24th February 2026

Lawrence Tallon
Chief Executive
Medicines and Healthcare products Regulatory Agency
10 South Colonnade
London E14 4PU

Dear Mr Tallon,

Thank you for calling the Pathways Trial protocol back for further consideration. You have prevented (or at least delayed) the progress of a dangerous and unjustified medical experiment on children.

Sex Matters is a charity which is concerned with ensuring clarity on the facts and the law about sex (that it is binary, immutable and important) in order to protect everyone's human rights. We understand you are in the process of examining whether there are any further matters which should be considered.

We wrote to the Secretary of State for Health and Social Care last year, on 28th April and on 24th November, and on 16th February of this year, raising concerns about whether parents and children could meaningfully assent/consent to medical treatment based on hoped-for outcomes which simply cannot be achieved within the framework of UK law.

I am enclosing these letters. **Please consider them, together with this letter, to be representations concerning the trial.**

Our concerns are separate but complementary to the procedural and medico-ethical issues raised by the Bayswater Support Group, Keira Bell and James Esses in their Statement of Facts and Grounds, which was sent on 4th February 2026.

Please be on notice that we will seek to raise these points in intervention in relation to the Judicial Review.

Condition 10 of Part 2 of Schedule 1 to the Medicines for Human Use (Clinical Trials) Regulations 2004 require that **benefits justify risks for individual subjects**:

> "Before the trial is initiated, foreseeable risks and inconveniences have been weighed

> against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks."

Condition 12 in Part 4 requires European Medicine Agency guidelines to be followed in trials involving minors, putting even stronger emphasis on the balance between direct benefit and risk:

> "Experimental interventions or procedures that present greater than low risk to participants must offer a sufficient prospect of clinical benefit to justify or outweigh exposure of a pediatric population to such risk."

The judicial-review claim and the MHRA's letter to KCL (as well as the advice the Secretary of State received from the Commission on Human Medicines) focus on the grave foreseeable *physical* risks and likely harms caused by the GnRHa drug regimen on cognition, bone mineralisation and fertility.

The claimants further argue that the Research Ethics Committee (REC) did not consider the strong association between taking puberty blockers and proceeding to cross-sex hormones, which entails significant further risks. The REC not only failed to consider these risks but asked for "transition", the motivating rationale for the diagnosis and treatment, to be taken out of the title of the study "so as not to imply that this study relates to transitioning".

The MHRA in its letter avoids this obfuscation and correctly recognises that puberty blockers are the start of a medical pathway towards transition:

> "it is likely that further GRHa treatment could be needed for many years (particularly if participants are significantly below the age of 16 at trial completion) as a bridging measure as cross-sex hormones are only prescribable from the age of 16."

Any consideration of the risks and purported benefits of any part of this treatment pathway must assess whether the expected destination in terms of what it could entail to "live as the experienced gender" is realistically conceived of by all concerned.

It is clear that it is not. On 16th April 2025 the Supreme Court confirmed that man/male and woman/female in the Equality Act 2010 are the two sexes. They are defined as a matter of biology and not "experienced gender". The Equality Act is the law that regulates conduct in a wide swathe of life, including employment, service provision, education and sport.

This was not a change in the law, but a correction of a widespread misunderstanding of it.

The UK's legal framework protects the human rights of transsexual persons (those that are proposing to undergo, undergoing or have undergone a process of gender reassignment which can but does not have to involve body modifications). However neither the Equality Act 2010 nor the Gender Recognition Act 2004 provide a legal means for a person to change from being a man to a woman or vice versa. The identifiable legal purposes for which a person can change sex under the Gender Recognition Act 2004 are limited to marriage and pensions.

Other laws (and other people) continue to recognise a person's sex. The clarified interpretation of the Equality Act and the recognition that other people have human rights rule out the promise that a person can expect to use opposite-sex services and spaces or demand that other people treat

them as if they were the opposite sex, whatever physical interventions they undergo.

This judgment no doubt has led to disappointment for children, parents, adult patients and clinicians who believed the law was something other than this, and these emotions have been strongly expressed. Following the judgment, a group of gender clinicians and other scientists, including many involved in NHS gender medicine, wrote to the Minister for Women and Equalities to "request that the government take action to restore the rights of trans & non-binary individuals to access public spaces."[1] In fact no rights were removed by the Supreme Court. There was never a right to access opposite-sex facilities in the first place.

The Supreme Court judgment has led to a careful reconsideration of guidance provided to service providers and employers by the Equality and Human Rights Commission (EHRC) and to schools by the Department for Education. On 13th February 2026 the High Court confirmed that the EHRC was correct to say that separate-sex facilities are lawfully provided on the basis of sex, not gender identity (or "experienced gender" in the language of the trial protocol). The Secretary of State for Education has also published a new version of the statutory safeguarding guidance, *Keeping Children Safe in Education* (KCSIE), which confirmed that children cannot lawfully be permitted to use opposite-sex facilities at any time during their school career.

The messages being presented and the promises being made to patients must also be reassessed. Providing medical interventions with known physical and cognitive harms in pursuit of unachievable goals is unethical and likely to be unlawful.

That children, parents and clinicians have unrealistic expectations for transition based on the idea that "experienced gender" should override sex in life and law was an eminently foreseeable risk. It is inherent in the Pathway trial's own research survey tool into child and parental attitudes.[2] It was irresponsible that the disjoint between ideology and reality was dealt with by the REC by requesting that the study protocol not be explicit about "transition" in its title.

As far as we know the REC did not ask the sponsors whether they had legal advice in relation to transition expectations. We urge you now to consider whether the study is based on an accurate understanding of the UK's legislative framework and the legal constraints on hoped-for transition outcomes. If it is not, how can it be based on a robust assessment of foreseeable risks and possible benefits?

Yours sincerely

Maya Forstater
CEO

[1] May 2025 – Biology is not binary: a letter from biologists, doctors, and other experts to Bridget Phillipson, Minister for Women and Equalities https://t.co/vz2uWK41mQ

[2] Parental Attitudes of Gender Expansiveness Scale for Youth (PAGES-Y) (Adapted)