# IN THE HIGH COURT OF NEW ZEALAND WELLINGTON REGISTRY

# I TE KŌTI MATUA O AOTEAROA TE WHANGANUI-A-TARA ROHE

CIV-2023-485-146 [2023] NZHC 3855

UNDER the Judicial Review Procedure Act 2016 and

the Declaratory Judgments Act 1908

IN THE MATTER of an application for judicial review, and for

declarations under the Declaratory

Judgments Act 1908, in respect of clause 15

of Schedule 5 to the Smokefree

**Environments and Regulated Products** 

Regulations 2021

BETWEEN ALT NEW ZEALAND LIMITED

First Applicant

VEC LIMITED Second Applicant

MYRIAD PHARMACEUTICALS

LIMITED
Third Applicant

AND ATTORNEY-GENERAL

Respondent

Hearing: 18-20 September 2023

Appearances: D A Laurenson KC and L I van Dam for Applicants

H W Ebersohn and V A Howell for Respondent

Judgment: 21 December 2023

#### JUDGMENT OF CHURCHMAN J

This judgment was delivered by me on 21 December 2023 at 4:00 pm pursuant to r 11.5 of the High Court Rules 2016.

Registrar/Deputy Registrar

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#### Introduction

- [1] The applicants are three related companies founded and incorporated between 2015 and 2018. They manufacture, import and sell vaping products:
  - (a) ALT New Zealand Ltd (ALT) manufactures a single product, the "alt" device, which uses replaceable pods and is distributed through over 4,500 retail stores and petrol stations;
  - (b) VEC Ltd (VEC) manufactures and imports vaping products, and is also a retailer trading under the names "Vapo" and "Value Vaper"; and
  - (c) Myriad Pharmaceuticals Ltd (Myriad) provides research, development and quality control services to ALT and VEC and also manufactures eliquids for VEC and flavours for the alt product line, employing its own scientists and pharmacologists for this task.
- [2] Between them, the applicants own 30 retail stores, a factory, a laboratory, a warehouse, a head office and a large distribution centre. They employ 259 staff in roles ranging from manufacture, assembly and design, to engineering, pharmacy, finance, human resources, retail, technology, sales and marketing.

## The interim application

- [3] This decision is a sequel to an earlier decision in these proceedings.<sup>1</sup> The applicants had sought interim orders preventing the promulgation and/or enforcement of regulations reducing the maximum nicotine strength of reusable nicotine salt vaping products from 50 mg/mL to 28.5 mg/mL pending the determination of the substantive application for judicial review.
- [4] Although, at the time of the hearing in that matter (16 August 2023) the challenged regulations<sup>2</sup> had not yet been considered or approved by Cabinet, by the time the decision was issued (23 August 2023), the Cabinet decision had been made.

<sup>&</sup>lt;sup>1</sup> ALT New Zealand Ltd v Attorney-General [2023] NZHC 2300.

The Smokefree Environments and Regulated Products Regulations 2021 (the Regulations).

Because of this development, Ellis J held that the applicants no longer had a position to preserve.<sup>3</sup>

#### Relevant facts

- [5] The history of the regulation of vaping products and the background to the promulgation of the Smokefree Environments and Regulated Products Regulations 2021 (the Regulations) is comprehensively set out at [11]-[65] of Ellis J's decision. It is not necessary to repeat it here. However, in order to make this decision intelligible to those who have not read Ellis J's decision, I will briefly summarise the relevant factual background.
- [6] Nicotine is an addictive chemical compound found naturally in tobacco plants. Tobacco was introduced to New Zealand by the early European colonists and its use was quickly adopted by Māori. The most common form of consuming tobacco has been smoking. The smoking of tobacco causes significant adverse health consequences. Benjamin Youdan, an expert in tobacco addiction, smoking cessation and harm reduction policy, who filed an affidavit on behalf of the applicants, expressed the view that tobacco smoking is the biggest cause of preventable death in New Zealand.
- [7] While nicotine itself is a toxic substance, it is the act of smoking tobacco that creates the greater adverse health effect due to the carcinogens associated with the combustion of tobacco.
- [8] As the adverse health consequences of smoking became known, Parliament legislated to prevent, as far as was reasonably practicable, the detrimental effects of smoking. The current legislation was initially enacted in 1990 as the Smoke-free Environments Act.
- [9] The inhalation of nicotine by vaping is a relatively recent phenomenon that has occurred over the last decade.

<sup>&</sup>lt;sup>3</sup> ALT New Zealand Ltd v Attorney-General, above n 1, at [79].

- [10] Vaping differs to smoking in that it does not involve the combustion of tobacco but delivers nicotine by way of an inhaled aerosol or vapour.
- [11] In November 2020 the name of the Smoke-free Environments Act 1990 was amended to become the Smokefree Environments and Regulated Products Act 1990 (the Act). This was New Zealand's first vaping specific legislation. The Act included a new category of notifiable products that were vaping products. Section 84 of the Act permits the making of regulations relating to notifiable products by the Governor-General, by way of Order in Council. Section 84(1)(a) permits regulations "prescribing safely requirements for regulated products that are notifiable products".
- [12] It is that regulation-making power and the regulations made pursuant to it that is in issue in the present case.
- [13] On 11 August 2021 the Regulations came into effect. Schedule 5 to those Regulations was headed "Product safety requirements for vaping products". Regulation 14 said "The strength of free-base nicotine in a vaping substance must not exceed 20mg/mL".
- [14] Regulation 15 said "The strength of nicotine salt in a vaping substance must not exceed 50 mg/ml".
- [15] There are two types of nicotine used in vaping products: free-base (or pure) nicotine and nicotine salts. Pure nicotine is highly alkaline and even at low levels can burn or irritate the throat. At levels comparable to those obtained by smoking a cigarette, free-base nicotine is unpalatable. Nicotine salts are a compound of pure nicotine and a suitable acid, usually, but not exclusively, benzoic acid. It is because nicotine salts are constituted only partly of nicotine that it has been necessary for the regulations to separately address the level of nicotine and nicotine salts in vaping products.

Vaping products included: (a) a vaping device; (b) a vaping substance; (c) any one or more components of a vaping device; and (d) a package containing two or more items described in any of (a) to (c): s 2 definition of "vaping product".

<sup>&</sup>lt;sup>4</sup> The latest version of the Act dates from 1 January 2023.

[16] The difference between free-base nicotine and nicotine salts was central to the earlier phase of this litigation with the respondent ultimately conceding that the interpretation adopted by certain officials at the Ministry of Health of the maximum permitted amount of nicotine salt permitted in vapes was wrong.

## The proceedings

[17] On 15 August 2023, Ellis J issued a Minute making a declaration by consent that: <sup>6</sup>

The words "the strength of nicotine salt in a vaping substance must not exceed 50 mg/mL" in clause 15 of Schedule 5 to the Smokefree Environments and Regulated Products Regulations 2021 means that the "nicotine strength in a nicotine salt vaping substance must not exceed 50 mg/mL".

[18] That declaration resolved what had been the original issue in these proceedings which was whether the intention of the legislature in setting the maximum nicotine salt strength in a vaping substance was to set a limit of 50 mg/mL or 28.5 mg/mL. Counsel for the respondent had conceded that the interpretation contended for by the respondent (which had significant and immediate ramifications for the applicants) was wrong.

[19] The making of that declaration did not completely resolve the first part of these proceedings because the applicants became aware that in tandem with defending the declaration proceedings, the Ministry was also promoting an amendment to the Regulations which would achieve the same outcome as the interpretation it had incorrectly claimed should be given to the Regulations. In other words, instead of the maximum allowable nicotine limit in vaping products being 50 mg/mL, it was to be 28.5 mg/mL.

[20] The applicants had sought interim orders under s 15(3)(b)(i) of the Judicial Review Procedure Act 2016 (the JRPA) declaring that the respondent ought not take any further action to make regulations reducing the maximum nicotine strength of reusable nicotine salt vaping products, to bring such regulations into force or notify

<sup>&</sup>lt;sup>6</sup> ALT New Zealand Ltd v Director-General of Health HC Wellington CIV-2023-485-146, 15 August 2023 (Minute of Ellis J) at [2].

them in the *New Zealand Gazette*. As noted at [4] above, because, by the time Ellis J had issued her decision, the Regulations had received consent and were imminently about to be gazetted, the Court held that the applicants no longer had a position to preserve, the situation was not urgent and therefore the basis for interim orders had not been established.

[21] The focus of the proceedings then changed to the substantive action for judicial review in relation to the amended Regulations.

#### **Evidence**

- [22] Extensive affidavit evidence was filed, with a number of matters being disputed. What was not disputed was that smoking is harmful, that vaping is less harmful than smoking (although the long term consequences of vaping are unknown), that the availability of vape products containing nicotine can be an important tool in encouraging smokers to transition from smoking to vaping, that while many ex-smokers vape there has been a significant uptake of vaping among young people who have never smoked, particularly Māori women, and that the consumption of nicotine (including by vaping) is addictive.
- [23] Matters on which there were diverse views included: the relationship between the level of nicotine in vape products and the addictiveness of those products; and the minimum level of nicotine a vape product required in order to replicate the nicotine hit generated by smoking, and therefore the utility of vape products to be seen by smokers as a genuine alternative to smoking. It is not possible to resolve these differences on the basis of the affidavit evidence before the Court. Neither is it necessary to do so for the purposes of this decision.
- [24] Although a very substantial quantity of evidence was placed before the Court by way of affidavit, much of it was only of peripheral, if any, relevance. These are judicial review proceedings. They focus on the lawfulness of the process by which cl 15 was amended. This case is not about the relative harm of smoking as compared to vaping.

## **Admissibility**

[25] The applicants have objected to the admissibility of aspects of the respondents' evidence. They say that certain passages of the evidence are an expression of opinion, when neither the Minister or Dr Sarfati are qualified to give opinion evidence as experts in accordance with r 9.43 of the High Court Rules 2016. Rule 9.43 requires that an expert witness confirms that they have read the Code of Conduct for expert witnesses set out in sch 4 to the Rules and they agree to comply with it. The evidence of an expert witness who has not complied with this requirement may only be offered with leave of the Court. I indicated to counsel that I would address the objections to admissibility in this decision and now set out my conclusions.

[26] In relation to Minister Verrall, the first evidence objected to is the third and fourth sentences of [7]. These read:

... Although nicotine plays a minor role, if any, in causing smoking-induced diseases, addiction to nicotine is the proximate cause of these diseases. This is discussed in the *Nicotine Addiction* article in the New England Journal of Medicine ...

[27] Minister Verrall deposes that she was an infectious diseases physician at the Capital & Coast District Health Board and a Senior Lecturer at the University of Otago's Department of Pathology and Molecular Medicine. I accept that given those qualifications she is entitled to express an opinion on whether nicotine is the proximate causes of the consequences of smoking referred to. Although Minister Verrall did not, in her affidavit, depose that she had read the code of conduct for expert witnesses and agreed to comply with it, I grant leave under r 9.43(3) of the High Court Rules for that evidence to be tendered.

[28] The next objection is to the third to fifth sentences of [11]. These sentences say:

... Many of the long-term health effects of vaping are still unknown, and there is growing evidence to demonstrate that these products are not harmless. A recent report from the World Health Organisation suggests that vaping can have negative effects on heart rate and blood pressure, and that daily use has been shown to be associated with increased risk of myocardial infarction. A copy of this report is annexed as "AJV-3".

<sup>&</sup>lt;sup>7</sup> High Court Rules 2016, r 9.43(3).

[29] Effectively Minister Verrall is drawing the Court's attention to an academic article rather than tendering the information as her own evidence. I do not place any weight on this aspect of the Minister's evidence beyond accepting the statement of the obvious that the long-term effects of vaping are presently unknown.

[30] The applicants also object to [43] where Minister Verrall says:

The precise level of nicotine needed to reduce the harm to non-smokers does not need to be known, any reduction in nicotine will reduce its negative effect.

[31] I accept that this opinion goes beyond the level of expertise that might be expected from someone with Minister Verrall's qualifications and for that reason is inadmissible.

[32] The applicants object to the third to sixth sentences of [44]. These say:<sup>8</sup>

... Any addiction can be a burden and resulting harm can extend to impact on educational attainment, psychological harm and economic harm. There is rapidly emerging evidence that vaping is associated with physical and behavioural health risks. Vaping has been consistently associated with depression, Attention deficit hyperactivity disorder (ADHD), and conduct disorder in adolescents. Nicotine exposure has been shown to adversely affect brain development in animal models, and increases the risk of problems of learning and memory.

[33] That evidence is footnoted to:

The ARFNZ/SPANZ Vaping in NZ Youth Survey, page 4.

[34] I am prepared to accept that there is a survey that says that. However, whether the content of that article, upon which Minister Verrall appears to base her opinion, is correct is not a matter that has been established.

[35] In relation to Dr Sarfati's evidence, there is an objection to the third sentence of [9], the second sentence of [10] and the first sentence of [11].

The ARFNZ/SPANZ Vaping in NZ Youth Survey, page 4.

[36] The third sentence of [9] refers to an article in the International Journal of Drug Policy. Dr Sarfati is not herself purporting to give that evidence as her own. It is not something that I have regard to.

[37] The second sentence of [10] comes immediately after a sentence which states that "nicotine in vaping is an addiction". The sentence in question reads:

This has an ongoing economic impact on people and vaping can have negative psychological effects.

[38] There is a footnote at the end of the sentence that refers to a Public Health Communication Centre Aotearoa publication. Dr Sarfati does not claim qualifications in economics or psychology and is therefore not in a position to express a view on the accuracy of the contents of this article.

[39] The first sentence of [11] says:

Where vaping products contain nicotine, there is a significant relationship between the frequency of vaping and the nicotine dose used.

[40] The following sentence footnotes a 2021 survey. As it is not clear whether the contents of paragraph [11] are judgments made within Dr Sarfati's area of expertise, I am not able to place any weight on them.

#### **Grounds of review**

[41] Pursuant to leave granted by Ellis J,<sup>9</sup> the applicants filed a second amended statement of claim dated 4 September 2023. That statement of claim challenged the 2023 Regulations which had amended cl 15 of the Regulations so as to achieve the interpretation of the maximum strength of nicotine salts in vapes that the Ministry officials had previously wrongly claimed had always been intended.

[42] The applicants claim that the new clause (which became cl 14) was ultra vires and invalid. They have advanced a number of grounds in support of that claim.

<sup>&</sup>lt;sup>9</sup> *ALT New Zealand Ltd v Director-General of Health* HC Wellington CIV-2023-485-146 {Minute of Ellis J).

#### Consultation

- [43] It was alleged that the Ministry:
  - (a) undertook a consultation process which was unlawful because at the time it was undertaken, the proposal had progressed beyond a formative stage in that a decision to amend (then) cl 15 had already been made by the Minister;
  - (b) misrepresented the nature and significance of the proposed amendment to (then) cl 15 in either or both of a 12 June 2023 email or the consultation document or a 12 June 2023 news article in the following ways:
    - (i) the proposed maximum nicotine concentration of 28.5 mg/mL was "in line with the ... intent" of cl 15 and was what "was intended";
    - (ii) the purpose of the cl 15 amendment was "to clarify how nicotine levels for vaping products are expressed";
    - (iii) that "if we do not make this change, and leave the regulations as they currently are, it is likely that the confusion regarding the interpretation of clause 15 ... will continue";
    - (iv) "higher levels of nicotine mean an increase in the risk of addiction", when the available evidence did not support, and was contrary to, that statement;
  - (c) failed to provide sufficient time to allow proper engagement on a fundamental shift in public health policy;
  - (d) failed to engage appropriately with Māori and Pacific communities despite the Ministry having evidence that the cl 15 amendment would have "health equity consequences for vulnerable populations who

already carry a high burden of disease", including for Māori and Pacific communities;

- (e) failed to consult Te Aka Whai Ora;
- (f) failed to consult Te Whatu Ora, which provides smoking cessation services;
- (g) failed to consult other smoking cessation service providers;
- (h) failed to provide information to allow stakeholders to respond in an informed way;
- (i) failed to provide adequate time to obtain (including through consultation), and to give genuine consideration to, relevant information relating to the significant change proposed; and
- (j) failed to genuinely consider the submissions made in the cl 15 consultation.
- [44] The resolution of this part of the applicants' claim requires an analysis of the nature and extent of the duty to consult in respect of subordinate legislation.

## Legitimate expectation

- [45] The applicants also advanced a claim of breach of legitimate expectation. The expectation was said to be that any material change to the maximum nicotine strength provided for in cl 15 which was based on advice from the Technical Expert Advisory Group (TEAG), would be informed by independent expert analysis and/or advice. This expectation was said to have been breached because the decision to make a cl 15 amendment:
  - (a) was not based on independent expert analysis or advice; and

- (b) is contrary to independent expert analysis and advice, including that provided:
  - (i) by TEAG; and
  - (ii) in the Bullen affidavits and Youdan affidavits.

#### Relevant considerations

[46] A further ground was failure to take into account relevant considerations, the particulars being the decision to amend cl 15 was flawed and/or failed to take into account relevant considerations because it was based on the 1 July Cabinet paper, the 13 July note and/or the advice of Te Pou Hauora Tūmatanui | the Public Health Agency, which failed to provide fair, accurate and adequate advice on the proposed cl 15 amendment.

#### Unreasonableness

[47] It was also claimed that the decision to amend cl 15 was unreasonable, outside the scope of the empowering clause and failed to advance the purpose of the Act. The particulars of this claim were that:

- (a) a purpose of the Act from 1 January 2023 was to provide for the regulation of notifiable products in a way that seeks to minimise harm, especially harm to young people and children;
- (b) the amended purpose was a simplification of, and includes previous purposes of the Act, including to support smokers to switch to regulated products that are significantly less harmful than smoking; 10
- (c) the Governor-General is empowered under s 84(1)(a) of the Act, to make regulations prescribing safety requirements for regulated products that are notifiable products;

Section 3A(1) of the Act does not expressly contain a purporse of supporting smokers to switch to regulated products.

- (d) the cl 15 amendment was not based on evidence, including independent expert analysis and/or advice, capable of supporting the conclusion that a maximum nicotine strength of 28.5 mg/mL is required to address a safety requirement and/or to minimise harm; and
- (e) the cl 15 amendment is contrary to the independent expert advice and analysis available to the Ministry, including that provided that TEAG and in the Bullen affidavits and the Youdan affidavits to the effect that further:
  - (i) there are no safety issues associated with a maximum nicotine strength of up to 60 mg/mL; and
  - (ii) a maximum nicotine strength of 28.5 mg/mL will not minimise harm because:
    - (1) it is unlikely to be sufficient to support smokers to switch to vaping products that are significantly less harmful than smoking;
    - (2) it is likely to result in compensatory behaviour where vapers inhale more vapour to get the same amount of nicotine unnecessarily exposing them to chemicals in the vapour;
    - (3) it is unlikely to assist with the issue of youth vaping; and
    - (4) it is unlikely to assist with the issue of addiction and dependence on nicotine.
- [48] A further ground alleges that cl 15 amendment was invalid because a maximum nicotine strength of 28.5 mg/mL is:
  - (a) arbitrary and/or unreasonable;

- (b) does not address safety as required by the empowering clause; and
- (c) does not advance the purpose of the Act, which is to minimise harm.

## Relief

[49] By way of relief the applicants seek a declaration that the new cl 14 is ultra vires and unlawful; an order quashing the new cl 14 and reinstating the maximum nicotine strength of 50 mg/mL for reusable nicotine salt vaping products; and an order that, if the Ministry wishes to consider reducing the nicotine strength of reusable nicotine salt vaping products from 50 mg/mL, it is required to engage in a lawful process in accordance with the findings of this Court.

#### **Respondent's position**

- [50] The respondent denies that the Regulations are invalid, irrational or unreasonable. It says that reliance on expert advice from the Ministry of Health does not make the decision on the amendment of cl 14 of the Regulations irrational.
- [51] As to the alleged failures in consultation, the respondent says that the Act did not require a consultation process and that without a legislated procedural requirement, subordinate legislation is not ordinarily invalidated for a failure to consult.
- [52] It is admitted that the Ministry officials made a mistake as to the level at which the preceding regulations set the nicotine levels in vaping products, but this is said to be irrelevant on the basis that the consultation process that led to the amendment to the Regulations explained the reason for the proposal, which was to balance the need for smoking cessation while protecting young people from becoming addicted.
- [53] It denies there was any legitimate expectation that independent expert advice would be relied on in making the Regulations, but that in any event, such advice was obtained during the consultation process.
- [54] The respondent's case is that the setting of a maximum level of nicotine in vaping products involves a balance between two competing public health issues,

namely the benefits of vaping as a smoking cessation tool, and the risk that people, especially young people who do not smoke, will become addicted to vaping.

- [55] In setting the new maximum level of nicotine in vaping products, a balance has been struck to reduce the nicotine level in vaping to protect people, especially young people, while still permitting a level of nicotine as a smoking cessation tool. The respondent says irrespective of the applicants' challenge to the medical evidence, Cabinet's reliance on expert advice from the Ministry of Health does not make the decision irrational.
- [56] There was no failure in respect of consultation. The Act did not require a consultation process, and without such a legislated procedural requirement, subordinate legislation is not ordinarily invalidated for a failure to consult. The respondent says that to the extent fairness or natural justice required consultation, consultation sufficient for that purpose did occur. Essentially, the respondent says the alleged failures in respect of consultation are a red herring.
- [57] The respondent submits the grounds of judicial review in the context of delegated legislation are limited, namely the conferral of authority on the actor, the action being one within the power conferred, breach of the procedural provisions for acting, fraud, and (in some cases) unreasonableness.<sup>11</sup>
- [58] The respondent's submission is that the classical formulation of natural justice recognises a right to be heard where an authority is discharging judicial, and possibly administrative, functions, but not legislative ones. There is therefore no legitimate expectation of a hearing before the making of either primary or delegated legislation, unless the statute imposes a duty to consult.<sup>12</sup> The respondent concedes that in modern law there are some exceptions with regard to subordinate legislation, where natural

Philip A Joseph Constitutional and Administrative Law in New Zealand (5th ed, Thomson Reuters, Wellington, 2021) at 1193. The respondent notes that an exception is that a duty to consult may arise where a person's interests are affected in a significantly different way from the interests of others, for example where an occupational license is cancelled: see Fowler & Roderique Ltd v Attorney-General [1987] 2 NZLR 56 (CA).

Graham Taylor *Judicial Review: A New Zealand Perspective* (4th ed, LexisNexis, Wellington, 2018) at 497.

justice may require that a person or certain persons are consulted, notwithstanding there being no express duty to consult.<sup>13</sup>

- [59] Subordinate legislation may be challenged on the basis it is outside the scope of the empowering provision, and the empowering provision may require consultation. <sup>14</sup> The respondent says, however, that unless that is the case, there is no general duty to consult. The respondent submits that though the government may consult with interested groups before introducing legislation, this does not support the existence of an enforceable duty. <sup>15</sup>
- [60] The respondent accepts a mistake of law was made by the Ministry as to the level at which the preceding regulation set the nicotine level. However, while it says this was regrettable, the validity and success of the consultation process was unaffected, given that the consultation process was expressly about the maximum nicotine concentration of 28.5mg/mL (which just happened to be the same level that the Ministry had previously unsuccessfully argued had originally been fixed by the earlier version of the regulations).
- [61] The respondent says both that there was no legitimate expectation that independent expert advice would be relied upon in making the regulations and, that in any event, such advice was obtained during the consultation process.
- [62] The response to the causes of action advanced by the applicants is:
  - (a) a duty to consult does not exist;
  - (b) that the amendment is not ultra vires when the changes are within the express purposes of the Act;

The respondent contends that subject to the statutory scheme, this can arise in circumstances where there is no general duty to consult but natural justice requires a particular party to be consulted. This can occur when a regulation affects the interests of a person in a way that is significantly different from the way in which it is likely to affect the interest of the public generally, such as the cancellation of a license. The respondent points to for example *Fowler & Roderique Ltd*, above n 12; and see also *Bates v Lord Hailsham of St Marylebone* [1972] 1 WLR 1373 (Ch) as an example of the general principles and of a statutory provision that provided for consultation.

Ross Carter, Jason McHerron and Ryan Malone *Subordinate Legislation in New Zealand* (LexisNexis, Wellington, 2013) at 228.

<sup>&</sup>lt;sup>15</sup> Joseph, above n 12, at 1193.

- (c) as to the science behind the amendment, the Act itself recognises the harm of vaping to people, especially to young people; and
- (d) the additional grounds relied on by the applicants do not provide a recognised basis on which to invalidate subordinate legislation.

### Discussion

## Subordinate legislation

[63] Most subordinate legislation, including that in the present case, is "delegated legislation", being legislation made by some body or person under powers conferred by Act of Parliament. The most common type of subordinate legislation is regulations, made by the Governor-General by Order in Council. The Legislation Act 2019 calls all subordinate legislation "secondary legislation". All secondary legislation is subject to the Legislation Act. The term "secondary legislation" replaces earlier terms such as "regulations" and "legislative instruments". While I use the term "subordinate legislation", the term may be considered interchangeable with "delegated legislation" and "secondary legislation".

## Amenability of subordinate legislation to judicial review

[64] The making of subordinate legislation involves the exercise of statutory power. Therefore judicial review is available in respect of the validity of subordinate legislation.<sup>21</sup> No person or body, including Parliament's delegate, may usurp Parliament's powers of legislation.<sup>22</sup> As the authors of *Subordinate Legislation in New Zealand* state, "[a]ccordingly, judicial scrutiny of subordinate legislation upholds the rule of law and the sovereignty of Parliament."<sup>23</sup>

Ross Carter *Burrows and Carter Statute Law in New Zealand* (6th ed, LexisNexis, Wellington, 2021) at 16.

<sup>&</sup>lt;sup>17</sup> At 16.

<sup>&</sup>lt;sup>18</sup> At 19.

Legislation Act 2019, s 5.

<sup>&</sup>lt;sup>20</sup> Carter, above n 16, at 20.

Under the Judicial Review Procedure Act 2016.

Fitzgerald v Muldoon [1976] 2 NZLR 615 (SC) at 622, quoting AV Dicey Introduction to the Study of the Law of the Constitution (10th ed, Macmillan & Co, London, 1959) at 39-40; and see Carter, McHerron and Malone, above n 14, at 228.

<sup>&</sup>lt;sup>23</sup> Carter, McHerron and Malone, above n 14, at 228.

[65] Subordinate legislation is subject to traditional challenges in a court of law.<sup>24</sup> As Wild CJ noted in *Fitzgerald v Muldoon*, quoting AV Dicey: "no person or body is recognised by the law ... as having a right to override or set aside the legislation of Parliament."<sup>25</sup> The validity of subordinate legislation may be challenged in the courts by virtue of the same principle.<sup>26</sup>

[66] Parliament's delegates entrusted with delegated legislative powers must comply with the limits imposed by Parliament and act within the spirit of the enabling statute.<sup>27</sup>

[67] The starting point for the Court is therefore whether the subordinate legislation complies with the description of the subordinate legislation which the delegate is authorised to make.<sup>28</sup> If a regulation is outside the scope of the regulation-making powers conferred by the empowering provision, it is invalid.<sup>29</sup> In *R (The Public Law Project) v Lord Chancellor*, the United Kingdom Supreme Court quoted with approval a passage from *Craies on Legislation* that "as with all delegated powers the only rule for construction is to test each proposed exercise by reference to whether or not it is within the class of action that Parliament must have contemplated when delegating."<sup>30</sup> Subordinate legislation must not be inconsistent with (or "repugnant to") statute law and must not be unreasonable or uncertain.<sup>31</sup>

[68] Sections 81-85 of the Act specifically authorise the making of regulations. As noted at [11] above, s 84(1) provides that the Governor-General makes the regulations by Order in Council. The applicants have not argued that there was no statutory basis for the making or amendment of the regulations. I conclude that the regulations are a type of subordinate legislation that the delegate was authorised to make.

<sup>&</sup>lt;sup>24</sup> Carter, above n 16, at 18.

<sup>&</sup>lt;sup>25</sup> Fitzgerald v Muldoon, above n 22, quoting Dicey, above n 22, at 39.

<sup>&</sup>lt;sup>26</sup> Carter, McHerron and Malone, above n 14, at 228.

<sup>27</sup> At 228

<sup>&</sup>lt;sup>28</sup> McEldowney v Forde [1971] AC 632 (HL) at 658 per Diplock J (dissenting).

<sup>&</sup>lt;sup>29</sup> Carter, above n 16, at 18.

R (The Public Law Project) v Lord Chancellor [2016] UKSC 39; [2016] AC 1531 at [26], quoting Daniel Greenberg Craies on Legislation (10th ed, Sweet & Maxwell, London, 2012) at [1.3.11].

Taylor, above n 11, at [14.28].

### Breach of natural justice by failing to undertake a lawful consultation process

[69] The first cause of action requires a consideration of the existence and potential scope of the contended duty to consult and whether there was there a failure to undertake a lawful consultation process by misrepresenting the nature and significance of the consultation, misleading stakeholders over the intention underpinning cl 15, failing to provide sufficient time for the consultation, failing to engage properly with Māori and Pacific communities, and failing to provide information to allow stakeholders to respond to information in an informed way?

[70] When making regulations pursuant to s 84(1) the Governor-General acts on the advice of the Executive Council, which is the collective of the Ministers. In *CREEDNZ Inc v Governor-General*, the Court of Appeal considered it would be "very unusual" for Parliament to impose on the Executive Council or Governor-General a duty to consult.<sup>32</sup> Cooke P quoted the comment of the Supreme Court of Canada that there was "no need for the Governor in Council to give reasons for his decision, to hold any kind of a hearing, or even acknowledge the receipt of a petition".<sup>33</sup> Cooke P stated that the decision "illustrates how slow the Courts are to treat the Executive Council or Cabinet as under any duty to follow a procedure at all analogous to judicial procedure."<sup>34</sup>

[71] This counts significantly against a general duty to consult. The fact that Parliament did not impose a duty to consult is supported by the fact that the Act specifically defines when there is a duty to consult: in relation to te Tiriti o Waitangi | Treaty of Waitangi obligations;<sup>35</sup> suspending or cancelling the approval of a smoked tobacco retailer;<sup>36</sup> when determining an application process for the approval of smoked tobacco retailers or the maximum number of approved smoked tobacco retail premises,<sup>37</sup> before suspending or cancelling an approval or temporary approval of a

<sup>32</sup> CREEDNZ Inc v Governor-General [1981] 1 NZLR 172 (CA) at 177–178 per Cooke P, 188 per Richardson J and 206 per Somers J.

At 178, quoting Attorney-General of Canada v Inuit Tapirisat of Canada (1980) 115 DLR (3d) 1.

<sup>34</sup> At 178

<sup>&</sup>lt;sup>35</sup> Smokefree Environments and Regulated Products Act 1990, s 3AB.

Sections 20J-20K.

<sup>37</sup> Sections 20L-20N.

smoked tobacco product for sale, manufacture, import or supply in New Zealand;<sup>38</sup> or when cancelling or suspending notification of a notifiable product.<sup>39</sup>

[72] Section 3AB makes it clear that there is no duty on the Minister to consult when preparing regulations for the Executive Council's referral to the Governor-General. Sections 3AB(a)-(c) require the Director-General, when approving applications for tobacco retailers and the maximum number of retailers, to consult with various Māori interests and to have systems in place for the purposes of carrying out that consultation process. Section 3AB(d), however, only requires the Minister, before preparing regulations relating to the requirements for smoked tobacco products, to consider the risks and benefits to Māori. An inference can therefore be drawn that there is no duty on the Minister to consult with Māori when preparing regulations. The use of the word "preparing" in s 3AB(d) is important. This illustrates the distinction between the Minister *preparing* the regulations and the Governor-General in Council *making* the regulations.

[73] The statute clearly defines when a person has a right to be heard, and that determines when consultation must occur. On its face, the statute clearly does not require consultation in the present circumstances.

[74] In the absence of an express statutory duty to consult, there would appear to be no general or common law duty to consult in respect of subordinate legislation.

[75] The Court of Appeal addressed this point in *Wellington City Council v Minotaur Custodians Ltd*, noting that where there was no specific statutory duty to consult:<sup>40</sup>

Because the clear intention of [the operative part of the Local Government Act] is to give councils a wide discretion in this field, it will always be difficult to establish a concurrent common law duty to consult except in truly exceptional cases ... But there is no need to establish a separate and additional common law duty to consult to bring irrationality principles into play in a consultation case, because, as we explain, the requirement to act rationally is inherent in [that part].

Sections 74-75, which require a prior opportunity for the affected supplier to be heard.

<sup>38</sup> Sections 57C–57E.

Wellington City Council v Minotaur Custodians Ltd [2017] NZCA 302, [2017] 3 NZLR 464 at [48] (emphasis added).

[76] The Court held that it was for the local authority to decide whom to consult, but that "it must do so rationally and in pursuit of the purposes of the LGA generally and those in [the operative part of the LGA] specifically". The Court considered that how far a council goes in consulting affected or interested parties would also be a matter for the local authority, provided it complied with the applicable statutory provisions. The Court held that in determining whether the Council had acted irrationally, the "only relevant question" was "whether having embarked on a programme of consultation, the Council was obliged to extend to Minotaur a benefit of the same treatment it offered other affected parties with whom the Council consulted directly". \*43\*

[77] The Court of Appeal decision in *Minotaur* is authority for the proposition that there is no need to establish a separate and additional common law duty to consult to bring irrationality principles into play in a consultation case. Relatedly, the author of *Judicial Review: A New Zealand Perspective* considers that "[a]pplying a duty of consultation where there is a nation-wide policy can pose real problems". <sup>44</sup> The author suggests it is "unlikely that a duty to make local consultations on nation-wide policy would ever be held". <sup>45</sup>

[78] Indeed, the author considers that the concept of a duty to consult is "inherently ambiguous", and that it is "probably for this reason that the duty to consult is now most commonly encountered in the context of a legislative provision to consult". The author says such provisions "commonly identify what is the subject of consultation and what is involved in that consultation" and that "[u]nlike natural justice, creation of a duty to consult on one subject implies that there is no duty to consult on another". <sup>46</sup>

[79] The authors of *Subordinate Legislation in New Zealand* state that empowering provisions in a statute often stipulate pre-conditions to making subordinate legislation,

Wellington City Council v Minotaur Custodians Ltd, above n 40, at [49].

<sup>&</sup>lt;sup>42</sup> At [49].

<sup>43</sup> At [50].

<sup>&</sup>lt;sup>44</sup> Taylor, above n 11, at 640.

At 640, citing *Wellington Regional Council v Post Office Bank Ltd* HC Wellington CP720/87, 22 December 1987 at [16]; and *West Coast United Council v Prebble* (1988) 12 NZTPA 399 (HC).

At 639, citing Move Over Probation Inc v Chief Executive, Department of Corrections HC Christchurch CIV-2010-409-1197, 21 April 2011.

including "that people who, or who represent interests that, are or may be affected by the proposed subordinate legislation have been consulted on it, or have been given a reasonable opportunity to make representations on it".<sup>47</sup> In a note to this comment, however, the authors suggest that pre-enactment consultation may be relied on.<sup>48</sup> The authors also comment that consultation with people outside the state sector "should not be undertaken in such a way that inhibits Cabinet decision-making".<sup>49</sup>

# [80] The authors later state:<sup>50</sup>

Consultation, which is a laudable part of the ordinary processes of government, does not require specific statutory authorisation. Rather, subject to any statutory directions, it can be done at the discretion of a Minister or other decision-maker in such a manner as the decision-maker thinks appropriate in the circumstances.

## Consultation adequately discharged

[81] Drawing the above principles together, I conclude that there was no requirement on the Governor-General to consult before making the amendment, and although consultation is a "healthy practice", the courts have generally not recognised an enforceable duty (unless consultation is imposed by the statute). The absence of any duty to consult is sufficient to dismiss this ground of review, but in any case the Minister did consult, as part of that "healthy practice", and the consultation process was adequate in canvassing the views of stakeholders.

[82] I do not accept the criticisms made by the applicants about the consultation process. It has not been established that stakeholders were misled as to either the nature or the significance of the consultation. Irrespective of whether the respondent's interpretation of cl 15 was correct, those being consulted on the amendment clearly understood that the level being proposed was a reduction, particularly given the reasoning that was provided as explanation for the proposed change, and particularly given that the other stakeholders in the targeted consultation were involved in tobacco or vaping fields.

<sup>&</sup>lt;sup>47</sup> Carter, McHerron and Malone, above n 14, at 72-73.

<sup>&</sup>lt;sup>48</sup> At 73

<sup>&</sup>lt;sup>49</sup> At 98, citing Cabinet Office *Cabinet Manual* (2008) at [7.44] with reference to [7.85].

<sup>&</sup>lt;sup>50</sup> At 237.

- [83] In respect of the time allowed for the consultation, although there was only two weeks provided, this must be seen in the context of the ongoing consultations, which included consultations around amendments that involved tightening restrictions on smoking and vaping, and reducing the addictiveness of single use vapes. Because the product, being an addictive substance, has consequences in terms of product safety requirements, those involved in the business of manufacturing, importing and selling vaping products, as well as other stakeholders, such as medical professionals working in the field, should already know and have the information available on which to make a submission. I accept that the Minister had a good reason for keeping the consultation period short, given the limited number of Cabinet meetings remaining until Parliament adjourned and given the urgency in addressing the rapid rise in youth vaping. As the respondent says, in any case, a substantial number of stakeholders did make submissions.
- [84] Because the consultation process was directed towards stakeholders who could be expected to have sufficient information to make an informed submission, there was no error in failing to provide information to allow stakeholders to respond to information in an informed way.
- [85] In terms of consultation with Māori and Pacific communities, while there was no consultation aimed specifically at Pacific communities, the consultation process included various Māori stakeholders and there was significant consultation with both Māori and Pacific communities in the preceding consultation in respect of single use vapes. Because the regulations concern a public health issue, the consultation that did occur was aimed at those working in the health profession and industry, which includes people who should be able to make informed submissions. In any case, any failure in this respect does not mean this ground is made out, as the Minister had a discretion as to how to conduct the consultation.
- [86] I accept the respondent's contention that it is incorrect that the Ministry failed to consult Te Aka Whai Ora (Māori Health Authority) and Te Whatu Ora (Health New Zealand). As both are Crown entities, they were consulted separately. In any case, Dr Hayden McRobbie of Te Whatu Ora was the chair of the Technical Working Group and commented that a reduction of the nicotine level to the proposed 28.5mg/mL was

arguably "justifiable as the landscape has changed" since the recommendation of the Technical Working Group in 2018, and that the position of Te Aka Whai Ora was that they "strongly support[ed] the recommendations towards making [vaping products] less addictive for youth" by reducing nicotine levels.

[87] In response to the applicants' claim that the decision to set the level at 28.5mg/mL was determined prior to any consultation, rendering any consultation process meaningless, the Minister was entitled to have a preference in respect of the new nicotine level and that does not render any consultation process meaningless. Because there is no enforceable duty to consult, some deficiency in consultation does not result in invalidity. As Professor Philip Joseph has noted in this regard, "Governments are, as a matter of constitutional propriety, expected to consult interested groups before introducing legislation, but that expectation does not support an enforceable duty." <sup>51</sup>

[88] In respect of the applicants' claim that the Ministry failed to consult other undefined smoking cessation providers, I accept that the consultation was a targeted consultation focused on manufacturers and importers which had previously notified vaping products to the Ministry under s 60 of the Act, to which list it added clinical groups, relevant non-governmental organisations and Māori interests. The decision as to who to consult was within the Minister's discretion. In any case, the Minister was entitled to focus consultation on relevant stakeholders, particularly given that the amendment of cl 15 is a public health issue guided by public health evidence, and there was no obligation to ensure that the public or every person who may have relevant knowledge had the opportunity to consult. It cannot be said that the Minister's decision on who to consult was irrational.

## Legitimate expectation to be consulted

[89] The respondent acknowledges that while the courts do not recognise a legitimate expectation to be consulted when making subordinate legislation, courts have more recently extended the reach of natural justice to found a legitimate expectation for certain persons to be consulted in the processes leading to the making

<sup>&</sup>lt;sup>51</sup> Joseph, above n 12, at 1193.

of certain types of subordinate legislation, and a corresponding duty to consult in such cases. Such cases may arise when a regulation affects an economic interest of a certain person or persons in a way that is significantly different from the way in which it is likely to affect the interest of the public generally.

[90] The leading case is the Court of Appeal decision in Fowler & Roderique Ltd v Attorney General. <sup>52</sup> In that case, Somers J and Casey J held there was no general requirement on the Minister to call for submissions before limiting the number of oyster dredging licences for conservation reasons, but given the circumstances of the applicant, namely that virtually every step taken by the Ministry, and every recommendation made by it over several years, was prompted by the appellant's interest in the restricted areas, it should have had an opportunity to make submissions. <sup>53</sup> Cooke P agreed and held that "in light of the unusual history and special circumstances" of the appellant, the Minister ought to have afforded it an adequate opportunity of being heard before issuing the directive in question. The respondent points out that other licence holders did not have to be consulted, even though the limitation in question in that case would effectively bar those holders from expanding their businesses.

[91] In the present case, the cl 15 regulation is a general regulation that applies to the public and is aimed at improving the general health of New Zealanders. The principles articulated in *Fowler & Roderique Ltd* can be distinguished on the basis that there are not the same special circumstances here as in that case. In particular, this case does not involve the cancellation of a licence and the presence of an involved party such as the applicant in that case. Importantly, the present case involved a public health regulation driven by health imperatives in circumstances where the statutory context establishes that there is no right to consultation. The principle in *Fowler & Roderique Ltd* can therefore have no application in this case.

[92] However, even if the principle in *Fowler & Roderique Ltd* were to apply, those who have a commercial interest in the regulations *were* consulted (and that consultation was adequate).

<sup>&</sup>lt;sup>52</sup> Fowler & Roderique Ltd, above n 12.

At 77 per Casey  $\hat{J}$ .

[93] The Governor-General, Executive Council and Minister were not bound by any legitimate expectation to consult. The fact they did undertake some consultation does not alter that situation. The Canadian Federal Court of Appeal in *Apotex Inc v Attorney General (Canada)*, dealt with a case where a Minister had actually written to the president of the Canadian Drug Manufacturers Association and stated "Rest assured that you will be consulted before any such regulations are established". The majority of the Court held that the undertaking was not enforceable in law, commenting that a minister could make a legally enforceable undertaking only with respect to a decision that was theirs and theirs alone to make. <sup>54</sup> In the absence of an express statutory delegation of authority, the majority of the Court held that a minister "[could not] bind the Governor in Council in the exercise of its regulation making power". <sup>55</sup> That observation applies equally in the present case.

[94] The consultation process undertaken by the Minister in the present case was essentially simply a part of the process of informing herself adequately on the relevant matters. In *Fowler & Roderique Ltd*, Casey J stated:<sup>56</sup>

... The contribution that could be made by an interested party to the decision-process [the Minister] may pay regard to, but is not obliged to ... in the end it is for the Minister to decide how much advice he wants as a matter of individual judgement.

[95] Those comments are apt here. The Minister in this case had sufficient information before her to make the referral to the Cabinet and Executive Council, including information from the Ministry of Health (including the Public Health Agency), which had been checked through the consultation process with experts in the fields and followed a preceding consultation regarding single use vapes.

[96] The applicants claim that they had a legitimate expectation that any material change to the maximum nicotine strength provided for in cl 15 would be informed by independent expert analysis and/or advice.

<sup>&</sup>lt;sup>54</sup> Apotex Inc v Attorney General (Canada) (2000) 188 DLR (4th) 144 (FCA) at [18].

<sup>&</sup>lt;sup>55</sup> At [18]

<sup>&</sup>lt;sup>56</sup> Fowler & Roderique Ltd, above n 12, at 77.

[97] The respondent says no such legitimate expectation could exist in this context, but that, if it did, any representation supporting such a legitimate expectation would have to be sufficiently focused and clear, unambiguous and unqualified.<sup>57</sup>

[98] The respondent says that the representation being relied on by the applicants appears to be the use by the Minister of the TEAG in 2017 when the regulations were made. I accept the respondent's submissions that having an expert advisory group such as the TEAG on an occasion when there is a significant regime overhaul does not create a representation that on each occasion a regulation is amended, independent experts will be consulted.

[99] In any case, the Minister referred the amendment to Cabinet on the basis of expert evidence and following a consultation process in which external experts were engaged.

[100] This particular claim of legitimate expectation appears to fall in the fourth category of legitimate expectation set out by Ronald Young J in *Talleys Fisheries Ltd* v *Cullen*, namely that a procedure not required by law will be held.<sup>58</sup>

[101] As contended by the respondent, I accept that such an expectation must be reasonable and usually based on a representation which was clear, unambiguous and unqualified. The Court stated that a legitimate expectation may arise either from an express promise given on behalf of the public authority or, more relevantly in this case, from the existence of a regular practice which the claimant can reasonably expect to continue.<sup>59</sup> The Court held that the more the decision is in the policy/political field, the less intrusive the courts are likely to be.<sup>60</sup>

[102] In implying a commitment from past practice, that commitment must be unambiguous, regular, well-established and covering the actual commitment that it will be followed.<sup>61</sup> A practice adopted in respect of one matter does not found a

<sup>&</sup>lt;sup>57</sup> Joseph, above n 12, at 1162.

Talleys Fisheries Ltd v Cullen HC Wellington CP287/00, 31 January 2002 at 48, adopted in Sinclair v Accident Compensation Corporation [2012] NZHC 406; [2012] NZAR 313.

<sup>&</sup>lt;sup>59</sup> At [48].

<sup>&</sup>lt;sup>60</sup> At [48].

<sup>61</sup> Green v Racing Integrity Unit Ltd [2014] NZCA 133, [2014] NZAR 623.

legitimate expectation in respect of a similar situation. <sup>62</sup> In *Southern Ocean Trawlers Ltd v Director-General of Agriculture and Fisheries*, the Court of Appeal held that even though the respondent had decided to allow overseas ownership beyond a certain limit in a particular fishing company, this did not give rise to a legitimate expectation of a hearing on the part of other quota holders. <sup>63</sup>

[103] Legitimate expectation of the nature of that pleaded by the applicants under this ground of review did not arise in this case. The fact that the Ministry had used the TEAG in respect of a preceding regulatory change did not mean that there was a clear and unambiguous representation that the Ministry would engage with the TEAG, or a body similar to it, in future regulatory change proposals. There is no evidence the use of such a body was an established practice, nor that it was a practice that was regular and one the applicants could reasonably expect to continue.

#### Failure to take into account relevant considerations

[104] The third cause of action is that the decision to amend cl 15 was flawed and/or failed to take into account relevant considerations. The basis for this seems to be the contention that the advice provided to Cabinet was inadequate. The applicants say the advice failed to provide fair, accurate and adequate information about the proposed cl 15 amendment.

[105] This proposition appears to be based on the views of Professor Bullen and Benjamin Youdan that vaping is harmless and more nicotine in vape products does not make them more addictive.

[106] The respondent says that there was no valid basis for such consideration to have been put before the Executive Council because the Executive Council, comprising the Ministers of the Crown, is simply not able to weigh competing theories. The respondent submits that attaching Appendix A and Appendix B (which

63 Southern Ocean Trawlers Ltd v Director-General of Agriculture and Fisheries [1993] 2 NZLR 53 (CA).

Singh v Branch Manager, New Zealand Immigration Service [1998] NZAR 97; and see Botany Bay City Council v Minister for Transport and Regional Development (1996) 66 FCR 537, (1996) 137 ALR 281 (FCA).

outlined the results of the consultation process) to the Cabinet paper which approved the amendment was more than sufficient.

## Analysis

[107] I accept the respondent's submissions on this point. The Court of Appeal has clearly stated that the Executive Council, as the body "at the apex of the governmental structure", necessarily only deals with major issues in a broad way.<sup>64</sup> The Governor-General acts on the advice of the Ministers comprising the Executive Council and cannot be expected to analyse the validity of competing and conflicting views. I am satisfied that attaching the appendices outlining the results of the consultation process in this case was sufficient to demonstrate that the recommendation was based on adequate information and followed an adequate process.

#### **Ultra vires**

[108] The fourth cause of action is an ultra vires pleading, essentially based on irrationality. It is pleaded that the amendment is arbitrary and/or unreasonable, does not address a safety issue and is therefore outside the scope of the empowering clause, and fails to advance the purpose of the Act, which is to minimise harm.

[109] Part 4 of the Act regulates the safety of notifiable products, including vaping products. As already noted, s 84(1)(a) provides that the Governor-General may, by Order in Council, make regulations prescribing safety requirements for regulated products that are notifiable products, which includes vaping products. Section 69 provides that a notifiable product must not contain a substance in excess of any maximum limit and that any legislation declared under that section is secondary legislation.

[110] The respondent submits that the applicants' challenge to the subordinate legislation is primarily because it is ultra vires, which includes unreasonableness: namely, that without express Parliament authorisation, the legislation is so

<sup>64</sup> CREEDNZ Inc v Governor-General, above n 32, at 177-178 per Cooke P, 188 per Richardson J and 206 per Somers J.

<sup>65</sup> Smokefree Environments and Regulated Products Act, s 2 definition of "notifiable product".

unreasonable that it would not have been contemplated by Parliament, because Parliament "would not have intended to authorise a regulation that has no logical connection with the underlying objects of the empowering Act and for which no one can think of any sensible explanation". 66 What matters is "not so much whether a regulation is unreasonable, but whether Parliament intended to authorise it". 67 The focus therefore lies on the scope given in the empowering statute.<sup>68</sup> The respondent submits the regulations are within the scope of the empowering statute.

[111] The respondent says the statutory scheme recognises that vaping is harmful, that its use should be reduced, and that people, especially young people, need to be protected.

[112] The respondent says that the Governor-General was correct to be concerned about youth vaping. It says how that is balanced against vaping as a smoking cessation aid is ultimately a matter of political and medical judgement, not amenable to judicial review.

[113] The respondent says the balancing exercise undertaken in this case is far removed from what is needed to establish a valid cause of action of unreasonableness, as a form of irrationality. The respondent says the two imperatives that were balanced are both purposes of the Act, namely reducing harm by regulation of smoked tobacco products, and providing for the regulation of notifiable products (including vaping products) in a way that seeks to minimise harm, especially harm to young people and children.<sup>69</sup> The respondent submits there was a logical connection between the balancing of those purposes and the amendment to the regulations in this case.

[114] The respondent also says that the amendment to cl 15 was supported by most of the submissions from "key organisations", and that many of those involved in the process, both as contributors and as officials, are qualified medical practitioners.

Wielgus v Removal Review Authority [1994] 1 NZLR 73 (HC) at 79; and see Carter, McHerron and Malone, above n 14, at 289.

<sup>67</sup> Carter, McHerron and Malone, above n 14, at 289.

Section 3A of the Smokefree Environments and Regulated Products Act.

[115] The respondent submits that while the applicants are correct that the genesis of the limit of 28.5mg/mL was the misunderstanding of the previous regulations, that does not make the decision to set the maximum nicotine strength at that level arbitrary and/or unreasonable, as the applicants allege. The respondent suggests that merely because there is room for debate as to the level at which maximum nicotine strength should be set to maximise population health does not render a decision to set it at a particular level irrational. The respondent says the advice of the TEAG, which suggested a maximum level of 60mg/mL in vaping liquids using nicotine salt, was given in 2018, before the "significant increase" in youth vaping. The respondent says thought was given as to whether 28.5mg/mL was the correct level, and this level was decided upon to balance the competing health considerations.

[116] The respondent says those considerations included the following, for which there is an evidential foundation in respect of each:

- (a) Vaping is an important smoking cessation tool.
- (b) Nicotine is addictive and the amount of nicotine consumed is relevant to the extent of addictiveness.
- (c) Other similar jurisdictions are reducing their smoking rates and have a nicotine level in vapes set at 20mg/mL, less than the 28.5mg/mL provided for in the amended cl 15.
- (d) Vaping is considerably less harmful than smoking. 70
- (e) There has been a rapid rise in vaping, and in particular with young people who were never smokers, and daily vaping rates for Māori, particularly Māori girls, are disproportionately high.

[117] The respondent says all of these factors were covered in the document provided by the Minister to the Cabinet and Executive Council.<sup>71</sup>

The respondent accepts that the long-term risks to health of vaping are not yet fully understood.

As Appendix A.

[118] The respondent says the Minister, supported by the Ministry (including the Public Health Agency) advocated for 28.5mg/mL as balancing the public health interests. As the Minister noted to Cabinet:

... We understand that these recommended limits [of TEAG] coincided with what was on the market at the time and that the TEAG's intention was that a current smoker would receive a "hit" of nicotine that was equivalent to that experienced when smoking a cigarette ... The public health considerations for setting maximum levels of nicotine go beyond providing a current smoker with what would be an equivalent hit of nicotine. They must also take account of the risk to young people that comes with making very high levels of nicotine available (such as 50 mg/mL or 60 mg/mL) ...

A higher limit than that set in the EU for example is justifiable in New Zealand at a time when we are moving towards mandating cigarettes that are non or minimally addictive.

Manatū Hauora will continue to monitor vaping trends, including uptake by youth ...

[119] The respondent says the amendment was a judgement call that sought to balance competing health interests. It says it is not something that can be weighed with mathematical certainty, but neither does it make the identified limit irrational or unreasonable. Consequently, the amendment was not irrational or unreasonable or ultra vires.

#### Analysis

[120] As discussed above, the empowering statutory provision for the regulations is 84(1)(a), which, as noted, provides that the Governor-General may, by Order in Council, make regulations prescribing safety requirements for regulated products that are notifiable products, which includes vaping products.

[121] Subordinate legislation must be within the provision it is claimed empowers making them by reason of their effect or purpose. If the provisions expressly invoked do not in law authorise the legislation, it will be invalid.<sup>72</sup> In *Carroll v Attorney-General for New Zealand*, Ostler J stated:<sup>73</sup>

<sup>&</sup>lt;sup>72</sup> Jensen v Wellington Woollen Manufacturing Co Ltd [1942] NZLR 394 (CA).

<sup>&</sup>lt;sup>73</sup> Carroll v Attorney-General for New Zealand [1933] NZLR 1461 (CA) at 1478.

... If [the regulation] is within the objects and intention of the Act, it is valid. If not, however reasonable it may appear, or however necessary it may be considered, it is ultra vires and void ...

[122] The "objects and intention of the Act" in this case are clearly set out in the Act, in particular in s 3A. The purposes include to provide for the regulation of smoked tobacco products to reduce harm, and to provide for the regulation of notifiable products (including vaping products) "in a way that seeks to minimise harm, especially harm to young people and children".

[123] Subordinate legislation may be invalid for unreasonableness, even if only on the basis that Parliament cannot have intended to authorise regulations that are unreasonable in the sense that no reasonable person could have made them.<sup>74</sup> In this respect, in *Aviation Industry Association of New Zealand Inc v Civil Aviation Authority of New Zealand*, McGechan J noted that it was always open to Parliament to stipulate that regulations shall not be invalid on the basis that they are unreasonable, but that it was "hardly likely" that Parliament would do so.<sup>75</sup>

[124] However, it is a long-established principle that, generally speaking, the courts "have no concern with the reasonableness of the regulation; they have no concern with its policy or that of the Government responsible for its promulgation." Rather, the courts "merely construe the Act under which the regulation purports to be made" to determine whether the regulation is within the objects and intention of the Act. As the authors of *Subordinate Legislation in New Zealand* state: <sup>78</sup>

A court is not entitled to hold invalid regulations which appear to be within the intention of Parliament merely because the court considers them unreasonable. Nor has the court any power to hold valid regulations which are not within the intention of Parliament merely because the court thinks them reasonable.

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See *Turners & Growers Exports Ltd v Moyle* HC Wellington CP720/88, 15 December 1988 at 53-54, approved in *Westco Lagan Ltd v Attorney-General* [2001] 1 NZLR 40 (HC) at [72].

Aviation Industry Association of New Zealand Inc v Civil Aviation Authority of New Zealand HC Wellington CP289/00, 24 August 2001 at [49].

<sup>&</sup>lt;sup>76</sup> Carroll v Attorney-General for New Zealand, above n 73, at 1478.

<sup>&</sup>lt;sup>77</sup> Δ+ 1478

Carter, McHerron and Malone, above n 14, at 257-258, citing F E Jackson & Co Ltd v Collector of Customs [1939] NZLR 682 (SC) at 720 per Callan J, cited with approval in *Ideal Laundry Ltd v Petone Borough* [1957] NZLR 1038 (CA) at 1048 per Finlay ACJ.

[125] In *Healthcare Providers New Zealand Inc v Northland District Health Board*, McGechan J held that a court "must constantly be on its guard not to overstep the mark on the irrationality ground for review." He emphasised that the question is not whether the Court thinks the decision is wrong or not the best decision which could have been made. He considered there were some "debatable" assumptions in the model used by the respondent in that case. Nevertheless, he went on to state:<sup>81</sup>

However, "debatable" does not mean "irrational". Indeed, it may well signal the opposite. It is not for the Court, on an irrationality submission, to weigh competing arguments of that character.

[126] The respondent says the focus for determination in a judicial review is not the "debatability" of different balances or approaches to goals, but whether the balancing exercise was undertaken within the bounds and scope of the empowering statute. I agree. As long as the regulation was made within the scope of s 84(1)(a), bearing in mind the objects and intention of the Act, it was not ultra vires. In *Cossens & Black Ltd v Prebble*, Heron J considered "[t]he Court should resist strongly a temptation to get its hands into the work of policy." It is clear on the evidence in this case that the Minister recommended the amendment with the purposes of the Act as set out above in mind. The balancing of those purposes, and the manner in which those purposes are met, is ultimately a matter for the Minister to recommend to Cabinet and the Executive Council. As Cooke J said in *New Zealand Drivers' Association v New Zealand Road Carriers*, "[i]t is elementary that the Court is not concerned with ... assessing the comparative value of social policies." 83

[127] Though the applicants challenge the decision to implement the cl 15 amendment as not being based on evidence, including independent expert analysis and/or advice, there was evidence capable of supporting the decision ultimately reached by the Minister, with the effect that the conclusion reached by the Minister was not totally irrational. I am satisfied the making of the regulation in this case was within the scope of the empowering provision, and as such was not ultra vires.

Healthcare Providers New Zealand Inc v Northland District Health Board HC Wellington CIV-2007-485-1814, 7 December 2007 at [216].

<sup>80</sup> At [216].

<sup>81</sup> At [219].

<sup>&</sup>lt;sup>82</sup> Cossens & Black Ltd v Prebble HC Wellington A318/84, 11 August 1987 at 9.

New Zealand Drivers' Association v New Zealand Road Carriers [1982] 1 NZLR 374 (CA) at 388.

**Outcome** 

[128] The applicants having been unsuccessful on all causes of action, the

proceedings are dismissed.

Costs

[129] I invite the parties to resolve costs between themselves, but, if that is not

possible, the respondent is to file and serve submissions of no greater than five pages

in length by 30 January 2024. The applicants will have 10 days to reply. Costs will

then be dealt with on the papers.

Churchman J

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