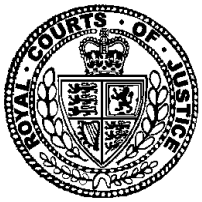

Neutral Citation Number: [2019] EWHC 832 (QB)

Case No: HQ17C01399

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 03/04/2019

Before :

MRS JUSTICE YIP DBE

- -

Between :

MRS RUTH ASHLEY DALTON	**Claimant**
- and -	
SOUTHEND UNIVERSITY HOSPITAL NHS FOUNDATION TRUST	**Defendant**

- -
- -

Ms Jessica Elliott (instructed by **Gadsby Wicks Solicitors**) for the **Claimant**
Mr Andrew Kennedy (instructed by **Browne Jacobson LLP**) for the **Defendant**

Hearing dates: 26, 27, 28 March 2019

- -

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MRS JUSTICE YIP DBE

Mrs Justice Yip :

1. The Claimant, Mrs Ruth Dalton, seeks damages for alleged clinical negligence resulting in a delayed diagnosis of breast cancer. Happily, despite the delay, she has responded well to treatment and I was told that she may now be considered 'cured'. That is not to minimise the impact that the delayed diagnosis had on her, both physically and psychologically. The parties sensibly agreed quantum (in the sum of £145,000), leaving the issues of breach of duty, causation and contributory negligence to be determined at trial.

2. I am grateful to both parties and their legal representatives for their sensible approach to the case, which has narrowed the issues considerably.

3. In February 2011, Mrs Dalton noticed what she describes as a small, hard lump in her right breast. She promptly consulted her GP, who referred her to the breast clinic at Southend Hospital. The referral letter records a finding on clinical examination of a 2-3 cm lump in the upper outer quadrant.

4. Mrs Dalton attended the breast clinic on 8 March 2011. It is common ground that she underwent assessment, including clinical examination, a mammogram and ultrasound, but no biopsy, and that she was reassured and discharged. By November 2013, she had noticed further changes in the same area of her right breast. Her GP referred her back to the breast clinic. A large Grade II ductal carcinoma was diagnosed.

5. Mrs Dalton's case, supported by her expert Professor Fentiman, is that she should have undergone tissue diagnosis in March 2011 and that this would have detected the cancer at that stage.

6. The Defendant, relying on expert evidence from Professor Wishart, denies this. His evidence was that a biopsy was not mandated on the basis of the clinical examination and radiography findings in 2011. He told me that Mrs Dalton would not have undergone a biopsy in his unit and that this is in accordance with the national guidelines for patients referred to hospital breast units. Even had a biopsy been performed, it is the Defendant's case that the tumour is unlikely to have been detected due to its small size. The parties agree that it is likely to have measured about 3mm in diameter at the time.

7. The Defendant also raised the issue of contributory negligence, contending that Mrs Dalton delayed in seeking re-referral to the breast clinic and accordingly did not take reasonable care for her own health and welfare. I shall deal with this briefly below but, quite rightly, Mr Kennedy did not press for a finding of contributory negligence in his closing submissions.

Application to amend the Particulars of Claim

8. Shortly before trial, the Claimant made an application to amend her Particulars of Claim. This came about because there was a change in Professor Fentiman's position after the experts' joint statement had been produced. At the time of the joint statement, the experts had disagreed as to the size of the tumour at the time of diagnosis. That meant that they arrived at different estimates for the size of the tumour in 2011. However, Professor Fentiman then reviewed the mammograms taken in November 2013 and realised that a measurement in the notes, upon which he had relied, was inaccurate. Taking account of the information from the mammogram, he felt able to

agree Professor Wishart's estimate that the size of the tumour in March 2011 was approximately 3mm. He reviewed his opinion on causation in light of that agreement. Professor Fentiman maintained his view that the tumour would have been identified had a core biopsy been performed. In addition, he raised a further point not previously pleaded: that had the biopsy missed the 3mm cancer, the Claimant's discrete lump would have remained unexplained, mandating a repeat biopsy or excision biopsy.

9. The proposed amendments to the Particulars of Claim corrected the Claimant's position given the agreement on measurements and dealt with the improved prognosis. Such changes were entirely uncontroversial. Perhaps more contentiously, the Claimant sought to add an allegation of negligence based upon the failure to carry out further tissue analysis had the first biopsy not identified the cancer. That would arise only in the event of a finding that a first biopsy should have been performed but that this would not, on balance, have detected the cancer.

10. I shall deal with this amendment briefly because no real objection was raised by the Defendant. Again, it seems to me that both parties took a sensible approach to this. The Claimant, through Miss Elliott, sought to clarify her case given the agreed measurements. Arguably, this fell within the existing pleadings, but it was sensible to set the position out clearly. The Defendant was able to meet the amended case and did not claim to be prejudiced. The whole of Professor Fentiman's hypothesis was to be explored anyway. In the event, the parties were content for the evidence to be called before a formal ruling on the amendment on the basis that Mr Kennedy would be afforded an opportunity to make submissions later if necessary. The Defendant's position on costs was also reserved.

11. No later objection having been raised to the amendments, I formally gave permission to amend the Particulars of Claim in the terms of the draft which was incorporated into the bundle during the trial. Consequential amendment of the Defence was unnecessary since the existing denials of breach of duty and causation cover the Claimant's revised case. On the Defendant's case, the need for a biopsy did not arise at all in March 2011, therefore there could be no question of a repeat biopsy. In the hypothetical situation where a biopsy had been performed but had not detected cancer, the Defendant denies that any form of repeat biopsy was required.

Findings of Fact

12. I heard evidence from Mrs Dalton and from the Defendant's consultant breast surgeon, Miss Gray. Both were impressive, sensible witnesses.

13. Miss Gray told me that she was the surgeon who saw Mrs Dalton in March 2011. Understandably, she has no record of the consultation now and was reliant on the records. She completed the examination and diagnosis sections of the record and signed the entry. This conflicts with the evidence of Mrs Dalton, who recalled that she saw a male surgeon.

14. Having heard from both women, I have no doubt that the Claimant was seen by Miss Gray. The records contain stamps noting the other clinicians involved. All were female. The only way a man may have been involved is if a male medical student was in attendance. However, that is unlikely as a medical student would normally then complete the history section whereas a nurse did so on this occasion. It is more likely that Mrs Dalton has misremembered, perhaps recalling a male doctor because she saw male clinicians when she reattended in 2013. This error is likely to have been

compounded by the fact that the relevant entry in the records has the name of a male surgeon at the top. The name is hard to read, and the Claimant's side had read it as "Mr Kotanie". In fact, it reads "Mr Rothnie". Miss Gray explained that he was formerly the clinical lead of the breast unit and the record sheets had been pre-printed with his name.

15. The identity of the surgeon makes little difference to the issues I have to determine. However, I am satisfied that I have heard from the correct doctor and therefore that Miss Gray's evidence as to the interpretation of the notes and her usual practice is relevant. My finding also means that, although generally I found the Claimant to be a reliable witness, the inference must be that she has no clear recollection of the March 2011 appointment. That is unsurprising. At the time, Mrs Dalton was reassured that there was nothing to worry about. The appointment, now eight years ago, is bound to stick in her mind far less than later ones when she received bad news.

16. The reality then is that neither the Claimant or Miss Gray can directly recall the events of 8 March 2011 and the medical records provide the best available evidence from that time.

17. I accept the Claimant's unchallenged evidence that she attended her GP in February 2011 having found a "small hard lump" in the upper outer quadrant of her right breast. Her GP examined her and confirmed the presence of a lump, which the GP described as being 2-3 cm. She was referred to the breast clinic.

18. On examination, Miss Gray noted that Mrs Dalton had "dense breasts", which was entirely unremarkable given her age. She identified the lump and marked it in the upper outer quadrant. She marked this "cyst". She then marked a further area in the lower breast by way of shading, which she captioned "?cysts" and wrote "BFC" which stands for benign fibrocystic change.

19. Miss Gray was able to say from this that, on examination, she would have been confident that what she could feel was benign, but she would be sending the patient for imaging. Miss Gray accepted that she ought to have included a "P score" in the note of her examination.

20. The relevant national guidelines, "Best practice diagnostic guidelines for patients presenting with breast symptoms" were published in November 2010 and aimed to raise the quality of the diagnostic process and ensure consistency. The foreword states:

> "These guidelines define, and bring together in one place, the key clinical and process markers of quality for the multidisciplinary diagnostic team to promote both quality and efficiency."

Miss Gray confirmed that the guidelines recorded what had been normal practice in her unit for around 10 years.

21. The guidelines are based around the "Multidisciplinary Triple Diagnostic Method". As the name suggests, there are three stages: clinical assessment; imaging assessment and needle biopsy. The level of suspicion for malignancy on clinical and imaging assessment should be recorded using a scale of 1 to 5. The "P score" relates to physical examination. P1 is normal; P2 is benign; P3 is uncertain; P4 is suspicious and P5 is malignant. Miss Gray's examination findings mean that the P score was P2, or possibly

even P1/P2. Miss Gray explained that there was also another form to complete to go with the patient to radiology. She may have written the P score on that. She should also have written it on the record of examination. However, that omission is of no significance since Miss Gray recorded all the necessary substantive information.

22. Mr Kennedy readily accepted that the benefit of any doubt about the P score at that time should be given to the Claimant. In reality, it makes no practical difference whether the score was P2 or P1/P2. I therefore treat Miss Gray's findings on clinical examination as P2 (benign).

23. The national guidelines require imaging for women presenting with a breast lump or lumpiness with a P2 score or above. The Southend breast unit operated the national guidelines with one variation. The guidelines recommend ultrasound imaging for women under 40 and X-ray mammography for women over 40. Mammography may be included for women under that age with clinically suspicious or malignant findings. At Southend, women over 35 routinely underwent mammography as well as ultrasound. That had been Mr Rothnie's practice before and he did not amend the unit's protocol when the guidelines were introduced. That meant the Claimant underwent a mammogram as an extra form of imaging although not mandated by the guidelines.

24. The Claimant's mammogram was scored "R1" for both breasts. "R" stands for radiography. The guidelines use "M" for mammography, but this is the same thing. A score of 1 meant "normal". The mammogram was reported as confirming "dense breast" with "no suspicious features". The ultrasound was scored as "U2", where a score of 2 is "benign". "Benign fibrocystic changes in marked area" were noted.

25. Having undergone imaging assessment, the Claimant was seen again by Miss Gray, who reassured and discharged her. Miss Gray wrote to the Claimant's GP:

> "Thank you for referring this 38-year-old mother of one who has noted a lump in the right breast along with some tenderness and clinical examination reveals what appears to be a cyst in the upper outer quadrant and a further area of benign fibrocystic change in the lower outer quadrant. Mammography showed dense breast and ultrasound showed benign fibrocystic changes in the marked area. I have quite happily reassured her and discharged her."

26. Looking at the records, Miss Gray confirmed that it had been her view that a core biopsy was not required. She accepted she had felt a discrete lump, which she thought was a cyst. She would have expected the ultrasound to show a fluid-filled cyst. In fact, no discrete cyst or mass was found on imaging to account for the lump she had felt. However, she felt the results of her clinical examination and the imaging were concordant. There were no suspicious findings. The scores were 2 (benign) on physical examination and ultrasound and 1 (normal) on the mammogram. Miss Gray's view was then, and remains now, that a biopsy was not required and that Mrs Dalton could be reassured and discharged.

27. I accept Mrs Dalton's evidence that she felt that the lump gradually got bigger from 2012. I also accept that she mentioned this to the practice nurse at her GP's surgery in February 2013. However, she understood the advice given to her was that she would need to return only if she had any new symptoms. In November 2013, the skin on the right side of her breast suddenly became puckered and indrawn. When that happened,

the lump became much easier to see and to feel. She immediately returned to her GP and was referred back to the breast clinic. By then, the lump was noted to occupy the whole of the right upper outer quadrant. Cancer was diagnosed.

28. The relevant facts may be summarised as follows:

    (i) Mrs Dalton presented to the breast clinic at the age of 38 with a small, hard lump in the upper outer quadrant of her right breast.

    (ii) Her GP had estimated the size of the lump as 2 to 3 cm.

    (iii) Miss Gray examined Mrs Dalton and found a discrete lump, which she believed was a cyst, and an area of benign fibrocystic change with possible cysts.

    (iv) On clinical examination, Miss Gray found no suspicious features indicative of malignancy. She scored her assessment P2 and sent Mrs Dalton for imaging.

    (v) The mammogram was normal.

    (vi) Ultrasound identified benign fibrocystic changes. It did not show a discrete cyst or any other discrete lesion. It did not reveal any signs of malignancy.

    (vii) In March 2011, Mrs Dalton did in fact have a small cancerous tumour in the upper outer quadrant of her right breast. It was then approximately 3mm in diameter.

    (viii) The tumour was not detectable through mammography or ultrasound.

    (ix) Based on her clinical findings and the imaging, Miss Gray did not require a biopsy and discharged Mrs Dalton.

    (x) The cancer diagnosed in 2013 was in the same part of the breast as the lump detected in 2011.

Contributory negligence

29. This issue has effectively fallen away since the Defendant does not press for a finding. Had it remained live, it would fall for consideration only if the Claimant succeeds on breach of duty and causation. However, I shall deal with the issue first as it seems to me that, the issue having been raised, the Claimant is entitled to have a clear ruling.

30. The Defence alleged that Mrs Dalton had failed to follow advice provided by Miss Gray to seek re-referral if the cyst enlarged and/or became painful. Accordingly, it was contended:

> "Mrs Dalton displayed unreasonable care for her own health and welfare. It is just and reasonable that she should be considered contributorily negligent and partially responsible for the consequences of the delay."

31. I find unhesitatingly that Mrs Dalton did not display "unreasonable care for her own health and welfare". I find, without any doubt, that she is an entirely sensible woman who consulted her GP promptly when she first found the small lump. She then continued to check her breasts and appropriately raised her concerns about what she should look out for with her practice nurse. She returned to her GP promptly when it

became apparent that there was cause for concern. Mrs Dalton bears no responsibility whatsoever for any delay in diagnosis.

32. Although it was alleged that she had been advised to return if the cyst enlarged, it was notable that when Miss Gray gave evidence, she said more than once that she would advise a patient to come back if they noticed anything "new or different". I consider that this fits with what Mrs Dalton understood and what she in fact did.

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

The expert evidence

34. Professor Fentiman and Professor Wishart fundamentally disagree on the issues of breach of duty and causation.

35. Professor Fentiman's opinion is that the lump felt in 2011 contained the cancer which was diagnosed in 2013. It was then at a very early stage, measuring only 3mm. He therefore accepts that what was felt cannot all have been tumour. Studies have shown that the size at which most tumours become palpable is around 15mm. Of course, there is variation. Professor Fentiman summed this up by saying, "A lot of 1cm cancers are not palpable. By the time you get to 2cm the majority are."

36. Professor Fentiman's hypothesis is that the 3mm tumour was surrounded by normal breast tissue which had been compressed by the outgrowing tumour, creating a variation in the tissue which did not show up on ultrasound, but which presented as a lump with an edge to it. This could feel like a cyst, which is a fluid filled sac with a wall. He accepted that this compressive effect could not account for a lump of 2-3 cm as noted by the GP. It could though create a lump of up to 9mm, approximately pea-sized. It is known that GP's often overestimate the size of lumps. Professor Fentiman acknowledged that it would be uncommon for a 3mm cancer to be detectable as a lump but said that he had encountered such cases in practice, although he could not begin to say how many times.

37. It is not in dispute that the ultrasound ruled out a discrete cyst. That was what Miss Gray expected. It was Professor Fentiman's evidence that the observed fibrocystic change could not account for the discrete lump found on clinical examination. Therefore, there was discordance between her clinical findings and the imaging. Therefore, her suspicions should have been raised and she should have applied common sense rather than using the guidelines as a tick-box exercise. The discordance between what she expected to find on ultrasound and what was in fact found should have led any reasonable breast surgeon to require a biopsy of the lump.

38. Professor Wishart does not agree. He supports Miss Gray's decision to reassure and discharge Mrs Dalton, stating firmly and clearly that he would have done the same. Had Mrs Dalton come under his care, he would not have ordered a core biopsy.

39. Professor Wishart did not accept Professor Fentiman's hypothesis that the lump was a 3mm malignant core with compressed tissue around it. He said that this hypothesis is not supported by the literature, it had not formed part of his training and it does not represent the teaching he now imparts to junior doctors. If right, it would mean that tumours would be found much earlier than is generally accepted to be the case.

40. Professor Wishart maintains that quite often focal nodularity can be felt which may be interpreted as a discrete lump. In his experience, it is not uncommon to feel what appears to be a benign lump which is not visible on ultrasound. Some women naturally have lumpier breasts than others. A lump can just be an area of dense tissue (particularly in this age group) or may be a collection of microcysts in the context of benign fibrocystic change. In the absence of any suspicious features on clinical examination, Professor Wishart would accept that benign fibrocystic change, as visible on the ultrasound, could present as a lump. Therefore, he would not accept that the clinical and imaging findings were discordant. On the contrary, the physical examination, mammogram and ultrasound had all pointed towards benign changes with no suspicious features.

41. Following the guidelines, said Professor Wishart, leads down the pathway to discharge on the findings available to Miss Gray in March 2011. The algorithm does not require a biopsy for a woman with a score of 2 on clinical assessment and on imaging. Miss Gray had followed the guidelines and is not to be criticised. Sadly, the Claimant fell into the very small number of women (0.2%) whose cancers are not detected although the guidelines are followed. He acknowledged that the fact that the failure rate is so small does not make it any easier for the women who fall into that 0.2%.

42. Professor Wishart said that it cannot be said whether the cancer was in the lump detected in 2011 or not. He accepted that it was entirely reasonable for the Claimant to feel that the lump and her cancer were one and the same. Intuitively, from a lay perspective, that appears to follow. However, he pointed out that most lumps, whether benign or malignant are to be found in the outer, upper quadrant, simply because that is where most breast tissue is. By the time the cancer was diagnosed, it was effectively filling the whole quadrant. It is hard to say at what point it started or whether it was in the lump felt in 2011 or nearby. Professor Wishart suggests that it may have been incidental that the Claimant had a 3mm carcinoma in an area of fibrocystic disease.

43. The differences in opinion between the experts as to what the lump was likely to have been and as to whether it can be said that the malignancy was at its core feeds into different views on causation.

44. It is agreed that because the lump could not be detected on ultrasound, any biopsy would have been "blind". However, Professor Fentiman considers that the palpable lump would have provided a reasonable target. The biopsy would aim for the middle of the lump and three samples of 1mm diameter would be taken. In Professor Fentiman's opinion it is more likely than not that this would have detected the cancer, which he believes was at the core of the lump.

45. Professor Fentiman raises a secondary case on causation, that is covered by the Amended Particulars of Claim. He says that, had the biopsy been negative, the lump would have remained unexplained. Therefore, there would still have been discordant findings. Therefore, further tissue analysis was required by way of vacuum assisted biopsy or excision biopsy. That would have detected the cancer. When pressed, Professor Fentiman confirmed that it was his view that a surgeon could not have been

satisfied by anything other than a finding of malignancy on biopsy. However, performing a biopsy was a stage in the process and therefore a responsible surgeon would not simply proceed to excision without one.

46. Professor Wishart rejects the notion that a biopsy was required. However, even if performed he says it is unlikely that the cancer would have been detected. He suggests that even if the very small carcinoma was in the lump, it represented a very small part of the total volume of that lump. Therefore, an unguided biopsy would have been unlikely to detect it.

Legal principles

47. The issue of breach of duty must be determined according to the very well-known principles from *Bolam v Friern Management Committee* [1957] 1 WLR 582 and *Bolitho v City and Hackney Health Authority* [1998] AC 232.

48. A doctor is not negligent if he or she has acted in accordance with a practice accepted as proper by a responsible body of medical opinion merely because there is another body of opinion who would take a contrary view. Given that Professor Wishart supports the decision not to proceed to biopsy in this case and clearly states that he would have taken the same course, it is worth restating what Lord Browne-Wilkinson said in *Bolitho* [at p.242].

> "In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.
>
> I emphasise that in my view it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgment which a judge would not normally be able to make without expert evidence. As the quotation from Lord Scarman makes clear, it would be wrong to allow such assessment to deteriorate into seeking to persuade the judge to prefer one of two views both of which are capable of being logically supported. It is only where a judge can be satisfied that the body of expert opinion cannot be logically supported at all that such opinion will not provide the benchmark by reference to which the defendant's conduct falls to be assessed."

49. It follows that the Claimant can establish breach of duty only if I am satisfied that no responsible breast surgeon would have failed to undertake a core biopsy at the

appointment in March 2011. To reach that point, I would have to conclude that Professor Wishart's opinion is not capable of withstanding logical analysis.

50. The Claimant bears the burden of proving causation on the balance of probabilities. When considering factual issues of causation, it is open to me to weigh the expert opinions and decide which I prefer. However, when considering what would have happened had a biopsy been undertaken but produced a negative result, I am required to consider whether it would have been negligent for Miss Gray not to perform a repeat biopsy in accordance with the principles from *Bolam* and *Bolitho* set out above.

Breach of duty

51. The national guidelines for the assessment of patients presenting to breast clinics are detailed and well-established. They are designed to give a standardised approach across the country. It is acknowledged by Miss Elliott that if Miss Gray properly applied the guidelines, she cannot be considered to have been negligent. The difference between the parties lies in the application of the guidelines given the findings on clinical examination and imaging.

52. The guidelines are clearly written and easy to follow. They make it clear that not all patients referred to a breast clinic will require all three parts of the Triple Diagnostic Method. The tests used are to be determined by the presenting symptoms, clinical findings and the age of the patient. Use of the Triple Diagnostic Method enables a diagnosis to be established in the majority of patients and the guidelines state that "diagnostic surgical excision should be rarely required." That is plainly a desirable aim, reducing the number of women who will have unnecessary invasive surgery. The rate of delayed diagnosis using the method is said to be 0.2%.

53. All patients will first undergo clinical assessment. This will inform the decision as to which other tests they are to undergo. Annexed to the guidelines are algorithms in the form of flowcharts, showing the assessment pathways. Algorithm A covers assessment of breast lumps and lumpiness.

54. On the basis that the clinical assessment was P2, imaging was required. Under Algorithm A, an imaging score of 3, 4 or 5 leads to a needle biopsy. If the imaging score is 1 or if a cyst is found, then provided that accords with the clinical examination, the patient will be discharged. If a solid lesion is seen on imaging but scored as 2, needle biopsy is not required if the lesion has typical features of specified benign conditions (none applicable here). Otherwise a solid lesion should be biopsied. The guidelines stress the need to check for concordance between the findings at the different stages of assessment. They make it clear that most solid lesions will require a needle biopsy to complete the triple diagnostic work up and to establish a diagnosis. They also state:

> "If there is any doubt about the nature of the lesion or discrepancy between the clinical and imaging features, needle biopsy should be performed."

Under the heading "Outcome of assessment", the guidelines say:

> "Following triple assessment, a definitive diagnosis of either benign/physiological changes or malignancy will be made in most patients. Where a definitive diagnosis is not established,

> repeat clinical assessment and needle biopsy should be considered."

55. Professor Fentiman's view is that the findings on clinical examination were not concordant with the imaging. Miss Gray thought she had found a cyst. However, imaging excluded a cyst. Therefore, she did not have an explanation for the discrete lump. There was doubt as to what it was and no definitive diagnosis. A needle biopsy was accordingly mandated.

56. Professor Wishart disagrees. There was concordance between the clinical examination and imaging. Both gave a score of 2 on the suspicion index. No suspicious features were identified at either stage. Everything was therefore pointing towards benign changes. His evidence was that it was not uncommon to feel something that presented as a lump but for the ultrasound not to identify any discrete abnormality. He said that clinicians rely heavily on the ultrasound. Here there had also been a mammogram. There was an area of textural change within dense breast tissue. In itself, having a discrete lump on examination was not a suspicious finding requiring a biopsy.

57. He was taken to a section in the guidelines which describes groups of patients who will not require all the elements of the triple assessment, including those with "areas of benign breast change and diffuse nodularity without a dominant mass." It was put to him that the discrete lump found on examination was a "dominant mass". Professor Wishart disagreed. He said that is a term used by radiologists and relates to the imaging findings rather than clinical examination.

58. Professor Wishart was adamant that applying the guidelines meant that the Claimant did not require a biopsy. In written evidence before me, he was critical of Professor Fentiman for relying on historical practice that was not relevant in 2011. He explained that prior to 2000 it was routine to sample clinically palpable lumps or lumpiness regardless of the breast imaging findings. However, that is no longer best practice. Needle biopsy is an invasive procedure with recognised complications. The current guidelines were based on findings from his unit in Cambridge demonstrating the low failure rate in the approach.

59. In cross-examination, Professor Fentiman agreed that his idea of concordance was probably lacking in the guidelines and that if the guidelines are followed literally Miss Gray cannot be criticised. However, he said that the guidelines could not be applied as a "tick-box exercise" and that there was an absence of common sense. Having not got what she expected from the imaging, Miss Gray was bound to think again. Professor Fentiman said that the guidelines are designed to be efficient and to get as many patients through the system as possible, but they cannot deal with every eventuality and in this case they did not.

60. It is fair to note that in re-examination, Professor Fentiman referred to the passages in the guidelines set out at paragraph 54 above as supporting his views. However, the way he expressed himself in cross-examination was telling. It was an apparent acknowledgment that a literal interpretation of the guidelines fitted with the views of Miss Gray and Professor Wishart.

61. Having heard the evidence of both experts and Miss Gray, I am inclined to prefer the interpretation of the guidelines contended for by Professor Wishart. I thought that he and Miss Gray both gave their evidence in a sensible, measured way. They each reasoned through their interpretation of the findings clearly and rationally. Overall, I

considered that their interpretation fitted with the general tone of the guidelines. The history identified by Professor Wishart of a move away from performing biopsies for all lumps and the reasons for that further supported their interpretation. Professor Wishart's experience of working in the Cambridge unit alongside the lead author of the guidelines and his detailed knowledge of the research that underpinned them is also relevant.

62. However, my preferred interpretation of the guidelines is not in fact relevant. It is not for me to weigh up the competing views and decide which is 'right'. I am entirely satisfied that Professor Wishart genuinely takes the same view as Miss Gray as to the application of the guidelines. The issue for me then is whether that is unreasonable or incapable of withstanding logical analysis.

63. In my judgment, the evidence of Professor Fentiman does not come close to demonstrating that the body of medical opinion into which Miss Gray and Professor Wishart fall is incapable of being logically supported. Despite her well-structured submissions and best efforts, Miss Elliott was not able to demonstrate any basis upon which I could reach such a conclusion. The most that she could say was that it was illogical to find two different benign diagnoses on clinical examination and imaging and to leave it at that. With respect, that is simply restating Professor Fentiman's opinion and does not address why the alternative view must be considered unreasonable.

64. I do have reservations about whether Professor Fentiman's opinion is one expressed with hindsight, knowing that the Claimant did in fact have a small carcinoma at the time. With hindsight the picture is very different. Indeed, I note the letter from Mr Tsokodayi dated 3 December 2013 which followed the Claimants diagnosis that "with hindsight perhaps we should have performed a core biopsy on clinical grounds". I agree with Mr Kennedy that this was no more than an understandable human reaction. To be fair, I doubt anyone would argue against the proposition that, with hindsight, it would have been better to remove the lump in 2011. However, the decision taken by Miss Gray cannot be considered with hindsight. It must be considered on the basis of the findings she had then.

65. Notwithstanding my reservations, I am prepared to accept that Professor Fentiman would have performed a biopsy because he would have remained concerned about the discrete lump after imaging. However, I am not persuaded that all responsible breast surgeons would have performed a biopsy in those circumstances. Indeed, having considered the guidelines, I do not think that Professor Fentiman's view represents a majority view. Certainly, I consider that Professor Wishart represents a responsible body of medical opinion that would not have performed a biopsy in the circumstances that existed in March 2011.

66. It follows that Miss Gray was not negligent in her management of the Claimant and the claim against the Defendant must therefore fail.

Causation

67. In light of my conclusions on breach of duty, causation does not remain a live issue. However, I shall deal with it briefly for completeness.

68. Had I found that a core biopsy was required, it would have been for the Claimant to prove that this would have led to the detection of the cancer. I am not persuaded that the evidence would have permitted such a finding.

69. As Professor Wishart and Mr Kennedy acknowledged, Mrs Dalton's intuitive belief that the growing carcinoma was in the lump she detected in 2011 is entirely understandable. There is no doubt that the lump found in 2011 was in the same area as the cancer identified in 2013. Mrs Dalton's contemporaneous belief, documented in her medical records, was that the original lump grew and was that found to be malignant in 2013.

70. Professor Fentiman's hypothesis is that the lump felt in 2011 had the very small carcinoma at its core surrounded by normal breast tissue that had become compressed to the extent that it appeared as a lump with an edge to it.

71. In arriving at that hypothesis, it seemed to me that Professor Fentiman had looked for an explanation starting from the premise that the lump had contained the small tumour. I am concerned that he cast aside any evidence that detracted from that premise.

72. For example, when making the referral, the GP estimated the size of the lump at 2 to 3 cm. Professor Fentiman accepted that his hypothesis could not account for a lump of that size. He concluded instead that the lump was likely to have been no more than 9mm in size. I accept his evidence that GP's often overestimate the size of lumps. However, here the GP had expressed a range and for Professor Fentiman's theory to fit that range must have been wrong by a factor of over 2 to 3 times.

73. In cross-examination, Professor Fentiman agreed that the compressive effect he had described would produce changes detectable on histological examination. However, he acknowledged that the pathology report from 2013 did not show any such changes. He sought to explain that by indicating that the tumour would have 'broken out' of the surrounding tissue as it expanded. However, I did not find his explanation particularly convincing, and again I am afraid I felt that he was simply seeking to make the evidence fit his hypothesis rather than weighing all the available evidence to arrive at the most likely explanation.

74. On the issue of causation, I preferred the more balanced evidence of Professor Wishart. He accepted that it was possible that the cancer was in the lump detected in 2011 but said that it could also have been nearby. Professor Wishart's opinion was that it was more likely that the benign fibrocystic change was presenting as a lump in 2011. Professor Fentiman accepted that it would be uncommon for a malignant lump measuring only 3mm to be found on palpation. He was unable to point to any specific literature to support his hypothesis and, although he said he had encountered such cases in practice, he could give no indication at all as to how frequently that had been.

75. If the cancer was in the lump detected in 2011, it is <u>possible</u> it would have been detected with a biopsy. However, I am unable to say that it is <u>probable</u> that it would have been detected. Since the lump could not be seen on ultrasound, the biopsy would have had to be performed freehand. Professor Fentiman accepted that if the lump was in fact 2 to 3 cm, as measured by the GP, the probability is that a needle biopsy would not have detected the cancer. I see no basis for finding that it is more likely than not that the lump was in fact 9 mm. It seems to me that doing so would be to make the evidence fit a finding that favours the Claimant rather than to reach a finding based upon the evidence as a whole.

76. Taking account of all the evidence before me, I find that it is possible, but cannot say it is probable, that a biopsy in 2011 would have detected the malignancy.

77. Had there been a negative biopsy, neither Miss Gray or Professor Wishart would have considered there to be a need for a repeat biopsy. They consider that a negative biopsy would have been concordant with the findings on clinical examination and imaging, all of which pointed towards a benign condition with no suspicious features.

78. I accept that this is a logical opinion. Therefore, applying the principles set out in *Bolitho*, I would not have found that it would have been a breach of duty for Miss Gray not to require a repeat biopsy even had an initial biopsy been mandated. On the contrary, I did not find Professor Fentiman's opinion to be entirely logical. His evidence appeared to be that, given what he considered to be discordance between the clinical findings and the imaging, no responsible breast surgeon could be satisfied by anything other than a finding of malignancy on biopsy. In those circumstances, it is hard to see why a core biopsy would be performed at all rather than proceeding straight to excision. I did not find Professor Fentiman's justification that it was just a stage in the process particularly compelling.

79. In all the circumstances, even had I found that failing to preform a biopsy in 2011 was a breach of duty, I would not have been satisfied that the Claimant had made out her case on causation on a balance of probabilities.

Conclusion

80. For the reasons set out above, I find that the Claimant has not established any breach of duty. Even had I found otherwise, I would not have been persuaded that causation was made out. Although contributory negligence therefore does not arise, I unhesitatingly reject any suggestion that the Claimant was in any way to blame for her delayed diagnosis. It seems to me that she was simply one of the very small proportion of women who are unfortunate in that their cancers are not detected at the first presentation despite proper application of the Triple Diagnostic Method.

81. It follows that this claim must be dismissed.