Federal Court of Australia

District Registry: New South Wales

Proceeding: NSD349/2023

Anthony Leith Rose & Ors

Applicants

The Secretary of the Department of Health and Aged Care Brendan Murphy

First Respondent

John Skerritt

Second Respondent

Paul Kelly, Chief Medical Officer

Third Respondent

Greg Hunt, Minister of the Department of Health and Aged Care

Fourth Respondent

The Commonwealth of Australia

Fifth Respondent

APPLICANTS' SUBMISSIONS

Leave – Written Submissions

1. The applicants seek leave to rely on written submissions with a page length of 20 pages.

Summary Judgement & Strike Out

2. The respondents seek summary judgement against the applicants. Such is not to be exercised lightly,[1] approached with exceptional caution,[2] and only granted if the Court is satisfied that the party has no reasonable prospect of success.[3] The onus lies with the respondents,[4] who must established that the proceeding *does not* have prospects which are *real and do not rise above the fanciful or merely arguable*.[5] The application is likely to fail where on a critical examination, the Court is satisfied that there appears a real question of fact to be determined,[6] or that success relies upon a question of law that is serious, important, difficult, likely to require lengthy argument, or involves conflicting authority.[7] The respondents' application fails substantially in these respects and ought to be dismissed. The application's timing and nature are misconceived. The respondents have not filed a defence. Where the proceedings involve questions of mixed fact and law as in this case,[8] the complexity requires a full hearing.[9] An application of this nature is undesirable where the factual foundations for determination have not been presented, tested or resolved.[10] The Court is in the invidious position of being asked to proceed upon a deficit of a complete factual and legal understanding in the absence of the fundamental steps of a filed defence or discovery,[11] retaining the discretion to deal with the motion at a later stage.[12]

3. The respondents apply in the alternative for all or part of the pleading to be struck out based upon various assertions by mischaracterization of the pleading as "vague" and "embarrassing". The onus here lies upon the respondents and is very high.[13] The striking out of the whole claim bringing the proceeding to an end "requires a firm conclusion that '*no reasonable amendment could cure the alleged defect and there was no reasonable question to be tried'…[which] is not a conclusion lightly to be reached*" and "*the absence of any reasonable basis upon which the case should proceed to trial must be clearly demonstrated*".[14] To succeed in the respondents' claimed bases of strike out require that the applicants' case "*must be so untenable that it cannot succeed*" and the use of a power "*exercised only in a plain and*

[1] ***ThoughtWare*** *Australia Pty Limited v IonMy Pty Ltd* [2023] FCA 906 per Derrington J at [48] citing ***Spencer*** *v Commonwealth* (2010) 241 CLR 118 at 131 – 132 [24] per French CJ and Gummow J, 141 [60] per Hayne, Crennan, Kiefel and Bell JJ).
[2] *Thoughtware* at [48].
[3] *ThoughtWare* at [48] citing Spencer at 140 – 141 [56] – [60] per Hayne, Crennan, Kiefel and Bell JJ.
[4] *ThoughtWare* at [51] citing ***Buurabalayji*** *Thalanyji Aboriginal Corporation v Onslow Salt Pty Ltd (No 2)* [2018] FCA 978 at [3].
[5] *Thoughtware* at [50] citing ***Prior*** *v South West Aboriginal Land and Sea Council Aboriginal Corporation* [2020] FCA 808 at [29].
[6] *ThoughtWare* at [50] citing Prior at [29] and *Australian Securities and Investments Commission v* ***Cassimatis*** (2013) 220 FCR 256 at [47].
[7] *ThoughtWare* at [50] citing Prior at [29] and Cassimatis at [48]; *Luck v University of Southern Queensland* [2008] FCA 1582 at [14]-[15].
[8] *Tooheys Ltd v Minister for Business and Consumer Affairs* (1981) 54 FLR 421 at 437 per Ellicott J cited with approval in ***SmithKline*** *Beecham (Australia) Pty Ltd v Chipman* [2002] FCA 674 at [30].
[9] *ThoughtWare* at [50] citing Prior at [29] and Cassimatis at [49].
[10] *SmithKline* at [35] citing *Rocklea Spinning Mills Pty Ltd v Anti-Dumping Authority* (1995) 56 FCR 406.
[11] *Thoughtware* at [51] citing Cassimatis at [46].
[12] *Thoughtware* at [51] citing Buurabalayji at [3]; *Kimber v Owners of Strata Plan No 48216* (2017) 258 FCR 575 at [62] per Full Court.
[13] ***Salvation Army*** *(New South Wales) Property Trust v Commonwealth of Australia* [2015] FCA 674 at [28] per Jagot J.
[14] *Elston v Commonwealth* [2013] FCA 108 at [32] per Logan J.

obvious case."[15] The pleaded and highly particularised case of the applicants disclose on their face the baselessness of the respondents' assertions - the pleadings make clear the case against them. The application should be refused, particularly because the legal and factual issues the Court must decide have not crystallised.[16]

4. Upon the correct approach, the application should proceed upon the basis that the pleaded allegations of fact are true as the respondents have elected not to adduce evidence,[17] and further inferences may also be drawn in favour of the applicants.[18] References to the Concise Statement are irrelevant to the application.[19]

The Negligence Claim

5. The respondents' submissions **("RS")** generally assert that the posited duty of care does not arise per the "salient features" standard,[20] is indeterminate,[21] incoherent with the law,[22] and regulates policy decisions.[23] The respondents further assert immunity pursuant to s. 61A of the *Therapeutic Goods Act 1989* **("the Act")**,[24] and a failure to properly plead breach and causation.[25] The respondents' submissions employ misapplication of principle and selective application of factual matters to the posited duty arising upon the applicants' case.

6. Generally, a duty analogous to a statutory duty and liability for breach arises in respect of a particular class when a power is intended to be exercised for the benefit or protection of that class as in this case.[26] Where the power is to control "conduct or activities which may foreseeably give rise to a risk of harm to an individual" and conferred for avoiding such risk as in this case, liability for any failure accords with the policy of the statute.[27] Tortious liability of government is approximate to citizens, only differing in concerns and obligations[28] arising in the purpose of the relevant powers. A duty owed by the respondents is unavoidably care for safety of those affected by their actions,[29] primarily physical integrity.[30]

7. The respondents suggest the salient features test indicates against the posited duty on the basis of indeterminacy,[31] but omits the preponderance of *positive* salient features establishing that duty.[32] Save

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[15] *Salvation Army* at [2] per Jagot J. citing *Hodges v Sandhurst Trustees Limited* [2014] FCA 1223 at [7].
[16] See *Salvation Army* at [28] per Jagot J.
[17] *Young Investments Group Pty Ltd v Mann* (2012) 293 ALR 537; [2012] FCAFC 107 at [6] per Emmett, Bennett and McKerracher JJ.
[18] *Adnunat Pty Ltd v ITW Construction Systems Australia Pty Ltd* [2009] FCA 499 at [37]
[19] See e.g. *Allianz Australia Insurance Limited v Delor Vue Apartments CTS 39788* [2021] FCAFC 121 at [140] - [154].
[20] RS [14] –[16] and [32].
[21] RS [17] –[21].
[22] RS [22] –[27]
[23] RS [28] –[31]
[24] RS [33].
[25] RS [34] –[35].
[26] ***Pyrenees*** *Shire Council v Day* (1998) 192 CLR 330 per Brennan CJ at [24], [25].
[27] *Pyrenees* per Brennan CJ at [25].
[28] ***Graham Barclay*** *Oysters Pty Ltd v Ryan (2002) 211 CLR 540* at [12] per Gleeson CJ.
[29] *Graham Barclay* at [90].
[30] ***Ku-ring-gai*** *Council v Chan* [2017] NSWCA 226 at [72] per Meagher JA (McColl JA, Sackville AJA agreeing).
[31] RS [16] –[21].
[32] 3rd Further Amended Statement of Claim, filed 7 May 2024 **("SOC")** para. 73.

for foreseeability, no salient feature is singly compulsory or determinative, but cumulative in effect[33] attaining significance upon the facts.[34] Salient features of the facts establish the posited duty.[35]

8. **Foreseeability of Harm**. Reasonable foreseeability remains the touchstone of the respondents' duty determined at "a higher level of abstraction" than breach or damage,[36] requiring that the Group Members were reasonably foreseeable as *members of a class who could be injured by the respondents' failure to take reasonable care*.[37] Heightened probability of serious harm carries a heightened obligation to act with precaution,[38] as does obviousness of risk.[39] The instant facts establish an extreme appreciation of serious injury,[40] and further[41] establishes the foreseeability of harm inherent in causing receipt of the Vaccines by Group Members,[42] knowledge establishing the absence of safety, efficacy and necessity in the Vaccines,[43] real-time knowledge of prolific reporting of adverse events among recipients of the Vaccines,[44] the respondents' concurrent making of bold public statements as to the safety, efficacy and necessity of the Vaccines[45] and absolute degree of control over the availability of the Vaccines for consumption,[46] the vulnerability of Group Members to the conduct of the respondents,[47] respondents acting with the knowledge and intent to cause the Group Members to consume the Vaccines,[48] respondents' knowledge that the circumstances would expose recipients to the risk of harm,[49] the respondents' knowledge that because of their respective positions, the Group Members would profoundly rely upon the respondents' acting with requisite care,[50] and knowledge of the obvious and inherent risk associated with such conduct.[51] That these facts plainly render as foreseeable severe harm to the consumer is self-evident and indicating that a relevant duty of care has arisen.

9. **Knowledge of the Risk**. The respondents' knowledge of the risk of harm to the Group Members is a relevant positive consideration, particularly where there is a vast disparity of knowledge regarding potential risks.[52] The respondents' knowledge of risk was profound and both inherent due to the nature

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[33] ***Makawe*** *Pty Ltd v Randwick City Council* [2009] NSWCA 412 at [48] per Hodgson JA.
[34] ***Dansar*** *Pty Ltd v Byron Shire Council* (2014) 89 NSWLR 1; [2014] NSWCA 364 at [109] per Meagher JA.
[35] ***Caltex*** *Refineries (Qld) Pty Ltd v Stavar* (2009) 75 NSWLR 649 per Allsop P at [102]. See further ***Crimmins*** *v Stevedoring Industry Finance Committee* (1999) 200 CLR 1 at [93] per McHugh J; *Graham Barclay* at [146], [149] per Gummow and Hayne JJ, [84] per McHugh J; ***Stuart*** *v Kirkland-Veenstra* (2009) 237 CLR 215 at [114] per Gummow, Hayne and Heydon JJ, 261–2 [137]–[138] and [149] per Crennan and Kiefel JJ.
[36] See *Sydney Water Corporation v* ***Turano*** (2009) 239 CLR 51 at [45] per French CJ, Gummow, Hayne, Crennan and Bell JJ.
[37] *Turano* at [45] per French CJ, Gummow, Hayne, Crennan and Bell JJ; ***Sullivan*** *v Moody* (2001) 207 CLR 562 at [42] per Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ.
[38] *Roads and Traffic Authority of NSW v* ***Dederer*** (2007) 234 CLR 330 at [59]; See also ***Farriss*** *v Axford* [2023] NSWCA 255 at [19] - Full Court.
[39] *Farriss* at [19] per Full Court.
[40] See particularly SOC para. 61-64, 69-71.
[41] See Foreseeability – SOC para. 22 to 38, 42 to 64, 69 to 75, 77, 78, and 80 to 84; Particulars - Schedule B para.1 to 155.
[42] Conduct - SOC para. 51-60. Causation SOC para. 83-84.
[43] See particularly SOC para. 42 and 43.
[44] See particularly SOC para. 37(n) and prolific adverse events reported at SOC para. 118-120.
[45] See particularly SOC para. 44 -50.
[46] See particularly SOC para. 61.
[47] See particularly SOC para. 70.
[48] See particularly SOC para. 51-60.
[49] See particularly SOC para. 69.
[50] See particularly SOC para. 63.
[51] See particularly SOC para. 74 – 82.
[52] *Pyrenees* at [108] per McHugh J), [168] per Gummow J), [246] per Kirby J; *Crimmins* at [3] per Gleeson CJ, [43] and [46] per Gaudron J, [93] and [101]–[102] per McHugh J, [233] per Kirby J; ***Armidale*** *City Council v Alec Finlayson Pty Ltd* (1999) 104 LGERA 9; [1999] FCA 330 at [27]; ***Amaca*** *Pty Limited v NSW & Anor* [2004] NSWCA 124 at [157]; ***Port Stephens*** *Shire Council v Booth* [2005] NSWCA 323 at [96].

of therapeutic goods and actual as to the absence of safety and efficacy in the Vaccines.[53]

10. **Vulnerability**. Vulnerability of the group members to the likelihood of harm by the respondents' conduct is a salient feature indicating a duty of care,[54] being their inability to protect themselves from the respondents' want of reasonable care.[55] Determination of safety, efficacy and lawful availability/access of the Vaccines was solely in the respondents' domain.[56] Their knowledge of those matters is "a significant factor establishing a duty of care".[57]

11. Statutory context is also relevant in determining reliance upon and vulnerability to the respondents' conduct.[58] The Act and its regulations[59] intentionally provide exclusive control over the availability of therapeutic goods in Australia.[60] The respondents told the Group Members that they were the sole source of authoritative information regarding Vaccines' safety, efficacy.[61] The Group Members' knowledge was determined by the respondents and expected to be based upon skill and expertise,[62] manifesting reliance which is "explained by reference to the notion of vulnerability….[wherein]…..the plaintiff is unable to protect itself from the consequence of the defendant's want of reasonable care because it has relinquished that ability by placing its reliance on the defendant for information or advice".[63] The respondents' prolific statements exhorted the Australian population to rely upon them,[64] Vulnerability of the Group Members and respondents' knowledge of the condition is established by the preponderance of facts.[65]

12. **Respondents' Control Over the Risk**. The respondents' control over the risk of harm from therapeutics used in Australia is a relevant consideration,[66] which is where "the powers vested by statute in a public authority may give it such a significant and special measure of control over the safety of the person or property of citizens as to impose upon the authority a duty of care….oblig[ing] the…..authority to exercise those powers to avert a danger to safety or to bring the danger to the knowledge of citizens otherwise at hazard from the danger….[and thereby] the factor of control is of fundamental importance"[67]

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[53] Respondents Knowledge - Known Serious Vaccines Risks and Conduct - Pre- Approvals SOC para. 42; Post- Approvals SOC para. 43.
[54] *Pyrenees* at [107] (McHugh J), at [247] (Kirby J); *Makawe* at [21] (Hodgson JA), [63] (Campbell JA), [168]–[178] (Simpson J). *Amaca* [156] (Ipp JA). Pyrenees [247] (Kirby J); *Crimmins* [43]–[46] (Gaudron J), [93], [101]–[102] (McHugh J), [233] (Kirby J); *Graham Barclay* [149] (Gummow and Hayne JJ).
[55] ***Brookfield*** *Multiplex Ltd v Owners Corporation Strata Plan 61288* (2014) 254 CLR 185 at [57] per Hayne and Kiefel JJ. ***Woolcock*** *Street Investments Pty Ltd v CDG Pty Ltd* (2004) 216 CLR 515 per Gleeson CJ Gummow, Hayne and Heydon JJ at [23].
[56] SOC para.61 - Respondents' Control of Therapeutic Goods in Australia.
[57] ***Perre*** *v Apand Pty Ltd* (1999) 198 CLR 180 at [10] per Gleeson CJ. Requite Knowledge pleaded at para. 70 SOC.
[58] *Ku-ring-gai* at [81] - [82] per Meagher JA (McColl JA and Sackville AJA agreeing).
[59] *Therapeutic Goods Regulations 1990* (Cth).
[60] Act s. 4(1)(a) – "provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods". See also Therapeutic Goods Bill 1989 Second Reading Speech, 5 October 1989 House of Representatives Official Hansard No. 169, 1989 Thursday, 5 October 1989 **("Act Reading Speech")** – pg. 1612 - 1613 - "The Bill provides a standard of regulation….to control therapeutic goods…[and] will provide Australia with uniform, national and comprehensive controls for therapeutic goods"; See also Therapeutic Goods Bill 1989 **Explanatory Memorandum** pg. 2 and 7.
[61] SOC para, 49(a1) – particulars Schedule G.
[62] SOC para. 61(c)(ii), 64.
[63] *Ku-ring-gai* at [71].
[64] SOC para, 49(a1) – particulars Schedule G.
[65] SOC para. 70 - the Known Vulnerability of the Australian Public – See further para. 10 to 18, 22 to 38, 42 to 64, 69 to 75 and 77 to 84.
[66] ***Brodie*** *v Singleton Shire Council* (2001) 206 CLR 512 [102]–[103], [140] (Gaudron, McHugh and Gummow JJ); *Crimmins* at [91]–[93], [104] (McHugh J), [166] (Gummow J), [276]–[286], (Hayne J), [357] (Callinan J); *Graham Barclay* at [20] (Gleeson CJ), [150-2] (Gummow and Hayne JJ); *Stuart* at [114] (Gummow, Hayne and Heydon JJ), [136]–[138], [149] (Crennan and Kiefel JJ); ***Burnie Port*** *Authority v General Jones Pty Ltd* [1994] 179 CLR 520 at 550-552 (Mason Deane Dawson Toohey Gaudron JJ); *Pyrenees* at [168] (Gummow J), [247] (Kirby J).
[67] *Brodie* at [102] per McHugh, Gaudron, Gummow JJ; See also ***Ibrahimi*** *v Commonwealth of Australia* [2018] NSWCA 321 at [234].

and manifests reasonable foreseeability *per se*.[68] The Act is purposed with *exclusive* control of the supply of therapeutic goods (including the Vaccines),[69] the common law duty arising independently of statute.[70] The respondents' absolute control over the presence or otherwise of the safety, efficacy and positive risk-benefit in therapeutics in Australia,[71] with the respondents' knowledge,[72] establish further the conditions and time of such availability.[73] The ubiquitous nature of the respondents' control over risks posed to the Group Members compellingly establishes a duty owed to the Group Members.

13. **Respondents' Assumption of Liability.** The respondents have by their express conduct assumed liability for harm to the Group Members, a powerful salient factor establishing the duty.[74] The Group Members' reliance is material[75] and dovetails in principle with assumption of responsibility by the respondents' express conduct – specifically, express and prolific inducement to consume the Vaccines as safe, effective and necessary.[76] The law imposes a positive duty of care to act in the protection of those Group Members where the respondents knew or ought to have known that the Group Members "as member[s] of the public rel[y] on it to exercise its power to protect their interests",[77] failure of which is a breach of that duty.[78] The Group Members' dependence upon the proper performance of the respondents' functions with their knowledge manifests assumed responsibility to the Group Members,[79] and is *the circumstance* upon which liability in negligence is "largely if not exclusively based".[80] Where this responsibility supplants *private* safety efforts, as in this case,[81] the Group members *must* look to respondents in total reliance, and liability naturally follows.[82] Foreseeability of *specific* reliance manifests duty.[83]

14. Reliance by the Group Members upon the respondents to protect their safety is abundantly evident,[84] predicated upon the respondents' positions of authority and responsibility,[85] factual knowledge,[86] and absolute control[87] in causing the Vaccines to become lawfully available to the Group Members[88] concurrently with statements of impeccable safety, efficacy and absence of any significant or known

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[68] *Turano; Vairy, Doubleday v Kelly* [2005] NSWCA 151.
[69] Act s. 4(1)(a); Act Reading Speech commencing pg. 1612 – 1613; Explanatory Memorandum pg. 2 and 7.
[70] *Graham Barclay* at [80] per McHugh.
[71] SOC para. 61.
[72] SOC para. 62.
[73] See particularly SOC para. 61-62 and further para. 10 to 18 and 25 to 56, 61 and 62.
[74] *New South Wales v* ***Spearpoint*** [2009] NSWCA 233 at [13]–[14] (Ipp JA); *Pyrenees* at [20] (Brennan CJ), [163] (Gummow J), [230]–[231] (Kirby J); Brodie at [307]–[308] (Hayne J); Stuart at [132] (Crennan and Kiefel JJ). *Makawe* re "general reliance" at [26] (Hodgson JA). Mason J explained "general reliance" in *Sutherland Shire Council v* ***Heyman*** (1985) 157 CLR 424 at 463–64.
[75] Specific Reliance - *Graham Barclay* at [310]; *Pyrenees* at [247] (Kirby J).
[76] Assumption of Responsibility Relied Upon - *Spearpoint* at [13]–[14] (Ipp JA). *Pyrenees* [20] (Brennan CJ), [163] (Gummow J), [230]–[231] (Kirby J); *Brodie* at [307]–[308] (Hayne J); *Stuart* at [132] (Crennan and Kiefel JJ).
[77] *Graham Barclay* at [81] per McHugh J.
[78] *Graham Barclay* at [81] per McHugh J.
[79] *Hill v* ***Van Erp*** (1997) 188 CLR 159 at 186 [68].
[80] *Heyman* at 461-2 [26] per Mason J.
[81] SOC para. 61.
[82] *Heyman* at 462-3 [27] per Mason J.
[83] *Heyman* at 463 [28] per Mason J - being "specific" as opposed to "general" reliance.
[84] SOC para. 10 to 18 and 25 to 56, 61–63.
[85] SOC para. 10 to 18 and 25 to 38.
[86] SOC para. 42-43.
[87] SOC para. 61-62.
[88] SOC para. 51-60.

potential for harm, the most rigorous assessment possible, that the risk of serious illness and death of failing to receive the Vaccines was significantly higher than the risks of injury from the Vaccines, that taking the Vaccines was essential to protect others from Covid and that everyone in Australia ought to receive them.[89] The Group Members relied on the statements to be accurate, fulsome and rationally determined on the evidence,[90] but the statements were not.[91] Undertaking as to the reliability of such statements may be express or, if reasonably foreseeable, implied[92] - here, the undertaking was express.

15. Those statements gave rise to *specific* dependence by the Group Members[93] in what Brennan J and Deane J described as "induced" or "encouraged" reliance.[94] Assumption of liability by the respondents ensued because they made representations to the Group Members "who placed reliance on the representation".[95] Where the respondents in those statements advised upon serious matters of Vaccines' safety, efficacy and need and by reason of their position were reasonably relied upon in their judgment, skill and ability to make careful inquiry together with reasonable awareness of reliance (reliance was expressly intended and encouraged),[96] the respondents warranted correctness of the statements, assumed liability for the foreseeable harm, and a duty of care arose for the consumer.[97] Proximity, as it was, arose by encouragement to partake of an activity which ultimately caused injury.[98] The respondents urged, without evident basis, the Group members to consume the Vaccines as soon as possible without delay[99] or further inquiry.[100] Concurrently a duty to warn arose due to a foreseeable risk that the Group Members would believe that the Vaccines were safe when they were not.[101] No warning has issued despite unprecedented reporting of death and injury[102] and data confirming lack of safety or efficacy[103] since Approvals - only continued declarations of safety and dismissal of data of side effects and injury.[104] This assumption of responsibility is a salient feature pointing towards the existence of a duty of care.[105]

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[89] SOC para. 44-50 and 72(b). Particulars e.g. - 2nd Res: Schedule G para. 44(a), (e) and (j); 1st Res: Sched. G para. 45(a), (a1) (b) and (b1); TGA: Sched. G para. 46(a), (c), (e) and (j); 3rd Res: Sched. G para. 47(a), (b) and (c); 4th Res: Sched. G para. 48(b2); Department: Sched. G para. 49(a1).
[90] SOC para. 63(b).
[91] SOC para. 80(b)(iv).
[92] *CN v Poole BC* [2019] UKSC 25 at [68] per Lord Reed DP; cited with approval - Full Bench in *HXA (Respondent) v Surrey County Council (Appellant)* [2023] UKSC 52 per Lord Burrows and Lord Stephens (with whom Lord Reed, Lord Briggs and Lord Sales agree).
[93] *Heyman* at 463 [28] per Mason J.
[94] *Heyman* at Mason J at 462-3 [27] and Deane J at 507-8 [16].
[95] *Fuller-Wilson v State of New South Wales* [2018] NSWCA 218 at [39] – [40] per Basten cited with approval in *Jennings v Police* [2019] SASCFC 93 at [87] Per Kourakis CJ., Stanley, Parker JJ agreeing.
[96] See e.g. express statements at Schedule G - para. 47(c), 49(a1); SOC – para. 50(a)(xi); Schedule A- para. 76.
[97] ***Esanda*** *Finance Corporation Ltd v Peat Marwick Hungerfords* (1997) 188 CLR 241 at 249-250[9] – [10] per Brennan CJ; *Ku-ring-gai* at [77] citing ***Tepko*** *Pty Ltd v Water Board* (2001) 206 CLR 1 at [73]–[75] Gaudron J, Gleeson CJ, Gummow and Hayne JJ at [47]; *Ibrahimi* at [216] per Payne JA, Meagher JA & Simpson AJA agreeing citing *Mutual Life v Evatt* (1968) 122 CLR 556 at 571(Barwick CJ); See also *Van Erp* at [68].
[98] *Vairy* at [82] per Gummow J.
[99] See e.g. express statements at SOC para. 45(b) and 48(b3) of Schedule G; para. 44(g)(vi), 4(b)(iii) of Schedule A; para. of Schedule G.
[100] See e.g. express statements at SOC para. 47(c), 49(a1) of Schedule G particulars, para. 76 Schedule A particulars. Para. 50(a)(xi) SOC.
[101] *Graham Barclay* at [64]. See also generally *Rosenberg v Percival* (2001) 205 CLR 434.
[102] See e.g. known data of prolific death and injury following vaccination with the Vaccines - Post-Approval - Sched. A para. 80, 89, 96, 98-107, 109-115, 117-121, 137-138; Exponentially High Safety Signals – Sched. A para. 141, 143-155; International Adverse Event Reporting Data Sched. B para. 100-108; Sponsor provided Adverse Event Safety Reports – Sched. B para. 114, 121; Excess Mortality Data confirming explosion in excess deaths commencing 2021 – Australia and International – Sched. B para. 109-112; Explosion in Adverse Event Reporting – Sched. B para. 115, 117-120, 130, 141, 143-148, 152, 155; PRR data - exponentially high safety signals for the Vaccines – Sched. B para. 137, 152.
[103] Not effective Post-Approval – Sched. A para. 81-88, 90, 91-95; No Positive Risk-Benefit - Pre-Approval – Sched. A para. 108, 109, 110.
[104] See e.g. express statements at Sched. G - para. 44(b), 44(b1)-(e), 44(h), 45(a)(vi), 45(c), 46(c), 46(j), 48(b3), 49(a1), 49(b).
[105] *Ibrahimi* at [221].

16. **Coherence of Posited Duty with Law.** The respondents assert the posited Duty's incoherence with the law and the Act but cannot say why. Coherence with the law is a relevant consideration[106] including consistency with the respondents' duties under the Act (and other legislation).[107] The duty must sit "coherently" with the Act but remains independent - the Act only provides "setting".[108] Whether the Act is intended to benefit the whole Australian population or only certain individuals is irrelevant to a duty owed to a particular class arising from purported performance under the Act.[109] As Gibbs CJ held: "the fact that a statutory provision, which confers powers or duties on a public authority, is enacted for the benefit of the public generally, and confers no private right upon an individual, does not mean that the individual has no right of action at common law if the [relevant entity] is negligent" and "unless the statute manifests a contrary intention, a public authority which enters upon an exercise of statutory power may place itself in a relationship to members of the public which imports a common law duty to take care".[110] The purpose of the Act is material. That purpose demonstrates coherence with the posited duty which asserts that the respondents owed a duty to *exercise reasonable care and skill and to minimise the risk of harm* when causing the lawful availability of therapeutic goods or making public statements as to their safety, efficacy and necessity.[111]

17. The express objects of the Act enunciate concern directed to the quality, safety, efficacy and timely availability of therapeutic goods[112] for use in humans.[113] McHugh J held that "if the legislature has invested the power for the purpose of protecting the community, it obviously intends that the power should be exercised in *appropriate circumstances*" and that "if the authority is aware of a situation that calls for the *protection of an individual* from a *particular risk*, the common law may impose a duty of care".[114] The legislature intended by the Act, aggregate control over therapeutic goods in Australia[115] purposed for the protection of the public from unsafe and ineffective products,[116] acceptable only upon establishing safety, efficacy and quality,[117] attained by assessment to establish those matters before

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[106] *Sullivan* at [54]; ***X v South Australia*** *[No 3]* (2007) 97 SASR 180 at [196] (Debelle J); ***Moorabool*** *Shire Council v Taitapanui* (2006) 14 VR 55 at [72] (Ormiston and Ashley JJA); ***Precision Products*** (2008) 74 NSWLR 102 at [119] (Allsop P).

[107] *Pyrenees* at [24]–[25] (Brennan CJ), 391 [175] (Gummow J), 421 [247] (Kirby J); *Crimmins* at [93]–[100] (McHugh J), 72 [203], 76–7 [213]–[215] (Kirby J); *Graham Barclay* at [146] (Gummow and Hayne JJ); Stuart at [52] (French CJ), [98], [112] (Gummow, Hayne and Heydon JJ), [131]–[132], [141] (Crennan and Kiefel JJ); Sutherland Shire Council v Becker [2006] NSWCA 344 at [100] (Bryson JA); *Meshlawn P/L & Anor v State of Qld & Anor* [2010] QCA 181 at [70] (Chesterman J); ***MM Constructions*** *(Aust) Ltd v Port Stephens Council* [2012] NSWCA at [98] (Allsop P); *Sullivan* at [54] and [62] (Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ); *X v South Australia* at [196] (Debelle J); *Moorabool* at [72] (Ormiston and Ashley JJA); *Precision Products* at [119] (Allsop P).

[108] See e.g. *FRM17 v Minister for Home Affairs* (2019) 271 FCR 254 [210] citing Pyrenees at [126]; *Sullivan* at [50] and [55] (Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ); *Leichardt Municipal Council v Montgomery* (2007) 230 CLR 22 at [137] (Hayne J); ***CAL*** *No 14 Pty Ltd v Motor Accidents Insurance Board* (2009) 239 CLR 390 at [41] (Gummow, Heydon and Crennan JJ)). Heyman at 434 (Gibbs CJ); Crimmins at [25] (Gaudron J), [154], [157] (Gummow J); *Graham Barclay* at [80] (McHugh J).

[109] *Heyman* at [13] (Gibbs CJ), [21] (Mason J).

[110] *Heyman* at [13] per Gibbs CJ.

[111] SOC para. 73.

[112] Act s.4(1)(a). See also Explanatory Memorandum pg. 2.

[113] Act s. 3 Interpretation – see definition of "therapeutic goods" and "therapeutic use".

[114] *Graham Oyster* at [82].

[115] Act Reading Speech – pg. 1612 - 1613 "The Bill provides a standard of regulation…as being necessary to control therapeutic goods….this legislation will provide Australia with uniform, national and comprehensive controls for therapeutic goods".

[116] Act Reading Speech pg. 1616 – "The legislation will….provide the means to protect the Australian public from substandard, unsafe and ineffective products".

[117] Act Reading Speech pg. 1613 - "Three parameters are used to define the acceptability of a product for therapeutic use….quality….safety….efficacy".

approval for consumption.[118] Safety is attained in comparing risk as against benefit,[119] maintained by surveillance of injuries after approval.[120] The approval regime under the Act seeks to ensure careful, skilful, evidence-based and rational determinations of safety and efficacy in therapeutic goods before registration,[121] wholly concerned with minimisation or avoidance of risk of harm to human consumers of those goods.[122] The instant case is distinguished from *Sullivan*, wherein the posited duty created obvious conflicts with (inconsistent) duties owed to third parties.[123] The duty here is solely directed to the consumers of the Vaccines in perfect coherence with the legislation. The respondents' reliance on *Sullivan* is incongruous. *Crimmins* is factually analogous, holding that a statute with a purpose of "securing of the safety of stevedoring operations" was thereby "entirely consistent with the existence of a common law duty of care…..to take reasonable steps to prevent the foreseeable risk of injury to persons engaged in those operations".[124] Profound coherence and consistency as between the Act and posited duty is self-evident.

18. The respondents point to "timeliness" as an object of the Act,[125] arguing that observance of "timely" function under the Act is encroached upon by the posited duty. The proposition is absurd on its face but further ignores the scope and intent of the Act, appearing to assert that timeliness may supplant all other obligations, erroneously citing the overlay of a "public health emergency of global concern" as demonstrative of conflict.[126] The Act indeed provides for expedient approval of therapeutic goods – the provisional approvals regime introduced by amendment in 2018,[127] and used in respect of *all* of the Vaccines for approval at unprecedented speed.[128] The regime was expressly purposed to bring therapeutic goods to the consumer *without compromising upon safety and efficacy of those goods and only where displaying a positive risk-benefit balance.*[129] Parliament similarly intended that the regime facilitated speedy approval *without* compromise on safety or efficacy expediting approval by "up to two years" achieving requisite "timeliness".[130] Further, the Act provided at all relevant times for exemption of normal listing and registration requirements in the event that the Minister is rationally satisfied that the

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[118] Act Reading Speech pg. 1614-1615 – "….a product…[is]….judged to be of an acceptable standard and….appear safe and efficacious on the basis of the premarket evaluation….Registered goods will require evaluation by [the] Department prior to approval for supply, the degree of evaluation being related to the perceived risks of that class of goods".
[119] Act Reading Speech pg. 1613 – "safety, that is its lack of toxicity or hazard or at least that the product has an acceptable level of risk compared to the expected benefits when it is used as directed".
[120] Act Reading Speech pg. 1613 – "Surveillance for unwanted effects must also continue after a product has been marketed".
[121] See Act s. 4(1)(a), 9D(1A)(b), 9D(3AC), 9D(3A)(b), 22G(3), 25(1)(d)(iii), 26B(1A), 30(2), 30EA(1), 31(1)(g), 32DA, 32DE, 42DI, 61(13), 61(15).
[122] See especially Act s.29D, s.32FA, s.30, s.32GA.
[123] *Sullivan* at [60] per Gleeson CJ, Gaudron, McHugh, Hayne and Callinan JJ. See the relevant posited duty at [7].
[124] *Crimmins* [17] Gaudron, [110] and [130] McHugh. Distinguished - no duty in *Minister for Environment v* ***Sharma*** (2022) 291 FCR 311 at [268] - "EPBC Act does not contain as an overall purpose the safety of human life".
[125] RS [25].
[126] RS [22].
[127] Act Part 3-2—"Registration and Listing Of Therapeutic Goods" - Division 1A "Provisional Determinations For Medicine". Amended Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 5 Mar 2018.
[128] SOC para. 80(b)(v)(8)(b)(i).
[129] Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 Explanatory Memorandum: "Second stage of legislative response to the Review of Medicines and Medical Devices Regulation" – "Provisional registration of promising new prescription medicines" pg. 1-2; "Schedule 1 - Provisional registration of medicine" pg. 19 – 25.
[130] 2nd Reading Speech of the Minister dated 14 September 2017.

matter is in the national interest or a national emergency declaration is in force requiring those goods be stockpiled as quickly as possible for availability urgently in Australia to deal with an actual threat to public health caused by an emergency.[131] This provision was *at no time invoked* in respect of the Vaccines.

19. The respondents also cite incoherence of the posited duty with the first to third respondents compliance with the Australian Public Service Values in s. 10 of the *Public Service Act*. As pleaded by the applicants, the same conduct which breached the posited duty itself, by its nature, plainly breached that provision and a number of the Australian Public Service Values.[132] The respondents' suggestion that the posited duty is inconsistent with the cited law is risible.

20. **Court's Ability to Determine the Matter**. The respondents contend that "the reasonableness of approvals granted under the Act, and statements made by public officials as to the 'safety, efficacy and necessity' of goods so approved, are not justiciable in negligence". The assertion proceeds upon a footing of obfuscation of the determinability of plain concepts of safety and efficacy and the breathtaking assertion that a *reasonable* determination of those matters is not a matter to which the Court can turn its mind. Negligence is an area of law 'which has reasonableness *as its central concept*'.[133] A salient consideration is indeed whether the decision in question is capable of being resolved judicially through "criterion by which a court can assess" its propriety,[134] which can be resolved by application of "questions of practicality and of appropriateness".[135] The expressions "safety" and "efficacy" are not ephemeral or flexible terms that may be compromised, as the respondents appear to suggest, by tensions due to time, but are concrete matters to be *rationally established*.[136] In respect of approval for registration of vaccines under the Act specifically,[137] Perry J held safety to be "the quality of being unlikely to cause hurt or injury" and "of not being dangerous or presenting a risk" and efficacy to be "the ability to bring about the intended result' … that is, effectiveness to bring about the intended therapeutic result for which the goods have been registered…".[138] It is the failure to rationally establish these facts upon which the respondents negligently proceeded[139] accompanied by effusive representations as to the safety efficacy, and absolute necessity of the Vaccines for all Australians,[140] whilst knowing or exercising wilful blindness as to the plethora of factual data[141] establishing precisely the opposite, or failing to establish

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[131] Act s. 18A and 32CB.
[132] SOC para. 90(g)(iii), 96(g)(iii), 102(g)(i).
[133] *Tame v New South Wales* (2002) 211 CLR 317 at [8]–[9], [14] and [35] per Gleeson CJ. See also [101] per McHugh J, [331] per Callinan J.
[134] ***Dorset*** *Yacht Co Ltd v Home Office* [1970] AC 1004 at 1067 (Lord Diplock); *Brodie* [310]–[311] (Hayne J); *Graham Barclay* at [8], [13], [15] (Gleeson CJ); *Crimmins* (1999) 200 CLR 1, [5] (Gleeson CJ); *Newcastle City Council v Shortland Management Services* (2003) 57 NSWLR 173 [80]–[82] (Spigelman CJ); *Refrigerated Roadways* at [267], [274], [281]–[283] (Campbell JA); ***Electro Optic*** at [201] (Jagot J).
[135] *Graham Barclay* at [15] per Gleeson CJ.
[136] *Minister for Immigration & Citizenship v* ***Li*** (2013) 249 CLR 332 at [14], [23]-[30] French CJ, [68]–[72] Hayne, Kiefel, Bell JJ, [105]–[112] Gageler J.
[137] Act s. 25(1)(d).
[138] *Australian Competition and Consumer Commission v Homeopathy Plus! Australia Pty Limited* [2014] FCA 1412 at [51] – [52] per Perry J.
[139] Conduct - SOC para. 51-60; Negligently Proceeding - Reckless Conduct – SOC para.74; Reckless Failures – SOC para. 77.
[140] See particularly SOC para. 44-50.
[141] Sched. C Particulars - Circumstances of Knowledge – arising from Commonwealth's own documents, sponsor provided data, public material.

safety, efficacy, or necessity.[142] The exercise of discretion must be the exercise of what is reasonable, constrained by the subject matter, scope and purpose of the legislation under which it is conferred.[143] The respondents' assertions (citing *Graham Barclay*) that in the present case "there is no criterion by which a court can assess where the balance lies between the weight to be given to one interest and that to be given to another",[144] are "issues that are inappropriate for judicial resolution…..ordinarily decided through the political process" [145] are repugnant to the clear strictures of the Act directed to safety and efficacy regulating the approval of therapeutic goods for use in Australia. Liability arises if the respondents entrusted with the discretion reached a conclusion so unreasonable as to show failure to do his duty[146] - irrationality or illogicality is legal unreasonableness *per se*.[147] Whether there was no evidence to support a factual finding, rendering it irrational, illogical and unreasonable, is a question of law determinable only by judicial decision.[148] The respondents' assertion that their conduct is not justiciable in negligence, is wrong in fact and law (however convenient it is for the respondents).

21. **Determinate Duty of Care.** The respondents assert that the posited duty is indeterminate as to the class to whom it is owed, and does not arise.[149] This is wrong as a matter of fact and applicable legal principle. Preliminarily, the "indeterminacy principle" is a negative salient feature, but finds general application at law in matters of pure economic loss and not personal injury,[150] but in any case the Group Members as a class are wholly ascertainable, being those receiving one or more of the Vaccines on or after specific points in time in Australia,[151] constituted by the subset of those whom suffered a serious adverse event by reason of injection with the Vaccines.[152] The respondents engage in a breathtaking misrepresentation of the reasoning of Beach J in *Sharma* asserting that "in the personal injury context, indeterminacy is 'an important control mechanism or salient feature'".[153] This is the precise opposite of both Beach J's actual reasoning and a long line of judicial authority. Indeterminacy is in fact *negatived* by a personal injury claim,[154] and operates only in respect of economic loss cases due to the inherent cascading effect of "financial harm endlessly and often in many directions" and would thereby be "onerous for defendants and burdensome for courts",[155] or as Gibbs J stated in *Caltex*, "might expose the person guilty of it to claims unlimited in number and crippling in amount", economic loss being "very much wider" than personal injury.[156] The respondents cite *Sullivan* which cites *Perre* holding that indeterminacy is

[142] SOC para. 42-43; Known Serious Vaccines Risks and Conduct - Pre-Approvals; Known Serious Vaccines Risks and Conduct - Post-Approvals.
[143] See *Li* at [14], [23] – [30] per French CJ, [68] –[72] per Hayne, Kiefel, Bell JJ, [105] – [112] per Gageler J.
[144] RS [28].
[145] RS [31].
[146] *Dorset* per Lord Reid at 1031 cited with approval - *Corbin v State of Queensland* [2019] QSC 110 (Ryan J) at [88].
[147] See e.g. *Li* at [72].
[148] *Kostas v HIA Insurance Services Pty Ltd* (2010) 241 CLR 390 at [91] per Hayne, Heydon, Crennan and Kiefel JJ.
[149] Se RS [17] –[21].
[150] See e.g. ***Johnson*** *Tiles Pty Ltd v Esso Australia Pty Ltd* [2003] VSC 27 at [886] citing Caltex.
[151] SOC para. 1(b)(i)(1)-(6).
[152] SOC para. 1(b)(ii).
[153] RS [17] citing *Sharma* [2022] FCAFC 35 at [741] per Beach J.
[154] *Woolcock* at [155] per Kirby J.
[155] *Johnson* at [870] citing Law of Torts by Professor Dobbs at para. 452.
[156] *Caltex* at p.551 per Gibbs J.

exemplified by "difficulty of confining the class of persons to whom a duty may be owed within reasonable limits".[157] Kirby J in *Woolcock* explained that recovery was allowed in *Perre* because that case involved personal injury and thereby had the "sting of indeterminacy" arising in economic loss cases removed.[158] Recovery was allowed in *Cattanach* because the loss suffered was "made concrete" in an economic loss case because it involved the personal physical state of one of the respondents thereby "dispelling the contention of indeterminacy".[159] *Sullivan* is of no application in any case as there was an obvious unascertainability of the flow of liability,[160] unlike the instant case wherein the duty is precisely defined, ascertainable and identifiable. Gillard J in *Johnson* described indeterminacy in *Caltex* was a factor relevant to whether or not a duty of care arises in pure economic loss cases only,[161] similarly to *Heyman*, due to "the law's concern about endless indeterminate liability",[162] holding expressly that "there is no suggestion that the principle would apply in a case involving personal injury".[163] The respondents cite *Sharma* and the dictum of Cardozo CJ[164] of the need to avoid the "the spectre of 'liability in an indeterminate amount for an indeterminate time to an indeterminate class'",[165] but *Ultramares* arose in respect of economic loss for advices conveyed to people never actually or possibly contemplated by the advisor.[166] The High Court said recently that the adoption of Cardozo CJ's statement is "reflect[ive of] policy concerns about the potentially excessive scope of liability for *financial loss*".[167] This has no application in the instant case.

22. The ascertainability of the posited duty in this case is analogous to injuries arising from the supply of a defective product, as there is a direct connection between the injured and want of care by the respondents.[168] The class of injured is determinate as "a negligently made article will only cause one accident"[169] – there can be no "ripple effect". Ascertaining the likely general heads of loss is sufficient[170] and the principle is not concerned with the size of the potential claim but only the ascertainability of their likely nature[171] - where number and nature of claims can be reasonably calculated, determinacy follows.[172] Determinacy captures those likely to be directly affected by the tortfeasor's conduct[173] and then the subset of those likely victims who were vulnerable because they were not able to take reasonable

[157] RS [17] citing *Sullivan* at [50] and [61].
[158] *Woolcock* at [155] per Kirby J.
[159] See ***Cattanach*** *v Melchior* (2003) 215 CLR 1 at [19], [30], [67]-[68], [148]-[149], and [300].
[160] *Sullivan* at [38].
[161] *Johnson* at [886] citing *Caltex*.
[162] *Johnson* at [886] citing *Heyman* at 465 per Mason J.
[163] *Johnson* at [892]. See also [889].
[164] RS [17]. *Sharma* at [706] per Beach J.
[165] ***Ultramares*** *Corp v Touche*, 255 NY 170 at 179 (1931) per Cardozo CJ.
[166] *Ultramares* at 174.
[167] ***Mallonland*** *Pty Ltd v Advanta Seeds Pty Ltd* [2024] HCA 25; (2024) 98 ALJR 956 at [31] per the Court.
[168] *Grant v Australian Knitting Mills Ltd* [1936] AC 85 at 104–5.
[169] *Byrne & Co Ltd v Heller & Partners Ltd* [1964] AC 465 at 483 per Lord Reid.
[170] *Perre* at [143].
[171] *Cattanach* at [32] per Gleeson CJ; *Sharma* at [743], *Perre* at [336].
[172] *Perre* at [107] per McHugh J.
[173] *Perre* at [107]–[109] per McHugh J, [336] and [337] per Hayne J, [340]–[342] and [352] and [409] per Callinan J.

protective measures themselves[174] explaining why they were likely to suffer loss.[175] This describes the Group Members and circumstances precisely.

23. The respondents proceed upon another fallacy - that determinacy of the class is eviscerated by its size. This is false. Indeterminacy or otherwise of a class and its nominal are utterly distinct and unrelated, as determinacy in a well-articulated group is possible at any size,[176] and the size of the class and magnitude is irrelevant to the question of determinacy.[177] Regarding representative proceedings in particular, consideration of nominal size is illogical and of no application to determinacy of class even in the millions.[178] The respondents draw false synonyms as between the instant case and *Agar*, *Electro Optic Systems*, on the basis that the "courts have rejected on indeterminacy grounds attempts to impose far more modest duties of care".[179] *Agar* had nothing to do with the "modesty" of the class, but involved a true case of indeterminacy due to the impossibility of *ascertaining* the class either in size or identity as it related to the rules of a voluntarily played sport played for recreation everywhere[180] giving rise to an "incalculable" number of claims worldwide.[181] The instant case has no comparison factually to *Agar* - the instant class is easily and readily definable, ascertainable and identifiable. In *Electro Optic Systems*[182] indeterminacy "weigh[ed] heavily against the existence of the posited duty of care"[183] because it involved those who would "*probably* suffer damage", "probability" plainly defying identification and rendering the class indeterminate.[184] The respondents also contort the reasoning in *Knowles*,[185] falsely asserting that the duty in the instant case is similar to that posited in *Knowles* which was for the respondents to "take all reasonable steps to ensure that the steps undertaken by them to compel injections and for the purposes of the National Plan against the Australian population, would cause or do no harm in particular to the applicants".[186] This was properly rejected because the "breadth of the persons to whom the alleged duty of care is said to be owed, without any attempt to identify or delineate the material facts relating to their circumstances".[187] The class boundaries and facts material to their circumstances are profoundly evident in this proceeding.[188] The TGA in fact produces a database recording the injured recipients of the Vaccines.[189] Unlike the Group Members, the class subsumed by the posited duty in *Knowles* cannot be discerned *ex-ante* or *ex-post*. In a further misuse of the reasoning on *Knowles*, the respondents

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[174] *Perre* at [10], [13]–[15] per Gleeson CJ, [32], [41]–[42] per Gaudron J, [206] per Gummow J and [296] per Kirby J.
[175] *Woolcock* at [23], [80].
[176] *Perre* at [107] and [139] per McHugh J and [336] per Hayne J; *Johnson* at [904]; ***Christopher*** *v The Motor Vessel 'Fiji Gas'* [1993] QCA 22; (1993) Aust Torts Reports 81–202 at 61,963; ***Johns*** *Period Furniture Pty Ltd v Commonwealth Savings Bank* (1980) 24 SASR 224 at 238.
[177] *Perre* at [139] per McHugh J. *Cattanach* per Gleeson CJ at [32].
[178] *Johnson* at [1209].
[179] RS [20].
[180] ***Agar*** *v Hyde (2000) 201 CLR 552* at [23] per Gleeson CJ.
[181] *Agar* at [116] and [127] per Callinan J.
[182] At [352]-[353] per Jagot J (Murrell CJ and Katzmann J agreeing).
[183] RS [20]
[184] *Electro Optic* at [353] and [733].
[185] RS [21].
[186] ***Knowles*** *v Commonwealth of Australia [2022] FCA 741* at [218].
[187] *Knowles* at [233].
[188] See Group Members defined in detail at SOC para. 1.
[189] Database of Adverse Event Notifications – see. SOC para. 37(n). See also para. 18(g) and (h)(ii) and (vii) and (x)(3) and (xvi)(1).

selectively cite the observation that the "power said to give rise to the duty 'applied to a large proportion of the Australian population, if not all of it'",[190] but fail to mention that the Court makes clear immediately after that the issues lie in a number of flaws none of which are "the large proportion of the population".[191] As the Courts have abundantly clarified, the nominal size of the group relative to a population or otherwise is "not a factor telling against a duty of care".[192] Claims of indeterminacy are inapposite and wrong.

24. **Prospective Nature of Class**. The respondents assert that because the Group Members to whom the posited duty is owed includes the injured, that the duty is "circular" and because the "duty inquiry is prospective" the duty "cannot depend on whether a person has in fact been injured".[193] This is wrong. The Group Members to whom the duty is owed are wholly a subset of the consumers of the Vaccines, a plainly foreseeable and ascertainable class of those affected by the negligent acts and omissions of the respondents. The duty's reduction to a subset of that class can possibly be no less ascertainable or foreseeable. The respondents claim that the applicants reference to the Australian population as subsuming the Group Members is "tacit acknowledgement" that the posited duty would be owed to the entire population *"*potentially" because it is owed to every "potential" vaccine recipient. This reasoning appears to employ a form of absurd inverse logic – there is no potentiality, only a well-defined and known class logically distilled from the wider population. The duty in its express form does not and cannot simply incorporate the entire population of Australia – it does not transmogrify into a duty directed to the whole Australian public because it may capture a large portion of the population, nor do significant numbers cause it to evaporate. The duty does not offend the principle in *Crimmins* but in truth accords with it.[194]

25. The authorities cited by the respondents for this assertion[195] consistently describe the true principle which the respondents misconstrue – that a duty must *avoid directing itself specifically to the impugned conduct of the defendants as and in the circumstances that it occurred* and "working backwards" from that point such that the duty is narrowly pointed to those narrow acts and circumstances.[196] The posited duty is directed to the respondents' conduct in making available therapeutic goods for lawful consumption, not narrowly to the impugned conduct complained of. The respondents cite *Roo Roofing*[197] which cites *Dansar* making this plain – the posited duty had "look[ed] to the way in which the public authority acted on the particular occasion in question and asking whether its doing so in fact required it to give

[190] *Knowles* at [232]
[191] *Knowles* at [233]
[192] *Johnson* at [1209]–[1210] per Gillard J. See also [919]–[920]. *Johnson* was cited with approval in *5 Boroughs* at [137] and [286]-[289] and in *Sharma* at [468].
[193] RS [18]
[194] *Crimmins* at [93(2)] cited at RS [20].
[195] *Sharma* at [285]; *Electro Optic* at [352]-[353]; ***Roo Roofing*** *Pty Ltd v Commonwealth* [2019] VSC 331 at [465]; *Dansar* at [159] (cited in *Roo Roofing*).
[196] See also *Romeo* at [163]-[164]. Vairy at [29], [54], [60]-[61], [122]-[129]; *Mulligan v Coffs Harbour City Council* (2005) 223 CLR 486 at [50]; *Dederer* at [65]; *New South Wales v Fahy* (2007) 232 CLR 486 at [57], [123], [125].
[197] *Roo Roofing* at [465] per John Dixon J.

consideration to conflicting claims, or engaged statutory obligations inconsistent with that duty".[198] This precise principle is restated in *Graham Barclay*,[199]*5 Boroughs*[200] and *CAL*.[201] Notably in *5 Boroughs* the issue arose because the posited duty dealt with "effective" action,[202] only be determinable retrospectively. The Group Members, as consumers of the Vaccines, are the reasonably foreseeable class of persons affected by the respondents conduct which as with duty, are "forward looking".[203] The duty goes no further than the duty posited in *Graham Barclay* owed by a manufacturer to take reasonable care to avoid injury to the consumer.[204] Defining the class as including the injured from a subset of consumers to whom the duty is owed is orthodox.[205] The final number of injured can only be ascertained *ex-post*, not *ex-ante*. The tortfeasors need only be able to reasonably foresee the class of persons whom may be affected by their negligence.[206] The duty captures this foreseeable group as the consumers of the Vaccines, precisely. The respondents misapply principle to obscure the obvious ascertainability of the class and posited duty.

26. **Policy Decisions**. The respondents deny the posited duty on the erroneous basis that the impugned conduct entails a "core policy function" or "core policy questions"[207] – this is wrong. Some reluctance to impose a duty of care in respect of "core-policy making decisions" has transpired intermittently,[208] however the High Court instead has sought to avoid stifling legislative or "quasi-legislative" functions of government.[209] The High Court expressly disavowed that a duty of care and liability cannot arise in respect of purely policy decisions, stating that "it is no answer to a claim in tort against the Commonwealth … that its wrongful acts or omissions were the product of a 'policy decision'…..still less that the action is 'non-justiciable' because a verdict against the Commonwealth will be adverse to that 'policy decision'".[210] The proper determinant is whether or not a decision is operational. Mason J stated in *Heyman* that "a duty of care may exist in relation to discretionary considerations which stand outside the policy category in the division between policy factors on the one hand and operational factors on the other".[211] The policy/operation distinction is employed in successive reasoning of the High Court.[212]

27. The impugned conduct is plainly operational in nature. "Policy decisions" go exclusively to matters, of financial, economic, social or political factors or constraints such as the allocation of resources and

[198] *Dansar* at [159].
[199] *Graham Barclay* at [192].
[200] *5 Boroughs* at [25].
[201] *CAL* at [68].
[202] *5 Boroughs* at [26].
[203] Ibid.
[204] *Graham Barclay* at [106].
[205] See e.g. *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905 at [3054] and [3624] per Katzman J. Duty pleaded in that case was posited as owed to injured group members – see pleading of 5FASOC [31], [35], [66], [74] where general duty owed to all consumers.
[206] *Turano* at [45] per the Court; *Sullivan* at [42] per the Court.
[207] RS [28].
[208] *Crimmins* per McHugh J at [87], [93] restated by McHugh J in *Graham Barclay* at [84].
[209] See e.g. *Crimmins* at [32] per Gaudron J; [170] per Gummow J, [288] per Kirby J, [291]–[292] per Hayne J.
[210] *Brodie* at [106] per Gaudron, McHugh and Gummow JJ.
[211] *Heyman* per Mason J at [38].
[212] *Graham Barclay* Gleeson CJ at [12]; *Crimmins* at [131] McHugh J – better approached as a question of breach.

budget, [213] as opposed to operational matters which are "the product of administrative direction, expert or professional opinion, technical standards or general standards of reasonableness".[214] Where the conduct is operational in nature "there is no reason for hesitating to assimilate the position of governments to that of citizens in imposing duties and standards of care", even where *including* budgetary considerations.[215] The Act gives no regard to the matters of policy, but requires rigid observance of safety and efficacy in the Vaccines. The impugned acts were plainly operational, including the statements, as not involving any of the well-defined categories of policy. The respondents' contentions are plainly wrong.

28. **Immunity per s. 61A and Bad Faith**. The respondents seek to rely upon a statutory immunity to suit afforded under the Act[216] despite accepting that the applicants' case alleges bad faith in respect of their impugned conduct,[217] and that immunity does not apply in those circumstances.[218] Any immunity to suit provided under statute is read to strictly limit the breadth of immunity by being "strictly, even jealously construed"[219] because "absolute immunity is in principle inconsistent with the rule of law".[220] The legislature did not express or intend that the provisions afforded any immunity to the respondents in the circumstances of bad faith,[221] but that "the TGA must remain responsible for its actions".[222] The respondents assert that the factual matters giving rise to bad faith are "not adequately pleaded".[223] This then (if correct, which it is not) properly becomes a strike-out argument, not summary judgement. Bad faith arises in the absence of an honest belief that the act is lawful,[224] distinguished from good faith which is the "carrying out [of] the statute according to its intent and for its purpose".[225]

29. The voluminous factual matters manifesting bad faith in the negligent conduct of the respondents are pleaded here and are highly particularised[226] - the absence of an honest belief that the act is lawful – include proceeding in the voluminous and ever-increasing knowledge as to the absence of safety, efficacy, necessity, benefit exceeding risk, or therapeutic advance in the Vaccines,[227] acting in breach of not only the provisions of the Act[228] but those statutes regulating the proper conduct of the respondents in their respective offices,[229] and acting contrary to their individual responsibilities and departmental

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[213] *Graham Barclay* at [12] per Gleeson CJ citing *Heyman* per Mason J at [39].
[214] *Graham Barclay* at [12] per Gleeson CJ citing *Heyman* per Mason J at [39].
[215] *Graham Barclay* at [14] per Gleeson CJ. See also [12].
[216] Act s. 61A.
[217] RS [33].
[218] Act s. 61A(2).
[219] *Brodie* at [97].
[220] *Brodie* at [97] citing *Darker v Chief Constable of the West Midlands Police* [2000] 3 WLR 747 at 756-757.
[221] Express terms s.61A. 2nd Reading Speech - 25 Nov 2009, Hansard Pg.12798 Therapeutic Goods Amendment (2009 Measures No.3) Bill 2009.
[222] 2nd Reading Speech -17 Mar 2010, Hansard Pg. 2767 - Therapeutic Goods Amendment (2009 Measures No.3) Bill 2009.
[223] RS [33].
[224] ***Three Rivers*** *District Council v Bank of England (No 3)* [2001] UKHL 16 at 191 per Lord Steyne. *Farah Custodians Pty Limited v Commissioner of Taxation* [2018] FCA 1185 at [103] per Wigney J.
[225] *Three Rivers* at 57 per Auld LJ.
[226] Reckless Conduct - Approvals – SOC para.74-75; Reckless Failures - Continuing Approvals – para.77-78; Misleading Statements para.80-81.
[227] See SOC para.74(a)(vii –(viii), 74(b)(vii)-(viii), 74(c)iv, 74(d), 76(a)(vii –(viii), 76(b)(vii)-(viii), 76(c)iv, 76(d), 80(b)(ii) –(v).
[228] See SOC para.74(a)(ii), 74(b)(ii), 76(a)(ii), 76(b)(ii).
[229] See SOC para.74(a)(v), 74(b)(v), 74(c)(iii), 76(a)(v), 76(b)(v), 76(c)(iii), 80(d).

purpose.[230] Any immunity afforded under the Act, where the actions of the respondents were in fact undertaken in connection with the Act,[231] has fallen away as intended by the Act's plain provisions.

30. **Pleaded Breach and Causation**. The respondents generally assert that the allegations of breach and causation are "vague" "general", "plainly embarrassing and inappropriate" and "like the pleading in *Knowles*", fairly characterised as "a jumble of general allegations against all the respondents, lumped together",[232] also alleging an absence of "link" between the alleged breaches and causation.[233] On their face the respondents' complaints appear to assert both excessive particularity and an embarrassing deficit of particularity at once. Plain reading of the applicants' pleaded case (and juxtaposition with *Knowles* relied upon by the respondents), disclose the acute absurdity of the respondents' sweeping claims.

31. Breach is established in the pleaded factual circumstances in the SOC: as to prior to the Approvals - para. 42, 43, 51, 54, 57 and 61 to 76; as to after the Approvals - para. 42, 43, 52, 55, 58 and 61 to 79; as to after the Misleading Statements of the respondents - para. 42, 43, 53, 56, 59, 60 and 61 to 82.

32. Causation is established in the pleaded factual circumstances of the SOC (para. 83-84), the respondents Control of Therapeutic Goods in Australia (para. 61-62), the Public's Reasonable Expectation and Reliance (para. 63), the Public Expectation of Skill (para. 64), the Known Gravity of the Approvals (para. 69), the Known Vulnerability of the Australian Public (para. 70), the Foreseeability of Risk and Harm (para. 71 – 72), the Respondents' Duty (para. 73), the Reckless Conduct – Approvals (para. 74-75), the Reckless Failures – Continuing Approvals (para. 77), the Known Post-Approvals Assessment Failures (para. 77(d)(iii)), and the Known Established Falsity of the Misleading Public Message (para. 80(b)(iv)).

33. The respondents complaints as to the absence of properly pleaded breach and causation are incongruous with the plainly and comprehensively pleaded and particularised case of the applicants. The assertions are baseless and cannot be credibly maintained in light of consideration of the pleading itself.

The Misfeasance in Public Office Claim

34. Bare assertions that the pleadings are "hopelessly vague" and "ambiguous"[234] are plainly controverted by the pleadings themselves which identify the relevant conduct with a high degree of particularity and clarity.[235] Pleaded conduct as further or alternative to other allegations of conduct in the same Respondent does not alter this position, particularly when viewed in context. The proceedings are at an early stage with no defence filed or discovery given in circumstances of a profound asymmetry of information between the parties.[236] The factual allegations made here are not speculative – they arise by proper inference predicated upon the voluminous factual matters pleaded as to each of the respondents' roles in

[230] See SOC para.74(a)(iii),(iv),(vi), 74(b)(iii),(iv),(vi), 74(c)(ii), 76(a)(iii),(iv),(vi), 76(b)(iii),(iv),(vi),76(c)(ii), 80(c).
[231] See Act. s. 61A(1). SOC. Para. 53(c)(i), 56(c)(i), 57(d), 58(e), 59(c)(i), 60(c)(i) – actions not connected with powers under the Act.
[232] RS [34].
[233] RS [35].
[234] RS [39].
[235] See SOC para. 51 – 60.
[236] ***Murphy*** *v Victoria* (2014) 45 VR 119; [2014] VSCA 238 at [35] per Nettle AP (as his Honour then was), Santamaria and Beach JJA.

bringing about the Approvals,[237] Continuing Approvals (continuing registration under the Act),[238] and Misleading Statements.[239] Such an approach is orthodox.[240] Preventing the applicants' the opportunity of obtaining discovery proving the pleaded case which is already *ex facie* implied by the multitudinous documents particularised in the pleading[241] would constitute a subversion of the civil justice process.[242]

35. **Public Power and Conduct Beyond Power.** The respondents assert that the pleadings cannot make out the impugned conduct to be an exercise of public power or is beyond power.[243] Misfeasance relates to the exercise of governmental or executive power.[244] Misfeasance is not confined to the exercise of power conferred by statute.[245] It extends to exercise of *de facto* power by senior public officials, including making public statements[246] and the exercise of powers and functions possessed by reason of or incident to the person's public office,[247] which need not be expressly attached to that office,[248] but only via a "link" established between the conduct and the "purported performance of a public office".[249] Public power includes the undertaking of "public duties",[250] the "functions of office", [251] a "de facto power….incident of the public office" or held by reason of the officer's "position", [252] "prerogative power conferred on the holder of the office",[253] the "purported exercise of official authority",[254] and most broadly "acts done apparently in furtherance of [the officer's] duty".[255]

36. The respondents by the nature of the impugned conduct[256] were undoubtedly acting at all times under purported powers, functions and/or responsibilities of their public offices and thereby performing a public duty as pleaded,[257] and public power, and in doing so acting *ultra vires*.[258] Undertaking public powers is unlawful where they are undertaken for a purpose other than that for which they are conferred, including as in the instant case, for a purpose contrary to the public good.[259] This unlawfulness and knowledge in the instant case have their genesis in the knowledge at the relevant times that the Vaccines

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[237] Approvals Conduct – SOC para. 51, 54, 57 – Approvals Misfeasance – SOC para. 90, 96, 102.
[238] Continuing Approvals Conduct – SOC para. 52, 55, 58 – Continuing Approvals Misfeasance – SOC para. 92, 98, 104.
[239] Misleading Statements Conduct – SOC Para. 53,56,59,60; Misleading Statements Misfeasance SOC para. 94, 100, 106, 108.
[240] *Murphy* at [35].
[241] See documents referenced in particulars – Schedules A, B, D, E, F and G.
[242] *Murphy* at [37].
[243] RS [39] –[40].
[244] See ***Leerdam*** *v Noori* (2009) 227 FLR 210; [2009] NSWCA 90 at [50] per Allsop P (as his Honour then was).
[245] *Northern Territory v* ***Mengel*** (1995) 185 CLR 307 at 355 per Brennan J. – "The tort is not limited to an abuse of office by exercise of a statutory power...Any act or omission done or made by a public official in purported performance of the functions of the office can found an action for misfeasance in public office".
[246] ***Nyoni*** *v Shire of Kellerberrin* (2017) 248 FCR 311; [2017] FCAFC 59 at [103], [108] and [118] per North and Rares JJ; ***Ea*** *v Diaconu* [2020] NSWCA 127 at [56]-[57] per Payne JA; [70]-[74] and [127] per White JA; [140]-[145] and [163] per Simpson AJA.
[247] *Nyoni* at [109]; *Ea* at [26] per Payne J. See summary in Ea at [139] per Simpson AJA.
[248] ***Obeid*** *v Lockley* [2018] NSWCA 71 (Bathurst CJ, Beazley P and Leeming JA) at [103].
[249] *Leerdam* per Spigelman CJ at [6].
[250] ***Sanders*** *v Snell (No 2)* (2003) 130 FCR 149; [2003] FCAFC 150 at [39]; Mengel at [23] per Deane J, Brennan [6].
[251] *Ea* at [157] –[158]; *Mengel* at [7] and [10]; Leerdam at [5], [6], and [48].
[252] ***Cannon*** *v Tahche* (2002) 5 VR 317; [2002] VSCA 84 at [40]; [50] – [51]; *Ea* at [76] -[77] (citing *Nyoni* at [118]), [85] per White JA; Nyoni at [113] and [118].
[253] *Ea* at [77], [85]; *Nyoni* at [118]; *Obeid* at [100].
[254] *Mengel* per Deane J at 364, 370.
[255] *Sanders* at [37].
[256] SOC para. 51 – 60.
[257] See SOC Functions and Responsibilities of Respondents para. 10-18; and 85 – 89.
[258] SOC 90(h), 92(h), 94(h), 96(h), 98(h), 100(h), 102(h), 104(h), 106(h), 108(h).
[259] *Sanders* at [89], cited in *Obeid* at [102]; *Ea* at [37]; *Cannon* at [28]; *Three Rivers* per Lord Steyn at 190.

were not rationally established to be safe, effective, or generally necessary, or rationally established to be otherwise.[260] This rendered the conduct to be unlawful and known to be (or with reckless indifference to the fact) by the respondents,[261] thereby exercising a "wilful blindness" as to those matters.[262] Notably in *Nyoni*, the use of authority derived from, and incident to, the office itself was the public power identified[263] and the impugned conduct making out the case for misfeasance arose by reason of the *misuse* of that power.[264] No statutory or common law power to engage in the impugned conduct was alleged or found to be engaged,[265] and was not a bar to a finding of misfeasance.

37. The impugned conduct was exercised (pleaded and particularised *in extenso*) in contravention of express duties arising under the Act,[266] other express duties attached to their respective offices enunciated in legislation regulating the respondents' conduct in office,[267] and critically, contrary to the purposes for which the respective powers were given[268] including the duty to act for the public good[269] arising essentially and inextricably in the performance of a public power.[270] Each and all of these are paradigmatic misuses of public office inconsistently with the honest performance of that office.[271] Each form of conduct was the purported performance of a function or power incidental to their office, inconsistent with honest performance of their respective office and thereby beyond power. This is not mere inaccuracy[272] - these are precisely the exercises of public power to which the tort of misfeasance is applied.[273] The respondents' assertions that the pleadings cannot make out the impugned conduct to be an exercise of public power or exercised beyond power is plainly wrong as disclosed on the face of the pleadings and fulsome particulars.

38. **Knowledge - Unlawfulness**. The respondents further proceed upon the twin bases of complaint that the applicants have no reasonable prospect of proving that the respondents were recklessly indifferent as to an absence of lawful authority[274] and as to the likelihood of injury to the applicants.[275] As to lawfulness of the conduct, the respondents rely upon the reasoning in *M83A*, but erroneously transform fact-specific *obiter* into statements of principle for general application. *M83A* has no factual application here. Whether

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[260] SOC. Para. 42 and 43 and Particulars – Schedule B para. 1-155, Schedule C, and Schedule D para. 42-43.
[261] SOC 90(i), 92(h), 94(i), 96(i), 98(i), 100(i), 102(i), 104(i), 106(i), 108(i).
[262] *Plaintiff **M83A**/2019 v Morrison (No 2)*[2020] FCA 1198 at [96] –[99] per Mortimer J; *Mengel* at [24] per Deane, J.
[263] *Nyoni* at [107]. See also *Ea* at [50].
[264] *Nyoni* at [113]. See also *Ea* at [50].
[265] *Ea* at [50] referring to *Nyoni* at [113]. Notably in *Ea*, summary dismissal was rejected with leave to replead - notwithstanding "inadequacies of the pleading" and "failure to articulate clearly the basis for his claim" due to the "blurry boundaries of the tort leave open the possibility that the applicant will be able to establish relevant misconduct".
[266] Approvals Statutory Breaches - SOC para. 90(g)(i), 96(b)(ii), 96(g)(i).
[267] Skerritt Public Governance Breaches - SOC para. 90(g)(iii); Secretary Public Governance Breaches - SOC para. 96(g)(iii); the Chief Medical Officer Public Governance Breaches – SOC para. 102(g)(i).
[268] Approvals TGA Functions Breaches SOC para. 90(g)(ii), 96(g)(ii); TGA Policies Approvals Breaches SOC para. 90(g)(iv), 96(g)(iv).
[269] Breaches of Duty to Act for the Public Good – SOC para. 90(e)(iii), 90(h)(v) and (viii), and 90(i)(ii), 92(e)(iii), 92(h)(v) and (viii), and 92(i)(ii), 94(e)(vi) and (vii), 94(h)(ii),(vi),and (ix)(3), 94(i)(ii), 96(e)(iii), 96(h)(v) and (viii), 96(i)(ii), 98(e)(iii), 98(h)(v) and (viii), 98(i)(ii), 100(e)(vi) and (vii), 100(h)(ii), (vi), and (ix)(3), 100(i)(ii), 102(e)(iii), 102(g)(ii), 102(h)(v)(3) and (viii)(3), 102(i)(iv), 104(g)(ii), 104(h)(iv) and (vii), 104(i)(ii), 106(e)(vi), 106(h)(ii),(vi), and (ix)(3), and 106(i)(ii), 108(h)(ii),(v), and (viii)(3), and 108(i)(ii).
[270] *Three Rivers* at 190 per Lord Steyne; *Cannon* at [28] and [40]; *Obeid* at [35] per Bathurst CJ.
[271] *Nyoni* at [113]. See also *Ea* at [50].
[272] RS [40].
[273] *Nyoni* at [109]; Mengel at 345.
[274] RS [42]
[275] RS [43]

legal advice was sought and whether the person acted upon may indeed be a relevant consideration in the recklessness standard.[276] Rares J held however that *understanding that there is a risk that the conduct may be unlawful* indicates recklessness where the officer *proceeded without advice*.[277] Mortimer J's reasoning in *M83A* that a lawfully complex situation may be exculpatory in the absence of advice due to lack of subjective knowledge[278] does not upset this proposition. Whether or not this is the case is unknown as the respondents have yet to file any defence. As to whether, when and how the respondents obtained legal advice in respect of their conduct may only be gleaned post-discovery and are undisclosed.

39. *M83A* is in any event factually distinguished. Causing the lawful consumption of the Vaccines in the concurrent knowledge of the absence of safety, efficacy and necessity in the Vaccines is on its face patently not a "legally complicated" proposition. The Act is solely purposed to these ends, and such is entirely consistent with a public duty to act for the public good. This *must* have manifested a subjective knowledge or reckless indifference as to the unlawfulness of those acts in the minds of each of the respondents at the time those acts and omissions proceeded, in the exercise of powers contrary to their intended purpose. By obvious reason of their offices, each of the respondents were aware of the scope of the Act, which as they all must have known, was saturated with "clear and unequivocal statutory prohibition[s] of which they could be assumed to be aware" (being one of the negating conditions of the need for legal advice stated by Mortimer J in *M83A*),[279] that is, that no therapeutic good can be lawfully registered for consumption in the absence of rationally demonstrated safety and efficacy. States of mind can only arise by reasonable inference. For the respondents at least, to know that the Vaccines were unsafe, ineffective and/or unnecessary was to know that their approval and distribution to the Group members was unlawful and contrary to the Act or any purpose for which power is given. The means by which the respondents "acquired knowledge of the…..unlawfulness of their proposed conduct"[280] are plainly pleaded,[281] and logically arise on the facts. The respondents' complaint is predicated on ignoring the facts and is wrong.

40. **Knowledge - Likelihood of Injury**. The contention that there is no prospect of the applicants establishing the respondents knew of the likelihood of harm[282] is plainly wrong as disclosed by the pleaded case. The applicants assert that each of the respondents knew or were reckless to the fact that their conduct would likely cause harm the group members.[283] The pleaded knowledge of the respondents[284] fundamentally must have created in the mind of respondents knowledge of the high likelihood of risk of harm in those consumers of the Vaccines, as illustrated by the absence of safety,

[276] *MM Constructions* at [305] citing *Minister of Fisheries v Pranfield Holdings Ltd* [2008] NZCA 216 at [118].
[277] *Brett Cattle Company Pty Ltd v Minister for Agriculture* [2020] FCA 732; 274 FCR 337 at [375] –[381].
[278] *M83A* at [112].
[279] *M83A* at [112].
[280] *M83A* at [112].
[281] SOC Sched. D Particulars – 1st Res: para.90(i), 92(i), 94(i);2nd Res: para.96(i),98(i),100(i);3rd Res: para.102(i),104(i),106(i);4th Res. para.108(i).
[282] RS [43].
[283] See generally - SOC para. 69(b)(ii), 70(d)-(e); specifically - SOC para. 90(i)(iv), 91(h)(vi)(2), 91(h)(viii)(2), 91(i)(iv), 94(h)(vii)(2), 94(h)(ix)(2), and 94(i)(iv).
[284] SOC para. 42-43; para. 1 to 155 Schedule B; Schedule C; para. 42-43 Schedule D.

efficacy, necessity, and positive risk/benefit balance in the Vaccines. The respondents have not adduced any evidence to the contrary. That the respondents would have been aware of the potential of harm to group members is inevitable in the context of the respondents' knowledge.

41. The respondents submission that the applicants are required to plead facts that are *only* consistent with dishonesty should be rejected.[285] The applicants are required to plead facts and circumstances which, if established by evidence at trial, are capable of supporting an inference of malice in the requisite sense.[286] It is open for the Court to infer malicious intent from the allegations in the SOC that the respondents acted with reckless indifference.[287] *A fortiori*, the fact that the same act could have been decided to have been done for lawful purposes can still be an abuse of power where done for improper purpose,[288] as is alleged.[289] In any case, the alleged knowledge is utterly incompatible with mere incompetence and only consistent with knowledge of or reckless indifference as to the acute and high risk of harm in those consuming the Vaccines.[290] The factual matters establish the probability of harm to the Group Members as a result of consuming the Vaccines, which the respondents vainly seek to recharacterise as a mere difference of understanding as to the degree of risk. This understanding must, post-Approvals, have become further galvanised in light of, for example, a known reporting rate of Vaccines' injuries exponentially above any previous similar therapeutic good[291] and unprecedented since surveillance of injuries was conducted by the Commonwealth.[292] The respondents' submission is wrong.

Conclusion

42. The respondents' application proceeds upon a misapprehension and misapplication of the law and assertions are made with apparent ignorance as to the factual matters in the evident pleaded and particularised case of the applicants. The application seeks to deny the applicants the opportunity to ventilate the material factual matters which can only be determined by hearing of the substantive matter at trial. The respondents have failed to discharge their onus to establish that the proceeding has no reasonable prospect of success or does not disclose the case against them or that any part of the pleading ought to be struck out. The application ought to be dismissed with costs.

M A Robinson SC, J M Manner and A C White

Counsel for the Applicants

11 November 2024

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[285] RS [41] and [43].

[286] *Finance & Guarantee Company Pty Ltd v Auswild (No 2)* [2016] VSC 559 at [40] per Sifris J; see also discussion of authorities in *Hitchcock v Pratt Group Holdings Pty ltd as trustee for the Pratt Family Holdings Trust* [2024] NSWSC 1292 at [143]-[153] per Meek J.

[287] *Alpert v Commonwealth of Australia (Department of Defence) (No 2)* [2024] FCA 447 at [99] per Snaden J. As to those allegations see for example SOC at para. 42(d)(vii), 42(d)(viii), 43(d), 90(g)(i)(3), and 90(g)(i)(6)(iv).

[288] *Nyoni* at [96].

[289] SOC para. 90(e)(iii), 90(i)(ii), 92(e)(iii), 92(i)(ii), 94(e)(vii), 94(i)(ii), 96(e)(iii), 96(i)(ii), 98(e)(iii), 98(i)(ii), 100(e)(vii), 100(i)(ii), 102(e)(iii), 102(g)(ii), 102(i)(iv), 104(e)(iii), 104(i)(ii), 106(e)(vi)(3), 106(i)(ii),108(i)(ii).

[290] Knowledge of Harm - SOC para.42-43; Particulars of Knowledge Sched. B, Sched. D para.42-43; Circumstances Knowledge – Sched. C.

[291] See Particulars Sched. B para. 134 – 138.

[292] See Particulars Sched. B para. 15, 17, 19 and 27.