R (Bayswater Support Group, Keira Bell and James Esses) v (1) Health Research Authority, (2) Secretary of State for Health and Social Care

Press Summary: For release at 2.10pm, 31 July 2026

This summary is provided by the Court for the assistance of those reporting the judgment (neutral citation [2026] EWHC 2043 (Admin)). It does not form part of that judgment.

Headline

1 Mr Justice Chamberlain has today rejected a challenge to regulatory decisions in relation to the PATHWAYS clinical trial for puberty suppressing hormones ("PSH").

Background

2 In 2020, NHS England commissioned the paediatrician Dr Hilary Cass (now Baroness 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.

3 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 Trial was co-sponsored by King's College London and the South London and Maudsley NHS Foundation Trust. They are interested parties in this case.

4 The sponsors submitted an application for regulatory approval in August 2025. Approval was given in November 2025 by the Medicines and Health Regulatory Agency ("MHRA") on behalf of the Secretary of State and by the Health Research Authority ("HRA"). The Secretary of State and the HRA are the defendants in this case.

5 There were then two developments. A group of clinicians wrote to the regulatory authorities to express their concerns and the Secretary of State for Health and Social Care announced a pause on new prescriptions for masculinising and feminising ("MAF") hormones for young people.

6 The MHRA 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. That application was approved by the MHRA and the HRA in June 2026.

The claimants

7 The first claimant, Bayswater Support Group, represents and provides advice and support to about 800 parents and guardians of children and young adults who identify as trans or nonbinary. It has members in all regions of the United Kingdom, as well as in the Republic of Ireland.

8 The second claimant, Keira Bell, 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.

9 The third claimant, James Esses, 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.

The claim

10 The claimants initially challenged the November 2025 decisions of the MHRA and HRA on five grounds. With the permission of the court, they amended their claim to add a challenge to the June 2026 decisions. They also made an application for an interim order to stop the Trial from going ahead while the case was considered.

Procedure

11 In judicial review, claimants require the permission of the court to proceed to a substantive hearing. In this case, the Court ordered that the application for permission to apply for judicial review should be considered at a hearing together with the application for an interim order.

12 The hearing took two full days on 27 and 28 July 2026. In advance, the parties filed including 31 witness statements, detailed written submissions and authorities. The documentation ran to over 13,000 pages.

Decision

13 The applications for permission to apply for judicial review and for an interim order were both refused.

Summary of reasons

14 The judge's reasons 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 paediatric consultants 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 defendants have exercised their functions contrary to the legislative scheme or otherwise unlawfully. These principles apply to both 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. After careful examination, 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 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 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 permission had been granted on one or more of the grounds which could lead to the quashing of the authorisations, interim relief would nevertheless have been refused. 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.

Ends