1. Stakeholders who are opposed to the Bill cited the recent Cass Review to argue against gender affirming medical treatment for young people. What is your view on the relevance of the Cass Review to understanding the proposed amendments?

The short answer is, it is not relevant.

The only part of the Equality Bill which pertains to gender affirming care is Schedule 3, items [2] and [3]. Mr Greenwich has indicated that he is withdrawing item [2], meaning that only Schedule 3, item [3] will be retained as part of the Bill.

Item [3] ensures that a child who has already obtained court authorisation for gender affirming care does not <u>also</u> require the consent of NCAT under s 175 of the *Children and Young Persons (Care and Protection) Act 1998* (NSW). This reduces procedural barriers to accessing care where the federal family courts or NSW Supreme Court have already determined, after considering an individual child's needs, that care should be provided because it is in the best interests of a particular child. Based on current federal family court authority, court authorisation is always required prior to providing a child with gender affirming care wherever there is a dispute as to their diagnosis, competence or treatment, or where any parent (or person with parental responsibility) has not provided consent to treatment for a child under 18 years: see *Re Imogen (No 6)* [2020] FamCA 761 at [35].

The Cass Report cannot be transported to the Australian context, and its findings are being misstated.

The Cass review emphasised randomised control trials as the gold standard – a research methodology that would require denying a cohort of trans young people medical treatment. Experts in this care have criticised this approach as it would require unethical approaches to research. Like every type of medical care, we have to use the evidence we have to help young people and their families make the best decisions they can based on what is known at the time of treatment, and support research on longer-term outcomes without denying or delaying care which is wanted and asked for now. AusPATH, Australia's peak body for professionals involved in transgender healthcare, have also released an up-to-date evidence brief on puberty blockers, which I have **attached**.

The Australia Standards of Care and Treatment Guidelines for trans and gender diverse children and adolescents prioritise holistic, individualised and person-centred care with the involvement of multidisciplinary teams of clinicians with all kinds of areas of expertise. These guidelines, published by the Royal Children's Hospital Melbourne and described by the Family Court in 2020 as the "orthodox middle" (*Re Imogen No 6* [2020] FamCA 761 at [4]), are **attached**.

Ultimately, decision-making about medical treatment are not political decisions and should not be politicised.

This inquiry has also not heard from critical voices within the medical and psychological profession, and therefore it would not be prudent to be making findings on gender affirming care without the benefit of that expertise informing this inquiry.

Here is a selection of some of the latest position statements specifically on gender affirming healthcare by Australian health peaks and others:

- The <u>2020 RACP advice</u> to Minister Greg Hunt.
- The Australian Medical Association (2023)
- American Psychological Association (2024) the Australian Psychological Association has a position statement under development
- Royal Australian & New Zealand College of Psychiatrists (2023)
- American Academy of Pediatrics (2023), reaffirming its 2018 position statement

None of these professional bodies, or AusPATH, were invited to provide evidence before the hearings, and therefore attempting to wade into the medical and clinical literature without the benefit of that expertise will be very difficult to do.

Attachment 1: 2024 AusPath Briefing on Puberty Blockers, see p 3 - 12

Attachment 2: The Australia Standards of Care and Treatment Guidelines for trans and gender diverse children and adolescents, see <u>australian-standards-of-care-and-treatment-guidelines-for-trans-and-gender-diverse-children-and-adolescents.pdf (rch.org.au)</u>



BRIEFING ON PUBERTY BLOCKERS

The Australian Professional Association for Trans Health (AusPATH) was established in 2009 and is Australia's peak body for professionals involved in the health, rights and wellbeing of all trans people – binary and non-binary. The AusPATH membership comprises over 600 experienced professionals working across Australia.

Who are transgender people?

- Some people are transgender, that is, their gender identity differs from their sex as registered as birth. Children, adolescents, adults and older adults can be transgender. Transgender people exist in all countries and cultures and have been present throughout history. As societal awareness and acceptance of transgender people grows, more people of all ages have become able to express their transgender identity openly (Coleman et al, 2022).
- Being transgender is not a mental illness (Royal Australian and New Zealand College of Psychiatrists, 2023).
- There is no known cause or reason for being transgender it appears to be a natural human variation.
- The Australian Government recognises transgender identity (Australian Government, 2013).
- The Australian Medical Association's Position Statement on LGBTQIASB+ Health supports the respectful, gender-affirming, person-centred care of transgender and gender-diverse people of all ages, including puberty suppression where indicated (Australian Medical Association, 2023).
- Conversion practices, or efforts to make a person not be transgender, are harmful (Australian Psychological Society, 2018 and 2021) and should not occur (Royal Australian and New Zealand College of Psychiatrists, Position Statement 103, 2023), and are specifically prohibited in Victoria, the ACT, NSW and Queensland.
- Transgender people of all ages have a right to respectful, high quality health care which prioritises their wellbeing and quality of life and respects their needs and wishes.
- Some transgender people want and need medical treatment to help their body better align with their gender, and others don't want medical treatment (Coleman et al., 2022).
- Many studies have found that listening to adolescents about their gender identity, loving acceptance from families, schools, and communities, and support to live expressing their gender as they feel most comfortable, are associated with better mental health. Transgender adolescents who are rejected by their families, and who experience victimisation or discrimination on the basis of their gender identity, have poorer mental health and more psychosocial difficulties (Coleman et al. 2022, page S52).



What are puberty blockers?

- Puberty blockers, or gonadotropin-releasing hormone analogues (GnRHa), are medications which pause puberty by preventing the body from producing sex hormones (Hembree et al., 2017).
- They have been used for more than 30 years to treat gender dysphoria in adolescents. They are also used to treat early onset (precocious) puberty in younger children who are not transgender. The use of puberty blockers is part of the clinical guidelines for options for treating gender dysphoria in Australia (Telfer et al 2020), other countries (Rafferty, American Academy of Pediatrics, 2018), and internationally (Hembree et al 2017; Coleman et al 2022, chapter 6).
- Puberty blockers can be used when a transgender adolescent reaches Tanner Stage 2 to 3 of puberty (early puberty) to avoid unwanted effects of puberty that can cause distress. This includes developing breasts, body hair, voice changes, and facial and larynx appearance changes which may otherwise require invasive surgery to change in the future. A young person may stay on puberty blockers for a few years (Hembree et al., 2017).
- If young people stop taking puberty blockers, puberty recommences (Hembree et al., 2017).
- From an ethical perspective, the young person's role in decision making about gender-affirming treatment is central, and responsible adults assist the young person in making the best-informed decisions possible (Ashley, 2023).
- Puberty blockers allow young people the time to mature emotionally and to make
 decisions about the right, if any, future gender affirming medical care for them. Later,
 older adolescents and young adults, supported by their families, can decide whether
 they want to start oestrogen or testosterone hormone treatment, to help them go
 through the puberty that aligns better with their sense of self.

What are the effects of puberty blockers?

- Puberty blockers are considered a safe and largely reversible treatment (Panagiotakopoulos et al 2020, Hembree et al 2017).
- Access to puberty blockers prevents permanent harm from unwanted puberty changes. They are associated with either stable mental health or improved mental health, and the absence of deterioration in mental health, with reduced self-harm observed in some studies. This has been well documented (De Vries et al 2011, Khatchadourian et al 2014, Costa et al 2015, Turban et al 2020, Van der Miesen et al 2020, Achille et al 2020, Kuper et al 2020, Carmichael et al 2020, Becker-Hebly et al 2021, Chen et al 2023).
- Not providing, or delaying, wished-for and medically indicated treatment for transgender young people is emotionally distressing and is associated with poorer outcomes (Coleman et al 2022, Turban et al 2020).
- Puberty blockers are generally well tolerated with few adverse effects. As with many medical treatments, there are risks of side effects. Most commonly reported are reduced bone density, mild fatigue, weight gain, and hot flushes (Hembree et al 2017, Coleman et al 2022).



- While there are indications that taking puberty blockers has links to decreased bone density, there is no evidence that there is a long-term harm from this effect. Taking vitamin D and calcium, as well as weight bearing exercise, is recommended to mitigate this risk (Navabi et al 2021, Stoffers et al 2019).
- A recent 15-year follow up of 75 trans adults who had received puberty suppression in adolescence reported reassuring bone density findings (van der Loos et al 2023).
- It has been questioned whether puberty blockers affect cognitive (brain) maturation. A real-life observational study of the educational achievement of 72 transgender young people who had puberty blockers in the Netherlands was reassuring over a 7 to 8 year follow up – the young people were doing educationally as well as expected for their pre-treatment IQ score, and better on average than the general Dutch population (Arnoldussen et al., 2022).
- Some people who take puberty blockers decide to stop medical affirmation treatments, and some go on to take other hormones for gender affirmation. There is no evidence that taking puberty blockers influences the choice to later take hormones or not (Nos et al 2022). Most young people who decide to take puberty blockers already feel clear that they are transgender and, at the time of starting puberty blockers, express that they already feel that they want to take hormone treatment in the future.

What does the evidence say on puberty blockers?

- There is substantial observational evidence reporting on the wellbeing of transgender young people on puberty blockers.
- The key studies of outcomes of puberty blocker treatment to date are listed in the table below. None found worsening of mental health or psychosocial function in young people on puberty blockers. Many found improvement in wellbeing over time, or apparent benefit related to a non-treated group. The studies found that most young people who start blockers continue gender-affirming medical treatment, and a few decide to stop.
- In qualitative studies young people on blockers have reported that "accessing blockers was described as providing a sense of relief and greater optimism, positively impacting the mental health of participants" (Pullen Sansfacon et al 2019).
- The World Professional Association for Transgender Health summarises the evidence regarding gender-affirming medical treatment of young people as: "...although the existing samples reported on relatively small groups of youth (e.g., n = 22-101 per study) and the time to follow-up varied across studies (6 months–7 years), this emerging evidence base indicates a general improvement in the lives of transgender adolescents who, following careful assessment, receive medically necessary gender-affirming medical treatment. Further, rates of reported regret during the study monitoring periods are low. Taken as a whole, the data show early medical intervention— as part of broader combined assessment and treatment approaches focused on gender dysphoria and general wellbeing can be effective and helpful for many transgender adolescents seeking these treatments." (Coleman et al., 2022, page S47).



- Many of the relevant scientific studies have been excluded from the reviews that the NHS England has relied upon. This is due to the strict exclusion criteria applied by these reviews; however, they are studies which provide important information (NICE, 2020).
- There are no randomised controlled trials (RCTs) of puberty suppression in transgender youth. It would be unethical to withhold treatment (i.e., access to puberty blockers) for the purposes of research. To do so would risk serious harm (Ashley, Tordoff et al 2023).
- It is also unethical to make it compulsory for patients to participate in research trials for established treatments such as puberty suppression; research participation must always be voluntary (NHMRC 2018; Bull and Lindegger 2011)
- The lack of randomised controlled trials in this area of healthcare categorises the data as "low quality evidence" according to the GRADE system. This is the case for many areas of medicine where RCTs would not be appropriate or ethical. For example, many other paediatric treatments and the vast majority of medicines used during pregnancy are based on "low quality" or "low certainty" evidence. Often, cohort and observational studies are the highest level of evidence which can be safely and appropriately conducted.
- Clinical guidelines across the world have found that the evidence supports clinicians being able to confidently prescribe puberty blockers where appropriate (Ashley, Tordoff et al 2023), always with individual weighing-up of the young person's needs and wishes, and the benefits, risks, and unknowns of the treatment in their personal situation (Coleman et al, 2022).
- It is very common for clinical guidelines in other areas of medicine (outside of transgender health) to base strong recommendations on evidence described as "low quality" according to the GRADE scale. Chong et al. (2023) found that, of the Irish National Clinical Guidelines, 63% were based on "low or very low certainty evidence". Venus and Jamrozik (2019) examined 10 Australian clinical guidelines containing 748 recommendations: they found that only 18% of recommendations were based on "high quality" evidence. Research on the systematic reviews on the Cochrane Database, looking at all 154 reviews that had been updated since 2013-2014, found that only 15 of the 154 (9.9%) found "high-quality evidence" (Howick et al 2020 and Howick et al 2022).
- A very large part of normal health care for adults and children is not guided by "high quality" or "high certainty" evidence. Every day, in all areas of health care, for people of all ages and with all kinds of medical conditions, doctors and other health professionals are providing care which has to be informed by basic science, expert opinion, and patient-centred practice, because there are many important clinical questions which are not informed by the "high quality" evidence provided by a randomised controlled trial or meta-analysis of randomised controlled trials.
- Thus, guideline recommendations about puberty blockers for transgender young people are not at all unusual in being based largely on observational evidence, expert consensus, and patient and family values and preferences.



How are puberty blockers used in Australia?

- The Australian clinical guidelines, The Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents, were developed by a consensus working group of 44 clinicians around Australia, peer reviewed and published in the Medical Journal of Australia. The Guidelines are endorsed by AusPATH. They emphasise a model of individualised care, the use of affirming approaches, and avoiding harm (Telfer et al 2018, 2020).
- The Australian Standards of Care and Treatment Guidelines list four criteria for the prescription of puberty blockers for adolescents who request them:
 - A diagnosis of gender dysphoria in adolescence made by a qualified mental health professional.
 - Medical assessment including fertility preservation counselling.
 - Tanner stage 2 of puberty is reached.
 - The treating team should agree that puberty blockers are in the best interest of the adolescent. Informed consent from them and their legal guardian is obtained.
- A co-ordinated, multidisciplinary assessment and treatment model is recommended by the Guidelines.
- Puberty blockers are usually provided as part of specialist hospital-based multidisciplinary team care.
- Fertility, and possible future wishes to be a parent, are discussed in great detail with young people and their families when they are deciding whether to go on puberty blockers. Puberty blockers temporarily reduce fertility. If a young person decides to stop puberty blockers, fertility returns as puberty development re-starts and progresses. Possible future gender-affirming treatments such as hormones and surgeries are separate decisions at a later time; these can have more effect on fertility. When a more mature person is considering treatment options that affect fertility, it is discussed again, and the person weighs up the pros and cons, risks and benefits of each treatment option, including any effect on fertility, according to their own personal values and preferences, and with the support of their family and treating professionals.
- Australian case law requires each parent (or person with parental responsibility) to consent to the administration of puberty blockers for a child for gender dysphoria, even where the child is *Gillick* competent. Otherwise, court authorisation is required: *Re: Imogen (No. 6)* [2020] FamCA 761.

Why has NHS England made access to puberty blockers harder in England?

- The NHS England has ceased the routine commissioning of puberty blockers. This
 decision comes prior to the release of the final report of the Cass Review (Horton,
 2024; Pang et al 2022), which is due in the coming weeks.
- The Cass Review was commissioned in September 2020 and examined NHS gender identity services for children and young people in England. These services were being provided by a single specialist clinic known as the Gender Identity Development Service via a model of care that differs significantly from the integrated, collaborative multidisciplinary model used in Australia (Pang et al 2022). It has been



reported that puberty blockers will only be available in the context of a formal research study protocol, with unclear eligibility criteria; this study has not started yet and there is no clear start date. There is no "ban" on puberty suppression, and those currently on puberty suppression have been reassured that their treatment will be continued. Some young people in England continue to access puberty blockers from private health care providers, However, the NHS decision creates a situation of health inequity, where financially disadvantaged families cannot access needed and indicated health care through the NHS.

- Many international guidelines and statements from health professional organisations support the use of puberty blockers where needed and appropriate. A 2022 statement from WPATH and other international bodies states: "We are deeply concerned that the NHS is taking inappropriate approaches to evaluating the established body of evidence and is therefore drawing erroneous conclusions underestimating the effectiveness of puberty suppression."
- It appears that NHS England has not drawn upon the existing international consensus regarding care of transgender young people (Pang et al 2022).
- It appears that NHS England has not placed value upon the expressed wishes, values and preferences of transgender young people and their families (Horton, 2021; Horton, 2024), and that NHS England has underestimated the benefits of puberty suppression and overestimated the potential risks.
- No recent NHS England statement has been issued about commissioning of puberty suppression for young people who are not transgender but have precocious puberty. NHS England has not offered an explanation of why puberty suppression appears to be considered safe enough for very young children who have precocious puberty, (who are presumably more vulnerable to adverse effects because of their young age) but are not considered safe enough for transgender adolescents who are older, physically more developed, and have more capacity to actively participate in decision-making and informed consent.

The following table lists studies, all but one of which were conducted in specialist paediatric gender clinics, that report on psychosocial outcomes and/or stability of gender identity of transgender young people treated with puberty blockers. There are many more which report on medical safety.

Cohen-Kettenis et al.	1998	Eur Child Adol Psych	n=1
De Vries et al.	2011	Sex Med	n=70
De Vries et al.	2014	Pediatrics	n=55 of the 70
Khatchadourian et al.	2014	J Pediatrics	n=27 (subgroup)
Costa et al.	2015	J Sex Med	n=121
Turban et al.	2020	Pediatrics	n=89 (on ne survey)
Van der Miesen et al.	2020	J Adol Health	n=178
Achille et al.	2020	Int J Ped Endo	n=34 (subgroup)
Cantu et al.	2020	Transgender Health	n=17 (subgroup)
Kuper et al.	2020	Pediatrics	n=25 (subgroup)
Brik et al.	2020	Arch Sex Beh	n=143
Becker-Hebly et al.	2021	Eur J Child Adol Psychi	n=11 (subgroup)
Carmichael et al.	2020	PLoS One	n=44
Chen et al.	2023	NEJM	n=25 (subgroup)



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