13 December 2024

Dr Diana Sarfati
Director-General of Health and Chief Executive
Ministry of Health
Via email diana.sarfati@health.govt.nz (copied to info@health.govt.nz)

Dear Dr Sarfati

1 Family First writes to require the Ministry of Health to remove the reference to the PATHA Guidelines in the Position Statement on the Use of Puberty Blockers (**PB**) in Gender-Affirming Care (**PS**) issued by the Ministry on 21 November 2024. We have been legally advised that such a reference may be illegal.

2 The PS states:[1]

> Overall, the evidence brief found significant limitations in the quality of evidence for either the benefits or risks (or lack thereof) of the use of puberty blockers. This means there is insufficient basis to say that puberty blockers are safe or reversible (or not) for use as an intervention for gender dysphoria in adolescents.

3 Despite these findings, the PS also states (emphasis added):[2]

> **Guidelines for gender-affirming care have been independently published in New Zealand. These guidelines set out the key considerations for health teams, including the prescribing of puberty blockers.** There are also local clinical pathways within primary care and specialist services across New Zealand, but there is not currently a nationally consistent approach.

4 Yet the *Guidelines for Gender Affirming Health care for Gender Diverse and Transgender Adults in Aotearoa New Zealand* by Oliphant J, Veale J, Macdonald J et al (Transgender research lab: University of Waikato)[3] are dated 2018 (**PATHA Guidelines**) and make statements on PBs which are not supported by the findings from the evidence brief, as summarised in the PS, nor by other probative evidence:[4]

> **Puberty suppression using GnRH agonists**
> **Health teams need to be aware of the positive impact of puberty blockers (GnRH agonists) on future well-being.** Be mindful of the need to refer promptly and be aware of referral pathways. Puberty blockers can be prescribed from Tanner stage 2 to suppress the development of secondary sex characteristics, although are still beneficial when prescribed later in puberty to prevent ongoing masculinisation / feminisation.

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[1] On page 4.

[2] On page 4 (emphasis added and footnotes omitted).

[3] https://patha.nz/Guidelines

[4] PATHA Guidelines, on pages 29 – 30 (emphasis added and footnotes omitted).

> **Puberty blockers are considered to be fully reversible and allow the adolescent time prior to making a decision on starting hormone therapy. They do not stop growth or weight gain,** and monitoring of height is recommended as adult height may potentially be increased if prolonged puberty suppression delays epiphyseal fusing. A bone age may be helpful to assess whether epiphyseal closure has occurred when considering what rate of hormonal induction to use as this may potentially impact on final height.
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> Puberty blockers halt the continuing development of secondary sexual characteristics, such as breast growth or voice deepening, and relieve distress associated with these bodily changes for trans young people. For trans women and transfeminine people, they will prevent further masculinisation of the face and body that typically occurs into early adulthood. For trans men and transmasculine people, the puberty blockers will induce amenorrhoea, reducing distress associated with menstruation, although other options for this are also available. If required the addition of non-hormonal contraception should be discussed.
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> Currently in New Zealand, goserelin (Zoladex®) SC implants have sole subsidy status, although leuprorelin (Lucrin®) IM injections continue to be fully funded for children and adolescents, who are unable to tolerate administration of goserelin, where the prescription is endorsed accordingly.
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> Consideration should also be given to those in early adolescence who may desire genital gender affirming surgery in adulthood. For trans women and transfeminine people, puberty suppression at Tanner stage 2-3 may limit the availability of penile and scrotal skin used to create a neovagina and labia. This needs to be balanced with the desire to avoid voice deepening and other secondary sexual characteristics which will progress if continuing past Tanner stage 2-3.
>
> There is some concern regarding the long term impact of puberty suppression on bone mineral density. It is advisable to encourage young people on puberty blockers to have an adequate calcium intake, provide vitamin D supplementation where needed and encourage weight bearing exercise. For those requiring a prolonged period on puberty blockers or who have other significant additional factors for reduced bone density, a Dexa scan to monitor bone densitometry should be considered.
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> **Puberty blockers should be continued until a decision is made regarding further treatment options** including: starting other anti-androgen agents or accessing orchiectomy or other surgical options for trans women and transfeminine people; starting testosterone for trans men and transmasculine people.

5 The consent forms in the appendices to the PATHA guidelines also state: *"Blockers are a reversible medication used to stop the physical changes of puberty. It can be started in early puberty (Tanner stage 2–3)."*[5]

6 The PS says that Health New Zealand is currently developing an updated set of guidance, and the Ministry of Health will work closely with HNZ.[6] But no timeframes have been given.

7 This position is reinforced by the reference in the Health NZ website to PATHA under "Resources for transgender New Zealanders and their whanau".[7] Clicking onto the PATHA link leads you straight to the PATHA Guidelines. This reference should also be removed.

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[5] See Appendices C and D on pages 46 – 49 – the Consent form for blocking male hormones and the Consent form for blocking female hormones, respectively. The consent forms make various other statements about the impacts of PBs that do not appear to be supported by the evidence to date such as their effectiveness at preventing puberty related changes and their side effects.

[6] On page 6.

[7] https://info.health.nz/keeping-healthy/transgender-gender-diversity/transgender-mental-health

8 Not removing the reference to the independent PATHA Guidelines is also inconsistent with the PS stating that *"Clinicians will continue to provide **careful guidance** to and follow up for people and families considering gender-affirming care."*[8]

9 There are four reasons why failure to remove reference to the PATHA Guidelines may be illegal.

10 **First**, **a lack of informed consent**. The findings of the Evidence Brief summarised in the PS mean that the PATHA Guidelines include fundamental mistakes of fact. Those Guidelines confidently state that PBs are safe and reversible (and effective). Yet the PS found that there is no quality evidence to support any of these findings. The substance and tone of the PATHA Guidelines and the information provided in the consent forms means those using these Guidelines and forms are not giving properly informed consent

11 **Second**, the Ministry of Health is effectively advising Doctors, parents, and young people over 16 that the PATHA Guidelines are safe and factually accurate guidelines to use in the interim while the Ministry works with Health NZ to devise clinical guidelines. **This advice is wrong given the PATHA Guidelines are inconsistent with the findings in the Ministry's PS and are factually incorrect**.

12 The **third** reason to remove reference to the PATHA Guidelines are **multiple breaches of the New Zealand Bill of Rights Act 1990** (**BORA**). In *R v Tavistock* in the United Kingdom, the Court of Appeal, referring to PB treatment, stated *"at present, it is right to call the treatment experimental or innovative in the sense that there are currently limited studies/evidence of the efficacy or long-term effects of the treatment."*[9] Section 10 of BORA provides that *"Every person has the right not to be subjected to medical or scientific experimentation without that person's consent."* But, if you read the PATHA Guidelines, you would not know you were "consenting" to being medically experimented on. The consent form is not for a medical trial or experiment. It does not set out the risks of harm due to the lack of quality research about lack of harm and reversibility. The PATHA Guidelines say PBs are safe and reversible as does the consent form you sign to start "treatment."

13 The PATHA Guidelines also potentially breach section 11 of BORA which provides that "Everyone has the right to refuse to undergo any medical treatment." Hard for any young person or their parents to exercise that right if they are misinformed that PBs to treat GD is safe and reversible. If they were given the factually correct information that there is no quality evidence that PBs are safe and reversible, they may want to exercise that right.

14 In *Four Aviation Security Service Employees* v *Minister of COVID-19 Response*, s 10 of BORA was argued alongside the s 11 right to decline medical treatment. The applicant argued that because the Pfizer vaccine had only provisional consent in NZ and was subject to conditions, it was therefore experimental, and people had the right to refuse medical treatment. Although this was rejected, the High Court said:[10]

> *"…the concept of experimentation in s 10 requires an intervention which aims to lead to a new standard of treatment or to advance knowledge. By contrast, medical treatment is characterised by its therapeutic aim, and connotes an existing measure used by healthcare professionals in treating or preventing illness.**26** The vaccine is a new treatment for a new virus. But it is plain that the vaccine has been approved and used here for therapeutic, not experimental, purposes."*

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[8] On page 5 (emphasis added).

[9] *R v Tavistock* [2021] EWCA Civ 1363 at [148].

[10] [2021] NZHC 3012; [2022] 2 NZLR 26. at [34].

15 Puberty Blockers are distinguishable as they not approved for GD. And the Evidence Brief and PS has now found there is no probative evidence that they are safe, reversible or efficacious to treat GD.

16 The PATHA Guidelines also potentially breach section 9 of BORA (emphasis added): *"Everyone has the right not to be subjected to torture or to cruel, degrading, or disproportionately severe treatment or punishment." Fitzgerald v R* is the key Supreme Court case here although it concerned punishment but Winkelmann CJ does discuss the s 9 threshold as torture or inhumane treatment.[11] The breach arises because any consent is given on the basis of the PATHA Guidelines – that PBs are safe and reversible for the treatment of Gender Dysphoria. The Evidence Brief summerised in the PS says that "there is insufficient basis to say that puberty blockers are safe or reversible (or not) for use as an intervention for gender dysphoria in adolescents." Being prescribed PBs and then finding out that PBs may harm you or be reversible may amount to torture physical side effects/mental and/or be disproportionately severed treatment.

17 For example, Dr Whitehall states that:[12]

> Proponents of the pathway declare the blocking of puberty to be 'safe and entirely reversible', but review of adults administered 'blockers' to reduce the production of sex hormones considered to be stimulating abnormal cell growth (as in prostate cancer in men and endometriosis in women), has suggested interference with brain function, which has been confirmed in veterinary studies. The limbic systems of 'blocked' sheep reveal sustained structural and functional damage: the activity of hundreds of genes has been found to be altered, leading to sustained interference in memory and emotions.
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> …
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> Proponents acknowledge many metabolic side effects of cross-sex hormone therapy, thus confirming the need for sustained medical supervision but do not mention effects on the brain. For example, MRI studies have found that the adult male brain exposed to oestrogen shrinks at a rate ten times faster than ageing, after only four months of exposure. What will happen to the growing brain exposed to cross sex hormones for life?

18 There is also the potential to breach section 8 of BORA which provides: *"No one shall be deprived of life except on such grounds as are established by law and are consistent with the principles of fundamental justice."* Applying the Court of Appeal in Wallace v Attorney-General, section 8 contains an implied right that a government department like then Ministry of Health would not issue a PS which could deprive a person of life – given no quality research about whether PBs are harmful or not.

19 Dr Whitehall found that suicide rates in transgendering adults are reported to be at least 20 times that of the general population.[13] Dr Whitehall also found that mental illness is strikingly associated with gender dysphoria.[14] Thus, it is even more critical when dealing with highly vulnerable young people that they are not treated with PBs whose effects, including on emotions and memory) have not been confirmed by any quality research. And when those effects could include impacts on emotions and memory.

20 The potential breaches of sections 8-10 of BORA must be viewed in the factual context that the Court of Appeal in the UK has found regarding PBs: *"the clinical interventions involve significant, long-term and, in part, potentially irreversible long-term physical, and psychological consequences for young persons*.

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[11] [2021] NZSC 131.

[12] *Children transitioning: Childhood Gender Dysphoria – A Paediatrician's Warning to New Zealand* by Dr John Whitehall October 2018 on page 4.

[13] On pages 3 – 4.

[14] On page 8.

The treatment involved is truly life changing, going as it does to the very heart of an individual's identity."[15] As Dr Whitehall says, it is a *"massive intervention into the minds and bodies of children."*[16]

21 **Fourth**, the reference to the PATHA Guidelines in your PS breaches the United Nations Convention on the Rights of the Child (**UNCROC**) which NZ has ratified and implemented into domestic law. Domestic law should be interpreted consistent with UNCROC. That includes BORA. **The misinformation in the PATHA Guidelines and included consent forms are not in the best interests of children under UNCROC**.

22 The status of international law in New Zealand is settled, in *Trans-Tasman Resources Ltd v Taranaki-Whanganui Conservation Board*[17] citing *Helu v Immigration and Protection Tribunal*.[18] The Supreme Court said:

> **[99]** We agree with the Court of Appeal that these instruments all inform the interpretation of the EEZ Act. The effect of such instruments on interpretation is set out in this way by McGrath J in *Helu v Immigration and Protection Tribunal* :
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> > **[143] Parliament takes differing approaches to the implementation of international obligations. It sometimes gives them effect by incorporating their exact terms into New Zealand law. At other times, it enacts legislation, with the purpose of giving effect to such obligations, using language which differs from the terms or substance of the international text. In such cases, the legislative purpose is that decision-makers will apply the New Zealand statute rather than the international text. Resort may still be had to the international instrument to clarify the meaning of the statute under the long-established presumption of statutory interpretation that so far as its wording permits, legislation should be read in a manner consistent with New Zealand's international obligations. But the international text may not be used to contradict or avoid applying the terms of the domestic legislation.**
> >
> > [144] Accordingly, **if the legislation confers a discretion in general terms, without overt links to pertinent international obligations, the application of this principle of consistency may, depending on the statute and, in some instances, the nature of international obligation, require that the power is exercised in a manner consistent with international law.** Or it may require that a decision maker take into account particular considerations arising from international instruments to which New Zealand is a party. If, however, Parliament has provided that a decision-maker is to have regard to specific considerations drawn from international obligations, the legislation must be applied in its terms, although they may be clarified by reference to the international instrument.
>
> **[100]** The EEZ Act has been enacted with the purpose of giving effect to New Zealand's international obligations, but has used language which differs from the international texts. In such cases, as McGrath J says, the legislative purpose was that decision-makers would apply the EEZ Act rather than the international text, but resort can be had to the relevant international instruments to clarify the meaning of the Act.

23 In the recently released case of *M v R* and *LF v R*, the Supreme Court discussed UNCROC in the context of youth justice and name suppression, as follows (emphasis added):[19]

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[15] *R v Tavistock*, above n 9 at [148].

[16] *Children transitioning*, above n 10, on page 3.

[17] [2021] 1 NZLR 801|[2021] NZSC 127

[18] [2015] NZSC 28

[19] [2024] NZSC 29.

> [54] **It is settled law that legislation should be interpreted in a manner consistent with New Zealand's obligations under applicable international instruments like the United Nations Convention on the Rights of the Child**.62 The starting point in terms of the relevant provisions in that Convention is art 3. Under art 3(1), in actions undertaken by the courts and other institutions concerning children, "the best interests of the child shall be a primary consideration". For these purposes, "child" is defined in art 1 as those below the age of 18.

24 The Supreme Court cited *Ye v Minister of Immigration,* the 2009 Supreme Court case that established this approach and talks about interests of a child as **a** primary consideration in interpreting the relevant statute in this case.

25 The real issue is whether the government is acting in the best interest of the child under UNCROC, which it has ratified, given the "paucity of high-quality research evidence about the benefits and risks of using" puberty blockers, when it has put out a PS with the PATHA Guidelines in it.

26 The Ministry is sending health professionals who are prescribing PBs to young children and adults under s 25 of the Medicines Act 1981 to the PATHA Guidelines by telling them in your PS that ***"These guidelines set out the key considerations for health teams, including the prescribing of puberty blockers"***[20]

Avoiding harm is a fundamental ethical consideration for health professionals and your own findings in the PS are that *"there is insufficient basis to say that puberty blockers are safe or reversible (or not) for use as an intervention for gender dysphoria in adolescents."*[21]

27 Finally, the Position Statement for Progesterone says:

> *"The Ministry of Health does not support or recognise the practice of 'abortion reversal' and is concerned about reports that this may be offered in New Zealand.*
>
> *'Abortion reversal' is not established by clinical research trials and could lead to severe side effects and adverse outcomes.*
>
> *Heath professionals should not be providing or offering 'abortion reversal. Those who promote the use of medicines for this purpose are breaching section 20 (2) of the Medicines Act 1981.*

28 We need to understand why there is not a similar PS in substance and tone for PBs given that the Evidence Brief evidences that it is "*not established by clinical research trials and could lead to severe side effects and adverse outcomes"* for the treatment of Gender Dysphoria. This is important given that PBs can continue to be prescribed by clinicians off label under s 25 of the Medicines Act.

29 Family First believes for these legal reasons alone, it is critical that the Ministry act immediately and makes regulations under the Medicines Act to stop the prescribing of PBs for delaying puberty in gender incongruent or gender dysphoric young people until there is sufficient quality evidence that PBs are both safe and reversible and efficacious in the treatment of gender dysphoria.

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[20] On page 2.
[21] On page 4.

30 We look forward to a timely and comprehensive reply before considering legal action based on the legal advice we have received.

Yours sincerely

Bob McCoskrie
Chief Executive
Family First New Zealand

Simon O'Connor
Director of External and Strategic Partnerships
Family First New Zealand

CC:
Dr Shane Reti, Minister of Health
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