NZDSOS

NEW ZEALAND DOCTORS SPEAKING OUT WITH SCIENCE

Rebuttal to Prof. P. McIntyre and Dr. Ian Town response to NZDSOS concerning Pfizer Comirnaty

On June 14 2021 Mr. Chris James from Medsafe replied to NZDSOS:

"Dear NZ Doctors Group

Thank you for your recent emails providing your views on COVID-19, COVID-19 vaccines and therapeutic options.

In response to the scientific and evidence base aspects of your correspondence I have asked Dr Ian Town, Chief Science Advisor Ministry of Health, for advice. Please find attached a copy of the expert advice commissioned by Dr Town.

This response does not address the issues detailed in your letter to MCNZ. We will leave you to discuss these with the Medical Council directly.

Dr Town is happy to discuss any aspects of the attached information if you wish to.

Kind regards

Chris"

Copy of the document titled **COVID Issues Rebuttal_FINAL.pdf** is attached

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NZDSOS has considered carefully the comments from Professor McIntyre and Dr. Ian Town, who we will refer to as the "authors" when not specifically addressing them by name. We have found significant deficiencies in their argument. Below we explain why.

On the exaggerated disease burden and comparison with influenza

The authors refer to a Lancet article [1] which compares hospitalised cases of COVID-19 to hospitalised cases of influenza from earlier years, and finds a relative risk of death 2.9 times higher in the COVID-19 compared to the influenza patients.

There are several reasons that this article is unsuitable for comparing the fatality of COVID-19 from influenza. This article does not address the issue of the infection fatality ratio for individuals at a population level of exposure to the virus. The comparison of age fatality does not compensate for the poorer metabolic profile of the covid-19 patients who have twice the prevalence of overweight

and obesity than the influenza group. In addition, a study over the same period showed that early ventilation in French patients, a policy in some centres at the time, resulted in a 74% increase in mortality for those who were ventilated early compared to those ventilated at higher levels of lung dysfunction. [2] This finding was similar to that demonstrated in the UK [3] and was also confirmed in interviews with North American intensivists. [4] It is, therefore, now clear that at least some of the high mortality observed early in the COVID-19 crisis was due to over treatment, rather than the virus itself. The authors make no mention of this in their response.

It is also now widely recognised that the early infection fatality rates of COVID-19 published by the World Health Organisation were overstated, as they were confused with case-fatality rates and inappropriate comparisons of statistics were made. [5] The authors claim that Ioannidis does not make a comparison directly with influenza, yet he does in one paper cited by our group. [6]

"*At a very broad, bird's eye view level, worldwide the IFR [infection fatality rate] of COVID-19 this season may be in the same ballpark as the IFR of influenza (0.1%, 0.2% in a bad year)*."

The authors claim that our group has mis-represented Ioannidis' studies. It is clear, however, that this is implied by his work, as Ioannidis himself states.

On the Safety and efficacy of COVID-19 vaccines

The VAERS database has had a 100-fold increase in the monthly incidence of post-vaccine deaths, compared with earlier trends (**Figure 1**).

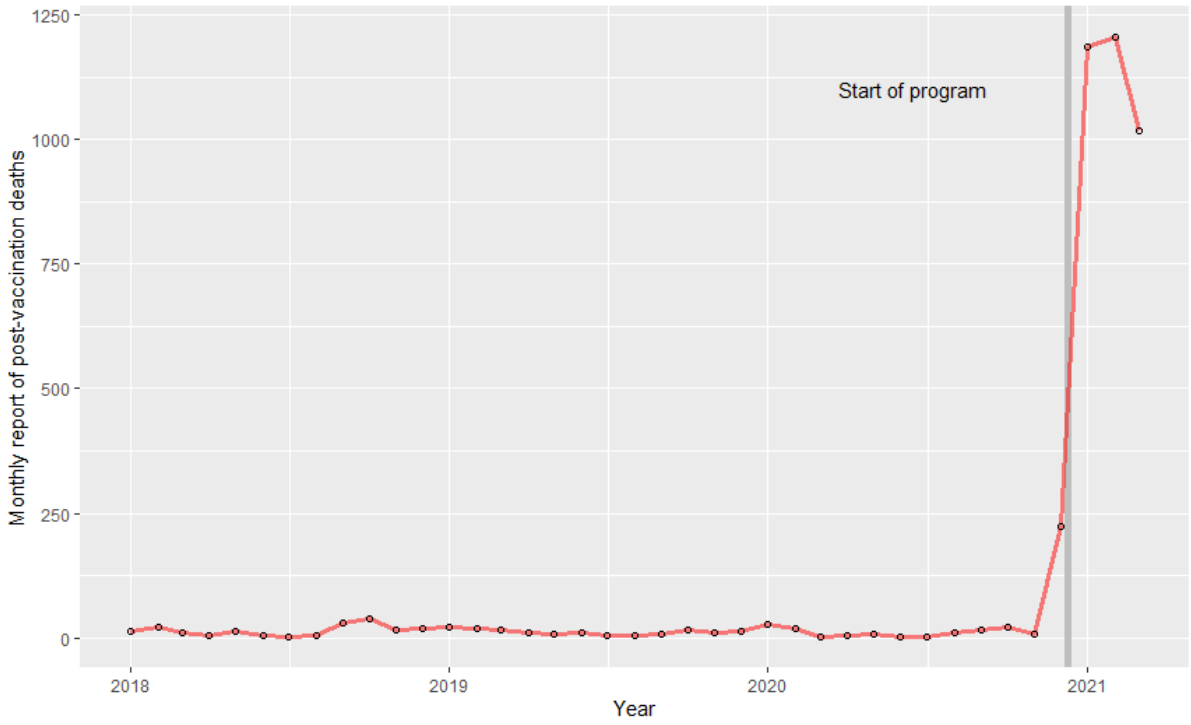

Figure 1. Line plot of monthly counts of post-vaccination death reports from VAERS (all ages, 2018 to present). Vertical line indicates start date of US covid-19 vaccination programme.

In line with our groups concerns, the authors dismiss this trend as attributable to the majority of vaccines occurring in subjects over the age of 65 years who are themselves at increased risk of

death.

Trends of increased reports of post vaccine deaths are occurring in people who have received the COVID-19 vaccine younger than 65 years, with a spike of deaths, five-fold higher than compared to background observed in people aged 0 to 45 years after COVID-19 vaccine, compared to background monthly rates (**figure 2**). Although many more people have been vaccinated in 2021 than in earlier years, people under the age of 45 years are at extremely low risk of sudden death, and a five-fold increase must surely be cause for concern and warrant further investigation and caution in recommending vaccination to younger age groups. Although, we acknowledge that VAERS is an early warning system, and the system accepts all reports made to it, it surely must now be clear that this early warning system has sounded, and that further investigations must be made to improve public confidence in vaccine safety. Considering the extremely low fatality of COVID-19 for this age group (~50/100,000 or 0.05%) [7], any harm attributable to the vaccine for this younger age group deserves close scrutiny. Estimates also show systematic under-reporting of adverse effects, when VAERS reporting rates are compared to the results of controlled studies. [8]

The authors lack of concern in these warning signals reflects what we believe is an overwhelming belief on behalf of the government and aligned academics in the safety of the vaccine despite data indicating otherwise. This refusal to acknowledge such trends underscores why we as practitioners have written the letter outlining our concerns to the government that such warning signals are being ignored.

The authors also fail to acknowledge that earlier catastrophic predictions about COVID-19 have not materialised. Insisting that COVID-19 is a much greater threat than it actually is can only serve to instill fear in the population and justify drastic measures that otherwise could not be sustained. The Ministry of Health has consistently avoided any public mention of any evidence that could help reduce fear of COVID-19 and has actively worked at undermining and suppressing any valid alternative treatments that could both help further reduce the morbidity of COVID-19 and negate the validity of provisional consents/emergency use authorisation for the experimental mRNA vaccines.

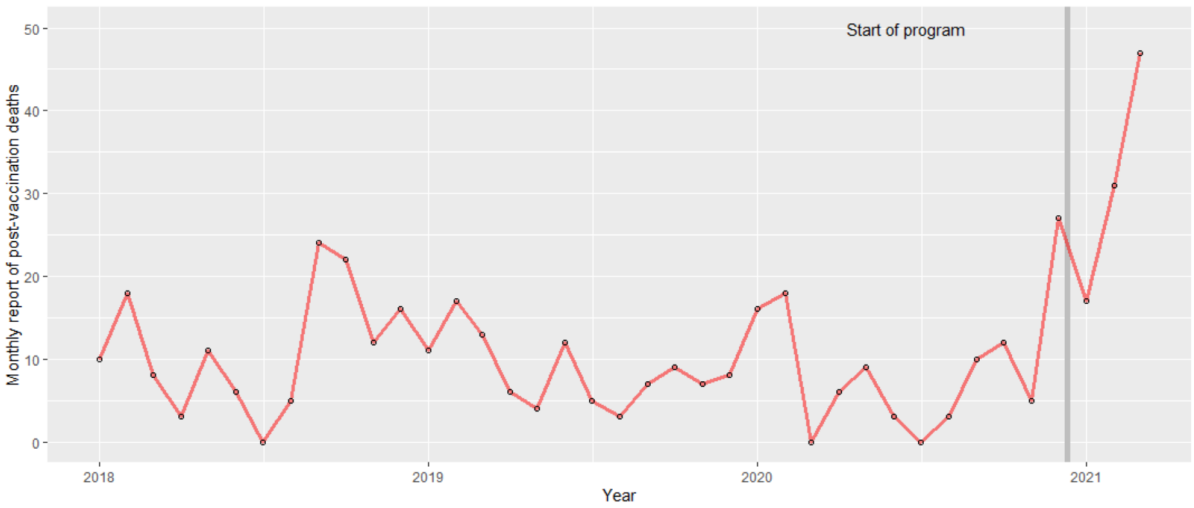

Figure 2. Line plot of monthly counts of post-vaccination death reports, aged less than 45 years from VAERS (2018 to present). Vertical line indicates start date of US COVID-19 vaccination programme.

The authors then assert that the vaccine has saved lives from COVID-19 by comparing projected deaths in the UK with observed. This is not convincing evidence, since modelled projections of deaths from COVID-19 have been consistently inaccurate throughout the pandemic. [9] The best information from trials does not show a convincing benefit for reduced overall mortality or COVID-19 deaths from the vaccine. [10] In fact, since the manufacturers of vaccines themselves state that since death from COVID-19 is so rare, such a trial that examines this issue will be prohibitively expensive and not feasible. [11] It is concerning that the government is relying on extremely weak, speculative evidence to indicate that the Pfizer vaccine will prolong survival as a result of its use.

Assertion that there is "no evidence of adverse effects" from the vaccine

The authors assert that there is 'no evidence of adverse effects' from the vaccine. This position is not consistent with even the trial evidence which highlighted several severe adverse events in the experimental group. Considering the trends in VAERS data and Eurosurveillance, surely the government's position cannot be so naïve? Importantly, the Norwegian Health authorities have concluded that the Pfizer vaccine was likely to be responsible for a cluster of deaths in rest home residents early in their vaccine programme. [12] Others have noted case-series of vaccine induced thrombosis and thrombocytopenia after the COVID-19 Pfizer and AstraZeneca vaccines. [13] A recent pre-publication release from the Official Journal of the American Academy of Pediatrics reports on seven cases of acute myocarditis or myopericarditis in healthy male adolescents who presented with chest pain all within four days after the second dose of Pfizer-BioNTech COVID-19 vaccination. [14]

While the link between these adverse events and the vaccine has not been definitively established, it is worrying that this is not raised at all by the authors in their bold claim of no evidence of adverse events from the vaccine. Clearly the VAERS data and emerging case-series are signals that the safety of these products should be closely examined and risk-benefit analyses carried out.

On concerns about other potential adverse effects:

1- O*n the concern that permanent alteration of DNA may occur.*

The science on this is still unfolding and we are concerned that the authors claim a definitive statement on this topic. The first reference the authors provide is the Centers for Disease Control and Prevention website which is aimed at providing the public with a simple overview of the mRNA injection. The second reference (and diagram) only shows the "*proposed* sequence of events leading to the generation of adaptive immune responses upon mRNA vaccination". From this the authors appear to conclude that it would be impossible for the injected mRNA to become integrated into our DNA because mRNA does not work that way. A study published in the 25 May 2021 by MIT and Harvard scientists [15] didn't prove specifically that the mRNA from the current COVID-19 vaccines is being integrated into our DNA but it did show, quite convincingly, that a viable cellular pathway exists whereby snippets of SARS-CoV-2 viral RNA could become integrated into our genomic DNA. A more recent publication has also revealed that human cells can write RNA sequences into DNA. [16] As stated by Richard Pomerantz, PhD, associate professor of biochemistry and molecular biology at Thomas Jefferson University, the study "will help us understand the significance of having a mechanism for converting RNA messages into DNA in our own cells." [17]

Clearly further research is needed on this topic before injecting people with an experimental gene therapy that could alter the recipient's DNA.

2- *On the concerns about immune suppression and exaggerated activation from pathogenic priming, ADE and vaccine interference.*

This concern was clearly identified by a plethora of mRNA vector researchers and scientists and was the subject of a published paper in early mid 2020 [18]: *"Because some Middle East respiratory syndrome (MERS) and SARS-CoV-1 vaccines have shown evidence of disease enhancement in some animal models, this is a particular concern for SARS CoV-2 vaccines…Continuous monitoring of this risk during clinical trials in an epidemic context will be needed."*

It is far from reassuring that this issue is being currently studied and monitored during the ongoing clinical trials scheduled to end in May 2023. The point we are making is simple: the people of New Zealand are not experimental subjects to study a novel vaccine based on gene therapy. At the very least if they are to be enrolled in a massive clinical trial it should be clearly disclosed, the risks explained and participation should be entirely voluntary, free of any propaganda and/or coercion, implied or otherwise.

3- *Concerns about the spike proteins causing endothelial cell mitochondrial damage.*

The authors mention that the quoted study refers to endothelial cell damage by infection, not vaccination. They then state that "*In human mRNA vaccine recipients, spike protein is produced intracellularly through mRNA transcription in the ribosome and then displayed on the surface of the antigen presenting cell to induce B cells to produce antibody to spike protein – this is entirely different and protective*." They fail to take into account recent evidence demonstrating that spike proteins produced by human host cells via mRNA coding do not remain "*displayed on the antigen producing cell*" but can be released and rather freely circulate in the blood of individuals who have received one or two mRNA injections. Free SARS-CoV-2 Spike Protein S1 Particles that allows the spike proteins to bind to ACE-2 are also present. We quote the researcher of this recently published study: "*We hypothesize that the cellular immune responses triggered by the T-cell activation, which would occur days after the vaccination, lead to the direct killing of cells presenting spike protein and an additional release of spike into the blood stream. The mechanisms underlying release of free S1 and the subsequent detection of the intact spike protein remain unclear and require further studies.*" [19]

Recently disclosed Pfizer animal studies [20] have shown that surrogate lipid nanoparticles (LNP-mRNA) were not only found at the injection site but also in various organs of test animals, including the liver, the ovaries, adrenal glands, spleen etc... This means that various types of cells, in addition to muscle cells, could be induced to produce spike proteins following the injection. If the same thing happens in vaccinated humans and these cells are then destroyed by the immune system of the vaccinee, this would explain freely circulating spike proteins and S1 after injection of Comirnaty.

Again a definitive statement by the authors is being questioned by recent research.

4- *Concern about 'the concept of shedding (presumably of spike protein) after vaccination, affecting unvaccinated bystanders, particularly in the form of hormonal disruption and/or clotting*

abnormalities in females of all ages'.

The authors are quick to dismiss the possibility of shedding as not scientifically credible. They also dismiss the possibility of environmental exposure to the study intervention (mRNA encapsulated in lipid nanoparticles - LNPs) as mentioned by the manufacturer as "routine part of good clinical practice guidelines for phase 1 and 2 studies and does not imply any concern about transmission."

We have shown earlier evidence of wide biodistribution of the LNPs in the Pfizer animal study. We have also explained that the spike proteins and S1 are freely circulating in the blood stream after injection with mRNA.

So what is the level of certainty with regards to the possibility of environmental exposure?
Is the hypothesis that NLP and the spike proteins freely circulating in the blood stream of individuals who have received the vaccine, could possibly be excreted in bodily fluids such as saliva, sweat, semen and breast milk, far-fetched?

Can we summarily rule out that credible hypothesis simply because of the lack of knowledge due to the lack of proper research?

In Pfizer PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001 [21] on pages 67-68 the manufacturer took specific precautions to exclude pregnant woman in the following situations:

"*•A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.*
A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
• A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.
• A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception. "

And **Exposure During Breastfeeding:**

An exposure during breastfeeding occurs* if:
• A female participant is found to be breastfeeding while receiving or after discontinuing study intervention.
• A female is found to be breastfeeding while being exposed or having been exposed to study intervention (ie, environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention by inhalation or skin contact.

*Note that Pfizer does not say exposure "*could"* or "*may occur",* they rather state that exposure "*occurs*".

Whether or not Pfizer was simply following good clinical practice guidelines (as claimed by the authors) and had no concern about transmission cannot be definitively determined by reading the

above excerpts from the trial protocol. However, in light of other scientific evidence discussed above, the wording is clearly justified.

5- *Concern that 'through molecular mimicry of syncitin-1, and with reports of increased miscarriages, there is concern in pregnancy and for fertility'.*

There remains significant concerns for fertility and pregnancy due to the large number of uncertainties surrounding the mRNA injections. We believe it was a gross oversight by the European Medicines Agency's Assessment report about Comirnaty [22] where they stated that, "*Several literature reports indicate that **LNP-formulated RNAs can distribute rather nonspecifically** to several organs such as spleen, heart, kidney, lung and brain. In line with this, results from the newly transmitted study 185350, indicate a broader biodistribution pattern with low and measurable radioactivity in the ovaries and testes*," but then dismissed safety concerns based on, "the absence of toxicological findings in gonads" and the relatively low concentrations found in the gonads.

The Pfizer biodistribution studies themselves were not included in the EMA's report and have only recently been disclosed. Fertility issues remain a serious concern as the studies reveal that distantly injected mRNA can indeed reach the gonads. **Any** mRNA reaching the gonads (and/or uterus) with subsequent generation of spike proteins is a concern, hence the implications for the effects on human fertility for both males and females remains unknown at this stage. Additionally there were no biodistribution studies done with the actual Pfizer injection being administered to humans.

Similarly, there ought to have been proper clinical trials to rule out possible effects on the syncytin proteins that *do* share a remarkable homology with the SARS spike protein. These placental implantation and immune-suppressing proteins are themselves the result of viral insertions into a common mammalian ancestor aeons ago (HERV-W, the human endogenous retrovirus W). Some work has been done in animals proving the effects of interfering with these proteins, but Pfizer and Moderna are only now running studies in pregnant women. Interestingly they are only recruiting women from 24 weeks, well after successful syncytio-trophoblastic attachment has successfully occurred. Of course, the results will be in only after the women have delivered their babies, reminding of the adage "absence of evidence of harm is not evidence of absence of harm."

We discuss this further in point 10.

6- *Concern about 'the potential for autoimmune reactions, or impaired or exaggerated infection responses, years after vaccination that short or even medium-term trials would not disclose'.*

By definition the authors cannot possibly have any knowledge about these potential long-term responses. These are ongoing clinical trials and no long-term data is now available. [23] It is unclear why they refer to an Australasian Society for Clinical Immunology and Allergy guide sheet as the ASCIA also have no possible knowledge of any long term data. It is equally unclear why the authors refer to a study in mice where they claim, "*mRNA vaccines may offer benefit in the treatment of multiple sclerosis.*" The mouse study involved induced experimental autoimmune encephalomyelitis and is not relevant to the concerns that we have raised about potential long-term immunopathology in humans.

7- *Concern about 'the potential for spike protein-as-prion disease' in the distant future.*

While we accept that Classens assertions lacks validation from peers, we find questionable the use of VegSource.com and Facebook as validation for their dismissal of Classen's concerns about potential prion pathology.

8- *Concern that 'vaccinated people may not have prolonged or broad-based immunity, including to the many new variants of concern, and have higher death rates when exposed'.*

The authors suggest that "*protection from the vaccine against severe disease to the variants is well preserved*" however a published study by researchers from Pfizer has shown that vaccine effectiveness is reduced for many of these variant strains. The vaccine was only 2/3 as effective against the South African strain as against the original strain [24] and Pfizer CEO, Albert Bourla, said on 15 April 2021 that while more research is needed, it is likely that people who receive Covid-19 vaccines will need booster shots within a year afterward, and then annual vaccinations, to maintain protection against the virus as it evolves. [25]

The medical media is awash with reports of so-called 'breakthrough cases following vaccination' and in April 2021 the CDC has moved to issue instructions that PCR testing of possible cases in the vaccinated is to use a cycle threshold of up to 28 only, here: https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html . This would seem a clear attempt to minimize cases, given the 'standard' cycle thresholds used have been from 35 to 45. Further they have now stopped even recording these cases, unless they result in hospitalisation or death. This cannot allow for valid comparisons and can only be seen as a plan to falsely attribute lower "case" numbers to the vaccines.

9- *Concern that 'the symptoms, oxidative stress and inflammatory phenotype of "long covid" syndrome may be produced solely by the spike protein, without presence of whole virus'.*

There are valid concerns regarding spike protein toxicity. Yuichiro Suzuki et al presented a strong argument that the spike protein by itself can cause a signaling response in the vasculature with potentially widespread consequences. [26,27,28] Furthermore, they suggested that a similar effect could happen in response to the mRNA vaccines, and they warned of potential long term consequences for both children and adults who received COVID-19 vaccines based on the spike protein. [29] The S1 subunit can promote loss of barrier integrity, suggesting that the spike protein acting alone triggers a pro-inflammatory response in brain endothelial cells. [30]

We would be remiss to highlight the lack of knowledge by the authors on this issue. Expectations based on assumptions cannot be enough to brush aside valid concerns.

10- *Concern that 'the effects on children (two reports on VAERS of deaths of young children in clinical trials), pregnancy, fertility, the elderly and infirm, interactions with medications, other chronic conditions, have not been studied'.*

The authors provide no reassurance that the experimental vaccines have been studied in these groups and concede that, "*it is true that evidence is only accumulating now about COVID-19 vaccines including Comirnaty when given to people with a range of chronic conditions including immunocompromising conditions, pregnant women and those who are very frail*." However they

proceed to make the sweeping claim that, "*the benefits of vaccination have been universally determined to greatly exceed the risks*." They go on to say, "*After hundreds of millions of doses, no evidence of adverse effects has emerged*." Neither of these claims are backed up with suitable evidence.

There is evidence that the COVID-19 vaccine can cause damage, as discussed above. The potential impact on male fertility of the spike protein generated endogenously by the vaccine could also negatively impact the male testes, as the ACE2 receptor is highly expressed in Leydig cells in the testes. [31] Several studies have now shown that the coronavirus spike protein is able to gain access to cells in the testes via the ACE2 receptor, and disrupt male reproduction. [32,33] A paper involving postmortem examination of testicles of six male COVID-19 patients found microscopic evidence of spike protein in interstitial cells in the testes of patients with damaged testicles. [34]

We argue that our analysis provided above of the virulence of the virus (very low) and the alarming spike in VAERS deaths leads to the complete opposite conclusion and the COVID-19 vaccines should be proscribed immediately unless for experimental use with full informed consent.

Therapies for COVID-19 that may prevent or successfully treat disease

The authors reject the description of mRNA vaccines as gene therapy when it has been shown that it is quite possible for RNA to be reverse transcribed into the DNA of the host cell. The synthetic mRNA itself is based on genetic technology. Their denial that it is a gene therapy is also in contradiction to common parlance as the largest online open source encyclopaedia clearly lists mRNA as a subtype of gene therapy including reference to BioNTech products. [35]

The definition of gene therapy is rapidly evolving to include mRNA gene therapy, regardless of its ability to be reverse-transcribed into cell DNA.

The severity of COVID-19 compared to influenza has been discussed above.

While the authors repeat the usual information provided by authorities and their chosen "experts" against the use of alternative treatments to COVID-19, they overlook that the government took steps to restrict access to such medication early in the pandemic and decided not to approve them. Meanwhile, Medsafe demonstrated unusual speed in neglectfully granting provisional consent to the Pfizer Comirnaty injection for the entire population of NZ above the age of 16 years. This decision was found to be illegal, after which, the government quickly changed the legislation, with no new risk assessment offered. So we are far from impressed by what is "recommended".

As an example, for Ivermectin there is an abundance of evidence for beneficial effects in preventing fatality after COVID-19 infection, including meta-analysis [36,37,38,39,40,41,42] and other reviews. [43,44,45,46,47]

In looking for signals as to the worthiness of Ivermectin research, the authors defer to the WHO – a private organisation that has been found severely wanting in many aspects of the pandemic, and whose biggest funders during the pandemic (China and the Gates Foundation) can hardly be said to be financially and politically neutral. The authors should read the research themselves and trust their own judgement. We have supplied the references again and summarise below. Intellectual

laziness will be no defence in any future enquiry should New Zealand experience a significant outbreak with lives lost needlessly due to suppression of clinical proof of Ivermectin's efficacy, or if the vaccine is acknowledged to be harmful and it emerges that it was never justified as "the only way out of the pandemic". Indeed, this single fact - the seemingly collective denial by major public health bodies of a lifesaving cure for COVID-19 illness – testifies to the apparent triumph of profits and politics over scientific medicine. The casual treatment of our concerns as some sort of 'rebuttal tennis' by the authors does nothing to reassure the public that they are being properly guarded.

A summary of some facts about Ivermectin are as follows:

- A meta-analysis of 3 trials, assessing 738 participants, found that Ivermectin prophylaxis among health care workers and COVID-19 contacts reduces the risk of COVID-19 infection by 86%.
- A meta-analysis of 13 trials, assessing 1892 participants, found that Ivermectin reduced the risk of death by an average of 68% compared with the control group.
- Ivermectin has a well-established safety profile with billions of doses used worldwide for parasitic infections. Various WHO documents on parasitic infections refer to Ivermectin long safety record.
- Ivermectin is affordable, and can be distributed by various means, e.g. post, and self-administered. It can therefore effectively reach traditionally 'hard-to-reach' and vulnerable populations such as undocumented migrants, homeless, the elderly living alone or in care homes, those lacking transport to reach health facilities, and those who lack access to adequate health care for other reasons.

The weight of medical and scientific opinion

The authors attempt to discredit scientific arguments by calling into question the background knowledge of the highly qualified professionals who made them speaks for itself and does not require further comment.

Summary

The authors claim that our concerns are not well founded has not been established by their response and we have presented further evidence rebutting these assertions and reinforcing our position.

For such a rapidly developed and still experimental pharmaceutical the bar should be set extremely low for recognising signals of potential and actual harm, and investigating any concerns with alacrity and vigour, given the mass population being targeted - soon to include children, if New Zealand continues to follow the same path as the United Kingdom, United States, Canada etc. We have clearly outlined that there are safe and viable alternatives to the novel mRNA injections.

We also emphasise newer and alarming information (of more deaths, heart inflammation in young people, and Dr Tess Lawrie's call to stop the roll-out based on her group's assessment of the UK's Yellow Card system [48]) that has emerged since our letter to Medsafe in May 2021 and that has

prompted us to write statements on informed consent and on injecting children. Our letters have been sent widely to the government, media and our medical bodies, with supporting references. [49] The extent and mechanisms of harm that are emerging from the injection deserve the utmost open-minded, rapid and willing assessment to enable the necessary action.

At NZDSOS we believe strongly that there is no urgent need for the use of this experimental vaccine in the New Zealand population and its use should be halted immediately.

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