

Neutral Citation Number: [2014] EWHC 61 (QB)

Case No: HQ11X01975

**IN THE HIGH COURT OF JUSTICE**  
**QUEEN'S BENCH DIVISION**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 23/01/2014

**Before :**

**MR JUSTICE GREEN**

-----  
**Between :**

**‘C’**

**Claimant**

(By his Father and Litigation Friend ‘F’)

**- and -**

**NORTH CUMBRIA UNIVERSITY HOSPITALS**  
**NHS TRUST**

**Defendant**

-----  
**Martin Spencer QC & Jane Tracy Forster** (instructed by **Burnetts**) for the **Claimant**  
**Stephen Miller QC** (instructed by **Ward Hadaway**) for the **Defendant**

Hearing dates: 11<sup>th</sup> December 2013  
-----

**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.

.....  
**MR JUSTICE GREEN**

**Mr Justice Green :**

**A. Introduction**

1. This case concerns a narrow question: Was it negligent for a midwife to administer a second dose of a drug that induces labour?
2. In this case I have made an order to protect the anonymity of the Claimant from press related coverage. An opportunity was afforded to the press to make representations but no objections were received opposing the making of the anonymity order. For the purpose of this judgment I refer to the father as “F” and to the mother as “M”. This claim is brought by F on behalf of his child who is the Claimant in this case and who I refer to as “C” throughout.
3. The case arises in tragic circumstances. M was 41 years old and in good health when she was admitted to hospital for the induction of labour for delivery of her second child on 9<sup>th</sup> December 2002. Both this and her previous pregnancy were conceived through the use of IVF. The pregnancy with her new child had progressed well and to term. At 41 weeks it was decided to induce labour. She was admitted to hospital on 9<sup>th</sup> December 2002 and a first dose of 3mg Prostin was administered. This is a drug which stimulates the natural contractions in the uterus. I describe below the composition and therapeutic effects of this drug. After 7 ½ hours the midwife administered a second 3mg dose. About 5 hours later M was experiencing substantial discomfort and in a very short time period her cervical dilation progressed from being 2cm to 9cm. M was now extremely distressed and in pain. She was urgently transferred to theatre and her baby was delivered by forceps shortly thereafter. M’s uterus had ruptured. She suffered from a cardiac arrest. Attempts were made to resuscitate her but she ultimately died on 14<sup>th</sup> December 2002. C was asphyxiated at birth. He was described as white and floppy and not breathing with a heart rate of 60bpm. His Apgar scores were 1 at one minute, 5 at four and five minutes, and 7 at ten minutes. He was resuscitated and his circulation was restored by 3 minutes. Spontaneous breathing was established by 11 minutes. He suffered a hypoxic-ischaemic encephalopathy in the neo-natal period and he has hypoxic cerebral injury typical of a period of acute profound asphyxia commencing immediately prior to birth. It is common ground, and agreed between the relevant experts, that the hypoxia was caused by the uterine rupture of M and that this probably occurred at about 1.38am. The Claimant now has microcephaly and dystonic athetoid cerebral palsy.
4. For the father what should have been the joy of a new birth turned into an unmitigated catastrophe.
5. The following is now common ground. First, that M’s death was due to negligent post-natal care. Secondly, that C’s condition is due to the administration of the second dose of Prostin. The Defendant NHS Trust has admitted liability for the death of M. It contests however the claim for damages which alleges negligence in the administration of the second dose of Prostin.
6. The father brings this claim on behalf of C. He attended the trial and endured a minute forensic analysis of the events surrounding the administration of the second dose of the drug and the subsequent calamitous events leading to the death of his wife and the birth of his child. To have sat through this trial plainly cannot have been easy. It goes without saying that he has the deepest sympathy of the Court.
7. The issue for me is a narrow one: It is whether in all the circumstances the administration of 3mg of Prostin at 19.00hrs on 9<sup>th</sup> December 2002 was below the

standard of care that can reasonably be expected of a midwife. This involves examining, closely, the precise events preceding and to some degree following the administration of that second dose and placing them in context of such matters as: the guidelines produced for the use of the drug by the manufacturer and other relevant guidelines; the existence of any contra indications at the time militating against the administration of the second dose; the level of risk involved which includes a consideration of whether the midwife in question should have sought the advice and assistance of the consultant Registrar and, if so, what that “hypothetical” advice might have been; and the extent to which the midwife addressed herself to all the relevant considerations.

8. I address these issues in the following order: first, the background facts (Section B); secondly, the law (Section C); thirdly, the evidence relating to the alleged breach (Section D); fourthly, analysis of the evidence (Section E); and fifthly, conclusion and outcome (Section F).

### **B. Background facts**

9. In this section I set out the background facts to the case. I deal with the very specific circumstances relevant to the issue arising for my determination in the section concerning breach of duty.
10. F brings this action on behalf of C who was born on 10<sup>th</sup> December 2002. C has a sister born in 1998. The first birth caused no problem. M was induced at 42 weeks and had a vaginal delivery, i.e. not through caesarean section. Both M and baby were fit and well.
11. M attended hospital on 6<sup>th</sup> December 2002 and was told that her cervix was 1cm dilated which was not unusual after a first baby. However this did not mean that she was in labour and she was told that unless labour had started spontaneously she would be induced the following Monday. On 9<sup>th</sup> December 2002 both M and F went to the hospital. M was found a hospital bed and told that induction would commence shortly.
12. At 10.00am she was assessed and everything was fine. The Clinical Notes say “Generally quite well” and “Baby active”. The baby was cephalic (i.e. presenting normally). A Cardiotocograph or “CTG” was applied at 10.12am. A CTG is a machine which monitors labour and in particular the fetal heart rate and the level of uterine contractions. It appears as two graphs which track the progression of the heart rate and uterine activity over time by the recording of a trace upon the graph. The CTG traces for the relevant period were in evidence during the trial.
13. I will need to examine much more closely the precise events as they unfolded and as they are recorded on the CTG and in the Clinical Notes. For the purpose of setting out the background facts it is sufficient to record that a first dose of 3mg of Prostin was administered at 11.30am. It was administered in the form of a tablet or pessary inserted into the vagina.
14. Between 11.30am and 7.00pm M was assessed by a series of three different midwives who were on duty in the ward and each gave evidence during the trial. Each entered their observations as to the condition of M and the baby onto the History Sheet which

requires that Clinical Notes be entered onto the sheet together with the date and exact time of the entry. Each entry must be signed by the midwife in question.

15. At 7.00pm the midwife attending to M (Midwife Bragg) formed the view that she was not in established labour, that a sufficient amount of time had elapsed since the administration of the first dose of Prostin, and that there were no contra-indications militating against the administration of a second dose. She did not consider that anything was untoward and she did not therefore consider that it was necessary to seek the advice of the Registrar, who was close by in the ward, prior to the administration of the second dose. Accordingly a second 3mg dose of Prostin was administered.
16. At about this time F decided to go home. At approximately 00.45am on 10<sup>th</sup> December 2002, early in the morning, he was contacted by the hospital and told that his wife had gone into labour but that there was no urgency. However he returned immediately arriving at approximately 1.15am. He entered the room and discovered that his wife was in extreme pain. In his evidence to the Court he recalls that she was in such extreme pain that even now he finds it difficult to find the right words to describe her condition. His impression was that she was not fully aware of what was going on around her and could not focus upon anything but the pain. Her lips were tight; her eyes were wide open and “wild”. He had never seen anyone before, nor has he since, who seemed to be in such pain. She appeared frightened and could barely speak to him. She was gasping and spluttering. He rang the bell for assistance and within moments a midwife arrived and checked the CTG. She conducted a vaginal examination and said that M’s cervix was 9cm dilated. As M started to push the waters broke and a large quantity of fluid and faecal liquor was discharged.
17. Within moments a number of doctors and midwives were in the room and M was transferred to theatre. Shortly thereafter C was delivered by forceps. F’s evidence as to what happened next was in the following terms:

“When I walked into the theatre it looked like a scene from a Spielberg movie. [M] was still in stirrups at this point. She was as pale as I had ever seen her. She looked grey and worn out. There was blood everywhere. The bottom of the blanket, which was at the foot of the bed, which had been green, was completely black. It was completely sodden with blood. [M] was then taken on the bed back across the corridor into her room. I was with her. She was still awake but bewildered. It was as though she was very drunk. She was trying to get up off the bed and was being restrained by one of the midwives. I suddenly realised that [M] appeared to have collapsed. A defibrillator was brought into the room. I was asked to leave which I did. I went to the waiting room. At one point I was told that they would have to do a hysterectomy to stop the bleeding. Time just dragged on. I was told when the hysterectomy had been completed and that [M] was being transferred to the Intensive Therapy Unit. Over the next few days [M]’s condition deteriorated. On the Saturday afternoon when I arrived at hospital, I was met by the anaesthetist who told me, in a matter of fact way, that the brain stem death tests had been carried out,

that there were no sign of life and that no medication would help. He asked me, quite brusquely, when I wanted the life-support machine turned off. I was devastated.

At the time that [M] was fighting for her life, [C] was on a baby life-support system. [C] was linked up to heat lamps, drips and monitors. [C] was on the life-support system for about 36 hours and was then transferred to an ordinary incubator. [C]'s oxygen levels were being monitored continuously and [C] was being fed by tube. On the third day after ... birth [C] started having fits. I was told that [C] had suffered trauma because of a bleed-back through the placenta. I thought I was going to lose both [M] and our baby”.

18. Over time C's condition improved. However in about March 2003 C's condition appeared to deteriorate and C started having further fits. It became difficult to feed the baby who had to be returned to tube feeding. Progress thereafter was slow but gradually C put on weight and started to grow. F now describes C as “bright and delightful”. However C is severely disabled and has no independent mobility, limited use of the hands and severe cognitive impairment. C is unable to carry out personal or social tasks and needs 24 hour care and attends a special school.
19. The Defendant NHS Trust conducted an independent review of the events leading to M's death. I take the following analysis from the report dated 23<sup>rd</sup> December 2003 of the review into the circumstances surrounding the death of M conducted by Mr B J Murray, a Consultant Obstetrician and Gynaecologist of 26 years experience in a large hospital with over 3000 deliveries a year and a commensurate gynaecological surgical workload. He conducted his review with the benefit of other specialists who formed an external review panel. His focus was upon the death of M, not upon the causes of C's condition. His conclusion was that there had been a rupture of the uterus and that following delivery of C and a repair no-one had appreciated that M was “hypovolemic with a maternal tachycardia of 120”. For reasons Dr Murray was critical of, M was transferred out of the operating theatre and back into the delivery suite. She collapsed and required resuscitation in a deeply unsatisfactory setting with difficulty in access to veins and difficulties in intubation and access to the vagina. There was a delay in performing the laparotomy. He concluded that the most likely cause of M's haemorrhage was a “...post partum haemorrhage following rupture of the uterus after a precipitate labour and the shock and haemorrhage may have been compounded by the presence of an amniotic fluid embolism”. The conclusion of Mr Murray and the review panel as to the adequacy of the care given to M was in the following terms:

“For a variety of reasons as outlined in the previous pages the standard of care will have to be regarded as sub optimal in the sense that there was a failure to appreciate the gravity of the situation by both midwifery and obstetric staff (*vis* precipitate labour, no medical input until acute foetal distress and the transfer of the patient out of the operating theatre back to the delivery room after delivery when she was on the verge of hypovolaemia). There was a failure of reasonable anticipation on the part of the anaesthetic staff (*vis* venous cannula inserted

rather than larger; failure to appreciate the significance of the tachycardia and failure to intubate promptly). There was a failure in leadership during the course of the crisis with the senior clinician involved taking a reactionary role rather than being proactive and taking an early decision in favour of laparotomy”.

### **C. The law**

20. There is no material difference between the parties as to the relevant test to be applied. I have below therefore set out the relevant authorities and then summarised the main principles to be applied. The test is usually called the “Bolam” test and derives from a direction given to a jury by McNair J recorded in *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583 at 587, where the judge stated:

“I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in this particular art...Putting it the other way around, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that would take a contrary view”.

21. In the present case, and re-formulating the *Bolam* test, the question is whether no reasonably competent midwife would have acted and exercised her judgement in the way in which Midwife Bragg, who administered the second dose, did.
22. It is therefore insufficient for a Claimant to demonstrate only that there exists a body of competent expert opinion which disagrees with the judgment which was taken upon the facts of the present case. This is no more than a recognition of the fact that in an area where professionals exercise a high degree of technical and medical expertise that there may be a range of different views all of which might quite legitimately be held about the same matter. Accordingly, if there exists a body of competent professional expert opinion which supports the decision as reasonable in the circumstances it matters not that other experts might disagree. Lord Scarman in *Maynard v West Midlands RHA* [1984] 1 WLR 634 at 638E stated:

“Differences of opinion and practice exist and will always exist in the medical and other professions. There is seldom only one answer exclusive of all others to problems of professional judgement. A Court may prefer one body of opinion to the other, but that is no basis for a conclusion of negligence”.

23. The test was subjected to analysis in *Bolitho v City and Hackney Health Authority* [1997] UKHL 46; [1998] AC 232. An issue was whether a Court was required to accept the views of one truthful body of expert professional advice even though the Court was unpersuaded of its logical force. It was submitted that to adopt such an approach was “wrong in law” because it was ultimately for the Court, not for medical

opinion, to decide what was the standard of care required of a professional in the circumstances of a particular case. Lord Brown Wilkinson stated as follows:

“My Lords, I agree with the submissions to the extent that, in my view, the Court is not bound to hold that a defendant doctor escapes liability for negligent treatment or diagnosis just because he leads evidence from a number of medical experts who are genuinely of opinion that the defendant’s treatment or diagnosis accorded with sound medical practice. In the Bolam case itself, McNair J stated...that the defendant had to have acted in accordance with the practice accepted as proper by a “*responsible* body of medical men”.

Later, he referred to “a standard practice recognised as proper by a competent *reasonable* body of opinion”. Again, in the passage which I have cited from Maynard’s cases, Lord Scarman refers to a “respectable” body of professional opinion. The use of these adjectives – responsible, reasonable and respectable – all show that the Court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis. In particular, in cases involving, as they so often do, the weighing of risks against benefits, the judge before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts directed their minds to the question of comparative risks and benefit and have reached a defensible conclusion on the matter”.

24. Later, having cited various authorities, Lord Brown Wilkinson stated:

“These decisions demonstrate that in cases of diagnosis and treatment there are cases where, despite a body of professional opinion sanctioning the defendant’s conduct, the defendant can properly be held liable for negligence (I am not here considering questions of disclosure or risk). In my judgment that is because, in some cases, it cannot be demonstrated to the judge’s satisfaction that the body of opinion relied upon is reasonable or responsible. 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 pre-supposes 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 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".

25. In the present case I have received evidence from 4 experts, 2 on each side. It seems to me that in the light of the case law the following principles and considerations apply to the assessment of such expert evidence in a case such as the present:
- i) Where a body of appropriate expert opinion considers that an act or omission alleged to be negligent is reasonable a Court will attach substantial weight to that opinion.
  - ii) This is so even if there is another body of appropriate opinion which condemns the same act or omission as negligent.
  - iii) The Court in making this assessment must not however delegate the task of deciding the issue to the expert. It is ultimately an issue that the Court, taking account of that expert evidence, must decide for itself.
  - iv) In making an assessment of whether to accept an expert's opinion the Court should take account of a variety of factors including (but not limited to): whether the evidence is tendered in good faith; whether the expert is "responsible", "competent" and/or "respectable"; and whether the opinion is reasonable and logical.
  - v) Good faith: A *sine qua non* for treating an expert's opinion as valid and relevant is that it is tendered in good faith. However, the mere fact that one or more expert opinions are tendered in good faith is not *per se* sufficient for a conclusion that a defendant's conduct, endorsed by expert opinion tendered in good faith, necessarily accords with sound medical practice.
  - vi) Responsible/competent/respectable: In *Bolitho* Lord Brown Wilkinson cited each of these three adjectives as relevant to the exercise of assessment of an expert opinion. The judge appeared to treat these as relevant to whether the opinion was "logical". It seems to me that whilst they may be relevant to whether an opinion is "logical" they may not be determinative of that issue. A highly responsible and competent expert of the highest degree of respectability may, nonetheless, proffer a conclusion that a Court does not accept, ultimately, as "logical". Nonetheless these are material considerations. In the course of my discussions with Counsel, both of whom are hugely experienced in matters of clinical negligence, I queried the sorts of matters that might fall within these headings. The following are illustrations which arose from that discussion. "Competence" is a matter which flows from qualifications and experience. In

the context of allegations of clinical negligence in an NHS setting particular weight may be accorded to an expert with a lengthy experience in the NHS. Such a person expressing an opinion about normal clinical conditions will be doing so with first hand knowledge of the environment that medical professionals work under within the NHS and with a broad range of experience of the issue in dispute. This does not mean to say that an expert with a lesser level of NHS experience necessarily lacks the same degree of competence; but I do accept that lengthy experience within the NHS is a matter of significance. By the same token an expert who retired 10 years ago and whose retirement is spent expressing expert opinions may turn out to be far removed from the fray and much more likely to form an opinion divorced from current practical reality. “Respectability” is also a matter to be taken into account. Its absence might be a rare occurrence, but many judges and litigators have come across so called experts who can “talk the talk” but who veer towards the eccentric or unacceptable end of the spectrum. Regrettably there are, in many fields of law, individuals who profess expertise but who, on true analysis, must be categorised as “fringe”. A “responsible” expert is one who does not adopt an extreme position, who will make the necessary concessions and who adheres to the spirit as well as the words of his professional declaration (see CPR35 and the PD and Protocol).

- vii) Logic/reasonableness: By far and away the most important consideration is the logic of the expert opinion tendered. A Judge should not simply accept an expert opinion; it should be tested both against the other evidence tendered during the course of a trial, and, against its internal consistency. For example, a judge will consider whether the expert opinion accords with the inferences properly to be drawn from the Clinical Notes or the CTG. A judge will ask whether the expert has addressed all the relevant considerations which applied at the time of the alleged negligent act or omission. If there are manufacturer’s or clinical guidelines, a Court will consider whether the expert has addressed these and placed the defendant’s conduct in their context. There are 2 other points which arise in this case which I would mention. First, a matter of some importance is whether the expert opinion reflects the evidence that has emerged in the course of the trial. Far too often in cases of all sorts experts prepare their evidence in advance of trial making a variety of evidential assumptions and then fail or omit to address themselves to the question of whether these assumptions, and the inferences and opinions drawn therefrom, remain current at the time they come to tender their evidence in the trial. An expert’s report will lack logic if, at the point in which it is tendered, it is out of date and not reflective of the evidence in the case as it has unfolded. Secondly, a further issue arising in the present case emerges from the trenchant criticisms that Mr Spencer QC, for the Claimant, made of the Defendant’s two experts due to the incomplete and sometimes inaccurate nature of the summaries of the relevant facts (and in particular the Clinical Notes) that were contained within their reports. It seems to me that it is good practice for experts to ensure that when they are reciting critical matters, such as Clinical Notes, they do so with precision. These notes represent short documents (in the present case two sides only) but form the basis for an important part of the analytical task of the Court. If an expert is giving a précis then that should be expressly stated in the body of the opinion and, ideally, the Notes should be annexed and accurately

cross-referred to by the expert. If, however, the account from within the body of the expert opinion is intended to constitute the bedrock for the subsequent opinion then accuracy is a virtue. Having said this, the task of the Court is to see beyond stylistic blemishes and to concentrate upon the pith and substance of the expert opinion and to then evaluate its content against the evidence as a whole and thereby to assess its logic. If on analysis of the report as a whole the opinion conveyed is from a person of real experience, exhibiting competence and respectability, and it is consistent with the surrounding evidence, and of course internally logical, this is an opinion which a judge should attach considerable weight to.

#### **D. The evidence relating to the alleged breach of duty**

26. I turn now to consider the evidence relevant to the question of breach of duty. I start by describing Prostin. I then consider the relevant guidelines, risk, the Clinical Notes, the decision not to seek a second opinion, and, the expert evidence.

##### **(1) Prostin**

27. Prostin contains Dinoprostone as its active ingredient. This is a naturally occurring female hormone also known as prostaglandin E2. Prostaglandins are involved in inducing natural labour. Dinoprostone has the same therapeutic effect as natural prostaglandine E2 and is inserted into the vagina artificially to induce the process of labour. It has the effect of inducing contraction of the uterine muscles, it softens the cervix and it increases the sensitivity of the myometrium to oxytocin which should lead to the onset of labour. It is extremely widely used.

##### **(2) Relevant guidelines**

28. The Data Sheet for Prostin E2 vaginal tablets is contained in the Compendium of Data Sheets and Summaries of Product Characteristics produced by the Association of British Pharmaceutical Industry ("ABPI") for 1998-1999.
29. In relation to dosage and administration it provides as follows: "**Dosage and administration** one tablet (3mg) to be inserted high into the posterior Fornix. A second tablet may be inserted after six to eight hours if labour is not established. Maximum dose 6mg".
30. In relation to contra-indications it is stated that Prostin E2 Vaginal Tablets should not be used where the patient is sensitive to prostaglandins or other constituents of the tablets. It then says as follows:

"Prostin E2 Vaginal Tablets are not recommended in the following circumstances: For patients in whom oxytocic drugs are generally contra-indicated or where prolonged contractions of the uterus are considered inappropriate such as: cases with a history of caesarean section or major uterine surgery; cases where there is cephalopelvic disproportion; cases in which fetal malpresentation is present; cases where there is clinical suspicion or definite evidence of pre-existing fetal distress; cases in which there is a history of difficult labour and/or

traumatic delivery; grand multiparae with over five previous term pregnancies”.

31. Under the heading “Other undesirable effects (frequency and seriousness)”, the following is stated:

“The most commonly reported events are vomiting, nausea and diarrhoea. Certain rare events that should be especially noted are: hypersensitivity to the drug; uterine rupture and cardiac arrest. Other adverse effects, in decreasing order of severity, reported with use of dinoprostone, are: pulmonary/amniotic fluid embolism; abruption placenta; stillbirth neo-natal death; uterine hypercontractility or hyper-tonus; fetal distress; hypertension-systemic (maternal); bronchospasm/asthma; rapid cervical dilation; fever, backache; rash; vaginal systems-warmth, irritation, pain.

In addition, other adverse reactions that have been seen with the use of prostaglandin E2 for term labour inductions have included: altered fetal heart rate patterns; uterine hypercontractility with fetal bradycardia; uterine hypercontractility without fetal bradycardia and low Apgar scores in the new born”.

32. The Data Sheet also states that the vaginal tablet should be used with caution in patients with compromised (i.e. scarred) uteri, i.e. in particular in women who have had a prior caesarean section. It is also stated that in labour induction cephalopelvic relationships should be carefully evaluated before use of Prostin E2 vaginal tablets and that during use uterine activity, fetal status and the progression of cervical dilation should be carefully monitored to detect possible evidence of undesired responses such as hypertonus, sustained uterine contractions or fetal distress.
33. Under the heading “Overdose” it is stated that uterine hypertonus or unduly severe uterine contractions have “rarely been encountered” but might be anticipated to result from overdosage. It states that where there is evidence of fetal distress or uterine hypertonus, prompt delivery may be indicated.
34. The British National Formulary (“BNF”) (March 1998) is based upon the Data Sheet, and contains the following in relation to Dinoprostone:

“Dose: by vagina, induction of labour, inserted high into posterior fornix, 3mg, followed after 6-8 hours by 3mg if labour is not established; max. 6mg [vaginal tablet]”.

35. In relation to side effects the BNF states as follows:

**“Side effects:** nausea, vomiting, diarrhoea; other side effects include uterine hypertonus, severe uterine contractions, pulmonary or amniotic fluid embolism, abruption placenta, fetal distress, maternal hypertension, brochospasm, rapid cervical dilation, fever, backache; uterine hypercontractility

with or without fetal bradycardia, low Apgar scores, cardiac arrest, uterine rupture, still birth or neo-natal death; vaginal symptoms-warmth, irritation, pain...”.

36. There was some disagreement between the experts as to the proper scope and effect of the guidelines. A number of observations were made by the expert witnesses and in submissions in the present case about the guidelines. First, a reference in both the Data Sheet and in the BNF to a second dose after 6-8 hours is a reference to the half life of the drug and operates upon the assumption that the effect upon the uterus will probably have ceased after 6 hours but almost certainly within 8 hours of the first dosage. Secondly, both the Data Sheet and the BNF indicate, inferentially, that a second dosage should not be administered if labour is “established”. This is relevant in the present case because it is common ground that at the point in time when the second dose was administered labour had not been “established”. Thirdly, all of the experts were agreed that even if labour was not “established”, but was only “latent”, that it would not necessarily be appropriate to administer a second dose of Prostin and that this was so even if the guidelines, inferentially, suggested that a second dose was perfectly safe before labour was “established”. Fourthly, there are no other local or national guidelines (including those published by NICE) which modify the Data Sheet or the BNF. These guidelines have been in force since 2002.

### (3) Risk

37. Uterine rupture is exceptionally rare. In the case of a woman who has not been subject to previous surgery the risk of rupture is in the order of 1:17,000-20,000 births. None of the witnesses who gave evidence in the course of the trial had encountered uterine rupture in their practices. This is notwithstanding that induction of labour using Prostin is common place.
38. There is a relative dearth of scientific medical literature about the connection between the administration of Prostin and uterine rupture. Two pieces of literature were before the Court. The first is an article by Miller, Goodwin, Gherman, and Paul entitled “Intrapartum Rupture of the Unscarred Uterus” (May 1997). This summarised the results of a study examining risk factors and maternal and neo-natal outcomes in ten cases of intrapartum rupture of the unscarred uterus, i.e. uterine ruptures in women without previous caesarean deliveries. The authors concluded that intrapartum rupture of the unscarred uterus is a “rare obstetric emergency”. They recorded that three women in the series that they investigated experienced uterine rupture following administration of a PGE2 suppository. In each case a single 3mg dose was administered, uterine hyperstimulation was not observed, and rupture occurred more than four hours after administration. The inference in these cases is that the rupture occurred following a single administration of 3mg Prostin and that a second dose was not administered. The authors conclude that prostaglandins “...should be used with caution, particularly in multiparous patients and in combination with oxytocin”. The second piece of literature referred to was the CESDI 5<sup>th</sup> Annual Report, “Confidential Enquiry into Still births and Deaths in Infancy” (1998). A table (7.3) revealed that in cases (in the small survey analysed) where there was no previous uterine scar there was only one case in which a tablet (pessary) form was used which led to uterine rupture and in that case only one 3mg dose was given. In relation to risk generally there was no literature before the Court indicating that a concern had hitherto been articulated about the safety of the administration of the second dose of Prostin 3mg in

circumstances where the first dose had failed effectively to trigger labour. The Defendant submitted that the evidence “such as it is” appears to be the rupture is as likely to follow the giving of one dose as two. A more accurate conclusion might simply be that the literature is anything but conclusive or indicative of anything. The most important statistic is that the risk of uterine rupture is very rare: circa 1:17000-20000.

#### (4) The Clinical Notes

39. The guidelines and the nature of the risk of uterine rupture are the context in which the events surrounding the administration of the second dose can be assessed. In this section I consider whether the evidence reveals that any indications occurred at the relevant point in time which should have put Midwife Bragg on alert and caused her to refrain from administering the second dose, or delay its administration, or seek the advice of the Registrar. I turn therefore to consider the events surrounding the administration of the second dose of Prostin to M. I propose to do this chronologically. The purpose of this exercise is to assess whether the judgement exercised by Midwife Bragg, when she administered the second dose of Prostin, was a reasonable one in all the circumstances. Before describing the evidence which comes from these sources I make two observations about the assessment of this evidence.
40. The analysis focuses predominantly upon the Clinical Notes drafted at the time, and, upon an analysis of the CTG.
41. First, considerable care must be exercised in analysing the Clinical Notes. They are not to be construed as if they were a literary or scientific text. The Notes reflect the views of a number of successive midwives who were on duty at the relevant times. They are prepared as a form of shorthand intended to be understood by other midwives and medical professionals. They reflect the impressions and conclusions of the various midwives as to the state of wellbeing of M over time. They express in particular views about M’s level of pain, and her ability to withstand pain. By way of example considerable debate occurred in the course of the trial as to the meaning of the entry “Prostin type pains”. Elsewhere in the Notes the reference to “Period like pains” is to be found. Evidence was tendered as to the inferences that could reasonably and properly be drawn from these entries. The level of discomfort or pain being experienced is one factor, amongst many, that a midwife will assess in judging whether labour is commencing and this, in turn, is a factor affecting whether to administer Prostin. However, as the evidence given to me by the midwives vividly demonstrates there is a degree of subjectivity in these entries. When a midwife enters “period like pains”, she is not, of course, indicating that M is having a period. She is recording a conclusion as to the severity of the pain, i.e. that it is similar to the sort of pain a woman will have when she is having her “period”. But of course different women experience period pains very differently. The Notes, moreover, do not indicate whether the expression “period like pain” is the assessment of the midwife or information conveyed to her specifically by M. The same may be said of the expression “Prostin type pains”. It is likely that a first time mother (who has never been induced before with Prostin) will not know what “Prostin type” pain feels like. In such a case the entry into Clinical Notes of that expression is likely to have been the assessment of the midwife. However a second time mother, having previously been induced, may have a recollection of what “Prostin type” pain actually feels like. It is therefore uncertain in this case whether the entry is the assessment of the midwife

or a reflection of the actual experience of M. Furthermore, evidence was given that midwives may use the expression “Prostin type” as shorthand for the sort of pain a mother will experience either by virtue of the drug or as shorthand for “period type” pain.

42. Secondly, a further reason for caution is that the recollection of the midwives who gave evidence was essentially based upon their interpretation as at the trial of the Clinical Notes. None of them had sufficiently clear recollection of the actual events to be able to say with confidence what they meant by a specific entry when they recorded it on the Clinical Notes. This was particularly the case with Midwife Bragg, who administered the second dose of Prostin. She accepted that the evidence that she gave to me was based upon her review of the documents; she had no clear recollection of the events as they occurred, over 10 years ago.
43. I turn now to consider the sequence of events as they unfolded at the relevant time.

*9<sup>th</sup> December 2002*

44. 10.00am: M was admitted to the Whitehaven Hospital for Prostaglandin induction of labour. The decision to induce labour was taken by the consultant obstetrician into whose care M had been assigned. She was, at this point, 6 days post-term. This was her second pregnancy; the first having been a Prostaglandin induction. On that occasion she had given birth by normal vaginal delivery.
45. 10.02am: The Clinical Notes record “Baby active”.
46. 10.12am: Midwife Grist examined M and nothing untoward was found. She conducted an abdominal palpation. The baby was cephalic, i.e. presenting normally. The CTG was applied and this indicated that the uterus was contracting or tightening at a rate of approximately 2:10, i.e. 2 contractions every 10 minutes. This suggested that labour had not yet commenced.
47. 10.50am: The CTG of the fetal heart rate suggested that the baby was in a “sleepy” state but the trace was becoming more active. M was seen by the on-duty obstetric Registrar, Dr Bukhari. He conducted an abdominal palpation and found that the baby’s head was high at four-fifths palpable above the pelvic brim. He authorised the giving of a first dose of Prostin. The Clinical Notes record “well up till now”. The fetal heart rate was approximately 140, which is perfectly satisfactory.
48. 11.27am: The Clinical Notes record “trace becoming more active”. There is nothing at this point which suggests that either M or the baby was distressed.
49. 11.30am: Midwife Grist conducted a vaginal examination in advance of the insertion of the Prostin pessary. The Notes state “vagina and external genitalia appear normal. Cervix thick and uneffaced. Multips os. Head above ischial spines. Cervix posterior Prostin pessary 3mg inserted into posterial fornix CTG continues”. No criticism is made of the administration of the first pessary. No Bishops Score was entered in the Notes. The Bishops Score is a method of assessing the state, if any, of labour. There was some dispute in the course of the trial as to whether the failure to ascertain a Bishops Score was an omission on the part of the midwife. Guidelines prepared at the Whitehaven Hospital dated November 2002 were in existence which stipulated that

the ascertaining of a Bishops Score was mandatory. However, the evidence was that these were not yet in place as of 9<sup>th</sup> December 2002. A conclusion endorsed by Mr Murray (see paragraph [19] above) who in his report of 23<sup>rd</sup> December 2003 reported there were no guidelines in place at the time. Dr Blott, the Claimant's expert, stated in her report, that it was standard practice to give a first dose of Prostin regardless of the state of the cervical dilation albeit that caution would always be advised in a multiparous patient with a favourable cervix.

50. 12.17pm: The Clinical Notes record "CTG removed – satisfactory trace". The entry was made by Midwife Grist.
51. 2.00pm: The Notes record that the fetal heart was regular at 140 beats per minute ("bpm") which is within the normal range for fetal baseline of 110-160bpm. The measurement was taken using a hand-held sonicaid device. This also recorded acceleration of the fetal heart. This was a reassuring sign. The Notes record that M said that she experienced "occasional period like pains". M was advised to contact staff if any pain relief was required. In fact it was not until 10.30pm that M was administered Paracetamol for the discomfort caused by (at that point) "period like pain".
52. 3.45pm: Midwife Nicholson checked the baby's heart rate with sonicaid. She recorded: "period type pain seemed to have eased off at moment".
53. 5.35pm: Midwife Bragg had started her shift at approximately 2pm. She now assumed care of M. She resumed the CTG monitoring for the administration of a second Prostin pessary. The Notes record as follows:

"CTG applied, prior to giving 2<sup>nd</sup> pessary. Still having Prostin type pains 4-5:10. [M] says she is not feeling these very much. CTG baseline. 140bpm very ability > 6bpm, initially showing sleep pattern, one small deceleration from baseline, shallow with good recovery".

In giving oral evidence Midwife Bragg told me that "Prostin type" pains may be similar to "period type" pains: See the observation I have made about this above at paragraph [41]. The CTG reflected an essentially normal fetal heart rate. There was one small deceleration which is marked on the CTG itself. In terms of perception of pain M stated that she was not feeling these pains "very much".

54. 6.10pm: The Clinical Notes for 6.10pm appear to merge with those entered at 5.35pm. However, I deduce from the Clinical Notes that at around 6.10pm the baby was having "good accelerations" prior to removal of the trace. The Notes record that M "...will have her supper before having pessary". Evidence given in the course of the trial suggests that a mother who is willing to eat will not, normally, be in considerable pain and this is evidence that labour has not onset.
55. 7.00pm: The Notes record "VE to insert 3mg Prostin pessary. Head presenting at station – 2. Cervix soft and posterior, just tipped. Pessary given". A "VE" is a vaginal examination. The reference to the cervix being "just tipped" is a reference to the fact that the midwife could feel the cervix with the tip of her finger. And this indicated that the cervix was too posterior for the midwife to reach the cervical os and, thereby,

assess the extent, if any, of the dilation. A significant issue in the present case is the implication of the fact that M experienced “Prostin type pains” of “4-5:10” at 5.35pm (see paragraph [53] above). The Claimant says that this indicated that labour was in the process of establishing, albeit that it is accepted that it had not established. The evidence of Midwife Bragg was that having spoken to M and having felt the abdomen that there was very little occurring and that this was confirmed by the vaginal examination at 7.00pm, 85 minutes later. The evidence of Midwife Bragg as to the position at 7.00pm in relation to M’s state may be summarised as follows:

- At 5.35pm the pain is categorised at “Prostin type”, i.e. attributable to the drug but not to the onset of labour.
- At 5.35pm M said that she was “not feeling these very much” which indicated that there was no significant pain being experienced by M which also suggests that labour had not started.
- The CTG fetal baseline of 140bpm was within the normal range.
- M was intending to eat a meal before the second pessary which also indicated that labour had not started.
- At 6.10pm the rate of contractions (which had been at 4-5:10) appeared to have slowed down somewhat which also suggested that labour had not commenced. The CTG is manuscript marked “Reassuring trace”.
- M had not asked for any form of pain relief.

56 7.16pm: Midwife Bragg re-applied the CTG which indicated that the fetal heart rate was normal. The Notes record that M was “feeling period type pains, irregular tightenings. CTG reassuring”. An examination of the CTG suggests that the rate of contractions had slowed. M was not feeling any form of severe pain. She did not ask for any form of pain relief.

57 9.15pm: The fetal heart rate was still normal (140bpm). The Notes record “[M] is going to have a shower”. This is indicative of a mother who remains relatively relaxed and is having a shower because that can help alleviate low level pain or discomfort.

58 10.00pm: Midwife Bragg recorded that M was complaining of “niggling and backache, but coping well”. Midwife Bragg did not construe this as labour starting.

59 10.30pm: M was given two paracetamol tablets “for period like pain”. Again, Midwife Bragg did not construe this as the onset of labour. This is confirmed by a vaginal examination over two hours later.

*10<sup>th</sup> December 2002*

60 12.30am: M contacted the midwife. The Notes say: “rang to say getting v. uncomfortable q distressed”. Midwife McGregor conducted a vaginal examination. The conclusion was similar to the vaginal examination conducted at 7.00pm on 9<sup>th</sup> December 2002. The Notes record: “cervix soft, uneffaced, long, admits of one finger easily”. The oral evidence given to me suggests that this would indicate that the cervix was 1-2cm dilated. This is an indication that M was still not in labour. This was about 5 ½ hours following the

administration of the second dose of Prostin. M was administered an opiate pain relief together with an anti-emetic.

- 61 12.55am: M was now very distressed. A decision was made to transfer her to a room on the labour ward. Midwife McGregor stated that this was not because they thought she was about to deliver but because had she stayed where she was she would have been likely to have disturbed other patients on the 4-bedded ward in the ante-natal department where she had been. However, the evidence of F was that when he was phoned by the hospital he was told that M was “in labour”.
- 62 1.00am: Care was now assumed by Sister Spencer. She recorded that M was very distressed contracting strongly 1:3-4. This refers to one contraction every 3-4 minutes but, by extrapolation, suggests 3-contractions every 9-12 minutes. This is six hours following the administration of the second Prostin 3mg pessary.
- 63 01.08am: CTG monitoring was re-commenced. M was feeling “nauseated” and she was encouraged to breathe through the pain. The fetal heart rate was 144bpm. There was reduced baseline variability but this was attributed to the fact that M had received an opiate injection, i.e. the baby may have been affected by the opiate taken by the mother. There was no reference in the Notes to anything untoward.
- 64 01.20am: Sister Spencer began to write up the record of the latent phase of labour. She put the dilation of the cervix at 2cm. There is however no evidence that she had personally conducted a vaginal examination and this entry is likely to reflect the measurement taken earlier. When she gave evidence it was her view that in fact the cervix would probably have dilated beyond 2cm at that point in time.
- 65 01.45am: The Clinical Notes were discontinued at that point because, it would appear, the urgency of what then ensued prevented the maintenance of a contemporary record. Notes were subsequently written up some considerable time later (i.e. some hours after the event). Sister Spencer returned at approximately 01.45am. She concluded that M’s waters had broken. M was now contracting at 1:2. Sister Spencer ruptured the membranes and thick fresh meconium-stained liquor drained out. This is an indication of fetal distress. The fetal heart rate recorded on the CTG had become bradycardic, i.e. below 100bpm which is a serious indication that the baby might become asphyxiated. A vaginal examination showed that the cervix had dilated to 9cms, i.e. full dilation is 10cms so M was almost fully dilated. The situation amounted to an extreme emergency.
- 66 01.45am: Dr Bukhari entered the room. The cervix was now fully dilated. The head was considered too high for instrumental delivery and M was taken to theatre having consented to a caesarean section. However, a decision was taken to make a forceps delivery.
- 67 02.07am: C was delivered by forceps in a poor condition. He had an Apgar score of 1 at 1 minute. This is a method of assessing the well-being of a newborn baby. There are five parameters in the score each of which is capable of scoring up to 2 points. A score of 1 at 1 minute indicates a very poor condition indeed. His Apgar reached 5 at 5 minutes after resuscitation.

(5) The decision not to obtain the opinion of a consultant before administering the second dose of Prostin.

68 One issue that I have to decide is whether at 19.00pm on 9<sup>th</sup> December 2002 it was negligent of Midwife Bragg not to seek a second opinion and, if it was, whether the second opinion would have been either (i) that there should be a delay in the administration of the second dose of Prostin and if so what would have happened or (ii) that no second dose should be administered at all.

69 Dr Bukhari did not give evidence in the course of the trial. It would have been him to whom Midwife Bragg would have turned in order to seek that second opinion. In my view the test as to what would have occurred must be objective i.e. what would a reasonable obstetrician have advised in the circumstances had he/she been asked. No doubt had Dr Bukhria given evidence this would have been helpful; but its absence is not problematic. If Dr Bukhria had given evidence and had said that had he been asked he would have indicated that a second dose should be administered or, perhaps, that Midwife Bragg should wait (say) for an hour (in which case the second dose would in all likelihood have been administered given that the evidence at circa 20.00 was that nothing much at all was happening), then the argument before the Court would have been that the Defendant was still negligent because Dr Bukhria would have adopted the same inadequate and negligent response that Midwife Bragg did. I have in mind the observation of Lord Browne-Wilkinson in *Bolitho* (ibid) that:

“ A defendant cannot escape liability by saying that the damage would have occurred in any event because he would have committed some other breach of duty thereafter.”

70 This seems apt to cover the situation of the hypothetical advice given by the Registrar whose opinion would have been sought had Midwife Bragg sought it. In my view it would at least in principle have been open to the Claimant to contend that the hypothetical advice was negligent and that the only advice that would or could be reasonable was the very precautionary approach which is at the heart of their case. This dictum and the general tenor of the *Bolitho* judgment indicates, in my view, that the test is not what Dr Bukhari would in fact have said or done but what a reasonable consultant should or would have said.

71 I return to this issue in the analysis section below.

(6) Expert evidence – The essential difference between the parties is the level of acceptable risk

72 I heard expert evidence from two midwives and two obstetricians. For the Defendant I heard evidence from Ms Susan Brydon (on midwifery) and from Dr Derek Tufnell (on obstetrics). For the Claimant I heard evidence from Ms Fiona Sommerville (on midwifery) and Dr Maggie Blott (on obstetrics). They produced written reports, participated in meetings with opposing experts to produce joint statements, and gave oral evidence.

73 The approach I take, consistent with *Bolitho*, is to assess the Defendant's evidence to see whether it falls within the bounds of reasonable evidence and is consistent and logical in the context of the wider evidence and I assess the Claimant's evidence not to see whether it is in and of itself reasonable (it is) but to determine whether it has the effect of placing the Defendant's expert evidence in such an altogether negative light that I should reject that evidence. The essential function of the midwifery evidence was to assess the conduct

of Midwife Bragg; the essential function of the obstetrics evidence was to assess what the hypothetical obstetrician would have done had he or she been asked for a second opinion. In reality the obstetrics evidence overlapped more or less completely with the midwifery evidence and the obstetricians gave evidence as to whether the decision Midwife Bragg was in fact negligent and they did not confine themselves to what the hypothetical consultant would have said or advised. I have concluded that I should look at the totality of the evidence in the round.

74 I should state at the outset that, applying the *Bolitho* criteria, I concluded that each of the experts gave their evidence in a professional manner. They were all experienced and highly competent. It goes without saying that they were “respectable” and gave their evidence in good faith. The evidence fell into two broad types: particular evidence about what a reasonable midwife would do based upon the Clinical Notes, the CTG and the background to M; and general expert evidence about the approach that any midwife should give to the administration of Prostin to induce labour.

75 In relation to the latter (general approach) I can summarise the expert evidence given relatively shortly because, boiled down to its bare essentials, the difference between the two sets of experts lay in their opinions as to the level of risk that it was acceptable for any midwife to accept in relation to the administration of Prostin and in particular a second dose thereof. The Claimant’s experts say that in the case of Prostin, where there is an acknowledged risk of uterine rupture (which can be catastrophic), a highly precautionary approach should be taken and, said Dr Blott, it was therefore “reckless” (i.e. negligent) to adopt anything other than a very cautious approach. She and Midwife Somerville highlighted the following factors as justifying this approach: First, the risk of not administering a second dose or delaying to await events was very small. This was not the sort of case where treatment was required urgently and where time was not on the midwives’ side. On the contrary there was simply no rush. Secondly, if labour was starting then there was in any event no need for a second dose so that the litmus test was not whether labour had established but whether it was establishing. And in the case of ambiguity (i.e. uncertainty as to whether it was establishing) then the competent midwife should always delay and not give a second dose. There would be ambiguity if there is any indication of pain or uterine contractility and then a second dose should never be administered or the very least it should be delayed to see what transpires (i.e. whether the mother moves into established labour) or a second opinion sought. Dr Blott construed the Data Sheet and the BNF in this light albeit that she accepted that there was a lack of clarity in the drafting. The Claimant’s experts also analysed the Clinical Notes and the CTG from this precautionary perspective and concluded that whether or not M was actually in labour or even establishing in labour there were nonetheless sufficient present clear contra-indications to compel withholding, at that point in time, the second dose of Prostin.

76 Mr Spencer QC for the Claimant in his clear and forceful closing submissions put the Claimant’s case in the following way:

“In the end, this case is all about risk. Where the medical profession intervene in natural processes and thereby cause things to be worse, not better, it is appropriate for those who suffer to take a long hard look at what was done and ask the question: why? It is appropriate also for the practitioners involved to examine their consciences, and question their own

actions when they have had such disastrous consequences. There can be no doubt that Prostin is a potentially dangerous drug, and the Datasheet so recognises in warning of the risks and potential side-effects: the fact that they are rare does not make them any the less real when they eventuate. In a multiparous woman who, at 41 weeks, is close to natural labour anyway, the giving of the second dose of Prostin was, or should have been, anything but automatic. It is submitted that, in the absence of urgency, a precautionary approach was appropriate. The corollary of this is that the second dose of Prostin should not have been given unless the midwife could be sure that this mother was not in the process of establishing in labour. With uterine contractions 4/5:10 and pain, more than 6 hours after the first dose, the midwife simply could not be so sure, and therefore she should not have given the second dose. In doing so, she fell below the required standard. In doing so, she set in train a sequence of events the outcome of which could not have been more tragic.

- 77 I should say that I found the evidence given by the Claimant's expert obstetrician, Dr Blott, to be impressive. It was well researched, very clearly presented and well thought out both in writing and orally.
- 78 Ultimately I have not however been able to accept it because in my view it articulates a test which is simply too rigorous and too cautious an approach and which sets the bar of reasonableness at too high a level. It would have been reasonable for Midwife Bragg to have adopted the Claimant's highly cautious approach but that it is not the benchmark; the test is whether that is the only possible reasonable reaction in all the circumstances. And as to this I have formed the clear view that a less cautious approach was not a negligent or unreasonable approach and also fell well within the bounds of reasonable and normal midwifery conduct.
- 79 I have concluded that the Defendant's expert evidence accurately reflects a reasonable position both in relation to the overall assessment of risk and as to the assessment of Midwife Bragg's conduct specifically. Their conclusion was that when all of the factors facing Midwife Bragg at 19.00pm on 9<sup>th</sup> December 2002 were taken into consideration there was nothing which was sufficient to justify a conclusion that the administration of the second dose of Prostin was unreasonable. She exercised her judgment based on a combination of factors and it was a reasonable one, notwithstanding the tragic consequences that ensued.
- 80 It follows that I do not consider it to be negligent for Midwife Bragg not to have sought a second opinion. However, I have considered (below at paragraph [87]) in the alternative the position that would have pertained had a third party consultant been approached.

### **E. Analysis of evidence and conclusion**

- 81 In this section I set out my analysis of the reasons why I have come to this conclusion. I have not referred at any length to the specific evidence of the expert witnesses and witnesses of fact. However, in forming my conclusions I have carefully taken all of their evidence into consideration. My conclusions are as follows.

82 First, the decision taken by any midwife will be based upon an all round assessment of the evidence which derives from (inter alia) the CTG traces of fetal heart rate, the level of discomfort experienced by the mother and which emanates from discussion between mother and midwife and observation by the latter of the former; the level of contractility reflected on the CTG and the evidence of abdominal palpation, evidence about the degree of dilation derived from a vaginal examination, and the mother's past history of childbirth. It is inevitable that there may be a considerable measure of judgment based in any decision. I do not accept the submission of the Claimant that the decision taken by Midwife Bragg was automatic and unthinking and that she intended to give the second dose regardless. This submission was based upon the fact that on one reading of the Clinical Notes it could be said that Midwife Bragg intended to administer the second dose come what may. In my view this is not a fair reading of the Clinical Notes nor of the evidence given in the trial. In my view the process which led to the administration of the second dose entailed a series of periodic assessments by successive midwives of all of the factors which would ordinarily go into a decision as to whether, and if so when, to give a second dose of Prostin. It was a routine assessment but not automatic or unthinking or predetermined. The assessment is not one that can be calibrated with precision or accuracy. It involves taking account of a combination of factors which include not only interpreting the CTG trace but also importantly judging the level of discomfort or pain of the mother which will inform the decision as to whether the mother is in labour or is establishing in labour. F's evidence was that in his view M was in real pain but that she was stoical and that accordingly her pain was greater than is recorded on the Clinical Notes. The evidence of the midwives was that a trained and experienced midwife will be very conscious that some mothers are better at bearing pain than others. They know that when asked how she is feeling some mothers will say through gritted teeth "I'm fine". A midwife may well interpret this as a mother experiencing pain indicative of labour. In my view there is no basis upon which I can properly conclude that M was in fact experiencing a level of pain that materially outstripped that recorded in the Clinical Notes. I assess the question of pain more specifically below (paragraph [85] below). For present purposes I use the point to illustrate the broader point which is that in assessing reasonableness it is important to recognise the multifaceted character of the judgment that is being made by the midwife and that is a starting point for determining negligence; in many cases there may well be more than one reasonable response to a situation.

83 Secondly, the level of risk associated with uterine rupture following on from the administration of Prostin is exceedingly low. It is common ground that the incidence associated with Prostin is circa 1:17,000-20,000. None of those who gave evidence, including the midwives who were present at the time, recall an incident of rupture in their periods of practice. This accepted level of risk is a material and important consideration in the present case. I must be very wary of being wise through hindsight. The fact that the administration of the second dose turned out to be catastrophic is not relevant. When Midwife Bragg came to administer the second dose she, as would any other trained midwife, would know that the risk of uterine rupture was exceedingly low. And she was entitled to act accordingly. This is very relevant to the Claimant's case which is that a very high degree of caution should be exercised precisely because of risk. Insofar as there is a correlation between risk and the degree of caution which this implies as to the practical application of the drug, then the fact that the risk is very low must clearly be seen as part of the reasoning which leans towards the conclusion that the decision to administer the second dose was not unreasonable. I accept the evidence of Midwife

Bragg that she was aware of both the general very low level of risk but also that exceptionally there was a risk of uterine rupture.

84 Thirdly, the decision of Midwife Bragg was in accordance with the Guidance (Data Sheet and BNF) in terms of (a) the time elapsing between doses; and (b), the state of the mother's labour at the time of the administration of the second dose. There are five main points to make about the guidelines:

- i. As to timing the wording of the BNF is to be read as permissive suggesting that a second dose "may" be given after "6-8 hours" (see paragraph [34] above). Insofar as the Data Sheet is less clear (see paragraph [29] above) it is at least to be inferred that a second dose after 6-8 hours may be given or is not inappropriate. The Defendant points out that these guidelines have been approved by regulators and professional bodies. They are not merely informal documents produced by manufacturers. They are intended to be relied upon and should accordingly carry considerable weight in favour of a midwife who acts consistently with them. In particular the guidance represents a balancing of risks and benefits such that if the guidelines are adhered to then that is inherently likely to reflect a properly balanced (reasonable) decision. The guidelines identify the risk of uterine rupture (as rare) and by indicating that a second dose is permitted 6-8 hours post first dose those guidelines translate risk into practical guidance. Midwife Bragg gave the second dose 7.30 hours after the first dose, which is well within the guidelines.
- ii. As to the position adopted by the guidelines in relation to the stage of labour reached when the drug is to be administered, the decision of Midwife Bragg was in accordance with the Guidance in terms of whether labour had been "established" and the same point may be made here as with the timing point in (i) above. Both the Data Sheet and the BNF suggest that a second dose can be given if labour is not "established". A reasonable inference from the guidelines is that the administration of a second dose if labour is not established is within accepted levels of safety. It is common ground that labour had not been established at 19.00pm on 9<sup>th</sup> December 2002 when the second dose was given.
- iii. When the guidance as to timing and state of labour are combined then the guidelines, by indicating that a second dose 6-8 hours post first dose absent established labour is permitted, translate risk into practical guidance. A midwife who is within the guidelines should, prima facie, not be acting unreasonably.
- iv. I use the expression "prima facie" in (iii) above because it is important to observe that both of the Defendant's experts accepted that even if labour was not established it was still *not necessarily always* reasonable to administer a second dose of Prostin and that the midwife (or other medical professional) had to take account of all of the other circumstances which might indicate that second dose should not be administered even if labour was not yet established. This is important since on one view it is hard to see why a professional whose actions accord with the approved guidelines should be held to be negligent when the consequences later turn out to be

adverse. But in this case there was consensus that the guidelines were not complete or comprehensive. Dr Blott (for the Claimant) was critical of the guidelines for lacking clarity in the way in which they failed to cover establishing labour (i.e. the stage prior to established labour) and for suggesting that a second dose could always safely be administered after 6-8 hours regardless of other circumstances. There may well be a serious point of criticism to be made about the guidelines in these respects; not least because, as I have already observed, all of those who gave evidence accepted that it was not automatically proper to administer a second dose before labour was established. The Defendant's experts (and indeed as did Midwife Bragg in her oral evidence) thus took a more cautious approach than do the guidelines themselves and they formed their views on a broader range of considerations than just the guidelines.

- v. In conclusion my view is that *prima facie* a midwife who acts in accordance with the guidelines should be safe from a charge of negligence. However, in the present case since it is common ground that in some regards the guidelines are not satisfactory I do not decide this case upon the basis that adhering to guidelines is sufficient. I consider that the fact that Midwife Bragg acted in accordance with the guidelines is a factor militating against negligence but I also assess Midwife Bragg's conduct against the benchmark of the other surrounding facts and circumstances.

85 Fourthly, a midwife would take into account the mother's history and in this case M was not in an especially vulnerable category in that (i) that she had only given birth once before and (ii) this had not been by caesarean section (which increases the risk because it leads to scarring of the uterus which makes the uterus more likely to rupture). M did not fall into one of the categories referred to in the guidelines which warrant extra caution.

86 Fifthly, at the point in time when the second dose was administered the level of uterine activity and M's experience of pain when combined with other factors were not such as to identify a particular risk of an unacceptable level associated with a second dose. At 17.35pm M's contractions were at a rate of 4-5:10 on the CTG and she experienced "Prostin type" pains. But M was not "feeling these very much" (see paragraph [53] above). The Fetal heart rate was normal. At 18.10pm M had her supper which was interpreted as indicating again that nothing much had happened and that M's level of discomfort was not great. These were the facts prior to the second dose. During the trial much was said by the Claimant's experts that the contraction rate of 4-5:10 was a strong contra-indication. In my view that was certainly one factor to be taken into consideration but it was not the only one. In addition Midwife Bragg analysed the discomfort as being "Prostin type" i.e. due to the drug but not labour; she recorded M's observation that she was "not feeling these very much". I have no reason to suppose that when M said that she was "not feeling" these pains very much she was being inaccurate. Midwife Bragg monitored the fetal heart rate which was normal. She recorded the fact that the mother was wanting her supper and was perfectly happy to eat; this was not an indication of labour. She gave evidence that she was aware of the overall risk and the mother's background (only one previous child but not by a caesarean section – which increases risk). In my view nothing jumped out of the situation that existed at 19.00pm which should have sent a message that there was a need suddenly to adopt a highly cautious approach.

87 Sixthly, the evidence that occurred after the administration of the second dose is corroborative of the decision taken at 19.00pm but is also relevant to what an obstetrician might have done had he or she been asked. Over 2 hours later (at 21.15pm) M went to have a shower (which would usually be a sign that labour had not yet started); 3 hours later (at 22.00pm) M was experiencing “niggling & backache” but was “coping well” which again is not indicative of labour and certainly supports the midwife’s judgment at 19.00pm; 3.30 hours later (at 22.30pm) M asked for pain relief and was given paracetamol for “period like pains”. Throughout the fetal heart rate was normal. In my view had an obstetrician been asked for an opinion at 19.00pm then upon the basis of the above I can see no reason why a perfectly reasonable answer might not have been: administer the second dose now; or, wait for one hour and then give the second dose; or even, wait for two hours and then give a second dose. Had these been the answers then even if the second dose had been delayed, by the time it came to be administered there would still have been no clear and unequivocal evidence that labour had established or that there was any materially increased risk associated with the new insertion. Indeed, the CTG shows that the rate of contractions actually reduced during that period from the high of 4-5:10 at 17.35. In short, had a third party obstetrician been approached it is of course possible that this person would have been highly cautious and adopted the approach advocated by Dr Blott. However, that is not the test. The question is whether if such a third party had advised “go ahead” that would have been negligent and for all the reasons set out above in relation to the position of Midwife Bragg I do not consider that it would have been.

88 I therefore conclude that Midwife Bragg acted within the bounds of reasonable judgment. I of course accept that she might, equally reasonably, have adopted a very cautious approach and had she done so this tragedy would not have occurred. But this reflects the fact that there are a range of possible reasonable actions that might have been taken in this case and Midwife Bragg’s decision was within that range.

#### **F. Conclusion / outcome**

89 For all of these reasons the claim does not succeed.

90