

### Vaccines, Long Vaccine Syndrome, and Long Covid

A submission by **CO**VERSE Ltd to the Australian Parliament Inquiry into Long Covid and Repeated Covid Infections

For questions about COVERSE visit coverse.org.au

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### Term of Reference Addressed in this Submission

- 1. The patient experience in Australia of Long Covid and those with repeated Covid infections, particularly diagnosis and treatment;
- 3. Research into the potential and known effects, causes, risk factors, prevalence, management, and treatment of Long Covid and those with repeated Covid infections in Australia;
- 4. The health, social, educational and economic impacts in Australia on individuals who develop Long Covid and/or have repeated Covid infections, their families, and the broader community, including for groups that face a greater risk of serious illness due to factors such as age, existing health conditions, disability and background;
- 5. The impact of Long Covid and those with repeated Covid infections on Australia's overall health system, particularly in relation to deferred treatment, reduced health screening, postponed elective surgery, and increased risk of various conditions including cardiovascular, neurological and immunological conditions in the general population; and
- 6. Best practice responses regarding the prevention, diagnosis and treatment of Long Covid and those with repeated Covid infections, both in Australia and internationally.

### 1. Executive Summary

COVID-19 vaccines are an essential aspect of the discussion of Long Covid and repeat Covid infection for four key reasons:

- 1. Vaccine risks, as well as benefits, must be openly discussed to ensure that trust in public health and vaccines is not undermined.
- 2. There is a *significant* overlap in the range of symptoms seen in Long Covid and the serious ongoing symptoms caused by COVID-19 vaccine adverse reactions.
- 3. Understanding the illnesses caused by COVID-19 vaccines is essential for isolating and mapping complications of Long Covid.
- 4. People who have suffered significant COVID-19 vaccine injuries are at a greater risk of severe complications, including Long Covid, if infected or reinfected with Covid.

Our submission focuses on COVID-19 vaccine Serious Adverse Events (SAE) and what we call "Long Vaccine Syndrome" *alongside* Long Covid. We explain the scientific and policy basis for addressing these conditions together.

We believe that urgent reforms to the Australian Government's pharmacovigilance efforts and management of adverse events are critical to ensuring the integrity of, and confidence in, vaccination programs and government public health measures.

There are many pressing issues facing the current parliament. As the challenges of social justice and equity issues, economic issues, environmental issues, and geopolitical issues come to a head, how we treat our own in times of crisis is a mark of our identity.

After heeding the call by our governments to step-up and get vaccinated for the good of our community, Australian citizens and residents suffering a COVID-19 vaccine injury have faced ongoing derision, gaslighting, and censorship, while suffering from oppressive health disabilities with zero support.

The extent to which our politicians and governments have almost completely turned their backs on the victims of COVID-19 vaccine harm is a stain upon our democracy and our enviable government-funded public health system. This situation does not bode well for future public health crises, and is a tragedy of significant proportion.

We are calling on the Parliament of Australia to urgently address this injustice. Our lives and livelihoods depend upon the integrity of this government to right the wrongs that have been inflicted upon this group of Australian citizens who have suffered so greatly for their civic contributions.

### 2. Recommendations

This submission details a series of issues that lead to the following recommendations:

1	Acknowledge the international and emerging research on COVID-19 vaccine injuries and Long Vaccine Syndrome.
2	Instruct doctors to fully comply with the reporting of all Adverse Events Following Immunisation (AEFI), irrespective of whether they are 100% certain the conditions are connected to the vaccine.
3	Accept COVID-19 vaccine-injured Australians into all Long Covid Clinics, regardless of whether they have had a COVID-19 infection or not.
4	<ul> <li>Provide Australian doctors and specialists with comprehensive education and training opportunities to:</li> <li>Access and follow COVID-19 vaccine Serious Adverse Event (SAE) medical research.</li> <li>Recognise COVID-19 vaccine-caused illnesses.</li> <li>Deliver frontline treatment protocols for these adverse events in line with leading-edge international innovations.</li> </ul>
5	Encourage all Australian research projects concerning Long Covid to include COVID-19 vaccine injuries.
6	Accelerate all of the above by pursuing collaborations with leading patient-led organisations and medical research undertakings already addressing COVID-19 vaccine reactions internationally (see Attachment A).
7	<ul> <li>Overhaul the COVID-19 vaccine claims scheme to: <ul> <li>Allow for claims against all injuries caused by the COVID-19 vaccines.</li> <li>Remove the hospitalisation requirement.</li> <li>Readjust the lost income test to adequately account for financial losses suffered by non-salaried workers (e.g. business owners who may not be able to demonstrate lost income).</li> <li>Remove the requirement that patients must have accrued minimum losses/costs of \$1,000.</li> </ul> </li> </ul>
8	Conduct an independent inquiry into vaccine approvals and pharmacovigilance processes of responsible government agencies, regarding the minimisation of, and disinterest in, serious adverse reactions.
9	Conduct an independent inquiry into potential collusion between government officials and media actors (including social media companies). Issues to assess include suppression of reasonable, scientific medical opinions and censorship of now-proven scientific facts about possible adverse vaccine outcomes that ran counter to the prevailing public health messaging strategies.
10	Conduct an independent inquiry into health profession regulators, who bullied and censored doctors who were attempting to raise concerns about vaccine safety and patient risk. This should focus not just on the improper regulation of doctors but on the abandonment of patients as a result of these measures.

### 3. About **CO**VERSE

**CO**VERSE Ltd is the only non-profit organisation in Australia run by and for people who have suffered a significant adverse reaction following their COVID-19 vaccinations.

The organisation was founded by a group of Australian professionals<sup>1</sup> who have had medically recognised, life-changing serious adverse reactions to COVID-19 vaccines but do not qualify for the Government's COVID-19 vaccine claims scheme.

We represent a larger group of genuinely injured and ill Australians suffering from serious adverse reactions to COVID-19 vaccinations. We estimate the number of Australian residents suffering significant ongoing adverse reactions to be in the many thousands.<sup>2</sup>

**CO**VERSE advocates against government neglect and medical abandonment of the COVID-19 vaccine-injured through good science, proactive medical industry engagement, inclusive public policy, and honourable political discourse.

We work voluntarily for all COVID-19 vaccine injured Australians. We also provide patients and health professionals with new and emerging information about COVID-19 vaccine injuries and leading-edge insights on how to treat them, based on peer-reviewed science and overseas studies. We provide this information due to the fundamental absence of Australian Government diagnostic and medical guides being provided for our conditions in any form whatsoever.

### 4. Introduction and Context

The COVID-19 vaccination program is the largest and most accelerated adult vaccination program in global history, undertaken during intersecting political crises and advanced, non-transparent, developments in the biomedical and ICT industries.

Australian public health authorities implemented this unprecedented vaccination campaign in an attempt to alleviate pressure on public health facilities and improve patient and public health outcomes in the midst of a pandemic. In all cases, the vaccines utilised were brand new products with no long-term safety data.<sup>3</sup>

Australia was in a novel situation at the commencement of the global vaccine rollouts, in so far as our border closures and domestic lockdowns prevented a majority of Australians from being infected prior to being vaccinated. This unique situation provided significant clarity around causation with regard to illnesses resulting from serious adverse reactions to COVID-19 vaccines, as distinct from COVID-19 itself. However, the Australian Government had no national medical plan for addressing the diagnostic or treatment needs of those injured by these vaccines, who all rolled up their sleeves for the public good.

Drug regulators typically demand very high standards of safety outcomes for vaccines, with serious adverse events being extremely rare, typically in the order of 1-in-1,000,000 to 1-in-100,000 individuals.<sup>4</sup> However, for the COVID-19 vaccines we are observing a significantly larger rate of adverse events than we might expect, perhaps as much as 100× greater.<sup>5</sup> Hence COVID-19 vaccines appear to be significantly more likely to cause serious and other adverse reactions compared with existing vaccines used throughout the general population.

<sup>&</sup>lt;sup>1</sup> For more information about **CO**VERSE see the About and FAQ sections of our website: https://coverse.org.au/ <sup>2</sup> Estimate based on the number of patients in our online support groups, and the far larger group of patients who are not part of any support groups.

<sup>&</sup>lt;sup>3</sup> [Haseltine2020] https://wapo.st/3AlhzCK

<sup>&</sup>lt;sup>4</sup> [DOHAC2020] https://doi.org/10.33321/cdi.2022.46.47

<sup>&</sup>lt;sup>5</sup> [Montano2022] https://doi.org/10.3389/fpubh.2021.756633

When a person first experiences significant issues following their COVID-19 vaccinations it is reasonable that they seek and expect medical care. It is also reasonable that, should they not receive proper medical attention, especially where vaccinations have been mandated, they could call a government hotline and be told of other routes to public assistance. Following proper medical attention, it would be reasonable also that health information on COVID-19 vaccine reactions — what to expect and what appropriate treatments to seek — might be given to them if they were confirmed to be a reaction case. None of this happens in Australia.

Despite thousands of peer-reviewed scientific papers and case studies that address COVID-19 vaccine reactions,<sup>6</sup> only extremely limited medical guidelines have emerged for Australian GPs or other specialists to aid doctors or patients with the diagnosis or treatment of serious complications caused by the COVID-19 vaccines. Even while Long Covid research and education becomes prioritised by doctors and patients, there is little to address COVID-19 vaccine sufferers at all.

We assert the scientific and public health rationality of our submission, following the publication of the article "Serious adverse events of special interest following mRNA COVID-19 vaccination in randomised trials in adults" in the journal *Vaccine*<sup>7</sup> (and subsequent open letter in the *British Medical Journal*),<sup>8</sup> the position statement by OzSAGE on the importance of managing COVID-19 vaccine adverse events,<sup>9</sup> and the release of raw data from the CDC (in the USA) from their V-Safe surveillance app showing alarming rates of reactions and hospitalisation.<sup>10</sup> Almost two years into the vaccine rollout, it is not scientific or responsible that the Australian Government continues to provide official information that misinforms the Australian public about the safety and risks of the COVID-19 vaccines and the degree of real ongoing harm they have caused in the community.

### 4.1. Data for All Australians

It is reasonable to expect that Australian citizens receive Government updates on COVID-19 vaccine reactions that reflect the severity and duration of COVID-19 vaccine illnesses. This data is not collected,<sup>11</sup> thus is not available to Australian Government decision-makers.

COVID-19 vaccine-injured Australians receive zero follow-up investigation of their case after having their cases reported to pharmacovigilance authorities. There is no evidence among the COVID-19 vaccine-injured in Australia of the Government's claims that it investigates or tracks any serious adverse events cases beyond one initial phone call (which seems aimed at merely confirming the victim's identity and the veracity of their initial reaction).

For this reason, **CO**VERSE questions the claim that COVID-19 vaccine-injuries are 'self-limiting', as the Government has collected *no ongoing data* with which to make this claim.

<sup>&</sup>lt;sup>6</sup> for example, https://react19.org/1250-covid-vaccine-reports

<sup>7 [</sup>Fraiman2022] https://doi.org/10.1016/j.vaccine.2022.08.036

<sup>&</sup>lt;sup>8</sup> [Doshi2022] https://www.bmj.com/content/378/bmj.o1731/rr-0

<sup>&</sup>lt;sup>9</sup> [OzSAGE2022] https://bit.ly/3X1fXrw

<sup>&</sup>lt;sup>10</sup> [ICAN2022] https://www.icandecide.org/v-safe-data

<sup>&</sup>lt;sup>11</sup> While pharmacovigilance agencies are required to accept and analyse reports of adverse reactions following immunisation (AEFI) they are not compelled to track these cases to determine ongoing and long-term impacts. The only way this information is gathered is via voluntary follow-up reports from patients and/or their doctors.

### 4.2. The Real Scope of Serious COVID-19 Vaccine Injuries

Despite claims of COVID-19 vaccine products to be both safe and effective, a diverse list of life-changing adverse reactions emerged during the clinical trials and the global rollout that have not been acknowledged by drug regulators.<sup>12</sup>

While some of these adverse reactions (such as thrombosis, myocarditis and pericarditis) have since been acknowledged by governments, there remain a large number of people suffering from a clear constellation of other adverse reaction illnesses that have not been recognised by drug regulators or governments, and who receive no assisted treatment or compensation.

Typically, an adverse reaction to a COVID-19 vaccine begins in the first hours or days following vaccination.<sup>13</sup> However, some reactions may occur within minutes, and others can have a more delayed onset, with some confirmed cases not emerging until 3 months after vaccination<sup>14</sup> (**CO**VERSE has suspicion of some cases emerging at up to 6 months post vaccination).

Following the acute phase of a serious COVID-19 vaccine injury, "Long Vaccine Syndrome" is the name being given to conditions of patients whose serious adverse reactions develop into multi-system illnesses with waves of sequelae, and no known end-point or duration.

Common and chronic ongoing symptoms of Long Vaccine Syndrome are similar to Long Covid, and include:

- brain fog
- extreme fatigue
- memory loss
- tinnitus
- headaches
- blurred vision
- chest pain
- abnormal heart rate
- myo/pericarditis

- shortness of breath
- circulatory issues
- blood pressure changes
- hair loss
- numbness
- tingling / burning
- internal tremors
- muscle twitching
- vascular bulging

- joint pain
- gastric issues
- food sensitivities
- menstrual issues
- rashes
- bruising
- reactivated diseases
- chronic pain
- organ dysfunction

The scientific link between Long Vaccine Syndrome and Long Covid is based on research that suggests that some (although clearly not all) Long Covid sufferers have the spike protein of the SAR-CoV-2 virus at the source of their problems.<sup>15</sup> This same protein is the antigen used in all of the COVID-19 vaccines currently available in Australia.

An expanded description of Long Vaccine Syndrome is included in Attachment B, and early data from **CO**VERSE's patient symptom survey is presented in Attachment C.

While there is evidence that Long Vaccine Syndrome chronic reactions, affecting multiple organs in the body, require frontline proactive treatment to alleviate them (as COVID-19 does), our injured members immediately come up against barriers to this.

For example, it is never stated in the media (or by the Government), that a significant percentage of individuals afflicted with acknowledged vaccine reactions such as myocarditis are also suffering ongoing and complex Long Vaccine Syndrome.

<sup>&</sup>lt;sup>12</sup> [Fraiman2022] https://doi.org/10.1016/j.vaccine.2022.08.036

<sup>&</sup>lt;sup>13</sup> https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

<sup>&</sup>lt;sup>14</sup> [2GB2022] https://www.2gb.com/teenagers-harrowing-journey-after-covid-vaccine-side-effect

<sup>&</sup>lt;sup>15</sup> [Schieffer] https://doi.org/10.3389/fcvm.2022.992686

Based on the health challenges being faced by members in our patient support groups, **CO**VERSE estimates that as many as two thirds of those afflicted with myocarditis or pericarditis from their vaccinations fall into this category, which is in stark contrast to government messaging that claims these conditions are mostly mild and resolve quickly. Across our community, this is simply not the case; furthermore, no research body in Australia is studying this chronically ill community of Australians.

Our data suggests that those people suffering from Long Vaccine Syndrome typically suffer for many months (6+) before seeing any improvement at all, and most have yet to make a full recovery. This also is in dramatic contrast to public health messaging around vaccine safety, which never relays the seriousness or longevity of symptoms being experienced by those whose reactions are not "mild" and not "short-lived".

The negative impacts that these vaccine products have had on an unknown but likely large number of Australians is not currently estimable, while the *almost total lack of support* that many people suffering adverse reactions in Australia have had to face is totally unendurable and politically unsustainable. Internationally, patient groups are continuing to lose members to suicide; our only recent incorporation prevents us from having suicide statistics for Australia.

Our submission therefore draws attention to the systemic inadequacies that must be addressed to ensure these people, alongside Long Covid sufferers, can get timely and effective diagnostics and treatments. The submission will further look at some of the research connecting these two conditions, and make the case for including vaccine-injured Australians in Long Covid treatment and research programs.

### 4.3. Reaction Frequency, Data Distortion and Censorship

The nature of COVID-19 — its emergence as a disease with no prior degree of immunity in human populations, its highly infectious nature, and initially significant rates of serious complications and death — led to the development, rollout and uptake of new vaccines in record time.

Despite considerable public messaging that no safety protocols were skipped,<sup>16</sup> the rapid development of these products in the midst of this pandemic did indeed give rise to various safety and other protocols being undermined or pragmatically deprioritised, due to a multitude of factors,<sup>17</sup> including political pressure.<sup>18</sup>

It is typical in a non-emergency approval process for as many as half of all adverse reactions to not be identified until a product enters the marketplace, sometimes not for several years. It is thus understandable that in the face of the rapid development process for COVID-19 vaccines, coupled with the limitations and compression of clinical trials, that important safety signals were missed and went unacknowledged and unreported. However, with thorough long-term research of side-effects after the emergency approval, it is important to acknowledge these injuries and take necessary action.

In September 2022, an independent reanalysis of the combined public data from Pfizer and Moderna's clinical trials demonstrated that the rate of occurrence of serious adverse events was not rare, and may be greater than 1-in-1,000.<sup>19</sup>

This is in dramatic contradiction to the claimed safety of these vaccines, with the public being repeatedly told that these vaccines went through all the same tests as more familiar vaccines on the family immunisation schedule, and had been declared equally as "safe and effective". This is just not correct.

<sup>&</sup>lt;sup>16</sup> [Khorshid2021] https://bit.ly/3Aj3zJN

<sup>&</sup>lt;sup>17</sup> [Prasad2022] https://ssrn.com/abstract=4276828

<sup>&</sup>lt;sup>18</sup> [Diamond2021] https://wapo.st/3TKix2h

<sup>&</sup>lt;sup>19</sup> [Fraiman2022] https://doi.org/10.1016/j.vaccine.2022.08.036

Since the introduction of these products, public health authorities have continued to make strong claims around their safety, particularly denying that they exhibited any number of worrying properties that were raised from time-to-time by members of the medical establishment or public. However, one by one, many of the safety and efficacy claims have turned out to be, at the very least, premature.

Some of the safety and efficacy claims that are now refuted by reputable peer-reviewed studies include: mRNA stays at the injection site;<sup>20</sup> mRNA is short-lived in the body;<sup>21</sup> the spike protein is short-lived in the body;<sup>22</sup> the spike protein alone cannot cause any harm;<sup>23</sup> the vaccines do not affect reproductive health;<sup>24</sup> breast-feeding mothers cannot pass the vaccine to their babies,<sup>25</sup> and; vaccines prevent transmission.<sup>26</sup>

Both scientific logic and common sense allow us to accept that the rapid introduction of such a product will reveal new evidence over time. Scientific literature now has significant numbers of findings and case studies of adverse reactions to these vaccine products that were not (and in most instances are still not) acknowledged by government authorities.

# 5. Patient Experience, Poor Treatment, and Abandonment of the Vaccine-Injured

Thanks to the consistent messaging from governments and media that (a) severe vaccine reactions are extremely rare, and (b) that anyone who says otherwise are misinformed anti-vaxxers, most of the vaccine-injured people in Australia have faced derision from public figures and unconscionable gaslighting and bullying by doctors, work colleagues, friends, and even from family. It is not rare among our members for intimate relationships to end and friendships and support structures to break down as we and our families confront this paucity of public recognition. For many of us, despite our best efforts to stay connected and request help, other vaccine-injured people are our main source of support, resources and hope.

This type of response towards people who are suffering a significant adverse reaction to their vaccinations is the most inappropriate and horrendous way to treat people who got vaccinated for the benefit of the society they are a part of. It is also hugely discriminatory and goes against all public health principles that vaccinated citizens committed to.

In addition to the following detail about the overall patient experience, we have attached to our submission a number of mainstream news articles covering the experiences of several individuals.

### 5.1. The Patient Experience

The complex condition of Long Vaccine Syndrome, like Long Covid, consists of a larger cluster of symptoms that varies from person to person.

Individuals can suffer varying degrees of disability on account of these symptoms, ranging from minor annoyances that do little to interrupt daily life, to significant impairment resulting in the inability to function on even a basic level, for weeks, months or years.

<sup>&</sup>lt;sup>20</sup> [Di2022] https://doi.org/10.1007/s11095-022-03166-5

<sup>&</sup>lt;sup>21</sup> [Röltgen2022] https://doi.org/10.1016/j.cell.2022.01.018

<sup>&</sup>lt;sup>22</sup> [Cosentino2022] https://doi.org/10.3390/ijms231810881 & [Cristoni2022] https://doi.org/10.5281/zenodo.5831816

<sup>&</sup>amp; [Patterson2022] https://doi.org/10.21203/rs.3.rs-1844677/v1

<sup>&</sup>lt;sup>23</sup> [Lin2022] https://www.mmri.edu/2022/08/02/revealing-covids-impact-on-the-heart

<sup>&</sup>lt;sup>24</sup> [Edelman2022] https://doi.org/10.1136/bmjmed-2022-000297

<sup>&</sup>lt;sup>25</sup> [Hanna2022] https://doi.org/10.1001/jamapediatrics.2022.3581

<sup>&</sup>lt;sup>26</sup> [Boucau2022] https://doi.org/10.1056/NEJMc2202092

These disabilities resulting directly from COVID-19 vaccines, meant to keep people safe from the impairments caused by Covid itself, are not at all recognised by the Australian Government.

Not unlike Long Covid, currently, there is a lack of appropriate tests and singular diagnostic frameworks available in Australia that can be used to identify the extent and specificity of such suffering. Internationally, organisations and institutes do pioneer diagnostic tests and treatments that are unavailable in Australia. Examples include cytokine testing,<sup>27</sup> specialised antibody testing,<sup>28</sup> biopsy analysis for Small Fibre Neuropathy,<sup>29</sup> and specialised microscopy for observing micro-clotting.<sup>30</sup>

After an initial period of self-advocacy in which the patient must work quite hard to be believed regarding their symptoms, the additional barrier to diagnosis is that the syndrome rarely displays any findings in standard diagnostic tests — most available serology testing is failing to find explanations for the symptoms, and various scans rarely indicate any injury (including in many instances of myocarditis and pericarditis).

We note, however, that through the use of highly-specialised processes, researchers at Yale University have observed microclots through a microscope,<sup>31</sup> and the National Institutes of Health (USA) have observed immune system damage.<sup>32</sup>

Given that this diagnostic hurdle is similar for Long Covid, **CO**VERSE advises that Long Vaccine Syndrome patients should be treated with the same degree of investigative enthusiasm, ethical sensitivity, and concern given to Long Covid patients. Except in rare cases, this is simply not happening.

Currently, in Australia, doctors work to the assumption that there are no reliable treatment options for Long Vaccine Syndrome, and furthermore that our symptoms might improve without intervention. This is unfortunate given that important international doctor-patient collaborations and lab projects do exist that are experimenting with protocols and treatment combinations that are showing promising outcomes and improvements in our health.

Vaccine-injured patients in Australia, without access to such specialised facilities or frontline treatments, have taken to self-experimentation out of their own pockets with a wide range of treatments, including pharmaceuticals, nutraceutical supplements, physical therapies, and other approaches.

Finally, it is worth emphasising that despite Long Vaccine Syndrome conditions not being recognised by the Australian Government, similar conditions were also experienced by participants during the clinical trials (but not identified by the pharmaceutical companies in their peer-reviewed trial results publications) of Pfizer<sup>33</sup> and AstraZeneca,<sup>34</sup> and likely others.

### 5.2. Medical Issues

Typically, unless a patient is displaying clear clinical symptoms and associated biomarkers of a familiar life-threatening condition (e.g. a large blood clot or heart attack showing up in ED imaging and pathology),

<sup>&</sup>lt;sup>27</sup> https://incelldx.com

<sup>&</sup>lt;sup>28</sup> https://www.celltrend.de

<sup>&</sup>lt;sup>29</sup> The Neurology Laboratory at the Brain and Mind Centre, University of Sydney, had planned to introduce the capability to undertake Small Fibre Neuropathy analysis from biopsies, however this has been placed on hold indefinitely. https://www.sydney.edu.au/brain-mind/our-clinics/clinical-service-partners/neurology-lab.html <sup>30</sup> [Grobbelaar2021] https://doi.org/10.1042/BSR20210611

<sup>&</sup>lt;sup>31</sup> https://twitter.com/VirusesImmunity/status/1589762087597019137

<sup>&</sup>lt;sup>32</sup> [Safavi2022] httpd://doi.org/10.1101/2022.05.16.22274439

<sup>&</sup>lt;sup>33</sup> e.g. [GiangPaunon2022] https://fxn.ws/3hFVOH9 & [Healy2022] https://davidhealy.org/disappeared-in-argentina

<sup>&</sup>lt;sup>34</sup> e.g. [CouzinFrankel2022] https://doi.org/10.1126/science.ada0394

they will most frequently receive a dismissive attitude from doctors, who will instruct them to take painkillers or simply rest.

Scientific literature has meanwhile emerged to show that many of the curiously negative biomarkers that appear in the preliminary investigations of serious Long Covid conditions are also missing in Long Vaccine Syndrome patients. For example, troponin may not be elevated in patients later proven via cardiac MRI to have heart inflammation or scarring, and D-dimer may not be elevated (or just go unchecked) in patients that are later proven to have blood clots from their COVID-19 vaccination — both are real situations that have been conveyed to us by multiple patients.

It is not at all uncommon among COVID-19 vaccine injury cases for a patient to be suspected of, or labelled with, a psychological disorder instead of receiving exhaustive diagnostic investigations.

Sadly, individuals in the initial reaction phase and Long Vaccine Syndrome phases of their illnesses are usually experiencing significant pain, cognitive dysfunction, motor skill issues, and many other disabilities. This makes their articulation of semi-novel and under-researched reaction symptoms even more difficult to translate to doctors who distrust their patient's assessment of dysfunction.

Some doctors take pains to explain to such patients that "coincidence is not causality" yet are making little or no effort to find any other cause — as if a patient simply mentioning a "vaccine reaction" is enough to assume that a patient is either lying, a hypochondriac, or suffering a psychological episode.

This tendency for patients to be treated as psychological cases by medical professionals leads many individuals to spend significant funds seeking a second, third, fourth and even fifth opinion before they find a practitioner who will undertake meaningful and thorough investigative tests, and/or refer the patient to appropriate specialists for further investigation.

This extremely challenging and alienating situation is facilitated and reinforced by continued public health messaging around the safety and efficacy of COVID-19 vaccines. If these messages were accompanied by instructions for patients and doctors to be on the lookout for new adverse reactions, then perhaps doctors would be less inclined to dismiss adverse reactions that have not been listed as acknowledged side effects.

While diagnosing these conditions is challenging in their own right, treatment is proving even more difficult. As with Long Covid, most treatments for COVID-19 vaccine injuries rely on addressing individual symptoms rather than the underlying pathologies.<sup>35</sup> However, there are a number of highly qualified groups who are actively pursuing a range of experimental treatment options with varying results, including some treatments that have been inexplicably banned for off-label use by regulators in Australia. Such groups include, but are not limited to, the Front Line COVID-19 Critical Care (FLCCC) Alliance,<sup>36</sup> University Hospital Marburg,<sup>37</sup> and IncelIDX.<sup>38</sup> A very small minority of Australians who can afford to access these do fly internationally to do so, given the total absence of comparable approaches available domestically.

### 5.3. Financial Issues

Whilst compassionate and helpful medical care has been difficult for the vaccine-injured to obtain, access to financial aid is virtually impossible.

<sup>&</sup>lt;sup>35</sup> [Greenhalgh2022] https://doi.org/10.1136/bmj-2022-072117

<sup>&</sup>lt;sup>36</sup> https://covid19criticalcare.com/treatment-protocols/i-recover

<sup>&</sup>lt;sup>37</sup> https://www.ukgm.de/ugm\_2/deu/umr\_kar/51186.html

<sup>&</sup>lt;sup>38</sup> https://www.covidlonghaulers.com

#### JobSeeker

The first government scheme they might access is JobSeeker, which has a provision to provide income support for people who are temporarily unable to undertake their normal work. However, the restrictions on this scheme (household income test, assets test, etc.) mean that many vaccine-injured are ineligible for such support, and for those who can access it only three months of payments are available.

#### Workers compensation

Some are "fortunate" enough to have been injured whilst being subject to a workplace vaccine mandate, which opens the possibility of workers compensation. However, even in these instances, many claims are being rejected on the basis that the patient's symptoms are not recognised by the TGA, or the medical specialist preferred by the employer will override previous diagnosis and symptom severity, to the benefit of the employer's case.

**CO**VERSE's early patient survey data suggests that two thirds of such patients are having their worker's compensation claims denied, which severely undermines the rationale for these mandates — if employers are not prepared to stand by their workers when they get injured complying with these mandates, then those employers have no business imposing such mandates at all, and this includes the federal and state governments.

#### COVID-19 vaccine claims scheme

The previous federal government established the *COVID-19 vaccine claims scheme*, aimed at compensating people for their economic losses resulting from an adverse reaction. However, to date only a handful of claims have been granted — less than 2% of claims submitted.<sup>39</sup> While some workers received leave payments for self-isolating with Covid and made use of schemes such as JobKeeper, the vast majority of the COVID-19 vaccine injured have received zero financial assistance or recognition of hardship since the very beginning of the rollout.

Attachment D includes a patient letter to the Minister for Government Services that details typical bureaucratic challenges being faced by patients applying to this scheme.

Compare this with Thailand, which has paid out over 10,000 vaccine injury claims, representing more than 70% of submitted claims.<sup>40</sup>

The government of Thailand has provided security for all Thai people receiving these vaccines by allowing claims for *all* vaccine injuries, not just those from a narrow list, and not just those requiring hospitalisation.

Furthermore, they pay out provisional claims quickly (within 5 days of application) regardless of ultimate determination of whether the vaccine was the cause of the injury.

Clearly the government of Thailand has given greater consideration into supporting its citizens who "took one for the team" than many other governments around the world, and by doing so has demonstrated its commitment to fostering trust in their public health institutions and policies through openness and transparency. The Thai people can feel secure, knowing that their government indeed does have their back if something goes wrong with their vaccinations.

<sup>&</sup>lt;sup>39</sup> [Evans2022] https://bit.ly/3GhT2Cr

<sup>&</sup>lt;sup>40</sup> [NHSO2022] https://bit.ly/3USdVYE

The Australian Government scheme suffers from multiple failings that ensure that the vast majority of vaccine-injured Australians cannot access it. This only serves to foster further distrust in government health messaging and in the government's motives.

The initial points of failure in the Government's treatment of the vaccine-injured and their financial compensation are (a) the requirement to have suffered one of only a very small and specific set of "approved" adverse reactions, and (b) to have been admitted to hospital as an in-patient.

The first of these requirements ensures that a large number of Australians whose lives are still in turmoil due to their vaccine complications are ineligible for compensation via the Government's scheme, even though they have medical reports that prove their conditions have been caused by their vaccinations.

The second requirement similarly excludes the majority of vaccine-injured patients who are suffering ongoing impairment and disablement due to the vaccine reactions but were never admitted to hospital.

It appears as though this scheme has been developed to minimise the numbers of eligible patients in order to improve the optics around how many Australians have been negatively impacted by these vaccines. However, it has achieved the exact opposite — it is causing many Australians to realise that their government cares little for them, and that the government is more interested in covering up these injuries rather than openly demonstrating compassion and support for *all* vaccine-injured citizens, and being transparent around the real risks associated with these products.

The third eligibility criteria for the vaccine claims scheme requires that patients must be able to demonstrate direct losses (e.g. loss of salary) and costs (e.g. medical costs) of at least \$1,000. This is prejudicial to low-income and unemployed people who rely solely on public health support yet still deserve compensation for the pain and suffering endured by themselves and their families.

For these patients, doctors fees have been paid for by Medicare, and many have not pursued further medication or therapies since either they cannot afford the additional expenses or they are not informed that any options exist. We do not yet have a confident idea of how many of these Australians have slipped through the cracks, and it will take a significant redirection in public health messaging to identify such cases and enable them to access the treatment and compensation they deserve.

Further to these eligibility and abandonment issues, the scheme asks applicants to provide evidence of their economic loss. This is a relatively easy task for employees, but is difficult for small business owners, freelancers, students or people on zero hour contracts who may not have been drawing a regular salary. In the case of small business operators already dealing with significant financial losses due to the pandemic, or who may have been growing a business and sustaining themselves from their savings whilst doing so, the current scheme simply fails to consider such adverse (yet common) situations at all.

The current scheme is wholly inadequate and inappropriate in every aspect. We urge the current government to revise every aspect of this scheme to be inclusive of *all* vaccine injuries.

#### Disability support

The final piece of the puzzle with regards to financial support for the vaccine-injured is recognition and support of new disabilities caused by the vaccines. At present there is no clear pathway for recognition of disability due to a vaccine injury, particularly Long Vaccine Syndrome, and we note that the situation is similar for Long Covid sufferers.

Whilst we are hopeful that all Long Vaccine Syndrome sufferers will heal and be able to resume their full and productive lives as before, we are mindful that in an environment where we are treated with derision by our

government such healing may never come. The government must actively develop pathways for these individuals to obtain recognition of their disability, and ways to access established disability support mechanisms such as the disability pension and the NDIS.

### 5.4. Exemptions for Mandated Workers

Amongst our vaccine-injured community are many professionals mandated to not only be vaccinated against Covid, but to remain up-to-date with their boosters. Even though they continue to suffer ill health on account of their vaccine injuries, current rules around exemptions have left many of them in a precarious situation — unable to obtain an exemption from getting further shots yet not being in a financial position to be able to walk away from their income.

There are a number of barriers for these workers to obtain an exemption:

- As with a significant number of COVID-19 vaccine-injured patients, many doctors have been unwilling to identify the patient's condition with the vaccinations, and so will not provide an exemption for them.
- In cases where doctors do recognise the vaccine reaction, many refuse to provide an exemption out of fear of attracting the ire of health profession regulators (discussed below in section 6.1).
- Even if patients are able to obtain an exemption from their doctor, this is too often being rejected by health authorities.
- For those with ongoing health challenges and have been able to successfully obtain an exemption, this is usually limited to a few months only, and it is very rare for them to successfully obtain further exemptions after their first one expires.

These workers are afraid of speaking to anyone in their workplaces, government or media about these challenges, out of fear of being bullied, sacked or simply not given any further hours (as has occurred in a number of instances), and many have been pressured into getting additional vaccinations which has caused their symptoms to worsen.

### 5.5. Silencing of the Vaccine-Injured

Perhaps the most insidious injustice being inflicted upon the vaccine-injured has been the silencing of their voices by the government, traditional media, and social media networks. Hardly a day goes by without a member of our community being locked out of their social media accounts for "breaches of community standards" (aka daring to share their very real story of pain and suffering on account of their vaccinations).

In the USA, it is emerging that government actors actively colluded with social media companies on which topics and even which individuals to censor in the high stakes discussion of Covid.<sup>41</sup> Whilst it might make sense to silence individuals inciting violence, it is hard to swallow that people already suffering huge social and medical injustice simply on account of their adverse reaction are being denied a voice and labelled as "misinformation" or "anti-vaxxers" following vaccination. This is a clear sign that our governments and many of our media corporations are in fact working against their citizens.

Many in our community have reached out to Australian journalists with their stories. Whilst a number of journalists are compassionate towards these patients, and the stories of abject failure by our governments

<sup>&</sup>lt;sup>41</sup> [Klippenstein2022] https://theintercept.com/2022/10/31/social-media-disinformation-dhs

and public health authorities to support them, most have revealed that they are simply not allowed to run such stories.

At any other time, in any other circumstance, these stories would make for prime-time journalistic coverage: ordinary honest citizens suffering at the hands of an unsympathetic and powerful government.

The fact that these stories are being actively suppressed leads us to suspect that political forces may be pressuring media outlets (perhaps through threats of funding cuts or the removal of tax concessions) to ensure that our stories remain hidden from the public eye, or that financial incentives (e.g. advertising) from large foreign pharmaceutical corporations is perverting the news narrative in Australia.

### 6. Medical Regulatory and Pharmacovigilance Failure

The first thing to remind the committee of, with regards to the monitoring and identification of safety signals from any vaccine, is that failure of pharmaceutical companies and pharmacovigilance agencies to publicise details of any given side effect is not evidence that said side effect is not caused by the vaccine.

The second thing to be reminded of is that causality in any given patient case cannot be denied in the absence of proper investigations.

Acknowledging these important and basic logic precepts is important, as much of our public health apparatus has doggedly insisted that individuals' adverse reactions cannot be related to their vaccination because government drug safety agencies have not publicised relevant safety warnings and the patient presents no evidence of causality.

The mantra "coincidence does not imply causality" has been inappropriately used to try and convince people of the safety of vaccines. However, in the world of actual science (as opposed to "science by policy"), coincidence is a reason to suspect causality and provides justification for further investigation.

Of all of the Australians that **CO**VERSE has spoken with who are vaccine-injured, not a single one has been contacted by drug safety agencies for follow-up investigations.

This fact is worth repeating:

Pharmacovigilance agencies have not conducted any follow-up investigation (nor have any other public health agencies).

With this fact, how can we be expected to believe any public health declarations associated with or reliant upon these regulatory bodies and their data? Significant reform is needed here.

### 6.1. Reporting challenges

When patients first experience an adverse reaction, they will generally seek medical help for their symptoms. Even though these reactions often occur relatively soon after vaccination, it is rare for doctors to prepare and submit an adverse event report to the appropriate authorities.

The reasons for this — based on what our doctors tell us — fall under three primary categories:

• The doctor is not certain that the symptoms are caused by the vaccine. Ironically, doctors often dismiss symptoms that might indicate a vaccine reaction if these symptoms have not been identified and communicated by drug regulators. This creates a vicious cycle, where doctors hence don't submit

an AEFI (adverse event following immunisation) report, which leaves drug regulators without relevant data to identify an appropriate safety signal. Without this safety signal, they will not inform doctors of the potential adverse reactions, and without this information, doctors often dismiss symptoms as vaccine reactions because they haven't been told about them...

- The doctor does not have the time to dedicate towards writing an adverse event report. It will typically take a doctor between 15-30 minutes to prepare and submit an adverse event report. These reports are mandated by law in many jurisdictions, yet too many doctors prioritise their waiting patients over fulfilling their obligations to their vaccine-injured patients and state medical authorities.
- Doctors are afraid of repercussions from their employer or from health profession regulators if they
  are seen to be "undermining" public health messaging around vaccine safety by submitting AEFI
  reports. This fear has been successfully instilled into the medical community by heavy-handed
  punishment of any doctor who dared to publicly question the safety of these vaccines or any other
  public health measure connected with the pandemic. Us, the vaccine-injured, are suffering due to this
  approach by health profession regulators.

This situation leads to significant under-reporting of adverse reactions by doctors — a situation that should not be allowed to have occurred during the rollout of new products under emergency use authorisation. While we cannot say to what degree this problem exists, we are confident in saying that the degree of adverse reactions being experienced by the public is likely well more than 10× greater than what is being reported.

In very many cases, patients experiencing a COVID-19 vaccine injury will have a large cluster of symptoms, but their doctors will not have a diagnosis for them. When reports do get submitted to drug safety authorities (either from the doctor or the patient), these consist largely of symptoms and no diagnoses.

In the complex cases of Long Vaccine Syndrome this means that drug safety agencies are receiving a significant number of reports with a wide variety of symptom clusters with no diagnoses and hence no firm conclusions as to what the vaccines may have done to the patients. Pharmacovigilance systems are poorly equipped to deal with such complex and disjointed symptom clusters, and without any dedicated case-by-case analysis, including active case updates on diagnoses later attained, these systems clearly fail to identify safety signals.

Many amongst our community have tried, in vain, to educate drug regulators about this situation, and in every single instance the regulators have shown zero interest in understand the complexities of these patient experiences or how they might begin to account for them in their analysis, and have steadfastly refused to undertake broader follow-up investigations with patients in order to better understand the progression of these symptoms.

It is also worth noting that Australia's national drug regulator is almost completely funded by the pharmaceutical industry — presenting a clear conflict of interest when it comes to the safety of Australian patients.

### 6.2. Pharmacovigilance shortfalls

The pharmacovigilance system in Australia consists of two parts. Firstly, AusVaxSafety, which conducts surveys of people who have recently received vaccines. For the COVID-10 vaccines, this survey process was time-limited to six weeks, and we would also argue that the most severely impacted of patients would have

been unlikely to have been well enough to complete the surveys. Moreover, this survey limited responses to pre-defined categories of symptoms only.<sup>42</sup>

The second part of Australia's pharmacovigilance system is the TGA's system of voluntary reporting. The TGA claims to be "actively monitoring" reports, however, this is a gross misrepresentation of what they actually do. Receiving voluntary reports and adding them to a database is most certainly not an "active" undertaking — it is a passive system that is not compelled to investigate anything. In fact, their own website states that even if they find a safety signal, they can simply choose to do nothing about it.<sup>43</sup>

Compare this situation with that of Germany. Their pharmacovigilance system has established an *ongoing* survey, in addition to passive reporting. This system has identified a "chronic fatigue"- like safety signal, which the Germany Federal Ministry of Health has labelled "Post-Vac-Syndrom".<sup>44</sup> Moreover, German data indicates serious adverse events occurring at a rate of 0.3-per-1,000 doses (in the Australian context, where the majority of adults have had at least three shots, this translates to a rate of a little over 1-in-1,000 individuals).<sup>45</sup>

Throughout 2021 and 2022, a number of patients wrote to the TGA with adverse event reports that detailed Long Covid-like symptoms stemming from their vaccinations. They argued that the TGA surely had enough data to identify this as a safety signal, and that by not alerting the public to this potential adverse event it was denying all future vaccine recipients the right to be fully informed (informed consent) of the potential risks.

As the vaccine booster programs began, our online support groups saw new people join — people who did not have any significant issues with their primary doses but developed Long Vaccine Syndrome and other issues upon having their boosters. When they discover that there are many Australians suffering similar symptoms, that the Government was notified (and warned) of this situation and that the Government subsequently did nothing to communicate the risks, these patients are understandably furious.

Further, doctors who were noticing these adverse reactions were actively discouraged from speaking out publicly, with health profession regulators threatening to suspend the registration of doctors who made any statements that might undermine the Government's immunisation rollout.

Moreover, as time progresses we learn worrying facts about the clinical trials of most of these vaccine products and can't help but conclude that drug regulators (in Australian and overseas) did not undertake a thorough analysis of the clinical trial data, and/or have been disinterested in pursuing accusations of:

- Clinical trial protocols not being adhered to;
- Clinical trial data being altered;
- Cases of serious adverse events being misreported;
- Cases of serious adverse events being excluded from data.

In November 2021, the British Medical Journal published the result of an investigation of reports from a whistleblower involved in Pfizer's clinical trial that the contract company she was employed with suffered from an alarming number of data integrity issues, failures to adhere to proper protocols, and even fraud.<sup>46</sup> These claims have appeared to have gone unanswered by the TGA.<sup>47</sup>

In our view, the Australian Government has grossly failed the Australian public in its pharmacovigilance duties.

<sup>42 [</sup>Deng2021] https://doi.org/10.5694/mja2.51619

<sup>&</sup>lt;sup>43</sup> https://www.tga.gov.au/safety/safety/safety-monitoring-medicines/tga-safety-monitoring-medicines

<sup>44</sup> https://twitter.com/BMG\_Bund/status/1540243408123478016

<sup>&</sup>lt;sup>45</sup> [PEI] https://www.pei.de/EN/newsroom/dossier/coronavirus/coronavirus-content.html?cms\_pos=6

<sup>&</sup>lt;sup>46</sup> [Thacker2021] https://doi.org/10.1136/bmj.n2635

<sup>&</sup>lt;sup>47</sup> [Chung2021a] https://bit.ly/3GiRhoy

### 7. Conclusion

Australian residents who have suffered an injury from their COVID-19 vaccinations have been abandoned by the governments and health authorities that pushed them all to get vaccinated and convinced them that these products were "safe & effective".

These Australians have been:

- Dismissed by the medical profession;
- Ignored by drug safety agencies;
- Derided by our politicians, and;
- Silenced by our media.

These Australians did everything that was asked of them, and for their pain and suffering they have been treated as sub-humans.

This situation is unbecoming of a compassionate nation and of a compassionate government.

Australians who are struggling with a vaccine-injury ought to be celebrated, and our governments and public health authorities should be clambering over themselves to help these public health casualties.

We call on this committee to immediately:

- Apologise, on behalf of the Australian Parliament, for having abandoned these people, and;
- Make a public commitment to dedicate all necessary resources to ensure these Australians get effective medical care and have access to appropriate financial compensation.

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### Attachment A: Studies and Support Organisations

#### A.1. Global studies into vaccine injuries

While there are a number of small and targeted studies happening in different research institutions around the world, currently there are only two major international studies that are considering the international community and that will produce statistically significant results:

- Yale University, *LISTEN Study* to understand Long Covid, post-vaccine injuries and the corresponding immune responses. https://www.kindred.hugo.health/research/listen-study
- Global Vaccine Data Network, *Genomics of COVID-19 Vaccine-Induced Adverse Events*. https://www.globalvaccinedatanetwork.org/genomics-covid-19-vaccine-induced-adverse-events

#### A.2. Notable patient support groups

There are a number of patient support groups who are involved with research efforts in their countries. The most prominent ones are:

- React19 (USA) https://react19.org
- UK CV Family (UK) https://www.ukcvfamily.org
- Post-Vac-Syndrom (Germany) https://nebenwirkungen-covid-impfung.org

### Attachment B: Scientific Summary of Long Vaccine Syndrome

Long Vaccine Syndrome is likely a form of post-vaccine Long Covid-like sequelae that become chronic after being induced directly by the vaccine antigen or by side effects from the body's immune response or a combination of these causes (Choutka2022; Schieffer2022).

Similar to Long Covid, it is the body's ongoing immune response that primarily keeps the body reacting over many months, even when the originating causative factor (namely the vaccine) has exited the system (Choutka2022; Schieffer2022; Patterson2022; Patterson2021a; Patterson2021b). Unlike Long Covid, which may have lingering viral components and infectious disease damage as contributing factors, Long Vaccine Syndrome is primarily a response to the spike protein itself, sufficient to create an extraordinarily debilitating condition (Schieffer2022; Patterson2022).

A full scientific breakdown of pathology is beyond the scope of this submission, and while the exact mechanisms involved are still unclear, the scientific literature presents several potential pathologies that may operate individually or in combination, which we summarise in short below:

- Immune system dysregulation, antibody response and ongoing autoimmune reaction: Immune response to the vaccine and the introduction of the spike protein into humans may lead to severe immune dysregulation, miscalibration and autoimmune reactions. Antibodies, anti-idiotype antibodies, and autoantibodies (all various forms of spike protein reactive immune responses) can lead to autoimmune reactions that cause symptoms extremely similar to Long Covid (hence the overlap with Long Vaccine Syndrome) (Hohberger2021; Wallukat2021). This may be due to the distribution of the lipid nanoparticles throughout body systems leading to the autoreactivity of many tissues after injection into the deltoid and subsequent widespread vascular circulation. Once perfused through many tissues, possibly including within long-lived immune cells, the inflammatory and autoimmune reaction builds, often for many months, until reaching a critical feedback point and becoming a chronic debilitating condition (Merchant2022; Patterson2022; Patterson2021a; Patterson2021b).
- Microclots and microthrombosis: The immune response and spike protein introduction can cause the blood to become hypercoagulable (clots quickly) and filled with microclots that perfuse microvasculature, causing microthrombotic events, which may lead to small vessel/capillary inflammation/damage in peripheral tissues (Grobler2020; Kruger2022; Pretorius2022; Nunes2022). These clots may not be detectable via standard clotting tests, however, they have been observed using specialised laboratory techniques (Grobler2020; Pretorius2022; Nunes2022).
- Endothelial injury and microvasculitis: Along with hypercoagulable blood, the blood vessels themselves can become systematically inflamed, and injury to their lining can lead to leakage, inflammatory microclotting and tissue injury perfusing into peripheral tissues, muscles and nerves (Kruger2022; RenzPolster2022; Turner2022). This may also include damage and leakage to the blood-brain barrier, leading to hyperactive immune responses due to foreign body infiltration, leading to various autonomic, neuropathic, and peripheral nervous inflammatory disorders (brain fog, blood/heart rate dysfunction etc.) (RenzPolster2022; Turner2022).
- Hypoperfusion, reperfusion and ischemic injury: Starvation of peripheral, muscle, nervous, and brain tissues leads to damage due to lack of nutrients and gas exchange, reperfusion injury (when clots clear dynamically) with shifting blood makeup, and finally, ischemic injury (lack of blood flow) to the tissues in the process (Wirth2021; Lubell2022; Turner2022; Grobler2020; Grist2022). This can lead to disability in the form of the inability to move, think, process or act, as well as a measured and dramatic ability to exert in any fashion (chronic fatigue) (vanCampen2021b; Wirth2021). Fundamentally, it leads to the entire body being unable to process materials correctly, specifically in

the nervous system, connective tissue, and microvasculature, analogous to multiple system starvation such as lack of oxygen, energy or food.

- Chronic inflammation and mast cell activation syndrome (MCAS): Tissue damage in the endothelial system across multiple organ systems leads to an activated inflammasome, in addition to damage increasing the presence of mast cell reactions in connective tissues (Glynne2022; Patterson2022; Patterson2021b). This causes systemic reactions in the gut, vasculature, connective tissues, brain and nerves, leading to a wide variety of hard-to-source symptoms, which can be initiated by food, stress, internal reactions, histamines and movement (Schieffer2022). This chronic systemic inflammation interacts with autoreactivity leading to a permanent homeostatic equilibrium of chronic fatigue, similar to permanent flu.
- Post-exertional malaise: A common co-occurrence with the above and below pathologies is that of
  post-exertional malaise (Choutka2022; Joseph2021). This involves a marked reduction in capacity,
  and an increase in symptoms, post inflammation and stress-induced exertion (Joseph2021;
  deBoer2022). It is one of the most dangerous components of this disease, causing any action to put
  the patient into further suffering, and exercise, in any form, should never be recommended in patients
  that become worse with exertion (vanCampen2021a; Choutka2022).
- Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and mitochondrial injury: Ongoing inflammatory damage can lead to the development of long-term or permanent ME/CFS, as well as mitochondrial injury, all of which can lead to a permanent and ongoing disabling reduction in the quality of life, energy and ability to work in any capacity (bed/housebound due to reduced energy production) (Choutka2022; RenzPolster2022; deBoer2022; Nunes2022). Fundamentally once in a diseased and stressed state, it becomes difficult for the body to self-heal back into a healthy equilibrium as the ability to act globally is dramatically and permanently impaired without outside intervention (Choutka2022; RenzPolster2022).
- Autonomic dysfunction: Various nerve, endothelial and hyperadrenergic reactions due to post-vaccine and post-viral illnesses can cause the development of various blood pressure dysregulation disorders such as; postural orthostatic tachycardia syndrome (POTS, high standing heart rate with normal exertion), orthostatic hypotension (low standing blood pressure), or hypertension (high blood pressure), etc. (Li2014; vanCampen2022a). These disable the ability of patients to move, walk, stand or carry out normal tasks due to poor blood pressure regulation (Li2014; vanCampen2022b). This interacts with hypoperfusion and ischemic regulatory issues, combined with CFS across the board, leading to a full body system essentially starved of blood, oxygen, and energy when it needs it most, during movement and thought.
- Nerve and muscle damage: Peripheral nerves and muscle fibres can be damaged by the multiple above pathologies, leading to the development of neuropathy (including small fibre neuropathy (SFN), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), rapid idiopathic sudden sensorineural hearing loss and non-length dependent neuropathy), fibromyalgia and muscle damage, causing debilitating symptoms that drastically impair the ability of anyone to function due to severe pain and suffering (Safavi2022; Stefanou2022; Oaklander2022; Schelke2022). Full body pins-and-needles, internal electric shocks, limb weakness, paralysis, hearing loss and other pain/nervous system reactions without a source can come from this damage (Safavi2022; Stefanou2022; Oaklander2022; Stefanou2022; Oaklander2022; Stefanou2022; Oaklander2022; Stefanou2022; Stef

• Genetic comorbidities, gender and vulnerable populations: Ehlers-Danlos Syndrome (EDS) and other connective tissue dysfunctions, as well as neurodivergent populations, are often cross-correlated with being vulnerable to post-vaccine and post-infection disorders (Monaco2022; Columbo2022; Golstein2021). Many with underlying comorbidities (such as CE/MFS) appear to be at greater risk, as are those with a history of viral/fungal infections that can become reactivated (such as Epstein–Barr virus (EBV), Lyme and shingles) due to the immune system damage caused by the vaccine, leading to chronic secondary infection (Choutka2022). Females generally have much stronger immune responses and are more likely to develop such an autoimmune syndrome, with patient-driven surveys suggesting that females may make up 60-80% of sufferers (Safavi2022).

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### Attachment C: early data from **CO**VERSE patient survey, indicating breadth and severity of symptoms

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### Attachment D: Letter to the Minister for Government Services

(included with permission)

The Hon Bill Shorten MP Minister for the National Disability Insurance Scheme Minister for Government Services Parliament House CANBERRA ACT 2600

Dear Minister,

I am writing to you with nowhere else to turn. On August 17, 2021, I was adversely affected by the Covid-19 vaccine. I had swelling in my heart and brain, nerve damage, autoimmune damage, and was diagnosed with acute severe pericarditis.

It has been over a year since this happened, however unfortunately I am still battling these conditions. Moreover, I am aware of many people in the community who are suffering much worse than I am.

On February 17, 2022, I submitted a claim to the *COVID-19 Vaccine Claims Scheme*, and joined the many thousands of others who are a part of this process. Since then, there has been almost no communication from Services Australia into the status, update, and progression of this claim.

Despite submitting over 200 pages of evidence, I received a letter from Services Australia in May 2022 stating that I needed to provide more information. I was also given a phone number at this time. Upon speaking to a representative from Services Australia, I was told that I had to put the information I had already provided into a form that had just been created by Services Australia. They also mentioned that they sent this letter out to everyone who has made a claim as a "catch-all statement."

On July 22, 2022, I received a notification in my MyGov inbox that my claim had "progressed" and had been referred to an external Medical Officer for consideration. I spoke to a representative of Services Australia who said that they had not heard anything from the external Medical Officer, and could not provide me with any further information.

Minister, I am writing to you because I would like some clarification and justification in some of the processes as part of the *COVID-19 Vaccine Claims Scheme*, namely:

#### - External Medical Officer Review

Is it true that the external Medical Officer that reviews the claims are representatives from the Therapeutic Goods Association (TGA)? What expectations have been put on the TGA to review these claims in a timely manner? What consultation and communication do they have with Services Australia with regards to this scheme? Will their findings and review be made available to the claimant?

#### - Scheme Timeframe

I note the COVID-19 Vaccine Claims Scheme website states the following: "We have implemented a claims scheme for people who suffer a moderate to severe impact following an adverse reaction to a TGA-approved COVID-19 vaccine.

We have done this to provide a simple, streamlined process to compensate eligible people, without the need for complex legal proceedings."

Minister, these words are the furthest thing from the truth. Submitting a claim within this scheme was an extraordinarily difficult procedure. I am aware of many other Australians who aren't able to submit a claim because the scheme is far too complex. I am also aware that the scheme's policy is almost identical to that of the Civil Liability Act, which would in turn make it the absolute definition of a 'complex legal proceeding.'

If this matter was taken up as part of a common legal proceeding, there would be reviews, hearings, and constant correspondence to determine an outcome. Through the *COVID-19 Vaccine Claims Scheme*, such actions and mediums of communication are non-existent. This is putting a serious amount of stress on Australians who are already battling health and stress conditions – to no fault of their own. Minister, I wish to inform you that as a result of the abhorrent communication to claimants, many claimants will have no choice but to withdraw their claim (or not submit one in the first place), and instead take this matter to court in what will be an absolute stain on the Australian government.

Can you please provide clarification on what Services Australia means by stating the *COVID-19 Vaccine Claims Scheme* is a "simple, streamlined, process" in light of the information you have received in this letter?

#### - Review of Policy

Minister, since my submission in February 2022, the *COVID-19 Vaccine Claims Scheme* policy has changed to now not include providing a percentage calculation of pain and suffering.

It appears there are two major, high-level factors to assessing the claim:

- 1. 'Was the patient's harm caused by the Covid-19 Vaccine?'
- 'What is the appropriate pain and suffering calculation pertinent to the claimant?'

Through the policy and also in the timeframe of my claim review, it is clear that these are the two major factors.

In this sense, could you please explain how it is fair that claimants need to wait for this process to take place? It should be a simple, streamlined process to determine if the harm was caused by the Covid-19 vaccine, given the amount of evidence that has to be provided before submitting a claim.

From there, the scheme should allow a reimbursement to the claimant of their out-of-pocket medical expenses and past lost earnings <u>at the very least</u>. The government could also then make it much easier for claimants to access

Centrelink and other funding support networks while they wait for the legal process of the scheme to take place.

The response to whether the patient's harm was caused by the Covid-19 vaccine should not – in my case – be taking upwards of 8 months to determine. On many of my phone calls to Services Australia in this matter, they have blamed staffing issues and lack of workforce to keep up with the volume of claim submissions.

In September 2021, the scheme opened a 'notice of intent to make a claim' where people could notify the department that they were going to make a claim. The scheme then opened 3 months later in December 2021. Senate hearings and media reports showed that 10,000 Australians had registered their intent to make a claim. How then could the government not have been prepared with the appropriate staffing and training for something they knew was going to have 10,000 submissions?

I understand that when my claim has been reviewed by the TGA, that it will then be referred to an external legal panel to determine the value of my reimbursement.

Can you please inform me on what corporations/associations/companies are a part of this legal panel? If not, please justify how you won't release this information despite it being of necessary importance to the Australian public.

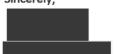
For future claimants, will you consider changing the policy to allow some form of immediate accessibility to funds upon determination that the claimant's harm was caused by the vaccine?

Finally, Minister, all I really want is for someone to talk to me like a human being. The content of this claim is my information – it's my personal, medical harm – it's my life that has been ruined – it's my condition that will significantly impact the rest of my life. I can't stand constantly being told that no one can give me any information, or provide anything to help my situation. I, along with many thousands of other Australians, have been beyond let down by this whole process. It has caused an extraordinary amount of stress to what is already a horrible situation.

I don't imagine you will consider responding to this letter. As disappointingly expectant as that is, this is more to document my process in dealing with the Australian Government, and will come in handy in the future. The Australian Government has failed me. The Australian Government has failed Australians. In the spirit of all Australians and what we represent, I just want someone to put a hand on my shoulder and say: "Sorry to hear what you've gone through, mate."

Let that be you if you want to restore this Australian's faith in his country.

Sincerely,





#### COVID-19

## Vaccines may cause rare, Long Covid–like symptoms

Researchers probe reports of brain fog, headaches, and blood pressure swings

#### By Jennifer Couzin-Frankel and **Gretchen Vogel**

n late 2020, Brianne Dressen began to spend hours in online communities for people with Long Covid, a chronic, disabling syndrome that can follow a bout with the virus. "For months, I just lurked there," says Dressen, a former preschool teacher in Saratoga Springs, Utah, "reviewing post after post of symptoms that were just like my own."

Dressen had never had COVID-19. But that November, she'd received a dose of AstraZeneca's vaccine as a volunteer in a clinical trial. By that evening, her vision blurred and sound became distorted-"I felt like I had two seashells on my ears," she says. Her symptoms rapidly worsened and multiplied, ultimately including heart rate fluctuations, severe muscle weakness, and what she describes as debilitating internal electric shocks.

A doctor diagnosed her with anxiety. Her husband began to comb the scientific literature, desperate to help his wife, a former rock climber who now spent most of her time in

a darkened room, unable to brush her teeth or tolerate her young children's touch. As time passed, the Dressens found other people who had experienced serious, long-lasting health problems after a COVID-19 vaccine, regardless of the manufacturer. By January 2021, researchers at the National Institutes of Health (NIH) began to hear about such reports and sought to learn more, bringing Dressen and other affected people to the agency's headquarters for testing and sometimes treatment.

The research drew no conclusions about whether or how vaccines may have caused rare, lasting health problems. The patients had "temporal associations" between vaccination and their faltering health, says Avindra Nath, clinical director at the National Institute of Neurological Disorders and Stroke (NINDS), who has been leading the NIH efforts. But "an etiological association? I don't know." In other words, he can't say whether vaccination directly caused the subsequent health problems.

NIH's communications with patients faded by late 2021, though Nath says the

#### A Long Covid patient at a hospital in Poland plays a virtual reality game to test reaction skills.

work continues behind the scenes. Now, some other researchers worldwide are beginning to study whether the biology of Long Covid, still poorly understood, overlaps with the mysterious mechanisms that may drive certain postvaccine side effects.

Other, better defined complications connected to the vaccines have been recognized. including a rare but severe clotting disorder that occurs after the AstraZeneca and Johnson & Johnson vaccines, and heart inflammation documented after the messenger RNA (mRNA) vaccines manufactured by Pfizer and Moderna. Probing possible side effects presents a dilemma to researchers: They risk fomenting rejection of vaccines that are generally safe, effective, and crucial to saving lives. "You have to be very careful" before tying COVID-19 vaccines to complications. Nath cautions. "You can make the wrong conclusion. ... The implications are huge." Complex and lingering symptoms such as Dressen's are even more difficult to study because patients can lack a clear diagnosis.

At the same time, understanding these problems could help those currently suffering and, if a link is nailed down, help guide the design of the next generation of vaccines and perhaps identify those at high risk for serious side effects. "We shouldn't be averse to adverse events," says William Murphy, an immunologist at the Univer-sity of California, Davis, who has proposed that an autoimmune mechanism triggered by the SARS-CoV-2 spike protein might explain both Long Covid symptoms and some rare vaccine side effects. "Reassuring the public that everything is being done, researchwise, to understand the vaccines is more important than just saving every Murphy, an immunologist at the Univeris more important than just saying everything is safe," he says. Like others, he continues to urge vaccination.

HOW FREQUENTLY side effects like Dressen's occur is unclear. Some online communities include many thousands of participants, but no one is publicly tracking these cases, which are variable and difficult to diagnose or even categorize. The symptoms also include fatigue, severe headaches, nerve pain, blood pressure swings, and short-term memory problems. Nath is convinced they are "extremely rare."

Long Covid, in contrast, affects anywhere from about 5% to more than 30% of those infected by SARS-CoV-2. Researchers are making tentative progress in untangling the underlying biology. Some studies suggest the virus may linger in tissues and cause ongoing problems. Other evidence indicates aftereffects of the initial infection might play a role.

For example, evidence from animal studies supports the idea that antibodies targeting the SARS-CoV-2 spike protein—the same protein that many vaccines use to trigger a protective immune response—might cause collateral damage, notes Harald Prüss, a neurologist at the German Center for Neurodegenerative Diseases (DZNE) and the Charité University Hospital in Berlin.

Early clinical data point in a similar direction. Research groups have detected unusually high levels of autoantibodies, which can attack the body's own cells and tissues, in people during and after a SARS-CoV-2 infection. In part to understand whether these autoantibodies harm people, DZNE is checking the cerebrospinal fluid of Long Covid patients for antibodies that react to mouse brain tissue—if they do react, they might attack human neural tissues as well. In a paper Prüss and

his colleagues are about to submit, they describe finding autoantibodies that attack mouse neurons and other brain cells in at least onethird of those patients.

Some researchers are looking at another possible culprit for Long Covid: tiny clots in the blood. Resia Pretorius, a physiologist at Stellenbosch University in South Africa, and her colleagues published preliminary evidence in August that microscopic clots can linger after a SARS-CoV-2 infection clears. They might interfere with oxygen delivery, which could explain some Long Covid symptoms such as brain fog.

Pretorius suspects COVID-19 vaccines might also sometimes trigger subtle clotting issues. She says she has preliminary evidence that vaccination can lead to microclots, although in most cases they go unnoticed and quickly disappear—an effect she and a colleague saw in their own blood, which they sampled as part of a larger study.

**IN JANUARY 2021**, the Dressens sought out Nath, who had been studying Long Covid. Nath responded quickly and asked Brianne Dressen to join an ongoing study he leads on the natural history of inflammatory diseases of the nervous system.

Dozens more patients describing postvaccine complications found their way to Nath and Farinaz Safavi, an NINDS neurologist. "I promise you we will report your issue and other cases we are reviewing now," Safavi wrote to Danice Hertz in March 2021. Hertz, a retired gastroenterologist who lives in Southern California, had developed debilitating symptoms after one dose of the Pfizer vaccine. Senior officials at the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and Pfizer, among others, were copied on the email, which Hertz shared with *Science*.

Over the first half of 2021, Nath and Safavi invited Dressen and others to NIH for testing and, in some cases, short-term treatment, for example with high-dose steroids or intravenous immunoglobulin, which can quell or modulate immune responses. The patients underwent neurological, cardiac, and other tests, including lumbar punctures and skin biopsies.

The NIH researchers were "trying to help people," says a health care worker whose symptoms began after the Pfizer vaccine, one of four people in the study who spoke to *Science*. Nath says 34 people were enrolled in the protocol, 14 of whom spent time at NIH; the other 20 shipped their blood samples and in some cases cerebrospinal fluid.



Blood drawn from Brianne Dressen, who suffered complications after a coronavirus vaccine, is part of a National Institutes of Health study.

As time passed, however, the patients say the NIH scientists pulled back. A September visit Dressen had scheduled for neurologic testing was converted to a telemedicine appointment. In December, Nath asked her to stop sending other patients his way. "It is best for such patients to receive care from their local physicians," he wrote to her.

For patients, the silence from NIH was distressing, especially as they struggled to find support and care elsewhere. The scientists "took the data and left us hanging," says a person who traveled to NIH in the spring of 2021. "I have no treatment, I have no idea what's happening to my body."

Nath told *Science* that NIH facilities are not equipped to treat large numbers of patients long-term. Says the health care worker of the effort: "It's too much for two people at the NIH to do."

Two top medical journals declined to pub-

lish an NIH case series of about 30 people, which Nath says he first submitted in March 2021. He understands the rejections. The data weren't "cut and dried; it was observational studies." This month, the scientists submitted a case series of 23 people to a third publication, and Nath says his group has proposed expanding a Long Covid study to include patients with postvaccine side effects.

Regarding persistent effects after vaccination, a Pfizer spokesperson wrote to *Science*: "We can confirm that it's something we're monitoring." Other vaccinemakers said they take side effects seriously and report them to regulators. FDA and the European Medicines Agency told *Science* they continue to monitor the vaccines' safety.

Researchers note that the scientific community is uneasy about studying such effects. "Everyone is tiptoeing around it," Pretorius says. "I've talked to a lot of clinicians and researchers at various universities, and they don't want to touch it."

Still, her group and others are pushing ahead. Prüss has detected autoantibodies in some patients with postvaccine symptoms, although not in others. Susan Cheng, a cardiologist at Cedars-Sinai Medical Center, and her colleagues are planning to use sophisticated imaging and diagnostic tests to study both Long Covid patients and those with postvaccine symptoms. And Pretorius and her colleagues are hoping to recruit at least 50 people to study clotting patterns before and after vaccination.

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At Yale University, immunologist Akiko Iwasaki, who has been studying Long Covid, is planning to collaborate with Nath and look at any potential link between Long Covid and postvaccine effects, she says. She

has spoken with affected patients, and her lab intends to collect samples from them, potentially of blood or saliva. Murphy says more work is needed in animal models to trace the body's response to vaccination. "We need to look at this in controlled situations," he says.

Prüss is hunting for autoantibodies following COVID-19 vaccination in mice. And he continues to care for patients, both postvaccine and postinfection. His clinic hopes to soon start a clinical trial of a treatment that removes most antibodies from a patient's blood. However, even if it works well, the procedure is expensive and might not be widely available.

**PEOPLE WITH LASTING** health problems after vaccination welcome any attention to their plight. "You have this ugly stain on you, and you're marginalized and abandoned," Dressen says. At first, "I was really afraid of

causing vaccine hesitancy," she says. However, when it appeared that regulators were not promptly investigating the apparent side effects, her frustration outweighed her reluctance. She took part in a June 2021 press conference about vaccine side effects held by Senator Ron Johnson (R–WI), who has been outspoken against COVID-19 vaccinations. "Talking to politicians was not our plan A ... not even close," Dressen says. "It was more like plan J."

Jana Ruhrländer, too, feels caught. After a single dose of the Moderna vaccine, the microbiology graduate student in Kassel, Germany, developed the sensation of internal electric shocks Dressen experienced, muscle weakness, intense thirst, and wild swings in her heart rate and blood pressure. Doctors dismissed her, saying their tests found nothing wrong. She played detective, realizing her symptoms overlapped with those controlled by a hormonal system called the renin-angiotensin-aldosterone system that regulates blood pressure and fluid balance. She has connected with doctors trying to learn whether auto antibodies targeting that system might be causing her symptoms.

Despite her experience, "I still think the vaccines are great," Ruhrländer says. And the mRNA technology "has so much potential." But these side effects, which for her have improved somewhat but haven't disappeared, should be acknowledged and understood, she says. "We have to speak openly about it."

Some patients who spoke with *Science* say medications that tamp down the immune system have offered a measure of relief. Nath hopes results from an NIH clinical trial testing immunoglobulin and steroids in Long Covid patients "will be applicable to the vaccine-related complications." None of the seven patients with whom *Science* spoke has fully recovered.

Researchers exploring postvaccine effects emphasize that the risk of complications from SARS-CoV-2 infection far outweighs that of any vaccine side effect. "You see 10, 100, 1000 times less risk from the vaccine," Prüss says. But understanding the cause of postvaccine symptoms—and whether early treatment can help prevent long-term problems—could be crucial for designing even safer and more effective vaccines, Murphy says, as well as potentially providing clues to the biology of Long Covid.

Cheng has heard from dozens of people who describe chronic postvaccine problems, and she finds the overlap between their symptoms and those of Long Covid compelling. Now, she wants to move deliberately and scientifically in a search for answers. "We've got to retain rigor," she says. "There's just this complete dearth of data."



#### Vaccines may cause rare, Long Covid–like symptoms

Jennifer Couzin-FrankelGretchen Vogel

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## Myocarditis, pericarditis: Are rare Pfizer Covid vaccine heart issues underreported to TGA? | news.com.au — Australia's leading news site

Dan Petrovic describes himself as an avid "pro-vaxxer" who has long advocated vaccines to his more hesitant friends – so it was a "comedy twist" when he was the one who suffered a rare side effect.

The marketing executive, 42, spent six weeks after his second Pfizer shot with constant chest pains, which his GP ultimately said was likely <u>a mild</u> <u>case of pericarditis</u>, or inflammation of the lining around the heart.

On September 18, four days after his jab, Mr Petrovic began to feel unwell while watching TV.

"I can't lean to the left side, I feel a bit short of breath," he said.

"It's just like constant pain and palpitations. It doesn't go away. Imagine enduring six weeks of that."

Mr Petrovic, the managing director of search engine marketing firm Dejan, said he was bemused that for "six weeks of pain, they classify it as subtle and mild".

"This wasn't a little bit of pain, this hits really hard and it was lingering for a long time," he said.

"It's a debilitating condition – can't work, can't walk, can't walk up and down the stairs, can't play with my daughter." After weeks of "ping pong" between appointments and \$3000 in medical costs, he has now largely recovered with only a "little bit of pain" once a week.

While he still doesn't regret taking the <u>vaccine</u>, Mr Petrovic says one thing concerns him.

Neither his cardiologist nor his GP would submit an adverse event report to the Therapeutic Goods Administration (TGA).

### 'Too busy'

After his experience, he fears that the TGA, which <u>monitors adverse</u> <u>vaccine reactions</u>, may not be getting the full picture.

"I asked my doctor, 'Are you going to submit this to the TGA as suspected pericarditis?'" Mr Petrovic said.

"He said, 'You can go online to do it. I'm too busy."

Similarly, his cardiologist, having ruled out more serious myocarditis, or inflammation of the heart itself, would not submit a report as he didn't "see any damage" on his scans.

"Shouldn't this be mandatory for medical practitioners?" Mr Petrovic said.

"There's a big difference between a doctor report and a patient selfreport. I cannot make a medical diagnosis, I'm not a practitioner."

He did submit his own, which now appears in the <u>Database of Adverse</u> <u>Event Notifications</u> – the TGA's anonymised list of raw, unconfirmed reports – but it's unclear whether his case is included in the regulator's overall numbers of pericarditis.

"My problem is that I have absolutely zero visibility into how my submission of an adverse effect has been treated, collected, processed and classified," he said.

In its weekly safety report, the TGA lists cases assessed as "likely" myocarditis, as well as a larger number that are "suspected".

Among likely cases, those classified as "level one" are "confirmed to be myocarditis based on strong clinical evidence including the patient's symptoms, and results of tests and imaging".

Mr Petrovic stresses he is still a strong supporter of vaccination against <u>Covid-19</u>.

"The pamphlet was saying [the risk of rare heart inflammation] is one in 100,000 – even if it was one in 10,000 I would have gone ahead and done it anyway," he said.

"I was willing to accept the risk to protect the community."

But he is concerned – from a data perspective – about what appears to be a lack of rigorous protocols for medical practitioners to report adverse events.

"I believe every doctor, every medical professional, when a patient complains of a complication after a vaccine, they should make a report," he said.

Even if the doctor is not 100 per cent convinced the reaction is connected to the vaccine, he argues, the TGA should still be receiving this "dirty data".

"I don't appreciate working with bad data," he said.

"Bad data means bad science. To me that's not OK. In my profession I work with data – if I have bad data I make bad decisions for clients, and that's just marketing. In health there is an even bigger responsibility." Inquiry into Long OVID Infections Attachment 1

Submission 516 Myocarditis, pericarditis: Are rare Pfizer Covid vaccine heart is news.com.au - Australia's leading news site



Dejan managing director Dan Petrovic, right, at a marketing conference.

#### **Reports encouraged**

In a statement, the TGA said it uses "all valid adverse event reports, regardless of their origin, to look for patterns or 'signals' that may indicate a safety issue requiring investigation".

"Our investigations are aimed at determining whether vaccination is likely to cause an adverse event," a spokeswoman said.

"Reports received by the TGA of suspected myocarditis and pericarditis for the Covid-19 mRNA vaccines are reviewed against internationally accepted criteria to classify the likelihood of myocarditis. This assessment does not determine whether cases have been caused by vaccination."

The spokeswoman said the TGA may request additional information "to

assist in our assessment of classifying the likelihood of myocarditis and/or pericarditis following the Covid-19 vaccine".

"In the case of reports from consumers, we contact the consumer's health care professional if the contact details are provided," she said.

"We also work closely with the state and territory health departments to follow up any missing information needed for our assessment. We may also contact the individual if required."

A spokeswoman for the Royal Australian College of General Practitioners said all immunisers were "strongly encouraged to report all adverse events that are serious, unexpected or require medical attendance".

"In most states and territories, immunisers are required to report on adverse events following Covid-19 immunisation, including New South Wales, Western Australia, Queensland, the Northern Territory, South Australia and the Australian Capital Territory to the relevant health department," she said.

"Reporting is not mandated in Victoria and Tasmania, but it is strongly encouraged."

Mr Petrovic worries that people being brushed off by health practitioners only fuels mistrust and conspiracy theories.

"The public cannot lose trust and confidence in science and the scientific method," he said.

"It's a slippery slope. If this is just laziness of doctors or bad administration, that's OK, we can fix that. But if it's, let's just keep it quiet, hush hush, vaccinate as many people as possible and release the reports later ... that's conspiracy talk. But we can't have people sweep things under the rug just so we get the vaccinations now." He is now wrestling with whether to vaccinate his daughter, who has asthma and so is in a higher-risk group for Covid-19 – but wants to know if she may be genetically predisposed to suffering the same reaction.

Similarly, he doesn't know what this means for his booster shot.

Neither his GP nor his cardiologist were able to offer him any guidance.

"So what do we do? I don't want to go through this again, and I definitely don't want my daughter to," he said.

Mr Petrovic says he does not want to fuel vaccine scepticism, hesitancy or misinformation.

"That said, what I've been through needs better attention and understanding in order to prevent or minimise it from happening in the future," he said.

"We need to understand the exact mechanism of how this happens and whether certain people should be given a different vaccine or the existing vaccine can be modified to eliminate the adverse effect entirely."

#### Second dose paused

In the US, researchers have <u>begun to explore possible explanations</u> for rare inflammatory heart conditions associated with mRNA vaccines, but there is still no proven theory.

The most common serious side effects associated with the Pfizer and Moderna vaccines are myocarditis and pericarditis.

Myocarditis is reported in about one out of every 100,000 people after receiving the Pfizer vaccine, according to the TGA, but is more common in young men and teenage boys after the second dose at four to seven cases in 100,000 people.

Several countries have now turned to a single-dose vaccination tactic for that age group, <u>in order to provide partial protection</u> from Covid-19 while reducing the risk of rare side effects.

In September, <u>Hong Kong recommended a single dose</u> of the Pfizer vaccine for children aged 12 to 17.

England and Norway have recommended a single dose for children 12 to 15 and are awaiting further <u>data to make a decision on second doses</u>.

Taiwan last week followed suit, <u>suspending the second Pfizer vaccine</u> for children aged 12 to 17, *Taiwan News* reported. The country also said it would hold off approval for children under 12 until the second dose issue was settled.

The TGA says as of November 7 it has received 288 reports assessed as likely to be myocarditis – an increase of 35 on the prior week – from about 22.7 million doses of the Pfizer vaccine.

Of the likely cases, around half have been treated in hospital with 11 treated in intensive care, according to the <u>TGA's most recent weekly</u> <u>safety report</u>.

Most patients treated in hospital were discharged within four days.

The youngest case classified as "likely myocarditis" to date was 12 years old.

There have also been an additional 446 suspected myocarditis cases – an increase of 65 on the prior week – either alone or in combination with pericarditis, and 1202 cases of suspected pericarditis, an increase of 117.

"We encourage people to seek medical attention if they experience symptoms that could suggest myocarditis or pericarditis," the TGA says. "This includes chest pain, palpitations (irregular heartbeat), fainting or shortness of breath, particularly if they occur within one to five days of vaccination."

frank.chung@news.com.au

Read related topics: Vaccine

## Pfizer vaccine side effects: Woman suffering migraines, tinnitus six months on | news.com.au — Australia's leading news site

A Sydney finance worker suffering severe neurological problems more than six months after her Covid-19 vaccine says she feels abandoned by the government and the medical community.

Daniella Lenarczyk, 34, says she has experienced migraines, tinnitus, neck pain and numbness in her arm since receiving her first Pfizer dose on September 3 – but that doctors have been left "stumped" and unable to give her any answers.

Ms Lenarczyk, who fears she may have to give up her "dream job" due to her ongoing health problems, has spent close to \$4000 on out-of-pocket medical expenses for specialist appointments, tests, scans and medications and still "no one knows what to do".

She provided news.com.au with copies of hospital discharge summaries as well as Medicare claims records detailing more than 30 visits to GPs and specialists between September and February.

"They shrug their shoulders and say it's stress," she said.

"It just breaks my heart how we followed all the rules, we listened to what the government said – now we're asking for help but we're (called) antivaxxers.

"I got the vaccine because I trusted the government, the state and federal politicians, the chief medical officers. Now that trust is broken because I'm asking for help and there's just a lot of finger pointing." Ms Lenarczyk says she is now on a "strong concoction" of painkillers and preventatives to cope with her symptoms, which, to her frustration, are not officially acknowledged even as uncommon side effects of the <u>vaccine</u>.

"I have permanent damage to my ears – I do not know what silence sounds like," she said.

"The whole weekend I had a migraine, Friday, Saturday, Sunday, I was crying every day because I was in pain. I have severe neck pain and pins and needles running through my arm, my fingertips are freezing cold.

"GPs can't provide you any answer because they just follow the guidelines provided by the government. At the end of the day the body isn't black and white, there are so many other things happening to our body which haven't been accounted for."



Daniella Lenarczyk, 34, believes the vaccine caused her ongoing migraines and tinnitus.

While health authorities including the US Centers for Disease Control and Pfizer itself have denied any <u>causal link</u> between the vaccine and neurological symptoms like those experienced by Ms Lenarczyk, some experts have called for more investigation.

Last week, vaccine researcher <u>Gregory Poland</u> from the Mayo Clinic told *MedPage Today* he had developed life-altering tinnitus soon after receiving his second dose of Pfizer a little over a year ago.

"It was like someone suddenly blew a dog whistle in my ear," Dr Poland told the publication. "It has been pretty much unrelenting. I can only begin to estimate the number of times I just want to scream because I can't get rid of the noise or how many hours of sleep I've lost."

Dr Poland said more research was urgently needed to determine what caused his symptoms, which he believed may affect potentially millions of people worldwide.

The publication noted there was some research showing evidence of neurological complications post-vaccination – notably rare reports of Guillain-Barre syndrome (GBS).

Dr Elliott Kozin, a neurotologist at Massachusetts Eye and Ear in Boston, told *MedPage Today* there were "ongoing research efforts to understand if Covid-19 vaccines may be related to various auditory complaints, including hearing loss and tinnitus", but that there were "no definitive studies on the subject".

"Temporality is not causality," Dr Poland acknowledged.

"Rather, it forms a hypothesis, and then what you do is carefully collect information to determine (whether) this potential syndrome or side effect (is) above and beyond the background rate before there was Covid or a Covid vaccine, and is the rate different in people who got the vaccine and people who didn't."

He added, "My own best guess is that this may be an off-target inflammatory response, inflammation of the temporal lobe area of the brain where sounds are generated or made sense of."



Ms Lenarczyk says no doctors or specialists can give her any answers.

According to Ms Lenarczyk, she immediately fell sick after her <u>first dose</u>, experiencing nausea and sweating within minutes.

Her symptoms worsened over the following weeks, but trips to the hospital and multiple scans turned up nothing wrong.

"The ENT, audiologist, immunologist, neurologist, all are saying they can't help or it could be stress-related," she said. "I've had an X-ray, CT scan, an MRI of my brain and neck. It's just frustrating. I had to move in with my parents, I couldn't work. Painkillers weren't working. It felt like my face was going to explode.

"I'm in pain every single day – my breakfast is painkillers. I was told to see a psychologist as it was assumed I have a tension headache due to stress."

An immunologist consulted by Ms Lenarczyk requested information from Pfizer.

The drug company responded with a letter summarising the available literature, citing a <u>paper published</u> in the *International Journal of Audiology* last year detailing three case reports of tinnitus following vaccination.

"The authors hypothesised that history of atopy and auto-immune disorders in these patients could have triggered an abnormal autoimmune response that affected the cochlea-vestibular system," Pfizer wrote in the letter.

"They also considered immunisation anxiety-related reaction and a coincidental event as other possible causes of the tinnitus and concluded that larger well designed studies are needed to establish if tinnitus is an adverse effect of the Covid-19 vaccine."

In her research online seeking answers, Ms Lenarczyk came across what sounded like another woman's similar experience detailed in the journal *Science* earlier this year, in an <u>article headlined</u>, "In rare cases, coronavirus vaccines may cause Long Covid-like symptoms."

Brianne Dressen, a former preschool teacher in Utah, had received a dose of the AstraZeneca vaccine as a volunteer in a clinical trial in November 2020. That evening, her vision blurred and her hearing became distorted. "I felt like I had two seashells on my ears," Ms Dressen said.

Her symptoms "rapidly worsened and multiplied, ultimately including heart rate fluctuations, severe muscle weakness, and what she describes as debilitating internal electric shocks", *Science* wrote.

Ms Dressen told the publication people suffering lasting health problems after vaccination often felt forgotten.

"You have this ugly stain on you, and you're marginalised and abandoned," she said. "(At first) I was really afraid of causing vaccine hesitancy."

Ms Lenarczyk said she had tried calling the Covid-19 vaccine helpline, the NSW Immunisation Specialist Service and even Pfizer itself for assistance.

"I've contacted so many numbers and they've got no idea," she said. "You can report reactions to the TGA but there's nowhere for help."

Ms Lenarczyk wants to speak out because she believes there must be others in her situation.

"I know so many friends and family who had the vaccine and they're fine, they don't see any holes in the system because they're not going through anything," she said.

"But for the people who do have vaccine injury it's really hard to get help."

Last month, the Australian government began paying out the first claims under its vaccine injury <u>compensation scheme</u> – but legal experts have argued the program is too complex and narrowly targeted towards a very limited number of officially recognised adverse effects.

A search of the Therapeutic Goods Administration's Database of Adverse Event Notifications shows 770 total results for tinnitus linked to the Pfizer vaccine, 914 for migraine, 576 for neck pain and 59 for ear congestion.

But neither the medicines regulator nor Pfizer's <u>product information</u> sheet acknowledge these symptoms as side effects.

"Many of us don't fit into the sphere of what the Australian government declares an injury," Ms Lenarczyk said.

A spokeswoman for the TGA said in a statement that tinnitus, migraine, blocked ears and neck pain "are not recognised side effects of Comirnaty".

"Publication of a report in the DAEN does not mean that the vaccine caused the reported event," she said.

"We encourage reporting of adverse events even if people think there is only a small chance the event could be linked to vaccination. Some events would have happened anyway, regardless of vaccination.

"This is particularly the case when millions of people are being vaccinated."

frank.chung@news.com.au

Read related topics: Sydney Vaccine

## Pfizer vaccine side effects: Scientist suffers 'long vax' neurological symptoms, brain fog | news.com.au — Australia's leading news site

An Australian scientist, left unable to work for eight months after a debilitating neurological reaction he blames on the Covid shot, has likened the treatment of people suffering vaccine injuries to that of returning veterans with health issues after the Vietnam War.

Dr Rado Faletic has slammed the Therapeutic Goods Administration's (TGA) adverse event reporting process, saying the medicines regulator tasked with vaccine safety surveillance was "simply uninterested" in investigating his symptoms despite submitting multiple reports.

"I'm similar to thousands of Aussies. After the vaccine I had a huge constellation of symptoms from head to toe," the 46-year-old said, describing it as similar to "mutant long Covid".

"The worst has been an oppressive brain fog. I've had headaches, chest pains, abdominal pains, unbelievable muscle twitching, issues focusing my vision. Basically I've been unable to work for eight months. I'm only now just starting to feel a little bit normal. This is not a mild side effect – this has been life-changing."

Dr Faletic said doctors and specialists were unable to find anything obviously wrong with him.

"You go to the hospital, they take your blood, do an echocardiogram or Xray or MRI and don't find anything," he said. "They say, 'Well you look fine, go home and rest.'" He added, "I don't necessarily blame the doctors. The problem is there hasn't been a test to find out what's wrong. I know some people are getting misdiagnosed with anxiety or functional neurological disorder – that's not what's going on. It's a physical injury."



Rado

Dr Faletic, who earned his PhD in hypersonic technology from the ANU and now runs an international research consulting firm based in Canberra, says his faith in the scientific and medical community has been badly shaken by his experience.

He received his first Pfizer dose on October 19 last year and his second on November 9. He had a bad reaction to both "within hours", but says the second was "dramatically off the charts".

"I waited a little while [to take the vaccine] - I work with technology and

have a science background, so I understood that with a new product, new technology, there could be some things we don't know about," he said.

"I thought, enough time has passed, surely our government would have flagged any reactions of concern. I took it and all this stuff happened to me. It's not a matter of it being a coincidence – it all happened within hours of the shots. Then I thought, surely the government would be interested in what's happened to me? Nope."

Dr Faletic says it soon became clear to him that the TGA wasn't interested.

"I've done 50 rounds with the TGA on this," he said.

"They've said, 'We can find no safety signals,' which I think is disingenuous if not outright lying. In my small personal circle I know over a dozen people with different long vax problems, [ranging from] ongoing headaches, memory problems or brain fog to some people who were basically bedridden for months."

When he went searching for answers, he found "hundreds of people" in online groups who had experienced similar symptoms and submitted reports themselves.

"The TGA still claims there is nothing to see," he said.

"We are being treated with the same type of derision and condescension as Vietnam vets when they came back damaged. The government doesn't want to acknowledge us, people in the community look down on us. There are a lot of parallels."

In the 1970s, Australian troops who had returned from Vietnam began to experience high incidences of cancer and other illnesses, with the government initially denying exposure to Agent Orange and other chemicals sprayed by the US military was to blame. While health regulators and drug manufacturers including Pfizer have previously denied any causal link between the vaccines and neurological symptoms, the tide appears to be slowly turning as a growing number of experts call for more investigation.

Earlier this year, Sydney woman <u>Daniella Lenarczyk</u>, 34, spoke out about her persistent symptoms that included migraines, tinnitus, neck pain and numbness in her arm.

In the US, the National Institutes of Health conducted a small observational study last year of patients who reported neurological problems within one month of Covid vaccination, including pins and needles in the face or limb, orthostasis – sudden decrease in blood pressure when standing or sitting – heat intolerance and palpitation.

That paper, currently in preprint, concluded that "a variety of neuropathic symptoms may manifest after SARS-CoV-2 vaccinations and in some patients might be an immune-mediated process".

"There doesn't seem to be a majority theory," Dr Faletic said.

"Whilst we've all been damaged in the same way, our cluster of symptoms vary from person to person."

In a statement, the TGA said it "monitors the safety of Covid-19 vaccines using information from a variety of sources, including analysis of adverse event reports submitted to the TGA, emerging published literature, worldwide safety data submitted by vaccine sponsors and information shared by international regulators".

"If the TGA identifies a safety concern it will take regulatory action to address the safety issue and promptly provide information to the public," a spokeswoman said.

"The recognised adverse effects of Covid-19 vaccines are included in the

approved Product Information (PI). These are updated as new safety information is identified. To date, the TGA has undertaken 26 actions with the sponsors to include new safety information in the PIs for Covid-19 vaccines."

Those have included the addition of hypoaesthesia (reduced sense of touch or numbness) and paraesthesia (an unusual feeling in the skin, such as a tingling or crawling sensation) to the PIs for Comirnaty (Pfizer) and Vaxzevria (AstraZeneca).

### Handful of injury claims approved

Meanwhile, new figures obtained by news.com.au reveal the federal government's vaccine injury compensation scheme has approved just 16 payouts in six months of operation.

The Covid-19 vaccine claims scheme allows people to claim a one-off payment ranging from \$1000 to \$20,000 for lost wages or other expenses if they suffer a bad reaction, and in cases of death the family may be able to claim <u>funeral costs</u>.

But the scheme has been criticised by legal experts and victims as <u>overly</u> <u>complex</u> and narrowly targeted towards a very limited number of officially recognised adverse effects.

Services Australia confirmed it had received 2225 applications as of June 2. Of these just 16 have been approved, 49 have been withdrawn and 671 are "waiting further information from applicants".

"The assessment process can be complex, and claims may also be reviewed independently by medical and other appropriately qualified experts," a spokesman said.

"In many cases, Services Australia has had to seek additional information from applicants in order to further progress consideration of their application. In other cases, applications have also been withdrawn. If found eligible, applicants are given up to six months to accept an offer of compensation, therefore finalisation of claims may also take some time."

Services Australia declined to provide any data on the amounts of payouts or types of claims, citing privacy concerns due to the small number involved.

According to the TGA's most recent <u>safety update</u>, there have been 129,995 total adverse event reports from 59.4 million vaccine doses administered to June 5.

Eleven deaths have been ruled as likely linked to vaccination, all after AstraZeneca.

No deaths have been officially linked to Pfizer in Australia from around 41 million doses administered.

In New Zealand, <u>three deaths</u> have been ruled as likely due to vaccineinduced myocarditis after Pfizer, from around 11 million doses.

Last month, the family of one of the 11 Australians who died after receiving AstraZeneca spoke out for the first time.

Victorian woman Robyn, a "fit and healthy" 77-year-old, died in September last year from Guillain-Barre syndrome.

Speaking to <u>ABC Radio</u>, her children said while they still supported Covid vaccination, they felt let down by the lack of government support.

They said they believed they were entitled to a lump-sum payment of \$70,680 plus funeral expenses, but were critical about the complexity of the application process.

Her son Ross said reading through the vaccine claims policy, it felt callous.

"It's a policy that's designed to protect medical professionals from legal repercussions if something happens, like to my mother," he said.

"My understanding is that it is to facilitate the actual vaccine rollout, so the doctors aren't scared to administer vaccines. But for people who have suffered from the side effects, it feels like we're just an afterthought to that."

Dr Faletic said he had also looked over the scheme carefully and "it's absolutely clear they've written it to not include people like me".

"From a philosophical point of view we had these massive, broad, sweeping economic sanctions on all of us – lockdowns, travel shutdown – all done because someone may transmit Covid, the precautionary principle," he said.

"But when it's these vaccines it's the exact opposite – you have to prove every single thing."

frank.chung@news.com.au

## QLD vaccine mandates: Teacher's life 'ruined' after severe Pfizer reaction | news.com.au — Australia's leading news site

A young Queensland teacher who suffered a severe adverse reaction to her first Covid shot says her life has "essentially been ruined" after the state's vaccine mandate left her unable to work unless she took her second dose.

Bek Bickerton, 27, received her first Pfizer vaccine in October and immediately began experiencing side effects, including changes to her menstrual cycle and fatigue, which continued to worsen.

By November she was hospitalised for a week with dizziness, blurred vision, tingling down her arms, extreme fatigue, low blood pressure and what was later diagnosed as postural orthostatic tachycardia syndrome (POTS).

"My heart would accelerate to extreme levels when I stood up," she said.

"A brain MRI showed multiple lesions and inflammation. I also had trouble regulating blood pressure and heat. I had a wide range of symptoms but the worst ones were severe brain fog and fatigue."

She was sent home with a diagnosis of POTS and "spent the next two months in bed", unable to look after her two young children.

"It was over the school holidays so it didn't affect my work too much, but I opted not to get the second vaccine so as a result I haven't been able to go back to work," she said. Ms Bickerton was among more than 1200 Queensland teachers and school staff affected by the mandate, which ends this week.

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Bek

#### Doctors insist on second shot

Under the rule announced last November, "high-risk" workers were required to have their first dose by December 17 and be double-dosed – formerly referred to as <u>"fully vaccinated"</u> – by January 23.

Ms Bickerton said despite her suspected reaction, multiple GPs and specialists including two neurologists refused to write her an exemption.

"None of them would link my symptoms to the vaccine," she said.

"The first neurologist said he agreed the timing was suspicious but recommended the second shot. The second, I sent through some research articles from the US – he refused to read them and said I absolutely should get the shot."

Ms Bickerton said she "didn't expect to be believed or listened to" by doctors. "I knew as soon as I brought it up it would be written off, they would never entertain the thought that it could be linked to the vaccine," she said.

"I guess I felt they were putting me in the anti-vax territory."

She even hesitated telling her friends she thought her symptoms were linked to the vaccine because "I knew they would disagree".

Ms Bickerton eventually found a Gold Coast-based GP who specialises in POTS who agreed the vaccine likely caused her illness.

"He's treating many other patients who have had these symptoms come on," she said.

The doctor was willing to write her a three-month exemption, which has since run out.

"During that time there was still no school that would hire me unless it was for relief work," she said.

"My life has essentially been ruined as we're now on a single income, I spend days at a time in bed trying to care for two preschool-aged children and we now can't afford the mortgage to upgrade our home as we'd planned."

She added that the Therapeutic Goods Administration "never got back to

me after I reported my side effects and no specialist has linked the vaccine to my symptoms so I have no access to compensation, or even acknowledgment that I was forced to suffer this debilitating illness".

"It's all been a lose-lose situation," she said.

It comes after an <u>Australian scientist</u> also suffering ongoing "long vax" symptoms hit out at the medicines regulator and government for failing to thoroughly investigate or acknowledge neurological reactions.

"I've done 50 rounds with the TGA on this," Dr Rado Faletic told news.com.au.

"They've said, 'We can find no safety signals,' which I think is disingenuous if not outright lying. In my small personal circle I know over a dozen people with different long vax problems, [ranging from] ongoing headaches, memory problems or brain fog to some people who were basically bedridden for months."

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Ms Bickerton has been unable to care for her young children. Picture: Supplied

#### Vaccine mandates to end

Last week, the Queensland government announced the teacher vaccine mandates would <u>be ending</u> as the state lifts some of its last remaining Covid restrictions.

"Queensland has remained strong," Premier Annastacia Palaszczuk <u>told</u> <u>reporters</u> on Friday.

"Restrictions that protected us have eased in sensible stages. I once again pay tribute to the resilience of Queenslanders for the strength of response to this pandemic."

From 1am on Thursday, June 30, the <u>high-risk worker</u> vaccine mandate will be revoked, meaning vaccinations will no longer be required in

schools, early childhood education, outside school care, kindergartens, family day care, prisons, community corrections, work camps, police watch houses, youth detention centres and airports.

"Decisions around mandatory vaccinations [will] instead be made <u>by</u> <u>employers</u>," Health Minister Yvette D'Ath said.

In addition, vaccination will no longer be required for visitors to residential aged care, disability accommodation or corrective service facilities.

"The public health directive mandating the Covid-19 vaccine for workers in healthcare, hospitals, aged care and disability care remains unchanged," Ms D'Ath said.

"We will also be removing the public health direction that requires postarrival testing for those who have travelled to Queensland from international locations."

Ms Bickerton says she fears many schools will opt to keep their vaccine requirements in place.

"To be honest I'm still not back at full health, I don't know if I could handle a full-time teaching load," she said.

#### 1200 staff suspended

A spokeswoman for the Queensland Department of Education said as of June 24, a total of 549 teachers and 660 non-teaching staff were suspended due to the vaccine mandate.

"All school staff and non-school workers will no longer be required to be vaccinated to attend schools or early childhood centres in Queensland from 1am on June 30, 2022," she said.

"This applies to all workers in a school, including contractors, volunteers,

service providers, regulators and auditors. Vaccination requirements will remain in place until this time. This means that they will be able to return to their school workplace where they are normally based."

The spokeswoman added, "No staff have had their employment terminated in relation to this issue. However, disciplinary processes already in place will be continuing. The decision was made by the chief health officer and the department will continue to follow the advice received from Queensland Health."

Ms Bickerton said she expected the government would stand by its decision to impose mandates even as they came to an end.

"I think they'll absolutely defend it," she said.

"The majority of people who got the vaccine two or three times will defend it."

More than 92 per cent of over-16s in Queensland have received two doses of a Covid vaccine, 71 per cent of 12- to 15-year-olds, and 31 per cent of five- to 11-year-olds.

According to the TGA's most recent <u>safety update</u>, there have been 132,155 total adverse event reports from more than 59.9 million doses as of June 19.

"Vaccination against Covid-19 is the most effective way to reduce deaths and severe illness from infection," the TGA says.

"The protective benefits of vaccination continue to far outweigh the potential risks. Like all medicines, Covid-19 vaccines may cause some side effects. The most frequently reported include injection-site reactions (such as a sore arm) and more general symptoms, like headache, muscle pain, fever and chills." frank.chung@news.com.au

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## DJ tyDi 'paralysed' after Moderna vaccine, doctors won't officially confirm | news.com.au — Australia's leading news site

An award-winning Australian musician who was left partially paralysed claims he was told privately by five different doctors that it was almost certainly a reaction to the Moderna vaccine but they would not put it in writing out of fear of being deregistered.

Tyson Illingworth, aka tyDi, who shot to fame at age 17 after being signed by Armin van Buuren's Armada label, says he is still in constant pain and taking daily medications and injections, more than six months after being hospitalised and going through rehab to "learn to use my hands and feet again".

The 35-year-old was forced to take six months off touring and says his "life was torn apart emotionally", both by his injury and the alleged refusal of doctors to officially acknowledge what they told him in private.

"I was in hospital for quite some time doing rehab, learning to use my hands and feet again, walking between traffic cones," he told news.com.au.

"I understand rare side effects might happen – I was unlucky. But why have five different doctors all said to me, 'I know what this is, it's a vaccine reaction, there's no other explanation, but I can't say anything because I'll get deregistered'?"

The body overseeing Australia's 800,000 registered practitioners and 193,800 students last year warned that anyone who sought to

"undermine" the national Covid vaccine rollout could face deregistration or even prosecution.

The Australian Health Practitioner Regulation Agency (AHPRA) told news.com.au it was dealing with a "number" of cases and that a "handful" of doctors had been suspended or slapped with conditions because "the alleged behaviour of a practitioner poses a serious risk to the public".

But AHPRA insisted "doctors do not need to be afraid to take notes about the vaccine".

"It is good medical practice and a professional obligation for doctors to make accurate medical records," a spokeswoman said.

"We encourage practitioners to discuss the various vaccines with their patients and use their professional judgement and the best available evidence to help the patient make the safest choices."

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#### Inquiry into Long COVID and Repeated COVID Infections Submission 516 - Attachment 1 DJ tyDi 'paralysed' after Moderna vaccine, doctors won't officially confirm | news.com.au — Australia's leading news site



Australian DJ and composer Tyson 'tyDi' Illingworth. Picture: Supplied

#### Side-effect not recognised

Illingworth, a graduate of Griffith University's prestigious Queensland Conservatorium, who has worked with major clients including Disney on Ice, says he is risking his reputation by speaking out about his "frustrating" experience.

"I have been so pro-science and pro-vaccine and so outspoken [about getting vaccinated] prior to this happening to me," he said.

"I still think people should have the vaccine, I just think we should be able to have a damn conversation about it. The only way to get to the truth is through civil discourse. What world are we in when doctors are no longer able to fulfil their oath? If doctors can't have a conversation about it, all they can do is prescribe a Band-Aid that might be more dangerous as opposed to getting to the bottom of the real problem."

Illingworth received his first Moderna vaccine at the start of this year.

A few weeks later he began to experience "extreme neurological pain" and red marks like veins or stretch marks appeared on his sides.

His motor skills "rapidly decreased" and he started to lose feeling in his hands and feet, before waking up partially paralysed.

"I couldn't move my legs, couldn't move my hands, which is terrifying for someone who uses their hands for a job," he said. "I couldn't even write my name down."

He was taken to hospital where doctors quizzed him about his drug use. Illingworth told them he didn't take drugs but admitted to using nitrous oxide when he was younger – which they then listed as the cause.

Doctors discharged him with "neuropathy due to past drug use" and told him it was "OK for me to take another Moderna shot".

Neuropathy is not a recognised side-effect of Moderna.

Heavy or frequent use of nitrous oxide can cause neurological damage leading to peripheral neuropathy, but Illingworth says the "timelines don't match up".

"I got the second and sure enough, everything came back but worse," he said.

#### Inquiry into Long COVID and Repeated COVID Infections Submission 516 - Attachment 1

DJ tyDi 'paralysed' after Moderna vaccine, doctors won't officially confirm | news.com.au — Australia's leading news site



Illingworth lost feeling in his hands and feet. Picture: Instagram

#### 'They will lose their licence'

Illingworth was hospitalised twice more and was discharged both times with no answers. He then saw "doctor after doctor to try and find out what's happening", and says he was told it was "not a coincidence that the timing lines up exactly".

"They won't write it down," he said.

"I felt played by the system. Doctors take an oath to help their patients, but if they're afraid of deregistration like this how can they do their job? How can I get help? My life won't ever be the same. Doctors couldn't give me an answer – will this last forever? They said they don't know."

Illingworth says he is grateful to have his movement back but has

"permanent scars" on his sides, and still takes strong painkillers. He also has "moments where my vision goes extremely blurry".

"I have extreme pain in the morning – waking up is the worst," he said.

"It's like being electrocuted – it starts at the brain and goes down to my fingers and feet, down my spine. I'd never felt it in my life before. They call it neuropathic pain."

Illingworth stressed he was "not anti-vax".

"I caught Covid after this – maybe I could have died, who knows, maybe the vaccine did its job," he said.

"My concern is I can't sit and talk to you and say these are the facts, because the doctors can't give me the facts because they've admitted they will lose their licence."

He added, "I can't say 100 per cent for sure [it was the vaccine] – I don't think any scientist would ever be 100 per cent. But I went from being able to swim laps in the pool to no longer able to do it. The only variable between that happening and me being normal was taking the vaccine."

According to the Therapeutic Goods Administration (TGA), there have been 6722 <u>adverse event</u> reports from about 4.6 million doses of Moderna as of June 26.

The TGA's Database of Adverse Event Notifications lists the most common reported side effects as chest pain, followed by headache and injection site reaction.

"Like all medicines, Covid-19 vaccines may cause some side effects," the TGA says.

"Vaccination against Covid-19 is the most effective way to reduce deaths

and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks."

## 'Handful' of doctors suspended

In a <u>position statement</u> published in March 2021, AHPRA and National Boards warned doctors against any conduct that could "undermine" the vaccine rollout.

"Any promotion of anti-vaccination statements or health advice which contradicts the best available scientific evidence or seeks to actively undermine the national immunisation campaign (including via social media) is not supported by National Boards and may be in breach of the codes of conduct and subject to investigation and possible regulatory action," it said.

"Health practitioners are reminded that it is an offence under the National Law to advertise a regulated health service (including via social media) in a way that is false, misleading or deceptive. Advertising that includes false, misleading or deceptive claims about Covid-19, including antivaccination material, may result in prosecution by AHPRA."

Brett Simmonds, head of the Pharmacy Board and co-chair of the forum of National Registration and Accreditation Scheme chairs, said in a statement at the time that "there is no place for anti-vaccination messages in professional health practice, and any promotion of antivaccination claims including on social media, and advertising may be subject to regulatory action".

AHPRA was unable to say how many health practitioners had either been deregistered or faced other regulatory action for undermining the vaccination campaign.

"We are managing a number of cases that have arisen because of

statements allegedly made by registered practitioners in breach of National Boards' Codes of Conduct, which was specifically addressed in the Covid-19 position statement," the spokeswoman said.

"There are a handful of practitioners whose registration has been suspended, or made subject to conditions, because a National Board has determined the alleged behaviour of a practitioner poses a serious risk to the public, or because it believes it is in the public interest to have acted. They are interim decisions that serve to protect the public while our investigations continue."

She added, "While we will intervene where the public is at serious risk, the majority of practitioners are doing the right thing and have led the remarkable public health response to the Covid-19 pandemic in Australia. We commend them for this sustained public health response."

In a subsequent statement, she said National Boards "consider the need to take action in response to reports of breaches of their standards and guidelines on a case-by-case basis".

"We only intervene where the public is at serious risk," she said.

"The Boards' expectations of registered health practitioners in relation to vaccination and public health matters is not new and predates the Covid-19 pandemic."

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# The major problem with Covid-19 vaccine compensation claims

Jack Evans

Payouts from a government program set up for Australians who suffered adverse reactions to Covid-19 vaccines have been described as "absolutely pitiful" by experts.

New figures reveal less than 2 per cent of the thousands of Australians who applied for compensation have had their claim approved.

The Covid-19 Vaccine Claim Scheme was set up in December 2021 to compensate people who suffered moderate to significant adverse reactions to an approved Covid-19 vaccine.

But out of the 2,987 people to apply for compensation, only 59 were successful.

A total of \$3.8 million has been paid out under the scheme.

But top minds in personal injury law believe the process causes unnecessary headaches for applicants.

A Services Australia spokesman told news.com.au that the assessment process was "complex", with some claims needing independent review by "medical and other appropriately qualified experts".

"In many cases, Services Australia has had to seek additional information from applicants in order to further progress consideration of their application. In other cases, applications have also been withdrawn," he said.

In addition to the 59 approved claims, 1379 claims are awaiting further

information from applicants, 153 claims were withdrawn, 186 claims were deemed "not payable", and 1210 claims are in progress with the agency.

He said applicants are given up to six months to accept the offer of compensation once approved.

"Therefore, finalisation of claims may also take some time," he said.

### Layers of hurdles for applicants

According to two leading personal injury lawyers, many issues with the scheme make the lodgement process extremely difficult, potentially resulting in a seemingly low approval rate.

Donna McManus, the founder of Premier Legal and Murphy's Law Group, describes how arduous and unclear the process is – even for experienced compensation lawyers.

"The requirements to be met are very complex and involved. No legal costs are payable under the scheme depriving people of access to justice and leaving them vulnerable to poor outcomes," she told news.com.au.

"There is no reporting system for decided vaccine injury claims as there is in some other jurisdictions. This makes it impossible to assess damages against other decided claims to advise clients on the viability of their claims.

"It also prevents an understanding of the areas where particular focus needs to be given."

Ms McManus described the plight of one client who initially attempted to navigate the application themselves before seeking legal advice after the initial claim was rejected.

"There is no disclosure of those who made the decision, so it is not

possible to even know whether the decision was made by appropriately qualified experts. This is very unusual – decisions and processes should be open."

Her Brisbane-based firm, Murphy's Law, is among a number to offer assistance to those seeking to lodge a claim under the scheme. She said her firm alone has many people calling to seek advice.

Among other hurdles for applicants, Ms McManus was worried clinicians were reluctant to link injury and the vaccine – which the scheme requires for eligibility.

"People generally are finding it difficult to gain appropriate expert evidence because medical specialists, generally, are non-accepting of their injuries or are fearful of repercussions professionally," she said.

"We were told by one client that their doctor told them that he was berated for reporting their injury to the TGA [Therapeutic Goods Administration]."

On March 9, 2021, Australia's health regulator AHPRA and the National Boards outlined their expectations of registered health practitioners and students regarding the Covid-19 vaccination in a joint statement.

"Any promotion of anti-vaccination statements or health advice which contradicts the best available scientific evidence or seeks to actively undermine the national immunisation campaign (including via social media) is not supported by the National Boards and may be in breach of the codes of conduct and subject to investigation and possible regulatory action," the statement said.

She described the Scheme as "complex" and "onerous".

"The Scheme requires admission to hospital or a waiver certificate. These requirements are too onerous," she said.

"For example, we have people who suffered myocarditis but can't access the Scheme because they weren't admitted to hospital and don't qualify under the specific waiver terms even though they have significant problems."

### 'Set and forget' policy doesn't keep up

Shine lawyers' national practice leader in medical law Clare Eves agreed the scheme was extremely difficult to navigate, describing the payout figures as "absolutely pitiful".

She believes the policy has not kept up with developments in adverse reactions to vaccines, leaving claimants with legitimate, recognised injury or loss high and dry.

"It's not really evolved as to what the current situation is," she told news.com.au.

"With any vaccine-related issue, particularly where you've got a mass amount of vaccines, there's going to be things evolving all the time ... they put the scheme in place, and they made it very restrictive.

"The problem then is there are other things evolving, that are not necessarily within those conditions that are eligible, but the scheme is not really refreshing or looking at that.

"I feel it was a bit of a government PR exercise – they set a very hard criteria, and then it's a set-and-forget.

"And nobody's really bothering to see if it's working or if it's still current and relevant."

Ms Eves said the complexity of the claims potentially deterred many with injuries or loss from claiming.

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Lawyer Clare Eves. Picture: Ryan Young

"With all of the hoops you've got to jump through, and the paperwork you've got to do and the medical support you've got to find with evidence, you'd be thinking: 'Is it even really worth it?"," she said.

"It's probably a lot more hassle and stress for somebody than the benefit of the other end."

And like Ms McManus, Ms Eaves also believed seeking a written opinion from a medical professional which links the vaccine to injury would be difficult.

"There's been a real reluctance in the medical profession to say: 'Yes, it does relate for the purpose of claiming under this scheme," she said.

"They're not all immunologists ... I think it's placed a bit of an unfair expectation on the medical profession, which has then not helped the individual again."

#### What is the Covid-19 Vaccine Claims Scheme?

According to the government portal, the scheme covers losses or expenses of over \$1000 due to the administration of a TGA-approved Covid-19 vaccine, or; "due to an adverse event that is recognised to be caused by a Covid-19 vaccination".

Services Australia website said it offers people a way to be compensated with a one-off payment "instead of going through legal proceedings".

Eligible applicants can apply for money to cover various financial losses, including lost earnings, out-of-pocket expenses, care services and even funeral costs.

Harm covered by the scheme includes anaphylactic reaction, thrombosis with thrombocytopenia syndrome, myocarditis, pericarditis, capillary leak syndrome, demyelinating disorders including Guillain Barre syndrome, and some physical administration related injuries.

But psychological and psychiatric conditions, secondary injuries (from fainting etc.) and common post-vaccine symptoms are not covered.

Applicants need to have their claim verified with a medical report from their treating doctor or hospital physician "with the treating doctor's opinion on the diagnosed condition or injury and likely link to vaccination."

"Claimants will need to submit evidence demonstrating the clinical condition or injury suffered and substantiating the loss(es) claimed," the government says.

The claims are then categorised into three tiers.

The first-tier vaccine recipients have suffered an eligible clinical condition or injury and can claim losses of between \$1,000 and \$19,999.

Tier two covers those who suffered injury or loss over \$20,000.

Tier three covers vaccine recipients who died if the vaccine was proved to have caused or materially contributed to the death.

The scheme will remain open for two years from the official end of the emergency period, which concluded on April 17.

But according to Ms McManus, many still remain unaware the scheme even exists.

"There's been very little promotion of the scheme. Some online advertisements that we have attempted aimed at informing the public about the Scheme only (and nothing more) have been disallowed," she said.

"Almost every member of the public that I talk to about the scheme is unaware of its existence."

Ms Eves believed the scheme had abandoned the small amount of Australians who were injured or suffered loss while doing their part to curb the impact of the pandemic.

"They're all safe approved, the manufacturers have done the relevant testing, and we're trying to contain the pandemic," she said.

"We want everybody to get vaccinated and the unlucky few who have an adverse reaction, which is going to be a small amount, we want to help and support and look after you. And that's not what the scheme has done at all."

# Teenager's harrowing journey after COVID vaccine side effect



# A 17-year-old girl from Tasmania is speaking out about the side effects she suffered from the coronavirus vaccine.

Faith's specialist from Launceston General Hospital wrote in her medical report, "There is no question Faith has had a delayed reaction to the second vaccination."

Faith has since been diagnosed with "functional neurological disorder".

More than 63 million doses of the COVID jab have been administered in Australia.

The Federal Government believes there have been 136,500 adverse reactions which means the chances of suffering a side effect is 0.2 per

cent.

Faith was vaccinated in August last year and became sick three days later.

She suffered severe abdominal pain and had her appendix removed but it didn't make her any better.

She lost a significant amount of weight and developed sudden muscle tics and twitches.

Faith wants people to see a video that she says illustrates those side effects.

### \*WARNING – Confronting footage\*



Teenager's harrowing journey after COVID vaccine side effect

Her mother Tania has told Ben Fordham, "Faith is the one who wanted the video out there".

"It doesn't happen to everyone and it's very rare. But Faith wants people to know that this can happen." Tania says she has been to countless experts to try and help her daughter.

2GB Healthy Living host Dr Ross Walker agreed to examine Faith's medical history.

"What's happened is that the COVID vaccine has pulverised Faith's gut bacteria," he told Ben.

### Press PLAY below to hear the full interview

Dr Ross Walker has put Faith and her family in touch with a new specialist for further treatment.

The Federal Government has a vaccine claim scheme for people who have suffered jab side effects.

However, Faith doesn't qualify for funding because she doesn't fit the criteria.

Her health condition is not eligible for assistance.

Faith's diagnosis has cost her family tens of thousands of dollars and a GoFundMe page has been set up to assist with the huge medical bills.

If you'd like to help the family, click <u>HERE</u>