the claimant's symptoms at that time as "lots of pains in her abdomen mainly before opening her bowels in the morning. She is still taking Ibuprofen and paracetamol for pain and feels shivery and cold when the pain relief is low. She also gets severe headaches in the morning. She suffers from sinus's (sic), she had Hormone Replacement Therapy patches on two occasions and found it did not give her any relief of her menopausal symptoms, she stopped them a week ago. The headaches are very likely not related to the Hormone Replacement Therapy. She is having to wake up every 30 minutes to 2 hours to change her bedding because of night sweats. She also noticed heavy vaginal discharge." The first defendant reported that she had carried out a vaginal examination which did not disclose any abnormalities, she had taken swabs and prescribed antibiotics "on empirical grounds while we await the results of her swabs." She also prescribed a form of oral Hormone Replacement Therapy, advised a headache diary was kept and to stop the Hormone Replacement therapy if severe headaches were thought to be linked to it. The GP was asked to continue the prescription or an alternative oral oestrogen preparation "if necessary".

57. The next follow up appointment was on 1 March 2017. The first defendant's clinical note states:

    - *Started work yesterday. Stabbing pains last night.*

    O/E vag walls healed v. well atrophic change. No tape erosion. On E2 [oestrogen] tablets will continue

    Plan: ? local E2

58. The first defendant reported the consultation to Dr Glynn (copied to the claimant) in consistent terms, "She had an uneventful recovery but started to work over the last few days and started to have stabbing pains." On examination the first defendant recorded that her vaginal wall had "healed very well, she had atrophic changes and I advised her to continue with her oestrogen tablets." The first defendant wrote that she had "advised her to start trying intercourse and if that is uncomfortable she will

benefit from local oestrogen such as Gynest vaginal cream or Vagifern vaginal pessaries". She said she would be "quite happy to see her if necessary".

59. Between March and November 2017 the claimant attended GP appointments for matters not directly relevant to the issues in this trial. On 10 July there was a review of the Hormone Replacement Therapy that had been started after the hysterectomy on 14 January; and the claimant asked for medication to help with anxiety on flying (because she was due to go on holiday).

60. On 8 November 2017 the claimant saw Dr Rooproy at her GP surgery. His notes of the consultation are as follows:

History: 1) had hysterectomy and TVT inserted for prolapse – in January 2018 - has stress incontinence and also having pelvic pain – wondered if TVT and wants to see specialist privately …

Plan: for BT and review and will also do private referral letter to Miss S. Elneil

61. The reference to "January 2018" is almost certainly a typographical error for January 2017, when the surgery had been performed. The claimant's evidence is that the reference to stress incontinence is also an error as this was not a symptom she was experiencing or reporting at that time.

62. Dr Rooproy's referral letter to the second defendant dated 8 November 2017 stated:

Thank you for seeing this 52 year old lady who in January had a vaginal hysterectomy, anterior posterior repair and tension free tape. She states that since she has had the tape she has been feeling increased abdominal and pelvic pain since the operation and feels her stress incontinence is returning. She does not have bowel symptoms and denies other urine symptoms.

She is concerned this is a consequence of the TVT due to recent media reports and has requested an appointment to discuss the options and possible cause of her symptoms.

63. On 18 January 2018 the claimant returned to Dr Rooproy. He recorded:

History: seen has gynae referral from pelvic pain and TVT – wants something for the pelvic pain – worsening feels nerve related – no bowel or urine symptoms no PV discharge

64. The second defendant saw the claimant for the first time on 2 February 2018. The material part of her reporting of that appointment is as follows:

In her post operative period, she developed significant problems with pain and nine days post-surgery she had a urinary tract infection and required pain management.

Within a few months after surgery she resumed the gym but she noticed increasing groin (sic) and by September 2017 she stopped going to the gym. In November she noticed worsening soreness in her groins and pain in her hip. She has been taking Nortriptyline but the back pain and the buzzing sensation as well as the aching legs and nerve pain have persisted.

Her bladder function is normal and she tells me that when she had the tape put in, it was only for very minor urinary stress incontinence. Her major symptom prior to that was the prolapse.

She has a feeling of heaviness in the rectum. She has not been able to have sexual intercourse …

On examination I could feel the edge of an obturator tape in the right anterior sulcus. She also had a constriction ring in the mid-point of the vagina and was tender along it.

I am arranging a 3D ultrasound scan with Miss Renee Thakar and provisionally booking her for excisional surgery as the mesh does feel as if it is very close to the surface and may erode through at some point soon.

Once she has had all of her ultrasound scan and check, we will arrange the surgery then, but in the meantime, we will make sure we have got all the imaging done first.

65. The history and examination findings recorded on the second defendant's clinical note are consistent with this report. In the plan recorded in the clinical note, she recorded contemporaneously the arrangement for the ultrasound scan, provisional surgery to include removal of vaginal mesh and vaginal reconstruction; and "pros and cons discussed." At some time after February 2019 (when the original notes were sent to the claimant's solicitors) she made the following addition to the reference to "pros and cons" in the original notes:

<u>Incl</u> (emphasis in original) remnant mesh

CPP

USI recurrence

66. Dr Thakar performed the ultrasound on 28 February 2018. The "History" recorded on the report is:

Vaginal hysterectomy and pelvic floor repair and TVT Abbrevo – 14th Jan 2017

Significant pain and one UTI after, pain in both groins, noticed after going to gym

No stress incontinence, no frequency urgency

Sex is painful

67. The "Mesh position" is noted as "Mid-urethra". No cystocele or rectocele was found in the 2D ultrasound imagery. The "OVERALL CLINICAL OPINION" records "Tape located in the mid urethra, not eroding, lies flat. Left side curled and right arm is located at a lower level than the left, Tape does not change shape on Valsalva. The tape is most likely to be a TOT".

68. On 16 March 2018 these results were reported to the claimant's GP, Dr Bruce and copied to the claimant although the text of the letter is directed to the claimant rather than her GP:

I have received the results of your ultrasound scan result. It shows that the mesh is located in the mid-urethra and is not eroding. However, the left arm is curled and the right arm is located at a different position to the left. Interestingly as well the tape did not move during straining, which kind of suggests that it is rather fixed.

I look forward to seeing you when you come in.

I did give you a ring today, 16th March 2018 but unfortunately, we could not speak.

69. It is common ground that the second defendant did not speak directly to the claimant at this time, consistent with her letter.

70. The claimant's first surgery performed by the second defendant was on 20 March 2018. The admission form for surgery records symptoms of "groin pain, leg hip and back pain, sore abdomen, buzzing sensation".

71. The second defendant's surgical note records the procedures undertaken as "EUA [examination under anaesthetic], cystoscopy, removal of vaginal mesh, vaginal reconstruction, urethroplasty.

72. The contemporaneous surgical note (so far as relevant) records:

Indication: Voiding Dysfxn + mesh in urethral muscle.

Pt prepared for Sx

Mesh embedded in L obturator fossa + v difficult to retrieve

Mesh also embedded in urethral muscle [right more than left]

Incision made. Mesh retrieved.

Urethra reconstructed + urethroplasty done w/ 2/0 v/gel

Vagina reconstruct w/ 2/0 v/gel

73. The notes include diagrams consistent with the note of the mesh position. Approximately 8cm of the central part of the tape was excised during this procedure.

74. The second defendant reported the surgery to Dr Bruce as follows:

Examination under anaesthesia revealed adhesions in the vagina between the anterior and the posterior wall at two spots. There was a thick adhesion anteriorly and a second smaller adhesion posteriorly.

Examination showed nothing untoward and there was no mesh in the bladder or the urethra, though there was an inflammatory exudate quite evident on the base of the bladder.

Following careful dissection into the anterior vaginal wall we were able to identify the mesh high up in the left anterior fornix. It was tracking into the obturator fossa.

Following careful dissection of this mesh, we realised that the mesh was actually tracking not just from the fossa along the bladder wall on the left, but it was actually going into the urethral muscle on the right and transecting across to the right obturator fossa.

This was quite complex surgery in order to try and retrieve the mesh out of position. It took a significant period of time and it did involve dissecting part of the anterior urethral muscle wall in order to be able to access it directly into the retropubic space in the end on the right-hand side. There was quite a huge amount of inflammatory tissue and it was quite difficult to actually access all the mesh that we required.

Following the procedure, we were able to get a substantial amount of mesh out from both these areas.

The anterior urethral wall and muscle were reconstructed followed by a urethroplasty and then a vaginal reconstruction.

A catheter will need to be left in for 14 days followed by a cystogram.

It is highly likely she will get recurrent stress incontinence. It is likely also that she will require further surgical treatment for this.

75. On 31 March 2018 the second defendant wrote to the claimant reporting to her the histopathology results from the examination under anaesthetic. She wrote, "I am happy to say that the mesh has proven what we expected, which is a foreign body giant cell reaction and fibrosis." She enclosed a copy of the report.

76. The second defendant arranged for the claimant to have a micturating cystourethrogram performed by Dr Rickards, consultant radiologist. Dr Rickards reported, "Bladder outline was unremarkable. Bladder neck slightly open at rest but reasonably well supported and no obvious stress seen today."

77. On 14 April 2018 the claimant attended a follow up appointment with the second defendant. The second defendant reported to the claimant's GP:

She is three and a half weeks post vaginal mesh removal and since then she has had problems with hives and swelling in both groins.

I have examined her today and both groins have got enlarged lymph nodes, which I suspect is due to all the problems she has had in the past with the mesh. She clearly has got some changes to her immunity given her history that she related to me today.

The hives are responding to antihistamines.

Examination of the vagina showed a well healing anterior vaginal wall and urethral wall.

I am sure things will generally improve.

She obviously has an allergic response to the mesh and so I am arranging for her to have a video urodynamic assessment at the end of June/beginning of July 2018 and she will probably need to have the mesh removed, just simply because of the impact it is having on her system. If she has urinary stress incontinence then we will do a colposuspension at the same time.

78. The contemporaneous record of the clinical notes had a four-stage plan. At some time after February 2019 the second defendant changed her original note to add two further stages:

5) May need bilateral paralabial incision to remove any remnant mesh.

6) PIL [Patient Information Leaflet] – mesh complications

QOL [Quality of Life questionnaire] – to be filled in.

79. The second defendant initialled next to the additional items but did not date them or otherwise indicate they had been added subsequently.

80. On 20 June 2018 the claimant consulted Dr Abu-Sitta, a consultant haematologist. He reported that the claimant's blood testing showed eosinophilia and mild thrombocytosis and wrote:

She tells me that she had Hysterectomy in January 2017 for uterine prolapse and I believe a TVT mesh was inserted during which has apparently led to foreign body giant cell reaction and fibrosis. She had a recent procedure during which the mesh was partially removed.

Her symptoms are mainly of moderate, but constant pelvic pain which is attributed to an inflammation in the operation area…

I suspect the Thrombocytosis and Eosinophilia are reactive to the inflammation in the pelvis. The treatment would be to treat the underlying cause and I believe she is going to have major surgery to remove the mesh completely on 10th July.

81. The second defendant referred the claimant back to Dr Rickards for X-ray UDS. On 27 June 2018, following investigation, he reported "… her urodynamics are normal. The bladder neck was open at rest and well supported and I saw no stress today."

82. The report has been annotated by the second defendant as follows (all emphasis is in the original):

6/07/2018

D/w DR Rickards

Images show open BN – No stress noted on Images

BUT pt. stated this is not usual & she can have USI throughout the day & feels heaviness PV suggesting a cystocele may be forming w/ full bladder.

For EUA, cysto +/- colpos/ paravaginal repair as pt symptommaty (sic).

83. The provenance of that annotation is a matter of dispute. My findings on this issue are set out later in this judgment.

84. On 5 July 2018 the claimant emailed the second defendant to update her about her condition and enquire about when further surgery would be scheduled. She made no reference to any bladder or urinary issues.

85. The second defendant replied on 6 July 2018 about the scheduling of the claimant's next surgery.

86. There was no further contact between the second defendant and the claimant until the day of the next operation on 28 July 2018. When the claimant was admitted. the procedures that would be undertaken were recorded as "EUA, cystoscopy, open removal of mesh arms, colposuspension, paravaginal repair." The recorded benefits were recorded as "To remove mesh and Rx [treatment] Urinary stress incontinence." There is a list of "serious or frequently occurring risks" recorded but these are illegible on the copy in the trial bundle.

87. The second defendant's surgical note describes the operation as "EUA, Open colposuspension & cystoscopy & paravaginal repair". The note records:

Dissection into Retropubic space

- *no mesh arms noted. Small single fragments of mesh seen & removed.*

88. There is then reference to the siting of Ethibond sutures, the cystoscopy and drainage.

89. The reporting letter to Dr Bruce, dated 24 August 2018, contained greater detail. The second defendant wrote:

    Examination under anaesthetic revealed a prolapsed bladder neck and anterior vaginal wall prolapse in the form of a grade 2 cystocele. On opening up the retropubic space it was evident there was some flex of mesh from the obturator tape, which was removed and the area was cleaned up. A colposuspension and paravaginal repair was performed using Ethibond sutures.

90. The first post-operative review was on 14 September 2018. Positive and negative symptoms were recorded. The claimant's fatigue had improved; her groin pain was gone (recorded as secondary to mesh) and she remained under the care of her haematologist. She was complaining of bilateral hip pain, aching leg, pain in ankles, and urgency of urine with urine flow improving.

91. The second defendant contemporaneously recorded a three stage plan. At some time after February 2019 the second defendant added a fourth stage:

    Not for paralabial

    Sx [symptoms] as <u>not reqd</u> – Groin pain gone.[emphasis in original]

92. There was a further review on 5 December 2018. This recorded the claimant's continuing reported symptomology. One of the contemporaneous items recorded is "R sided groin pain". At some time after February 2019 the second defendant changed the note to add the annotation, "Groin pain gone but occ pain on R" and "Not sure if because of hip pain".

93. The single stage plan recorded contemporaneously was "To see AP B + R/V 3 – 4/m". At some time after February 2019 the second defendant added to this note by adding "1)" to the original single stage of the plan and added as a second stage, "2) ?updated USS re mesh remnants".

94. The second defendant did not date any of the late annotations to the clinical records (that is, those made after disclosure of the original records to the claimant's solicitors). She did not draw attention to them as additions to the original records in any way at all. She did not, at the time they were sent to the claimant's solicitors in August 2022 provide any explanation for the records having been augmented from their original form.

95. Shortly after the second defendant's December review, she referred the claimant to Dr Baranowski, Pain Medicine Specialist.

Evidence

96. I have heard oral evidence of fact from the claimant, her husband and both defendants.

The claimant

97. When giving her evidence I am satisfied the claimant has honestly responded to the questions asked of her. She offered calm and considered responses from the witness box and approached the giving of evidence carefully. She made some reasonable and fair concessions, confirming, for example, her initial view of the second defendant as an empathetic doctor, even though by virtue of these proceedings she must feel very let down by her. Her restrained dignity throughout this trial has been impressive and humbling to observe. I am absolutely sure it has been extremely difficult for her to listen to detailed forensic analysis of intimate aspects of her medical history but she has remained calm and composed throughout.

98. It is the reliability of her recollection and its inherent likelihood that has been the focus of challenge.

99. On many issues she maintained a consistent position, despite strong challenge. On other, important issues (such as whether the first defendant discussed supervised pelvic floor exercises with her at all), her oral evidence differs significantly from her witness statement.

100. There are issues of fact on which the claimant's evidence differs from the evidence of each of the defendants. There are obvious difficulties in resolving these factual differences.

101. It is of the nature of this case that each party is giving evidence about events from many years ago. For the claimant it has been an understandably traumatic period of her life. It began with anxiety about a possible cancer diagnosis. She then underwent a series of major surgical procedures within a short space of time with post-operative symptoms. She has become anxious and upset about the potential implications of TVT-A tape implantation, due at least in part to her exposure to adverse publicity about this treatment. Each of those features both alone and in combination is bound to affect the quality of her recollection.

102. The claimant plainly wishes that she had never had the TVT-A tape implantation procedure which began the course of events that has led to this claim. There is a risk that the quality of her recollection and the accuracy of her narrative will be influenced by these strong feelings.

103. I also remind myself, as all counsel and witnesses have emphasised, of the vulnerability of a person in the claimant's position, seeking treatment from and relying on experts regarding particularly intimate and personal medical issues.

Mr Biggadike

104. Mr Biggadike too was an honest witness who approached the task of giving evidence seriously. The value of his evidence on issues of breach of duty is limited. He did not attend any of the relevant consultations. He did not read the correspondence that followed from them. I have no doubt that his focus was to offer support to his wife in whatever decision she took; rather than to engage proactively with the decision-making process or to influence it.

Miss El Farra

105. The first defendant is an experienced consultant in the sub-specialist field of urogynaecology. She has extensive experience in both the public and private sector. She gave her evidence calmly and professionally. She accepted criticism of her record-keeping with good grace. But she remained adamant about her usual and long-established practice on matters she clearly regarded as fundamental (explaining conservative alternatives to surgery and the risks and benefits of surgical procedures, for example).

106. In giving evidence, she does not pretend now to have a detailed independent recollection of what was said or done during her interactions with the claimant which for her, were routine in nature. In giving evidence, the first defendant primarily relies on her contemporaneous records and correspondence together with her normal practice.

107. There is no challenge to her probity. Rather, the suggestion is that the first defendant's contemporaneous records are limited; and after the passage of time and opportunity for reflection on the events of 2016/17, the first defendant has conflated what she did say and do with what she wishes had occurred. Just as for the claimant, it is her accuracy and reliability that is challenged.

Professor El-Neil

108. In assessing the evidence of the second defendant, there are two separate aspects of her evidence to consider.

109. The first aspect is her extensive experience and expertise as a distinguished urogynaecologist and surgeon with a specialist interest in vaginal mesh and its complications. Her unchallenged evidence of experience and expertise set out in her first witness statement includes her appointment as Clinical Lead for the London Mesh Complications Centre 2020 – 2024 and Deputy Chair of NHS England Pelvic Health Group overseeing Research and Education on continence and prolapse mesh complications from 2021 to date. In oral evidence she said that she performed 909 mesh removal procedures between 2005 and 2020. She is entitled to respect as an expert in her field.

110. The second aspect is the honesty with which she has dealt with these proceedings. In this area I have very regrettably found her evidence wanting. It is not a light

decision to impugn the honesty of any witness, particularly one with such impressive credentials and reputation. I have been driven to the conclusion that the second defendant has not told the truth about why she made additions to her clinical notes well after her consultations with the claimant; and about the reasons for and timing of an annotation she made to a UDS report dated 27 June 2018 (annotation purportedly dated 6 July 2018). I deal with my reasoning and conclusions about the latter annotation later in this judgment.

111. It is not in dispute that in February 2019, the second defendant provided a set of medical records to the claimant. At that time the second defendant was not a party to these proceedings. The medical records (which I will refer to as "the original records") did not include the report of the results of urodynamic testing carried out by Dr Rickards at the second defendant's request on 27 June 2018.

112. The second defendant was subsequently joined as Second Defendant to the claim. Medical records disclosed in August 2022 included the urodynamics report which had a handwritten annotation dated 6 July 2018. Other handwritten records had annotations that had been added to the original records at some time between February 2019 and August 2022. None of the additional annotations was dated or otherwise identified as having been made at a different time from the original records (save that the annotation on Dr Rickards' report was dated 9 days after the date of the report itself).

113. This prompted an application by the claimant for an explanation for these apparent discrepancies in the handwritten clinical records. On 24 March 2023 Master Stevens ordered that the second defendant respond to Part 18 questions directed at these apparent anomalies. The second defendant made a further witness statement signed with a statement of truth on 26 April 2023.

114. The explanation offered in that witness statement was that the original clinical records were scanned into an electronic record keeping system and preserved. The paper copies were kept in a patient folder and the annotations had been made on those paper records as an "aide memoire" for the second defendant. She accepted that she had not identified the fact that the additions to the original records were not made contemporaneously. She said in her witness statement that because the claimant's solicitors had been provided with both versions of the records, the additions would, however, have been obvious to them. She offered the same reason for omitting any comment about the additions in her first witness statement. In her oral evidence she accepted that it would not be obvious that the records had been augmented if only the additionally annotated records were analysed; but she said she had not concealed anything. That was because, she said, the claimant's solicitors would have been readily able to see the comparison for themselves without her drawing it to their attention.

115. My starting point in evaluating this explanation is that for a medical professional as experienced as the second defendant, it must be axiomatic that if a contemporaneous clinical record is much later changed, it is necessary to identify what has been changed or added and the date the addition was made. I cannot accept that she honestly believes it is sufficient or acceptable to leave it to the diligence of the reader to compare electronic and paper records to determine what is in fact contemporaneous and what is not. The transparency of record-keeping is self-evidently important whether medical or legal issues are in contemplation. Anyone coming to hand-written clinical records would reasonably expect them to be original source material, contemporaneously recorded, unless the contrary was clearly identified. That is best illustrated by the evidence of Dr Sokolova, the second defendant's own expert, who was provided only with the annotated records and believed them to be entirely contemporaneous.

116. The quality of a contemporaneous clinical record is necessarily different from a record created from memory months and possibly years after the consultation recorded. That would not come as a surprise to the second defendant.

117. Secondly, the additions themselves are written in a way that suggests contemporaneity.

118. Events that have already occurred are referred to prospectively. On 14 April 2018, for example, the contemporaneous note in the original records sets out a plan with four parts. The plan is looking forward to a surgical procedure anticipated for July 2018). Fifth and sixth parts have been added to the plan. The sixth part reads "PIL [patient information leaflet] – mesh complications QOL [Quality of Life questionnaire] – to be filled in". By the time this annotation was added, the time for completing and evaluating this questionnaire had well passed.

119. Where the added note has been made after the end of the original record (rather than squeezed into the original text), it is initialled but not re-dated. This suggests to the reader it has been made contemporaneously and not much later. In the record for 14 April 2018, for example, the original four stage "Plan" is initialled twice, once after the first two parts and then again after the fourth. That was probably because when the original record was made, the second defendant recorded a two-stage plan; reflected and added two additional parts contemporaneously. She re-initialled what had become the end of the contemporaneous record for that consultation, entirely properly. The 5th and 6th parts of the plan which were added after February 2019 are initialled in exactly the same way as the contemporaneous additions without any re-dating. I do not accept this would have been done for the purposes of an "aide memoire". The second defendant knows her own handwriting. The more likely reason to re-initial but not re-date is to give the impression that the plan was expanded contemporaneously and not very much later.

120. Thirdly, the content of the additions has a potentially self-serving character.

121. The additions to the record for 2 February 2018 (the claimant's first appointment with the second defendant), for example, expand on the "pros and cons discussed" [of mesh removal surgery] to add specificity. The additions to the record for 14 April add a reference to a patient information leaflet on mesh complications, potentially relevant to allegations of a defective consenting procedure.

122. In a review after surgery, on 14 September 2018 the original notes record "Groin pain gone ([secondary to] mesh). The original notes from the next review on 5 December 2018 record "R sided Groin pain" as a current symptom. The annotations added to the record for 5 December 2018 include, "Groin pain gone but occ. pain on R" and after the original reference to symptoms of right sided groin pain, "Not sure if because of hip pain". My impression when reading these notes together is that the second defendant has made the additions intending to minimise this particular symptom and suggest a cause unrelated to the recent surgery. Even if I am wrong in that impression, it is difficult to accept she would have had the recollection of detail suggested by the addition (that the pain on the right was "occasional") many months after this consultation.

123. My conclusion is that when the second defendant made the annotations, she was intending to pass them off as contemporaneously made. To that extent they are deceptive. I do not go so far as to say the content of the additional notes is false or not reflective of the second defendant's usual practice. I make no finding to that effect.

The experts in urogynaecology

124. I heard evidence from three expert urogynaecologists, each of whom was well-qualified and experienced in that subspecialisation. Each was cross-examined in detail. I set out in the body of this judgment why in a particular instance I preferred one view over another.

125. Dr Sokolova was not initially instructed to address issues arising from mesh excision. She accepted that her expertise in complications from mesh excision was limited. Mr Robinson and Mr Toozs-Hobson have greater personal experience in this area. However, in the public sector, the majority of complex mesh excision is now performed in specialist tertiary centres. Neither Mr Robinson nor Mr Toozs-Hobson has a role in a complex mesh centre. Mr Toozs-Hobson continues to perform mesh excision surgery privately. Mr Robinson last performed mesh excision in 2020.

126. Mr Toozs-Hobson and Mr Robinson (to a lesser extent) were subject to cross-examination which attacked their integrity as independent experts. The questioning sought to suggest that they had some personal, professional and/or financial interest in the outcome of this trial and/or had a financial interest in the supply of vaginal mesh products.

127. During the course of the trial each had attended and shared a platform speaking at a seminar for urogynaecologists. The seminar had been planned in advance of the trial. Due to changes in the trial timetable, Mr Robinson was in the process of giving his evidence over the weekend of the seminar; Mr Toozs-Hobson had yet to give his evidence. Each said he had informed his legal team of this professional commitment; but neither had informed the court nor apparently the second defendant or her lawyers.

128. It would certainly have been preferable, in the interests of transparency, if this commitment had been volunteered to the court and to the second defendant. However, had it been disclosed, I would have done no more than to remind the experts that the case should not be discussed between them at all; and that Mr Robinson, who was in the process of giving evidence, was prohibited from discussing his evidence with any other person. This was what in fact was done, after hearing submissions from all Counsel.

129. It has become plain during the course of this trial that the sub-specialist world of urogynaecology is a small one. Mr Robinson and Mr Toozs-Hobson knew each other before being instructed as experts. Each of them already knew each of the defendants. It is entirely artificial to think that the organisation and attendance at the weekend seminar would have any effect or impact on their evidence. Mr Robinson and Mr Toozs-Hobson had each already provided written reports and then a Joint Statement addressing a detailed agreed agenda. The quality of the substance of their opinion could be and was properly explored through the trial process.

130. I reject the suggestion that either Mr Robinson or Mr Toozs-Hobson has approached the task of giving evidence in this trial other than in accordance with the duties owed by an expert to the court. I reject the suggestion that either has given evidence that has been improperly influenced by any hidden agenda of protecting personal, professional or financial interests. I reject the suggestion that either has a personal stake in achieving any particular outcome in this litigation or has manipulated his evidence for any improper reason or purpose, including the suggested motivations of defending mesh claims made against him or financial connections with the mesh industry.

131. I entirely accept and endorse Mr Toozs-Hobson's pithy response to cross-examination attacking his independence when he said, "This case isn't about me". That applies equally to Mr Robinson.

132. I recognise that some of those practising in the field of urogynaecology have strong and different views about the efficacy of vaginal mesh treatment. This case is not about those issues. It is concerned only with the particular allegations of negligence made by the claimant and is confined to the facts of this particular case.

The other experts

133. I have considered the written reports of other experts in the disciplines of pain management (Dr S. Law and Dr N. Plunkett), psychiatry (Dr M. Bott and Dr R. Latcham) and care and occupational therapy (Ms L. Barnes and Ms J. McGovern). Although this expert evidence was not agreed, no oral evidence was called.

134. Instead, the parties adopted a pragmatic approach. The claimant and first defendant agreed both a global figure for quantum and a breakdown of the total. The second defendant did not agree but did not object to either the global figure or the proposed breakdown; and did not either make submissions or call evidence to contradict either. The real dispute between the parties has been over how the figures should be apportioned.

135. In those circumstances the written expert evidence (save for that of the urogynaecologists) has been of limited value in disposing of the issues between the parties.

The Case against the First Defendant

Evidence and analysis

Background to the referral

136. The claimant's unchallenged evidence is that she had begun to develop symptoms of incontinence around 2015, about a year or so before the August appointment. She says she would not have consulted her GP about these symptoms but for the fact that she had an episode of post-menopausal bleeding while on holiday in 2016. She was concerned this might be a sign of cancer.

137. I accept the claimant's evidence that the symptom of greatest concern to her when she consulted her GP and was first referred to the first defendant was the episode of post-menopausal bleeding. It is likely, as she says, that her symptoms of prolapse and stress urinary incontinence had been present for some time by then, but they were not the symptoms that prompted her to consult her GP. Her evidence about this accords with human experience, that a fear of cancer is much weightier than symptoms that cause inconvenience or even discomfort but are not potentially life-threatening. She says that when she consulted her GP about the bleeding, she mentioned the symptoms of incontinence only to give the GP a complete picture and not because they were, of themselves, having a significantly adverse effect on her life. She says she regarded the symptoms as mild and insufficiently intrusive for her to seek medical attention or to recommence the pelvic floor exercises she had done in 2000 when she had been treated for stress incontinence following the birth of her second child.

138. It is common ground that the first time these symptoms were raised with the claimant's GP was on 8 August 2016, when the episode of bleeding was reported. I attach no significance to the order in which the claimant's symptoms were recorded in the GP's clinical record. Her main concern at that time was whether the episode of

bleeding might have a sinister cause, but she does recall there being some conversation with the GP about incontinence which included conversation about treatment with "TVT tape" and "possibly a pessary".

139. The GP referred the claimant to the first defendant by letter dated 8 August 2016.

15 August 2016

140. It is common ground that the first defendant had not treated the claimant before this referral. Before the consultation on 15 August 2016, the only information that the first defendant had about the claimant's presenting symptoms was the referral letter from the GP.

141. The claimant does not now dispute that the first defendant made an accurate contemporaneous note of her first consultation. There is no challenge to the accuracy of the note about the claimant's medical and social history and presenting complaints (save for disagreement about whether the claimant mentioned only "jogging" as an activity she was avoiding because of stress incontinence or "jogging and other strenuous exercise").

142. There is no dispute that the first defendant examined the claimant and there was then discussion about a plan.

143. The claimant's pleaded case was that a referral for pelvic floor exercises was neither made nor discussed. In her first witness statement the claimant said, "I recall that she briefly mentioned that there were options for dealing with a prolapse including surgery or pessary management. There was, however, no mention of pelvic floor physiotherapy or a referral to Nora Roberts, (my emphasis) who I now understand is an incontinence nurse."

144. In her oral evidence the claimant moved considerably from this position. She conceded that the first defendant did mention pelvic floor exercises but that "the decision was to put everything else aside and look at the reason for the bleeding". She agreed that she would have understood what pelvic floor exercises involved, because of her previous physiotherapy in 2000 but that there was no discussion with the first defendant about her treatment in 2000. She said she "did not remember" if the first defendant had mentioned the name of a specialist nurse who could provide pelvic floor exercises which was a significant shift from the position in her witness statement when she was clear that the nurse had not been mentioned at all. In her oral evidence she said that her understanding at the end of this consultation was that "she said she would refer me on [for treatment with pelvic floor exercises]" which was not consistent with her original stance that there had been no mention of a referral. She did deny categorically that the first defendant had given her a compliments slip with Nurse Roberts' details with instructions for the claimant to follow up pelvic floor exercise treatment with Nurse Roberts directly.

145. The claimant says, understandably, that her focus at that first consultation was on the cause of the bleeding because of her fear that it might be indicative of cancer.

146. The first defendant's evidence is that in accordance with her normal practice she took a full history from the claimant. That included an account of the vaginal delivery of her two children and the "fast birth" of the claimant's second child as recorded in the clinical notes. The first defendant says that through that questioning she might well have established that the claimant had been treated with pelvic floor exercises many years before. In asking about a patient's obstetric history she would, as a matter of course, seek to cover these issues, even though there was no specific reference to this in her contemporaneous note. (Whether or not she did in fact establish this is of no consequence, because the claimant agrees that she understood what was meant by pelvic floor exercise treatment.)

147. When recording symptoms, the first defendant's evidence was that whatever may have been the patient's order of priority in her mind, she recorded the order in which the patient told her about her symptoms. Her note is that the first symptoms recorded is "feels a prolapse +/- 1m ago", then "S.I. [Stress incontinence] followed by "had one episode of PMB [post] menopausal bleeding] a week ago".

148. She recorded what the claimant told her about her experience of stress incontinence – that she experienced this on "cough & laughing not very bad. Avoids jogging …" The first defendant agreed that the phrase "not very bad" came from the claimant herself. She said that the use of three dots after the word "jogging" was her own shorthand for "similarly vigorous exercise". She agreed that the claimant was not complaining of a complete loss of control but the symptoms were sufficiently intrusive for them to affect some of her activities.

149. She recorded that the claimant reported no urgency and "occ [occasional] nocturia" (a need to pass urine during the night).

150. She conducted an examination that was limited due to the very significant levels of pain the claimant experienced during the examination. Part of her plan was to examine the claimant again under anaesthetic which would avoid discomfort and in any event allowed a more reliable assessment of the prolapse. She recorded from her vaginal examination a "mild/mod rectocele [prolapse of posterior vaginal wall with bowels) "No obvious cystocele (prolapse of anterior vaginal wall with the bladder) and "No uterine prolapse. She believed, mistakenly, that the vulva and vagina were atrophic because the claimant was experiencing such significant pain during the examination.

151. The first defendant recorded a four-stage plan contemporaneously. The first stage was to arrange an ultrasound to check for endometrial thickness.

152. The second stage of the plan was for pelvic floor exercises. That was represented by her shorthand of "PFE". She says that she facilitated this by handing to the claimant a compliments slip with the details of Nora Roberts, the continence nurse specialist, with advice to the claimant to make an appointment with her. She kept the compliments slips in her desk drawer and her usual practice was to hand one to her patient at the consultation. She had adopted this practice because past experience had been that when appointments were made for the patient, there was a high rate of non-attendance. This could be for any number of reasons, including that the appointment might not be covered by their insurance and the patient had found a cheaper alternative, or the patient simply did not wish to have physiotherapy. She had found that when a patient had responsibility for arranging their own appointment, many fewer appointments were wasted.

153. The third part of the plan was "HRT". This was a reference to Hormone Replacement Therapy that had been discussed during the consultation and appears in the body of the notes as well as in the plan. The first defendant said she planned to re-visit this part of the plan after the possibility of cancer had been excluded because it could not be commenced until that had been done.

154. The fourth part of the plan was "Review in 2 – 3 months if not better for ? surgical treatment/exam again". The first defendant says she advised the claimant to make a follow up appointment in 2 – 3 months or sooner if she felt the prolapse was worsening. The first defendant says the period of 2 – 3 months was for the claimant to have the time for pelvic floor exercise treatment.

155. The only other contemporaneous evidence about this consultation is in the letter written by the first defendant to the claimant's GP on the same day as the consultation. This letter (like the others written by the first defendant) was copied to the claimant. It largely follows the clinical notes save that there are two particular matters of note.

156. Firstly, in referring to the claimant's symptoms of stress incontinence, the first defendant wrote, "she had been avoiding jogging <u>and external exercise</u> (my emphasis) due to that." That is consistent with the first defendant's evidence that the three dots she wrote following the word "jogging" in her notes are her own shorthand for "other strenuous external exercise".

157. Secondly, in relation to the plan, she wrote, "… I also will refer her for pelvic floor exercises with our bowel and bladder nurse specialist Nora Roberts…" The use of the future tense in relation to the referral for pelvic floor exercises is relied on by the claimant to support her contention that she was expecting the first defendant to make the referral and physiotherapy appointment. She denies that the first defendant gave her a compliments slip on the day of the consultation with instructions to make her own appointment.

17 August 2016

158. The ultrasound investigation was undertaken just two days later on 17 August when the claimant had a further consultation with the first defendant.

159. The notes from that consultation show that there was increased endometrial thickness found so the plan was to proceed to hysteroscopy and biopsy and to assess the degree of prolapse under general anaesthetic. This is consistent with the reporting letter sent to the claimant's GP the same day.

10 September 2016

160. The examination under anaesthetic on 10 September 2016 was preceded by a consultation the same day.

161. It is common ground that the first defendant agreed she would inform the claimant about the results of the investigation. An appointment was booked for 6 weeks' time.

162. The first defendant wrote to the claimant on 21 September with the good news that the biopsy was normal.

19 October 2016

163. The next consultation with the first defendant was on 19 October 2016. It is agreed that this consultation was around 15 – 20 minutes in duration. What was said and done during this consultation is disputed.

164. It is the claimant's evidence that the first defendant told her that she needed a hysterectomy because the uterus was prolapsed and she needed a bladder repair because of what she understood to be movement of the bladder. The claimant says that the first defendant told her that when she had performed a hysterectomy and removed the uterus, the claimant's symptoms of stress incontinence might become worse. The first defendant told her that as part of the surgery, she would insert TVT tape to manage the risk of any worsening symptoms of incontinence, rather than having to have a second procedure at a later date.

165. The claimant's evidence is that she did not recall any discussion relating to a posterior prolapse repair.

166. The claimant said she was surprised that she was being advised to have three surgical procedures including a hysterectomy; but she trusted the first defendant and took her advice without question. When challenged about why, on her case, the claimant didn't ask about the conservative alternatives that had been suggested at previous consultations (including as is common ground, treatment for prolapse using a pessary), she said, "I trusted her advice and that was it". She denied that she had

actively rejected conservative treatments in favour of surgery. She was pressed about why, if she believed there was to be a referral made for pelvic floor exercises that had not in fact been made, she did not question what had happened. Her response was that she felt "we'd moved on" from the initial conversation about pelvic floor exercises and she did not know that having the referral might mean she would not need to have surgery. She said she expected that if the problem identified was capable of conservative management, that this would have been made clear by the first defendant.

167. She denied that any alternative conservative options for treatment of the prolapse and incontinence were discussed during the appointment on 19 October; or that she was offered the option of doing nothing. Her recollection is that the "whole focus of the consultation was on having surgery". She denied that there was any further detailed discussion about incontinence symptoms. She accepted that the possibility of two separate operations was mentioned (treating the prolapse followed by review and treatment of any worsened incontinence) but that the first defendant's advice was to treat the incontinence as part of a single operation.

168. The claimant denied that the first defendant gave her any information leaflets or other written material or discussed any risks of surgery with her. She denied that the first defendant drew her the diagram that appears in the clinical notes or that there was any discussion between them using the diagram as an aid.

169. It is the claimant's recollection that the only reference to risk was as she was leaving the consultation when the first defendant said something about "a couple of lawsuits in America to do with the tape but nothing to worry about". She took this as a throwaway remark which did not cause her concern. She denied any suggestion or advice to undertake any online research about this.

170. Although the claimant recognised that there would be some risk associated with any surgical procedure, she said she accepted the first defendant's advice without further question. That was because she expected the first defendant to bring to her attention any real risks and reasons not to proceed as proposed and she had not done so.

171. The first defendant's evidence about this consultation is different.

172. She said she reassured the claimant about the biopsies being benign as she had informed her in writing some weeks previously.

173. She said the claimant told her she felt uncomfortable with the prolapse and wanted a surgical solution for it. She was also complaining about leakage of urine on jogging and sneezing and wanted a surgical solution for these problems too.

174. The first defendant maintained that the reference to "Risks and benefits" ticked in her contemporaneous record is shorthand for a discussion of the range of treatment

options and their respective risks and benefits. This would have included the option to have pelvic floor exercise physiotherapy. She said it is her usual practice to re-visit all alternatives to surgery, even if they have been previously rejected because a patient might change their mind. She said, "I would not have gone on to surgery without going through these options again as part of the risks and benefits as ticked on the clinical notes."

175. In her witness statement she identified a high success rate as the intended benefit of surgery to correct prolapse and stress incontinence. She said, "I always explained the usual risks of surgery including bleeding, infection, deep vein thrombosis, narrowing of the vagina, recurrence of prolapse and stress incontinence, bladder instability and urinary retention, narrowing of the vagina leading to dyspareunia, groin pains and thigh pains."

176. The first defendant's evidence, based on her usual practice, is that she would check whether the patient had seen a specialist for pelvic floor exercises and if not, ask the reason why; but ultimately would accept the patient's reasoning and wishes. She would not have documented all of this detail because she regarded it as implicit in the reference to "Risks and benefits" in accordance with her normal and routine practice.

177. It is the first defendant's evidence that the claimant was "adamant" that she wanted something more than a conservative solution for her symptoms. In support of this position, the first defendant relies on the terms of the letter she wrote contemporaneously to Dr Glynn (copied to the claimant) on the day of the consultation. She wrote, "She feels uncomfortable with the prolapse and would like something done about it and so I booked her for vaginal hysterectomy and repair together with tension free tape as she does have stress incontinence on jogging and sneezing." The reference to "would like something done about it" was her way of describing the claimant's insistence on a surgical solution and she intended it to refer to both the prolapse and stress incontinence.

178. The first defendant's evidence is that she had a full discussion about the surgical option. She says she explained the rationale for performing a hysterectomy followed by an anterior prolapse repair because this prolapse was significant. The posterior wall prolapse was not as bad so her plan, as she said she explained to the claimant, was that she would decide whether to proceed with the posterior prolapse repair during surgery, and would only do so if it was achievable without unacceptably narrowing the vagina. It would not definitely form part of the operation but was contingent on her assessment during the operation. She said this was understood by the claimant.

179. While explaining the surgical procedures the first defendant says she drew a diagram to assist the claimant to understand what would be involved. That diagram is part of the clinical note. Its appearance is of a diagram that has evolved through

discussion rather than a diagram prepared in advance or after the event. The diagram in its current form requires commentary to be understood. That is because parts of the diagram have been drawn and then drawn over again to show, for example, how the surgical procedures would address the claimant's symptoms. The first defendant says that the diagram was used as a tool to demonstrate to the claimant the mechanism causing incontinence, the areas of prolapse that had been found on examination, and how an anterior repair would push the bladder back and provide support from the surrounding structures. The diagram does not show a posterior repair, although the first defendant says this was discussed in the terms set out above.

180. The first defendant's evidence is that she wanted to show the claimant (in a two-dimensional image) how the TVT tape differed from TVT-A tape. She says that she explained that whereas the former travelled upwards retropubically, the tape she proposed would be placed sideways and forward. She said that she had to explain that with reference to the diagram because she knew that she only had brochures about TVT tape and not TVT-A tape; and she wanted to ensure that the claimant understood that the tape she was talking about using was different from the tape in the brochure. That was particularly important because TVT-A tape was an advancement on other tapes. It was shortened so that the mesh would not go beyond the obturator membrane into the thigh or groin muscles, thereby reducing the potential for thigh and/or groin pain and she wanted to explain this to the claimant.

181. She said she was clear about the precise tape she intended to use. She had written "TVT-A" in the clinical notes. It was not her practice to speak generically about "tape" and she would have been specific about using TVT-A tape, particularly because it was an advancement on other types of tape and to differentiate it from the tape described in the brochure.

182. The first defendant said she gave the claimant brochures – one on each of the surgical procedures discussed, (save that the tape implantation brochure was for TVT and not TVT-A tape.) The reference to "EIDO" which is ticked in her notes is to patient information leaflets. EIDO produces brochures which are considered to be the "gold standard" for patient information leaflets. The first defendant said she had them in her consulting room to hand out to patients during a consultation. She was clear in her evidence that she would not have ticked on her clinical notes to show that this had been done if it had not.

183. If provided to the claimant, it is not disputed that these patient information leaflets clearly inform about the treatment options and advantages of pelvic floor exercises.

184. The first defendant says that as part of her "risks and benefits" counselling, she explained to the claimant that there was ongoing litigation in the USA involving patients who had had complications from tape insertion. She said that she had prepared a printed slip of paper with a list of websites dealing with this litigation that

she routinely gave to patients who were contemplating vaginal mesh surgery. The first defendant said she was very well aware of the advice from the British Society of Urogynaecologists ("BSUG") that patients should be alerted to the ongoing litigation and that subject to providing that information, the view of BSUG and of NICE was that use of vaginal mesh tape could continue. The list of websites was provided to the claimant (and to other patients of the first defendant who were contemplating mesh implantation) so that the patient could undertake further research if they wished to.

185. The first defendant agrees that the claimant was told that by correcting the prolapse the incontinence might worsen, but this was after the claimant had said she wanted a surgical solution for the existing incontinence and not to encourage her to have an incontinence procedure in contemplation of this potential contingency.

186. It is common ground that the first defendant did not discuss with the claimant the possibility of her undertaking UDS before being booked for surgery. I address the implications of this later in this judgment.

20 December 2016

187. The claimant attended a pre-operative assessment with a nurse on 20 December 2016. She accepts that at that appointment she was given four patient information leaflets – one for each of anterior prolapse repair, posterior prolapse repair, hysterectomy and use of TVT tape. As Christmas was approaching the claimant said she did not read them immediately but sat down with her husband and read them after Christmas, but before the date of surgery.

188. The claimant accepted that each of the leaflets (which dealt with each procedure respectively) referred to pelvic floor exercises as an effective non-surgical treatment likely to lead to improvement in symptoms.

189. Mr Biggadike recalled reading the leaflets with his wife. He did so to try and understand what the surgery would involve and its risks. He had not attended any of the consultations or read the first defendant's letters to his wife. He wanted to support his wife "in whatever she wants to do". She had told him that she needed an operation. Although his inclination was towards conservative treatments, he did not question the plan or raise any query about the conservative options that he agreed were set out in the leaflets they read together.

14 January 2017

190. The claimant's first surgery was on 14 January 2017 (an earlier date in November having been changed at the claimant's request).

191. It is common ground that prior to surgery the claimant met with the first defendant on the ward and signed a consent form. The procedure was described as "vaginal hysterectomy, repair and tension free tape (TVT-A). The "intended benefits"

were listed as "To correct prolapse & stress incontinence". The "significant, unavoidable or frequently occurring risks" were listed as "Infection, Bleeding, deep vein thrombosis, injury to surrounding structures, Mesh erosion, urinary retention, Bladder instability".

192. The form is countersigned by C. Musseu, a registered nurse. All of the standard form boxes indicating consent and understanding have been ticked.

193. The claimant denied there was any discussion with the first defendant about the risks of surgery or whether she had read the leaflets. She did not recall any second stage of the consenting procedure involving the presence of a nurse. She said that by this stage she was "geared up" for surgery.

194. The first defendant's evidence is different. She says the reference to "repair" was deliberately non-specific. That was because she did not know whether she would perform a posterior repair until she had completed the anterior repair and could decide whether she could repair the posterior prolapse without unacceptably compromising the vaginal area. She said this had been explained to the claimant on 19 October and she explained it again on the day of the operation. She checked that the claimant had read the patient information leaflets about the procedures because that was in accordance with her invariable practice. She had a conversation with the claimant about the risks of surgery. She accepted that other risks could have been recorded on the consent form (chronic pain, dyspareunia and groin and thigh pain) but she was clear that these had been discussed with the claimant at the appointment in October, well in advance of the day of surgery.

Reliability of evidence

195. There are some important areas in which the reliability of the claimant's recollection is demonstrably flawed.

196. The first and very important area is her change of evidence in relation to whether there was a discussion of PFE on 15 August. The allegation that this was not mentioned at all formed a very significant part of her original case. It was not an incidental or minor issue. Her case has moved from a complete denial that this was mentioned at all to a positive assertion that she was expecting the first defendant to make a referral for her for PFE.

197. Secondly, I reject her assertion that she was not shown and talked through the diagram sketched in the clinical notes of this consultation. Mr Robinson confirmed that the only purpose for drawing a diagram of this type is for the clinician to use it as an explanatory tool in discussions with a patient. It has no utility otherwise. The sketch is plainly a "living diagram" which has evolved through discussion. It is not credible that the claimant was not talked through this as an aid to understanding what some (at least) of the proposed surgical procedures involved.

198. Thirdly, the clinical notes of 19 October record "EIDO" with a tick. I cannot accept that the first defendant would have made this note if she had not provided the claimant with at least one EIDO patient information leaflet. While there is every possibility, as the first defendant accepts, that her notes may be incomplete and omit detail (as has been demonstrated by the absence of a reference to treatment with a pessary which the claimant accepts was discussed initially though not recorded in the notes); that is very different from her recording something which did not in fact happen at all.

199. Fourthly, the claimant has no recollection of the second stage of the consenting process on 14 January when she was questioned by a nurse who countersigned the consent form. It is likely that by this stage she was very anxious about the impending surgery, but it is some indication that she did not take in all of the detail of what occurred on that day, including what was said to her by the first defendant.

200. There are other features of the evidence that support the reliability of the first defendant's evidence over that of the claimant.

201. At the initial consultation on 15 August, the plan was for a review in 2 – 3 months' time which was qualified in the notes by a reference to "if not better, [then] ? surgical Rx/exam again". Mr Robinson confirmed that this is consistent with a plan that included a recommendation for pelvic floor exercises because of the timescale for review. It is also consistent with a recommendation for conservative treatment in the interim because of the reference to later consideration of whether the claimant would then be "better".

202. The first defendant has provided a consistent and rational explanation for her established practice of providing a compliments slip with contact details of the continence nurse for patients to arrange their own appointment for pelvic floor exercises. There is no logical reason why she would have departed from it in the claimant's case. Although the first defendant's letter to the claimant's GP is expressed in the future tense, my conclusion is that is more likely due to grammatical error rather than reflecting a variation from her usual practice.

203. The clinical notes of the consultation on 19 October include a reference to "Risks and Benefits" though no detail is recorded. It is inherently unlikely that the only discussion of risk was a throwaway reference to lawsuits in the USA as the claimant was leaving the room. It is much more likely that more was said, and that the claimant has simply not remembered it.

204. The claimant's evidence that there was no discussion about the possibility of a posterior repair is supported to some extent by the reference in the clinical notes for 19 October of "Repair Ant" and the absence of an indication on the diagram of what would be involved in a posterior repair. However, this must be considered in the context of the first defendant's evidence that while she was sure she would undertake

an anterior prolapse repair during surgery, she would only go on to undertake a posterior repair if the vagina would not be unacceptably compromised. This would not be clear until after the anterior repair had been performed. The crucial piece of evidence that supports the first defendant's evidence, that the possibility of a posterior prolapse repair was discussed as part of the plan, is the undisputed evidence that the claimant was provided with a patient information leaflet about posterior prolapse repair procedure on 20 December 2017. This did not prompt any confusion or query from the claimant at the time of the pre-operative assessment or later when she sat down to read it.

205. The claimant's evidence is that the first defendant referred only to "TVT tape" and not to "TVT-A". The claimant said she did not know about different types of tape and denied there had been any discussion with the first defendant about TVT-A tape being shorter and associated with fewer complications. The accuracy of this recollection is undermined by the clinical note that refers to "TVT-A" and the diagram. Although imperfect, the diagram does show a wavy line rising upwards diagonally and a much shorter horizonal line under the urethra. The first defendant's evidence was that the longer diagonal line was intended to demonstrate a TVT tape and the short line was to demonstrate the TVT-A tape. She said it was important to explain that the TVT-A tape was shorter and would not go into the thigh and groin muscles so that it was more likely that any thigh and/or groin pain would be reduced or prevented.

206. The first defendant does not dispute that a better view of the difference between the tapes could have been given by a second drawing from a front to back perspective (rather than only the side view she drew). But the importance of this aspect of the diagram is that it supports the first defendant's evidence that she gave the claimant an explanation of what a TVT-A tape was and its mechanism.

207. The consultation of 19 October was particularly important in the context of this case because it took place some weeks after the claimant had received reassurance about a cancer diagnosis and when she initially committed herself to a surgical solution for symptoms of prolapse and incontinence. Taking the factors above that relate only to the consultation of 19 October, they support the conclusion that the claimant's recollection of what was said and done during that consultation is significantly flawed.

208. In those circumstances and notwithstanding the limitations of the clinical records, the claimant does not persuade me that the first defendant failed to follow her usual practice. That would have included re-visiting of previously discussed conservative treatments (including pelvic floor exercise treatment) and providing a full and sufficient explanation of the risks and benefits of a surgical solution, as she sets out in her witness statement and has maintained through her oral evidence.

209. There is a significant difference between the claimant and the first defendant on the issue of the extent to which the claimant reported her symptoms of stress incontinence to be troublesome and how she wanted them addressed. The claimant has maintained that they were very mild, nonintrusive and that she was led into a surgical solution because of the likelihood that repair of the prolapse would make her symptoms worse. The first defendant maintains that although the claimant's symptoms of incontinence were not of the most serious, they were sufficiently troublesome for the claimant that she wanted a surgical solution for them, quite apart from the risk that the repair of the prolapse might worsen them. The first defendant's position is that she judged the significance of the symptoms by the subjective perception of her patient and not by an objective standard applied paternalistically by a doctor.

210. The features of the evidence that support the claimant's position are the objectively mild nature of the symptoms, the fact that they did not cause her to make any complaint to her GP until the episode of post-menopausal bleeding when they are described as "slight", and the reference in the clinical notes of 15 August to "S. I. on cough & laughing not very bad (my emphasis) avoids jogging …" The first defendant accepted that "not very bad" were the words used by the claimant at the time.

211. The position taken by the first defendant is supported by these matters. When the claimant first consulted her GP, Dr Glynn recorded the comment "refer to gynae for further investigation and query TVT or vaginal pessary (my emphasis)". The claimant's evidence was that there had been a discussion with the GP at this consultation about treatment of incontinence. Even at that early stage it was not being treated dismissively.

212. The reference to "avoids jogging …" was said by the first defendant to be shorthand for "jogging and similar activities". That is consistent with her letter dated 15 August to Dr Glynn in which she wrote that the claimant had been avoiding jogging and external exercise due to stress incontinence. The first defendant describes the claimant as being a very "sporty" person. She was aged only 51 at the time. Her witness statement dated 10 March 2021 confirms her enthusiasm for sport. At paragraph 85 she said, "I was a huge sport and fitness fanatic before the surgery. It was a big part of my life." It is likely in that context that the symptoms of stress incontinence were having an impact on aspects of her life that were important to her.

213. The clinical note on 19 October, after the claimant had known for some weeks that the investigations had ruled out a cancer diagnosis, records "…TVT-A [because] leaks on jogging, sneezing fit". This contemporaneous note is more consistent with a discussion of current stress incontinence symptoms and how they would be treated, rather than a justification for surgery that was primarily prophylactic. It supports the first defendant's evidence on this issue.

214. It has always been a central part of the claimant's case that had she been offered PFE she would have followed this up to treat her symptoms. That supports the conclusion that the claimant did feel that her symptoms were sufficiently intrusive that she wanted some treatment for them (albeit she maintains not a surgical one).

215. For the reasons set out above, I am persuaded that pelvic floor exercises were recommended on 15 August and time allowed prior to review for this treatment to be pursued. Patient information leaflets advocating pelvic floor exercises as an effective treatment for stress urinary incontinence (and to treat prolapse symptoms) were given to the claimant on 19 October and again on 20 December.

216. My conclusion is that the most likely reason for the claimant proceeding to surgery for these symptoms is that her preference at that time was for a surgical solution. That is consistent with what the first defendant said she intended to convey in her letter to Dr Glynn dated 19 October in which she said the claimant "feels uncomfortable with the prolapse and would like something done about it and so I booked her for vaginal hysterectomy and repair together with tension free tape as she does have stress incontinence on jogging and sneezing." Although the terms of the letter referred to wanting something done in the context of the prolapse, the first defendant said she intended this to apply also to the incontinence. When the claimant was asked about this, there was this exchange:

Q: You were looking for a surgical solution.

A: Not necessarily.

Q: You weren't happy with conservative treatment.

A: No – "wanting something done" doesn't mean surgery.

217. The ambivalence at the start of this exchange supports the first defendant's account. While "wanting something done" in the abstract does not necessarily mean non-conservative treatments, in the context in which it was used, it cannot reasonably be understood to mean anything different from a surgical option.

218. Further, her evidence that she was motivated to have surgery only because of the risk of her stress incontinence worsening is undermined to an extent by her acceptance that the first defendant raised the possibility of the claimant having the prolapse repair first, followed by an incontinence procedure in a second operation. Although the claimant's evidence was that the first defendant advised her to have it all done at one time to "save me coming back", her rejection of a "wait and see" option offers some support for the first defendant's evidence, that the claimant felt her current symptoms justified surgical intervention.

219. I accept that Mr Biggadike was given the impression from the claimant that she needed surgery. However, he did not attend any appointment with her and did not

read the copy letters from the first defendant to the claimant's GP. By the time they were sitting down and reading the leaflets sometime after Christmas 2016, the claimant may well have made what she felt was her final decision to proceed to surgery and presented it to her husband in this way. His focus was in supporting her whatever she chose to do, rather than interrogating her thought process. I therefore regard this piece of evidence as neutral.

220. I prefer the first defendant's evidence about what was said and done during the consultations and on the day of surgery. My key factual findings are therefore as follows.

Key findings

221. At the consultation on 15 August the first defendant advised the claimant about effective conservative treatments including pelvic floor exercises (and a vaginal pessary). The first defendant gave the claimant a compliments slip with the details of Nurse Nora Roberts (as was her normal practice) with the recommendation that the claimant make direct contact with her to arrange for supervised pelvic floor exercises. The period of review proposed in that consultation was to allow time for the claimant to pursue this treatment for 2 – 3 months to see whether her symptoms resolved.

222. The claimant chose not to contact Nurse Roberts or pursue pelvic floor exercise treatment elsewhere.

223. It has been argued on behalf of both the claimant and the first defendant that the claimant's previous experience of PFE in 2000 would have informed her thought processes. The real importance of the earlier treatment is the claimant's undisputed knowledge of what PFE entailed. Her circumstances in 2016/17 were very different from 2000 when she had just had a baby. She had a different range of medical problems. She had different domestic pressures. Her evidence was that she did not connect her current circumstances with those in 2000. There is no reason to think that she would necessarily have chosen the same type of treatment in 2016 for symptoms of incontinence as she chose in 2000.

224. By 19 October 2016 the claimant had known for several weeks that the episode of post-menopausal bleeding that had been the initial focus of her concern had resolved. I find that she wanted a surgical solution for her symptoms of stress urinary incontinence. Although objectively mild, they interfered with her lifestyle to an extent she found intrusive. She made that clear to the first defendant.

225. At that consultation the first defendant gave the claimant an explanation of what surgery was intended to achieve with the aid of a diagram she sketched as she spoke. She explained each of the procedures proposed and its intended benefit, but with the caveat that the posterior prolapse repair would only be undertaken if, after the repair of the anterior prolapse, it could be achieved without unacceptably compromising the

vagina. She informed the claimant about the material risks associated with surgery and the availability of conservative options, including PFE. She gave the claimant a copy of four leaflets produced by EIDO, each relating respectively to each of the surgical procedures planned – hysterectomy, anterior prolapse repair, posterior prolapse repair and implantation of tape. She explained the difference between the tape she would be using, TVT-A, from the tape referred to in the leaflet because she did not have a leaflet for TVT-A tape. She also followed BSUG guidance by alerting the claimant to litigation about mesh implantation in patients in the USA. She gave the claimant a slip of paper with website addresses for the claimant to follow up through personal research.

226. She did not offer the claimant urodynamic testing or explain why she was not doing so.

227. On 20 December 2016 the claimant was given a second copy of each of the leaflets. She read them prior to surgery. Each leaflet contained an accurate summary of the risks and benefits of the surgery proposed. Each leaflet included information about the effectiveness of PFE as a conservative treatment.

228. On the day of surgery there was a further discussion between the claimant and the first defendant. The first defendant checked that the claimant had read and understood the leaflets about the various procedures planned and there was a further short discussion about the principal risks associated with the operation.

229. The consent form was deliberately non-specific about the "repair" that would be undertaken. This was because it was understood by the claimant that the decision whether to proceed to a posterior prolapse repair would be taken only after the anterior prolapse repair had been performed.

230. The consent form did not contain a complete list of relevant risks. There had been a full discussion of risks during the consultation on 19 October 2016 which identified all those listed in the first defendant's witness statement and which were material in accordance with her usual practice.

231. The consent form was countersigned by a nurse after the claimant's understanding was checked.

Has the claimant proved breach of duty on the part of the first defendant?

Pelvic floor exercises

232. The relevant part of the NICE Guideline CG171 recommended as follows:

1.3.1 Offer a trial of supervised pelvic floor muscle training of at least 3 months' duration as first-line treatment to women with stress or mixed UI.

233. I am satisfied this was done and the duty discharged.

234. Ms Power argues that "offer a trial" carries with it an obligation to follow up the offer of pelvic floor exercises to see how the patient was progressing.

235. I am satisfied that it is more likely than not that the issue of pelvic floor exercises was re-visited during the consultation on 19 October 2016 as part of the first defendant's risks and benefits counselling. It is not specifically recorded in the clinical notes. Although I accept that it would have been good practice to record the patient's reasons for rejecting conservative treatments, the absence of this record is not sufficient to prove to me that it did not happen in this case. Firstly, the quality of the claimant's recollection of this consultation is poor. Secondly, there is positive evidence that the first defendant did not record all of the detail of conservative treatments discussed. It is common ground that at some stage she talked to the claimant about treatment with a vaginal pessary, but this does not appear in the notes at all.

236. I accept the first defendant's evidence that it is her standard practice to re-visit the possibility of conservative treatments ("in case a patient has changed their mind"). I accept that on the balance of probabilities she followed her usual practice in this case and the claimant chose to pursue a surgical solution.

UDS

237. The relevant section in the NICE Guideline CG 171 provides as follows:

Urodynamic testing

1.1.19 Do not perform multi-channel cystometry, ambulatory urodynamics or videourodynamics before starting conservative management

1.1.20 After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry before surgery in women who have:

- *Symptoms of OAB leading to a clinical suspicion of detrusor overactivity,* ***or***
- *Symptoms suggestive of voiding dysfunction* ***or*** *anterior compartment prolapse,* ***or***
- *Had previous surgery for stress incontinence.*

1.1.21 Do not perform multi-channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination.

1.1.22 consider ambulatory urodynamics or videourodynamics if the diagnosis is unclear after conventional urodynamics.

238. NICE Guideline CG171 also contains a section headed "Strength of recommendations." It distinguishes between those interventions that coincide with a legal duty or where the consequences of not following the recommendation could be extremely serious or potentially life threatening where "we usually use 'must' or 'must not'"; interventions where "we are confident that for the vast majority of patients, an intervention will do more good than harm, and be cost effective" where "we use 'offer' (and similar words such as 'refer' or 'advise')"; and interventions where "we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective" where "We use 'consider'". In this last category of recommendation, the choice is said to be more likely to depend on the patient's values and preferences than for a strong recommendation.

239. The first defendant accepted in evidence that the claimant's symptoms of stress urinary incontinence which was concomitant with anterior compartment prolapse fell within the scope of the recommendation to "perform" UDS. The first defendant's evidence is that she did not overlook this guidance but made the positive decision that urodynamic testing was not mandated in the claimant's case, based on her holistic assessment of the claimant and her wishes.

240. The first defendant's reasoning was that the patient's symptomology was clear and established. She was experiencing stress incontinence which though mild objectively, was interfering with the claimant's life to a level the claimant found subjectively to be unacceptable. The claimant had been offered but chosen not to pursue conservative treatments. The first defendant did not consider the picture to be complex based on the history she had taken. The claimant had no symptoms of voiding difficulty, obstruction, or overactive bladder, for example. The "occasional nocturia" noted was very unlikely to be anything more than an occasional need to urinate during the night and not significant. It did not indicate detrusor instability or any other complexity. She did not regard the cystocele as a complication.

241. Her view was that there was no need to subject the patient to UDS because the results would add no value to the decision-making process. The claimant had already decided that her stress incontinence symptoms were sufficiently intrusive that she wanted a surgical solution. UDS might show that the incontinence was objectively worse than the symptoms the claimant described, in which case they would support the claimant's decision. Alternatively, they might show very mild symptoms or no symptoms at all. As the claimant had already decided that the incontinence symptoms she was actually experiencing were sufficiently adverse that she wanted a surgical solution for them, UDS would not alter that course. For that reason, the claimant was distinguishable from a patient who wanted only a surgical prolapse repair where the UDS had a role to play in informing the decision-making process about how to address concomitant symptoms of stress incontinence.

242. The first defendant said that even if UDS had been performed and had given a negative result, she would still have accepted the claimant's description of symptoms; albeit she accepted that in that scenario, the negative test result would have prompted a further discussion about whether the claimant did still wish to proceed with surgery rather than explore alternative conservative treatment. She said, "I am not treating the test but the patient. The test guides me on my discussions. If the patient says my symptoms are not that bad but I want this sorted I would not say she is imagining it."

243. She emphasised in her evidence that she always kept UDS in mind. She did not apply the NICE Guideline approach robotically, but assessed whether it was appropriate in the particular case.

The experts' views

Mr Robinson

244. Mr Robinson's written opinion in his first report dated 15 June 2023 at para 126 was:

> *Given her urinary symptoms, and concomitant prolapse symptoms, urodynamic investigations are important to verify a diagnosis of urodynamic stress incontinence before surgery, to exclude underlying detrusor overactivity (which would mean surgery was contraindicated) and also to exclude voiding dysfunction. In addition urodynamic investigations are also useful to exclude "occult urodynamic stress incontinence" which may only be "revealed" following surgery. I would therefore conclude that it was essential to perform urodynamic investigations in order to provide appropriate pre-operative counselling.*

245. In the joint statement the experts were asked (Question 8), "Were the Nice Guidelines (CG171) applicable in considering whether any further investigations were required prior to recommending surgery for stress urinary incontinence for the claimant?" Mr Robinson replied, "NICE Guidelines were applicable. Whilst prolapse was not demonstrated at the initial consultation a large cystocele, second degree uterine descent and a mild/moderate rectocele were identified at EUA. Given those findings urodynamic investigations were indicated."

246. When asked at Question 9 whether any further investigations were required and in particular whether UDS should have been arranged prior to surgical intervention he replied, "NICE Guidelines were applicable and urodynamic investigations were indicated given her urinary symptoms and anterior compartment prolapse."

247. Question 10 asked if the failure to arrange UDS prior to surgery was a breach of duty. Mr Robinson replied, "Given the symptoms of nocturia in addition to stress urinary incontinence and anterior compartment prolapse urodynamic investigations were indicated and this would be in keeping with the NICE Guidelines (CG 171). I

would suggest that failure to perform urodynamic investigations in this clinical situation is a breach of duty."

248. He was next asked what urodynamics prior to surgery would likely have demonstrated and the relevance of subsequent UDS results from 27 June 2018 (video urodynamics) and January 2020 (ambulatory urodynamics). He replied, "I would suggest that had UDS been performed they would have been normal or they may have demonstrated urodynamic stress incontinence. They are unlikely to have demonstrated voiding dysfunction or detrusor overactivity. The subsequent UDS in 2018 and 2020 show no evidence of urodynamic stress incontinence. The claimant has never had any UDS which have shown stress incontinence even after tape excision. It is therefore possible that they would not have shown urodynamic stress incontinence even if they were performed by the first defendant."

249. After the experts met, Mr Robinson added a short addendum to this part of his opinion by way of clarification. He expressed the view that if UDS had been performed it was "probable and more likely than not" (rather than "possible") that they would have been normal and not demonstrated urodynamic stress incontinence. He went on to add that although NICE did not recommend UDS in primary mono-symptomatic stress urinary incontinence, there was substantial disagreement with this approach (80% based on Basu et al 2009) and that 89% of urologists and urogynaecologists continued to perform urodynamic investigations prior to surgery in these cases (quoting Hilton et al 2012). In his oral evidence he said that at his own hospital, a derogation from the current NICE Guideline approach had been granted so that they continued to perform UDS in patients with stress urinary incontinence and no concomitant symptoms even though this was not recommended by the Guideline.

250. In his oral evidence, Mr Robinson made no criticism of the first defendant's history taking on 15 August. At that stage he agreed that little distinguished the claimant's case from one of pure stress incontinence. His view was that after discovery of the anterior prolapse during the examination under anaesthetic on 10 September 2016 there was a significant change and that UDS were then indicated. His rationale was as follows.

251. Firstly, UDS would exclude voiding dysfunction and detrusor overactivity secondary to the prolapse. He did accept that voiding dysfunction was not identified in the history taken by the first defendant (and in his written evidence he had opined that it was unlikely that voiding dysfunction would have been present on testing). He suggested that the "occ [occasional] nocturia" recorded could be an indication of an overactive bladder and possibly detrusor overactivity though readily accepted that the claimant had no symptoms of urgency so the occasional need to urinate during the night could have a range of other causes. In his written evidence he had considered it unlikely that detrusor overactivity would have been present on testing.

252. Secondly, UDS would verify that a patient had stress incontinence. He did accept that a key issue in assessing symptoms of stress incontinence was the impact on the lifestyle of any particular patient. He did agree that the patient's subjective feelings about the presence and level of incontinence would be apparent from the history taken.

253. Thirdly, UDS would determine if the patient had "occult" stress incontinence which was masked by the prolapse and would become symptomatic after correction of the prolapse. The claimant already had overt stress incontinence, but it was objectively mild. If the anterior prolapse was repaired, there was a risk the incontinence would be made worse. Performing UDS where the prolapse was reduced by a pessary to see if the incontinence would worsen after repair, could inform the discussion with the patient before the patient finally decided on a surgical solution.

254. Fourthly, UDS could assist in determining the extent of incontinence. Mr Robinson conceded that it was the impact of symptoms on the patient that was crucial, rather than the significance of any particular quantity or volume as a benchmark. However, his opinion was that if the UDS demonstrated a mild level of stress incontinence, particularly in conjunction with a mild level of symptoms, this would prompt a further discussion of the benefits of conservative treatment for incontinence, even if the patient elected to proceed with a surgical repair of the prolapse.

255. In his opinion no body of responsible clinicians would fail to perform UDS where there was concomitant urinary stress incontinence and anterior compartment prolapse.

Mr Toozs-Hobson

256. Mr Toozs-Hobson took a different view. In his written report dated 20 June 2023 Mr Toozs-Hobson addressed the need for further investigation of the claimant's urinary symptoms at para 8.4. He wrote (at para 8.4.2), "The NICE 171 1.1.21 guidance makes clear that if the sole urinary symptom is stress incontinence, no further investigations are required prior to surgery."

257. In answering the questions raised in the joint statement, he agreed (at Question 8) that NICE Guideline CG171 was applicable in considering whether further investigations were required prior to recommending surgery for stress incontinence for the claimant, but went on to say, "Based on OP [outpatient] assessment further investigations not indicated as prolapse not identified." That was, of course, true for the examination on 15 August but was an incomplete answer because it did not acknowledge the finding of the cystocele on examination under anaesthetic.

258. When answering Question 9 (whether further investigations were required prior to the first defendant advising the claimant as to her treatment options and in particular, whether UDS should have been arranged prior to surgical intervention), he

wrote, "No on BOP [balance of probabilities] would have shown USI and excluded voiding difficulty and detrusor overactivity."

259. When asked in Question 10 whether the failure to arrange UDS prior to surgery was a breach of duty, he replied, "By *Bolam* no as a good body of similar consultants would not do. The general ethos of NICE was not to do with sole symptom of SUI." This answer prompted the suggestion, which he denied, that his opinion had proceeded on an erroneous view of the facts in that he had mistakenly overlooked the presence and significance of the anterior prolapse. He denied this and it is unlikely. His response in the Joint Statement was part of a detailed discussion with Mr Robinson. The finding of the cystocele following the examination under anaesthetic had been expressly addressed by Mr Robinson in answer to Question 8 of the Joint Statement.

260. Mr Toozs-Hobson's written opinion in the joint statement was that if performed, UDS would have shown "USI (excluded voiding dysfunction and DO) in my opinion subsequent UDA [UDS performed on 27 June 2018 and January 2020] not relevant at this point in time."

261. In his oral evidence, Mr Toozs-Hobson did agree that NICE Guideline CG 171 recommended UDS where there was concomitant USI and anterior prolapse. He sought to emphasise that despite providing an interpretation aid to the strength of its recommendations, the terms of the guideline itself did not use that language in the body of the guideline in this context. He did accept though, that no "soft" words were used to qualify the recommendation to "perform" UDS for a patient in the claimant's circumstances.

262. The thrust of his oral evidence was that UDS played an essential role in answering a clinical question. If the answer was already known, then there was no need to perform the test. If, for example, a patient had a prolapse but no symptoms of stress incontinence, then it was necessary to use UDS to determine whether repairing the prolapse would cause incontinence symptoms. But if a patient reported stress incontinence symptoms, then in over 98% of instances that would be confirmed by the findings of UDS. UDS testing would not change the information available for the decision-making process.

263. Here, he said, the relevant question to be asked prior to surgery was whether the claimant had stress incontinence. The answer to that was already known from the history taken by the first defendant. Even if the degree of incontinence was objectively mild, it was for the patient and not the doctor to decide if the symptoms were sufficiently intrusive to justify surgery. Provided the patient understood what was involved, it was then a decision for the patient to make.

264. He answered in his evidence the justifications for UDS relied on by Mr Robinson.

265. He agreed that nocturia could be a symptom of an overactive bladder but considered that was extremely unlikely for the claimant. He was clear that in a woman of the claimant's age, an occasional need to get up during the night to pass urine would be extremely unlikely to indicate an overactive bladder in the absence of symptoms of urgency (which the claimant did not have). It added nothing to the picture.

266. He similarly rejected the suggestion that there was a need for UDS to exclude the possibility of voiding dysfunction. His view was that a clinician of the first defendant's experience could properly infer from taking the claimant's history that she had no voiding difficulties. He drew some support for his view from the fact that as the claimant had not demonstrated voiding difficulties after surgery, it was extremely unlikely that she had any voiding difficulties before the operation.

267. He believed, like Mr Robinson, that UDS, if performed, would have excluded detrusor overactivity and voiding dysfunction.

268. He believed the test would have confirmed the presence of stress incontinence which was already known. It would have shown whether the repair of the prolapse might cause the incontinence to worsen, though would not reliably have indicated the likely degree of any worsening.

269. He disagreed with Mr Robinson's view that if performed, UDS would probably have been normal, and further disagreed that it was appropriate to draw any inference from the results of the post-surgery UDS. Even though in general terms, the risk of incontinence increased with repeated surgery, that ignored the fact that by the time the tape excision was undertaken, 14 months had passed since it had been implanted. The tape was intended to work by forming scar tissue which provided structural support to prevent stress urinary incontinence. Over the course of 14 months, this scar tissue had already formed so that even after the second defendant removed the middle section of the TVT-A tape, the protective effect of the scar tissue remained. He further noted that the ultrasound results showed no mesh erosion (into the urethra or otherwise), but the second defendant's surgical notes from March 2018 referred to a urethral reconstruction and urethroplasty. He understood that to be two separate procedures which suggested to him that a further procedure had been undertaken at that stage to prevent future incontinence.

270. Mr Toozs-Hobson described himself in his own practice as a proponent of UDS. His opinion though, was that it could not be said that no responsible body of clinicians would fail to perform UDS for a patient presenting as the claimant had done. His evidence was that he knew clinicians in his own hospital who would decide that no UDS was necessary in those circumstances. That was because the result of UDS would be confirmatory of what was already known and discussed.

<u>Conclusion on the failure to offer UDS</u>

271. My conclusion is that the failure to perform UDS was not a breach of duty. I prefer Mr Toozs-Hobson's opinion on this issue.

272. When interpreting the relevant part of NICE Guideline CG 171, the language is consistent with the middle category of strength of recommendation. It is stronger than "consider" but short of "must". The recommendation is a strong one in the claimant's circumstances. But it is common ground that NICE Guidelines do not have the force of law, and that a clinician is not necessarily in breach of duty if s/he departs from them. The key question is whether the departure from the recommendation is sufficiently explained and justified in the context of this particular case.

273. I conclude that there is some genuine divergence in approach among clinicians on this issue. There is a responsible body of clinicians (the majority) who would have performed UDS in this case. They would do so to confirm the claimant's symptoms (notwithstanding those symptoms had already been identified from her history); exclude potential contraindications for surgery (even if they were very unlikely); and go on to use the results of the UDS as an additional opportunity to counsel the claimant about the benefits and risks of surgery.

274. But there is also a responsible body who, like the first defendant, would not subject the claimant to the unpleasantness of UDS to confirm what was already established. Rather than commission UDS, those clinicians would rely on detailed history-taking and clinical experience to exclude symptoms of overactive bladder and voiding dysfunction. They would discuss with the patient the risk of incontinence worsening with the correction of a prolapse rather than simulate the outcome through UDS. They would respect the wishes of a patient who wanted to proceed to surgery, even if the symptoms complained of were known to be objectively mild.

275. That group, like the first defendant, would see no "value added" in performing UDS. The results would not influence their treatment plan or offer any real advantage over a detailed consultation.

276. The logic of the latter approach draws support from the view of both Mr Robinson and Mr Toozs-Hobson that there is at least a broad correlation between a patient's symptoms and the results of UDS (Mr Toozs-Hobson would say over 98%; Mr Robinson would say that the more intrusive the symptoms the more likely the UDS would be positive).

277. It also draws some support from the Evidence Review for urodynamic assessment prior to primary surgery for stress incontinence (the 2019 NICE review). Under the heading "Benefits and harms" the review recorded, "The committee noted that urodynamic testing is most likely to be of benefit in situations where the diagnosis was unclear from detailed clinical assessment. This includes … anterior prolapse …In these cases the committee considered that urodynamic testing <u>may</u> (my emphasis)

outweigh the intrusive nature of the test." The use of the word "may" indicates some degree of uncertainty.

278. Under the heading "cost-effectiveness and resource use", the review recorded, "The committee also noted that in most cases urodynamic information rarely changes the primary diagnosis of SUI and only occasionally changes treatment plans and so no treatment benefit is realised. Urodynamic testing does not influence clinicians to cancel, change or modify their planned surgery. …However the committee noted that there may be value in performing urodynamics in more complex situations e.g. if the diagnosis is unclear or if the woman has symptoms of voiding dysfunction, anterior or apical prolapse, or a history of surgery for SUI." While the thrust of this passage is supportive of UDS where there is concomitant anterior prolapse, it does also underline the limited practical impact of the UDS results where surgery is planned to treat stress urinary incontinence.

279. I am satisfied that the first defendant did not overlook UDS but rather took a positive decision not to perform UDS. That was because in her assessment and logically, based on my factual findings, UDS would not have influenced the treatment plan. I am not satisfied the departure from the recommendation in the NICE Guideline was a breach of duty in those circumstances.

What difference would UDS have made?

280. If I am wrong in my conclusion, I have gone on to consider what difference performing UDS would probably have made.

281. Neither expert suggests that overactive bladder or voiding dysfunction would have been disclosed.

282. At that time, the claimant had stress urinary incontinence symptoms. It seems to me likely that UDS would have confirmed mild symptoms commensurate with what she had described. I reject Mr Robinson's reasoning for concluding the likely result would be negative based on subsequent testing; and find Mr Toozs-Hobson's analysis of why the later tests showed no stress incontinence more persuasive. Further, both experts agree that there is a correlation between symptoms and UDS results. In 2016 the claimant had symptoms of stress incontinence. It is more likely than not that UDS testing would correlate with those symptoms. When she underwent UDS testing much later, she did not have symptoms of stress urinary incontinence. The UDS results then were consistent with her being asymptomatic at that time.

283. If the first defendant had arranged for UDS before surgery, the results would have been reported and there would then probably have been a further discussion with the claimant about the risks and benefits of a surgical solution compared with conservative treatments.

284. Having found the claimant wanted a surgical solution because she found her level of symptoms intrusive, it is unlikely her view would have changed when the UDS confirmed what she already knew. At that stage, before she experienced her post-surgery difficulties, she was likely to have been optimistic about the prospects of success of surgery. Further discussions with the claimant might well have resulted in a further short delay before surgery was undertaken (although it had already been deferred by a couple of months at the claimant's request); but it is more likely than not she would still have come to surgery well before the pause in use of vaginal tape in 2018.

Informed consent

285. I have preferred the first defendant's account and accepted her evidence about what was said and done during the consultation on 19 October for the reasons set out above. It follows from those factual findings that the claimant was sufficiently informed about the extent and nature of the procedures involved in a surgical solution; there was a full and sufficient discussion about the material risks and benefits of surgery (which included a re-visiting of the alternative options of pelvic floor exercises and other conservative treatments); and the claimant was provided with appropriate and sufficient patient information leaflets about each of the surgical procedures and possible alternative treatments.

286. That was sufficient to discharge the *Montgomery* duty. In those circumstances, the admitted omission of some risk factors on the consent form signed by the claimant on the day of surgery is of no consequence.

287. Ms Power argues that the failure to inform the claimant that the first defendant was not following NICE guidelines for UDS prior to surgery renders the consenting process defective. Mr Toozs-Hobson expressly rejects that suggestion. When addressing the consenting process in the Joint Statement, whatever his views about compliance with the NICE Guideline, neither expert suggested that the absence of discussion about UDS was a material issue that had an impact on the consenting process. I therefore reject Ms Power's submission on this point.

288. I am satisfied that the first defendant discharged her duty to obtain informed consent from the claimant to the surgery she performed.

The claim against the second defendant

289. There are two parts to the claim against the second defendant.

290. The first part arises from a late amendment to allege that the mesh excision was in breach of duty because it was not justified. It was always part of the Defence of the first defendant that this was a breach of duty owed by the second defendant to the claimant that was sufficient to break the chain of causation between any proven negligent act or omission on the part of the first defendant and any loss and damage

sustained by the claimant after the mesh removal. However, it was not until the start of the trial that this allegation was adopted by the claimant. The second defendant asserts that mesh excision was clinically indicated, and should have been performed at a much earlier stage, when the claimant was still under the care of the first defendant. It is not alleged by the claimant that the second defendant failed to obtain her informed consent to mesh excision.

291. The second part relates to the colposuspension procedure which was undertaken as part of a second surgery performed by the second defendant on 28 July 2018. The claimant alleges that the second defendant was in breach of duty in undertaking this procedure because it was not clinically justified; and that her informed consent to it was not obtained.

292. Before turning to each of these issues, I have considered how I should approach the second defendant's allegation against the first defendant.

Was there a culpable failure to excise the mesh on the part of the first defendant?

293. This is not a part of the second defendant's pleaded case and there is no expert evidence to support it (albeit I recognise that the position might have been different if the amendment had been made at an earlier stage.) The allegation relies on these propositions drawn from the claimant's description of her post-operative symptoms and an article co-written by Mr Toozs-Hobson (Managing pain after synthetic mesh implants in pelvic surgery):

a. the claimant was reporting disproportionate symptoms immediately following the first defendant's surgery;

b. immediate pain which is highly disproportionate is an indication of direct injury;

c. removal of the mesh at this stage is straightforward and symptoms usually resolve;

d. the claimant was also reporting disproportionate symptoms at 6 weeks or so after surgery;

e. delayed presentation of pain symptoms at 6 weeks to 3 months after surgery is an indication of nerve compromise from tape implantation;

f. excision of tape at this stage results in resolution of pain in 60 – 90% of cases.

294. When Mr Toozs-Hobson was asked about the validity of this analysis he drew attention to the disparity between the claimant's reported symptoms and the contemporaneous records of the claimant's symptoms of pain.

295. He is right to do so. The contemporaneous records from the nursing team when the claimant was an inpatient do not reflect her evidence about the level of pain she experienced immediately following surgery. It is recorded, for example, that on the first two days following surgery pain was assessed by the claimant as "within acceptable range according to pain scale (0-3 on 0-10 scale)". She was then discharged home.

296. The contemporaneous records from the first defendant do refer to complaints of pain, mainly when opening her bowels, but this part of the first defendant's evidence was not explored during cross-examination. She did not have the opportunity to comment, for example, on whether the claimant's presenting complaints were in fact disproportionate, which is an essential foundation for the propositions advanced on behalf of the second defendant. That is particularly significant when considered in the context of her reporting letter to Dr Glynn dated 1 March 2017 when she wrote, "She had an uneventful recovery but started to work over the last few days and started to have stabbing pains."

297. The suggestion that there might have been a culpable failure to remove the mesh was not suggested to the first defendant. No questions were asked of her at all on behalf of the second defendant.

298. In those circumstances there is no sufficient evidential basis from which to conclude that there was any culpable failure on the part of the first defendant to remove the mesh she had implanted and I do not do so.

Background to the mesh excision – the claimant's perspective

299. There is no dispute that the claimant sought a referral to the second defendant from her GP after she was alerted by her sister in about September/October 2017 to a radio programme about vaginal mesh. She also researched and joined the "Sling the Mesh" online group. She describes in her witness statement a range of symptoms that by that time she suspected were caused by the mesh. She was referred to the second defendant by her GP on 8 November 2017.

300. The claimant attended an initial consultation with the second defendant on 2 February 2018. The second defendant's contemporaneous notes of that consultation and report to the claimant's GP record the claimant complaining of soreness in her groins, pain in her hip, back pain, a buzzing sensation, aching legs and nerve pain. She had symptoms of "sexual dysfunction".

301. The claimant's evidence is that she immediately felt at ease with the second defendant and felt that the second defendant would be her "saviour". The claimant firmly believed that her ongoing symptoms were due to the mesh. She felt those suspicions were confirmed when the second defendant told her that on examination she could feel the mesh and it was "close to eroding". The claimant described feeling

very emotional when told this. The second defendant then provisionally arranged mesh excision surgery for the claimant.

302. The second defendant arranged for ultrasound tests which were reported to the claimant on 16 March 2016 by letter. They showed that the mesh was in the mid urethra and was not eroding. The claimant did not speak to the second defendant to discuss the ultrasound results prior to surgery on 20 March 2018. However, she says she believed that the mesh was the cause of her current pain, was close to eroding (albeit not yet eroded) and not placed correctly. She had been told by the second defendant there was a possibility she might have had an adverse reaction to the mesh and that after the first surgery this would be investigated with histology.

303. The second defendant came to see the claimant immediately after surgery. The claimant understood from her that she had removed some of the mesh but that she would need further mesh removal surgery and possibly a colposuspension.

304. The results of histopathology were reported to her by letter dated 31 March 2018 as a "foreign body giant cell reaction and fibrosis". The claimant's understanding of these results was that she had reacted badly to the mesh and an adverse reaction was contributing to her symptoms. The second defendant wrote to her GP on 14 April 2018 to report "She obviously has an allergic response to the mesh …" which served to confirm the claimant's fears.

305. By June 2018 the claimant was very unwell with other symptoms, including sweating and shortness of breath. She had lost weight. She was referred to Dr Abu-Sitta, a consultant haematologist. He wrote to the claimant's GP on 20 June 2018 following her appointment to say, "I suspect the Thrombocytosis and Eosinophilia are reactive to the inflammation in the pelvis. The treatment would be to treat the underlying cause and I believe she is going to have major surgery to remove the mesh completely on 10th July". This further reinforced the claimant's belief that the mesh was making her very ill.

306. The claimant accepted in evidence that there was no doubt she wanted the mesh removed. She had believed the second surgery would achieve that. After the entirety of the mesh had still not been removed after the second excision procedure, and despite the problems the claimant had experienced due to the surgery itself, she continued to pursue further procedures with a view to removing the residue of the mesh. The advice she had received was that no further mesh excision could be carried out safely. She said in oral evidence that had she not received this advice, she would still have wanted the mesh completely removed and undergone further procedures to achieve this.

307. She was asked, on behalf of the second defendant:

Q: Even if Professor El-Neil had not begun the two stage mesh removal process in March 2018, you would have pushed to get the mesh out, especially after the histology report?

A: Yes, I think I would.

Has the claimant proved that the second defendant was in breach of duty by performing mesh excision surgery on 20 March 2018?

308. The second defendant's position is that the removal of the mesh was a reasonable treatment option.

309. Her evidence and contemporaneous clinical notes are consistent that she could feel the edge of the mesh on examination on 2 February 2018. Her oral evidence is that the claimant was complaining of pain in an area corresponding with the area in which the mesh could be palpated and which was consistent with the mesh being a significant component in its causation. The second defendant said she observed the claimant having difficulty walking. That is consistent with the symptoms of which the claimant was complaining and which were recorded contemporaneously. She described the claimant being in distress, which accords with the claimant's own evidence. She said the claimant had already tried management of her pain symptoms conservatively.

310. The second defendant was challenged about whether instead of mesh removal she ought to have performed less invasive surgery to treat the claimant's symptoms by dividing the vaginal adhesions caused by the prolapse repair. Her response was that the adhesions were detected at the time of surgery and in her view were not the only cause of the claimant's symptoms. Based on her own extensive clinical experience of mesh excision, she said there was a difference in outcome when a division of adhesions was attempted in patients with and without vaginal mesh. In the absence of mesh, she agreed it was a reasonable first step, "you can probably just do that and hope for the best". For patients with implanted mesh, she said, the position was different. She had found that in that patient group there was a high risk of infection and worsening pain, because after the release of adhesions the mesh became exposed even if not exposed at the outset. In that patient group the prosthetic material of the mesh caused a dense inflammation, so the division of adhesions alone was not a sufficient solution.

311. In any event, she said she had carried out a division of adhesions as part of the operation in March. That had not in fact resolved the claimant's symptoms. If the mesh removal had not been commenced during that operation, it would simply have been deferred and the claimant would have had to face yet more surgery.

312. The letter written by the second defendant reporting the surgery to the claimant's GP is consistent with this evidence. The second defendant reported finding adhesions in the vagina. She describes finding "a huge amount of inflammatory tissue".

313. Following late amendment of the claim, Dr Sokolova was asked to consider the issue of mesh removal for the first time at trial. She acknowledged her own limited experience of mesh removal when giving her evidence, but made some observations having heard the second defendant give her evidence.

314. In assessing the second defendant's approach, Dr Sokolova attached weight to the claimant's complaints of pain, and inability to have vaginal intercourse. Although the mesh had not eroded, it was felt, on examination, to be close to the vaginal skin. The second defendant had found a correlation between the area of palpation that elicited pain and the position of the mesh. This all supported the conclusion that it was likely there was an association between the mesh and the claimant's symptoms.

315. She further noted that the decision-making would have had to be informed by the claimant's preferences and priorities; and the level of surgical risk and risk of complications that was acceptable to the claimant. If the claimant wanted the mesh removed and the clinical presentation was one of pain (with other symptoms), then excision of the mesh was a reasonable treatment option. While she accepted the general principle that it was preferable to undertake a less invasive procedure wherever possible, she observed that it was a necessary part of the balance to consider the likely benefit from a less invasive procedure and the patient's expectations.

316. Mr Toozs-Hobson was critical of the decision to remove the mesh and of the consenting process for surgery on 20 March. The latter does not form any part of the claimant's case against the second defendant.

317. In his written report, he suggested that the claimant's symptoms should have been explored in more depth and that less invasive options should have been considered. He suggested it would have been reasonable to consider doing nothing; or undertaking conservative management through physiotherapy (for her musculo-skeletal symptoms) and using vaginal dilators with the option of vaginal oestrogen; or by releasing any vaginal constriction. He suggested as a further lesser alternative to extensive excision, "and even if the tape were tender (which is not documented), local excision of the focal area of tenderness as well as the complete removal of the vaginal component" (para 8.10.6 of his report).

318. At para 8.10.11 of his report he wrote, "In the absence of documented local pain or extrusion of the mesh, the options of more conservative surgery should have been discussed and offered …"

319. In addressing this issue in the Joint Statement, he and Mr Robinson agreed that the reasonable treatment option for the claimant was a division of adhesions within

the vagina and subsequent review. They opined that this procedure was likely to have substantially improved the claimant's pelvic discomfort. The decision to remove the tape in the first instance amounted in their joint opinions to a breach of duty.

320. In oral evidence Mr Toozs-Hobson's view was that the division of vaginal adhesions could have been performed without affecting the integrity of the mesh. It was suggested to him that in view of the symptoms of pain elicited along the line of the mesh on examination and of "female sexual dysfunction", the excision of the mesh was a reasonable option. His response was, "A mesh excision should be discussed but it is the nuclear option because once removed it cannot be reinstated. It is within the range of possibilities and there is a need to discuss it." He agreed that if a patient wanted the mesh removed, that would feature in the decision making; but that he would expect there to be clear discussion about the risks of pain remaining or worsening after surgery. His view was that most surgeons would quote a 50% chance of success. He agreed that if told there was a 50% chance of the pain improving, it was quite likely the claimant would have made the decision to proceed to mesh excision even if other alternatives were part of that discussion. Mr Toozs-Hobson replied, "I agree that. Patients are vulnerable. Some patients are insistent on surgery for other reasons. I would always see a patient at least twice and put it in the notes so it is clear they are aware of the risks and benefits because there is no need to do it quickly".

321. The opinion expressed by Mr Robinson in the Joint Statement (agreeing with Mr Toozs-Hobson) was a shift in position from his first written report. In that report he had written, "There was no discussion regarding a conservative approach and pain management prior to proceeding immediately to mesh excision. However, given her history of dyspareunia and the fact that tenderness was demonstrated over the mesh on examination, mesh excision was reasonable although conservative measures and pain management should have been discussed and she should have also been comprehensively counselled regarding the risks and benefits of mesh excision."

322. When challenged about this shift, Mr Robinson characterised it as a "strengthening of his position" rather than a change; although he conceded that this was an important issue, the way in which his opinion had been expressed in the two reports was different, and he had not seen any additional material relevant to this issue between the time of preparing his first report and the joint statement.

323. Mr Robinson agreed that even if the second defendant had limited the surgery to a division of adhesions, it would have been good practice to investigate through histology whether the mesh was causing an allergic reaction. He further agreed that the claimant was anxious about the mesh and if she had been told she had an allergic reaction to it, she would not disagree (although he did not accept that the histology showed that she had).

Conclusion

324. I am not persuaded that the mesh excision in March 2018 was outside the range of reasonable treatment options for the claimant.

325. Each of the experts has highlighted as significant a finding of localised pain over the mesh on examination. Mr Robinson (in his first report) and Dr Sokolova rely on this as partial support for mesh excision surgery. In his first written report, Mr Toozs-Hobson suggested local excision and removal of the vaginal component would be a reasonable alternative treatment option if localised pain over the mesh had been found. I accept the second defendant's evidence that this is what she did find on examination on 2 February 2018, albeit it is not clearly documented.

326. Both Dr Sokolova and Mr Robinson (in his first report) also comment on dyspareunia being a significant symptom when considering whether to undertake mesh excision. Mr Robinson qualified this by reference to appropriate discussion of risks and benefits but I bear in mind that the claimant makes no allegation of an inadequate consenting process.

327. The division of adhesions that was undertaken by the second defendant in March 2018 proved insufficient to resolve the claimant's symptoms. That supports the reliability of the second defendant's pre-operative assessment that more needed to be done; as does her surgical finding of dense inflammation that she ascribes to an allergic reaction.

328. Finally, I attach weight to the claimant's own wishes and feelings prior to March 2018. There is a weight of evidence that she was significantly distressed about the presence of mesh in her body. She felt very strongly that it was the cause of her extensive symptoms and she wanted it removed.

329. If I am wrong in my conclusion and the performance of a mesh excision procedure before attempting less invasive surgery was in breach of duty, I am not satisfied causation of damage has been proved. If only a less invasive procedure had been attempted (and no mesh excision), it is highly likely that the claimant would have continued to press to have the mesh removed very shortly thereafter. She had become very ill with an allergic reaction she believed was related to the mesh. Mr Abu-Sitta provided some support for that belief. The claimant did go on to undergo further mesh excision as part of the surgery in July 2018. Her evidence is that even now she would, if safe to do so, have the remainder of the mesh excised.

Has the claimant proved the performance of the colposuspension was a breach of duty?

330. There is no dispute that if the claimant had recurrent symptoms of stress urinary incontinence, a colposuspension would have been a reasonable treatment option.

331. In answer to Question 35 of the joint statement, Mr Robinson and Mr Toozs-Hobson were asked "Was colposuspension clinically justified. If yes, please provide reasons. If no, do you consider that the decision to proceed to surgery was a breach of

duty?" Both agreed that colposuspension was not justified. Their reasoning was, "The patient was asymptomatic and the urodynamics were normal. This amounts to a breach of duty."

332. In her own written report dated June 2023, Dr Sokolova wrote at paragraph 4.2.20, "I understand the criticism with regard to the justification of the Colposuspension procedure in this case is because of the absence of a SUI condition on video Urodynamics. No reasonable surgeon would perform a colposuspension procedure, or any SUI procedure, in the absence of an SUI condition. However, given the limitation of Urodynamics, conventional or video, as mentioned above, and taking the whole picture into account, including the presenting history and the need for urethroplasty procedure, I believe it is not unreasonable to perform a Colposuspension procedure concomitantly with stage II mesh removal and the paravaginal repair surgery."

333. In the Joint Statement Dr Sokolova's view was, "Colposuspension was justified. There is a discrepancy between the UDS and the symptoms. I believe there is a possibility that the claimant could have contracted the pelvic floor during the investigation to avoid embarrassment. I also note she had previously had stress incontinence and had had a continence procedure. Following removal of the mesh there is a high risk of recurrent stress incontinence especially in the context of urethroplasty."

334. Putting this evidence together, the essential difference between the written opinion of Dr Sokolova and the other two experts is a factual one. Dr Sokolova suggests the claimant was or may have been symptomatic for urinary stress incontinence, even though the urodynamics did not demonstrate these symptoms. The other experts base their opinion on the claimant being asymptomatic. None of the experts suggest that colposuspension was justified in the absence of symptoms of stress incontinence.

335. Dr Sokolova was invited to consider whether her opinion would change if she disregarded the second defendant's annotation dated 6 July 2018 on Dr Rickard's report. In place of the annotation, Dr Sokolova referred to the referral letter dated 8 November 2017 as evidence of the claimant's history of recurrent stress urinary incontinence. She also noted the finding of open bladder neck on UDS which she said was capable of correlating with severe symptom of incontinence because it could indicate intrinsic sphincter deficiency.

336. At paragraph 42 of her witness statement, the second defendant stated, "Based on the information that I had available to me, the patient informed she had recurrent symptoms of SUI and prolapse. Thus, it was appropriate to offer a surgical option for both conditions." At the start of her oral evidence, the second defendant agreed that a colposuspension (or other surgical treatment for stress urinary incontinence) would not be performed in an asymptomatic patient with normal urodynamics.

337. The UDS performed by Dr Rickards were normal. The central factual issue to resolve in considering this allegation of breach of duty is therefore whether the claimant had or had reported symptoms of recurrent stress urinary incontinence to the second defendant which would justify performing the colposuspension.

338. It is the claimant's case that she did not have any symptoms of stress incontinence after the implantation of the tape by the first defendant. Her evidence is that she did not report symptoms of stress urinary incontinence to the second defendant or any other medical professional after the initial surgery in January 2017.

339. The claimant's evidence is that she knew that the second defendant had arranged for UDS to be performed prior to surgery. The results were not reported to her. At that time she did not appreciate that if the UDS did not demonstrate stress incontinence, she would not need to have the colposuspension because she did not have symptoms of stress incontinence.

The annotation dated 6 July 2018

340. The provenance of this note is an important issue between the parties. The claimant (and the first defendant) assert that this note was made after February 2019 and not on 6 July 2018. They assert that the content of the annotation is contrived to support the second defendant's case and provide retrospective and false justification for the colposuspension procedure she performed.

341. The second defendant maintains that the note was made on 6 July 2018 as the result of a discussion with Dr Rickards. Its contents are accurate and truthful. They reflect not only what the claimant told the second defendant but also what she reported to Dr Rickards about her symptoms.

342. Bearing in mind my findings that the claimant's recollection has proved unreliable on some issues, I have considered the contemporaneous documentary evidence about her symptoms at that time in some detail.

343. Save for the disputed annotation, the only other documented reference to the claimant experiencing recurrent symptoms of stress incontinence after the tape implantation is a note made by her GP, Dr Rooproy on 8 November 2017. He recorded "has stress incontinence and also having pelvic pain – wondered if TVT and wants to see specialist privately". When he referred the claimant to the second defendant, the same day, Dr Rooproy wrote, "She states that since she has had the tape she has been feeling increased abdominal and pelvic pain since the operation and feels her stress incontinence is returning. She does not have bowel symptoms and denies other urine symptoms…"

344. The claimant says this was a straightforward error on the part of the GP. She says she did not have any ongoing or returning symptoms of stress incontinence after the implantation of the tape and did not tell him anything different.

345. She is supported in her recollection by a further GP entry following an appointment on 18 January 2018. Dr Rooproy recorded the history at that consultation as "has gynae referral for pelvic pain and TVT – wants something for the pelvic pain – worsening feels nerve related – no bowel or urine symptoms no PV discharge".

346. The second defendant's clinical notes from her consultation on 2 February 2018 record that the claimant's bladder was normal. The only reference in her clinical note to stress incontinence at all is a bracketed "minor USI" as part of her record of the claimant's surgical history and the background to the insertion of vaginal mesh. Her letter to the claimant's GP is consistent with her clinical note and states, "her bladder function is normal and she tells me that when she had the tape put in, it was only for very minor urinary stress incontinence." I am satisfied that as would be expected from a consultant, the second defendant did not rely on the referral letter but took an independent history and satisfied herself that the claimant was not reporting incontinence symptoms.

347. The report from an ultrasound investigation arranged by the second defendant following the claimant's first consultation is consistent with normal bladder function and not with symptoms of stress incontinence. The "History" recorded in Dr Thakar's report records, "No stress incontinence, no frequency urgency". The ultrasound investigation disclosed no presence of cystocele or rectocele.

348. The second defendant wrote to the claimant's GP immediately following mesh excision surgery on 20 March. At the end of that letter she wrote, "It is highly likely she will get recurrent stress incontinence. It is likely also that she will require further surgical treatment for this." This was plainly a reference to a future possibility (or probability) of symptoms developing but was not compatible with the claimant having reported any current symptoms of stress incontinence.

349. Following surgery the claimant was catheterised to reduce the risk of her developing a fistula. The catheter was removed by Dr Rickards on 3 April 2018 and he performed a micturating cysto-urethrogram. He reported "Bladder outline was unremarkable. Bladder neck slightly open at rest but reasonably well supported and no obvious stress seen today."

350. The second defendant saw the claimant following surgery on 14 April 2018. The clinical notes record the symptoms which the claimant was reporting at that time. There is no reference to any complaint of symptoms of stress incontinence or prolapse. The absence of those symptoms or any complaint of them is supported by the second defendant's reporting letter to the claimant's GP on the day of the consultation. She explained that she would be arranging for a video-urodynamic assessment and that she felt that the claimant would probably need to have further mesh removed because of the impact it was having on her. Her reference to the colposuspension was in these terms, "If she has urinary stress incontinence then we will do a colposuspension at the same time." This comment makes no sense if the

claimant had already told the second defendant that she had symptoms of stress incontinence.

351. The video urodynamics were carried out by Dr Rickards on 27 June 2018. He reported "the bladder neck was slightly open at rest, well supported and I saw no stress element today. Therefore her urodynamics are normal."

352. The disputed handwritten note is made on this report and is dated 6 July 2018.

353. It is common ground that the claimant did not see or speak to the second defendant between 14 April and the day of the second surgery on 28 July 2018.

354. Having reviewed the contemporaneous records, I am satisfied the claimant did not experience any symptoms of stress incontinence after the implantation of the tape and did not report any symptoms to the second defendant. The GP entry is in error. On this issue the claimant is accurate.

355. I am unable to accept that the annotation which purports to be dated 6 July 2018 is a genuine record of a discussion between the second defendant and Dr Rickards. I do accept the likelihood that as the second defendant asserts, in the absence of multidisciplinary meetings, informal discussions took place routinely between the second defendant and Dr Rickards about the results of investigations performed by him at her request. But I reject her evidence that her annotated note is a true or contemporaneous record of any discussion there might have been between them. I find it to be a contrived and false piece of evidence. Its purpose is to support the second defendant's Defence and provide retrospective justification for performing the colposuspension. My reasons for this conclusion are these.

356. Firstly, the annotation is the only record of the claimant reporting symptoms of stress urinary incontinence after the tape implantation (other than the original report to her GP on 8 November 2017 which, as set out above, was contradicted by the second defendant's own clinical note on 2 February 2018). The annotation purports to refer to a very significant symptom ("USI throughout the day"). It is striking that the second defendant has not recorded this complaint contemporaneously anywhere else in her clinical notes or in correspondence.

357. Secondly, there was no opportunity for the claimant to have told the second defendant about this symptom between the consultation on 14 April 2018 (when the contemporaneous correspondence is incompatible with current symptoms) and 6 July 2018 when the annotation purports to be made.

358. Thirdly, the evidence of both Mr Robinson and Mr Toozs-Hobson is that there is a close correlation between the severity of symptoms of stress incontinence and UDS results. Mr Toozs-Hobson would put it at more than a 98% correlation. Mr Robinson was not asked to comment on this suggested figure, but his view is that the more significant the symptoms, the more likely they would be demonstrated on UDS. His

view is that a complaint of "USI throughout the day" is not consistent with normal urodynamics on testing. It must, at the very least, be taken to be a very unlikely combination.

359. Further, some of the second defendant's evidence about the justification for performing a colposuspension lacks consistency with her evidence about the provenance of the annotation. In her witness statement (paragraph 61) and in her oral evidence, the second defendant said that the claimant had demonstrated urinary stress incontinence during surgery on reduction of the cystocele. The second defendant said she had carried out an abdominal pressure test which she described as providing "certainty" that the colposuspension was justified. All of the urogynaecological experts agree that an abdominal pressure test carried out on a supine and anaesthetised patient is not diagnostic of urinary incontinence. At best, it may be a relevant finding as part of an overall picture. I was not able to elicit a clear and rational response from the second defendant as to why she relied on this test to inform her decision to proceed to colposuspension if, as she maintains, the claimant had reported significant symptomology to justify the procedure prior to 6 July 2018.

360. Finally, I attach considerable weight to the unsatisfactory and evolving nature of the second defendant's account about when the annotation was made, its context, purpose and why it was disclosed so late.

361. After the annotated report was disclosed in August 2022, the second defendant was directed by Order of Master Stevens dated 24 March 2023 to explain a number of discrepancies in her clinical records. When she made her witness statement complying with this Order, she said this about the handwritten note on the Dr Rickards' report, "I can confirm that the handwritten note was made by me, some time after February 2019 and that my annotations were made as an aide memoire." It is material that in this response, the second defendant was directing her mind to this particular note. She could not plausibly have muddled her explanation about this note with her explanation for the additional annotations in the other clinical records.

362. The context in which the second defendant was explaining anomalies in her records was also important. It was obvious, as she accepted in her oral evidence, that care was needed by this stage, if not before, to ensure that the evidence she gave in her second witness statement was accurate.

363. When she started giving oral evidence, the second defendant sought to "correct" what she now said was an "error" in this particular response. Her evidence was now that the annotation had actually been made on 6 July 2018 contemporaneously with a discussion she had with Dr Rickards when she received his report. The explanation previously offered was wrong.

364. I cannot accept there was here any genuine error. It is not plausible that in complying with a Court Order obtained because of concerns over the integrity of her

records, the second defendant would have responded with such carelessness. She herself acknowledged that "her team had gone over and over the evidence to check its accuracy". It is more likely that the evolving nature of her evidence on this issue is an indicator of untruthfulness.

365. She also said, for the first time from the witness box, that the symptoms recorded in the note had not only been reported to her by the claimant, but also to Dr Rickards. That was such a significant omission from her first witness statement on an issue of obvious importance that it undermined her credibility.

366. The report from Dr Rickards had not been sent to the claimant's solicitors at the same time as the other medical records in February 2019. In oral evidence the second defendant said this was because the report was in a separate folder and she had a new assistant who overlooked it when she was collating the medical records at that time. That explanation came for the first time from the witness box, despite the opportunity to provide it in her second witness statement. The timing of the explanation undermined its credibility.

367. I reject her evidence about this note and accept the submissions made on behalf of the claimant and first defendant about it.

Justification for colposuspension

368. I find that before the operation on 28 July the claimant had not experienced or complained of symptoms of urinary stress incontinence or prolapse since the implantation of the mesh. The UDS results were normal. The second defendant knew the claimant to be asymptomatic in relation to stress incontinence. The colposuspension could not be justified on grounds of symptomology or UDS evidence of stress incontinence.

369. I am not satisfied it was justified on other grounds.

370. There was some difference between the experts on the significance of the finding of "slightly open bladder neck" in the context of justification for colposuspension. Mr Robinson and Mr Toozs-Hobson both agreed that an open bladder neck is not diagnostic of urodynamic stress incontinence (see their answer to Question 32 in the joint statement). Dr Sokolova opined in answer to Question 32 that an open bladder neck was a "relevant" finding and "suggestive of stress urinary incontinence" in the context of the claimant's history. Mr Robinson and Mr Toozs-Hobson disagreed with this view.

371. In her oral evidence, Dr Sokolova agreed that most women with stress urinary incontinence had a closed bladder neck because the mechanism for their symptoms was a failure of the supportive mechanism of the urethra. In a minority of cases, the mechanism was intrinsic sphincter deficiency. In the latter cases, she said she would expect the finding of an open bladder neck at rest to correlate with severe

incontinence symptoms. She further agreed that for 20% of women an open bladder neck was normal and not indicative of any symptoms.

372. I have found that the claimant did not have any symptoms of stress urinary incontinence at the time of Dr Rickards' testing, far less severe symptoms. In the absence of symptoms, and applying Dr Sokolova's evidence, the finding of a slightly open bladder neck at rest would have no relevance in this case. It could not, of itself and without symptoms, justify the colposuspension procedure undertaken.

373. The second defendant placed some reliance on the results of the abdominal pressure test performed during surgery, while the claimant was anaesthetised, to justify performing a colposuspension.

374. Mr Robinson and Mr Toozs-Hobson were dismissive of the significance of this test, maintaining that no responsible body of clinicians would rely on abdominal pressure testing on a supine and anesthetised patient to diagnose stress urinary incontinence. Dr Sokolova's evidence was also that an abdominal stress test in these circumstances was not sufficient or reliable on its own to diagnose stress urinary incontinence. She said "In my practice I would probably deal with it differently. I would consider establishing this prior to the patient being in the operating theatre and anaesthetised rather than doing it as a last step in theatre." I did not glean from her evidence any support for the view that any responsible body of clinicians would diagnose stress urinary incontinence in this way.

375. I am not satisfied that any responsible body of clinicians would rely on an abdominal pressure test alone as a justification for performing a colposuspension procedure to treat stress incontinence.

376. Further, there is an obvious tension between the second defendant's initial justification for performing the colposuspension which relied on the overt symptoms she annotated and recorded in her witness statement; and some alternative justification that purports to be based on "occult" symptoms elicited during the operation. The conclusion to which I am driven is that the note was contrived because the second defendant knew that in the absence of reported symptoms of urinary stress incontinence, there was no other justification for the procedure she performed.

377. I find this allegation of breach of duty is proved. The procedure was not clinically justified.

The consenting process

378. It inevitably follows that the omission to report and discuss the normal results of the UDS testing with the claimant before the second surgery vitiated the consenting process for the colposuspension. The results and their implication were highly material. In the absence of symptoms of stress urinary incontinence, the results of the UDS removed any clinical justification for colposuspension. Whatever might have

been the second defendant's experience of the usual incidence of patients requiring a continence procedure following mesh removal, it was not clinically indicated in the claimant's case. The second defendant failed to obtain her informed consent to this part of the surgery undertaken.

379. I am satisfied that had the claimant been informed that this procedure was not clinically indicated, she would not have agreed to undergo it. By July 2018, she had already undergone two major operations. She was very unwell. She was focussed on having the mesh removed. The mesh was causing her considerable anxiety. She was facing a further operation she hoped would achieve complete removal of it. It is extremely unlikely at that time or subsequently she would have consented to an additional and unnecessary procedure that carried the risk of further complications if she had been informed of the true position.

380. Even if, contrary to my conclusion above and the second defendant's case, there might have been justification for undertaking a colposuspension on prophylactic grounds, the UDS results were highly material. They demonstrated there were no signs of stress incontinence on formal testing notwithstanding an absence of symptoms. A *Montgomery* compliant consenting process would have needed a full discussion of the implications of the results and then a detailed analysis of the risks and benefits of a prophylactic procedure, to include the likelihood of stress incontinence recurring despite the UDS results and of the risks associated with the procedure itself (for example, of actually causing incontinence as has proved to be the claimant's experience). For the same reasons as are set out in the preceding paragraph, my conclusion is that if properly informed, the claimant would not have consented to undergo this procedure prophylactically in the context of her recent experience of surgery. She had already experienced two major operations that she felt had not achieved the results she had been hoping for,

381. Ms Power argues that the second defendant's omission to report the UDS is no different from the first defendant's omission to arrange them. I reject that submission. The very significant difference here was that the results of the UDS in 2018 demonstrated there was no justification for a surgical procedure (in the absence of symptoms). It answered the diagnostic question of whether or not the claimant fell into the majority of mesh excision patients (estimated by the second defendant at over 80%) who developed stress incontinence following that surgery. That was in contradistinction to the position in 2016/17 when the results of the UDS would not have altered the decision to proceed with a continence procedure in circumstances in which the patient was experiencing symptoms she found intrusive.

Causation and quantum

382. The second defendant does not agree but does not object to the global figure of £500,000 which was agreed between the claimant and the first defendant as being a fair assessment of the level of compensation for the claimant's injury, loss and

damage resulting from all three operations carried out by both defendants. The breakdown of that figure (which again is not objected to by the second defendant) is annexed to this judgment as Appendix A.

383. Having found only the second defendant to be in breach of duty with respect to the unnecessary colposuspension only, I must determine what damages flow from the proven allegations and so should be attributed to the second defendant's negligence.

384. I have found the claimant did not have symptoms of urinary incontinence or other bladder dysfunction from the time the mesh was implanted until after the colposuspension procedure. I find that the colposuspension caused the claimant to have symptoms of overactive bladder which she did not have before. The urodynamic finding of detrusor overactivity which postdates the colposuspension accounts for these symptoms. In making that finding I have considered the experts' answers to Question 48 in the Joint Statement. They agreed that mesh excision had no impact on symptoms of overactive bladder; and that the colposuspension would have contributed to "worsening of her symptoms of OAB". This opinion was predicated on the belief that the claimant had developed symptoms of overactive bladder prior to the colposuspension procedure. She did not. It must follow, and I find, that it was the colposuspension that was the cause of these symptoms.

385. I accept the joint opinions of Mr Robinson and Mr Toozs-Hobson that over-active bladder is a long-term condition which is likely to deteriorate with ageing.

General damages for pain, suffering and loss of amenity

386. The claimant's unchallenged evidence is that she has symptoms of frequency, urgency and urge incontinence. She voids hourly throughout the day and two to three times at night (albeit her sleep is also disturbed due to pain). She has urgency when listening to running water and in the shower. She loses control at times (for example, when filling the kettle) and will have an accident. She wears pads day and night. If she stays away from home she needs to have an en suite toilet facility. She avoids travelling in other people's cars and cannot use public transport. If she is on a long journey she will take a change of clothing. Her symptoms affect her socially and cause her embarrassment. Mr Toozs-Hobson opines that this level of symptoms of detrusor overactivity would be considered "severe".

387. The appropriate bracket in the Judicial College Guidelines (17th edition) for this level of impaired bladder function is chapter 6(J)(c) which provides for a range of awards from £78,080 to £97,540 for "Serious impairment of control with some pain and incontinence".

388. I assess general damages for pain, suffering and loss of amenity just below the lower end of this bracket at £70,000. The reduction is for two reasons. Firstly, the claimant's pain is multi-factorial. Each of the operations she has undergone has

contributed to it, but it is unlikely that the colposuspension alone, as only one of the procedures undertaken in the third operation, has made a very significant contribution to her overall pain level. Secondly, the claimant has a range of other symptoms that are significant and pre-dated the colposuspension. There is overlap between the day to day impact of these symptoms and the limitations caused directly by the bladder impairment.

Past losses

389. After the third operation, the claimant required care and assistance, some of which was referable to incontinence. Her bed linen needed changing and laundering around twice each week due to leakage. I assess these past losses at £4,360.32 from the end of September 2018 calculated at 1.5 hours per week on average and at the gratuitous care rate quoted in the first defendant's counter-schedule.

390. She purchased incontinence products claimed at £1,085.40 which I find to be reasonable and award accordingly.

391. Of the miscellaneous costs claimed as past losses, the sums referable to increased laundry costs, underwear and bed linen are reasonably claimed and I award £471.44 in total.

392. Past losses excluding interest total £5,917.16.

Future losses

393. Mr Robinson and Mr Toozs-Hobson agree that the claimant's bladder symptoms will put her at a disadvantage in the open labour market. She will need to have easy access to a toilet. She will be unable to travel. However, her employment prospects are, without the bladder impairment, already significantly affected by other symptoms, including musculoskeletal limitations and chronic pain. Limiting damages for loss of earnings to the additional limitations referable only to the bladder condition, I approach damages under this head by assessing the claimant's additional disadvantage on the open labour market due only to the overactive bladder symptoms. I assess these damages at £8,000 (approximately 10% of the figure for loss of earnings in the breakdown).

394. Some future domestic care (primarily help with additional laundry but also some additional cleaning due to occasional accidents) will be reasonably required in connection with the claimant's chronic and worsening bladder impairment. She is independent in managing her personal incontinence needs. I assess this requirement at an average of 1.5 hours per week for life at the rate of £12.95 per hour, reaching a total of £28,098.27.

395. The future cost of medical treatment referable only to symptoms of over-active bladder is £76,600.58. Mr Robinson's unchallenged evidence describes the treatment which accounts for this figure.

396. The figure in the appended schedule (to which the second defendant does not object) for aids and equipment is £4,862.65. The only applicable reduction from this figure is the cost of a perching stool which has no connection with bladder symptoms. The other items claimed are solely referable to bladder symptoms (mattress protector and incontinence pads). I award £4,771.65 under this head after subtracting the claimant's costing for the perching stool.

397. Of the miscellaneous items claimed, I allow additional laundry costs which I assess at £2,500 as a reasonable proportion of the total in the appended schedule (to which the second defendant does not object).

398. The total future losses are £119,970.50.

Total

399. Excluding interest (which I invite Counsel to calculate), the total damages award is £195,887.66.

400. By way of a cross check, this figure equates to around 40% of the global figure (after deduction of around £16,000 special damages for which the claimant concedes the second defendant cannot be responsible). If I had found both defendants to be liable, this would have been within the range of a reasonable and fair apportionment of damages, reflecting the intrusive, severe and chronic nature of the bladder symptoms.

Outcome

401. The claim against the first defendant is dismissed.

402. There is judgment for the claimant against the second defendant in the sum of £195,887.66 with interest to be calculated.

403. I have no doubt the claimant has had a very difficult and distressing time over the past seven years. I wish her well for the future.

Appendix A

AGREED QUANTUM FIGURES
(as between the claimant and first defendant; the second defendant not objecting)

HEAD OF LOSS	AGREED FIGURE
PSLA	
Interest on PSLA	
PSLA + interest	**£108,937.20**
PAST LOSSES • Loss of Earnings • Care and Assistance • Medical Expenses and Treatment • AXA subrogated claim • Gardening • Miscellaneous • Travel • Interest	
Subtotal	**£78,410.83**
FUTURE LOSSES	
Loss of Earnings	£83,838.83
Care and Assistance	£96,414.66
Case management	£0.00
Occupational therapy	£1,353.16
<u>Medical treatment/ therapies</u> • Physiotherapy • OAB • Pain management • Psychosexual counselling • Psychotherapy & EMDR	 £507.22 £76,600.58 £24,963.01 £2,012.13 £2,916.98
Aids and equipment	£4,862.65
Medical expenses	£87.19
Gardening and DIY	£11,650.04
Miscellaneous	£3,353.55
Travel	£4,191.94
Subtotal	£312,652.97
TOTAL	**£500,000.00**