EDITORIAL NOTE: CHANGES MADE TO THIS JUDGMENT APPEAR IN [SQUARE BRACKETS]

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IN THE FAMILY COURT
AT PUKEKOHE

I TE KŌTI WHĀNAU
KI PUKEKOHE

FAM-2017-057-000138
[2022] NZFC 1708

IN THE MATTER OF	THE CARE OF CHILDREN ACT 2004
BETWEEN	[EVA HARTLEY] Applicant
AND	[ADAM WOOD] Respondent

Hearing:	18 February 2022
Appearances:	P Chan for the Applicant J Attfield for the Respondent J Harland as Lawyer for Child
Judgment:	9 March 2022

RESERVED DECISION OF JUDGE P S GINNEN

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[1] On 17 January 2022 the Pfizer paediatric vaccine[1] was made available for use on children aged between 5 and 11 years old. [Kyle Wood] turned five years old on [date deleted] 2021. His mother, [Eva Hartley] wants him to be vaccinated against Covid-19. His father, [Adam Wood], does not consent to him being vaccinated.

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1 A Covid-19 vaccine (Comtrary) for use on children aged between 5 and 11.

Ms [Hartley] has applied for an order resolving a dispute between guardians, which is defended by Mr [Wood]. I need to decide whether [Kyle] will be vaccinated against Covid-19 or not.

[2] Mr [Wood] filed voluminous affidavit evidence in support of his opposition, which I do not intend to summarise here. Later I will address each of his grounds as set out in his lawyer's submissions. Essentially, his position is that having balanced the benefits and risks for [Kyle], the risks outweigh the benefits, so he should not be vaccinated with the Pfizer vaccine at this time.[2]

[3] Ms [Hartley] produced a medical certificate dated 8 February 2022 from Dr [name deleted], who is [Kyle]'s usual general practitioner. The medical certificate says:

> "This is to confirm that [Kyle Wood] is my patient. He is a fit and healthy 5 year old boy. He does not have any medical problems and should have the Covid-19 vaccination as per Ministry of Health advice."

[4] Ms [Hartley] also provided a copy of [Kyle]'s immunisation record. He has received all immunisations appropriate for his age in the New Zealand Immunisation Schedule. There is no evidence that [Kyle] has ever displayed any adverse reaction to vaccinations in the past.

[5] Ms [Hartley] is concerned about the surging numbers of Covid-19 infections. Now that [Kyle] is attending school, he has a greater exposure to Covid-19 and the risk of him catching it is increased. She trusts the Ministry of Health advice that the Pfizer paediatric vaccine is safe and accepts the Ministry of Health's recommendation that children and aged between 5 and 11 receive the vaccine.

[6] Ms Harland who is lawyer for child supports an order being made that [Kyle] be vaccinated. She points out the risk of [Kyle] catching Covid has greatly increased since a decision was made on 14 January 2022 that he should attend school. She noted he is at greater risk not just at school, but in any activity that he may undertake in the

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[2] Interesting, Mr [Wood] is vaccinated against Covid-19. His lawyer Ms Attfield reported that if he had been able to retain his job without being vaccinated, he would not have been vaccinated. His concern is motivated by the risks of the vaccine to [Kyle], who is only 5 years old.

community, which is reflected by the growing number of children who have been vaccinated. She referred to a New Zealand Herald article of 17 February 2022 which stated that 46% of eligible 5 to 11-year-olds have had the first dose of the Covid-19 vaccine.[3]

[Kyle]'s views

[7] Ms Harland noted that section 6 of the Care of Children Act 2004 preserves [Kyle]'s right to express a view. However, given his age and the issue at hand regarding vaccination, she submitted [Kyle] is too young to understand and express a view on vaccination.

[8] [Kyle] has only recently turned five years old. I agree that he is not of an age or maturity to fully understand the issue or formulate a competent view. I have considered what is known as the *Gillick* principle[4] that children with sufficient maturity and understanding may be capable of providing consent without requiring their parent's consent. This is because those children are deemed responsible enough to make authoritative decisions about their own body and health. The younger the child, the more likely it is that decisions about important matters will need to be made by his or her guardian. As the child gets older and becomes more mature, the guardianship role changes to that of an adviser or a counsellor, endeavouring to assist the child to make good decisions.[5]

[9] At just five years old, [Kyle] is clearly too young to understand or decide about being vaccinated against Covid-19. The decision needs to be made on his behalf by either his parents and guardians, or in the absence of agreement, by the court.

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3 *Covid 19 Omicron outbreak: Record 1573 new cases; Jacinda Adern says infections her concern, not "illegal" protest,* New Zealand Herald, 17 February 2022, https://www.nzherald.co.nz/nz/covid-19-omicron-outbreak-record-1573-new-cases-jacinda-ardern-says-infections-her-concern-not-illegal-protest/T5CEVXKLRSD5HKPRQW3OFMR32M/

4 Taken from the case *Gillick v West Norfolk v Wisbech Health Authority* [1986] AC 112, sometimes described as *Gillick* competency.

5 *Hawthorne v Cox* [2008] 1 NZLR 409 per Justice Heath.

Case law regarding Covid-19 vaccinations for children

[10] There are relatively few decisions considering whether children should be vaccinated against Covid-19, and most relate to children aged between 12 to 17 years old. I have considered the following Family Court decisions:

(a) *Chief Executive Oranga Tamariki Ministry for Children v JA and DC*[6] where the Chief Executive sought a guardianship direction that children aged 6, 10 and 13 be vaccinated against measles and Covid-19. Judge Rogers acknowledged the absolute sincerity of their father's concerns:

> "But the Court's position is that in determining health matters, we must be guided by the advice of experts. The expert position as reflected in the national immunisation schedule is that the risks of immunisation are outweighed by the much greater risks of not being protected against diseases such as measles."

Later she said:

> "I do not purport to have any expertise in medical matters. But as I have already observed, in the absence of evidence to the contrary, the Court must be guided by mainstream medicine and its practitioners. Provided they assess immunisation as being necessary for the children, then the children should be vaccinated."

She ordered that each of the children was to receive all the immunisations recommended by any medical practitioner responsible for their care. Unless there was any contraindication, she anticipated the children would all in due course be vaccinated against Covid-19. She directed that prior to recommending immunisation for any of the children, the medical practitioner concerned is to undertake a child specific assessment as to whether there is any elevated risk or side effects for that child.

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6 *Oranga Tamariki Ministry for Children v JA and DC* [2021] NZFC 3068, 7 April 2021, Judge Rogers.

(b) In *[W] v [W]*[7] the father was not opposed to his 12-year-old daughter being vaccinated, if she wished to be. She did want to be vaccinated, but her mother did not consent. Judge Munro supported the child's wishes and ordered that she be vaccinated. Judge Munro held:

> It is quite clear that there is not yet research into long-term effects of vaccination on children of this age group because they have only recently started receiving vaccinations and I accept Ms [W]'s concern that the longer-term effects are still unknown.
>
> The short-term effects according to information that has helpfully been provided to us today by [witness name deleted] from Starship Hospital in Auckland is that the effects on children of that age are not much different from the effect on adults. The side-effects are generally minor and serious side-effects are very rare.
>
> I am not going to quote further aspects from the reports that have been filed but the general consensus is that the serious risks of vaccination of children of this age are rare. The general consensus appears to be that the benefit outweighs the risk. It is a decision that probably does not have a strong argument one way or the other.

(c) In *[Gour] v [Moss]*[8] the child was nearly 14 years old and there was medical evidence of him having specific breathing issues and a high risk of his lungs being impacted by contracting Covid-19. He expressed a clear wish to be vaccinated but his mother did not consent. Judge Parsons held that his views must be paid regard to given his age and taking into account the *Gillick* principle. She also took judicial notice of the fact that the Ministry of Health has taken the position that supports the vaccine being available to those aged between 12 and 15, a position that was taken from August 2021.

She noted the decision of *Stone v Reader* where Judge Otene held that it is appropriate to take judicial notice of government health advice in the absence of medical or other expert evidence. The government agency responsible for the management and development of the New Zealand health system recommends a schedule of vaccination for all New Zealanders based upon a body of medical evidence. On this basis,

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7 *[W] v [W]* [2021] NZFC 9602, 23 September 2021, Judge Munro.
8 *[Gour] v [Moss]* [2021] NZFC 12883, 20 December 2021, Judge Parsons.

the best evidence before the Court of protection of the children from disease is by way of the Ministry of Health recommended immunisation schedule.[9]

(d) In *[Pearce] v [Bird]*[10] an order was made that the children aged 8, 11 and 12 years old were to be vaccinated and their father's contact was suspended until they were. The 11-year-old was particularly vulnerable if they contracted Covid-19 due to underlying conditions. The specialist and general practitioner highly recommended vaccination, as did the 8-year old's general practitioner. The Judge said he took

> "…judicial notice of the research adopted by the New Zealand Governments, and Governments around the world, that the Pfizer vaccine is safe to be administered to children. It is safe."[11]

(e) In *[Long] v [Steine]*[12] a 12-year-old child expressed clear views that he did not want to be vaccinated. His belief was guided by his father, who together with his stepmother had provided him with misinformation about the vaccine. Applying the *Gillick* principal, Judge Coyle held that the child's views carried significant weight. The child had told him that if he ordered him to be vaccinated, he would refuse it when he attended the vaccination clinic. Judge Coyle went on to consider the child's best interests and welfare, as even when children's views are given significant weight, that is not determinative, and a welfare and best interest assessment is required. He noted that the risks of Covid-19 being life-threatening for the child were low. He held:

> I am not satisfied that it is in [the child]'s best interests and welfare to require him to have the vaccination. A number of cases have made it clear that in relation to younger children, where vaccination is recommended by the Ministry of Health guidelines (such as for polio, rubella and measles) that the Courts will require young children to be vaccinated,[13] but [the child] is of an age where his views need to be given weight, and this case can therefore be distinguished from those

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9 *Stone v Reader* [2016] NZFC 6130 at paragraph [21] per Judge Otene.
10 *[Pearce] v [Bird]* [2022] NZFC 1042, 10 February 2022, Judge Greig.
11 At paragraph [16].
12 *[Long] v [Steine]* [2022] NZFC 251, 14 January 2022, Judge Coyle.
13 See for example *Stone v Reader* [2016] NZFC 6130; *Sudworth v Lovell* [2019] NZFC 2584; *Bullock v Elliston* [2019] NZFC 10254.

cases which consider a dispute between guardians in relation to the vaccination of much younger children.

(f) In *[Lovell] v [Metcalf]*[14] the child (aged between 12 and 15) wanted to be vaccinated against Covid-19. His primary concern was being excluded by being unvaccinated; he wanted to go to restaurants with family and friends, go swimming at the pools and not have to wear a mask at school. He had no underlying conditions and his general practitioner supported him being vaccinated. His father did not consent. The Judge had regard to the Ministry of Health recommendations that children between the ages of 12 for 15 ought to be vaccinated against Covid-19, a position supported by the World Health Organisation. She gave some weight to the child's views and ordered that he be vaccinated for all Covid-19 vaccinations as soon as possible and then receive any booster vaccinations that are required to be administered.

[11] The general theme of the above cases is the court's preparedness to be guided by government health advice. In the one case where the Covid-19 vaccination was not ordered the 12-year-old child was assessed as competent to make a decision about his own health and his views were accorded significant weight. Only two of the cases concern children aged under 12 years old, and none for a child as young as [Kyle]. However, the principle remains the same, that I am entitled to take judicial notice of government health advice in the absence of medical or other expert evidence; and to be guided by that advice. That principle has been applied in a long line of cases about the vaccination of children against other diseases.

[12] Ms Attfield on behalf of Mr [Wood] urged me not to follow that previous line of cases. She pointed out that the New Zealand immunisation schedule was established to contend with diseases that have far more serious consequences for children than Covid-19. Further, the vaccines contained in the New Zealand immunisation schedule had all been tried and tested for decades, which is obviously not the case for the Pfizer paediatric vaccine.

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14 *[Lovell] v [Metcalf]* [2022] NZFC 715

[13] However, the principle remains the same. The government through the Ministry of Health and its other agencies has available to it a wealth of expert medical advice. It is far better positioned than I am to assess the safety of vaccines, and to make recommendations about their use.

[14] Both counsel referred me to the relatively recent High Court decision of *MKD v The Minister of Health*, *the Group Manager of MEDSAFE, the Minister for Covid-19 Response and Pfizer NZ Ltd*[15] The *MKD* case is about an application for judicial review of the decision of the government to grant provisional consent under s 23 of the Medicines Act 1981 for the Pfizer vaccine to be used for 5 to 11 year olds. The applicant sought interim relief pending their substantive application for judicial review. Ms Attfield contended the decision has little relevance, as it is an interim decision only; and did not directly address the issue before me now, which is to resolve a dispute between guardians about their son [Kyle].

[15] Nonetheless, the decision is of some interest, as the applicants' grounds for opposition to the rollout of the Pfizer paediatric vaccine are similar to those advanced by Mr [Wood] against [Kyle] being vaccinated. The applicants contended that the consent to the vaccine rollout was based on an error of law, because the health risks of the paediatric vaccine outweigh its therapeutic benefits. They argued:

(a) Paediatric vaccination for Covid-19 carries few benefits because children aged 5 to 11 suffer mild symptoms when affected by Covid-19 and the vaccine does not prevent transmission of Covid-19 by children to others;

(b) Paediatric vaccination presents material (though rare) risks such as myocarditis and anaphylaxis, and safety data (especially long-term data) about the Pfizer vaccine is inadequate.

[16] These are some of the grounds of Mr [Wood]'s opposition. Although Justice Ellis was concerned about whether the Minister's decision was unlawful rather than

[15] *MKD v The Minister of Health*, *the Group Manager of MEDSAFE, the Minister for Covid-19 Response and Pfizer NZ Ltd* [2022] NZHC 67, 1 February 2022 Ellis J.

resolving a dispute between two guardians, her analysis of the consenting process is detailed and illuminative. She set out the contrary evidence and said[16]:

> (a) Pfizer's clinical trial of the initial Covid-19 vaccine included approximately 44,000 participants. Its paediatric clinical trial included 5,500 participants, 3,100 of whom received the paediatric vaccine. These are large by the standards of normal vaccine trials. While neither were large enough to identify rare adverse effects like myocarditis, that is not the purpose of such trials, which seek to identify vaccine efficacy and more common risks. Rare adverse effects are meant to be identified by subsequent passive reporting systems. They were identified by these systems at very low rates.
>
> (b) Pfizer's trials each took place over multiple months. It has not been able to provide long-term safety data regarding the vaccine's effects over 2 to 3 years, as some of the applicant's experts suggest would have been appropriate. However, this is because the pandemic was urgent, and a delay of that period would have prevented people from accessing vaccine protections.
>
> (c) Although mRNA vaccine technology may be newer than that of other vaccine technologies, researchers have been working with and studying mRNA vaccines for decades, particularly in the context of the influenza, rabies and Zika viruses. There is significant scientific understanding about how they work.
>
> (d) While children aged 5 to 11 typically suffer mild symptoms from Covid-19, the disease can cause serious complications like respiratory failure, myocarditis and multi-organ failure. Pfizer's paediatric trials indicate the vaccine has a 91% efficacy rate against symptomatic Covid-19.
>
> (e) In terms of health risk, an analysis by the United States Centre for disease control of adverse effect reports following 8.7 million doses of the paediatric vaccine found just 100 reported serious adverse effects (a rate of 0.0000011%), including 12 reported cases of myocarditis.
>
> And although, for present purposes, it is unnecessary for me to decide whether the wider community benefit of vaccinating children was (as the applicants assert) an irrelevant consideration, it is difficult to see how the best interests of children can be assessed only through the narrow lens suggested by the applicants. In particular, it can hardly be in the best interests of children whose whanau include vulnerable adults for those adults be put at risk of serious disease and death necessarily.

[17] Ellis J went on to summarise a technical report by the European Centre for Disease Prevention and Control (ECDC) in early December 2021, which noted that, amongst other things, myocarditis was reported up to 37 times more often in

[16] At paragraph [60] and [61].

unvaccinated children less than 16 years old with a Covid-19 diagnosis compared to other patients from the same age group.

[18] She said[17]:

> The short point is that notwithstanding sincerely held views (of both laypersons and experts) to the contrary, there appears to have been ample, cogent, information that supported the decision to approve the paediatric vaccine. Given the high threshold (discussed earlier) it is not possible to conclude that the applicant's case for a merits-based review of that decision is strongly arguable. My own interim view is that it is barely arguable at all.

[19] Ms Attfield argued that another reason the *MKD* decision is not relevant is that one of considerations in *MKD* was the potential expiry and wastage of valuable vaccine, contrary to New Zealand's obligation as a good global citizen. I do not place any weight on that submission. That was a factor in the assessment of the adverse public and private repercussions of granting interim relief (pausing the rollout), which counted against the exercise of the court's discretion in the applicants' favour. It did not go to the assessment of the lawfulness of the government decision to authorise the rollout and has no bearing on the current case.

[20] Ms Attfield also properly noted that the *MKD* case was about a decision the Minister had made before the new Omicron variant was prevalent in New Zealand. Provisional consent for the Pfizer paediatric vaccine was granted when the focus of New Zealand's Covid-19 response was principally on the virus's original Wuhan strain and the more contagious Delta strain. Accordingly, the court specifically put to one side the submission that the therapeutic value of the Pfizer vaccine is less in relation to Omicron then earlier strains. This point was an important one for Mr [Wood], when undertaking a risk-benefit analysis for [Kyle]. The Pfizer vaccine is less effective against Omicron, evidenced by the campaign for doubly vaccinated New Zealanders to receive a booster shot. The booster shot is not yet available for 5 to 11-year olds.

[21] I accept that is a relevant consideration for the risk benefit analysis to be applied for [Kyle]. However, the *MKD* decision is still useful for the information it contains about the clinical trials and the health risks.

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[17] At [63].

[22] Mr [Wood] produced an article from Health and Science published 10 January 2022[18] which said that real-world data from United Kingdom has shown that Pfizer's and Moderna's vaccines are only about 10% effective at preventing symptomatic infection from Omicron twenty weeks after the second dose, according to a study from the UK Health Security Agency. However, the original two doses still provide good protection against severe illness, the study found. Ms Attfield questioned the benefit of Pfizer as a protection against Omicron for [Kyle], when twenty weeks after the second dose it will be only 10% effective. She submitted I could take judicial notice of the fact that the efficacy would be gradually reducing after the second dose so as to reach 10% effectiveness after twenty weeks. The benefit, therefore, of administering the Pfizer vaccine is greatly reduced which swings the balance so that the risks to [Kyle] of being vaccinated outweighed the benefit.

[23] On behalf of Ms [Hartley], Mr Chan pointed to the Ministry of Health guidelines set out on its website. The page headed *"Omicron in the Community: what does this mean to you"*[19] has a subheading *"Things you can do to protect yourself at all phases"* and lists the following things:

- Get your COVID Booster shot
- 5 – 11 year olds first vaccination
- Continue to Mask, Scan and Pass wherever you go
- Good hygiene, physical distancing, and stay home if unwell.

[24] Accordingly, the Ministry of Health recommendation is still for 5 – 11-year old children to be vaccinated with the Pfizer paediatric vaccine as a protection against Omicron. I accept it is less effective against Omicron, and its efficacy reduces over time. However, it is still advanced by the Ministry of Health as a protection against Omicron.

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18 *Pfizer CEO says Omicron vaccine will be ready in March*, Health and Science, 10 January 2022.

19 https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-response-planning/omicron-community-what-means-you

Mr [Wood]'s specific grounds of opposition

[25] Some of the grounds of Mr [Wood]'s opposition to the vaccine have been addressed above. For the sake of completeness, I address each ground as set out in Ms Attfield's submissions:

(a) *The Pfizer vaccine does not prevent a person catching or passing on the virus.* There is evidence though that being vaccinated can reduce serious illness, including in children.

(b) *Children are at low risk of becoming seriously ill with Covid-19 and the illness in children is most commonly a mild flu like illness which nearly all children recover from fully.* Again, the Ministry of Health provides guidance[20]:

> **Effects of COVID-19 on unvaccinated children**
>
> COVID-19 generally has mild effects in children and is rarely severe or fatal.
>
> Children and [sic] who have COVID-19 will commonly have no symptoms or only mild respiratory symptoms – similar to a cold. However, some can become very sick and require hospitalisation. Rare complications can include Multisystem Inflammatory Syndrome (MIS-C) that may require intensive care. Children can also suffer long-term side effects (known as long COVID), even after mild cases of COVID-19.
>
> Like adults, if your tamariki are infected with COVID-19 they may transmit the virus to other people. Immunising tamariki helps protect whānau members whose health makes them more vulnerable to COVID-19.

(c) *The Pfizer vaccine is recommended by the Government but is not mandatory.* No vaccination is mandatory in New Zealand. However, the government health advice to get vaccinated is based on expert evidence and, in the absence of expert evidence to the contrary, is the best recommendation available to the court.

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[20] https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-children-aged-5-11

(d) *There are no restrictions on unvaccinated children that would impact upon [Kyle] in his day-to-day life, and if restrictions existed these would be unlawful.*[21] Unvaccinated children are not prevented from attending school. Initially it was a confusing situation about children's participation in school and club sport.[22] It is largely resolved with most sports clubs accepting that children under 12 are not required to be vaccinated. That does not rule out family or friends being uncomfortable about [Kyle]'s participation in events if he is unvaccinated. I do not have any direct evidence of that being a potential problem for him. Restrictions on [Kyle] in his day-to-day life is a consideration in weighing up the benefits of vaccination, but it is not a major one for [Kyle].

(e) There is no safety data available, and no one knows the long-term effect of the Pfizer vaccine upon a young developing child. There is safety data available, as set out in the *MKD* decision and available on the Ministry of Health website. No-one can know the long-term effect of the Pfizer vaccine upon a young developing child, because it is a new response to a new pandemic. However, the government health advice recommends the vaccination, based on expert evidence, which includes a risk analysis. They are better placed to do that than me.

(f) *The Pfizer vaccine is still in an experimental stage until 2023 and has not been administered to a large child population to establish its safety*. I refer to the evidence in the *MKD* decision set out above.

(g) The World Health Organisation had issued an interim recommendation around the use of the Pfizer vaccine and had found there was no efficacy or safety data for children below the age of 12 years, and therefore it recommended that children below the age of 12 years should not be routinely vaccinated. In his evidence Mr [Wood] relied on World

21 Covid-19 Public Health Response (Protection Framework) Order 2021.

22 COVID-19: Schools confused about whether kids' sport can go ahead under new rules, Newshub 25 February 2022, https://www.newshub.co.nz/home/new-zealand/2022/02/covid-19-schools-confused-about-whether-kids-sport-can-go-ahead-under-new-rules.html

Health Organisation information provided on 2 September 2021, updated on 5 January 2022.[23] Mr Chan provided the same document that was updated by the World Health Organisation on 21 January 2022, which now says:

> **Is this vaccine recommended for children and adolescents?**
>
> This vaccine is safe for use for those aged 5 and above, with an adjustment in the recommend dosage for those aged 5-11.
>
> A Phase 3 trial in children aged 12-15 years showed high efficacy and good safety in this age group, leading to an extension of the previous age indication from 16 years down to age 12 and above. A Phase 3 trial in children aged 5-11 showed similar immune response and safety results.
>
> WHO recommends that countries should consider using the vaccine in children aged 5 to 17 only when high vaccine coverage with 2 doses has been achieved in the high priority groups as identified in the WHO Prioritization Roadmap.
>
> Children and adolescents aged 5-17 years of age with comorbidities that put them at significantly higher risk of serous COVID-19 disease, should be offered vaccination, alongside other high-risk groups.

Ms Attfield pointed out that [Kyle] is a fit and healthy boy, as evidenced by his doctor's medical certificate, so he is not a child with comorbidities at significantly higher risk of serious COVID-19, which is the group of children WHO recommends the vaccine is offered to. My reading of the above passage is that the second two paragraphs contain the WHO public health advice about distribution of the vaccine, and do not qualify the advice in the first two paragraphs, which confirm its safety and high efficacy for children aged 5 and above.

(h) *The overseas studies of the safety of the Pfizer vaccine for children were small in size. This raises issues as to whether the study was sufficient to identify the risks appropriately and adequately for children.* Again,

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[23] *The Pfizer BioNTech (BNT 162b2) COVID-19 vaccine: What you need to know;* World Health Organisation, 2 September 2021, updated 5 January 2022, pursuant to updated interim reccomendations.

I refer to the *MKD* decision, which sets out the scale of the trials which Ellis J held were "large by the standards of normal vaccine trials."

(i) *There are known side-effects for children receiving the Pfizer vaccine including myocarditis and pericarditis, particularly following the second dose of the Pfizer vaccine.* The side effects of the vaccine are rare. There are also risks that Covid-19 in children can cause serious complications like respiratory failure, myocarditis and multi-organ failure[24] or MIS-C that may require intensive care, or long-term side effects such as long Covid.[25]

(j) *The Pfizer vaccine is only provisionally approved by Medsafe*. No person may sell or distribute a new medicine without the consent[26], or provisional consent[27], of the Minister of Health.[28] Every provisional consent has effect for a period of only two years or less.[29] The Ministry of Health website explains the provisional approval as follows:[30]

> **What provisional approval means**
>
> Provisional approval was included in the Medicines Act so people in New Zealand can get early access to medicines if it's to meet an urgent clinical need.
>
> It allows a vaccine to be used with conditions in place. This restricts how the vaccine is used by health professionals depending on the supporting data available at the time.
>
> COVID-19 vaccines have been given provisional approval in New Zealand because data to support the longer-term safety and efficacy of COVID-19 vaccines is not yet available.
>
> […]

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24 The *MKD* decision, at paragraph [60].
25 Above, at note 20. See also the ECDC report noted in paragraph [17].
26 Full approval under s 20 of the Medicines Act 1981.
27 Provisional approval under s 23 of the Medicines Act 1981.
28 Section 20(2) Medicines Act 1981.
29 Section 23(4) Medicines Act 1981, although subs (4A) permits two-year extensions of the period determined under subs (4).
30 https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-assessing-and-approving-vaccines

The approval process for Pfizer

The Pfizer vaccine (Comirnaty) has been provisionally approved (with conditions) for use in New Zealand.

This means it's been formally approved after a thorough assessment, but Pfizer must give Medsafe ongoing data and reporting to show that it meets international standards.[31]

Medsafe is the New Zealand Medical Devices Safety Authority. It is the business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand. Medsafe's mission is to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit.[32] Given high public interest and the fact that some data relating to safety was missing (due to the vaccine's rapid development) Medsafe's evaluation team recommended that the application for consent be referred to the Medicines Assessment Advisory Committee (MAAC). MAAC unanimously recommended that the paediatric vaccine receive provisional consent.[33]

Medsafe and MAAC are made up of experts who are far better placed than I am to assess the vaccine's safety. They have assessed that the vaccine is safe to be administered to 5 to 11-year olds now, which is why provisional approval has been given now. I am not persuaded that the vaccine is not safe for [Kyle] until full approval has been given.

(k) *Scandinavian countries are taking a different approach in respect to vaccinations of children and recommend vaccinations only for children who are at risk. The focus is on the individual child, as opposed to the sake of society*. Scandinavian public health policy does not assist me in the deciding whether being vaccinated against Covid-19 is in

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31 The Ministry of Health website sets out what Medsafe assesses and details the approval process.

32 https://www.medsafe.govt.nz/other/about.asp

33 See the *MKD* decision paragraphs [26] to [34], which details the provisional consent process for the paediatric vaccine. The provisional consent is subject to conditions, including that Pfizer provide Medsafe with a range of further information when it became available, including final reports from Pfizer's clinical study of 5-to-11-year-olds and periodic safety reports.

[Kyle]'s best interests or not. In any event, the focus in this case is on [Kyle] the individual child, as opposed to the sake of society.[34]

(l) *The current Pfizer vaccine was not developed for the strain of the virus that is most common in New Zealand; the Omicron variant.* The Pfizer vaccine is less effective against the Omicron variant than earlier variants of Covid-19, which is why a booster shot is recommended for adults. The booster shot is not available for children. Pfizer is developing a vaccine that is much better at preventing infection from Omicron.[35] However that vaccine is not ready yet; and will take time to go through the rigorous New Zealand approval process. In the meantime, as set out above, the Pfizer paediatric vaccine remains the recommended response to the Omicron outbreak. There are also still cases of the Delta variant circulating in the community, against which the Pfizer vaccine has proved to be effective.[36]

[26] In oral submissions it was suggested that the other recommended practices to protect [Kyle] from catching Covid-19 could be utilised to keep him safe, such as wearing a mask, practicing good hygiene and physical distancing. I am told that [Kyle] is an active, engaged 5-year-old. It is unrealistic to expect that he can safely navigate any of those things in a school class or playground filled with equally active and engaged 5-year-olds. He is at most risk catching Covid at school, which he attends full time. Primary schools have seen a particularly rapid growth in case numbers[37]. By late February 2022 over half the schools in Auckland were affected.[38]

Care of Children Act 2004

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34 The evidence of the Medsafe group manager in the *MKD* decision was that his decision was based solely on an assessment of the therapeutic benefits and risks of the vaccine to 5-to-11-year-olds; any potential benefits to vulnerable adults from the vaccination of children played no part in it: paragraph [32] of the *MKD* decision.

35 *Pfizer CEO says Omicron vaccine will be ready in March*, Health and Science, 10 January 2022.

36 *Covid 19: Delta rates 'holding steady' amid Omicron wave.* New Zealand Herald 18 February 2022.https://www.nzherald.co.nz/nz/covid-19-delta-rates-holding-steady-amid-omicron-wave/YXZM5WCVR2A2MEEK7C6M4WWLDE/

37 One News, 17 February 2022, https://www.1news.co.nz/2022/02/17/covid-cases-found-at-320-schools-and-eces-around-nz/

38 Radio New Zealand, 24 February 2022, https://www.rnz.co.nz/news/national/462211/hundreds-more-schools-and-centres-dealing-with-covid-19-cases.

[27] As in all decisions to be made under the Care of Children Act, the welfare and best interests of [Kyle] in his particular circumstances must be the first and paramount consideration.[39] I must consider *this* child in *his* particular circumstances. Submissions were made that I should not be influenced by what is in the greater public good, that is the health benefits for the population as a whole if there is a large uptake of children receiving vaccinations. It was argued that I should not be influenced by the fact that [Kyle] could transmit the virus to other people, including vulnerable people in the community, even if he only suffers mild or no symptoms. Those submissions deliberately overlook the reality that [Kyle] is not a child who lives in isolation. He belongs to communities made up of his family members, school community, neighbourhood, friends and so on. Nevertheless, the law requires me to consider his individual welfare and best interests in his particular circumstances, and that is what I have done. I have not been guided by the greater public good, or the risk that he might infect vulnerable members of the community.

[28] I must take into account the principles contained in s 5 when considering what is in [Kyle]'s welfare and best interests. The relevant sections are:

(a) Section 5(a) which states that a child's safety must be protected. I am satisfied that the vaccine is safe for [Kyle]. I am guided by the government health advice about the safety of the vaccine generally, and by [Kyle]'s doctor's opinion that he should have the Covid-19 vaccination.

(b) Ms Harland submitted on behalf of [Kyle] that s 5(d) requires consideration, whereby he needs to have continuity in his care, development and upbringing. She submitted that not being able to carry out [Kyle]'s day-to-day activities may be impact on his care, development and upbringing. That is a factor, but not one I attribute a lot of weight to as children are not generally subjected to vaccine mandates and I have no evidence before me about him being excluded from whānau or community events directly relevant to him.

[39] Section 4 Care of Children Act 2004.

(c) Section 5(e) contains the principle that [Kyle] should continue to have a relationship with both his parents and his relationship with his family group should be preserved and strengthened. Ms Harland submitted that may be impacted if [Kyle] is set apart through not been vaccinated or if he contracted Covid, which could be likely given the current explosion of numbers.

[29] I have weighed up the risks and benefits of [Kyle] being vaccinated against Covid-19 and the risks and benefits if he is not. I have accepted Mr [Wood]'s submission that the benefit of the current paediatric vaccine is reduced in respect of the Omicron variant, which is by far the more common variant circulating in the community.

[30] I still consider it is in [Kyle]'s welfare and best interests for him to be vaccinated against Covid-19. In making that decision I rely on the Ministry of Health guidelines, which recommend that children aged 5 to 11 be vaccinated. I also rely on the recommendation of [Kyle]'s own doctor that he be vaccinated against Covid-19.

[31] Accordingly, the application to resolve a dispute amongst guardians is granted. I order that [Kyle] receive the first Pfizer paediatric vaccination as soon as possible, and then receive the second at the Ministry of Health recommended interval. If a booster shot is later recommended by the Ministry of Health for 5 to 11-year olds, I order that he receive that too.

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Judge P Ginnen
Family Court Judge | Kaiwhakawā o te Kōti Whānau
Date of authentication | Rā motuhēhēnga: 09/03/2022