IN THE SUPREME COURT OF NEW ZEALAND

I TE KŌTI MANA NUI

SC 141/2016
[2018] NZSC 60

BETWEEN	NEW HEALTH NEW ZEALAND INCORPORATED Appellant
AND	SOUTH TARANAKI DISTRICT COUNCIL First Respondent
	ATTORNEY-GENERAL FOR AND ON BEHALF OF THE MINISTER OF HEALTH Second Respondent

Hearing:	16 and 17 November 2017
Court:	Elias CJ, William Young, Glazebrook, O'Regan and Ellen France JJ
Counsel:	M T Scholtens QC, L M Hansen and T Mijatov for Appellant D J S Laing and H P Harwood for First Respondent A M Powell and S K Jameson for Second Respondent
Judgment:	27 June 2018

JUDGMENT OF THE COURT

A **The appeals from the decision of the Court of Appeal in relation to CA529/2015 and CA615/2014, referred to respectively as the Regulations and Medicines Act appeals, are dismissed.**

B **Costs are reserved. Any memoranda on costs may be filed by 31 July 2018.**

REASONS

ELIAS CJ, GLAZEBROOK, O'REGAN AND ELLEN FRANCE JJ
(Given by Ellen France J)

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Introduction

[1] This is an appeal against aspects of a decision of the Court of Appeal which dealt with a number of issues relating to the fluoridation of water in New Zealand.[1]

[2] The Court of Appeal decision addressed appeals by New Health New Zealand Inc (New Health) against three separate High Court judgments dealing with different questions concerning the legality of fluoridation.[2] New Health was granted leave to appeal on all aspects of the Court of Appeal's decision.[3] We heard these matters together but this judgment deals only with the issues arising out of what are referred to as the Regulations and the Medicines Act appeals. Judgment on the third set of

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1 *New Health New Zealand Inc v South Taranaki District Council* [2016] NZCA 462, [2017] 2 NZLR 13 (Randerson, Wild and French JJ) [*New Health* (CA)].

2 *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834 (Rodney Hansen J) [Council judgment]; *New Health New Zealand Inc v Attorney-General* [2014] NZHC 2487 (Collins J) [Medicines Act judgment]; and *New Health New Zealand Inc v Attorney-General* [2015] NZHC 2138, [2015] NZAR 1513 (Kós J) [Regulations judgment].

3 *New Health New Zealand Inc v South Taranaki District Council* [2017] NZSC 13.

issues, described as the Council appeal, is being delivered at the same time as this judgment.[4]

The Regulations Appeal

Introduction

[3] This part of the judgment concerns the validity of the Medicines Amendment Regulations 2015 (the Regulations) which came into force from 30 January 2015. The Regulations amended the Medicines Regulations 1984 by inserting a new reg 58B. Regulation 58B(2) provides that "[f]luoridating agents for use in fluoridating drinking water are not medicines" for the purposes of the Medicines Act 1981. Further, reg 58B(3) states that the addition of fluoridating agents to the drinking water supply would not be a medicine for the purposes of the Medicines Act. "Fluoridating agents" for these purposes are defined as:[5]

> (a) hydrofluorosilicic acid [(HFA)]:
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> (b) sodium fluoride:
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> (c) sodium silicofluoride [(SSF)]:
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> (d) any other substance that releases fluoride when added to water.

[4] The Regulations were promulgated following the decision of Collins J dismissing New Health's application for a declaration that HFA and SSF were medicines as defined in the Medicines Act.[6] Collins J found neither compound was a medicine but, in the course of the judgment, the Judge suggested that the Ministry of Health "may wish to consider recommending a Regulation that exempts HFA and SSF from the definition of 'medicine' when those compounds are used to fluoridate water".[7]

[5] After the Regulations came into force, New Health brought judicial review proceedings challenging their validity on a number of grounds including improper

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4 *New Health New Zealand Inc v South Taranaki District Council* [2018] NZSC 59 [Council appeal].
5 Regulation 58B(4).
6 Medicines Act judgment, above n 2.
7 At [51].

purpose and failure to take into account relevant considerations. Kós J dismissed New Health's application for judicial review of the Regulations[8] and New Health then appealed unsuccessfully to the Court of Appeal. The Regulations appeal relates to the Court of Appeal's decision to uphold the decision of Kós J.[9] We address the issues arising on this aspect of the case after first setting out the background facts, the statutory framework and a summary of the judgments below.

Background

[6] The narrative of events following the delivery of the judgment of Collins J on the Medicines Act on 9 October 2014 is set out in the decision of the Court of Appeal.[10] For present purposes we need only note some key matters.

[7] The first point to note is that New Health filed an appeal against the judgment of Collins J (the Medicines Act appeal) on 28 October 2014. Various procedural applications were made after that including an unsuccessful application by New Health to have the Medicines Act appeal fast-tracked to the Court of Appeal.

[8] Second, the hearing of the Medicines Act appeal was subsequently adjourned by the Court of Appeal pending the decision of Kós J on the validity of the Regulations. Ultimately, as we have noted, the Court of Appeal heard the three appeals together, that is, the Council appeal (relating to the power to fluoridate), the Regulations appeal and the Medicines Act appeal. The Court decided that the Medicines Act appeal was moot.

The regulation-making power in the Medicines Act

[9] Section 105 of the Medicines Act provides for the Governor-General to make regulations for any of the listed purposes after a consultation process has been undertaken. The listed purposes include identifying the substances that are or are not medicines. Section 105(1) relevantly states:

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8 Regulations judgment, above n 2.
9 *New Health* (CA), above n 1.
10 At [168]–[175].

> (1) The Governor-General may from time to time, by Order in Council made on the advice of the Minister tendered after consultation with such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations, make regulations for all or any of the following purposes:
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> …
>
> (i) specifying, by name or description, substances or articles, or kinds or classes of substances or articles, that are, or are not, medicines or medical devices for the purposes of this Act:
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> …

[10] Where a regulation specifies that a substance is not a medicine, the effect is to remove the substance from the statutory definition of "medicine" in s 3(1). Section 3(1) provides, relevantly, that "unless the context otherwise requires" medicine means substances manufactured and sold principally for administering for a therapeutic purpose. The definition then excludes various substances including those declared by regulations not to be medicines. Section 3(1)(c) states that "medicine" does not include:

> (i) a medical device; or
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> (ii) any food within the meaning of section 2 of the Food Act 1981; or
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> (iii) any radioactive material within the meaning of section 5(1) of the Radiation Safety Act 2016;[11] or
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> (iv) any animal food in which a medicine (within the meaning of paragraph (a) or (b)) is incorporated; or
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> (v) any animal remedy; or
>
> (vi) any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act.

[11] We add that, as the Court of Appeal noted, the process leading to the promulgation of the Regulations began on 20 November 2014 when the Minister of Health received a report from officials recommending regulation.[12] A consultation process ensued and, after the period for consultation closed on 9 January 2015, a draft

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11 At the time of the Medicines Act judgment this referred to s 2(1) of the Radiation Protection Act 1965.

12 *New Health* (CA), above n 1, at [170].

Cabinet paper was provided to the Minister on 16 January 2015. Ultimately, an Order in Council was made on 27 January 2015.

The approach taken in the High Court and the Court of Appeal

[12] Kós J rejected the claim the Regulations were made for an improper purpose. The Judge said it was open to the Executive to confirm whether or not HFA and SSF were covered by the Medicines Act regime. Further, Kós J found that the Regulations did not extinguish New Health's appeal although they did impair its "practical utility".[13]

[13] The Judge also rejected both New Health's complaints about the consultation process and its claim that the decision to make the Regulations was irrational. Nor did the Judge consider that the regulations were inconsistent with s 27(2) of the New Zealand Bill of Rights Act 1990 (the right to apply for judicial review). Finally, Kós J dismissed an argument that the Minister had failed to take into account relevant considerations.

[14] The Court of Appeal similarly found the Minister had not acted for an improper purpose. The Court considered it was not improper to give "certainty to those distributing and using [the relevant compounds] for the purpose of water fluoridation or for the purpose of averting collateral challenges in the High Court to the judgment of Collins J".[14] The impact on New Health's rights of appeal was "a consequence of the legitimate exercise of the power of the Executive Council and not unlawful".[15]

The arguments on appeal

[15] The key points of the appellant's case that the Regulations are invalid can be summarised in this way. First, invalidity arises because the Regulations were made on the basis of an error of law. Second, and associated with the first point, it is contended that in the exercise of the regulation-making power it was necessary to squarely confront whether the Medicines Act should apply to the various compounds.

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13 Regulations judgment, above n 2, at [46].
14 *New Health* (CA), above n 1, at [195] per Randerson J.
15 At [199].

This required that the Minister must understand the present status of that substance. Finally, the appellant says the Regulations were made on the basis of an improper purpose, namely, to render New Health's appeal in relation to the decision of Collins J on the Medicines Act moot.

Discussion

[16] We turn first to the submission that the Regulations were made on the basis of an error of law. The argument in this respect is that the Regulations were premised on the High Court correctly stating the law. On this basis, the submission is that the correctness of the High Court decision is a condition precedent to the lawful exercise of the regulation-making power.

[17] It is not necessary in addressing this submission to traverse the principles relating to the approach to determining challenges to the validity of delegated legislation.[16] The short answer to this (and the other submissions made by New Health on this aspect of the case) is that there is no improper purpose where the effect of the Regulations is prospective. We need only address New Health's submissions briefly.

[18] The first of the arguments made by New Health is based on a false premise. The evidence on the making of the Regulations makes it clear the concern was to clarify the law. Although the position taken by the Ministry of Health was that the compounds dealt with in the Regulations were not medicines, it was considered desirable to clarify the position. Three examples will suffice.

[19] The Ministry of Health's briefing paper to the Minister, dated 20 November 2014, recommended accepting advice from the Crown Law Office to progress an amendment to the Regulations "to provide legal clarity". The consultation paper published by the New Zealand Medicine and Medical Devices Safety Authority (Medsafe) in November 2014 explained the perceived benefits of the proposed amendment as being to "preserve the status quo and provide legal clarity about the

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16 For a discussion of the authorities see Philip A Joseph *Constitutional and Administrative Law in New Zealand* (4th ed, Thomson Reuters, Wellington, 2014) at 1124–1125, 1127–1131 and 1134–1139. See also *Cropp v Judicial Committee* [2008] NZSC 46, [2008] 3 NZLR 774 at [6] and [25]–[26] per Blanchard J citing *Drew v Attorney-General* [2002] 1 NZLR 58 (CA) at [68]; and *Harness Racing New Zealand v Kotzikas* [2005] NZAR 268 (CA) at [56]–[62].

regulatory status of the fluoride compounds". Finally, the Cabinet paper of January 2015 said the purpose of the Regulations was to "provide legal clarity".

[20] Accordingly, even assuming for these purposes that an error of law of the nature contended for could lead to invalidity, there was no error of law.[17] As the Court of Appeal noted, the Regulations in this case were made for the purpose of "promoting legal certainty".[18] That was a lawful purpose.

[21] The appellant also argues that the error arises because the Regulations were made to confirm an incorrect view of the law, namely, that the compounds were not medicines. As we have indicated, this argument fails because the Regulations are prospective. In any event, s 105 of the Medicines Act answers the point. Section 105(1)(i) expressly contemplates the making of a Regulation which clarifies whether or not a substance is a medicine for the purposes of the Act. Ms Hansen for New Health accepted that if there was no mistake about the status of the compounds, they could be exempted from coverage of the Act. Whether, as the Court of Appeal said, the substance was, or was not, a medicine under the Act before the Regulations were made is not material.[19]

[22] The authorities relied on by New Health in this context are not on point. The submission is that these cases support the view that if the Regulations were based on a decision that was subsequently determined to be unlawful, the actions taken in reliance on the Regulations are vitiated. However, the authorities relied on reflect different factual circumstances and do not deal with the validity of the exercise of a regulation-making power.[20]

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17 We are not to be taken as commenting on whether or not an error of the type alleged could provide a basis to invalidate regulations.

18 *New Health* (CA), above n 1, at [199].

19 At [190].

20 For example, *McNally v Attorney-General* [2010] NZCA 571, [2011] 2 NZLR 137 concerned a judicial review of a decision to stay a prosecution under the Fisheries Act 1996 and raised questions about the impact of an earlier judicial decision subsequently held to be incorrect; *R v Governor of Brockhill Prison, ex parte Evans (No 2)* [2001] 2 AC 19 (HL) dealt with a claim of false imprisonment arising from the calculation of a release date which was based on earlier decisions of the Divisional Court subsequently overruled; and *Kleinwort Benson Ltd v Lincoln City Council* [1999] 2 AC 349 (HL) concerned the recovery of money paid on the basis of settled law which was subsequently changed by a judicial decision. See also Lord Woolf and others *De Smith's Judicial Review* (8th ed, Sweet & Maxwell, London, 2018) at [4-067]–[4-069].

[23] Ms Hansen referred in particular to *R (Shoesmith) v OFSTED*.[21] That case dealt with the fallout from an inquiry into child protection services provided by a local authority. Ms Shoesmith was summarily dismissed from her position as Director of Children's Services by OFSTED[22] (her employer) at the direction of the Secretary of State. The direction was found to be unlawful because the Secretary of State had acted unfairly.[23] By a majority, the Court of Appeal concluded the decision to dismiss was vitiated by the finding of unlawfulness in relation to the direction.[24] Those circumstances are distinguishable from those in the present case because the Regulations are effective and not contingent on the validity of the determination made by Collins J. In contrast the dismissal in *OFSTED* was dependent on the lawfulness of the direction.

[24] We also do not see any merit in New Health's second point, that is, that the decision-making process failed because there was no consideration of the merits of the application of the Medicines Act. The evidence shows that the effect of the consultation process was to raise for consideration the concerns expressed by the appellant about the appropriateness of the application of the Medicines Act to the compounds in issue. The consultation process also raised issues about the perceived inadequacy of the other statutory regimes providing for the regulation of the compounds.

[25] A large number of the submissions received as part of the consultation process were opposed to the proposed change and raised the same sorts of concerns advanced by New Health in its submission.[25] The material before us indicates these concerns were considered as part of the consultation process. As Kós J put it:[26]

> … the key consideration for the Minister here was whether, if the compounds were exempted from the Act's controls, they would nonetheless be controlled effectively through the wider statutory framework. And the Minister was entitled to conclude that they would.

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21 *R (Shoesmith) v OFSTED* [2011] EWCA Civ 642, [2011] LGR 649.
22 Office for Standards in Education, Children's Services and Skills.
23 At [67] and [75] per Kay LJ.
24 At [138] per Burnton LJ and [148] per Lord Neuberger MR.
25 Kós J notes 1411 submissions were received including New Health's submission and that 1339 of that total opposed the proposed change: Regulations judgment, above n 2, at [15].
26 At [89].

[26] We turn then to the final argument that the regulations were based on an improper purpose because of their effect on New Health's Medicines Act appeal. It is relevant in this context, as we have said, that the Regulations applied prospectively, not retrospectively. The prospective nature of the Regulations distinguishes the present case from that of *R (Reilly) v Secretary of State for Work and Pensions (No 2)* which is the high point of the case for New Health on this aspect.[27]

[27] The appellants in *Reilly* had succeeded in the Court of Appeal of England and Wales in showing that the Jobseeker's Allowance (Employment, Skills and Enterprise Scheme) Regulations 2011 (which affected their receipt of a jobseeker's allowance) were ultra vires.[28] While appeals by the Secretary of State from the decision of the Court of Appeal were pending, legislation was introduced and enacted which validated the 2011 Regulations thereby depriving the appellants of the fruits of their litigation. The appellants sought judicial review on the basis the Jobseekers (Back to Work) Schemes Act 2013, by retrospectively validating the actions of the Secretary of State under the Regulations, was inconsistent with art 6 the European Convention on Human Rights.[29] Before the application for judicial review was considered the Supreme Court, on the Secretary of State's appeal from the decision declaring the 2011 Regulations ultra vires, concluded that the 2011 Regulations were ultra vires but allowed the appeal because the 2013 Act had come into force.[30]

[28] Lang J concluded that the 2013 Act was inconsistent with the protection in art 6(1) of the European Convention on Human Rights of the right to a fair and public hearing by an independent and impartial tribunal. Lang J said that the power to legislate to overrule the effect of a judgment: [31]

> generally ought not to take the form of retrospective legislation designed to favour the executive in ongoing litigation … brought against it by one of its citizens, unless there are compelling reasons to do so. Otherwise it is likely to offend a citizen's sense of fair play.

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27 *R (Reilly) v Secretary of State for Work and Pensions (No 2)* [2014] EWHC 2182 (Admin), [2015] QB 573 [*Reilly* (HC)], upheld on appeal in *R (Reilly) v Secretary of State for Work and Pensions (No 2)* [2016] EWCA Civ 413, [2017] QB 657. The latter decision did not disturb the reasoning of Lang J.

28 *R (Reilly) v Secretary of State for Work and Pensions* [2013] EWCA Civ 66, [2013] 3 All ER 67.

29 Convention for the Protection of Human Rights and Fundamental Freedoms, 213 UNTS 221 (opened for signature 4 November 1950, entered into force 3 September 1953).

30 *R (Reilly) v Secretary of State for Work and Pensions* [2013] UKSC 68, [2014] AC 453.

31 *Reilly* (HC), above n 27, at [82].

[29] Here, where the purpose was to clarify the law prospectively, albeit with a consequential effect on the utility of the appellant's appeal, the same concern does not arise. Indeed, Lang J in *Reilly* considered that the "usual course" would be to prospectively amend the regulations to correct the earlier error.[32]

[30] For these reasons, we would dismiss the Regulations appeal.

Was the Court of Appeal correct to find the Medicines Act appeal was moot?

[31] The Court of Appeal declined to hear the Medicines Act appeal on the basis it was moot. The Court said there was no longer a live issue as between the parties and that the making of the Regulations settled the controversy for the future. The Court did not accept there was any utility in determining what the position was in the period prior to 30 January 2015 when the Regulations came into force.[33]

[32] New Health takes issue with this conclusion noting, first, the Regulations were prospective. Secondly, New Health advances several bases which it is said show a live issue remains which should be decided. These grounds can be summarised as follows:

(a) the Court's determination of the issue will demonstrate whether or not the Crown has complied with its obligations under the Medicines Act;

(b) whether the Medicines Act has been properly administered is a question of wider public significance especially where the effect of the decision of Collins J is to create a loophole; and

(c) if the Court decided HFA and SSF were medicines this would lead to the invalidation of the Regulations.

[33] We consider the Court of Appeal was right. The Court in rejecting New Health's argument on this part of the appeal applied the applicable principles,

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32 At [90]. Lang J's observation was made in the context of her Honour's acceptance that the first claimant had given no thought to the possibility the Government would legislate retrospectively in this way if her claim was successful.

33 *New Health* (CA), above n 1, at [212].

those set out in *R v Gordon-Smith*.[34] The Court in *R v Gordon-Smith* confirmed the jurisdiction to hear a moot appeal but noted the cautious approach adopted to hearing such appeals.[35] Nothing raised by New Health overcomes that caution. That is because the point of the appeal has been overtaken by the Regulations, which have been validly made. The Regulations prevent the relief New Health may have obtained on appeal if successful and that is what makes the appeal moot. In the course of oral argument Ms Hansen also suggested that there was utility in hearing the appeal because of the implications for costs for New Health in relation to the High Court and the Court of Appeal. This submission was not pressed and, in the present context where the utility is said to stem from broader public issues which are now moot because of the change to the Regulations, was rightly not at the forefront of the argument.

[34] For these reasons, we would uphold the decision of the Court of Appeal that the Medicines Act appeal is moot.

The Medicines Act appeal

[35] On this approach, it is not necessary to address the Medicines Act appeal and we do not do so.

[36] For completeness, we add a brief comment about the argument addressed by William Young J (in the judgment on the Council appeal being delivered at the same time) that fluoride comes within the definition of "food" in s 2 of the Food Act 1981.[36] If fluoride is a "food" as defined in the Food Act, that brings it within one of the express exclusions from the definition of "medicine" in s 3(1)(c) of the Medicines Act. We do not need to consider the correctness of that approach and we do not do so.

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34 *R v Gordon-Smith* [2008] NZSC 56, [2009] 1 NZLR 721.

35 At [16]–[18] and see [24] and [29] per McGrath J.

36 The Council appeal, above n 4, per William Young J at [201]. The definition in force at the time of the Medicines Act judgment encompassed "anything … used or represented for use as … drink for human beings;" and included "anything that is or is intended to be mixed with or added to any food or drink;": s 2. The current definition in s 9 of the Food Act 2014 is not materially different.

Conclusion

[37] Accordingly, that part of the appeal relating to the Regulations appeal and as to the correctness of the Court of Appeal's decision that the Medicines Act appeal was moot is dismissed. The Medicines Act appeal accordingly falls away and is formally dismissed.

[38] The position as to costs is unclear. Costs are accordingly reserved. Any memoranda on costs may be filed by 31 July 2018.

WILLIAM YOUNG J

[39] I agree that the Regulations appeal should be dismissed for the reasons given by Ellen France J.

[40] As will be apparent from my reasons in the Council appeal, I am of the view that the judgment of Collins J in the Medicines Act litigation was correct, albeit for different reasons. So I would have been content to dismiss the Medicines Act appeal on that basis. I do, however, agree with Ellen France J that there is no practical need to decide the Medicines Act appeal and that, for this reason, it can properly be regarded as moot.

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