NOTICE OF FILING

Details of Filing

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File Title:	ANTHONY LEITH ROSE & ORS v THE SECRETARY OF THE DEPARTMENT OF HEALTH AGED CARE, BRENDAN MURPHY & ORS
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The date of the filing of the document is determined pursuant to the Court's Rules.

Form NCF1

Concise Statement

No. NSD349 of 2023

Federal Court of Australia
District Registry: NSW
Division: GENERAL

ANTHONY LEITH ROSE and others
Applicants
THE SECRETARY OF THE DEPARTMENT OF HEALTH AND AGED CARE, BRENDAN MURPHY and others
Respondents

PROCEEDING AND GROUP

1. The group members, including the applicants, have suffered serious adverse events including hospitalisation, serious and/or permanent injury, and death, caused by injection of one or more of the therapeutics described as "Covid-19 vaccines" sponsored by Pfizer Australia Pty Ltd, Moderna Australia Pty Ltd and AstraZeneca Pty Ltd **("Vaccines").** Those injuries were caused after the respective dates of purported "provisional approvals" issued by the Therapeutic Goods Administration **("TGA")** allowing them to be used by the Australian population, issued in the period of 25 January 2021 to 20 January 2023 **("Approvals")** purportedly pursuant to the *Therapeutic Goods Act 1989* **("Act")** and *Therapeutic Goods Regulations 1990* **("Regulations")**. The Approvals remain in force subsequent to the respective approval dates and have not been revoked **("Continuing Approvals").** The Vaccines were said to be approved to act against the SARS-CoV-2 virus **("Virus")** and the consequent symptomatic disease known as Coronavirus Disease **("Covid")**.

DEPARTMENT & TGA

2. The Department of Health is responsible for the betterment of the health and wellbeing of the Australian population and regulating medicines for that purpose, including through the approved functions of the TGA under the Act. The TGA was required to do this by assessing medicines' safety, efficacy, quality and risk-benefit profile before approval and after approval by continuing to monitor those medicines for safety and efficacy based upon reported adverse events data and other collected safety and efficacy data. The TGA is the sole body through which lawful supply of the Vaccines occurred to the group members and was purportedly guided by widely published policy that it only approves and maintains on the register a vaccine for use in Australia if it has established following rigorous assessment of the best available scientific evidence that the vaccine's benefits greatly outweigh any risks for the Australian public. The overarching requirements of maintaining safety, efficacy and quality are reflected in statute (s.4 of the Act).

3. The National Covid-19 Vaccine Taskforce, of which the first and second respondents were members, implemented mass distribution of the Vaccines to the Australian population, undertook a public

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information campaign to cause the highest possible uptake of the Vaccines by the Australian public, collected and monitored all available Covid and Vaccines data and advised the Minister of that data. The Commonwealth Science and Industry Technical Advisory Group, of which the first and third respondents were chair and deputy chair respectively, provided advice in that role as to the scientific validity or otherwise of research into the safety and effectiveness of the Vaccines.

RESPONDENTS

4. The five respondents are each identified along with their primary roles and responsibilities in the Third Further Amended Statement of Claim at [10] to [14]. They were bound at all times by a duty to act for the public good.

RESPONDENTS KNOWLEDGE

5. The Vaccines were purposed and declared publicly by the respondents to the Australian public to be for the prevention of transmission of the Virus, infection with the Virus, Covid, severe Covid, hospitalisation from Covid, and death from Covid.

6. The respondents at all material times knew and/or had reckless disregard as to the existence of facts and data prior to the Approvals and following distribution of the Vaccines to Australians establishing that the Vaccines were unsafe; were ineffective for the contended Vaccine purposes; produced risk for the recipient which significantly outweighed any benefit; were not a major therapeutic advance; were unnecessary for the Australian population due to the low infection fatality rate from Covid; were never tested for: any of the contended purposes of the Vaccine (except symptomatic Covid), safety or efficacy in certain groups of people for whom the vaccine was intended to be and was in fact used (e.g. pregnant women), long-term efficacy, genotoxicity, carcinogenicity, long-term safety, risks associated with the use of novel mRNA technology and adjuvants, Vaccine Associated Enhanced Disease; and that the data provided by the Sponsors was not patient-level direct data but rather Sponsor summaries and characterisations of trial data.

7. Subsequent to the Approvals, the respondents at all relevant times knew and/or had reckless disregard as to the existence of facts and data that disclosed an historically unprecedented exponential proliferation of adverse events in Vaccine recipients including serious injury and death following the Approvals and distribution of the Vaccines to the Australian public. These were disclosed to the respondents and in terms of absolute volume, the reported death and injury in Vaccines recipients exceeded the combined preceding 50 years of recorded data for every vaccine ever approved for use in Australia by ~500%, and in respect of rate of injury, exceeded previous injury rates in certain types by up to ~5000%. Subsequent to the Approvals, further factual matters and data continued to be disclosed to the respondents, making manifestly known to them that the Vaccines were harmful, inefficient and unnecessary.

SKERRITT AND THE SECRETARY – ACTS AND OMISSIONS

8. Notwithstanding the matters at Para. 6 herein above, the first and second respondents caused the Approvals to be made and wrongly directed and/or advised the persons imbued with such power that the Vaccines were safe, effective and necessary and that the Approvals ought to be granted, and/or failed or refused at any time to advise or direct that the Approvals ought not be granted because the Approvals would create an imminent risk of death, serious illness or serious injury to members of the Australian population and the Vaccines did not meet the critical safety and efficacy requirements. Notwithstanding and in the circumstances of their knowledge subsequent to the harm and the injury and the deaths caused by the Approvals, the first and second respondents continued to advise and affirm that the Vaccines continued to meet the critical safety and efficacy requirements, and/or failed or refused to undertake, direct, and/or advise the persons imbued with such power that the Approvals be or ought to be cancelled or that a failure to cancel the Approvals would create an imminent risk of

death, serious illness or serious injury to the Australian population, or that the Vaccines did not meet the critical safety and efficacy requirements. The first and second respondents' acts and omissions through the Approvals and Continuing Approvals caused or materially contributed to the wide distribution of and receipt of the Vaccines by the Australian population including the group members.

CHIEF MEDICAL OFFICER – ACTS AND OMISSIONS

9. Notwithstanding and in the circumstances of his knowledge prior to the Approvals of the Vaccines, the third respondent, the Chief Medical Officer directed and/or advised the Commonwealth, its officers and/or persons imbued with power to grant the Approvals that the Vaccines met the critical safety and efficacy requirements, that wide distribution of the Vaccines to and consumption of the Vaccines by the Australian population should proceed as soon as possible and that this would further the health and wellbeing of the Australian population, and/or failed or refused at any time to advise and/or direct the Commonwealth, its officers and/or persons imbued with power to grant the Approvals that the Vaccines did not meet the critical safety and efficacy requirements, that wide distribution of the Vaccines to and consumption of the Vaccines by the Australian population should not proceed, and that such distribution would be detrimental to the health and wellbeing of the Australian population and create an imminent risk of death, serious illness or serious injury.

10. Notwithstanding and in the circumstances of his knowledge subsequent to the Approvals of the Vaccines and the harm and deaths they were causing, the Chief Medical Officer continued to advise and affirm that the Vaccines continued to meet the critical safety and efficacy requirements and/or failed or refused to undertake, direct, or advise the Commonwealth, its officers and/or persons imbued with power to suspend the Approvals that the Vaccines did not meet the critical safety and efficacy requirements, should not be distributed or used by the Australian population and that to do so would create an imminent risk of death, serious illness or serious injury to the Australian population. The Chief Medical Officer Approvals and Continuing Approvals caused or materially contributed to, and the Chief Medical Officer knew, that those acts and omissions would and did cause wide distribution of the Vaccines to and receipt of the Vaccines by the Australian population.

RESPONDENTS' MISLEADING STATEMENTS

11. Notwithstanding and in the circumstances of their knowledge prior to and subsequent to the Approvals of the Vaccines' harm, inefficacy and unnecessity and the known reported injury and deaths, the first, second, third and fourth respondents made or caused to be made voluminous public statements to the Australian public as to the safety, efficacy and necessity of the Vaccines which were misleading and which individually and in confluence, directly or impliedly represented to the Australian public including the group members, *inter alia*, that the Vaccines were unquestionably safe and effective for the contended purposes of the Vaccines and had been subjected to the most rigorous assessment for safety and efficacy possible prior to and subsequent to the Approvals; that if people did not take the Vaccines they would be at a high risk of dying or becoming seriously ill; and that the Vaccines possessed a positive risk-benefit profile for the entire Australian population in the indicated age ranges of the Approvals. These statements were misleading because they were contrary to the matters known to the respondents, being that the Vaccines were known to be harmful, they were inefficient and unnecessary and that they caused injury and death. The statements were made for the primary and improper purpose of inducing the greatest number of the Australian public possible to receive one or more of the Vaccines without hesitation or delay, and in the knowledge that those statements would be relied upon by the Australian public for that purpose. The respondents knew or were recklessly indifferent to the fact that the matters contained in the misleading statements were known to have been rationally established as false or alternatively not rationally established as true.

NEGLIGENCE

12. By reason of their position and powers incident to their office the respondents controlled the lawful and practical access to the Vaccines in Australia by the Australian population, and public statements made on behalf of the Commonwealth as to the Vaccines' safety, efficacy, necessity and risk-benefit profile. The respondents were aware of this position of control and reliance, and knew that the Australian public would rely upon the conduct of the respondents as being made lawfully, in pursuit of the betterment of the Australian public's health and wellbeing, in good faith and with reasonable care and skill, and that statements as to the Vaccines' safety and efficacy were true and based upon rational determinations arising from the known evidence. The respondents were aware of the gravity of their acts and omissions, being that the Australian public would be exposed to the risks of serious harm if those acts and omissions were not exercised lawfully, with reasonable care, for legitimate purpose, or in good faith. They further knew the vulnerability of the Australian public where those acts and omissions would provide access to and injection with the Vaccines and therefore directly affect the likelihood of serious personal injury and harm. By the making of the misleading statements, each of the respondents claimed the Vaccines to be safe, effective and necessary for the group members and thereby personally assumed responsibility for the safety, efficacy and necessity of the Vaccines for the group members and any arising harm. It was reasonably foreseeable that those acts and omissions would cause the group members to take the Vaccines, and that where not undertaken with reasonable care, would expose the group members to the probability and likelihood that they would suffer serious personal injury, loss and harm. The respondents owed a duty of care to the group members to exercise reasonable care and skill when undertaking acts and omissions which would cause the Vaccines to become lawfully available and distributed to the group members and when declaring the Vaccines to be safe, effective and necessary for use by the group members.

13. The impugned conduct (that is, the conduct outlined in [5] to [11] herein) was therefore unlawful; in breach of the Act, the Regulations, the TGA policies and the TGA functional responsibilities (as regards Skerrit and the Secretary); in breach of the department's purpose for the betterment of the health and wellbeing of the Australian population; in breach of the relevant public sector legislation; undertaken for an ulterior purpose inconsistent with an honest attempt to act lawfully or in accordance with the purpose for which the power to act was conferred and in bad faith and so unreasonable that no reasonable person could have so acted or failed to act. The impugned conduct was thereby undertaken in breach of the duty of care owed to the group members. The impugned acts and omissions of the respondents caused or materially contributed to the group members receiving one or more of the Vaccines and thereby suffering injury, loss and/or damage.

MISFEASANCE IN PUBLIC OFFICE

14. Alternatively, each of the first to fourth respondents has, by the impugned conduct engaged in misfeasance in public office. They were each at the relevant times public officers holding public office, discharging a public duty for and on behalf of the Commonwealth, and each owed and were acting under a duty of care to the group members to exercise the powers incident to their office for the public good and not for any ulterior purpose. In undertaking the impugned conduct, they: (a) possessed at the relevant times knowledge of, or reckless indifference to the facts of the known Vaccine harm, inefficacy and unnecessity and the known reported vaccines injury and deaths, (b) were bound by and purportedly acting pursuant to powers incident to their respective offices, the provisions of the Act and Regulations (particularly s. 22D(2), s. 24(2)(b) and (d), and s. 25(1)(d)(i) of the Act and r. 10L(1)(a) and (c) of the Regulations), the TGA's Statutory Purpose, the widely published TGA policies, the TGA responsibilities (as to Skerritt and Secretary), the department's purpose, the relevant public sector legislation, and duties to act in good faith, with reasonable care and for the public good, (c) did so for an improper purpose, (d) acted in a fashion that was legally unreasonable, or that was so unreasonably that no reasonable person could have so acted, (e) did not have jurisdiction or power to do so, (f) acted

for a purpose other than a purpose for which the power is conferred and unlawfully, (g) acted inconsistently with the public good, (h) acted in a manner likely to cause harm to the group members, (i) acted in bad faith, and (j) knew or alternatively were recklessly indifferent as to the existence of those matters.

15. Accordingly, the respondents in the impugned conduct knew or were recklessly indifferent as to the fact that their impugned conduct was unlawful, undertaken without any lawful power to do so and likely to cause harm to the group members, and had thereby undertaken misfeasance in public office.

CAUSATION

16. The impugned conduct of the first to fourth respondents in the circumstances caused and further or alternatively, materially contributed, as to the first and second respondents, to the occurrence of the Approvals and the Continuing Approvals, as to the first to fourth respondents, the wide distribution of the Vaccines to the Australian population including the group members, the injection of one or more of the Vaccines by the group members, harm, loss and damage to the group members. The Commonwealth is vicariously liable for the tortious actions of these respondents.

DAMAGES

17. The applicants have suffered loss and damage as a consequence of the impugned conduct of the respondents and the applicants on their own behalf and on behalf of other group members, seeking damages including damages for personal injury, general damages, and economic loss, and exemplary damages.

Certificate of lawyer

I Natalie Strijland certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 7 May 2024

Signed by Natalie Strijland

Lawyer for the Applicant