THE HIGH COURT

[2018 No. 81 J.R.]

BETWEEN

THE NATIONAL MATERNITY HOSPITAL

APPLICANT

AND

THE MINISTER FOR HEALTH

RESPONDENT

AND

THE HEALTH INFORMATION AND QUALITY AUTHORITY

NOTICE PARTY

JUDGMENT of Mr. Justice Meenan delivered on the 6th day of September 2018

Mrs. Malak Thawley

1. On 8 May 2016 the late Mrs. Malak Thawley attended with her husband at the applicant hospital (the hospital). Earlier that day Mrs. Thawley had attended a private clinic and was directed, after having had an ultrasound scan, to attend the hospital. In the hospital Mrs. Thawley was taken to the Foetal Assessment Unit for review. Following an ultrasound Mrs. Thawley was found to have a right side ectopic pregnancy. At the Foetal Assessment Unit Mrs. Thawley was seen by a second year specialist registrar. After carrying out a review on Mrs. Thawley, the specialist registrar contacted a consultant obstetrician and gynaecologist who was on-call. The specialist registrar was advised to proceed to surgery in the form of a laparoscopic salpingectomy. At 16:08 Mrs. Thawley was taken to theatre.

2. The laparoscopic operation commenced under general anaesthetic at 16:38. A Veress needle was inserted, following which carbon dioxide flowed into the abdomen. A primary 11mm trocar was inserted by the operating doctor. When the laparoscope was inserted some blood was noted and visualisation of the abdominal cavity was obscured. The laparoscope was removed and then reinserted but blood was still noted. The doctor carried out a number of procedures to identify the source of the bleeding. At that stage Mrs. Thawley's vitals were reported as being stable. At 16:50 the operating doctor was informed by the anaesthetist that Mrs. Thawley's pulse was 96 beats per minute and her blood pressure unreadable. The operating doctor decided it was necessary to proceed to an immediate laparotomy due to the extent of the bleeding as he suspected either a ruptured ectopic pregnancy or a vascular injury. The telephone records indicate that the consultant obstetrician and gynaecologist on-call was contacted at 16:53 and he was asked to attend theatre immediately for a laparotomy. The consultant was in attendance in the theatre at 17:03.

3. The pneumoperitoneum was released while a laparotomy set was being prepared. The anaesthetic nurse went to the laboratory to obtain a number of units of blood and red cell concentrate. The consultant took over as the primary surgeon upon arrival. He proceeded immediately to the laparotomy. On opening it was clear that they were dealing with a major vascular injury and the consultant immediately sought the assistance of the vascular team from St. Vincent's University Hospital. This team arrived at approximately 17:35.

4. Despite ongoing resuscitative attempts, Mrs. Thawley's heart continued to fail and the cardio thoracic team from St. Vincent's University Hospital was called. This team arrived at 19:13. Despite further attempts to save her life, Mrs. Thawley was certified as dead at 19:57. The Coroner's inquest in June 2017 recorded that the cause of death was by reason of exsanguination caused by a laceration of the abdominal aorta due to trauma sustained in the course of a laparoscopic salpingectomy. A verdict of medical misadventure was recorded.

5. The death of Mrs. Malak Thawley was a profound tragedy for her husband Mr. Alan Thawley and their families. The Court expresses its condolences to them on their tragic loss.

6. Following the tragic death of Mrs. Thawley a number of inquiries ensued. Firstly, the hospital directed an internal inquiry on 9 May 2016 (this resulted in the NMH Report). A Coroner's inquest took place over two days in June 2017 and there was a further HSE report under the chairmanship of Dr. Peter McKenna of the National Women and Infant's Programme (the HSE Report). There is reference to a report by Mr. Lynch but, in fact, this was a contribution to the HSE Report. I will be referring to the inquest and reports later in my judgment.

7. Mr. Thawley commenced legal proceedings on 24 January 2017. On 25 January 2017 the hospital admitted negligence and breach of duty and apologised to Mr. Thawley. The claim was settled on 16 January 2018.

8. On 3 November 2017 the respondent (the Minister) directed the notice party (the Authority) to carry out an investigation under s. 9 of the Health Act 2007 (the Act of 2007).

Section 9 of the Act of 2007

9. Section 9 (as amended) provides:

> "(1) The Authority may undertake an investigation as to the safety, quality and standards of the services described in *section 8 (1)(b)* if the Authority believes on reasonable grounds that—
>
> *(a)* there is a serious risk –
> (i) to the health or welfare of a person receiving those services ...
>
> (2) The Minister may, if he or she believes on reasonable grounds that—
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> *(a)* there is a serious risk of the kind mentioned in paragraph (a) of subsection (1), and
>
> *(b)* the risk may be the result of any act, failure or negligence of the kind mentioned in paragraph (b)(i)…

require the Authority to undertake an investigation in accordance with this section."

10. In requiring the Authority to undertake the investigation the Minister must have believed, on reasonable grounds, that there was a serious risk to the health or welfare of a person receiving services from the hospital. It is necessary to pause for a moment to consider the implications of this decision. The Minister, through various agencies, has responsibility for the safety and welfare of patients using services provided by various health institutions, including the hospital. The hospital is a major tertiary maternity hospital in the country. Patients are frequently referred to the hospital by general practitioners, consultants and HSE units for complicated and major surgeries. In reaching his decision the Minister is stating that he believes, on reasonable grounds, that there is a serious risk to the health and welfare of persons receiving services at the hospital. The far reaching implications of this are self-evident for patients, those who refer patients and the medical and nursing/midwifery staff of the hospital. This is all the more so, as what gave rise to this decision was the tragic death of a young woman whilst in the care of the hospital.

Judicial review proceedings

11. Prior to making his decision to direct an investigation under s. 9 there were lengthy exchanges of correspondence and a number of meetings between the Minister and/or his officials involving the hospital and also involving Ms. Caoimhe Haughey of C.M. Haughey Solicitors, the solicitors acting on behalf of Mr. Alan Thawley. I will return to this correspondence and meetings in the course of the judgment but, at this point, it should be stated that the hospital accepted the need for an external review and suggested that it be carried out by the Royal College of Obstetricians and Gynaecologists (RCOG) a UK body which, in the opinion of the hospital, had the expertise to carry out such a review. The objection of the hospital was to a s. 9 investigation.

12. By order of the High Court (Noonan J.) on 29 January 2018 the hospital was granted leave to apply by way of judicial review for certain reliefs. The reliefs sought were, *inter alia*:-

> (i) An order of *certiorari* quashing the decision of the Minister to commence an investigation pursuant to s. 9 of the Act of 2007.
>
> (ii) A declaration that in making the said decision the Minister acted ultra vires.
>
> (iii) A declaration that the Minister fettered his discretion and/or failed to lawfully use his discretion in deciding to commence the said investigation.
>
> (iv) A declaration that the decision of the Minister was irrational, unreasonable, vitiated by errors of fact and arbitrary.
>
> (v) A declaration that in making the said decision the Minister acted in breach of fair procedures and/or natural and constitutional justice.
>
> (vi) A declaration that the Minister failed to provide reasons and/or adequate reasons and/or articulate grounds for his decision.

13. Somewhat surprisingly for a Minister who on 3 November 2017 directed an investigation as he had reasonable grounds to believe that there was a serious risk to the health and welfare of persons receiving the services of a major tertiary maternity hospital the statement of opposition was not delivered until 4 May 2018. Indeed, the statement of opposition and an affidavit were only filed after a peremptory order of court had been made against the Minister.

14. The Notice party did not take part in the proceedings before me.

Applicable legal principles

15. Judicial review proceedings are directed against the decision making process rather than the decision itself. In this case the decision of the Minister to direct a s. 9 investigation is attacked by the hospital as being irrational, unreasonable and vitiated by errors of fact. It is suggested that the process which resulted in the Minister's decision failed to set out all the relevant and material facts upon which a rational and reasonable decision could be based.

16. The legal principles which a court ought to apply in an application such as this are well settled. I refer to the *State (Keegan) v. Stardust Compensation Tribunal* [1986] I.R. 642., where Henchy J., at p. 658, stated: -

> "[W]hether the conclusion reached in the decision can be said to flow from the premises. If it plainly does not, it stands to be condemned on the less technical and more understandable test of whether it is fundamentally at variance with reason and common sense…
>
> I would myself consider that the test of unreasonableness or irrationality in judicial review lies in considering whether the impugned decision plainly and unambiguously flies in the face of fundamental reason and common sense. If it does, then the decision-maker should be held to have acted ultra vires, for the necessarily implied constitutional limitation of jurisdiction in all decision-making which affects rights or duties requires, *inter alia*, that the decision-maker must not flagrantly reject or disregard fundamental reason or common sense in reaching his decision."
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> The decision in Keegan was approved in *O'Keeffe v. An Bord Pleanala* [1993] 1 I.R. 39 where, at p. 72, Finlay C.J. stated: -
>
> "I am satisfied that in order for an applicant for judicial review to satisfy a court that the decision-making authority has acted irrationally in the sense which I have outlined above so that the court can intervene and quash its decision, it is necessary that the applicant should establish to the satisfaction of the court that the decision-making authority had before it no relevant material which would support its decision."
>
> I refer also to *Meadows v. Minister for Justice* [2010] 2 I.R. 701 where Fennelly J., at p. 827, stated: -
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> "[449] I prefer to explain the proposition laid down in *The State (Keegan) v. Stardust Compensation Tribunal* [1986] I.R. 642 and *O'Keeffe v. An Bord Pleanála* [1993] 1 I.R. 39, retaining the essence of the formulation of Henchy J. in the former case. I would say that a court may not interfere with the exercise of an administrative discretion on

substantive grounds save where the court is satisfied, on the basis of evidence produced by the applicant, that the decision is unreasonable in the sense that it plainly and unambiguously flies in the face of fundamental reason and common sense"

17. The hospital contends that the Minister failed to afford fair procedures to the hospital in reaching his decision to direct an investigation under s. 9. This raises the issue as to what extent fair procedures ought to apply in a process of investigation that may lead to an inquiry. The various authorities on this issue were recently considered by Noonan J. in *Independent News and Media Plc v. The Director of Corporate Enforcement* [2018] IEHC 319. Noonan J. referred to the decision of the Supreme Court in *Crayden Fishing Company Ltd v. Sea Fisheries Protection Authority & Ors* [2017] IESC 74. In giving the judgment of the Supreme Court, O'Donnell J. considered what were apparently conflicting decisions. O'Donnell J. stated:

> "31 I do not consider it appropriate, necessary or indeed possible at this stage to offer a single bright line rule resolving all these issues. That may have to be addressed in circumstances where the issue arises and where it may be necessary to consider a wider range of authority than arose in this case. Even then there is no reason to be optimistic that a single rule may be discerned. I would however hesitate to accept, without careful and detailed analysis the contention that *O'Ceallaigh* represents a trend towards greater fair hearing rights at a preliminary stage, which should in turn be expanded upon. Rather I would approach the case on the basis that the default position is that a person conducting a preliminary investigation which itself does not lead directly in law to a binding and adverse decision, is not normally under an obligation to comply with a requirement of a fair hearing."

In citing this passage Noonan J. stated: -

> "54. *Crayden* shows that it is neither desirable, nor possible, to attempt to divine or devise a rule that will apply in all cases. The conflict in the cases discussed by O'Donnell J. is testament to that. It does however emphasise that there is no evolving jurisprudence towards a requirement for fair procedures at the preliminary stage of a process which is not of itself conclusive of anything but the ultimate stage of which does afford such procedures. In the foregoing passage, the Supreme Court drew particular attention to the dangers of a mandatory requirement for fair procedures at early stages of such processes before what might be described as the "main event". Importantly Crayden decides that the default position in such situations is that fair procedures are not required at the preliminary stage."

18. It was contended that in directing an inquiry under s. 9 the Minister had fettered his discretion. The factual basis for this submission was an agreed statement following a meeting of officials from the Department of Health with Mr. Thawley and his legal advisors. The statement read: -

> "The Minister has agreed to meet again with Mr. Thawley in the near future to examine this report. If at this stage Mr. Thawley is still of the view that an external review is required, the Minister will accede to this request."

The report referred to is the HSE Report.

19. The Court was referred to the Supreme Court decision of *O'Neill v. Minister for Agriculture* [1998] 1 I.R. 539. That case concerned a licensing scheme for artificial insemination under the Livestock (Artificial Insemination) Act 1947 (the Act of 1947). Under the scheme the State was divided into nine areas with only one such licence to be granted in each area. The applicant challenged the exclusivity of the scheme claiming that in adhering to the scheme the first named respondent had fettered the exercise of his discretion. In giving judgment, Keane J. (as he then was) stated at p. 545: -

> "There is, accordingly, no doubt that the first respondent complied with his obligation to hear and respond to the case being made by the applicant that the policy should be altered so as to accommodate his application. On that ground, there can be no criticism of the first respondent. The matter, however, does not end there: it is unquestionably the case that the first respondent, as he made clear in his correspondence with the applicant, had fettered the exercise of the discretion conferred on him by the Act of 1947 by excluding the possibility of granting a licence which would conflict with the exclusivity scheme. The first issue that arises, accordingly, is as to whether the first respondent was entitled under the Act to impose that constraint on the exercise of his discretion or whether it was an unlawful abdication of the powers vested in him under the Act of 1947."

In the event the court held that the exclusivity scheme was ultra vires the Act of 1947.

The decision of the Minister to require an investigation under s. 9 of the Act of 2007

20. The Court has to examine the basis for the decision of the Minister and assess if he had reasonable grounds to believe that there was a serious risk of the health or welfare of persons receiving the services of the hospital. It is necessary to examine the sources of the Minister's knowledge in circumstances where the Minister, through his officials, did not carry out any investigation into the hospital. This is in contrast to the situation that prevailed when the Minister directed a s. 9 investigation into a hospital in Portlaoise where a preliminary investigation was carried by Dr. Tony Holohan, Chief Medical Officer (CMO) of the Department of Health. With regards to the hospital, the Minister had available to him the internal report compiled by the hospital (NMH Report), the evidence on oath given at the Coroner's inquest in June 2017 and the report carried out under the chairmanship of Professor McKenna (the HSE Report). It is necessary to look at these reports and the evidence at the inquest in some detail.

NMH Report

21. The investigators for this report were Dr. Peter McPartland, consultant obstetrician and gynaecologist at the hospital, Dr. Hugh O'Connor, consultant obstetrician and gynaecologist from outside the hospital, Dr. Ingrid Browne, consultant anaesthetist, Ms. Anne Rath, assistant director of midwifery and nursing at the hospital, together with others. The aim of the report was to: -

> (i) establish the factual circumstances relating to the death of Mrs. Thawley;
>
> (ii) identify any key causal factors which may have occurred;
>
> (iii) identify the factors that contributed to the key causal factors;
>
> (iv) recommend actions that will address causal and contributory factors as well as incidental findings so that the risk of future harm arising from these factors is eliminated or if this is impossible is reduced as far as is reasonably practicable.

This investigation report was further reviewed by two independent external experts, one a vascular surgeon and the other an

overseas gynaecologist with special expertise in laparoscopy/endoscopy. It should also be noted that the investigation team had no prior involvement in any aspect of the matters being investigated.

22. This investigation was undertaken predominately in compliance with the incident investigation methodology outlined in the HSE Investigation Processes Working Group (2015) "Guidelines for System Analysis Investigation of Incidence", an internationally recognised methodology for investigating adverse incidents and events in health care.

23. The Report contains a detailed "incident background" on the matters being investigated which states: -

> "The incident background presented below focuses on pertinent events which took place immediately prior to the scope of the incident under investigation."

There then followed an almost minute by minute account of the events between 14:21, when Mrs. Thawley attended at the hospital, 16:08 when she arrived in theatre and 19:57 the time certified for death.

24. The report found three "key causal factors": -

> (i) vascular injury of aorta during laparoscopy;
>
> (ii) delay in recognition of vascular injury;
>
> (iii) delay in commencing surgery and resuscitation.

25. Arising out of these three factors a number of detailed recommendations were made together with a timeline for their implementation. In particular, in respect of a consultant obstetrician/gynaecologist and consultant anaesthetist not being physically present in the hospital at the time of the vascular injury to Mrs. Thawley, it was recommended that: -

> "Consideration be given to the onsite presence (in the hospital) of a consultant obstetrician/gynaecologist and consultant anaesthetist at all times as opposed to the current on call arrangements. This should be considered at a national level.
>
> The investigation team recommends consideration of co-locating (the hospital) with a general hospital to better manage rare cases such as this tragedy."

There were numerous other recommendations including vascular implements being immediately available in the hospital.

Coroner's Inquest

26. The inquest took place on 21/22 June 2017. Though the purpose of an inquest is to determine, *inter alia*, the cause of death it affords an opportunity for the medical and nursing staff involved in the care of the late Mrs. Thawley to give evidence, on oath, of the events leading up to her death.

27. The doctor who carried out the laparoscopy on the late Mrs. Thawley gave evidence of his qualifications and experience. At the time the doctor was working as a second year specialist registrar in the hospital. During his time in the hospital he had completed a laparoscopic surgical skills course awarded by the Royal College of Physicians of Ireland and, prior to 8 May 2016, had performed 92 laparoscopic proceedings as primary operator, 15 of which had been independently performed.

28. The consultant obstetrician/gynaecologist on-call also gave evidence. He said he was at home when at 16:53 he received a telephone call from the circulating nurse. When the consultant arrived into the operating theatre at 17:03 he took over the laparotomy procedure. The consultant concluded that it was not a ruptured ectopic pregnancy but rather a major vascular injury and he directed the theatre nurse to immediately call the vascular team from St. Vincent's University Hospital. At approximately 17:35 the vascular team arrived. Mrs. Thawley's condition was deteriorating and the cardio-thoracic team in St. Vincent's University Hospital was called.

29. In the course of the hearing the following exchange took place: -

> "Coroner. . Then when you were contacted, the evidence we've heard from Dr - is if he proposed to do any emergency surgery that he would first need to be required to discuss that with his consultant; is that the case?
>
> Consultant. . Absolutely, and that would pertain to any case of any patient taken to theatre."

30. In concluding the inquest, the Coroner stated: -

> "As the coroner has a role in recording or bringing in recommendations or riders of a general nature designed to prevent future similar tragedies, I think we have heard an exposition of many of the changes and developments that have taken place following this tragedy, and I would wish to endorse each of those and those that are proposed to be actioned in the future".

A verdict of "medical misadventure" was recorded.

The HSE report

31. As stated, the NMH report was undertaken predominantly in compliance with the investigation methodology outlined in the "Guidelines for Systems Analysis Investigation of Incidents". In order to ensure that this was in fact the case, a further report was commissioned titled "HSE Maternal Death Investigation Report Review". The expert panel for this report comprised of, *inter alia*, Dr. Peter McKenna, Clinical Director NWIHP (Chair), Professor Paddy Broe, Consultant Vascular Surgeon, Ms. Angela Dunne, Director of Midwifery National Women and Infants Health Programme, Professor Fergal Malone, Consultant Obstetrician/Gynaecologist (Rotunda Hospital) and Dr. Jeanne Moriarty, Anaesthetist and Clinical Director for Surgery, Anaesthesia and Critical Care (St. James' Hospital). The HSE report also considered the Coroner's "summation, findings and the depositions".

32. Apart from some minor matters, the HSE report concluded that the NMH report was in compliance with the said guidelines. The report did state that if a future review were to be conducted independently then the expert panel would sugget that focus should be paid, *inter alia*, to; -

(i) the period between 16:38 and 17:07;

(ii) the practice of carrying out non-urgent surgery out of hours;

(iii) explore the resources necessary if non – urgent surgery is carried out at the weekend or out of hours, whether the normal weekday staffing is required, i.e. consultant in charge should be in attendance?

However, the HSE report recorded: -

> "The panel found that the report (the NMH report) identified the cause of death as exsanguination due to a delayed diagnosis of a major vessel trauma. This concurred with the findings of the coroner's report. It is the view of the panel that the investigation report examined the case appropriately from a clinical perspective".

The report also confirmed that the recommendations in the NMH report would, if implemented, reduce the risk of such a tragic event occurring in the future.

33. It should be noted, as appears from correspondence between the hospital and the Minister, that the hospital expressed concerns with the HSE report due to a lack of interaction between the expert panel and the hospital.

Information before the Minister

34. In light of these reports and the evidence given at the Coroner's inquest it is necessary to examine what information was before the Minister when he made the decision to direct the s. 9 investiagtion. A number of briefing notes were exhibited in the affidavits and I will now examine these notes to see to what extent they reflect the findings of the reports and took into account the evidence, given on oath, at the inquest from the doctors and nurses involved.

35. The briefing note of 28 August 2017 made reference to the NMH Report. There was no reference however to the various recommendations or corresponding implementation timelines.

36. There was no reference to the fact that the HSE Report concluded that the NMH Report had examined the case appropriately from a clinical perspective. Nor is there any reference to the fact that the HSE Report confirmed that the recommendations set out in the NMH Report would, if implemented, reduce the risk of such a tragic event occurring in the future.

37. There is no reference to the sworn evidence given at the inquest by the specialist registrar or the consultant on-call concerning the decision to operate on the late Mrs. Thawley.

38. On 10 October 2017 representatives from the hospital met with a number of officials from the Department of Health, including Dr. Tony Holohan, CMO. The notes of the meeting record the following:

> "2. … - the Minister has decided that an external review is required; there is further learning (not necessarily confined to the maternity service) to be gained from the system which should have the full implementation levers behind it …"

and

> "8. (Dr. Tony Holohan) outlines that this meeting was not about the McKenna Report (the HSE Report) and repeated number 2. Understood the depth of feeling but believed that the situation was not irretrievable;
>
> Their learnings and these could be applied across the Health Service. The need for a further review was not as a result of identified deficiencies in the earlier reviews but rather as a means to identify the learning that could be applied and how that learning could be applied."

39. In my view, the note of this meeting shows that there was an acknowledgment that there was a need for further learning arising from the circumstances of the tragic death of Mrs. Thawley. This learning however was not to be confined to maternity services at the hospital but would have a broad application across the health service.

40. The briefing note to the Minister of 23 October 2017 recommended that he direct an investigation under s. 9(2) of the Act of 2007. It was envisaged that the terms of this investigation would include:

(i) Practice of surgery outside of the core hours in maternity services and beyond.

(ii) The seniority of staff present outside of those core hours.

(iii) The readiness of hospitals to respond to major emergencies in such circumstances.

(iv) The implementation of early warning systems from the clinical recognition and management of a deteriorating patient, and

(v) The need, if any, for the development of new standards for the system.

However, this briefing note, like that of 28 August 2017, made no reference to the recommendations in the NMH Report, neither was there any reference to the conclusions of HSE Report or to the evidence given by the medical personnel involved to the Coroner's inquest.

41. In summary, both the briefing notes provided to the Minister and the meeting between representatives of the hospital and officials from the Department of Health make it clear that there was an acceptance by the hospital and the Minister for the need to learn from the death of Mrs. Thawley. Issues concerning "out of hours" surgery were common not just to the hospital but across all hospitals in the health service that perform surgery. Indeed, given the nature of the maternity services provided by the hospital it was argued that the term "out of hours" surgery had little application to the hospital.

Correspondence

42. I will now look at the correspondence that passed between the hospital and the Minister both before and after the decision to direct a s. 9 investiagtion. In reviewing this correspondence, reference was also made to correspondence passing between the

Minister and Ms. Haughey of CM Haughey Solicitors, the solicitors acting on behalf of Mr. Alan Thawley. I will start with the letter of 31 July 2017 from the hospital to the Minister which notes that an external review will be called regardless of the outcome of the HSE Report. The letter states that the Board of the hospital is very anxious to receive clarification on this matter as urgently as possible and requests a meeting. This letter was responded to by the Minister on 9 August 2017 to the effect that the Minister had agreed that if following the receipt of the HSE Report Mr. Thawley was of the view that an external review was required then the Minister would facilitate such.

43. Following receipt of the HSE Report the hospital wrote to the Minister on 6 September 2017. The hospital expressed in detail a number of objections to the HSE Report, in particular, that the hospital was not consulted in its preparation. The letter requested an urgent meeting with the Minister and concluded:

> "During this discussion we hope to address the potential benefit of further external review and how it would advance our understanding and learning from the events surrounding Mrs. Thawley's tragic death".

44. Following this letter from the hospital the Minister stated on 13 September 2017 that he would welcome "thoughts in relation to the further external review that I intend to commission and how it would advance the understanding and learning from the events surrounding Mrs. Thawley's death".

45. In response to a further letter from the hospital the Minister, having requested the thoughts of the hospital in relation to a further review, stated in a letter dated 25 September 2017 that:

> "[W]hile I am not drawing any conclusions, I believe that given the gravity of a maternal death in such circumstances, that it is important that all the learning and the wider patient safety implications, which are not exclusive to the National Maternity Hospital are identified".

46. It is noteworthy that, again, the Minister was concerned with learning and wider patient safety issues "which are not exclusive" to the hospital.

47. Following the meeting of 10 October 2017, the note of which I have already referred to, the hospital wrote to the Minister on 13 October 2017. This letter referred to the HSE Report and the Coroner's inquest and stated that a specific clinical deficiency had not been identified. The letter confirmed the hospital's willingness to participate in an external review and stated:

> "As discussed we stressed the importance that this external review would follow international and national best practice in terms of its conduct and that it would be transparent and inclusive. We would like to suggest that RCOG UK as a body who have the expertise to carry out such an external review. We would also request that the review would include all of the processes to date including our own system's analysis report, the McKenna Report, the Lynch Report and the coroner's report …"

48. Following the Minister's decision on 3 November 2017 to direct a s. 9 investigation, the hospital, by letter dated 13 November 2017, strongly objected to such an inquiry stating:

> "The hospital operates in a tertiary context and provides care to patients referred from HSE units all over Ireland offering advanced specialised services to them which are not available in the majority in HSE hospitals. We cannot understand how you have formed the view that a serious risk is posed to all those persons being cared for by the hospital. Further, we are advised that in the absence of a "… a serious risk to the health or welfare of a person receiving those services" a discreet external review, as distinct from the s. 9 process, is appropriate …"

The letter then went on to refer to the hospital's apprehension of "the associated and unavoidable reputational and operational implications were a s. 9 investigation to proceed. The magnitude of a s. 9 investigation and its damaging impact to the staff and services provided at the hospital cannot be overstated."

49. The letter of 13 November 2017 was not replied to by the Minister. A further letter of 22 December 2017 from the hospital to the Minister referred, again, to the meeting of 10 October 2017 in the course of which, the letter states, the CMO (Dr. Holohan) was asked if he had identified a clinical deficiency in the hospital and that he confirmed no such risk was perceived or existed. The letter concluded:

> "The Board and Management of NMH find it inconceivable that you continue to refuse to engage with us given your apparent view of the clinical risk which prevails and the care being provided at NMH. You have consistently failed to set out any legitimate grounds for a s. 9 investigation. If it is truly your position that grounds exist for the invocation of s. 9 then it is incumbent upon you to explain why you have waited for eighteen months to do so"

50. The contents of this letter highlights one of the striking features of this case in that in November 2017 the Minister claimed to have reasonable grounds to believe that there was a serious risk to the health or welfare of persons attending at the hospital but failed to inform the hospital what these serious risks were and the reasonable grounds upon which he believed them to exist. It would appear that the hospital was only informed of what these serious risks were when the Minister filed his statement of opposition in these proceedings on 4 May 2018, having been directed to do so by order of court on a peremptory basis.

51. The Minister responded to the letters of 13 November 2017 and 22 December 2017 in a letter on 8 January 2018. This letter confirmed his decision to direct a s. 9 investigation and stated:

> "I believe that there are potential patient safety issues which need to be addressed, such as the practice of surgery outside core hours, the seniority of staff on site out of hours and the readiness to respond to major emergencies in such circumstances"

52. On a reasonable construction "potential patient safety issues" fall short of a "serious risk" to the health or welfare of patients. In reaching this view I would have thought that if the Minister had reasonable grounds for believing the existence of such a serious risk that he would have directed the hospital to cease the practice of surgery "outside of core hours" pending the determination of the s. 9 investigation.

53. Finally, I refer to a letter, dated 25 January 2018, from Dr. Holohan to the Master of the Hospital, Dr. Rhona Mahony. In the course of this letter, Dr. Holohan seeks to explain the basis for directing the s. 9 investigation. It states:

> "I would firstly note that the Department's sole interest in this matter relates to a wish to understand the circumstances surrounding the death of Mrs. Thawley as fully as possible, and ensuring that the possibility of such an event occurring within the health service is minimised to the greatest extent possible."

I think that it is significant that Dr. Holohan refers to the need to avoid such a tragedy "occurring within the health service" rather than at the hospital alone.

> Further, the letter reiterates the need for learning: -
>
> "[T]he Minister, having considered in detail the various reports which had been generated … came to the view that there continues to be areas where further lessons can be learned arising out of this incident. These would include, for example, the practice of undertaking non-emergency surgery outside of core hours without the presence of relevant consultants on site. While it is recognised that such practices are long standing and likely occur across the wider health system, it would now appear appropriate and justified to examine the particular role which this issue may have played in the circumstances of this particular incident"

Again there is no requirement or advice from the CMO to the hospital as to what steps might be taken to counter the "serious risk" identified by the Minister. Furthermore if the Minister was of the view that patients attending the hospital were being exposed to a serious risk to their health or welfare then there must be serious implications of the CMO expressing the view that "it is recognised that such practices are long standing and likely occur across the wider health system".

54. In conclusion, having considered the relevant correspondence, it is apparent that the need for learning is recognised. The correspondences do not, however, provide much assistance in trying to identifying either the "serious risk", or the "reasonable grounds" for believing that such a risk exists, to the health or welfare of persons using the hospital required to direct an investigation under s.9.

Affidavit of Dr. Tony Holohan
55. There were numerous lengthy affidavits filed in this action. However, one paragraph, in particular, stands out. Paragraph 14 of the affidavit of Dr. Tony Holohan, CMO (sworn 17 July 2018) states: -

> "14. There are pressing issues arising from the facts of this case which require further investigation. An investigation into the decision by the applicant to commence surgery at the relevant point in time is as important from a patient safety prospective as the investigations into the events that transpired during surgery. Certain facts, such as the passing of twenty minutes between blood being requested and a transfusion commencing; that cross matching was not performed in advance of surgery; that the relevant vascular instruments were not on site at the commencement of surgery but had to be brought to the applicant's hospital under garda escort from other hospitals during surgery and the procurement of ice from a nearby public house, are matters that are of considerable concern to the respondent in the area of patient safety"

56. These assertions by Dr. Holohan on the issue of patient safety stand up to no analysis. Firstly, the decision to commence surgery on the late Mrs. Thawley was taken by the doctor during consultation with the consultant on-call. This was the evidence given at the Coroner's inquest and Dr. Holohan did not have an issue with this. Secondly, the transfusion of blood and cross-matching were not issues in the events which ended in the death of Mrs. Thawley. Thirdly, the issue of vascular instruments was addressed in the NMH Report with the recommendation that such instruments be present. Fourthly, the procurement of ice was not in any way relevant to the death of Mrs. Thawley. Hospitals, including the hospital, are under a direction not to keep ice on site because of fear of infection. If these were specific issues of patient safety one would have expected an immediate direction to the hospital to implement the necessary changes. There was no such direction.

Evidence of Dr. Tony Holohan
57. In the course of the hearing, Dr. Tony Holohan, CMO, was cross-examined on his various affidavits. Dr. Holohan confirmed that the hospital was not told what the reasonable grounds were upon which the Minister formed his opinion of the serious risk. On the issue of having on site consultants at all times Dr. Holohan accepted that this was not the case either in the hospital or other hospitals and, indeed, went on to state that "there is no country in the world where that exists as a standard". Furthermore Dr. Holohan agreed that he did not have a problem, based on the sworn evidence of the doctors involved to the Coroner's inquest, with the procedures followed or the decision to commence surgery in Mrs. Thawley's case. It has to be said that there was no evidence whatsoever, or even a suggestion of such, that the procedure followed in Mrs. Thawley's case would not be followed in other cases.

58. The concerns expressed by Dr. Holohan at para. 14 of his affidavit (see para. 55) were questioned by counsel for the hospital during cross-examination. He confirmed that the availability of vascular instruments was not an issue nor was the cross-matching or availability of blood. He also confirmed that hospitals are directed not to have ice on site for infection reasons.

59. Other issues which emerged in the course of the proceedings included the co-location and governance of the hospital. Dr. Holohan confirmed that discussions with the Department of Health on the future co-location of the hospital to the campus of St. Vincent's University Hospital ended once proceedings had issued. Further, the Department of Health would consider what implications these proceedings would have for the future governance of the hospital.

60. In the course of his evidence Dr. Holohan described how a s. 9 investigation proceeded in the case of a number of infant deaths at a hospital in Portlaoise. In that case Dr. Holohan was asked to undertake an investigation into the hospital to establish immediate questions concerning safety. He also confirmed that a number of interim measures were taken to ensure safety both within the hospital in question and generally pending the outcome of the investigation. Dr. Holohan also confirmed that the Authority had set up a monitoring programme advising all maternity hospitals. It would appear that this programme would cover a number of issues which the Minister has identified as being a problem within the hospital and the wider health service.

"Statement of opposition"
61. In referring to the reasonable grounds necessary to direct an investigation under s.9, the statement of opposition states:-

> "… that belief was based on and arose from the lack of information and clarity about the decision making process in Mrs. Thawley's case to commence surgery outside core hours when it may not have been necessary to operate immediately and where there was no on site consultant presence and basic preparatory steps may not have been taken, about whether there is a clear protocol or procedure within the hospital that determines the circumstances in which surgery, both emergency and non-emergency in nature, is initiated outside of core hours or in the absence of consultants on site, and whether, if such procedure exists, it was in fact followed in these circumstances …"

62. It is clear based on the evidence given at the Coroner's inquest, which I have already referred to, what was the basis for and circumstances surrounding the decision to commence surgery on Mrs. Thawley on 8 May 2016. As I have already referred to, Dr. Holohan did not take issue with this nor did he express any reason why the procedure followed in Mrs. Thawley's case would not be followed in others. This ground advanced by the Minister is not supported by the evidence of CMO and, as I have observed earlier in this judgment, there was no reference to the evidence given at the Coroner's inquest in the briefing notes to the Minister which advised him to direct a s. 9 investigation.

63. The statement of opposition contends that there were no specific recommendations on these issues contained in the NMH Report. As referred to at paras. 35-37 and 40 above this is not the case and, indeed, as I have already noted there was little if any regard to the NMH Report in the briefing notes before the Minister.

64. In the course of the judgment I have set out, in some detail, the correspondence between the hospital and the Minister/Department of Health and what meetings were held. It is clear from the correspondence that the hospital sought urgent meetings with the Minister on numerous occasions. The Minister did not accede to the requests for such meetings. In light of this I find it difficult to understand the following in the statement of opposition: -

> "8. Without prejudice to the foregoing, in the absence of positive and cooperative engagement by the applicant during the period in which considerations as to the nature of the further external review were ongoing … the direction of the respondent notice party to conduct the investigation pursuant to s. 9(2) of the Health Act, 2007 was, in all the circumstances an appropriate exercise of his discretion."

65. Having reviewed the relevant documentation, the affidavits and the evidence of Dr. Holohan, I make the following findings:-

> (i) Prior to directing an investigation under s. 9 the Minister, through his officials, did not carry out any investigation of his own but claimed to rely upon the NMH Report, the HSE Report and the evidence given by the doctors and nurses involved at the Coroner's inquest. It is clear to me that the findings, recommendations and conclusions of these reports were not properly considered. Further, no regard was given to the evidence, on oath, at the coroner's inquest.
>
> (ii) The briefing notes to the Minister which advised that he direct a s. 9 investigation reflected the deficiencies referred to at (i) above.
>
> (iii) The grounds for the s. 9 investigation set out in correspondence between the hospital and the Minister fell short of the grounds required for such. The Minister, or his officials, stated on numerous occasions that the s. 9 investigation would be a learning exercise and that the practices which were being inquired into were not unique to the hospital but were practiced across hospitals in the health system.
>
> (iv) Dr. Holohan was incorrect in identifying in his affidavit, that the circumstances of the decision to commence surgery, the availability of blood for transfusion and cross matching, the non-availability of vascular instruments and ice were issues of patient safety. A consideration of the NMH Report, the HSE Report and the sworn evidence of doctors and nurses at the Coroner's inquest would have prevented this error.
>
> (v) Dr. Holohan, in his evidence to the Court, confirmed that he did not have any issue with how the decision to operate on Mrs. Thawley was taken.
>
> (vi) Neither the "reasonable grounds" nor the "serious risk" identified by the Minister were communicated to the hospital despite repeated requests to do so.
>
> (vii) At no stage was the hospital advised or directed to take steps to either eliminate or reduce the serious risk, identified by the Minister, to ensure the health or welfare of its patients either pending the outcome of the s. 9 investigation or at all.
>
> (viii) The grounds relied upon by the Minister in the "statement of opposition" are not supported by the relevant reports, correspondence and evidence given at the hearing.

66. I am of the view that what is envisaged by s. 9 of the Act of 2007 is an investigation by the Authority into a situation which exists in a hospital in respect of which either the Minister or the Authority has reasonable grounds to believe poses a serious risk to the health or welfare of its patients. The object of the investigation must be to eliminate that risk rather than to be a learning exercise. In this case, the Minister has accepted that the serious risk he claims to have identified in the hospital also exist in hospitals across the health service. In my opinion, it is irrational and unreasonable for the Minister to direct a s. 9 investigation into a hospital in circumstances where the practices that are being inquired into exist, without any intervention by or on behalf of the Minister, in many other hospitals across the health service.

Submissions of the Minister

67. In giving his evidence Dr. Holohan stated that an event as serious as the death of Mrs. Thawley is considered to be a "never event". The "never event" is treated as an existing risk until proven otherwise. It was suggested that this risk was ongoing and would provide a basis for a s. 9 investigation. Were it not for the conclusions and recommendations of the NMH Report and the HSE Report such a view would not be unreasonable. However, these reports, together with the evidence at the Coroner's inquest, clearly identified and made recommendations to eliminate such risk. As the Minister was relying on these reports when he reached his decision, it could not, in my view, be said that "reasonable grounds" to direct a s. 9 investigation existed.

68. The Minister relied upon correspondence and meetings which were held with the Authority after the decision to hold the inquiry. Initially the Authority expressed serious misgivings about the holding of a s. 9 investigation but eventually agreed to do so and produced Terms of Reference which were specifically directed to the hospital. This is in spite of the fact that correspondence between the hospital and the Minister, already referred to, made clear that what was being looked into occurred across the health service.

69. In his evidence, Dr. Holohan expressed the view that, although he did not have an issue with how the decision to operate was made in the case of Mrs. Thawley, there could be a variation in the cases of other patients. This, it was submitted by the Minister, was a reasonable ground for a s. 9 inquiry. I do not see how this could be the case in the absence of the Minister making basic inquiries with the hospital on this issue. Without making such inquiries as to whether or not there was a variation, was speculation on the part of Dr. Holohan. Speculation is not a basis for a s. 9 investigation. In any event, importantly, the evidence of the consultant

involved at the Coroner's inquest made it clear that the decision making process in Mrs. Thawley's case would be followed in every other case.

70. In response to the criticism by the hospital that at no stage did the Minister give details of what he saw to be a serious risk in the hospital, Dr. Holohan stated that were the Minister to do so it might be considered, in some sense, to be a finding by the Minister. I find this difficult to understand. Informing the hospital as to what he had reasonable grounds to consider a serious risk at the hospital does not amount to a finding. Under s. 9 the finding is made by the Authority not the Minister.

Application of Legal Principles
71. At para. 14 above, I have set out the authorities which established the legal principles which I must apply to this application. I have set out my findings on the documentation, the affidavits and the evidence of Dr. Holohan. In light of these, I reach the conclusion that the decision of the Minister to require the Authority to undertake an investigation under s. 9(2) of the Act of 2007 was "unreasonable in the sense that it plainly and unambiguously flies in the face of fundamental reason and common sense" (as per Fennelly J. in *Meadows v. Minister for Justice*).

72. If I had any doubt about the conclusion I have reached it would be dispelled by a number of actions which the Minister did not take. Patient safety must be a priority, if not the first priority, for the Minister. Bearing in mind that the proposed s. 9 investigation was as a result of the tragic death of a young woman, the Minister decided, on what he considered to be reasonable grounds, that there was a serious risk to the health or welfare of patients of the hospital. In these circumstances, if the Minister had such a belief, I find it inconceivable that he would not have:-

(a) advised or directed the hospital to take all necessary steps to eliminate such serious risk;

(b) advised or warned doctors and other referring health institutions of the existence of such serious risk at the hospital;

(c) informed the general public of the steps he had taken to eliminate the serious risk he had identified.

It would not have been acceptable for the Minister to have awaited the outcome of the s. 9 investigation before taking such steps.

73. The hospital, therefore, is entitled to an order of *certiorari* quashing the decision of the Minister requiring the Authority to undertake an investigation under s. 9 of the Act of 2007.

Other Issues:
74. In the course of the hearing, a number of other issues arose which require comment.

75. It was submitted by the hospital that the Minister had fettered his discretion. The basis for this submission was a commitment made by the Minister to Mr. Thawley that if, following the release of the HSE Report, he were still of the view that an external review was required that he, the Minister, would accede to this request. Whereas it might have been preferable to await the outcome of the HSE Report before directing a further inquiry, I do not believe it can be maintained that the further inquiry envisaged by the Minister would necessarily have to be a s. 9 investigation. Indeed, if the Minister had acceded to the request of the hospital that the further inquiry be carried out by RCOG or another suitably qualified body then the instant proceedings would have been avoided. Therefore, I do not find that the Minister fettered his discretion.

76. I do not accept the hospital's submission that they were entitled to fair procedures in the lead up to the decision of the Minister to direct the investigation. I have referred to the judgment of O'Donnell J. in *Craydon* and adopt what he described as the "default position", that a person conducting a preliminary investigation which of itself does not lead directly to a binding and adverse decision is not formally under an obligation to comply with the requirements of a fair hearing. In a case such as this, however, where the Minister decided to rely upon reports and made no inquires with the hospital as to what he considered to be a serious risk, the decision to hold an investigation is vulnerable to the charge that it is unreasonable.

77. Unfortunately, it became clear during the course of the proceedings that relations between the hospital and the Minister/Department of Health had deteriorated. Discussions on co-location of the hospital on the campus of St. Vincent's University Hospital ceased shortly after the commencement of the proceedings. In the events leading up to the tragic death of Mrs. Thawley both a vascular team and a cardio-thoracic team had to be summoned to the hospital at Holles Street from St. Vincent's University Hospital some distance away. Though the distance was small it was, nonetheless, a distance. One of the benefits of the proposed co-location is that such teams would be on the same campus. The decision to end talks on co-location could hardly be considered to be in the best interests of patient safety.

78. The issue of governance was also raised. In my view, good governance of the hospital entails maintaining the confidence of patients in the services provided. This is all the more so when those attending the hospital are women at a particularly vulnerable time of their lives. Given the decision of the Court, not to have challenged the decision to hold a s. 9 investigation, with all that it implies, would have been an absence of governance.

Conclusion:
79. I have quashed the decision of the Minister to direct a s. 9 investigation. However, as was stated in the HSE Report:-

> "Internationally it is recognised that the potential for learning from some patient safety incidents is so great, or the consequences to patients, families and carers, staff or organisations so significant that these incidents warrant a comprehensive response."

In the case of the tragic death of Mrs. Thawley there has been such a response but it is now necessary to apply the learning. There is agreement between the hospital and the Minister of the need for a further review. This should be followed up so that the lessons learnt from this tragedy can be applied across the health service and such a tragic event avoided in the future.