Neutral Citation Number: [2026] EWHC 2043 (Admin)

Case No: AC-2026-LON-000818

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 31/07/2026

Before :

MR JUSTICE CHAMBERLAIN

- -

Between :

THE KING
on the application of

(1) BAYSWATER SUPPORT GROUP
(2) KEIRA BELL
(3) JAMES ESSES — **Claimants**

- and -

(1) HEALTH RESEARCH AUTHORITY
(2) THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE — **Defendants**

- and -

(1) KING'S COLLEGE LONDON
(2) SOUTH LONDON AND MAUDSLEY NHS FOUNDATION TRUST — **Interested Parties**

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Angus McCullough KC, Alasdair Henderson and Allyna Ng (instructed by **Conrathe Gardner**) for the **Claimants**
Jenni Richards KC (instructed by **Hempsons**) for the **First Defendant**
Julian Milford KC, Jon Darby and Alice Walker (instructed by the **Government Legal Department**) for the **Second Defendant**

Andrew Sharland KC and Oliver Jackson (instructed by **Eversheds Sutherland**) for the **First Interested Party**
Fiona Scolding KC and Anna Bicarregui (instructed by **Bevan Brittan**) for the **Second Interested Party**

Hearing dates: 27-28 July 2026

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Approved Judgment

This judgment was handed down in Court 1 at 2pm on Friday 31 July 2026.

Mr Justice Chamberlain:

Introduction and summary

1. The claimants challenge decisions taken in November 2025 and June 2026 by the defendants, the Health Research Authority ("HRA") and the Medicines and Healthcare Products Regulatory Agency ("MHRA"). The decisions relate to a clinical trial of gonadotropin-releasing hormone analogues (also known as puberty suppressing hormones or "PSH") for the treatment of gender incongruence in children and young people, called the PATHWAYS Trial ("the Trial"). It is co-sponsored by King's College London ("KCL") and the South London and Maudsley NHS Foundation Trust ("SLAM"), who are interested parties. The preparatory stages of the Trial are due to start on 1 August 2026, though no hormones will likely be administered before November 2026.

2. The claim was filed in February 2026 and initially challenged the November 2025 decisions to approve the Trial. A rolled-up hearing of that challenge was originally listed on dates in early July 2026. In the meantime, the Secretary of State for Health and Social Care ("the Secretary of State") announced a pause on new prescriptions for masculinising and feminising ("MAF") hormones for young people and the defendants asked further questions of the co-sponsors with a view to considering whether to maintain the approvals. The co-sponsors made an application to modify the Trial protocol. The process of considering this application would not be complete until 18 June 2026. This made a rolled-up hearing in July impossible. Instead, directions were given for a two-day hearing to consider permission to apply for judicial review and interim relief.

3. Between them, the parties filed material including 31 witness statements, detailed written submissions and authorities. The documentation ran to over 13,000 pages. I heard oral submissions over two full days on 27 and 28 July from counsel for the claimants, defendants and interested parties. I then re-read those parts of the evidence and the authorities referred to in counsels' oral and written submissions. I am grateful to all counsel and solicitors and to their wider instructing teams for their excellent work, done under great pressure of time. Because the preparatory stages of the Trial are due to start on 1 August, all parties agreed that a judgment was needed by 31 July.

4. My conclusions can be summarised as follows:

   (a) The Trial was commissioned by NHS England and designed by its co-sponsors with conspicuous care, in consultation with other expert bodies. The participants will be children with persistent gender incongruence who are receiving treatment from specialist gender services. Each child will have been assessed over many months by specialist doctors. In each case, the treating team will have formed the opinion that the child has a reasonable prospect of receiving a clinical benefit from the treatment. There is a detailed process to ensure that the child assents and a parent consents to the treatment, having been fully informed of what it involves and of its potential outcomes. A second opinion will be obtained from a National

Multi-Disciplinary Team ("NMDT") of paediatric and other specialists to ensure that participation is clinically appropriate in the individual case.

(b) UK law requires clinical trials to be approved by two specialist bodies. The MHRA is responsible for the safety of the clinical trial and the safeguarding of participants. It undertook a rigorous process to assess the trial before giving its initial approval in November 2025. It later took on board concerns raised by a group of sceptical clinicians and considered the impact of an intervening decision by NHS England to pause prescriptions of MAF hormones for young people. It asked a series of questions of the trial co-sponsors before concluding in June 2026 that the Trial could proceed with a modified protocol. The HRA was required to and did refer the question of ethical approval to a Research Ethics Committee ("REC") including both experts and lay people. The REC gave that approval in November and, having reconsidered the position in the light of subsequent developments, affirmed its approval of the modified protocol in June 2026.

(c) Where regulatory functions have been conferred on a specialist regulator with technical or scientific expertise, it will generally be because the function is best performed by persons who have been trained in the scientific method. In assessing an application for approval in a context such as this, the specialist regulator can use its prior experience to spot gaps, ask probing questions and evaluate the responses. If the regulator's decision is challenged on rationality grounds in judicial review proceedings, the court must be very cautious about interfering with that decision. The court's function is not to say whether it agrees with the decision under challenge, but rather to examine whether the defendant has exercised their function contrary to the legislative scheme or otherwise unlawfully. These principles apply to both of the regulators whose decisions are challenged here.

(d) The claimants advanced their challenge to the HRA's and MHRA's November 2025 and June 2026 decisions under five grounds. Having examined them carefully, I have concluded that none of them is arguable with a realistic prospect of success:

(i) In its June 2026 decision, the MHRA properly recognised that the likelihood that trial participants would have access to PSH and/or MAF hormones after their participation in the trial came to an end ("the destination therapy issue") was critical to its decision. Its conclusion, taking account of that issue, was rational. The MHRA rationally concluded that "[s]ome direct benefit for the group of patients involved in the clinical trial is to be obtained from that trial". The HRA's research ethics committee ("REC") did not fail to take account of any of the relevant matters identified by the claimants.

(ii) The HRA was not required by the regulatory regime to place third-party comments before the REC. Its decision not to do so in the lead-up to the November 2025 decision has been fully explained and was rational. Its decision as to which of the third-party comments to place before the REC before the June 2026 decision was also rational.

(iii) By the end of the hearing, only one of the claimants' six complaints about the HRA's processes advanced under ground 3 was maintained—lack of

transparency. In relation to the November 2025 decision, the REC published an adequate summary of the research it had reviewed. Although it did not publish a summary of the reasons for its opinion, the claimants now know the reasons and, as a result of this judgment, so does the public. In those circumstances, no useful purpose would be served by the grant of permission. In relation to the June 2026 decision, the decision was only taken six weeks ago and the law does not set a deadline for publication.

(iv) None of the claimants' irrationality complaints is well-founded. The design and purpose of the Trial were fully explained in the application materials. The suggestion that the Trial lacked a valid testable hypothesis is based on a misunderstanding of its purpose: it was a pragmatic trial designed to assess the benefits and risks of PSH. Whether to approve a trial with this purpose was quintessentially a question of judgment for the MHRA and HRA.

(v) The regulatory regime imposes a duty on the MHRA to give reasons in some circumstances, but not when it approves a clinical trial or the modification of a trial protocol. There are no particularly strong policy reasons to impose a common law duty. In any event, there would be no point in granting permission on this ground given that the claimants now have a vast amount of material explaining the MHRA's and HRA's reasons for the approvals and, by virtue of the publication of this judgment, so does the public at large.

(e) Because none of the grounds of challenge has a realistic prospect of success, the question of interim relief pending a substantive hearing does not arise. Even if I had granted permission on one or more of the grounds which could lead to the quashing of the authorisations, I would nonetheless have refused interim relief. The harm that would be done to the public interest and the interests of Trial participants in the scenario where interim relief is granted but the claim later fails firmly outweighs any harm that might accrue to Trial participants in the scenario where interim relief is refused but the claim later succeeds.

Background

The Cass Review and the response from the Secretary of State and NHS England

5. Until recently, the treatment given by the NHS for children and young people presenting with gender incongruence and gender dysphoria was provided by the Tavistock and Portman NHS Trust's Gender Identity Development Service ("GIDS"). In some cases, it involved the administration of PSH. In 2020, NHS England commissioned the paediatrician Dr Hilary Cass to chair a review of gender identity services for children and young people. A central finding of what became known as the Cass Review was that the evidence base for the use of PSH in children and young people with gender incongruence was very weak.

6. In 2022, the interim report of the Cass Review made criticisms of the treatment provided by GIDS and recommended that new regional gender services centres should be established. Later that year, she recommended "the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for hormone treatment into a formal research programme with adequate follow up into

adulthood, with a more immediate focus on the questions regarding puberty blockers". She continued:

> "Without an established research strategy and infrastructure, the outstanding questions will remain unanswered and the evidence gap will continue to be filled with polarised opinion and conjecture, which does little to help the children and young people, and their families and carers, who need support and information on which to make decisions".

7. The final report of the Cass Review was published in April 2024. It reiterated these recommendations.

8. The Secretary of State, having consulted the Commission on Human Medicines ("CHM"), made a series of orders under the Medicines Act 1968 prohibiting the prescribing of PSH to children and young people under the age of 18 other than in pursuance of an NHS prescription. By the time the first emergency order came into force, both NHS England and NHS Scotland had stopped prescribing PSH as a treatment for children and young people with gender incongruence and/or gender dysphoria. The final order, which remains in force, is the Medicines (Gonadotropin-Releasing Hormone Analogues) (Restrictions on Private Sales and Supplies) Order 2024 (SI 2024/1319). With effect from the start of 2025, this prohibits the supply of PSH other than in pursuance of an NHS prescription. "Supply" for these purposes is expressly stated not to include "supply for the purposes of a clinical trial that has been authorised by the licensing authority" (see art. 3).

The genesis of the Trial

9. Meanwhile, in response to Dr Cass's recommendations, NHS England and the Secretary of State commissioned a clinical trial designed to address the "evidence gap" identified by the Cass Review: the Puberty Suppression and Transitional Healthcare with Adaptive Youth Service or PATHWAYS Trial. The first meeting of the PATHWAYS planning group took place in September 2023. In the following month, Professor Emily Simonoff, Professor of Child and Adolescent Psychiatry at the Institute of Psychiatry, Psychology and Neuroscience at KCL, was appointed as Chief Investigator. The trial came to be co-sponsored by KCL and SLAM.

10. The main funder of medical research in the UK is the National Institute for Health and Care Research ("NIHR"). Its Scientific Director, Prof. Danny McAuley, has provided a witness statement in these proceedings. He explains as follows (I have throughout omitted references to exhibits):

> "10. The PATHWAYS Trial underwent a thorough and rigorous funding application and approval process, involving multiple internal and external reviews. That process was as follows:
>
> a. In September 2023, there was an initial workshop to discuss the initial design of the trial, attended by two NIHR Programme Directors, the Chair (Consultant Advisor), and individuals with a broad range of clinical experiences (including those with expertise in Child and Adolescent Psychiatry, Paediatrics, Epidemiology, Safeguarding, Adolescent

Services, Paediatric Endocrinology and, Growth and Puberty). It was also attended by a Representative of the Cass Review, Clinical Trials Unit representatives with methodological and statistical expertise, NHS England, and observers from the Department for Health and Social Care ("DHSC") and devolved administrations.

b. We then received a draft trial protocol and held a further workshop to consider that draft proposal in March 2024. There were a range of individuals in attendance, including a Consultant Advisor (who was a physician that works within the NIHR coordinating centre, with lots of trial methodology experience). It was also attended by the funding committee, who are independent experts in their fields covering expertise in Paediatric Endocrinology, mental health and wellbeing, transgender, psychology and statistics and methodology. The applicant team were also in attendance.

c. In April 2024, there was a formal funding committee meeting, where the applicant team were not present. Following this we provided feedback to the applicant team to be considered when submitting the full application. The full funding application was submitted in July 2024.

d. In August 2024, in addition to undergoing an independent review by the funding committee, the funding application was also sent out for external peer review. The application went through eight reviews in total, undertaken by: the NHS England Specialised Commissioning Clinical Team, two Endocrinologists, a specialist General Paediatrics and Safeguarding, a specialist in Child and Adolescent Psychiatry, a Clinical Psychologist and Gender Specialist, and a Psychologist. There was also additional input via NHS England separately. It is unusual for a funding application to undergo eight peer reviews. Typically, the level of review would link to the size of funding but would usually be between four to six reviews for a trial in the range of £2m-£6m. In this instance, it was necessary to have eight reviews because of the importance of the subject area of the clinical trial and the scale of the funding sought.

e. In September 2024, the peer review comments were shared with the applicant team so that they could respond to any issues raised. A final workshop then took place that same month, to discuss any outstanding questions. This workshop was attended by the Programme Director and Chair, two Consultant Advisors, and experts in Paediatric Endocrinology, Psychology, Medical Statistics and Trials Methodology, Endocrinology and a member of the public. We would not usually meet with the application team this much. Typically, when an application goes to the funding committee, they will provide their feedback, the applicant team will respond, and then we make a decision which is either 'fund' or 'no fund'. However, with this particular application, we wanted to maximise the chances of getting the best scientific quality from the clinical trial. We cannot do this for every trial, as it is highly labour intensive and simply would not be possible. However, in this instance, it was considered to be

> the most efficient and effective way of ensuring that all information was obtained and scrutinised to enable the funding decision to be made.
>
> f. In September 2024, a formal funding committee meeting took place which was again attended by the Programme Director and Chair, two Consultant Advisors, and experts in Paediatric Endocrinology, Psychology, Medical Statistics and Trials Methodology, Endocrinology and a member of the public. The decision made was 'fund with changes'. This means that funding was subject to the applicant team responding to some additional points that arose at the final review. Those additional points were addressed, and a final funding decision was made by NIHR and passed to NHS England and DHSC in November 2024."

11. In her witness statement for these proceedings, Prof. Simonoff explains what happened next:

> "19. Between December 2024 and August 2025, significant work went into preparing the application for regulatory approval for submission to the [HRA] and the [MHRA]. We appointed advisory boards with lived experience, i.e. young adults with non-binary gender and parents/carers of young people with experience of gender incongruence. Final aspects of the study design, including confirmation of study measures and development of participant-facing information were completed with our lived experience advisory boards. Final costings for all aspects of the PATHWAYS Trial were completed. This included the full range of safety checks including blood and urine tests, measures of bone health and cognition (learning and memory) and brain development. We established final details on how the study PSH would be administered and how any adverse effects would lead to modification in administration. The latter involved working with a very experienced group of clinicians who have delivered this intervention to many young people in the past, but where their practice has not required them to follow a strict trial protocol for all patients. Hence, we needed to ensure that good clinical practice was captured in a treatment protocol that would ensure that all participants at every trial site would receive the same treatment and care.
>
> 20. A further piece of work between the PATHWAYS research team and the clinicians in the NHS Gender Services was to describe the detailed clinical eligibility process and the steps that are needed to determine a young person's potential eligibility for the trial. This work was undertaken between February and June 2025. It involved a series of joint meetings to agree the principles underpinning different eligibility criteria (the different characteristics that need to be present for a young person to be considered eligible to take part in the Trial), how these would be measured objectively, and how the information would be recorded for the [NMDT]. A distinctive feature of the PATHWAYS trial is that the young person must themselves want the intervention. That is necessary but not sufficient. They must also pass through the clinical eligibility pathway, NMDT review, consent/assent process and baseline safety checks."

12. In parallel with the discussions between KCL and the NIHR, there were also scientific discussions between KCL, the MHRA and NHS England. These are described as follows by Dr Alison Cave, Chief Safety Officer at the MHRA, in her witness statement as follows (para. 54):

> "a. On 6 September 2024 KCL (on behalf of the NHSE Specialised Services Clinical Team) submitted a request to MHRA for expert advice regarding [PSH] for children and young people with gender incongruence. The request for advice stated that the 'aim is to establish whether the planned trial of puberty suppression in youth with gender incongruence will supply sufficient evidence to support a future licence variation application'. That reflected the fact that once the PATHWAYS programme was complete, NHS England planned to consider whether a change in clinical policy and clinical practice was indicated in terms of routine NHS access to [PSH]. The 'licence variation' to which KCL's request refers would be a variation to the licenced [PSH] products to include an indication for gender incongruence. The request was accompanied by a list of specific questions for MHRA scientific advice.
>
> b. On 27 November 2024 MHRA met with NHSE Specialised Services Clinical Team and KCL to discuss the pre-application request for scientific advice. In advance of that meeting NHSE and KCL produced a briefing document. As a result of that meeting a list of actions were recorded for the trial team.
>
> c. Following the meeting on 27 November 2024 MHRA provided its final scientific advice in response to the 6 September 2024 request from KCL and NHSE on 23 December 2024. The MHRA's advice was based on the questions and documentation submitted to the MHRA by NHS England at the time. It does not, and cannot, account for the future changes and developments in scientific knowledge or regulatory requirements developed since then. Aspects of the discussion of note for the purposes of this claim include:
>
> > i. The MHRA suggested that the trial team might wish to consider more robust eligibility criteria - for example, that participants had 'exhausted non-endocrine interventions for clinicians to consider puberty suppression, as judged by their clinician and the [NMDT]'.
> >
> > ii. The MHRA recommended consideration of setting a minimum age for trial participation, rather than sole reliance on Tanner stage 2 criteria for admission to the Trial. 'Tanner stages' are a standardised S-point scale used by healthcare providers to track physical development during puberty. The scale measures secondary sexual characteristics (such as breast and genital development). Tanner stage 1 is prepubertal, and Tanner stage 5 represents adult sexual maturity.
> >
> > iii. The MHRA acknowledged the inherent difficulty in making such a trial 'blind' because the knowledge of puberty suppression was a major component of the intervention. It further acknowledged that there was a risk of comparator participants taking [PSH] out-of-protocol, or

> comparators not being directly comparable to Trial participants due to being ineligible for [PSH] for preference or clinical reasons.
>
> iv. The MHRA accepted the use of the KIDSCREEN-10 tool to measure health-related quality of life in Trial participants as a primary outcome.
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> v. As to longer-term follow up to assess benefits and risks beyond the initial Trial period, the MHRA emphasised 'it would be important to follow up for as long as possible and ensure joined up services as children and young people transition into adult services. Concerns include long term benefits, future fertility, bone health, future genital surgery, sexual function and cognitive development/maturation and long term follow up could be required for a period of up to 20 years.'…"

The application for regulatory approval

13. On 21 August 2025, KCL submitted an application to the MHRA and HRA for approval. There are very detailed requirements about the information that must accompany such an application. As at November 2025 (the time of the initial approvals), they were contained in the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended (SI 2004/1031), reg. 14(6) and Part 1 of Sch. 3. It is not disputed that the required information was submitted. Some of it was contained in the Trial Protocol (version 1).

14. Dr Cave describes the Trial, as described in the application, as follows:

> "56. The Trial entailed providing 226 participants under the age of 16 with [PSH]. Participants were to be randomly assigned either to start treatment immediately, or after a one-year delay. The two groups would be compared over two years to assess 'how the timing of treatment affected quality of life, mental health, gender identity/dysphoria and body satisfaction impact on cognition and brain development, and physical effects including bone density. The primary objective of the Trial was to measure the short and medium-term benefits and risks/harms of [PSH], and (by comparing the two groups) to determine whether early intervention improves outcomes.
>
> 57. Alongside the PATHWAYS Trial, the application included a participant group known as PATHWAYS HORIZON INTENSIVE, made up of 300 patients not wishing to take, or not eligible for, [PSH]. The intention was to broadly match patients in PATHWAYS HORIZON INTENSIVE to those in the Trial, and to provide the same physical and cognitive measures to that group, thus providing information on the developmental trajectories of those characteristics among young people with gender incongruence who do not receive endocrine interventions. The study also involved PATHWAYS CONNECT, a study of brain development using MRI, which involved examining a subset of 150 participants in the Trial and 100 participants in PATHWAYS HORIZON INTENSIVE.
>
> 58. It was explained that all the participants in the study were already under the care of [NHS England's] specialist gender services and would undergo a

> clinical eligibility process before being approached for research, which involved assessment for eligibility by both their local clinical team and the [NMDT]. A detailed consent and capacity checklist would need to be completed by clinicians over multiple sessions, including 1:1 sessions with the child or young person ('CYP') and their parent(s), and at least one person with parental responsibility would need to provide consent. Participants must have had persistent gender incongruence for a minimum of 2 years and must have a strong desire to 'transition' and live as the experienced gender; and their request for puberty suppression must persist after receiving other care prior to the initiation of [PSH]."

15. The processes undertaken by the MHRA and HRA take place in parallel. There was very detailed evidence about these processes. I set out here the main elements of each of these processes up to and including the initial decisions on 6 and 7 November 2025 to approve the trial, insofar as relevant to the grounds of challenge advanced by the claimants.

The MHRA process leading to the November 2025 decision

16. So far as the MHRA's process was concerned, Dr Cave explains that applications for approval are considered by the MHRA Clinical Investigations and Trials ("CIT") Team, which comprises three teams of assessors. These are:

    (a) the clinical/medical assessment team, focussed on elements such as the dose, duration and dose escalation; the potential efficacy and overall risk; the trial population; potential hazards and risk mitigation measures; safety monitoring and reporting; and whether the trial design is appropriate;

    (b) the pharmaceutical/quality assessment team, focussed on elements such as safety of the drug substance and product and consideration of any adventitious agents; and

    (c) the non-clinical/pharmacology/toxicology assessment team, focussed on elements such as the basic pharmacokinetics, evidence of efficacy in animal models, safety pharmacology and (if relevant) genotoxicity/carcinogenicity.

17. In the present case, a substantial team from CIT were involved in assessing the Trial protocol, consisting of the Head of Clinical Trials, the Head of Pharmaceutical Assessment and the Head of Medical Assessment, supported by a team of four assessors, under the oversight of the MHRA's Deputy Director, Clinical Investigations and Trials. In addition, the Interim Executive Director of Innovation and Compliance was involved, together with three assessors and four members of the Safety and Surveillance Team (led by the Deputy Director of Risk Evaluation II).

18. In addition, the MHRA sought the advice of the CHM and the Clinical Trials, Biologicals and Vaccines Expert Advisory Group ("CTBVEAG"). There was a series of formal exchanges between the MHRA and KCL, where written questions were posed and answered and a joint meeting was held between the MHRA, KCL, the CHM and an expert member of the CTBVEAG on 18 September 2025. MHRA's assessment proceeded in stages, which are described in detail in Dr Cave's witness statement.

19. One key exchange, which is material to the claimants' grounds of challenge, concerned the wording required from the child's treating clinician before the child could be regarded as eligible. The MHRA wrote to KCL on 22 September 2025 asking for (inter alia) a statement of expected benefit for each trial participant in these terms:

> "The clinician in the [children and young people's gender services] leading on care for that [child or young person] believes 'the [child or young person], with persistent gender incongruence despite other appropriate care, is likely to' benefit from [PSH]. This benefit 'is expected to' be achieved in relation to quality-of-life parameters (e.g., confidence in peer and family relations, participation in school and/or leisure activities, improved sense of well-being), mental or physical health."

20. KCL made clear that it would not be possible to make a statement in those terms and suggested the following alternative:

> "The clinician in the [children and young people's gender services] leading on care for that [child or young person] considers that [PSH] for that [child or young person] for puberty suppression offers a reasonable prospect of benefit. That benefit might be achieved in relation to quality-of-life parameters (e.g. confidence in peer and family relations, participation in school and/or leisure activities, improved sense of well-being), mental or physical health."

21. Dr Cave explains that the CIT determined that this, and KCL's other responses, were acceptable and that KCL had sufficiently addressed the CHM's concerns, so that no further advice was required from the CHM. On the wording of the statement of expected benefit, Dr Cave says this (at para. 81b):

> "The CIT was satisfied that KCL's proposed wording on benefit at paragraph 80.b above [and as set out at para. 20 of this judgment] was also sufficient. KCL pointed out in discussions that it would be impossible for an individual clinician to predict the outcome of treatment in relation to an individual child; they could only assess that the child had a reasonable prospect of benefit. Whether such benefit was in fact established was (as with all clinical trials) what the Trial was designed to assess. The CIT was satisfied with that explanation, which it considered sufficiently addressed the benefit/risk balance, in light of the tests which a Trial participant would satisfy, before taking part in the Trial (i.e., persistent gender incongruence, assessment as suitable by the NMDT and local Clinician, and several rounds of consent process)."

22. The exchange between KCL and the MHRA resulted in various changes to the trial protocol, which were incorporated into a second version dated 9 October 2025. On the basis of that second version, the MHRA gave its approval on 7 November 2025.

The HRA's process leading to the November 2025 decision

23. The HRA is a non-departmental public body sponsored by the Department of Health and Social Care. It was put on to a statutory footing by the Care Act 2014, which also

provides for the establishment or recognition of RECs with the function of approving research.

24. The composition of RECs is explained in the UK Research Ethics Committee Policy Document as follows:

> "3.4.1 Each REC is made up of a range of people with individual expertise and experience, including registered health and social care professionals, research professionals, and a wide range of people with much broader experience, including members of the public who have experience using health and social care services and no professional knowledge of research or health and social care.
>
> 3.4.2 REC members are appointed to provide a broad range of perspectives on the committees, which scrutinise the rationale, aims and objectives of the proposed research to reconcile this effectively with protecting the dignity, rights, safety and well-being of the people who are likely to take part.
>
> 3.4.3 REC members are appointed independently of their employing organisation and are expected to reflect their own experience and ethical judgement on an individual basis, bringing sound judgement and personal experience to undertake the REC review, underpinned and supported by relevant training and REC SOPs."

25. REC members are volunteers. They are appointed through a system of open application and comprise lay and expert members, who undergo training before sitting.

26. The way RECs work is explained by an HRA Senior Manager who has given a witness statement in these proceedings. For reasons which I explained at an earlier stage in these proceedings, the HRA has permission to file this statement without giving the name of this individual. The statement explains (at para. 19) that:

> "the HRA is one of several bodies that hold key responsibilities and accountability for different aspects of a clinical trial application and approval process. This is important because it is a consequence of the way in which the HRA approaches its health and social care research that it, and the REC, when they perform their roles, must take 'assurances' from others that they have performed their respective roles…"

27. Some RECs are formally recognised by the UK Ethics Committee Authority to give an ethics opinion on a clinical trial of an investigational medicinal product. Some RECs were "flagged" to indicate that they had been approved to deal with applications of particular types (though the system of flagging was discontinued on 28 April 2026). The REC which dealt with the application in this case was a recognised REC with a "paediatric flag", signifying that it had the expertise to deal with applications in respect of trials involving children and young people.

28. From September to November 2025, the REC which considered the application in this case comprised 13 members, made up of six expert members (including a paediatric expert and another expert with paediatric expertise) and seven lay members. In May

2026, the REC comprised a slightly different set of 13 members of which seven were experts and six lay. In June 2026, the REC comprised seven expert members and five lay. At all stages, the chair was an expert. At various points the REC delegated consideration of certain matters to a sub-committee of its members.

29. REC members read the application documents and other relevant material before meeting. Their meeting had three parts: first, a discussion in the absence of the applicants, led by a lead and second reviewer, followed by agreeing questions to put to the applicant; second, a session in which the questions are put to the applicants; and third, a discussion leading to conclusions on the key points and a decision, which can be "favourable", "favourable with conditions", "unfavourable" or a request for further information. Although in principle it is possible for a REC to proceed by majority vote, in practice "favourable" decisions are taken only once every member is satisfied.

30. The way the REC dealt with the application in this case is explained in a witness statement by its expert chair. Again, the HRA has permission to file this statement without giving the name of this individual. The discussion at the September 2025 meeting, and the conclusions reached, are described in some detail at paras 55 et seq. It ranged over the applicants' purpose and methodology, the risks and benefits, the participant population and statistical significance, how participants would be identified, MAF hormones, informed consent, provision for follow-up and wider assurances.

31. In the September 2025 meeting, in the light of the discussion with the applicants, the REC reached the view that the Trial was "capable of being ethical". The REC Chair explains as follows:

> "70. We were aware that the role of the national MDT was central to ensuring the right patient cohort was identified, and we asked for reassurance on how it would work. We were told by the sponsors that the national MDT would be composed of experienced expert members who understood both the science and the potential ramifications if the Trial went wrong. From our discussion, the REC were reassured that the national MDT and the applicants would not let anyone into the Trial unless they had been identified as having the most potential to benefit by their local clinical team and met very strict criteria (which I address below).
>
> 71. We, as a REC, felt that the local specialist gender services would have a good idea of how likely their patients would be to benefit from the Trial, and would have a very good idea of who they considered had that greatest potential to benefit. Once they had been recommended, the participants were then considered by a national MDT, with both organisations applying the eligibility criteria the applicants had proposed. We felt that the MDT was there to ensure the local teams were applying the eligibility criteria properly, and not picking participants inappropriately. They were therefore an extra safeguard and safety net to ensure only those who truly met the criteria were admitted. As in most drug trials, the question of who is suitable is normally made by the trial's investigator alone in conjunction with the patient, this three stage process was significantly more than a usual trial application."

32. The REC was not, however, satisfied at this stage that there was sufficient information to suggest that the benefits outweighed the risks. It therefore asked for further information, which was provided and considered at a meeting of a sub-committee to whom the REC had delegated this function on 28 October 2025. The sub-committee continued to have concerns about follow-up length, current and previous standard of care and alternatives, continued access to PSH and post-study follow-up and further changes to study documents. It therefore decided to issue another request for further information. The further information was provided and considered again by the sub-committee on 6 November 2025.

33. On the subject of the risk/benefit balance and the justification for implementing a trial, the Chair's statement says this:

> "97… I recall we found the response to Question 1 of the October RFI helpful and detailed. What we had been looking for was for the applicants to articulate in writing, and more extensively, why they considered that the Trial was needed and what purpose it was achieving. We were satisfied after reviewing these responses that they had done so. Their clear and detailed explanations of the Trial in the context of the Cass Report and the CHM report (including the recommendation that a trial be undertaken) were important factors in our decision, as both were both significant reports in the field and had gone into lots of detail about the specific issues it involved. If applicants were making specific recommendations about what sector specialists feel is required based on such reports, that information is both helpful for us to know and can be a factor guiding our decision.
>
> 98. We also noted that the applicants, a professional clinical organisation, still wished to undertake the Trial, that they had reasonable reasons for wishing to do so and clarity on the 'hoped for' outcomes – the question in our minds was whether this was reasonable. We were aware of the previous banning order and the CHM report obtained for that. The fact of the ban itself did not cause us to consider the Trial must necessarily be unethical. Instead, as Baroness Cass identified, it was banned as the wider public did not know those long term outcomes, those answers needed to be found out, and this would require a Trial. We were conscious that the Cass report had not categorically set out how a trial should be run, so we had to consider the Trial as it had been presented to us. Following our review of the information, we considered that how the Trial would be run was articulated here very clearly, and the applicants were very clear on risks and how they were to be mitigated. We took the applicants – as we must take all applicants, who are the masters of the science, and indeed Cass and other sector experts – at their word that there was an insufficiency of evidence. From what we had been presented with, it seemed reasonable for the applicants to have concluded that there was. Overall, we were satisfied that there was justification for implementing the Trial (as opposed to investigating other options without the Trial), and that it would be appropriate.
>
> 99. …Taking the previous information, and additional clarification from the applicants, we concluded we were satisfied by their responses and felt we could reach an overall 'favourable' view…

> 100. Throughout our consideration of the study, my colleagues on the REC and I were aware that the risks were to some extent known, but were to some extent unknown (especially the long term risks). We do not know what long term effects of [PSH] are once children have gone down the road, what their development in their late teens and early 20s would be. For the REC, we looked to establish the likely risks and what they could be (e.g. brain development, bone and mineral and fertility in particular), and asked whether those risks were acceptable, whether they were likely to be reversible, whether the participants could make an informed choice (which we already knew would be difficult as the potential participants are all under 18) and whether the information they were being provided with was sufficient so they fully understand what was going on. We were conscious that for some members of the public, they may say 'these are physically healthy children, so surely it must be unethical to do anything that might damage them physically', and we asked that question and how the risks were being mitigated. Ultimately, the applicants satisfied us with their responses.
>
> 101. We had considered the real-world context of the Trial, which we and the applicants' research team knew would be closely scrutinised. I found the applicants in our discussions to be taking the Trial, the risks and risk management very seriously. The REC and I considered that in having the brain scans, other checks, and offering options for fertility, that the applicants had done as much as they could to mitigate the risks. As we were considering a trial about young people who are very severely impacted by their condition, we formed the view that the benefits outweighed the risks from an ethical perspective."

Events following the November decisions

34. The approval of the Trial by the MHRA and HRA was made public on 22 November 2025. That gave rise to a significant volume of correspondence in late 2025 and early 2026 from Parliamentarians and others, raising a variety of safety and ethical concerns about the Trial. On 3 December 2025, the MHRA received a letter from the Clinical Advisory Network on Sex and Gender ("CAN-SG"), a group of clinicians which campaigns for "clearer dialogue, rigorous science and improved treatment options for gender dysphoria".

35. The CIT took the view that CAN-SG's concerns should be considered by the CHM at a meeting. A meeting was scheduled for 29 January 2026 and a paper prepared by the MHRA's assessors, addressing CAN-SG's concerns. The assessors' preliminary conclusion was that CAN-SG's points did not warrant reopening the approval given for the Trial protocol.

36. Separately, Prof. Jacob George had taken up the post of Chief Medical and Scientific Officer at the MHRA. He had been reading into the papers on the Trial. He was not satisfied with the assessor's draft paper for the CHM. This led to his writing to KCL on 13 February 2026 suggesting that amendments to the Trial protocol were required, in particular to introduce a minimum age of 14 for trial participants and to incorporate

further safety monitoring and withdrawal criteria relating to bone density, growth, vaginal bleeding and neurocognitive development.

37. On 23 and 24 February 2026, there were meetings between KCL and the MHRA.

38. Shortly afterwards, the Department for Health and Social Care became aware of posts on Prof. George's social media account concerning the rights of women and trans people. These were raised with Prof. George and he decided to recuse himself from any further involvement in the regulatory process on a precautionary basis. The discussions continued, led by Dr Cave for the MHRA. There were then meetings of the MHRA's Internal Trial Assessment Group, which considered that further exploration of the issues raised in Prof. George's letter was required.

39. At the same time, on 9 March 2026, NHS England announced a pause on its clinical policy concerning NHS prescribing of MAF hormones for children and adolescents with gender incongruence or dysphoria and a consultation on that policy. One possible outcome of the consultation is that MAF hormones will not be available to new patients with gender incongruence under the age of 18. KCL initially took the view that this was irrelevant. The MHRA did not agree. On the contrary, as Dr Cave explains:

> "119. This point was critical to the MHRA, because it recognised that for many participants in the Trial, the benefit of taking [PSH] from their point of view would be to allow them the possibility to transition their gender through access to MAF hormones, without having developed the secondary sexual characteristics of their birth sex. So, the potential pathway for accessing MAF hormones was a critical component of assessing the safety of trial participants: not least, because the MHRA wished to assure itself that a Trial participant who might have started in the Trial at an age as young as 11 (for a birth-registered female) would not need to take [puberty supressing hormones] for 7 years before being eligible for MAF hormones.
>
> 120. The MHRA position was that it was necessary to consider the long-term safety i.e. beyond the 2-year study period of the trial, for participants in its review of the Trial protocol. It also indicated to KCL that it would be necessary to ensure that for those children who wished to continue to take [PSH] after the end of the trial, an amendment should be submitted no later than Month 19 following the start of the Trial (i.e. Month 19 post-randomisation), to extend interventional access to [PSH] within the research context of the Trial."

40. KCL's initial response was that the level of scrutiny and documentary evidence now being required by the MHRA was excessive, but the MHRA did not back down. KCL addressed the MHRA's concerns in writing on 7 April 2026. It acknowledged the MHRA's request that it should submit an amended Trial protocol by 19-month post-randomisation for an open-label extension study of PSH. NIHR confirmed that it would fund such a study.

41. There was a further meeting between KCL and the MHRA on 14 April 2026. On 16 and 17 April 2026, KCL submitted an amended version of the Trial protocol. On 23 April 2026, the MHRA provided the CHM with a detailed paper identifying the issues for

consideration. The CHM considered this at an ad hoc meeting on 27 April 2026. The CHM was largely content with KCL's amendments, but still had concerns about the MAF hormones/destination therapy issue.

42. KCL therefore submitted further draft amendments to the Trial protocol on 29 April 2026. The MHRA assessed the amendments and sent a paper to the CHM on 19 May 2026, concluding that the amendments were acceptable in principle, subject to resolution of certain requests for further information. Separately, the MHRA investigated whether there could be any assurance from the Department of Health and Social Care that there would not be any impediment to Trial participants accessing MAF hormones via a potential future trial, from age 16.

43. NIHR and NHS England responded on 22 May 2026 that, irrespective of the position ultimately reached on prescribing MAF hormones, "we do not expect [NHS England's] clinical policy decision to in any way impede opportunities for future MAF research, including (should it be required) access to MAF for Trial participants within a separate, and appropriately approved, research study." A similar response was received from the director of Science, Research and Evidence at the Department of Health and Social Care.

44. Meanwhile, the CHM had met again to discuss safety considerations, the consultation concerning MAF hormones and the assurances sought by the MHRA, the importance of clinician-led puberty staging and the necessity of further research on the safety and efficacy of PSH.

45. On 29 May 2026, the MHRA issued a request for further information to KCL. One of the requests was to state in the Trial protocol that the open-label extension study or linked continuation protocol for any continued puberty suppressing hormone exposure would be submitted by month 12 of the first Trial participant randomisation and no later than month 15. KCL responded on 4 June 2026. Its response included this:

> "The sponsor confirms that MAF hormones remain outside the scope of the PATHWAYS Trial protocol. KCL is not currently aware of any sponsor-specific impediment to participating in or supporting the development of a future, separate research study of MAF hormones, should such a study be considered appropriate by the relevant bodies. However, KCL cannot provide assurance that any such study will be available, approved, opened, funded or suitable for individual PATHWAYS participants, as those matters are outside the scope of the current trial and would depend on future commissioning, protocol development and regulatory/ethical approvals."

46. The MHRA considered this response and also provided the CHM with the re-amended Trial protocol. The chair of the CHM confirmed that he considered that the responses to the first three requests for further information were acceptable. As to the fourth (which concerned MAF hormones), he said that he did not consider that the Trial should be stopped from going ahead based on existing uncertainty over whether participants could be given MAF hormones from age 16.

47. The MHRA considered, in the light of KCL's responses and the CHM's advice, that the re-amended Trial protocol should be approved.

48. Meanwhile, the amended Trial protocol had been sent to the REC on 30 April 2026, together with the list of questions the sponsors had answered. The REC sat as a full committee on 7 May 2026. The meeting adopted the usual-three stage format. The REC focussed on what had changed since its last consideration of the Trial.

49. The REC Chair explains (at para. 110):

> "We took assurance from the CHM minutes and the MHRA review process that led to the modification being submitted, that those aspects of the modification which the MHRA had asked to be made seemed, now they had been made, likely to be approved by the MHRA. We therefore felt that should we be satisfied that the ethical aspects of the modification were in order, then it looked likely the MHRA would also approve the modification, all things being equal."

50. On the MAF hormones issue, the REC Chair's evidence is as follows:

> "113. In considering the modification, we also considered the purpose of the Trial and clarified that it was not to allow or aimed at facilitating transition to the other gender, and that issues of potential future access to MAF hormones did not form part of the Trial itself. The applicants had previously explained, and reiterated, that any consideration of a young person for MAF would not be automatic after they had been on the Trial, but would only be considered following a thorough evaluation by local gender services and the national MDT (above) who would separately be considering whether this was indicated. We noted that extensive clarification that there should be no presumed or automatic link between the Trial, and GNRHa, and moving to MAF hormones had been provided in the covering letter, protocol and the participant information. That being said, we were also conscious from previous discussions and the original application, that in reality some participants in the Trial may go on to MAF hormones so we were aware we were reaching a judgment on the level of risk posed.
>
> 114. We were aware from the CHM minutes that MAF hormones had been 'paused' from being provided as a part of the NHS standard of care, and that there was some uncertainty in whether that standard of care would be resumed or not. We considered this but in our view, this was not a sufficient reason for the Trial not to proceed. One significant reason was that we considered that the Trial had independent value, distinct from whether participants went on to take MAF hormones, as its purpose was to identify the short, medium and long term effects of GnRHa itself where the evidential picture was not clear. However, we also had in mind that the Trial itself was intended to be a two year programme, and should any participants go on to consider MAF there would be a significant amount of time spent on the Trial before this decision was reached. I felt it was reasonable to expect that the question of access to MAF hormones to be resolved by this stage (i.e. by the end of the two year period), whether it progressed through a separate trial or as a part of a resumed NHS standard of care. There was also a possibility that the progress and outcomes from the Trial may themselves also impact on guiding those arrangements that may be made in relation to access to MAF

hormones in the future. We were also assured that the CHM reached the same view (that the lack of clarity should not prevent the Trial from proceeding), for the reasons it gave."

51. At the conclusion of the May 2026 meeting, the REC made a limited additional request for further information. However, subject to that, the REC Chair explains that the REC was satisfied as follows:

> "119.1 The consent arrangements for young people and their parents continued to be appropriate.
>
> 119.2 The way in which the Trial compared to the current standard of care available to potential participants (in relation to [PSH] – MAF being addressed above) had not changed.
>
> 119.3 The measures for minimising risks, burdens and intrusions to participants, and the anticipated risks and benefits (to individual participants and the group) were acceptable, subject to confirmation as to the [open label extension].
>
> 119.4 We considered that there remained the potential for some direct benefit for the group of patients involved in the Trial, who had not changed since the original application.
>
> 119.5 We agreed that the anticipated benefits outweighed the risks, having regard to a range of factors including the current standard of care, arrangements of consent, wider interests, and that this was so for individual participants (again, subject to confirmation as to the [open label extension]).
>
> 119.6 We also remained satisfied that the Trial was only such that it could be conducted with children and young people, and that it looked to be conducted in accordance with the GCP and Declaration of Helsinki principles."

52. There was a further meeting of the REC on 8 June, at which KCL's response to the requests for further information were considered. The REC decided to issue a "favourable with conditions" opinion. KCL responded and the HRA in due course confirmed that the conditions had been met.

53. On 18 June 2026, the MHRA communicated to KCL that it and the HRA had approved the application.

The legislative framework

54. The key legislative provisions applicable in this case are in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031: "the 2004 Regulations"). These were originally enacted under s. 2(2) of the European Communities Act 1972 to implement an EU Directive, but remain in force. They were amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538) with

effect from 28 April 2006. Where it is necessary to make clear which version of the Regulations applied, I shall refer to the 2004 Regulations as they applied at the time of the MHRA's and REC's decision-making between September and November 2025 as "the Old Regulations", and to the 2004 Regulations as amended and as they applied at the time of the REC's decision-making in May and June 2026 as "the New Regulations".

55. Regulation 12(1) of the 2004 Regulations prohibits the commencement or conduct of a clinical trial unless the conditions in Regulation 12(3) are satisfied, specifically that (a) an ethics committee has given a favourable opinion in relation to the clinical trial and (b) the clinical trial has been authorised by the licensing authority.

56. Regulations 14 and 15 of the Old Regulations dealt with applications to and decision-making by ethics committees. In particular, reg. 15(2) authorised the REC to request further information from the applicant. Regulation 15(5) required the committee, in preparing its opinion to consider a detailed list of matters:

> "(a) the relevance of the clinical trial and its design;
>
> (b) whether the evaluation of the anticipated benefits and risks as required under paragraph 10 of Part 2 of Schedule 1 is satisfactory and whether the conclusions are justified;
>
> (c) the protocol;
>
> (d) the suitability of the investigator and supporting staff;
>
> (e) the investigator's brochure or, where the investigational medicinal product has marketing authorization and the product is to be used in accordance with the terms of that authorization, the summary of product characteristics, or equivalent document, relating to that product;
>
> (f) the quality of the facilities for the trial;
>
> (g) the adequacy and completeness of the written information to be given, and the procedure to be followed, for the purpose of obtaining informed consent to the subjects' participation in the trial;
>
> (h) if the subjects are to include minors or persons incapable of giving informed consent, whether the research is justified having regard to the conditions and principles specified in Part 4 or Part 5 respectively of Schedule 1;
>
> (i) provision for indemnity or compensation in the event of injury or death attributable to the clinical trial;
>
> (j) any insurance or indemnity to cover the liability of the investigator or sponsor;
>
> (k) the amounts, and, where appropriate, the arrangements, for rewarding or compensating investigators and subjects;

> (l) the terms of any agreement between the sponsor and the owner or occupier of the trial site which are relevant to the arrangements referred to in sub-paragraph (k); and
>
> (m) the arrangements for the recruitment of subjects."

57. Regulation 15(6) provided:

> "If—
>
> (a) any subject of the clinical trial is to be a minor; and
>
> (b) the committee does not have a member with professional expertise in paediatric care,
>
> it shall, before giving its opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of paediatric care which may arise in relation to that trial."

58. Regulation 15(9) required the REC to publish a summary of its opinion.

59. Regulation 17 of the New Regulations provides that the MHRA's role in authorising a trial is to consider "the safety of the clinical trial and the safeguarding of clinical trial participants". However, as Dr Cave explains in her witness statement, that has always been its role.

60. Regulation 28 of the 2004 Regulations provides that clinical trials must be conducted in accordance with conditions and principles of good clinical practice. These are set out in Sch. 1.

61. Schedule 1 specifies in Part 2 conditions and principles which apply to all clinical trials and in Part 4 conditions and principles which apply if the participant in a clinical trial is a minor.

62. The conditions applicable to all clinical trials under the Old Regulations included:

    (a) a requirement that clinical trials be conducted in accordance with the principles of the Declaration of Helsinki (Part 2, principle 6);

    (b) a requirement that, before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit to the individual trial subject and other present and future patients and that the trial should be initiated and continued only if the anticipated benefits justify the risks (Part 2, condition 10);

    (c) a requirement that a trial should be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks (Part 2 para 12).

63. In the New Regulations, a different approach is taken in Part 2, which provides materially as follows:

> "1. Clinical trials must be conducted in accordance with the principles of good clinical practice set out in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice, as amended from time to time.
>
> 2. Except where it would be a contravention of these Regulations, clinical trials must be conducted in accordance with the principles of the Declaration of Helsinki."

64. The conditions and principles applicable to clinical trials involving minors under the Regulations (Old and New) are materially similar. They include requirements for the provision of information to the minor and to the person with parental responsibility, and for informed consent (Part 4, conditions 1-7) and then these conditions:

> "10. Some direct benefit for the group of patients involved in the clinical trial is to be obtained from that trial.
>
> 11. The clinical trial is necessary to validate data obtained—
>
> (a) in other clinical trials involving persons able to give informed consent, or
>
> (b) by other research methods."

65. The Declaration of Helsinki was approved by the World Medical Assembly at Helsinki in 1964 and amended on successive occasions since. Particular emphasis was placed on principles 21 and 28, which provide:

> "21. Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste. The research must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation…
>
> …
>
> 28. In medical research involving human participants incapable of giving free and informed consent, the physician or other qualified individual must seek informed consent from the legally authorized representative, considering preferences and values expressed by the potential participant.
> Those persons incapable of giving free and informed consent are in situations of particular vulnerability and are entitled to the corresponding safeguards. In addition to receiving the protections for the particularly vulnerable, those incapable of giving consent must only be included if the research is likely to

> either personally benefit them or if it entails only minimal risk and minimal burden."

66. Some time at the hearing was spent considering whether and to what extent the Old and New Regulations incorporated particular versions of the Declaration of Helsinki. I am prepared to assume for present purposes that, at least at the time of the June 2026 decisions, the New Regulations refer to the Declaration as most recently updated.

The *in limine* objections to the claim

67. The defendants make two *in limine* objections to the claim. I can deal with these shortly because I do not consider that, individually or cumulatively, they are sufficient to justify the refusal of permission on their own.

Standing

68. The first claimant is a company limited by guarantee which represents approximately 800 parents and guardians of children and young adults who identify as trans or nonbinary. It was established in 2019 to provide advice and support to families with trans-identified children. It has members in all regions of the United Kingdom, as well as in the Republic of Ireland.

69. The second claimant has personal experience of treatment for gender dysphoria and is a long-standing campaigner on issues relating to such treatment. She has brought litigation in the public interest before: *R (Bell) v Tavistock and Portman NHS Foundation Trust* [2021] EWCA Civ 1363, [2021] PTSR 593.

70. The third claimant is a practising psychotherapist and founder of the organisation Thoughtful Therapists and Just Therapy. He is an advocate for evidence-based treatment for gender dysphoria.

71. The defendants dispute that either the second or third claimants has a "sufficient interest in the matter to which the application relates" for the purposes of s. 31(3) of the Senior Courts Act 1981.

72. Even if I were confident that this point was correct, it would not prevent the claim from proceeding because it is common ground that the first claimant has standing. I am not, however, confident that it is correct.

73. As Lewis LJ observed recently, at the permission stage the Court is concerned primarily with "excluding hopeless cases where a claimant cannot establish he has a sufficient interest in the matter because, for example, he has no private interest in the matter and is not acting in the public interest or is otherwise a 'meddlesome busybody'": *R (Luton Landlord and Letting Agents Ltd) v Luton Borough Council* [2026] EWCA Civ 35, [2026] HLR 20, [47]. I do not consider that either the second or third claimant obviously falls into that category.

74. Although I appreciate that standing is a jurisdictional matter, I note that the second and third claimants are represented by the same solicitors and counsel and the first claimants, so any impact on costs of including them as claimants is likely to be minimal.

The ouster clause in relation to challenges to the MHRA

75. The legislation which first established the scheme for regulation of clinical trials (inter alia) was the Medicines Act 1968. Section 107 of that Act conferred a limited right on the person to whom a regulatory decision related to challenge that decision by application to the High Court. Otherwise, it provided that the validity of any such decision "shall not be questioned in any legal proceedings". A similar provision is now contained in reg. 322 of the Human Medicines Regulations 2012 (SI 2012/1916), which provides materially as follows:

> "(1) The validity of a decision of the licensing authority under Parts 3 (manufacturing and wholesale dealing), 5 (UK marketing authorisations), 6 (certification of homoeopathic medicinal products), 7 (traditional herbal medicinal products) or 8 (Article 126a authorisations) is not to be questioned in any legal proceedings.
>
> (2) The validity of a licence, authorisation, certificate or registration granted or issued, or other thing done, in pursuance of a decision of a kind mentioned in paragraph (1) is not to be questioned in any legal proceedings.
>
> (3) Paragraphs (1) and (2) are subject to the following provisions of this regulation.
>
> (4) A person to whom notice of the decision is given may make an application to the High Court to challenge the validity of the decision on the grounds that—
>
> > (a) the decision is not within the powers conferred on the licensing authority; or
> >
> > (b) a requirement of these Regulations in connection with the matter to which the decision relates has not been complied with."

76. This is applied to decisions of the MHRA in relation to clinical trials by reg. 47 of and Sch. 9 to the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1916).

77. Section 107 of the 1968 Act was considered by the Divisional Court in *R v Medicines Commission ex p. Organon Laboratories Ltd*, The Independent, 17 February 1989. In that case, one of the decisions challenged by the claimant was a decision to approve an application made by its competitor. The decision appears to have been challenged both under the statutory route and, in the alternative, by judicial review. Glidewell LJ (with whom Pill J agreed) quoted s. 107 and said this:

> "Those words mean, and can only mean, in relation to this particular licence, Beechams. Nobody else, in my view, is in a position to make an application in respect of the licences which relate to them. Organon were not in a position to do so. This application… therefore in my view must be dismissed.

> There is an alternative application for judicial review. But judicial review falls fairly and squarely within subsection (1) of section 107 which provides (as I have already read in the earlier judgment): 'Except as provided by the following provisions of this section the validity of the licensing authority's decision shall not be challenged in any legal proceedings'. That is an ouster clause, a perfectly effective ouster clause, since the right to challenge, which the statutory provision provides in subsection (2) to the licensee, is virtually co-extensive with judicial review the courts would not strain to say they can get round it somehow or other by way of judicial review."

78. Julian Milford KC for the MHRA submits that I should follow this reasoning. He may be right. He may also be right that there are strong policy reasons to restrict the class of persons who can challenge decisions about a clinical trials to the person to whom notice of the decision is given, i.e. the sponsors of the trial, and that this was the intention of Parliament in enacting s. 107 of the 1968 Act and of the Secretary of State in making the 2012 Regulations.

79. However, Alasdair Henderson for the claimants has persuaded me that it is at least arguable, with a realistic prospect of success, that the ouster clause is not effective to exclude judicial review, given the strong presumption against complete exclusions of judicial review: see *Anisminic Ltd v Foreign Compensation Commission* [1969] 2 AC 147; *R (Privacy International) v Investigatory Powers Tribunal* [2019] UKSC 22, [2020] AC 491. It is unclear from the report whether this point was argued in *Organon*. In any event, the reasoning of the Divisional Court gives no indication that that court considered *Anisminic* at all.

80. Mr Milford relied strongly on case law upholding partial ousters of judicial review, but it is at least arguable that, from the perspective of anyone who has not been given notice of the challenged decision, the ouster in reg. 322 is complete. If effective, it would, for example, exclude review by the court at the instance of anyone other than the applicant of a decision procured by corrupt means or otherwise taken in bad faith. Ousters having this effect engage the principle set out in *Anisminic* and applied in *Privacy International*.

81. Given that neither of the defendants' two *in limine* objections supplies a basis for refusing permission, I go on to consider the claimants' grounds of challenge.

The proper approach to judicial review of regulatory decisions

General

82. Parliament entrusts regulatory functions to individuals or bodies for good reason. An important function of judicial review is to check that these functions have been exercised by the right individuals or bodies. Many public law cases turn on precisely this kind of question. Has the Minister done something which can only be done with someone else's approval? Has a body impermissibly delegated its function? These questions sometimes seem technical, but they are fundamental. The rule of law is endangered if decisions are taken by persons other than those to whom they have been entrusted.

83. It is important to recognise, however, that this danger can also arise when a court takes over a function that Parliament has conferred on another individual or body.

84. Courts have some advantages over other kinds of decision-makers. They have structural features that ensure their independence and impartiality. They have formal adversarial processes designed to ensure fairness between a small number of parties. Their judges are trained to produce closely reasoned judgments. These advantages explain why, in many contexts, Parliament often entrusts them with decision-making functions.

85. However, court processes also have disadvantages. Judges are not generally experts in a particular subject matter. They sit alone or in very small panels. Their materials are typically limited to those put before them by the parties. Their processes can lead to delay and are generally not suited to inquisitorial decision-making, nor to iterative decision-making. These disadvantages are among the reasons why Parliament may decide not to allocate some functions to courts.

86. When Parliament or a subordinate legislator designs a regulatory scheme, it should be assumed that the scheme reflects a deliberate choice, which takes into account these advantages and disadvantages in a particular context. Courts must be astute to respect that choice.

87. This means that, in judicial review, the court must focus narrowly on whether the defendant has exercised their function contrary to the legislative scheme or unlawfully at common law. The categories of unlawfulness are not open-ended. They include irrationality in all its guises: see e.g. *R (KP) v Secretary of State for Foreign, Commonwealth and Development Affairs* [2025] EWHC 370 (Admin), [55]-[57]. But the court must not undermine the allocation choices made by the legislation and must not substitute its judgment for that of the decision-maker.

Regulation in technical fields

88. Where the regulation concerns technical or scientific matters, and the relevant function has been conferred on a body with technical or scientific expertise, there is a particular need for caution on the part of the court when adjudicating claims of irrationality. This is not because judges are incapable of understanding scientific matters; on the contrary, judges need and should have the ability quickly to acquire an understanding of complex subject matters, including scientific ones. But they are lawyers by training, background and practice and apply legal modes of thought and analysis. Where Parliament has conferred a function on a body with technical or scientific expertise, it will generally be because the function in question is best performed by persons who have been trained in the scientific method.

89. It is also important to bear in mind that most judges hearing a judicial review claim, even if they specialise in public law, will not have much if any experience of dealing with cases in that area of regulation. The regulatory bodies, by contrast, are likely to have a great deal of experience of performing this very function. Where, as here, the regulatory body is being asked to assess an application for approval, its members will be able to use their prior experience to spot gaps, ask probing questions and evaluate the responses. Where there is evidence of a regulatory body doing this, a court should be very wary about interfering with its conclusion.

90. This explains the well-known statements in the authorities to the effect that courts should afford a decision-maker wide latitude in cases involving scientific, technical and multi-factorial predictive assessments. For example, in *R (Mott) v Environment Agency* [2016] EWCA Civ 564, [2016] 1 WLR 4338 at [77], Beatson LJ (with whom McFarlane LJ and Lord Dyson MR agreed) said: "A reviewing court should be very slow to conclude that the expert and experienced decision-maker assigned the task by statute has reached a perverse scientific conclusion."

91. In *R (Justice for Health Ltd) v Secretary of State for Health* [2016] EWHC 2338 (Admin) at [186], Green J identified the following factors which tend to broaden the latitude afforded by courts to decision-makers in the field of healthcare policy:

> "where the decision maker is taking a decision in the health field with the objective of improving patient care; where the decision adopted is prospective and precautionary (i.e. based upon a prediction of future benefit and where there is perceived to be a benefit in acting sooner rather than later notwithstanding uncertainties); where the decision maker has indicated a willingness and intention to review the policy as it unfolds to ensure that it is in fact working adequately and to review and modify it to address emerging problems."

Application to this case

92. The factors which I have mentioned all plainly apply to the decisions of the MHRA under challenge here. The MHRA is a regulator operating in a highly technical field. Its staff have key relevant scientific expertise. It has the ability to call for additional advice, as it did in this case from the CHM and the CTBVEAG. The MHRA operates inquisitorially and can ask probing questions, as it did here. It can proceed iteratively, as it did here, asking questions in writing and orally, evaluating the answers, formulating follow-up questions, seeking external advice on those answers and then reaching a conclusion. Its decision-making involves nuanced predictive assessments about matters such as the prospect of treatments being available in the future, which cannot be foreseen with certainty. It has a continuing function of monitoring and reviewing a clinical trial ever after it has been initially approved. All these factors mean that a court should proceed with the utmost caution before concluding that its decision was irrational.

93. Mr McCullough submitted that the same caution does not apply to decisions of the HRA and REC, because their process was less intensive than that of the MHRA, because they are not expert bodies in the same sense and because their function involves resolving an ethical rather than a legal issue. I reject this submission.

94. I do not accept that the HRA's or REC's process was anything other than careful. Although the REC's process was less intensive than that of the MHRA, it still involved asking probing questions, which were answered in its meetings and in some cases writing. The answers were carefully considered and discussed and the witness evidence before the court indicates that the conclusions were balanced and well thought-through.

95. It is true that the Chair of the REC which considered this application said in his witness statement (at para. 8) that the REC "is not a committee of experts in the conventional sense", because it has both expert and lay members and because the expert members are

not necessarily experts in the precise subject area to which the application relates. But this does not, in my judgment, mean that the court should be any less cautious when adjudicating a claim that it has acted irrationally.

96. In the first place, RECs generally include persons who, even if not specialists in the precise subject matter under consideration, have highly relevant expert knowledge. In this case, the REC was a flagged and recognised REC, with paediatric specialist members. This alone means that the REC has a considerable advantage over the court.

97. Secondly, the suggestion that the ethical subject matter of the REC's function makes it less appropriate to apply a wide margin of discretion is, in my judgment, misconceived. There may be very good reason for allocating an ethical decision to a body with a particular composition. As the REC Chair points out (later in para. 8 of the witness statement), the membership of the REC is carefully calibrated, in accordance with the regulatory regime, to ensure the right balance of expert and lay members:

> "In my experience, the different types of members will pick up on and identify different issues. Expert members tend to have more background knowledge about the existing standard of care (or know where that information can be found) and tend to know more about e.g. the possible side effects of medication, possible risks, and whether a trial is necessary within a set of treatment options. The lay members are very good at analysing the participant information, looking at the burdens and impact of a trial on patients, and are generally better at asking those questions which would be important to real-world patients. This range of views is also why RECs benefit from having a range of people with different qualifications, backgrounds and experience."

Thus, the lay members of the REC also bring valuable experience to its decision-making function. The fact that it is carefully selected committee of a dozen or so individuals with a diversity of membership gives it a considerable advantage over a court in deciding the ethical issues before it.

98. Thirdly, RECs perform this precise regulatory function frequently. As noted above, this gives the REC an advantage over a court which is unlikely to (and in this case has not, as a matter of fact) had the opportunity to consider the regulation of clinical trials before.

99. None of this, of course, detracts from the importance of considering with care whether any of the grounds of challenge raises an arguable complaint that either regulator acted unlawfully. I shall turn to that issue in a moment, after addressing a procedural point.

Pleadings

100. It was once thought that pleadings matter less in judicial review than in other areas, because, in a case where the court is concerned with the public interest, it should not stand on technicality. There is an abundance of authority showing that this was a misconception: see e.g. *R (Talpada) v Secretary of State for the Home Department* [2018] EWCA Civ 841, at [67]-[69] (Singh LJ); *R (Bibi) v Secretary of State for the Home Department* [2025] EWCA Civ 622, [2025] 4 All ER 381, [80]

(Andrews LJ); *R (Anaesthetists United Limited) v General Medical Council* [2025] EWHC 2270 (Admin), [2026] PTSR 641, at [116] (Lambert J).

101. Pleadings matter because, in a public law case as in any other, the court has to act fairly. Fairness requires that the parties understand precisely the issues in dispute, so that they can gather and file evidence and prepare written and oral submissions focussed on those issues. By the same token, the court's function is not to conduct a wide-ranging inquiry into the decision under challenge. It is to evaluate precisely identified grounds of challenge, taking into account the responses (by way of evidence and submissions) to those challenges.

The permission threshold

102. Ordinarily, when considering whether to grant permission, the court asks in respect of each pleaded ground of challenge whether that ground is arguable with a realistic prospect of success: see the Administrative Court Judicial Review Guide (2025), para. 9.1.3 and the authorities cited there.

103. However, in some cases where the court has had the benefit of full argument and evidence at the permission stage, a more demanding threshold has been applied: see e.g. *Mass Energy Ltd v Birmingham CC* [1994] Env LR 298 at pp 307 to 308; *R (Hynot) v Secretary of State for Energy Security and Net Zero* [2025] EWHC 2644, [2026] Env LR 12, [71].

104. Angus McCullough KC for the claimants drew my attention to the decision of the Court of Appeal in *R (Plan B Earth) v Secretary of State for Transport* [2020] EWCA Civ 214, [2020] PTSR 1446, at [262]-[266], where it was said that the heightened test in *Mass Energy* was not appropriate.

105. On a proper reading of *Plan B Earth*, it seems to me that the Court of Appeal was not deprecating the approach in *Mass Energy*, but merely saying that it did not apply in the circumstances of the case before it, where the court had ordered a rolled-up hearing: see [4]. In any event, however, the point does not matter because in my judgment none of the grounds of challenge meets even the ordinary test for permission.

106. If that seems a bold conclusion after a permission hearing lasting two full days and involving consideration of 13,000 pages of evidence, submissions and authorities, it should not. The judge's task is "essentially the same whether the papers are few or voluminous, whether the putative issues are simple or complex; there should be no greater tendency to grant [permission] in the latter class of case than the former": *R v Local Government Commission for England ex p North Yorkshire County Council,* unreported, 11 March 1994 (Laws LJ), cited by Sir Michael Fordham, *Judicial Review Handbook* (8th ed.), para. 21.2.9.

107. As Keene J put it, "it is not to be assumed that there is an arguable point simply because a number, even a large number, of different points are raised and expanded upon at length in skeleton arguments and in oral argument. The approach of 'never mind the quality, feel the width' has no application in these proceedings. The points raised, however numerous, have to be examined to see if there is truly anything in them": *R v London Docklands Development Corporation ex p Frost* (1997) P & CR 199 at 204.

108. This is a case where a two-day permission and interim relief hearing has afforded a good opportunity for a thorough examination of the claimant's grounds of challenge. On examination, and notwithstanding the considerable skill with which they were advanced by Mr McCullough, none of them is arguable with a realistic prospect of success.

Ground 1

109. Under ground 1, the claimants make several complaints. I take them in turn, by reference to the claimants' Re-Amended Statement of Facts and Grounds ("RASFG").

The pleaded challenge to the MHRA

110. Before they received disclosure in this claim, the claimants pleaded that, in relation to the November 2025 decision, the MHRA had to be satisfied that the Trial would be in accordance with the conditions and principles set out in Sch. 1 to the 2004 Regulations; that there was insufficient evidence that it had adequately considered relevant matters; and that it therefore fell into public law error: RASFG, paras 172-174. These paragraphs, however, were later struck through. The current version of the RASFG makes clear that the only decision of the MHRA now challenged under ground 1 is the June decision: see paras 231 and 233 (which introduce the challenges to the November decisions and makes clear that the failure pleaded is a failure by the REC alone) and 234 (which makes clear that the challenge to the MHRA is to the June 2026 decision alone).

111. The challenge to the MHRA's June 2026 decision is pleaded as follows:

> "234. In relation to the June decision, both the REC and MHRA failed to take account of mandatory considerations in relation to the destination therapy issue (see §§215-230), by focussing on whether there was sufficient assurance around the OLE study, and by proceeding on the basis of an assumption that MAF would be available to trial participants in due course through a separate research study if needed, rather than stepping back and considering the relevant regulatory questions and in particular the overall benefit-risk balance again in light of this issue. As set out at §§201-202, the REC (despite being asked to consider the point) left it to the MHRA. The MHRA de facto delegated consideration of the point to the CHM – see §§227.
>
> 235. What is more, this was not compatible with reg. 22C(6) of the 2004 Regulations, which should have had the effect that if there were any concerns about the response to an RFI the MHRA had no choice but to reject the modified Trial protocol. The CHM response was that they still had concerns, and on that basis (although the CHM still thought the Trial should go ahead) the MHRA were bound to reject it. However, the MHRA approved the modified Trial."

112. This makes clear that the complaint about the MHRA's June 2026 decision is about the "destination therapy issue", as described earlier at RASFG paras 215-230. These paragraphs make clear that the issue relates to the therapy that will or may be available

to trial participants once they have had PSH for one or two years (depending on which cohort they are in).

113. The short answer to this point is that the process leading to the June decision was prompted in large part by concerns about the destination therapy issue. Thus, Dr Cave says this in her witness statement:

> "157. The MHRA was acutely aware that many Trial participants would likely wish to continue to take [PSH] after the end of the Trial and/or eventually to progress to taking MAF hormones, if their gender incongruence had not resolved. As I have explained above, the MHRA specifically took that fact into account when considering whether to give approval for the Trial protocol; and it and the CHM specifically considered in that regard the implications of a possible change in NHS prescribing conditions for MAF hormones (i.e., that they would not be available before the age of 18)…. The MHRA made no assumption that there would inevitably be an OLES, or a clinical trial of MAF hormones at the age of 16, in which Trial participants could take part, where that was desired and clinically appropriate. However, through the course of the assessment, DHSC has guaranteed funding for an OLES; and the Trial protocol requires any application for an OLES to be lodged by the Trial sponsor no later than Month 15 of the Trial (to give certainty for Trial participants).
>
> 158. While it is not possible for the MHRA to know with certainty how many [children and young people] may appropriately access MAF hormones after the Trial (if at all), the MHRA sought assurances, to the greatest extent possible, that there was no impediment to a MAF hormones clinical trial, as referred to in RFI4 of version 3 of the Protocol. Those assurances were then matters which fed into the MHRA's overall assessment that the benefit/risk balance of the Trial for participants was positive."

114. This is consistent with the minutes of the scientific dialogue meeting between Trial sponsors and the MHRA on 27 March 2026, which records:

> "the MHRA noted that given the change in NHSE's policy on the prescribing of MAF hormones could potentially impact considerations around the long-term safety or well-being concerns of the participants, or to the risk-benefit profile of the trial (for example if trial participants will need to transition to taking MAF hormones after taking part in the trial), then that policy (and the evidence in support of it), which may only become relevant after the trial period, should be taken into account in reaching a decision on the trial."

115. The same point emerges from the paper submitted by the MHRA for the CHM's meeting on 27 April 2026.

116. It follows that the "destination therapy issue" was squarely recognised by the MHRA as a critical one. Insofar as this ground of challenge is framed as a failure to take into account a mandatory relevant consideration, it is not realistically arguable. The point was taken into account and carefully considered.

117. Insofar as the complaint is that the MHRA assumed that MAF hormones would be available to Trial participants through a research study, the complaint is also clearly not well-founded. When Dr Cave wrote to NIHR and NHS England on 20 May 2026, she said this:

> "…MHRA has been considering the position of participants at the conclusion of the 2-year trial period, including the potential future availability of masculinising and feminising ('MAF') hormones where clinically appropriate. This is currently uncertain because on 9 March 2026 NHS England paused new prescriptions of MAF hormones to 16 and 17 year olds, while it consults on a revised policy under which MAF hormones would not be available as a routine commissioning option through the NHS Children and Young People's Gender Service. As you will know, this consultation is open for 90 days, until 7th June 2026 and its outcome is therefore not yet known.
>
> Against this context, we would be grateful for clarification as to whether any outcome of the ongoing consultation could, of itself, as a matter of policy affect or impede access for PATHWAYS trial participants to MAF hormones at 16 years of age, where such access were proposed within a separately approved research study.
>
> For the avoidance of doubt, this request is not intended to seek any commitment or make any assumption regarding the future commissioning, funding, authorisation or undertaking of a trial, nor to pre-empt the outcome of the ongoing consultation process. Rather, we seek only confirmation as to whether the consultation and/or its outcomes would affect or impede consideration of such access in a future research context."

118. This letter makes clear the MHRA's understanding that the position was to some extent uncertain, that the MHRA understood that it was not possible to eliminate the uncertainty entirely and that the assurances sought were properly understood as relevant to the degree of risk only. The task of the MHRA was to use its experience and expertise (and that of its external advisers) to gauge the level of uncertainty and factor that into its analysis of the benefits and risks to Trial participants. In this respect, the task was one which was both familiar to the MHRA and apt for a body with its expertise.

119. Insofar as it is contended that the MHRA improperly delegated its function to the CHM, the complaint is misconceived. It is flatly inconsistent with Dr Cave's evidence (para. 155) and with the clinical assessment summary, which makes absolutely clear that the MHRA correctly understood the CHM to be giving advice and correctly understood that it must consider for itself whether the modification to the Trial protocol was acceptable.

120. There is a tension between RASFG paras 234 and 235. The final sentence of para. 234 alleges an improper delegation to the CHM. I have explained why this complaint is not well-founded. Paragraph 235 then goes on to allege that, if the CHM still had concerns (albeit it considered the Trial should go ahead), the MHRA was bound to reject the modification. The MHRA was not so bound, precisely because the CHM's function was advisory only and the function of approving the Trial belonged to the MHRA.

121. Finally, there is nothing in the point that what occurred in June contravened reg. 22C(6) of the 2004 Regulations. Regulation 22C(6) deals with when a modification request is treated as rejected. None of the circumstances there set out applies here. The trial sponsor's amended modification request was made under re. 22B(3) and approved under reg. 22C(3)(b)(i). There was no irregularity here.

122. As against the MHRA, this pleaded ground is not arguable.

The unpleaded challenge to the MHRA's November decision

123. In his skeleton argument (paras 31-38) and in his oral submissions, Mr McCullough advanced a different challenge to the MHRA's November and June decisions. This challenge focussed on the statutory requirements applicable to clinical trials in general and to the specific requirements for trials involving minors. In particular, he submitted that the decision-making of both the MHRA and the HRA had failed properly to take account of the need to show that "some direct benefit for the group… is to be obtained" (Sch. 1, Part 4, condition 10) and that the anticipated benefits for the individual trial subject are justified by the risks (Sch. 1, Part 2, condition 10 in the Old Regulations). Reference was also made to the principles in the Declaration of Helsinki (which are said to have been incorporated by reference), including in particular principle 28.

124. The point, in short, was that KCL could not say if PSH will confer any expected benefit on any Trial participant. This is because no-one knows, one way or the other, whether PSH confer a clinical benefit on patients with gender incongruence. In those circumstances, Mr McCullough submitted that it was not rational for either the MHRA or the HRA to conclude either that there would be "some direct benefit for the group" or that the anticipated benefits to Trial participants justified the known risks associated with the drugs.

125. The significance of the conditions and principles, and the claimants' interpretation of them, was illustrated as follows at para. 32 of the claimants' skeleton argument:

> "To take an unrelated example, say that a potential trial sponsor wanted to test GLP-1 weight loss drugs in children, to see whether the benefits outweighed the risks. The MHRA and HRA would need to be convinced that (a) the evidence indicated there would be some direct benefit for the group taking part in the as a whole; and (b) that for each individual trial subject the benefits justified the risks. It will usually not be possible to say with certainty whether the benefit will outweigh the burden for any individual trial child subject, but there must be sufficient evidence to believe that it will. That would be fulfilled, in the ordinary course of events, by there being previous research which tended to show this drug was effective in achieving weight loss and that there were no major side-effects or other risks which meant the anticipated benefits were not justified (the Declaration of Helsinki principles requiring that for children and others unable to give informed consent there must be *minimal* risk or burden)." (Emphasis in original.)

126. In the course of oral argument, Mr McCullough confirmed that he was not submitting that Sch. 1, Part 4, condition 10 means that there must be an ascertainable direct benefit to every member of the group. It would be enough if there were a direct benefit to an

unascertainable proportion of the group, provided that the proportion was not de minimis. However, he submitted that the language of Part 4, condition 10 ("some direct benefit for the group… is to be obtained") and of principle 28 in the Declaration of Helsinki ("likely to… personally benefit them") was only consistent with a requirement that the regulators be satisfied that the direct benefit to this proportion of the group was more likely than not to accrue.

127. Although a great deal of time was spent at the hearing on this point, I would reject it on procedural grounds, at least insofar as it applies to the MHRA, and also because as a matter of substance it is not arguable.

128. As to procedure, the point was not pleaded. If it were to be relied upon, it should have been. I appreciate that the timescale for pleading was tight, but it was manageable. Two weeks were allowed for the claimants to amend their pleading following the June 2026 decisions. Because it was not pleaded, it was not addressed in the MHRA's evidence. No application to amend the RASFG was made. If it had been I would have refused it.

129. As to the merits of the point, the interpretations advanced by Mr McCullough of Sch. 1, Part 4, condition 10 and of principle 28 of the Declaration of Helsinki are not plausible, for three reasons.

130. First, they would turn a simple condition designed to be applied by scientific experts using their judgment and experience into a legal minefield. They would mean, for example, that a trial of a promising and potentially life-saving drug could not be approved if it could not be said in advance that the trial was more likely than not to benefit some greater than de minimis proportion of the group, even if—as here—there was a reasonable prospect of benefit for each trial participant. Even if the MHRA were satisfied that Mr McCullough's criterion was met, they could have no confidence that their assessment that the proportion was greater than "de minimis" would accord with the court's.

131. Secondly, although common lawyers make findings on a balance of probabilities, that concept is not universally applied in other contexts. One context in which it is almost certain to be inapt is that of a risk benefit analysis in the healthcare context. In that context, both the prospect of achieving a benefit and the nature of the benefit which may be achieved are relevant. Whether the prospect of a particular benefit justifies the risks associated with a particular treatment is a complex matter of clinical judgment. It does not turn on whether the chance that a benefit will accrue is 49% or 51%. Even if the "more likely than not" criterion is applied to the group (or some proportion of it), it is inapt for the clinical context.

132. Thirdly, turning to the language of Sch. 1, Part 4, condition 10, the requirement is that a direct benefit is to be obtained for the group. In ordinary parlance, an intervention which offers a reasonable prospect of achieving a gain in terms of quality of life does offer a direct benefit to the patient. The use of principle 28 of the Declaration of Helsinki takes matters no further. Even in a domestic statute, "likely" does not always mean "more likely than not": see e.g. *Cream Holdings Ltd v Banerjee* [2004] UKHL 44, [2005] 1 AC 253, [22] (Lord Nicholls). There is certainly no obvious reason to interpret "likely" as "more likely than not" when used in a declaration by an international medical association.

133. As to the facts, although Dr Cass said that the evidence that PSH confer a benefit was very weak, she did not say that there was no such evidence. In her witness statement for these proceedings (at para. 25), she noted that "families and clinicians give sufficient anecdotal accounts of benefit from PSH, supported by the weak but not non-existent evidence base". (An objection was taken to the admissibility of this statement, but the same point can be drawn from her report, whose admissibility is not in dispute.)

134. KCL included in version 2 of the Trial protocol a requirement that the treating physician make the statement set out at para. 20 above, to the effect that, in their clinical judgment, there was a reasonable prospect of benefit for that child. The passage from para. 81(b) of Dr Cave's witness statement set out at para. 21 above shows that the CIT considered that this was acceptable. Among the matters considered relevant to that judgment were the severity of the symptoms being experienced (persistent gender dysphoria) and the fact that the clinical judgment of the treating physician would have to be endorsed by the NMDT.

135. Against this background, the contention that it was not rationally open to the MHRA to conclude that the "direct benefit" test in Sch. 1, Part 4, condition 10 was met is not arguable with a realistic prospect of success. The benefit/risk test in Sch. 1, Part 2, condition 10 was a classic example of a matter for the judgment of an expert regulator. The argument that the MHRA's conclusion on that ground, after considering the answers to its probing questions, was irrational also has no realistic prospect of success.

The challenge to the HRA's November 2025 and June 2026 decisions

136. The challenge to the HRA's decision is pleaded at RASFG, paras 233-235. Para. 233 reads as follows:

> "In relation to the November and June decisions the REC failed to consider the following matters which were statutorily required, properly or at all:
>
> a. The requirement under reg 15(5)(h) and Sch 1, Part 4 condition 10 for 'some direct benefit for the group of patients involved in the trial', as set out at §§102-114 above.
>
> b. The inability, on the trial sponsors' own evidence, for the statutory risk/benefit balance requirement for individual trial subjects under reg 15(5)(b) and Sch 1, Part 2 condition 10 (also as read with condition 16) to be satisfied: see §§102-114 above.
>
> c. The requirement to validate data that had been obtained by other means, under Sch 1, Part 4 condition 11; including consideration of (i) animal studies and (ii) follow-up of individuals who had previous been prescribed puberty blockers for gender incongruence or dysphoria: see §§117-123 above.
>
> d. Compliance with EMA scientific guidelines; in particular as to risk mitigation and trials involving children: see §§67-68 above.

> e. Failure to consider the trial protocol design, as required by reg 15(5)(a), and in particular failure to ask any or any adequate questions about its underlying scientific rationale and ability to yield clinically meaningful data: see §§124-131 above."

Paras 234-235 are set out at para. 111 above.

137. Each of the points in para. 233 has a compelling answer:

(a) Insofar as it is based on the interpretation of Sch. 1, Part 4, condition 10 advanced by Mr McCullough, the claimants' point (a) is wrong for reasons set out at paras 132-134. Para. 119.4 of the REC Chair's statement (see para. 51 above) makes clear that the REC did conclude that there was a potential for direct benefit to the group. Once it is recognised that direct benefit for the group does not require that it is more likely than not that some proportion of the group will benefit, a potential for direct benefit is enough. Paras 70-71 of the REC Chair's statement (set out at para. 31 above) shows that the REC had a proper basis for concluding that there was a potential for direct benefit (the stringent eligibility criteria, the careful way in which trial participants would be chosen and the clinical opinion of their treating clinicians and the NMDT that the trial offered each participant a reasonable prospect of benefit in terms of quality of life).

(b) The statutory risk/benefit test was clearly addressed: see paras 97-101 of the REC Chair's statement (set out at para. 33 above).

(c) The limitations of the data linkage and animal studies was clearly explained in both the Cass Report and the Trial protocol, both of which were before the REC. The REC Chair explains at para. 98 (para. 33 above) that "We took the applicants – as we must take all applicants, who are the masters of the science, and indeed Cass and other sector experts – at their word that there was an insufficiency of evidence". That was a rational basis for concluding that there was a need to validate other data.

(d) The EMA scientific guidelines add nothing material to the other express requirements in the 2004 Regulations.

(e) The suggestion that there was a failure to consider the Trial design, or ask questions about its underlying rationale, is hopeless in the light of the careful iterative process undertaken by the REC (and described above at paras 23-33 and 48-53).

138. As to the challenge to the REC's June 2026 decision, the suggestion that the REC failed to take account of mandatorily relevant considerations in relation to the "destination therapy" issue is not realistically arguable, given the express consideration of both the open label extension study and the MAF hormones issue (see paras 50-51 above).

139. None of the criticisms made of the REC's decision-making under ground 1 has a realistic prospect of success.

Ground 2

140. Under ground 2, the claimants argue that, in relation to the November 2025 decision, the HRA withheld from the REC relevant material, namely representations from two groups of professionals, CAN-SG and a group of ten clinicians and researchers with expertise in neuroendocrinology, psychiatry, psychology and medical ethics, including Professor David Curtis (RASFG, paras 132-137 and 236).

141. The claimants concede that, in relation to the June decision, the HRA belatedly realized the flaw in its approach but failed to follow its own published policies in this regard and in any event the REC members did not adequately consider this material.

142. These are advanced as failures to take into account relevant considerations and breaches of the duty to gather relevant evidence and information ("the *Tameside* duty").

143. The fundamental difficulty with the first of these complaints is that the regulatory scheme stipulates in some detail the matters which the REC must consider: see the itemised list at reg 15(5)(a)-(m) (set out at para. 56 above). Third party comments do not feature in this list. Where a statute does not identify a particular matter as a mandatory relevant consideration, it is for the decision-maker to decide for itself whether it is necessary to take it into account, subject to review on rationality grounds only: see *R (Friends of the Earth Ltd) v Heathrow Airport Ltd* [2020] UKSC 52, [2021] 2 All ER 967, [116]-[121]. If the point is advanced as a breach of the Tameside duty, a failure to gather relevant evidence will be unlawful if and only if the failure is irrational: see *R (Balajigari) v Secretary of State for the Home Department* [2019] EWCA Civ 673; [2019] 1 WLR 4647, at [70].

144. To succeed on this point, therefore, the claimants would have to show that the decision not to place the third-party comments before the REC in November was irrational. The HRA Manager's witness statement contains an explanation of the careful process leading to the decision not to place CAN-SG's comments before the REC. Essentially, the HRA decided (having put some of the comments to the sponsors and considered their response) that CAN-SG's material did not raise issues going beyond those already identified. The process leading to the decision about Prof. Curtis' material is described at paras 85-89 of the HRA Manager's statement. The suggestion that the decision-making in relation to these materials was irrational is not realistically arguable.

145. In the lead-up to the June 2026 decision, a pragmatic decision was taken to put some of the material before the REC. This does not demonstrate that the initial decision was irrational. Nor does the allegation that the HRA's Standard Operating Procedures were breached assist the claimants. Nothing contained in those was legally obligatory. The decision-making has again been fully and satisfactorily explained. It is not arguably irrational.

146. Finally, the fact that the MHRA considered the third-party material also does not demonstrate that the HRA's decision not to put that material before the REC in the lead-up to the November 2025 decision was irrational. It is a feature of the rationality standard of review that two different public authorities can take two different but equally lawful approaches to the same issue.

Ground 3

147. Under ground 3, the claimants identified six alleged procedural flaws in the REC's decision-making process: see RASFG, para. 238: (i) the REC constitution did not meet the relevant statutory requirements; (ii) the REC constitution was not representative of the diversity of public opinion; (iii) the REC lacked the statutorily required expertise; (iv) there was an invalid delegation to a first sub-committee; (v) there was insufficient transparency contrary to the Governance Arrangements for Research Ethics Committees ("GAfREC"), in particular by failing to publish either a summary of the research reviewed or the REC's opinion of it; and (vi) there was invalid delegation to a second sub-committee.

148. In his skeleton argument and opening submissions for the hearing, Mr McCullough confirmed that complaints (i), (ii) and (iii) were abandoned. In reply, he abandoned (iv) and (vi).

149. That leaves complaint (v) (insufficient transparency), as to which the claimants rely on paragraph 5.6.1 of GAfREC, which provides as follows:

> "5.6 Transparency
>
> 5.6.1 RECs should publish a summary of the research they have reviewed, together with their opinion, whether favourable or otherwise."

150. The complaint identified at RASFG para. 171 is that the REC in the present case, despite having published its opinion in relation to the November 2025 decision, has not publicly provided a summary of the research they have reviewed and therefore has acted unlawfully by failing to comply with paragraph 5.6.1.

151. In relation to the November 2025 decision, the REC did publish an adequate summary of the research reviewed and recorded its favourable opinion (albeit without summarising its reasons for that opinion). There would be no point in entertaining a challenge to the failure to provide a summary of the reasons for the REC's opinion, because, even if this point were ultimately meritorious, it could not lead to an order quashing the REC's decisions in this case. The relief that would flow would be limited to an order requiring publication of the relevant summary (or a declaration that such a summary was legally required). Moreover, there is no point in granting that relief at this stage, given that the claimants now have a vast quantity of material witness evidence and other material (and this judgment), all of which explain the reasons for the REC's favourable opinion.

152. As to the June 2026 decision, there has not yet been publication of any relevant summary (whether of the research or of the reasons for the opinion), but the decision was only taken on 18 June, there is no express obligation to publish that summary within any particular time and it is fair to note that the relevant staff of the HRA have been preoccupied with responding to these proceedings. There is no reason to doubt that the HRA will publish a summary in due course.

153. For these reasons I would refuse permission to apply for judicial review on what remains of ground 3.

Ground 4

154. Under ground 4, the claimants advance an irrationality complaint, which they plead as follows at paras 240-241 of the RASFG:

> "240. Both the HRA/REC and the MRHA irrationally approved a trial protocol that lacked the essential components for a clinical trial; in particular (a) a clearly articulated scientific rationale; and (b) the ability to yield clinically meaningful data: see §§124-131 above. The ongoing confusion about the rationale is apparent even by the time of the June decision, when the REC accepted the primary benefit of GnRHa was 'time to think' whereas the MHRA accepted the primary benefit preserving the opportunity to initiate MAF before the development of secondary sexual characteristics. Both cannot be correct.
>
> 241. In relation to the June decision, both the REC and MHRA acted irrationally by failing to consider the risks and concerns raised by the destination therapy issue through the correct lens or 'spectacles' of the regulations and structure of the regulatory regime. In particular, as set out at §§201, 225-227 and 230, they did not ask themselves the questions set out in the 2004 Regulations and their Schedules (incorporating the ICH GCP and Declaration of Helsinki) or the EMA Guidelines, especially those relating to the balance of risk and benefit for children, but rather sought to reassure themselves that the sponsors' responses (and those from the NIHR and NHS England in relation to the OLE study) were sufficient."

155. Because these points are advanced as a rationality challenge, they squarely engage the principles set out at paras 82-99 above.

156. The design and purpose of the Trial were fully explained in the application materials. Its primary objective was said to be to measure short and medium-term benefits and risks/harms of puberty supressing hormones and (by comparing the two groups) to determine whether early intervention improves outcomes. The suggestion that it was irrational for either the MNHRA or the HRA to accept this as a valid purpose is hopeless.

157. The suggestion that the Trial lacked a valid testable hypothesis is based on a misunderstanding of the purpose of the Trial. As explained in the application materials, it was a "pragmatic trial" not a randomised controlled trial. It was not designed to test any particular hypothesis, but rather "to assess whether puberty suppression produces benefit, harm or no material difference across defined domains, using established methods and recognised statistical methods" (as Prof Simonoff put it in her witness statement at para. 64). Whether to approve a trial with this purpose was quintessentially a question of judgment for the MHRA and HRA.

158. The points at RASFG para. 241 are essentially the same as those considered under ground 1. For the same reasons, they are not arguable.

Ground 5

159. Under ground 5, the claimants make two complaints with regards to the MHRA's and HRA's failure to give adequate reasons. The first, in relation to the November 2025 decision, is that MHRA failed to give adequate reasons for accepting the sponsors' rejection of its requested amendment to inclusion criterion 5 in the Trial protocol (that Trial participants were "likely to" or "expected to" benefit).

160. The second, in relation to the June decision, is that both the REC and the MHRA failed to give any adequate reasons for it being safe to proceed on the assumption that MAF would be available in due course to trial participants who wished to take them, and for whom it was clinically appropriate.

161. There are strong arguments against a duty to give reasons to the public. The 2024 Regulations contain express duties to give reasons to an applicant for refusing an application for approval for a clinical trial and for refusing an application for modification of a trial protocol: see regs 18B(3)(b)(iii) and 22A(4)(b)(iii). There is no equivalent duty to give reasons to the public generally where a decision has been taken to approve a trial or modification.

162. There is no general duty to give reasons at common law: *R v Secretary for the Home Department ex p. Doody* [1994] 1 AC 531 HL at 564, per Lord Mustill at 564, *Dover District Council v CPRE Kent* [2017] UKSC 79, [2018] 1 WLR 108, [51]-[52] (Lord Carnwath). Although a common law duty can arise even when there is no expressed statutory duty (*Dover*, [51]) the use of the common law to carry out a "gap filling" exercise should be limited to circumstances where the "legal policy reasons are particularly strong": *Dover* [58].

163. Although the present approvals have attracted considerable public attention, they are unusual in that regard. I do not think it can be said generally that there are particularly strong policy reasons to impose a duty to give reasons on the MHRA and HRA in this context.

164. In any event, even if I had considered ground 5 to be arguable, there would be no point in granting permission in circumstances where the claimants now have a vast amount of material explaining the MHRA's and HRA's reasons for the approvals and, by virtue of the publication of this judgment, so does the public at large. In the light of this judgment, the question whether either regulator owed a duty to give reasons is academic. The point is not one that is likely to arise in another case, or one whose resolution is otherwise in the public interest so as to justify consideration of an academic issue.

Conclusion on permission to apply for judicial review

165. For these reasons, permission to apply for judicial review is refused. That being so, the question whether to grant interim relief does not arise. However, having heard argument on that issue, I set out briefly my conclusions on that issue.

Interim relief

The proper approach

166. Section 37 of the Senior Courts Act 1981 ("the 1981 Act") confers on the court a very wide power to grant an injunction "in all cases in which it appears to the court to be just and convenient to do so".

167. The parties agree that the basic test is that set out by the House of Lords in *American Cyanamid Co. v Ethicon* Ltd [1975] AC 396, modified as appropriate to public law cases: see e.g. *R (Medical Justice) v SSHD* [2010] EWHC 1425 (Admin), at [6]. This requires the claimants to demonstrate that: (i) there is a serious question to be tried; (ii) damages would not be an adequate remedy; and (iii) the balance of convenience lies in favour of granting the relief sought.

168. As I am refusing permission to apply for judicial review, it follows that there is no serious question to be tried and therefore no basis for interim relief. If I had concluded that one or more of the grounds which could lead to the quashing of the authorisations was arguable, the second stage of the analysis would be satisfied: no-one suggests that the claimants have any right to damages or that damages would be an adequate remedy. It would therefore be necessary to consider the balance of convenience.

169. Here, the question is whether the harm that would be done to public and private interests in the scenario where interim relief is granted but the claim later fails outweighs any harm that might accrue to trial participants in the scenario where interim relief is refused but the claim later succeeds.

170. In *R (FTDI Holding Ltd) v Chancellor of the Duchy of Lancaster* [2025] EWHC 241 (Admin) at [15], Singh LJ and I observed that there is a particular public interest in public law cases in allowing a public authority to exercise its powers in what it considers to be a lawful manner. At [17], we said this:

> "The weight to be accorded to this public interest will vary from context to context, but may be considerable. In many cases, the claimant would need to point to something very compelling to outweigh it. In deciding whether a claimant has done so, the court will consider both the prima facie strength of the claim and the gravity of the consequences that would follow if interim relief were not granted. It is not possible, and would not be desirable, to lay down anything more prescriptive than that."

171. Where the authority whose decision is challenged acts to protect public health, this has been recognised as a "very important objective" which "must carry great weight": *R v Secretary of State for Health ex p Eastside Cheese Co* [1999] CMLR 12 at [43] (Lord Bingham CJ). See also *R (RRR Manufacturing Pty Limited) v British Standards Institution* [2024] EWCA Civ 530, at [84]: "great weight must be given to the protection of public health" (Elisabeth Laing LJ), [96(b)] (Snowden LJ) and at [106] (Nugee LJ).

An unusual feature of this case

172. In most applications for interim relief the applicant seeks to protect a private interest of his or her own. Thus, for example, the Administrative Court Judicial Review Guide (2025), at para. 16.6.1, provides as follows:

> "The consideration of the balance of convenience involves balancing the harm to the claimant that would be caused if interim relief is not granted and the claim later succeeds against the harm to the defendant, any third parties and the public interest that would be caused if interim relief is granted and the claim later fails." (Emphasis added.)

173. In this case, the claimants' application for interim relief does not seek to protect any private interest of theirs. They say that the interest they are seeking to protect is the public interest in a clinical trial not proceeding unless it has been lawfully approved. In reality, however, the people whose interests would be "protected" by the interim relief sought are the children and young people who will become participants in the Trial.

174. There are, of course, established procedures for protecting the interests of children and young people. The person with the first duty to promote their interests are their parents or legal guardians. If there is a dispute between parents about whether a particular step is in a child's interests, an application can be made to the Family Division under the Children Act 1989 or under the parens patriae jurisdiction. In some cases, local authorities have responsibilities too and they can also make applications to the court to safeguard the interests of children and young people.

175. But the claimants fall into none of these categories. They know nothing about the lives of the children or young people who are potential participants in the Trial. The relief they seek would prevent those children and young people from receiving treatment which they want, which their parents want for them and which their treating doctors and (it must be assumed) independent doctors from the NMDT believe offers a reasonable prospect of an improvement on their quality of life—all in the context of a clinical trial which has been approved by two specialist regulators, whose decisions benefit from a presumption of validity.

176. Counsel were unable, between them, to direct me to any case where interim relief has been granted in remotely comparable circumstances. The defendants and interested parties conceded, however, that the court has jurisdiction to grant relief. I would prefer to express no concluded view on this question. The authority relied upon by Mr McCullough to establish jurisdiction (the decision of Julian Knowles J in *R (NN) v Secretary of State for the Home Department* [2019] EWHC 1003 (Admin)) involved very different facts, where the claimants had obtained interim relief for themselves and the only question there was whether they could also seek interim relief on behalf of others in the same position. It may have to be decided in another case whether the jurisdiction to grant interim relief extends to permit relief at the instance of a party who has no identity of interest with the group the interim relief is designed to protect.

177. I say no more about this because, even if I do have jurisdiction, the balance of convenience falls decisively against the grant of relief.

The balance of convenience in this case

Scenario 1: permission and interim relief are granted and the claim later fails

178. In this scenario, there would be a significant delay to the start of the Trial. Mr McCullough sought to suggest that the substantive claim could be heard quickly in the Michaelmas Term, so the delay would be short. This is unrealistic. If permission were granted, the defendants and interested parties would no doubt wish to file Detailed Grounds of Defence and may also wish to file further evidence. They would have to be given time to do so. The fact that we are approaching the August holiday period would have to be factored in. It would then be necessary for the claimants to be given the opportunity to respond to that evidence by further evidence of their own. Once that had been done, bundles and further skeleton arguments would have to be prepared and a hearing date fixed. Then a judgment would have to be produced. In my experience it is unrealistic to suppose that this could be all be done before the end of December 2026 at the very earliest. So, there would be a minimum of five months delay to the start of the Trial.

179. Mr McCullough submitted that this delay was insubstantial, given that there have already been significant delays in the process of approving the Trial. I do not accept that submission. Gender incongruence affects a substantial number of children and young people. The Cass Report identified gaps in the evidence base about what had, up to then, been a frequently prescribed treatment. The Trial seeks to fill those gaps. It may lead to PSH being prescribed more or less frequently for gender incongruence. Either way, it offers the prospect of a meaningful contribution to the evidence base available to clinicians. Whatever the result of the Trial, that will constitute a major benefit to the children and young people under the care of those clinicians. Delaying that benefit by at least five months would constitute a significant harm to the public interest and to the private interests of children and young people with gender incongruence.

180. In addition, the evidence establishes that delay gives rise to a real danger of harm to the children and young people who would otherwise participate in the Trial. The claimants objected to some of the evidence filed by the interested parties on the ground that it purports to offer opinions but does not comply with the requirements of CPR Part 35. I do not need to resolve this issue definitively given my other conclusions in this case.

181. In any event, the materials whose admissibility is not disputed make clear that many children and young people with gender incongruence are so distressed by their condition that they have resorted to self-medicating using hormones obtained abroad or online. I do not understand it to be disputed that this is dangerous to their health, because the hormones in question are being taken outside any clinical supervision and often at inappropriate doses. There is an obvious danger that Trial participants who have already faced considerable delays may be driven to doing this. The fact that it would be unlawful does not mean that I should ignore it.

182. It is also possible that a delay of five months will cause some prospective Trial participants to "age-out". The Trial has a maximum age limit of 16 years. Some participants who have been undergoing the lengthy eligibility process for over a year may lose the opportunity to participate at all.

183. Taken together, these constitute serious harms to the public interest and to the private interests of the prospective participants in the Trial. These harms would be directly attributable to the grant of interim relief. Taken with the strong, general public interest in giving effect to decisions taken by specialist regulators (see *FTDI*, [15]; para. 170 above), the claimants would need to show very compelling grounds for interim relief in this case.

Scenario 2: interim relief is refused but permission is granted and the claim later succeeds

184. In this scenario, it is possible that some harm may be done to those Trial participants to whom PSH are administered if it later emerges that these drugs cause damage to the health of the children. However, the number of children affected would be limited because there is a lengthy process of tests, clinical assessment and approval by the NMDT which must be undertaken before the hormones are administered. The number of children to whom hormones could be administered before the end of December 2026 is less than 20. More importantly, the Trial contains detailed provision for ongoing clinical monitoring, so there is some prospect that any harm to an individual would be picked up at an early stage and the child withdrawn from the Trial.

185. A separate harm that can be envisaged is the psychological harm that would flow from being enrolled in the Trial and then being faced with a judgment requiring treatment to stop. I do not underestimate the potential significance of this harm, but the psychological effect of the uncertainty caused by the litigation will depend on a number of child-specific factors, which in this scenario will have been carefully assessed by the treating clinicians and the NMDT before the child is entered in the Trial. The children affected by any sudden termination of the Trial will be those who were clinically assessed as capable of coping with that eventuality.

186. In any event, I note that success in these proceedings would not necessarily result in an order quashing the approvals. Much would depend on the particular ground or grounds which succeeded. The grant of remedies is discretionary and the court now has available a range of remedial options, some of which may not require the cancellation or even suspension of the Trial.

Conclusion on interim relief

187. For these reasons, I conclude that, even if I had granted permission to apply for judicial review, the balance of convenience would fall firmly against the grant of interim relief.

Citation

188. Although this judgment deals mostly with the question of permission to apply for judicial review, it has been produced after detailed argument over two days and contains material which may be of relevance in other cases. If permission is required to cite it, I give that permission.