IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-A-TARA ROHE

AFFIDAVIT OF PROFESSOR NIKOLAI PETROVSKY IN SUPPORT OF APPLICATION FOR JUDICIAL REVIEW AND INTERIM ORDERS

Dated 14 January 2022

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A Justice of the Peace
for South Australia
14/1/22

I, **Nikolai Petrovsky**, Physician and Vaccine Developer, of Adelaide, South Australia, affirm:

Qualifications and experience

1. I graduated from the University of Tasmania with a Bachelor of Medical Science in 1979 and a Bachelor of Medicine, Bachelor of Surgery in 1982.

2. In 1983, I completed an internship in Medicine at Launceston General Hospital. From 1984 to 1990, I was a Medical Resident/Registrar and from 1991 to 1992, I was an Endocrinology Registrar at the Royal Hobart Hospital. In 1993, I was an Endocrinology Registrar at the Royal Melbourne Hospital. Between 1994 and 1996, I was a NHMRC Scholar at the Burnet Clinical Research Unit at The Walter and Eliza Hall Institute of Medical Research at the University of Melbourne, where I completed a PhD in immunology, specifically relating to cytokine regulation in health and disease.

3. From 1998 to 2004, I was the Director of the National Health Sciences Centre in Canberra, a clinical research organisation, where I was engaged in conducting clinical trials. During the same period, I was also a Senior Endocrinologist at the Canberra Hospital. From 2002 to 2005, I was Professor of Medical Informatics at the University of Canberra. During this period, from 2003 to 2004, I was also Associate Professor at the Australian National University Medical School conducting immunology and vaccine research projects as part of my academic appointment.

4. Since 2004, I have been the Director of the Department of Diabetes and Endocrinology at Flinders Medical Centre in South Australia, with a conjoint position as a Professor in Medicine at Flinders University in South Australia. As Director of the Department of Diabetes and Endocrinology at Flinders Medical Centre, I manage the Department at a major teaching hospital which caters to a broad spectrum of diabetes and endocrine patients, conducts clinical trials and undertakes basic research.

5. I have been involved in vaccine research since 1998 through my various appointments. In particular, I have been actively involved in research related to the development of novel vaccines and vaccine adjuvants, including protein

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vaccines, DNA vaccines, mRNA vaccines and polysaccharide vaccines.

6. Almost from the time I commenced vaccine research, I was interested in coronavirus vaccines as development of a SARS vaccine was one of the objectives of my first NIH grant awarded in 2005.

7. In 2002, when still in Canberra, I founded Vaxine Pty Ltd (Vaxine), an Australian biotechnology company now based in South Australia, which specialises in vaccine development and formulation, vaccine adjuvants, vaccine clinical trials and immunology supported by almost continuous research grant funding from the US National Institutes of Health. I am an inventor on multiple vaccine patents held by Vaxine.

8. In my role as Chairman and Research Director of Vaxine, I have been involved in the development and formulation of vaccines for a range of pathogens, including SARS, MERS and SARS-CoV-2 coronaviruses, various seasonal and pandemic influenza viruses, pneumococcus, hepatitis B virus (HBV), malaria, Japanese encephalitis virus (JEV), West Nile virus, Ebola virus, rabies virus and Human Immunodeficiency Virus (HIV), amongst many others.

9. Over the last 13 years I have been a principal investigator or sponsor representative on at least 13 vaccine clinical trials including against pandemic and seasonal influenza, hepatitis B, insect sting allergy, and Covid-19. I have developed many other vaccines that have proved successful in animal testing.

10. These clinical trials were undertaken to ensure that the vaccine candidates I was developing met all required safety, efficacy, manufacturing and stability criteria required for approval by regulators. This required that I remain abreast of all key matters relating to development and approval of vaccines.

11. I have received continuous funding to support my vaccine research, and I have been the recipient, either solely or jointly, of more than 20 research grants totalling over AUS$50 million, the majority of which were for my research activities in the field of vaccine development. These research grants included, for example:

    (a) ACT Government R&D Grant (2002) "Development of a novel vaccine adjuvant", awarded to National Health Sciences Centre, $77,000;

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(b) Biotechnology Innovation Fund (2002) "Development of a novel vaccine adjuvant", awarded to Vaxine Pty Ltd, $250,000;

(c) START grant, (2004-2006) "Development of an aluminium-free hepatitis B vaccine", Chief Investigator (CI) Petrovsky, $770,000;

(d) DEST Innovation Access Program (2004-2006), awarded to Oz Nano2life consortium (one of six named investigators on grant), $1,000,000;

(e) National Institute of Health (NIH) Grant No. 5U01AI61142 (2005-2010) "Novel adjuvants for bioterrorism vaccines", Chief Investigator (CI) Petrovsky, USD$2.5 million;

(f) NHMRC Project Grant No. 375199. (2006), "Improved flu vaccines" Chief Investigators (CIs) Petrovsky and Cooper, $250,394.00; and

(g) Commercial Ready Grant (2006-2007), "Hepatitis B vaccines", awarded to Vaxine Pty Ltd. Chief Investigator (CI) Petrovsky, $1.5 million;

(h) IIFSA grant (2008-2010) Vaccine Manufacturing Facility. Chief Investigator (CI): Petrovsky, total $1 million;

(i) ARC Linkage Grant LP0882596 (2008-2011) "Nanotechnology-Enhanced Vaccines: New inulin bioconjugates to defeat global pandemic threats", Chief Investigator (CI): Ginic-Markovic, Matisons, Petrovsky and Cooper, total $140,530.00;

(j) National Institute of Health. 5U01AI61142 Grant Supplement (2008-2009) "Pneumococcal vaccine", Chief Investigator (CI): Petrovsky, USD$108,000;

(k) National Institute of Health. 5U01AI61142 Grant Supplement "GMP Adjuvant manufacture" Chief Investigator (CI): Petrovsky. 2008-2009, USD$875,000;

(l) US Department of Health. Contract HHSN272200800039C (2008-2013) Adjuvant Development Contract – Japanese Encephalitis Vaccine, Chief Investigator (CI): Petrovsky., USD$8.5 million;

(m) Bill and Melinda Gates Foundation. Global Health Grant (2012-2013)

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"Development of an Advax™ Adjuvanted, Temperature-Stable, Antigen Sparing, Enhanced Potency, Inactivated Polio Vaccine for Protection of Children in the Developing World" Chief Investigator (CI): Petrovsky. $534,784;

(n) National Institutes of Health BAA-NIHAI2013168, Contract. HHSN272201400053C (2014-2019) Adjuvant Discovery Contract, PI: Petrovsky, USD $10,786,491.00;

(o) National Institutes of Health HHSN272201800044C (2018-2023), Adjuvant Development Program, PI. Petrovsky USD $7,015,025 including options; and

(p) National Institutes of Health HHSN272201800024C (2018-2023), Advanced Development of Vaccines for Biodefense and Emerging Infectious Diseases, PI. Petrovsky, USD $18,541,473 including options.

13. I have published the results of my research in over 200 original research articles, the majority being in the fields of vaccines, vaccine adjuvants, immunology, and immune-informatics. I have also authored 36 refereed reviews, 16 book chapters, 38 editorials/abstracts and more than 66 conference papers, the majority of which are relevant to the fields of immunology, vaccines, vaccine formulation and adjuvants. I co-authored a review article on vaccine adjuvants in 2004, which is one of the most highly-cited review articles in the vaccine adjuvant field in the last 17 years (1072 citations) and continues to be cited as the content remains topical and relevant to the field of vaccine research.[1]

14. I have also held a number of editorial positions for scientific journals within the fields of immunology and vaccines, including:

(a) Guest Editor for special issues of Immunology and Cell Biology related to "Immuno-informatics" (2001) and "Vaccine adjuvants" (2004);

(b) Member of the Editorial Advisory Panel for Expert Review of Clinical

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[1] Petrovsky and Aguilar, "Vaccine adjuvants: current state and future trends," *Immunology Cell Biology* 82: 488-496 (2004) ["**My 2004 Review**"].

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Immunology (2005-current);

(c) Special Edition Editor of Vaccine adjuvants feature in Vaccine (2006);

(d) Editor-in-Chief for Immunome Research (2007-2014);

(e) Section Editor (Autoimmunity) for Open Immunology Journal (2008-2014); and

(f) Editor-in-Chief for Journal of Vaccines and Vaccination (2012-2015).

15. In addition to these editorial responsibilities, I have also been a reviewer for more than 20 peer-reviewed scientific journals, including Nature Biotechnology, Vaccine, Expert Reviews of Vaccines, Human Vaccines & Immunotherapeutics, European Journal of Immunology, Clinical Immunology, Immunology and Cell Biology, Bioinformatics, Immunogenetics, Journal of Molecular Medicine, Letters in Peptide Science, Expert Opinion on Therapeutic Patents, Pharmacogenomics, Clinical Research and Regulatory Affairs, Pharmaceutical Biology, Vaccines, and Expert Opinion on Drug Discovery.

16. I have held positions on a number of committees within the vaccine research and development community, including:

(a) Treasurer, Australasian Society of Immunology (2000-2003);

(b) Secretary-General, International Immunomics Society (2003-2014);

(c) Member, Clinical Trials Subcommittee, ACT Department of Health and Community Care Ethics Committee (2000-2004);

(d) Councillor, Australasian Clinical Research Network (2000-2003); and

(e) Convenor, Novartis Foundation Symposium (2002).

17. I have been an organiser of many international scientific conferences, including in the area of vaccines, including in the last 5 years:

(a) Organising Committee, Global Conference on Vaccines (Vaccines-2015) Dubai, UAE, April 13-15, 2015;

(b) Program Committee '1st International Workshop on Artificial Immune

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Systems: Systems & Synthetic Immunology, Computational Immunology & Immune-Inspired Engineering', Taormina, Italy, July 17-18, 2015;

(c) Meeting President and Chair of the Organising Committee, Asia Pacific Global Summit and Expo on Vaccines & Vaccination, Vaccines-2015, Brisbane Australia July 27-29, 2015;

(d) Chair, Organising Committee, American Global Summit and Expo on Vaccines & Vaccination, San Francisco, USA October 05-07, 2015;

(e) Organising Committee, 8th Indo Global Summit and Expo on Vaccines & Vaccination, Hyderabad, India, November 2-4, 2015;

(f) Organising committee member, "10th Euro Global Summit and Expo on Vaccines & Vaccination" Rome, Italy June 16-18, 2016;

(g) Organising committee member, 15th International Conference on Bioinformatics (InCoB), Singapore, September 21-23, 2016;

(h) Chair, NIH Workshop on Immune System Engineering For Targeted Tolerance in Type 1 Diabetes, Bethesda USA, Nov 2017;

(i) Chair, NIH Blue Ribbon Panel on Vaccine Adjuvants, Bethesda USA, March 2018;

(j) Chair, Organising Committee, Cleveland Clinic Research and Innovation Symposium, Port St Lucie, Florida, Nov 21-22, 2019; and

(k) Advisory board member, Vaccines R&D-2020, Washington DC, Nov 30-Dec 2, 2020.

18. I have been named as an inventor on four vaccine related patent families.

19. I have supervised many PhD students and postdoctoral fellows throughout my career. I have also regularly lectured to undergraduate students on vaccine development. My laboratory also regularly has exchanges of students and postdoctoral fellows from overseas universities and institutes.

20. From the completion of my PhD in 1998, the focus of my research has been on the development of vaccines including my co-discovery of a novel

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polysaccharide vaccine adjuvant formulation (based on the plant polysaccharide, inulin) that my research group has now applied to more than 50 different vaccines.

21. In 2005, I was awarded a US government National Institutes of Health (NIH) grant for research aimed at developing and enhancing biodefense vaccines through the use of novel vaccine adjuvants.

22. Given my vaccine expertise, I usually receive 5-10 invitations a year to give keynote or plenary talks on the topic of vaccines at international scientific conferences.

23. I was invited by NIH to chair two major internal workshops, to establish the NIH policies and future grant priorities, including a Blue Ribbon workshop on vaccine adjuvants.

24. I lead a team of scientists at Vaxine Pty Ltd that has successfully developed a vaccine against Covid-19. Leveraging prior experience in developing SARS and MERS coronavirus vaccines as well as pandemic influenza vaccines, under my direction, my team designed and formulated a recombinant protein-based vaccine incorporating our Advax adjuvant technology to create a Covid-19 vaccine known as Covax-19 or Spikogen. This vaccine was shown to be highly protective and prevent transmission in relevant animal models of infection. It has subsequently successfully completed Phase 1, 2 and 3 clinical trials where it demonstrated protection against symptomatic infection with the SARS-CoV-2 delta variant. It received emergency use authorisation from the Iran FDA in October 2021 and to date approximately 2 million doses of our vaccine have been distributed to immunization centres in Iran.

25. This affidavit has been prepared from my own knowledge gained over 30 years as a physician, academic and vaccine developer, together with a literature search and review of the relevant literature and reading of the relevant court documents.

26. **Annexed** and marked **"NP-1"** is a copy of my curriculum vitae.

Expert witness code of conduct

27. I have been given a copy of, read and agree to abide by the Code of Conduct for

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Expert Witnesses as stipulated in Schedule 4 of the New Zealand High Court Rules, and confirm that this evidence is within my area of expertise.[2]

28. My company, Vaxine Pty Ltd, has developed a successful protein-based Covid-19 vaccine (Covax-19/Spikogen) that currently has emergency use approval in Iran where mRNA vaccines are currently not in use. In the future it is possible that the vaccine I have helped developed may compete with the Pfizer mRNA vaccine. However, any views I express in this affidavit are my own and are based on my experience as a vaccine researcher and developer rather than as a developer of a vaccine that might at some time in the future be a potential competing vaccine to Pfizer. Where ever possible I have sought to support any opinions with independent published data.

Expert opinion

29. I have been asked to comment upon the issues and implications arising from the grant of provisional consent by the New Zealand Minister of Health under the Medicines Act 1981 for the use of the Pfizer/BioNTec (Comirnaty) COVID vaccine (**Pfizer Vaccine**) in 5-11 year old children.

30. I address the following issues in this affidavit:

(a) Traditional vaccine development;

(b) Risk/benefit analysis for vaccination is materially different between children and adults;

(c) Vaccines may have specific side effects in children not seen in adults;

(d) Novelty of mRNA vaccine use in humans and complete lack of knowledge of its potential for short and long term adverse effects and what form these may take;

(e) Provisional consent of the Pfizer vaccine further increases the risks for children;

[2] https://www.legislation.govt.nz/regulation/public/2016/0225/latest/DLM6953324.html

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(f) Waning protection conferred by vaccines;

(g) The Pfizer vaccine does not prevent infection and transmission of Covid-19;

(h) Pfizer Phase 3 clinical trials;

(i) Partial short term protection in adults

(j) Negative vaccine efficiency

(k) Vaccine trials and informed consent;

(l) Provisional approval of the Pfizer vaccine in 5-11 year olds

Traditional vaccine development

31. Traditionally vaccines have taken 15-20 years to develop starting from animal testing and then proceeding through Phase 1, then Phase 2 then Phase 3 trials before proceeding to a regulatory review and approval phase that itself could take 1-5 years to complete.

32. A typical breakdown of timeframes might be animal testing (5 years) Phase 1 (2 years), Phase 2 (3 years), Phase 3 (5 years), and regulatory submission and final approval (1-5 years). These time frames may be even more extended in the case of a completely new vaccine technology or new infectious disease being tackled, and may be slightly shorter where a well-established vaccine technology is being used or where an existing infectious disease with a known vaccine immune correlate of protection is being tackled.

33. The advantage of this traditional approach was that by the time a vaccine was finally approved the subjects in the Phase 1, 2 and potentially even Phase 3 trials would have up to 10 years of follow up data, to establish long term vaccine safety, and ensure there were no unexpected long-term safety issues.

The risk/benefit analysis for vaccination is materially different between children and adults

34. Establishing extremely high levels of safety is vastly more important for vaccines than therapeutic drugs as by and large very large numbers of perfectly

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healthy individuals will need to be vaccinated to stop even 1 case of the disease (number needed to vaccinate or **NNV**). This contrasts with therapeutic drugs where usually just a small number of people with the disease need to be treated to have a beneficial effect on the disease.

35. With a high NNV, vaccine safety considerations become extremely important. If the NNV for a particular vaccine is 1000 to prevent 1 serious infection, then this means the other 999 individuals who get the vaccine will get no actual benefit. If just 1 of these 999 healthy people are seriously adversely affected or harmed by the vaccine then we know numerically the harm caused by the vaccine (1 person) cancels out all the benefit (1 person) whose serious disease is prevented by the vaccine. This tenuous risk-benefit relationship is what keeps vaccine developers up at night as the risk benefit equation is extremely sensitive to even very small changes in risk, in this case an adverse event with a probability of 1:1000 cancelled out the benefit but for a vaccine with a higher NNV of 10,000 or 100,000 then any benefit could be completely cancelled by a side effect with a 1:10,000 or even a 1:100,000 incidence.

36. The risk benefit relationship for vaccines is also sensitive to large but not small changes in benefit. Unfortunately, unlike vaccine benefits, vaccine adverse effects are relatively age-insensitive and, if anything, are higher in the young than in the elderly, rather than the other way around. This is clearly shown by the examples of the adverse effects of myocarditis and thrombosis after mRNA and adenovirus vector vaccines, respectively, which are both significantly higher in young adults than in the elderly.[3]

Vaccines may have specific side effects in children not seen in adults

37. Additional considerations need to be taken into account when giving vaccines to young children, as they may have specific side effects not seen with the same vaccine in adults.

38. By way of example, a failed RSV vaccine in the 1950's that caused severe vaccine-enhanced RSV infections and unfortunate deaths of some vaccinated

[3] https://www.nature.com/articles/s41591-021-01630-0

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children when they became infected with the virus, do not cause similar sever adverse effects when given to adults[4]. Similarly, the Dengvaxia dengue vaccine was found to cause vaccine-enhanced disease upon exposure to dengue virus in young seronegative but not in older seropositive children or adults[5].

39. Pfizer's 6 month data clinical trial shows the absolute risk reduction of Covid-19 infection from administration of its mRNA vaccine was only 0.84%, whereas there was a 300% increase in risk for adverse events. This highlights that when the absolute benefit of a vaccine in reducing a serious case of infection is low, as is normal for most vaccines, it is easy for this benefit to be overwhelmed by numerically much larger adverse effects measured across the whole vaccinated population.

40. This also highlights the dangers and complexity of making risk benefit assessments based on mixing data from an entire population, rather than assessing age specific risk-benefit relationships, as for example if all the benefit of a vaccine is concentrated in one group, in the case of Covid-19 vaccines in the very elderly, but the harms of the vaccine are concentrated in another group, the very young, then if this data is all analysed together then it may appear on first appearance that the risk-benefit is reasonable, but when the risk-benefit assessment is performed on an age specific basis it immediately becomes apparent that there is a very large risk-benefit discrepancy, being strongly in favour of potential benefit in the elderly and strongly on the side of potential harm in the young.

41. More appropriately then in this circumstance, if the appropriate age-specific risk-benefit assessment was performed then the decision should be taken to target the elderly for vaccination and then only vaccinate younger individuals if their particular circumstances put them into a much higher risk category than others their age, for example children with high levels of disability and multiple comorbidities who have been shown to have much higher rates of serious disease and mortality from Covid-19 than other children who risks of developing such

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[4] Kapikian, A. Z., et al 1969. Am. J. Epidemiol. 89:405-421.
[5] https://pubmed.ncbi.nlm.nih.gov/33194810/

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problems in response to SARS-CoV-2 infection are exceptionally low.

42. The United States Center for Disease Control provided data that the risks of children aged 5-11 years being hospitalised with Covid-19 was ~30 cases per 100,000 population, which almost exactly equals the rate they provide for risks of children aged 5-11 years being hospitalised with influenza in 2019-2020 season of ~30 cases per 100,000 population[6]. The ultimate outcomes to the children was similarly not different between influenza and Covid-19 with only a tiny minority of hospitalised children with either infection requiring mechanical ventilation or dying from the infection (0.6%). This may make it look like Covid-19 is equal to influenza in severity in children but in fact the situation is that Covid-19 despite causing equal numbers of hospitalisations of children is actually a much less severe disease than influenza. This is because in a typical year only ~6% of children get exposed to influenza, whereas the CDC data shows that over the last 18 months to September 2021, 38% of children were positive to SARS-CoV-2 antibodies indicating previous infection. This means that the number of Covid-19 infections in children was likely of the order of 6 times that of influenza. Hence, given the similar total hospitalisation rates this would mean that in children aged 5-11 years Covid-19 infection is approximately 6 times less severe than seasonal influenza.

43. Influenza vaccination which has been proven over many decades of use in children to be extremely safe is not mandated for children. Given the similar disease burden and lower severity of Covid-19 than influenza disease in children, the higher proven risk of harm from the mRNA Covid-19 vaccines just considering the risk of myocarditis, and the unknown long-term risks of these mRNA vaccines, it would seem irresponsible to consider mandating mRNA Covid-19 vaccines for otherwise healthy children, or even recommending their routine use in this population, without conducting larger and longer duration clinical trials that would be able to more clearly define the exact risks and benefits of mRNA vaccines in these paediatric populations.

44. Indeed, given the extremely small size and short duration of the Pfizer trial of

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[6] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-Covid-Jefferson-508.pdf

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mRNA vaccine in children aged 5 to 11, the trial was not adequately powered to statistically assess either benefit or harm of vaccination[7]. This makes the trial essentially worthless for guiding public health policy. The reason for this is that with just 1,517 children in the trial receiving mRNA vaccine and 751 placebo, there were as expected no cases of serious Covid-19 disease or death in either group, hence the trial was unable to demonstrate or statistically quantify, a benefit, if any, of the vaccine on the overall health of these low risk children. Similarly, the trial was futile in its statistical design in respect of being able to detect or quantify harm. A trial of 1,518 individuals would only be able to detect a serious adverse effect if it occurred at a frequency greater than 1:1,518. As known serious adverse effects of mRNA vaccines such as myocarditis/pericarditis occurs in younger individuals at a frequency lower than the size of the Pfizer study, with myocarditis/pericarditis in adolescents aged between 12 and 17 years injected with Pfizer mRNA vaccine estimated in a Hong Kong study to be 18.52 per 100,000 persons vaccinated, or ~1:5400[8]. Hence this serious adverse effects would not be able to be detected by the Pfizer paediatric trial.

45. Any instance of myocarditis/pericarditis in a child aged 5-11 would be a very serious adverse event, and this possibility would need to be factored in to any risk-benefit assessment for approval of mRNA vaccine in children aged 5-11. As the Pfizer trial was never powered to detect such serious adverse effects, it is statistically invalid and unethical to claim that this trial confirmed the safety of mRNA vaccines in children aged 5-11 based on a lack of cases of myocarditis/pericarditis when the trial was never powered in the first place to detect such events.

46. Case reports indicate that myocarditis does occur in children receiving mRNA vaccines[9]. It is therefore inappropriate and misleading to quote the under-powered Pfizer paediatric trial to claim that the mRNA vaccine is safe in children. To make this claim the frequency of this serious adverse effect would need to be precisely quantified in a much larger properly powered paediatric trial

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[7] https://pubmed.ncbi.nlm.nih.gov/34752019/
[8] https://pubmed.ncbi.nlm.nih.gov/34849657/
[9] https://pubmed.ncbi.nlm.nih.gov/34088762/

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so this exact frequency could then be fed into the risk-benefit analysis when considering approval of this vaccine for 5-11 year olds. Currently all the Pfizer pediatric trial result can say is that the mRNA vaccine does not cause myocarditis in children aged 5-11 years old at a frequency much greater than 1:1,518. This does not say that the mRNA vaccine is safe.

47. The CDC reports that 94 children aged between 5 and 11 years have died during the pandemic to 16 October 2021 in a population of 24.4 million children of this age. This equates to a risk of 1 in 259,574 US children dying from Covid-19. The CDC data indicates 38% of US children were positive to SARS-CoV-2 antibodies indicating previous infection. Hence, it can be inferred that the risk of an actual Covid-19 infected child dying from that infection is approximately 1:98,638 which is much lower than the risk of a child infected with influenza dying from that infection. Furthermore, of the extremely small number of children dying from Covid-19, the majority have not been well healthy children but had other serious medical conditions.

48. Notably, in the Pfizer Covid-19 vaccine clinical trial, zero unvaccinated children 5 to 11 years of age suffered a severe case of Covid-19. In contrast, for every 10 cases of non-severe Covid-19 in the unvaccinated group, there were 3 to 8 cases of severe (grade 3) systemic reactions in the vaccinated group. Severe (grade 3) systemic reactions were listed to include fever greater than 102.1° F; vomiting that requires intravenous hydration; diarrhea of six or more loose stools in 24 hours; or severe fatigue, severe headache, severe muscle pain, or severe joint pain that prevents daily activity.

49. In the Pfizer Covid-19 vaccine clinical trial, zero unvaccinated adolescents 12 to 15 years of age suffered a severe case of Covid-19. In contrast, for every 1 case of non-severe Covid-19 in the unvaccinated group, there were 7 cases of severe (grade 3) systemic reactions in the vaccinated group with a total of 121 grade 3 reactions out 1131 subjects in mRNA arm versus a total of 22 grade 3 reactions out of 1129 subjects in the placebo group.[10] The Pfizer clinical trial also found

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[10] Wallace M. Grading of recommendations, assessment, development, and evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine. COVID-19 Vaccines Work Group of the Advisory

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that 1 in about 1,100 vaccinated children 12 to 15 years of age had a grade 4 systemic reaction (fever greater than 104.0° F) after the first dose that required an emergency room (ER) visit and withdrawal from the study. There were 5 serious adverse events in the mRNA arm versus only 2 in the placebo arm.

50. This all urges extreme caution when extending a vaccine from adults to children, as it means that not only are different safety issues encountered in children that might not be seen in adults but also that the risk-benefit relationship in children may be more than a thousand-fold different to that in older adults. This is particularly the case for Covid-19 where the vast majority of serious disease and fatal cases are concentrated in older adults and those with chronic comorbidities.

Novelty of mRNA vaccine use in humans and complete lack of knowledge of its potential for long-term adverse effects and what form these may take

51. The Pfizer mRNA vaccine has not followed a traditional vaccine route, with extremely limited animal testing before entering accelerated clinical trial testing and regulatory approval all within the space of less than 12 months.

52. Indeed, the interim Phase 3 efficacy data on which emergency use authorisation was granted by the FDA, represented a median follow up time of trial subjects of just 2 months after completion of vaccine administration[11].

53. This is an exceptionally short period of follow up with new vaccines typically requiring 2-3 years of follow up data to confirm safety before being submitted for approval.

54. While in the context of a pandemic, the risk associated with an accelerated approval may be justified, by a large offsetting benefit, for example prevention of the high mortality rate in the elderly, this extremely short follow up creates concerns when considering vaccine approval in young children who are known to have a thousand-fold lower absolute benefit due to their low rate of serious

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Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. 2021 May 12: 24, 25. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/03-COVID- Wallace-508.pdf

[11] https://pubmed.ncbi.nlm.nih.gov/33301246/

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disease, and hence have a thousand fold higher NNV to prevent one death.

55. It is particularly a concern given the newness of mRNA vaccine use in humans and the complete lack of knowledge of its potential for adverse effects where even the short term adverse effects are still in the process of being identified. The longer term adverse effects cannot be known except with the benefit of much longer periods of follow up. Potential problems such as increased cancer risk, autoimmune disease, cardiac dysfunction, fertility disturbance and chronic neurological disease may take many years or even decades to become evident, and their possibility cannot be excluded without much longer periods of follow up.

56. It is not possible to claim such potential long term side effects of mRNA vaccines are not plausible, as even 12 months ago if someone had suggested that mRNA vaccines would cause myocarditis/pericarditis, this would have been said to be not plausible.

57. The extreme lack of knowledge and experience with mRNA vaccines is highlighted by the fact that none of its own developers predicted from their studies that it would cause myocarditis/pericarditis and this issue was further missed in the Pfizer Phase 3 clinical trials, the issue only being identified very belatedly based on mounting evidence from post-marketing adverse event reporting almost a year after the initial mRNA vaccine approval.

58. Even today, its own developers and other scientists are completely at a loss to explain the mechanism whereby these mRNA vaccines are causing this known myocarditis/pericarditis[12]. If they cannot explain how the mRNA vaccines are causing this known side effect, then they cannot plausibly suggest knowledge that this technology will not cause other side effects now or in the future.

59. It would therefore be imprudent to accept any claim by mRNA vaccine developers and promoters that despite a complete lack of long-term safety data, it is certain this highly novel technology, never previously tested in large numbers of humans, will have no adverse long-term consequences in adults or

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[12] https://pubmed.ncbi.nlm.nih.gov/34960761/

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particularly in children undergoing development and puberty. This is something that cannot be foretold and will only be able to be known once the initial mRNA vaccinated individuals, the majority who received the vaccine in early 2021 have been followed up for at least 10-20 years.

60. By way of example, the FDA in their Guidance Document "Long Term Follow-up After Administration of Human Gene Therapy Products" recommends long term follow up of at least 5 to 15 years for such products.[13]

61. It is particularly concerning that closely related although not identical gene therapy technologies have been shown to have serious long term side effects, with well documented cases of gene therapy induced cancers.[14]

62. Whether or not a mRNA vaccine is considered a gene therapy or not, the point is that it is a completely new and largely unknown technology as applied to vaccines and therefore it would be most prudent to assume that it might have potential for causing serious long term side effects in some immunised children and turning out to be wrong, rather than optimistically and a lack of evidence assuming the converse and turning out to be wrong.

Provisional approval of the Pfizer vaccine further increases the risks for children

63. While New Zealand has only one provisionally approved vaccine for children, many other vaccines are available overseas or in development that are based on well-established vaccine platforms that have been safely used in children for many decades including whole inactivated viruses e.g. Sinopharm or recombinant protein e.g. Covaxin or Spikogen. These much better established vaccine platforms represent a safer and more predictable alternative for immunisation of children than the mRNA vaccines which are still in their infancy in relation to human use.

64. Rather than take undue risk in pushing still experimental mRNA vaccines into children who are at extremely low risk from serious Covid-19 disease, it would

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[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products
[14] https://www.nature.com/articles/3301946

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be sensible for New Zealand to explore accessing these more established vaccine platforms if it is considered a Covid-19 vaccine program is needed for children.

65. Despite mRNA vaccines having been given to hundreds of millions of people over the last 12 months this does not establish their safety. The number of people recently vaccinated with these vaccines does not change the inability to detect long-term adverse safety signals.

66. Two pathways exist for vaccine approval with Medsafe in New Zealand and TGA in Australia, the "provisional approval" pathway and the more commonly used, "approval" pathway. In the USA and other countries who have a second expedited approval pathway this is referred to as an emergency use authorisation (**EUA**) to distinguish it from the normal approval pathway. Hence, the EUA and provisional approval are both used to the same effect, where there is an urgent need to make vaccines or drugs more rapidly available before they complete their normal Phase 3 clinical trial testing.

67. In effect, the EUA and provisional approval pathways accept the risk of making such products available earlier and with less testing than normal is more than offset by the benefit of early availability.

68. However, by definition this EUA or provisional approval further changes and needs to be factored into the risk benefit relationship, as it further increases the risk over a vaccine that has been through the normal approval pathway.

69. Furthermore the EUA or provisional approval accepts that the authorised product still remains experimental in so far as the normal testing has still not been completed even if some preliminary data on efficacy and safety has been obtained.

70. The US FDA, on their website acknowledge an EUA is not equivalent to an approval, stating

> *"Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available*

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alternatives."

71. And

> *"FDA must ensure that recipients of the vaccine under an EUA are informed, to the extent practicable given the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product".*

72. In the US, a vaccine made available under an EUA must only be administered with voluntary informed consent.[15]

73. Regulators in different countries have different wording and mechanisms to cover vaccines being made available for use under emergency situations. In Australia and New Zealand,[16] the equivalent process to an FDA EUA is called a provisional approval. The Pfizer vaccine was made available in New Zealand by Medsafe granting it provisional approval. I would therefore regard the Pfizer vaccine in New Zealand as still in the experimental phase as its Phase 3 trials are ongoing.

74. As an experimental vaccine without full approval in New Zealand, the Pfizer vaccine should be administered voluntarily with fully informed consent, and with no coercion. This would mean that it should not be mandated as this would be a strong form of coercion that would negate informed consent. This would include the mandating of the vaccine for children in order for them to be allowed to attend school.

75. The Adult/adolescent Pfizer vaccine has provisional approval by Medsafe. On 28 October 2021, Medsafe announced its decision to renew the provisional approval for the Pfizer Covid-19 vaccine. The renewal of provisional approval

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[15] https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

[16] https://medsafe.govt.nz/COVID-19/status-of-applications.asp

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is for a period of two years, until 3 November 2023.[17]

76. On 16 December 2021, Medsafe granted provisional approval for the Pfizer Covid-19 vaccine for children aged 5 to 11 years old.[18] The provisional approval is for two doses of the paediatric vaccine, given at least 21 days apart.

77. The paediatric vaccine dose of Pfizer mRNA vaccine for children is one third of the dose for people aged 12 and over. Children aged 5 to 11 years will receive a 2-dose primary course of vaccination, given 8 weeks apart.

78. The Australian TGA on its website with respect to the Pfizer currently vaccine acknowledges that "The risk in children aged 5 to 11 years is not yet known. The clinical trial did not have enough participants to assess rates of myocarditis or pericarditis in children aged 5 to 11 years following receipt of the Pfizer Covid-19 vaccine" [19]

79. While the Australian TGA goes on to say " but no specific safety concerns have been identified so far from millions of doses of this vaccine administered overseas to children aged 5 to 11 years. The benefits of vaccination outweigh this very rare risk, and vaccination is still recommended for all eligible age groups", I disagree with this assessment as it is recognised that voluntary adverse event reporting systems that operate once a vaccine is on the market have major deficiencies and substantially under report adverse events. It is therefore not possible to rely upon such adverse event reporting systems to quantify the precise rate of any particular adverse reaction. Accurate quantification of adverse reactions can only be done in an apropriately-powered blinded randomised placebo-controlled clinical trial. The Pfizer pediatric trial does not meet this criteria as it was not statistically powered to detect myocaridits or pericarditis at the rate of approximately 1:5600 reported in young adult men, which should have factored into the design of the paediatric trial size. Without accurate information from a properly powered Phase 3 trial on the exact

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[17] https://covid19.govt.nz/news-and-data/latest-news/medsafe-renews-covid-19-vaccine-provisional-approval/

[18] https://www.rnz.co.nz/news/national/458053/covid-19-medsafe-gives-provisional-approval-for-pfizer-vaccine-for-children

[19] https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/approved-vaccines/pfizer (accessed 13 January 2022).

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frequency of myocarditis and pericarditis induced by mRNA vaccines in children 5 to 11 years of age, I do not see how the TGA can justify their statement "The benefits of vaccination outweigh this very rare risk, and vaccination is still recommended for all eligible age groups"

80. Furthermore, the Australian product information for Comirnaty (Tozinameran) Covid-19 vaccine [Tris/Sucrose Presentation][20] states:

> "COMIRNATY (Tozinameran) Covid-19 Vaccine has **provisional approval** for the indication below: Active immunisation to prevent coronavirus disease 2019 (Covid-19) caused by SARS-CoV- 2, in individuals 5 years of age and older. The use of this vaccine should be in accordance with official recommendations. The decision has been made on the basis of short term efficacy and safety data. Continued approval depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment."

This statement on the Pfizer product information clearly indicates only short term efficacy and safety data is available and clinical trials are ongoing, which I would interpret as meaning the mRNA vaccine is still at an experimental and emergency use phase with long term safety data still to be collected.

81. In New Zealand, Medsafe recently issued an "Alert Communication"[21] to remind people that the Comirnaty vaccination (Pfizer mRNA COVID-19 vaccine) can cause myocarditis and pericarditis, which it describes "as a new but rare side effect of vaccination with Comirnaty vaccine (Pfizer COVID-19 vaccine)."

82. Myocarditis after mRNA is not new, as presumably it has been occurring since the very first mRNA vccines were administered, but instead could be more properly described as a "newly-recognised adverse effect of mRNA vaccines". Myocarditis can also occur after Covid-19 infection but this does not explain myocarditis in Australia and New Zealand that occurred after mRNA vaccination at times when there was no circulating SARS-CoV-2 virus. I would

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[20] https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02442-1

[21] https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-reminder.htm

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regard it as a 'rare' side effect as in young men it is estimated to occur after mRNA immunisation at a rate of about 1:5600.

Waning protection conferred by the vaccines

83. Presuming SARS-CoV-2 circulates widely in New Zealand following lifting of restrictions then given the high transmissibility of the Delta and particularly Omicron strains, it can be expected that the majority of New Zealand children whether vaccinated or unvaccinated will eventually have one or more infections with SARS-CoV-2 virus, as already seen in children in the United States as reported by the CDC. Part of the reason for this is that the newly emerging variants including Delta and Omicron have demonstrated increasingly vaccine-resistance and vaccine protection against infection wanes rapidly.

84. Vaccination will ultimately not protect against everyone getting infection, although it may reduce disease severity in event of infection and slow down the rate at which the whole population becomes infected.

85. Protection of current mRNA vaccines is reduced against the Delta variant of SARS-CoV-2 and is known to wane rapidly over time. Since the Delta and Omicron variants have only recently become the most dominant SARS-CoV-2 variants of concern (**VOC**) worldwide, robust placebo controlled clinical studies examining long-term vaccine efficacy against theses variants do not exist for the Pfizer vaccine.

86. Studies in regions with relatively high vaccination rates and circulating Delta variant such as Israel, the UK and the USA have indicated much lower vaccine protection than was apparent against the original virus strains in the Phase 3 trials of these vaccines.

87. To measure protection provided by the Pfizer SARS-CoV-2 vaccine, Phase 3 studies measured infection rates over a short discrete time interval that was typically was just several months in average duration.

88. The headline vaccine protection percentage quoted is a relative rather than absolute measurement and only covers a discrete very short period during which protection was measured – typically starting two weeks after the administration of the second vaccine dose and up to an average of 2 months thereafter. If further

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time was allowed to pass, a greater number of individuals in the trial would have been exposed to infection, and hence if extrapolated far enough in time then eventually all the control but also the vaccine groups in a trial would be predicted to become infected, although it might take longer for all the vaccine group to become infected than the control group.

89. Vaccine protection is not constant but wanes over time. For example, vaccine protection is often low or negligible until after the second vaccine dose is given. Peak vaccine protection is obtained around 2-12 weeks post the second vaccine dose (the period during which vaccine efficacy has typically been measured in the Pfizer vaccine trials). Hence the published Phase 3 vaccine effectiveness data reflects this time of peak protection rather than trough protection.

90. After this initial 2-3 months of peak vaccine effectiveness, protection wanes, first against infection and transmission, then against symptomatic infection, then moderate infection and finally effectiveness wanes against severe infection, hospitalisation and lethal disease.

91. The rate of waning of protection post-vaccination is exacerbated by several factors:

    (a) Protection is either not gained, or lost faster, in elderly immunosuppressed individuals than young healthy individuals;

    (b) Protection is lost faster against the new variants such as beta, gamma, delta and omicron than against the original Wuhan strain of the virus that is no longer circulating; and

    (c) Protection is generally lost faster when the interval between the two vaccines doses is shorter, e.g. 3 rather than 12 weeks.

92. Based on the published data collected in other countries with high vaccination rates, it would be predicted that a reasonably high proportion of vaccinated New Zealand children will get exposed and infected with the delta, omicron or other variants that arise from time to time, with widespread infections accelerating as other interventions to restrict virus spread are lifted, but that the impact on New Zealand children is expected to be minimal with less than a 1:100,000 chance of an infected child dying from the infection, a rate lower than for influenza

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infection, and these few fatalities concentrated in children with disability and other major medical conditions. Hence, on a risk-benefit basis any recommendation to vaccinate children in New Zealand should first focus on protection of high-risk children with disability and other medical conditions putting them at elevated risk of serious disease, rather being applied as a blanket to all children.

The Pfizer vaccine does not prevent infection and transmission of Covid-19

93. Overall, Covid-19 vaccinated individuals that become infected with Delta or Omicron variants, have similar risks of transmitting the infection to others. A study of the AZ vaccine showed it had a negligible effect in reducing Delta variant transmission.[22] While the Pfizer vaccine had a modest effect on reducing Delta variant transmission for a few months at a time of peak vaccine effectiveness,[23] this effect rapidly wanes and in respect to the Omicron strain almost certainly any effect on transmission would be negligible as has apparently been acknowledged recently by the Director of the CDC.[24]

94. The Delta variant produces higher amounts of virus in infected individuals when compared to earlier virus strains, which is believed to account for the higher transmissibility observed from this variant.[25] Furthermore, the odds ratio of household transmission was shown to be 1.7 times higher in the Delta variant compared to the Alpha variant irrespective of vaccination status.[26]

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[22] Singanayagam, A., et al., Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. The Lancet Infectious Diseases;
Eyre, D.W., et al., The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv, 2021: p. 2021.09.28.21264260.

[23] Eyre, D.W., et al., The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv, 2021: p. 2021.09.28.21264260.

[24] https://www.msn.com/en-us/health/medical/cdc-director-covid-vaccines-cant-prevent-transmission-anymore/ar-AASDndg

[25] Luo, C.H., et al., Infection with the SARS-CoV-2 Delta Variant is Associated with Higher Infectious Virus Loads Compared to the Alpha Variant in both Unvaccinated and Vaccinated Individuals. medRxiv, 2021: p. 2021.08.15.21262077;
Wang, Y., et al., Transmission, viral kinetics and clinical characteristics of the emergent SARS-CoV-2 Delta VOC in Guangzhou, China. EClinicalMedicine, 2021. 40;
Li, B., et al., Viral infection and transmission in a large, well-traced outbreak caused by the SARS-CoV-2 Delta variant. medRxiv, 2021: p. 2021.07.07.21260122.

[26] Allen, H., et al., Household transmission of COVID-19 cases associated with SARS-CoV-2 delta variant (B.1.617.2): national case-control study. The Lancet Regional Health – Europe.

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95. Current data suggests that impact on transmission by vaccination is highly dependent on the study format, especially if only the Delta variant is included in analysis or if all variants are included, and if measurements are taken soon after vaccination, which does not necessarily reflect real-world events. For this reason, only studies that examined extended times post-vaccination and transmissibility of the delta variant have been included in the following analysis.

96. A recent UK study examining individuals at extended timepoints after second vaccination (median 74 days) described a probability of household transmission of 25% in vaccinated individuals compared with 38% in unvaccinated individuals.[27]

97. A retrospective study also performed in the UK also identified marginal reduction in delta transmission to household contacts, with a 24% reduction after Pfizer vaccine and 2% reduction after AZ vaccine, measured twelve weeks after the second dose, during a period of peak vaccine effectiveness.[28] Hence, there remains a high likelihood that a high proportion of vaccinated individuals infected with the Delta variant will transmit the infection to others. This means that despite someone being vaccinated it cannot be assumed that they will not be infected or capable of transmitting the virus to others.

98. Omicron is a relatively new variant of SARS-CoV-2 that has the highest level of transmissibility of any of the SARS-CoV-2 variants described to date and approaching the highest level of transmissibility of any known human virus.

99. The exceptional high transmissibility of Omicron is combined with features of vaccine-escape.

100. Vaccine escape is a mechanism whereby mutated viruses such as Omicron are able to avoid neutralizing antibodies induced by current vaccines, including the current mRNA vaccine, rendering them ineffective. The Pfizer mRNA vaccine is based on the spike protein sequence of the original ancestral Wuhan-01 strain

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[27] Singanayagam, A., et al., Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. The Lancet Infectious Diseases.
[28] Eyre, D.W., et al., The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv, 2021: p. 2021.09.28.21264260.

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of the virus and it is therefore provides poor protection against the Omicron variant.

101. Overall, as shown by the best available evidence, vaccinated individuals infected with Omicron variant are likely to have similar risks of transmitting that infection to other individuals, as an unvaccinated individual. Transmissions of Omicron by vaccinated individuals is clearly evident and for example all transmissions of Omicron into Australia have occurred through doubly-vaccinated travellers carrying this virus, as it is mandatory for all travellers to Australia to be doubly-vaccinated.

102. The effect of two doses of the Vaccine on infection with Omicron is modest and transient, rapidly waning to low levels. This recognition of rapidly waning immunity has prompted an increasing number of countries to recommend a third dose and in cases such as Israel, a fourth dose of Pfizer vaccine, to try and restore failing immunity and maintain at least some modest level of protection against Delta and Omicron variants.

103. While data remains sparse, the characteristics of Omicron relative to Delta, predict that the ability of the Pfizer vaccine to prevent Omicron infection and transmissibility will be less than even its ability to prevent infection by the Delta variant, which itself was lower than its protection against the original ancestral virus strains.[29]

104. The odds ratio of household transmission was shown to be 1.7 times higher for the Delta variant compared to the Alpha variant irrespective of vaccination status[30] and the odds ratio of transmission will be higher again for Omicron than for Delta.

105. Omicron was shown to have been transmitted between two doubly vaccinated

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[29] Luo, C.H., et al., Infection with the SARS-CoV-2 Delta Variant is Associated with Higher Infectious Virus Loads Compared to the Alpha Variant in both Unvaccinated and Vaccinated Individuals. medRxiv, 2021: p. 2021.08.15.21262077;
Wang, Y., et al., Transmission, viral kinetics and clinical characteristics of the emergent SARS-CoV-2 Delta VOC in Guangzhou, China. EClinicalMedicine, 2021. 40;
Li, B., et al., Viral infection and transmission in a large, well-traced outbreak caused by the SARS-CoV-2 Delta variant. medRxiv, 2021: p. 2021.07.07.21260122.

[30] Allen, H., et al., Household transmission of COVID-19 cases associated with SARS-CoV-2 delta variant (B.1.617.2): national case-control study. The Lancet Regional Health – Europe.

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travellers in a Hong Kong hotel.[31] Similarly, recent community outbreaks of Omicron in Australia are attributable to double vaccinated (a requirement for travel to Australia) Omicron-infected individuals entering Australia and then causing community outbreaks including through infection of vaccinated individuals, despite over 90% of Australian adults now being doubly vaccinated.[32] This confirms that double vaccination with currently available vaccines in Australia (and New Zealand) is unlikely to significantly reduce infection by, or transmission of, Omicron.

106. Assessment of any overall impact on Omicron transmission by vaccination will be highly dependent on the study format, particularly when measurements are taken in relation to vaccination. This may not reflect true real-world events as the most critical factor is not the strongest effect on transmission short-term but the weakest effect long-term. Hence, there is a high likelihood that individuals infected with the Omicron variant, will be equally likely to transmit the infection to others, regardless of their vaccination status.

107. Just because someone is vaccinated, it cannot be assumed that they are not infected or capable of transmitting the virus to others, as the mRNA vaccines have minimal effect on transmission of the recent variant strains.

108. A Norwegian study reported a Christmas dinner with 117 attendees where 74% (81/110) of the tested attendees became infected with the Omicron variant in a single outbreak. This was despite the 89% of attendees having recently (median time since receiving last vaccine dose of 79 days for cases and 87 days for non-cases) been vaccinated with two doses of mRNA vaccines and also being relatively young (average age of 39 years (SD: 9.2; median: 38; range: 26–68).[33] This case report indicates that vaccination with two doses of mRNA vaccine provides minimal if not no protection against Omicron infection even in young people who would be expected to respond best to vaccination.

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[31] https://wwwnc.cdc.gov/eid/article/28/2/21-2422_article
[32] https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/numbers-statistics
[33] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.50.2101147

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Pfizer Phase 3 Trial

109. It is my understanding that the Pfizer mRNA Covid-19 vaccine was initially justified for use in New Zealand to support the elimination strategy that New Zealand had taken to eradicate Covid-19 or at least suppress cases to extremely low levels. The principal evidence for provisionally approving the vaccine in New Zealand was the Pfizer Phase 3 trial in which approximately 40,000 participants were randomly allocated to receive either the vaccine or a placebo saline injection.[34]

110. The headline results from the trial were that after two doses of the vaccine in the period between 2 weeks and approximately 2 months post the second vaccine dose, there was a 95% reduction in incidence of symptomatic (at least one symptom of a respiratory infection) RT-PCR test-positive cases, with 8/18,198 = 0.04% cases of infection in the vaccinated and 162/18,325 = 0.9% cases of infection in the placebo group with the ratio of these two proportions being 95%. Notably, the vast majority of the cases of infection in the placebo as well as the vaccinated arms were only mild in severity.

111. While a 95% decline in incidence of symptomatic Covid-19 infections in the vaccine trial seems substantial and impressive, this may not translate into clinical significance. This is because the risk difference between the two groups (0.86%) translates to a number needed to vaccinate to prevent one case of mostly mild Covid-19 (the reciprocal of the risk difference) of 119. Since the median case fatality rate for SARS-CoV-2 infection is about 0.15% or 1/667 cases, then the number needed to vaccinate to prevent one Covid-19 death would be 79,373.

112. However, the vast majority of Covid-19 related deaths are in those over 80 years of age. Hence, this one prevented death for each 79,373 individuals vaccinated is likely to represent someone with an average age of 80 or more years, not someone in the working age population.

113. Of concern, in the Pfizer Phase 3 trial there was a higher absolute number of deaths in the vaccine group than in the placebo group, demonstrating that even

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[34] https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

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in a trial of approximately 40,000 participants in which approximately 20,000 received the vaccine, there was no demonstrable mortality benefit from receipt of two doses of the Pfizer mRNA vaccine.[35]

114. A tallying of unsolicited severe adverse events in the Pfizer Phase 3 trial showed that 262 such events occurred in the vaccinated group, compared to 172 in the placebo group. This means that the rate of these unsolicited severe adverse events was 262/21,270 = 1.2% in the treated, compared to 172/21,728 = 0.79% in the untreated. This means that the rate of severe adverse events was 56% higher in the vaccinated, compared to the placebo group, with the difference unlikely to be due to chance (P = 0.000014). Thus the pivotal Pfizer mRNA vaccine trial supporting its approval in New Zealand showed a higher rate of severe adverse events in the vaccinated compared to the placebo group.[36] The definition of severe adverse events included the sum of: severe Covid-19 cases, unsolicited severe adverse events and unsolicited life-threatening events. It is therefore difficult to argue with certainty that the health of the vaccinated people improved overall because of receiving the vaccine, since they experienced a higher (non-significant) rate of overall mortality and a significantly higher rate of severe and also total adverse events than the placebo group. This may outweigh the benefit in the vaccine group of reduction in the incidence of predominantly mild cases of Covid-19 infection.

115. In my opinion, Pfizer has not been fully transparent in public reporting of their Phase 3 trials. In a press release on Pfizer's website dated November 18, 2020 they used the headline "Pfizer and BioNTech Conclude Phase 3 Study of Covid-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints".[37] This headline falsely conveys the impression that the Phase 3 trial was fully

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[35] Baden LR, El Sahly HM, Essink B, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. N Engl J Med. 2021; 384: 403-416.
[36] Classen B. US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity". Trends Int Med. 2021; 1(1): 1-6.
[37] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine.

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completed, whereas the trial protocol specifies a 2 year safety follow up after the last vaccine dose meaning the trial will not be completed till 2022/2023.[38]

Inadequate safety date for the Pfizer vaccine

116. In my experience, 2-3 years of Phase 3 safety data would be considered the minimum for adequate assessment of safety of a new vaccine technology.

117. For vaccines the risk-benefit balance is usually heavily skewed in the direction of safety. This is because the majority of individuals being immunised are otherwise healthy individuals where the primary objective is to first do no harm. This takes into consideration that only a small percentage of the working-age adults being vaccinated are at actual risk of fatality if exposed to SARS-CoV-2, as shown by age-standardised case fatality rates.[39]

118. Very precise estimates of vaccine risk are needed to ensure that these risks do not exceed any estimated benefits. This can be expressed in terms of the relationship between the number needed to vaccinate to obtain a benefit and the number needed to vaccinate to cause a harm.

119. Given the low frequency of benefit in otherwise healthy individuals, this necessitates that vaccines, unlike therapeutic drugs, be exceedingly safe and be free of serious adverse effects where the incidence exceeds to any great degree rates of one serious adverse effect per million vaccinated subjects.

120. More recently, evidence has emerged calling into further question the reliability of the results from the pivotal Pfizer vaccine trials.[40] An incongruity in the reporting of the Pfizer trial are discordant overall numbers of deaths reported. In the six-month follow-up study,[41] the authors report that 15 deaths occurred in the vaccinated group, compared to 14 in the placebo group (see figure from the

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[38] https://cdn.pfizer.com/pfizercom/2020-11/C4591001_C56y_linical_Protocol_Nov2020.pdf
[39] https://www.abs.gov.au/articles/covid-19-mortality-1
[40] Thacker P. Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight. *BMJ* 2021; 375 doi: https://doi.org/10.1136/bmj.n2635
[41] Thomas SJ, Moreira ED, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months. New England Journal of Medicine 2021;385(19):1761-73. doi: 10.1056/NEJMoa2110345

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cited paper below). From this data it appears that deaths are numerically and statistically very well balanced between the vaccinated and placebo groups.

121. However, this Pfizer data conflicts with data contained in a report that was submitted by Pfizer to the Food and Drug Administration (FDA) in the US at around the same time that reported:[42]

> *"From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the COMIRNATY group and 17 in the placebo group."*

122. Although, the difference in deaths between groups in the trial is numerically small, the report to the FDA indicates a 23.5% increased risk of death in the Pfizer vaccinated compared to the placebo groups. Although the difference is not statistically significant (95% confidence interval: 35% decline to 134% increase, P = 0.65), it is nevertheless concerning for two reasons. First, this overall increased total mortality rate goes in the wrong direction for a vaccine that is claimed or presumed to reduce deaths.

123. The inconsistency between the published trial mortality, which appeared reassuring, and the data submitted by Pfizer to the FDA, which shows a concerning numerically higher death rate in the vaccinated group, casts doubts on the reliability of Pfizer's reporting of clinical data. In response to this inconsistency, a group of sixteen Swedish doctors signed an open letter in which they state.[43]

> *"The strong suspicion that parts of the clinical trial of Pfizer's vaccine were not performed in a scientifically acceptable manner, which is why the study results cannot be considered reliable, combined with the large extent of reported suspected adverse reactions after vaccination, including many of serious nature, makes us, doctors, researchers and immunologists deeply concerned, not least for*

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[42] https://www.fda.gov/media/151733/download Accessed 24/11/2021
[43] https://freewestmedia.com/2021/11/08/swedish-physicians-launch-petition-to-suspend-pfizer-jabs-after-trial-fraud-allegations-surface/

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A Justice of the Peace
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children who are at extremely low risk of serious Covid-19 disease, but who are at risk of serious side effects."

124. In a publication in the New England Journal of Medicine of a Pfizer trial of their mRNA vaccine in 2,260 adolescents, the Abstract states "*there were no vaccine-related serious adverse events and few overall severe adverse events.*"[44]

125. However, a mother of one of the participants in the trial, Maddie de Garay of Cincinnati Ohio, a 13 year-old, has claimed that her daughter who was previously healthy had a severe adverse event starting after the second vaccine dose with this adverse event not having resolved several months later and requiring multiple hospital admissions.[45] Even if this condition was classified as a functional disorder it should have been reported as a "vaccine-related serious adverse event".

Partial short term protection in adults

126. The vaccines currently approved in New Zealand, when given as the current two dose regimen, provide, at best, only partial short-term protection against SARS-CoV-2 infection, particularly when directed against the Delta or Omicron variants. Over time, any effectiveness of these vaccines against infection rapidly decreases, which is further impacted by age and the presence of long-term health conditions.[46]

127. A large US study examining Pfizer effectiveness up to 6 months after the second vaccination found it to be just 53% protective against any infection by Delta.[47]

128. Hence vaccine immunity against any infection, including both asymptomatic and symptomatic infections, is always incomplete and wanes rapidly with time after vaccination. Notably, there is next to no data on these aspects of the vaccine in

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[44] https://www.nejm.org/doi/full/10.1056/NEJMoa2107456
[45] https://thecovidblog.com/2021/07/08/maddie-de-garay-ohio-13-year-old-cannot-and-did-not-consent-to-vaccine-clinical-trials/
[46] Pouwels, K.B., et al., *Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK.* Nature Medicine, *2021. Oct 14.doi: 10.1038/s41591-021-01548-7. Online ahead of print.*
[47] Tartof, S.Y., et al., Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. The Lancet, 2021. 398(10309): p. 1407-1416.

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children as mRNA vaccine use in children remains highly experimental with very few facts known outside of the relatively small clinical trials that have been done.

129. Observational studies from Israel and the USA show that vaccine effectiveness against infection peaks at early time points after the second vaccination and then rapidly falls.[48]

130. Studies out to 6-9 months after second vaccination have found significant waning of vaccine protection over time. This was even more pronounced in vulnerable populations, with protection first being lost against total infections (irrespective of severity and including asymptomatic infections) and also against transmission, then after a slightly longer time interval protection was lost against symptomatic infection, after several more months protection was lost against moderate infection, and finally after 6-9 months, protection starts to fall against severe infection and death.[49]

131. Boosting in an Israeli population with a third dose of Pfizer vaccine 5 months after the second vaccination, was shown to reduce the rate of severe illness by a factor of 19.5, when compared to subjects that had just had 2 doses[50]. The high rate of infections in the Pfizer 2-dose control group in this study indicates that 2 doses of Pfizer vaccine provides minimal protection against serious or mild Delta infections just 5 months after the second dose.

132. Epidemiological studies suggesting higher levels of protection against Delta infection are likely to be significantly overestimating protective efficacy due to the many biases in epidemiological studies.[51]

133. The evidence indicates that vaccination with the vaccines currently approved for

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[48] Goldberg, Y., et al., *Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel.* medRxiv, 2021: p. 2021.08.24.21262423;
Shitrit, P., et al., *Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021.* Eurosurveillance, 2021. **26**(39): p. 2100822.
[49] Andrews, N., et al., *Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK.* medRxiv, 2021: p. 2021.09.15.21263583.
[50] Bar-On, Y.M., et al., *Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel.* New England Journal of Medicine, 2021. **385**(15): p. 1393-1400.
[51] Lopez Bernal, J., et al., *Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant.* New England Journal of Medicine, 2021. **385**(7): p. 585-594.\

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use in Australia or New Zealand offers minimal effect on the overall transmission rates of Delta[52] and the situation is even worse for the vaccine-resistant Omicron variant. The CDC Director Rochelle Walensky was recently reported admitting that Covid-19 vaccines are no longer effective at preventing transmission of the virus, being quoted as saying *"Our vaccines are working exceptionally well ... but what they can't do anymore is prevent transmission."*[53]

134. Notably the Pfizer Phase 3 clinical trials was not designed to assess vaccine efficacy against asymptomatic infection or transmission, but only designed to measure efficacy against symptomatic infection.

135. The mRNA vaccines currently approved for use in New Zealand provide only partial protection at best against infection with the Delta variant of SARS-CoV-2, with this protection waning rapidly from peak levels soon after the second dose.[54] Hence, vaccination has minimal effect on the transmission rates of the Delta variant.[55]

136. This situation will be exacerbated even further by increasing frequency of the

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Pouwels, K.B., et al., *Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK.* Nature Medicine, *2021. Oct 14.doi: 10.1038/s41591-021-01548-7. Online ahead of print*

;[52] Wang, Y., et al., Transmission, viral kinetics and clinical characteristics of the emergent SARS-CoV-2 Delta VOC in Guangzhou, China. EClinicalMedicine, 2021. 40;
Singanayagam, A., et al., Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. The Lancet Infectious Diseases;
Eyre, D.W., et al., The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv, 2021: p. 2021.09.28.21264260; and
Chia, P.Y., et al., *Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study.* medRxiv, 2021: p. 2021.07.28.21261295.

[53] https://www.msn.com/en-us/health/medical/cdc-director-covid-vaccines-cant-prevent-transmission-anymore/ar-AASDndg

[54] Pouwels, K.B., et al., *Effect of Delta variant on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK.* Nature Medicine, *2021. Oct 14.doi: 10.1038/s41591-021-01548-7. Online ahead of print;*
Lopez Bernal, J., et al., *Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant.* New England Journal of Medicine, 2021. **385**(7): p. 585-594.

[55] Wang, Y., et al., Transmission, viral kinetics and clinical characteristics of the emergent SARS-CoV-2 Delta VOC in Guangzhou, China. EClinicalMedicine, 2021. 40;
Singanayagam, A., et al., Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. The Lancet Infectious Diseases;
Eyre, D.W., et al., The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv, 2021: p. 2021.09.28.21264260; and
Chia, P.Y., et al., *Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study.* medRxiv, 2021: p. 2021.07.28.21261295.

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highly transmissible and vaccine-resistant Omicron strain to which the existing 2-dose mRNA vaccines provide minimal long-term protection and even protection after a third dose has been shown to rapidly wane. As a consequence, Israel has already authorised a fourth booster dose of mRNA for people over 60 and health workers in a hope to restore some immunity and protection.[56]

Negative vaccine efficiency

137. Waning levels of protection has been observed in countries with further elapsed time after vaccination. In particular, a Danish study shows negative vaccine efficacy in the period 91 to 150 days after vaccination for the Omicron variant from both Moderna and Pfizer products (for Pfizer, vaccine effectiveness -76.5%; 95% confidence interval: -95.3% to -59.5% and for Moderna, -39.3%; 95% confidence interval -61.6% to -20.0%).[57] Negative vaccine efficacy indicates that the vaccine is increasing the risk of infection for a vaccinated person compared to the risk for an unvaccinated individual. This comes under the category vaccine-enhanced disease. The most recent official statistics from the United Kingdom government also shows negative vaccine efficacy,

138. A Swedish cohort study similarly showed efficacy of all vaccines used in the country were not statistically distinguishable from unvaccinated individuals at 8 months post-immunisation.[58]

Vaccine trials and informed consent

139. Having committed much of my life to development of vaccines, my professional view is that Covid-19 vaccine mandates do not serve any useful public health purpose. Instead have the potential to cause more harm than good.

140. I have witnessed first harm emotional, mental and financial harm that vaccine

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[56] https://www.news.com.au/world/coronavirus/health/israel-starts-fourth-covid-vaccine-rollout-amid-omicron-surge/news-story/7ea9e21b9af77f161171fa448f8810e1

[57] Hansen CH, Schelde AB, Moustsen-Helm IR, et al. Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study. medRxiv Published Online First: 2021. doi:10.1101/2021.12.20.21267966

[58] Nordström P, Ballin M, Nordström A. Effectiveness of heterologous ChAdOx1 nCoV-19 and mRNA prime-boost vaccination against symptomatic covid-19 infection in sweden: A nationwide cohort study. 2021;11:100249. doi:10.1016/j.lanepe.2021.100249

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mandates have imposed on affected individuals, who for medical, cultural, religious or other reasons have not wished to have a particular vaccine, but were placed under extreme pressure to override they rights and allow themselves to be injected although unwilling.

141. As a vaccine developer, I believe vaccine use should be encouraged in a positive and benevolent environment supported by strong and transparent education programs that maintain and strengthen the community's faith in vaccine policies, rather than polarise the community and build mistrust.

142. A successful pandemic public health response should avoid resorting to any one very blunt and potentially harmful tool such as vaccine mandates or vaccine related restrictions, and instead try to provide the community with as much flexibility and options as possible, whether this is options in different vaccine technologies, options to adapt work environments or practices to reduce risk, use of rapid antigen testing in place of vaccines, and extensive consultations with workers to find acceptable policies that manage risk while being socially inclusive rather than exclusive.

Provisional approval of the Pfizer vaccine in 5-11 year olds

143. The Minister of Health has granted provisional consent for the use of the Pfizer vaccine in 5-11 year old children.[59] The Ministry of Health's webpage refers to the "Research and data" that appears to underpin the decision to grant provisional consent.[60] In particular, reference is made to a Pfizer study in 5-11 year old children. This appears to be a reference to a study titled "Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age".[61]

144. As the Pfizer trial was not powered to detect serious adverse effects, such as myocarditis, it is statistically invalid to claim that this trial confirmed the safety of mRNA vaccines in children aged 5-11 even in an absence of such cases as the trial was never powered in the first place to detect such events at their known

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[59] https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp
[60] https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-health-advice/covid-19-vaccine-and-children-information-parents-and-caregivers
[61] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8609605/

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frequency.

145. Case reports indicate that myocarditis does occur in children receiving mRNA vaccines.[62] It is therefore inappropriate and misleading to quote the unpowered Pfizer trial to claim that the mRNA vaccine is safe in children.

146. To claim the Pfizer mRNA vaccine is suitably safe in children would require much larger studies at least the size of the adult Phase 3 study which was conducted in ~40,000 participants

147. Without data from appropriately powered paediatric clinical trials, the frequency of myocarditis in children should be assumed to be at least as high as the frequency reported in young adults, which has been estimated to be ~1:6000 or higher.[63] I believe that any risk-benefit analysis that takes this risk of myocarditis into account would find that the risks of vaccinating young children heavily outweigh any potential small benefits to those children.

Conclusions

148. In my opinion as a vaccine developer myself, mRNA vaccines should continue to be considered as experimental vaccines until such time that long-term safety data becomes available and, at a minimum, their Phase 3 clinical trials are completed. In the meantime, there is a high level of uncertainty around their long-term benefits and also their long-term safety.

149. It has only recently become apparent that these vaccines can cause serious life-threatening adverse reactions such as thrombosis and myocarditis at much higher rates than would be expected of other established vaccines used in childhood or adult immunization programs, such as the hepatitis B and seasonal influenza vaccines. The extremely late identification of this serious mRNA vaccine-induced side effect raises the risk that there are other serious mRNA vaccine-induced side effects yet to be identified.

150. Of considerable concern is that these serious life-threatening adverse events were not identified in the limited animal testing that was performed prior to

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[62] https://pubmed.ncbi.nlm.nih.gov/34088762/
[63] https://pubmed.ncbi.nlm.nih.gov/34849657/

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testing these vaccines in humans. These serious life-threatening adverse events were not identified in the Phase 3 clinical trials. In this situation, I consider it cannot be correctly said that the new mRNA vaccines and their effects are sufficiently well understood and characterized as to consider non-experimental or proven to be safe.

151. The mechanisms whereby the mRNA vaccines cause severe adverse effects such as myocarditis, thrombosis or menstrual irregularities, are still unknown and the long-term clinical significance of these severe adverse effects is not known.

152. The key positive attribute of the mRNA vaccines is that they provide short-term protection against the moderate to severe spectrum of SARS-CoV-2 disease.

153. As a highly experienced clinical trial investigator, I am very aware of the principles of informed consent that apply to administration of any experimental treatment. The principles of informed consent are breached by any lack of full disclosure, duress, or coercion and hence any use of experimental vaccines would void any informed consent. Given the many uncertainties and unknowns around these new vaccine technologies, I believe these vaccines should only be administered with full informed consent. Such informed consent must include all known information regarding the benefits and potential risks of these vaccines, including detailing of all potential future risks.

154. As an experimental vaccine without full approval in New Zealand, the Pfizer vaccine should be administered voluntarily with fully informed consent, and with no coercion or mandates.

155. I am of the view that the extremely limited clinical trial safety data of mRNA vaccines in 5-11 year old children, plus the extremely low risk of complications of Covid-19 infection in this age group, does not justify the granting of provisional approval for the Pfizer vaccine for use in 5-11 year old children.

156. Having assessed all of the available data, I remain of the view that a proper risk-benefit assessment taking into account all the known and unknown risks of short and potential long term harmful effects arising from the mRNA vaccine in young children, such an assessment would show that the risks of giving mRNA vaccines to healthy young children would significantly outweigh any potential

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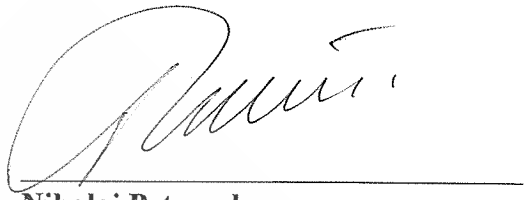
benefits.

AFFIRMED at Adelaide)

This 14th day of January)

2022 before me:)



Nikolai Petrovsky

MARIE SNOOK J.P. 25068
A Justice of the Peace
for South Australia

333 Sturt Rd
Bedford Park SA 5042

Name, address and capacity of person authorised to take oaths or affirmations

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AFFIDAVIT ANNEXURE

THIS IS THE **ANNEXURE** MARKED NP-1) of 47 pages.

REFERRED TO IN THE AFFIDAVIT OF

NIKOLAI PETROVSKY

HEREUNDER ANNEXED,AFFIRMED AND DECLARED

The 14 Day of JANUARY 2022

Deponent

MARIE SNOOK J.P. 25068
A Justice of the Peace
for South Australia

* ☐ Police Officer of or above the rank of Constable

☒ Justice of the Peace

* ☒ Cross applicable

Revised: 23/12/2021

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ANNEXURE "NP-1" TO THE AFFIDAVIT OF NIKOLAI PETROVSKY AFFIRMED 14 JANUARY 2022

CURRICULUM VITAE: NIKOLAI PETROVSKY BMedSci, MBBS, PhD, FRACP

Nationality: Australian

CURRENT APPOINTMENTS

2004- Director, Diabetes and Endocrinology Department, Flinders Medical Centre
2004- Full Academic Professor (Level E), Flinders University
2002- Research Director, Vaxine Pty Ltd

QUALIFICATIONS

1976-79 Bachelor of Medical Science (University of Tasmania)
1979-82 Bachelor of Medicine, Bachelor of Surgery (MBBS), University of Tasmania
1990 Fellowship, Australian Institute of Company Directors (FAICD)
1994 Fellowship, Royal Australasian College of Physicians (FRACP)
1998 Doctor of Philosophy (PhD) University of Melbourne
2002 Graduate Certificate in Educational Studies (Higher Education), University of Sydney

EDUCATION/TRAINING

1-82 University of Tasmania Medical School, Hobart, Tasmania, Bachelor of Medicine, Bachelor of Surgery (MBBS) 1982
1983 Internship, Launceston General Hospital, Launceston.
1984-90 Medical Resident/Registrar
1991-92 Endocrinology Registrar, Royal Hobart Hospital, Hobart.
1993 Endocrinology Registrar, Royal, Melbourne Hospital, Melbourne
1994-96 NHMRC PhD Scholar, Burnet Clinical Research Unit, The Walter and Eliza Hall Institute of Medical Research, University of Melbourne

PAST APPOINTMENTS

2002-05 Professor of Medical Informatics, University of Canberra
2003-04 Associate Professor, ANU Medical School, Australian National University
1998-04 Senior Endocrinologist, The Canberra Hospital
1998-04 Director, National Health Sciences Centre, Canberra

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SPECIAL ACHIEVEMENTS AND HONOURS

1974	Dux of school, 1974
1975	Academic Colours, (Geelong Grammar School), 1975
1994	NH&MRC Postgraduate Medical Research Scholarship, 1994-6
	Career Development Award, Australian Diabetes Society/Fisons
1995	Cleveland Young Investigator Award, Royal Melbourne Hospital
	Edith Moffat Award, The Walter and Eliza Hall Institute of Medical Research
1996	Inclusion in The Business Who's Who of Australia
2000	Inclusion in Strathmore's Who's Who Milennium Edition 2000-2001
2001	Prize for Best Abstract, 5th Immunology of Diabetes Society Congress, Chennai, India.
2002	Inclusion in Marquis Who's Who in Medicine and Healthcare,2002
2003	Inclusion in Who's Who in Science and Engineering, 2003-2004 and Who's Who in the World, 2003
	Invited Plenary Speaker, World Science Festival 2003 & International Dialogue to Celebrate Golden Jubilee of DNA Double Helix Discovery, New Dehli, India Feb 2003.
2005	Distinguished Speaker Award, International Immunomics Society
	Flinders University Public Affairs and Alumni Media Award 2005
2007	Flinders University Public Affairs and Alumni Media Award 2007
2009	Marquis Who's Who in Medicine and Healthcare, 2009-2010 Edition
	AMP National Innovation Award, 2009 Telstra Business Awards (Vaxine)
	Statewide Small to Medium Services Award, 2009 Business SA Export Awards (Vaxine)
	AusIndustry Innovation Award, Australian Anthill Cool Company Awards (Vaxine)
	Coolest Company Award, Australian Anthill Cool Company Awards (Vaxine)
2010	Advax™ adjuvant selected for Australian Anthill Smart 100
	Ernst and Young Entrepreneur of the Year Award - Technology and Emerging Industries, Central Region
	Finalist, Best Vaccine Development in Asia, Vaccine Industry Excellence Awards, Singapore
	Finalist, Australia Museum Eureka Award for Translational Medicine
2011	BioSpectrum Asia Pacific Emerging Company of the Year Award (Vaxine)
	Most Innovative Asian Biotech, Vaccine Industry Excellence Awards, World Vaccine Congress-Asia (Vaxine)
	Emerging Exporter Award at the 2011 South Australian Export Awards (Vaxine)
	APBioNet Meritorious Service Award
2013	BioPharma Asia, Asian Executive of the Year Award
2017	Laureate, 19th National Concours for the assistance of creation of innovative technology companies, awarded to Nikolai Petrovsky as applicant by the French government for the formation of Alms Therapeutics
	Chair, NIH Blue Ribbon Panel on Vaccine Adjuvants, National Institutes of Health
2018	Health and Biotechnology Award, South Australian Export Awards (Vaxine)
	Co-Chair, NIH Blue Ribbon Panel on Immune Engineering and type 1 diabetes, US National Institutes of Health
2021	Company to Watch out for in 2022, Asia Pacific Vaccine Excellence Awards 2021

PROFESSIONAL ORGANISATIONS

Endocrine Society of Australia, 1993-2018
Australasian Immunology Society (incl. Treasurer), 1993-
Australian Diabetes Society (incl. Executive Council member) 1993-

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International Immunomics Society (incl. Vice President) 2003-
International Society of Vaccines (Executive Council Member) 2015-2020

PEER REVIEW

GRANT PANEL MEMBERSHIP
NHMRC Grant Review Panel 2d, 2010
NHMRC Centre of Research Excellence Clinical Review Panel, 2011
NHMRC Centre of Research Excellence Clinical Review Panel, 2012
Singapore NMRC Centre Grant Scheme Advisory Board, 2015, 2016, 2017
Singapore NMRC TCR Flagship Program 2015, 2017
NHMRC Development Grant Assessor Panel, 2017
Singapore Open Fund Large Collaborative Grant (OF-LCG) panel, 2018 -
Singapore RIE025 Centre Grant Panel, 2021
Singapore NMRC Clinical Trial Infrastructure Review Panel (CTIRP), 2021

GRANT REVIEWS
Diabetes Australia Research Trust,
NZ Child Health Research Foundation,
NZ Lottery Grants Board,
Eli and Edith Broad Foundation,
Royal Netherlands Academy of Arts and Sciences Innovational Research Incentives Scheme
Canadian Institutes of Health Research Randomized Controlled Trials Committee,
Academic Research Committee grant - Ministry of Education (Singapore),
International Grant Reviewer for Edward Jenner Institute for Vaccine Research.
Government of the Hong Kong Special Administrative Region, Innovation and Technology Commission
Czech Science Foundation
Singapore National Medical Research Council 2014 - current
Luxembourg National Research Fund PRIDE Doctoral Training Program

EDITORIAL RESPONSIBILITIES
Editor-in-Chief, Journal of Vaccines & Vaccination (Founding Editor retired 2015)
Editor-in-Chief, Immunome Research (retired 2014)
Editorial Board, AIMS Microbiology
Editorial Advisory Panel, Expert Review of Clinical Immunology
Section Editor (Autoimmunity), Open Immunology Journal
Special Edition Editor 2004 Vaccine adjuvants feature in Vaccine journal
Guest Editor, Immunology and Cell Biology special features 2001- "Neuroendocrine-immune interaction", 2002- "Immuno-informatics", 2004 – "Vaccine adjuvants"

MANUSCRIPT REVIEW
Nature Biotechnology, Vaccine, Expert Reviews of Vaccines, Human Vaccines & Immunotherapeutics, European Journal of Immunology, Clinical Immunology, Diabetes Research and Clinical Practice, Immunology and Cell Biology, Bioinformatics , Psychosomatic Medicine, American Journal of Pathology , Histochemical Journal, Immunogenetics , Journal of Molecular Medicine, Letters in Peptide Science, Expert Opinion on Therapeutic Patents , Stress and Health, Pharmacogenomics, Molecular and Cellular Endocrinology, Arthritis and Rheumatism, Clinical Research and Regulatory Affairs, Pharmaceutical Biology, Vaccines, Expert Opinion On Drug Discovery

COMMITTEES

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Executive Council Member, International Society of Vaccines, 2016-18
Treasurer, Australasian Society of Immunology, 2000-03
Secretary-General and Vice-President International Immunomics Society, 2003-14
Councillor, Australian Diabetes Society, 2000-02
Honorary Editor, Australian Diabetes Society Newsletter, 2000-02
Federal Councillor, Australian Salaried Medical Officers Federation, 2000-04
Southern Area Health Service Diabetes Expert Advisory Group, NSW, 2000-04
Member, Clinical Trials Subcommittee, ACT Department of Health and Community Care Ethics Committee, 2000-04
Member, Interview Panel, TCH RMO Appointments Committee, 2001.
Chair, Health Care and Education Committee, Diabetes Australia, 2000-02
Integrated Clinical Attachments Supervisor (Endocrinology), Canberra Clinical School, 2000-02
Member, Canberra Clinical School Advisory Board, 2000- 03
Performance Indicators Subcommittee, ACT Diabetes Council, 2000-02
Director, Cardiac Rehabilitation Programme, MBH, 1996-98
Chair, Medical Quality Assurance Committee, MBH, 1997-98
Director, Postgraduate Medical Training Programme, MBH, 1996-98
Convenor, The Canberra Hospital Endocrine Journal Club, 1999-00
Chair, Diabetes in a Chronic Disease Framework Working Group, ACT Diabetes Council, 2001-03
Member, ACT Biotechnology Consortium, 2001-03
Member, The Canberra Region Postgraduate Committee in Medicine, 2000-01
Councillor, Australasian Clinical Research Network, 2000-03
Member, Medical Affairs Subcommittee, Australian Diabetes Society, 2000-02
Member, Scientific Affairs Subcommittee, Australian Diabetes Society, 2000-02
Member, Diabetes Australia Research Council, 2000-02

PATENT FAMILIES

1. Australian Patent No 2004905032 (granted in multiple countries): New polymorphic form of inulin and uses thereof. 2005.
2. PCT/EP2012/061748, Enhanced immunological composition. Filed: 19 June 2011.
3. PCT/EP2015/051856, New Target for Diabetes Treatment and Prevention, Filed 29 Jan 2015. Joint patent with University of Strasbourg
4. PCT/US2019/022549, Compositions and methods for vaccination against respiratory syncytial virus infection. Joint patent with University of Pittsburgh.
5. U.S. Provisional Application No. 63/249,281 entitled "Malaria immunogen and methods for using same". Joint patent with University of New Mexico

SCIENTIFIC MEETING ORGANISATION

2001

Organising Committee, Australasian Society of Immunology Annual Scientific Meeting 2001

Chair, Organising Committee, Canberra Annual Scientific Meeting 2000 & 2001

2002

Convenor, Novartis Foundation Symposium "Immunoinformatics: Bioinformatic strategies for better understanding of immune function" London, UK 2002.

2004

Scientific Advisory Committee, 2nd International Workshop in Vaccine Adjuvants and GlycoCongugates (Adjuvant2004), Varadero, Cuba 2004.

Organising Committee, First International Immunoinformatics Meeting, Yokohama, Japan 2004.

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2005
Organising Committee, Second International Immunoinformatics Meeting, Boston, USA 2005.

2006
Scientific Advisory Committee, 3rd International Workshop in Vaccine Adjuvants and GlycoCongugates (Adjuvant 2006), Varadero, Cuba 2006.

International Advisory Board, International Congress of Immunogenomics and Immunomics, Budapest, Hungary October 2006

2008
Scientific Advisory Board, World Vaccine Congress Asia, Singapore June

Scientific Advisory Board, Next Generation Vaccines Asia, Beijing Nov 2008

2010
Program Committee, InCoB 2010, official meeting of Asia-Pacific Bioinformatics Network (APBioNet), Tokyo Japan Sept 2010

Program Committee, Immunoinformatics and Computational Immunology Workshop, ICIW 2010, ACM International Conference on Bioinformatics and Computational Biology, Niagara Falls, NY, U.S.A. Aug 2010

2011
Advisory Board, meeting chairman and invited speaker, "Vaccine Technology and Innovation World" India 1-3 March, 2011

Program committee, Second Immunoinformatics and Computational Immunology Workshop (ICIW2010) Chicago, USA August 2011

Member, Program Committee, InCoB2011, official meeting of Asia-Pacific Bioinformatics Network (APBioNet), Malaysia, Dec 2011

2012
Program Committee, 2nd ISV Pre-Conference Computational Vaccinology Workshop, Shanghai, China, Oct 2012

Program Committee, 11th International Conference on "Artificial Immune Systems" - ICARIS 2012: Taormina, Sicily - Italy, 28-31 August 2012

2013

Program Committee, InCoB 2013, Taicang, China. September 20-22, 2013

Program committee, ICARIS 2013 (12th International Conference on Artificial Immune Systems)

2014
Program Committee, InCoB 2014, Sydney, Australia.

Scientific Program Committee, 4th Computational Vaccinology workshop, 8th International Vaccine and ISV Conference, Philadelphia, 25-28 Oct 2014

Meeting President, Vaccines-2014 congress, Valencia Spain, 24-26 Sept 2014

2015
Organising Committee, Global Conference on Vaccines (Vaccines-2015) Dubai, UAE, April 13-15, 2015

Program Committee '1st International Workshop on Artificial Immune Systems: Systems & Synthetic Immunology, Computational Immunology & Immune-Inspired Engineering', Taormina, Italy, July 17-18, 2015.

Meeting President and Chair of the Organising Committee, Asia Pacific Global Summit and Expo on Vaccines & Vaccination, Vaccines-2015, Brisbane Australia July 27-29, 2015

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Chair, Organising Committee, American Global Summit and Expo on Vaccines & Vaccination, San Francisco, USA October 05-07, 2015

Organising Committee, 8th Indo Global Summit and Expo on Vaccines & Vaccination, Hyderabad, India, November 2-4, 2015

2016

Organizing committee member, "10th Euro Global Summit and Expo on Vaccines & Vaccination" Rome, Italy June 16-18, 2016.

Organizing committee member, 15th International Conference on Bioinformatics (InCoB), Singapore, September 21-23, 2016.

2017

Chair, NIH Workshop on Immune System Engineering For Targeted Tolerance in Type 1 Diabetes, Bethesda USA, Nov 2017

2018

Chair, NIH Blue Ribbon Panel on Vaccine Adjuvants, Bethesda USA, March 2018
Chair, Organising Committee, Cleveland Clinic Research and Innovation Symposium, Port St Lucie, Florida, Nov 21-22, 2019

2020

Advisory board member, Vaccines R&D-2020, Washington DC, Nov 30-Dec 2, 2020

POSTGRADUATE EXPERIENCE – TEACHING

1982 – 1992	I regularly took clinical tutorials for medical students at the Royal Hobart Hospital and Launceston General Hospital
1991 -1996	I gave tutorials and lectures in Endocrinology at the Royal Hobart Hospital and Royal Melbourne Hospital
1997-1998	I was the Director of the Postgraduate Medical Training Program at Mildura Base Hospital and regularly took clinical tutorials for resident medical staff and registrars.
1998 -	I was involved in teaching as follows: (a) Member, Canberra Clinical School Advisory Board, (b) Integrated Clinical Attachments Supervisor (Endocrinology), Canberra Clinical School, 2000-2002 (c) Examiner, FRACP Part 1 Examination, 2000-01 (d) Clinical Supervisor, multiple overseas elective students in endocrinology (e) Supervisor of multiple ongoing and completed and one Masters and PhD students (f) In 2002, I completed the Graduate Certificate in Educational Studies (Higher Education), University of Sydney (g) I have examined Honours and PhD theses for the University of Canberra and the University of Newcastle (h) In 2001, I was a member of an interview panel for selection of entrants into the 2002 USyd Graduate Medical Program.
2004-	I was appointed a Full Academic Professor in the Department of Medicine at Flinders University alongside my appointment as Director of Endocrinology at Flinders Medical Centre. In this role, I provide endocrinology and diabetes tuition for the postgraduate medical program, as well as for nursing staff, dieticians and GPs and supervise Honours, Masters and PhD students.

CURRICULUM DEVELOPMENT. In 1999, I introduced an innovative seminar program for University of Sydney GMP3 medical students to introduce them to the relationship between

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medical research and clinical practice based on current research being undertaken by my laboratory. I also redesigned the endocrinology and diabetes seminars to make them more visual and interactive. These changes were positively received by the students. I was the Course Convenor of the Graduate Diploma in Clinical Trial Management at the University of Canberra from 2001 to 2003 and during that time implemented considerable changes to the curriculum including introducing a Graduate Certificate in Good Clinical Practice, adding a graduate diploma, and moving to use of WebCT for curriculum delivery. I have been involved in widespread promotion of the course and have significantly increased student enrolments. I was the foundation Director of the Medical Informatics Centre at the University of Canberra that has become a successful multidisciplinary research centre exploring use of information technology to improve medical care and biomedical research.

SUPERVISION OF POSTGRADUATE RESEARCH STUDENTS

PRINCIPAL OR CO-SUPERVISOR

Dr Amal Hassani, Master of Medicine, University of Sydney
Project: Pathogenic Mechanisms in Gestational Diabetes Mellitus (awarded 2002)
Dr Diego Silva, PhD, Australian National University
Project: Role of the Fas apoptosis pathway in b -cell death leading to type 1 diabetes (awarded 2004)
Dr Todor Arsov, PhD student, Australian National University
Project: Identification of the genetic defect causing the metabolic syndrome in Fat Aussie mice (awarded 2006).
Delicia Ooi, Honours student, Flinders University
Project: Transcriptional complexity in the genome (awarded 2005)
Dr Luis Socha, PhD student, Australian National University (awarded 2008)
Project: Novel transgenic model of b -cell failure leading to diabetes development
Fariba Shadabi, PhD student, Medical Informatics Centre, University of Canberra (awarded 2008)
Project: Artificial neural networks in renal transplant outcome prediction
Dorothee Girard, PhD student, Flinders University,
Project: Effect of mutations in ALMS1 on neuronal and islet cell function (awarded 2013)
Dr Sotoodeh Abhary, PhD student, Flinders University,
Project: The Genetic Study of Diabetic Retinopathy (awarded 2013)

MEMBER SUPERVISORY PANEL

Purna Rana, Masters of Science, Australian National University (awarded 2003)
Project: NK cell inhibitory receptors in type 1 diabetes and cord blood
Dr Carolyn Cho, Master of Medicine, University of Sydney (awarded 2003)
Project: Circulating Cytokine Levels in Peripheral Vascular Disease
Dr John Woodall, PhD student, Australian National University (awarded 2006)
Project: Immune System Development in the Foetal Lamb
Linda Wu, PhD student, Flinders University (awarded 2007)

CORPORATE EXPERIENCE

Chairman, Australian Innovation Ltd 1997-1998 (ASX listed company)
Director, Cybergraphic Systems 1996-1998
Director, National Health Sciences Centre, 1999-2004
Chairman and Research Director, Vaxine Pty Ltd, 2002-present
Chairman, Mylexa Pty Ltd, 2014-present

RESEARCH GRANTS

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1. Victor Hurley Medical Research Award, Royal Melbourne Hospital, 1994 "Whole blood assay for the detection of GAD-reactive T cells in IDDM" $5000.00
2. The Canberra Hospital Private Practice Fund, 1998. "The use of endocrine hormones to manipulate immune responses through their ability to differentially regulate human cytokine function." $33,870.00
3. The Canberra Hospital Private Practice Fund, 1998. "Effects of intra-amniotic infusion of triiodothyronine (T3) alone or beclamethasone and T3 on the development of the immune system in the foetal lamb. " Co-investigator with John Woodall. $5,000.00
4. The Canberra Hospital Private Practice Fund, 1999. "Research project to clarify the molecular basis for an inherited immunodeficiency disorder associated with lack of expression of the interferon gamma receptor alpha chain." $25,410.00
5. University of Sydney and Australian Research Council, 1999. "Neural-network based prediction of renal transplantation outcome." $24,000.00
6. The Canberra Hospital Private Practice Fund, 2000. Principal investigator. "The role of islet-antigen specific T cells and human MHC alleles in conferring susceptibility to type 1 (insulin-dependent) diabetes mellitus" $65,755.00
7. Canberra Region Medical Foundation, 2000. Co-investigator with Dr Michael Peek. "Do plasma levels of TNF-a predict the severity of gestational diabetes?" $18,800
8. The Canberra Hospital Private Practice Fund, 2001. The role of Fas-Fas ligand interaction in beta cell death – PhD scholarship and support for Diego Silva. $100,000
9. The Canberra Hospital Private Practice Fund, 2001. Redevelopment of the Canberra Hospital animal facilities. $50,000.
10. ACT Government R&D Grant, 2002. "Development of a novel vaccine adjuvant" Awarded to NHSC. $77,000
11. Biotechnology Innovation Fund 2002. "Development of a novel vaccine adjuvant". Awarded to Vaxine Pty Ltd. $250,000
12. The Canberra Hospital Private Practice Fund, 2003. Principal Investigator. "Beta cell apoptosis in type 1 diabetes". $64,000
13. Clive and Vera Ramaciotti Equipment grant 2003 "A real time PCR machine for the Canberra Hospital. CI's Cavanaugh, Willenborg, Taupin & Petrovsky. $30,000
14. National Office of the Information Economy, ITOL grant, 2004. Awarded to NHSC consortium "Transforming diabetes healthcare". (Principal Investigators - Shadbolt and Petrovsky) $200,000
15. Juvenile Diabetes Research Foundation Innovative Grant, CLIP expression in type 1 diabetes. CI Petrovsky, USD$55,000. 2004.
16. START grant. CI Petrovsky. Development of an aluminium-free hepatitis B vaccine. $770,000. 2004-2006
17. DEST Innovation Access Program. Awarded to Oz Nano2life consortium. $1,000,000 (One of six named investigators on grant). 2004-2006
18. NDSS Diabetes Australia grant, 2004. "Transforming diabetes healthcare". (CIs: Shadbolt, Petrovsky) $200,000. 2004-2005
19. National Institute of Health. No 5U01AI61142. CI: Petrovsky. Novel adjuvants for bioterrorism vaccines. USD$2.5 million 2005-2010.
20. NHMRC Project Grant No 375199. Improved flu vaccines. CIs: Petrovsky, Cooper. Total $250,394.00;
21. Commercial Ready Grant. Hepatitis B vaccines. Awarded to Vaxine. CI: Petrovsky. $1.5 million. 2006-2007
22. IIFSA grant. Vaccine Manufacturing Facility. CI: Petrovsky. 2008-2010, total $1 million.
23. ARC Linkage Grant LP0882596. CIs Ginic-Markovic, Matisons, Petrovsky, Cooper. Nanotechnology-Enhanced Vaccines: New inulin bioconjugates to defeat global pandemic threats. 2008-2011. Total $140,530.00.

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24. National Institute of Health. 5U01AI61142 Grant Supplement. Pneumococcal vaccine. CI Petrovsky. 2008-2009, USD$108,000.
25. National Institute of Health. 5U01AI61142 Grant Supplement "GMP Adjuvant manufacture" CI Petrovsky. 2008-2009, USD$875,000.
26. US Department of Health. Contract HHSN272200800039C. Adjuvant Development Contract – Japanese Encephalitis Vaccine. CI Petrovsky. 2008-2013. USD $8,394,390.
27. NHMRC Project Grant 595918. CIs: Burdon, Craig, Gillies, Petrovsky, Daniell, Charlesworth: A genome-wide association scan to identify genetic risk factors for sight threatening diabetic retinopathy, 2010-2012; $970,786.
28. Bill and Melinda Gates Foundation. Global Health Grant. CI: Petrovsky. Development of an Advax™ Adjuvanted, Temperature-Stable, Antigen Sparing, Enhanced Potency, Inactivated Polio Vaccine for Protection of Children in the Developing World, 2012-2013. $534,784.
29. ARC Linkage Grant LP140100920, CIs. Rossjohn, Prof Jamie; Godfrey, Prof Dale I; Petrovsky, Prof Nikolai, Exploring the immunomodulatory potential of Natural Killer T cells. Total $590,922; 2014 $98,487, 2015 $196,974, 2016 $196,974, 2017 $98,487.
30. ARC Linkage Grant LP140100424, CIs. Zhao, Chun-Xia; Middelberg, Anton P; Petrovsky, Nikolai. Engineering an improved nanoparticle-based adjuvant for enhanced vaccine effectiveness. Total $300,000; 2014 $50,000, 2015 $100,000, 2016 $100,000, 2017 $50,000
31. ARC Linkage Grant LP140100142, CIs. Barclay, Thomas G; Garg, Sanjay; Petrovsky, Nikolai; Cooper, Peter D. Chemical Modification of Inulin Particles for Targeted Delivery of Drugs to the Immune System. Total $330,000; 2014 $55,000.00, 2015 $110000, 2016 $110000, 2017 $55000.
32. Industry SA Grant. A new health and medical research translation collaboration between SA and Dresden University. CI: Worley, Petrovsky. 2014, $79,900.
33. BioSA Bioscience Industry Development (BID) Grant, PI. Petrovsky, Development of a Novel Asthma Therapeutic. 2014-2015 $250,000
34. National Institutes of Health BAA-NIHAI2013168, Contract HHSN272201400053C. Adjuvant Discovery Contract. PI. Petrovsky, 2014-2019, USD $10,786,491
35. 2014 National Computational Merit Allocation Scheme (NCMAS), CI. Petrovsky, 200,000 core hours on Raijin/NCI.
36. 2016 National Computational Merit Allocation Scheme (NCMAS), CI. Petrovsky, 200,000 core hours.
37. 2017 National Computational Merit Allocation Scheme (NCMAS), CI. Petrovsky, 1,000,000 core hours.
38. NHMRC Project Grant APP1102597. Multistage vaccines for the prevention of tuberculosis. CIs Triccas, Petrovsky and Britton. 2016-2020.
39. 2019 National Computational Merit Allocation Scheme (NCMAS), CI. Petrovsky, 250,000 core hours on Raijin/NCI.
40. National Institutes of Health, Adjuvant Development Program, HHSN272201800044C, PI. Petrovsky, 2018-2023, USD $7,015,025 including options
41. National Institutes of Health, Advanced Development of Vaccines for Biodefense and Emerging Infectious Diseases, HHSN272201800024C, PI. Petrovsky, 2018-2023, USD $18,541,473 including options

CLINICAL INVESTIGATOR/STUDY DIRECTOR

1. FIELD study - use of fenofibrate to prevent cardiovascular events in type 2 diabetes). Sponsor: NHMRC Clinical Trials Centre, 2000-2006. $500,000.00
2. 4T Study - efficacy of triple therapy incorporating troglitazone in type 2 diabetes. Sponsor: Parke-Davis, 2000. $60,000.00
3. Mitiglinide study - Efficacy of combination therapy of mitiglinide and metformin. Sponsor: Servier, 2000. $80,000.00

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4. GLAQ study - Efficacy of pioglitazone versus sulphonyureas in combination with metformin in type 2 diabetes. Sponsor: Eli Lilly, 2001. $50,000.00
5. BIAsp Study - Efficacy of a novel mixed insulin in type 2 diabetes. Sponsor: Novo Nordisk, 2001. $50,000.00
6. CL2 - Phase 2 study of novel dual action hypoglycaemic agent in drug naive type 2 diabetes. Sponsor: Servier, 2001. $70,000.00
7. DIRECT study - Ability of angiotensin 2 receptor blockers to prevent diabetic retinopathy. Sponsor: Boehringer-Mannheim, 2002. $120,000.00
8. NAVIGATOR - Ability to prevent progression from impaired glucose tolerance to type 2 diabetes. Sponsor: Novartis, 2002. $50,000.00
9. HMR3005 Study - Efficacy study of a new short acting analogue insulin in type 2 diabetes. Sponsor: Aventis, 2002. $25,000.00
10. DREAM Study - Ability of ramipril and/or rosiglitazone to prevent progression to type 2 diabetes. Sponsor: Aventis, 2002. $100,000.00
11. HMR3004 - Efficacy of a new short acting analogue insulin in combination with glarginine for treatment of type 1 diabetes. Sponsor: Aventis 2002. $40,000.00
12. ADVANCE Study – Effect of intensive glycaemic and blood pressure control compared to standard treatment. Sponsor Servier, 2002. $80,000
13. Phase 2 studies of a novel PPAR agonist. Sponsor Bristol-Myer Squibb. 2003. $100,000.00
14. Phase 3 study of extended release Niacin-Laropiprant in type 2 diabetes. Sponsor MSD. 2007-08. $60,000
15. D1690C00019. Dapagliflozin in type 2 diabetes. Sponsor Astra-Zeneca. 2010-2012
16. REDUCE-IT study. Fish oil in prevention of heart disease in patients with hypertriglyceridaemia. Sponsor: Amarin Pharmaceuticals. 2013-2018.
17. HBV001. ACTRN12607000598482. A study in healthy adults of a randomised, controlled vaccine intervention study evaluating the safety and immunogenicity of a Hepatitis B vaccine containing Advax adjuvant. 2006-2007. Sponsor Vaxine Pty Ltd.
18. FLU001. ACTRN12607000599471. A randomised, controlled Phase 1/2 study in healthy adults of a seasonal influenza vaccine containing an inulin-based adjuvant to evaluate safety and immunogenicity. Sponsor Vaxine Pty Ltd.
19. FLU002. ACTRN12608000364370. Randomized, controlled Phase 1/2 study to evaluate the safety and effectiveness of an enhanced potency adjuvanted seasonal influenza vaccine in patients with chronic disease and the elderly. Sponsor Vaxine Pty Ltd.
20. FLU004. ACTRN12608000350325. A randomised, controlled Phase 1/2 study in healthy adults to evaluate the safety and immunogenicity of an inulin-adjuvanted antigen-sparing seasonal trivalent inactivated influenza vaccine. Sponsor Vaxine Pty Ltd.
21. FLU005. ACTRN12609000674235. A randomised, controlled, study in healthy adults to evaluate the safety and immunogenicity of an adjuvanted recombinant 2009 H1N1 pandemic swine influenza vaccine. Sponsor Vaxine Pty Ltd.
22. FLU006. ACTRN12612000709842. A randomised controlled trial to evaluate the immune response to an adjuvanted 2012 seasonal trivalent inactivated influenza vaccine in adults delivered via needle and syringe or jet injector device. Sponsor Vaxine Pty Ltd.
23. BEE001. ACTRN12608000379314. A randomised, controlled Phase 1/2 study of adults with bee venom allergy to evaluate the safety and efficacy of an Advax-adjuvanted bee venom desensitisation regime. Sponsor Vaxine Pty Ltd.
24. HBV002. ClinicalTrials.gov NCT01951677. Single-center, randomized, controlled, blinded Phase 1/2 study to compare the safety and effectiveness of Hepatitis B vaccine formulations in individuals with renal impairment, diabetes mellitus or age greater than 40 years. Sponsor Vaxine Pty Ltd.
25. FLU003. ClinicalTrials.gov NCT02335164. A Phase 1 Study to Evaluate the Immunogenicity and Safety of a Pandemic Avian Influenza Vaccine in Adults.

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26. FLU007. A Phase 1 Study to Evaluate the Immunogenicity and Safety of a Recombinant H7 Pandemic Avian Influenza Vaccine in Adults.
27. COVID-19. ClinicalTrials.gov NCT04453852. A Randomised, Controlled, Phase 1 Study to Evaluate the Safety and Immunogenicity of a Candidate Adjuvanted Recombinant Protein SARS-COV-2 Vaccine in Healthy Adult Subjects
28. COVID-19. ClinicalTrials.gov NCT04944368. Phase II Clinical Trial of CinnaGen COVID-19 Vaccine (SpikoGen)
29. COVID-19. ClinicalTrials.gov NCT04944368. Phase III Clinical Trial of CinnaGen COVID-19 Vaccine (SpikoGen)

RESEARCH

1994-1996 PhD: Role of cytokines in human health and disease
(Walter and Eliza Hall Institute of Medical Research, University of Melbourne)

INTERNATIONAL COLLABORATIONS

1. Hepatitis B vaccine. Butantan Institute, Brazil
2. Influenza and Japanese encephalitis vaccines. Kitasato Institute, Japan
3. HIV vaccine. Advanced BioScience Laboratories, Inc. USA
4. Influenza vaccines, Sanofi Pasteur/Protein Sciences Corp. USA
5. NKT cell agonists. Prof Moriya Tsuji, Rockefeller University, USA
6. Anthrax vaccines, Dr Tod Merkel. FDA, USA
7. Camel vaccines, Dr Ulli, CVRL, Dubai, UAE
8. Pulmonary administration of influenza vaccines Dr. W.L.J. Hinrichs, University of Groningen, The Netherlands
9. Ricin vaccines. Prof Ellen Vitetta, The University of Texas Southwestern Medical Center at Dallas, USA
10. Ciliopathy disorders. Dr Vincent Marion. University of Strassbourg
11. Pneumococcal and other polysaccharide vaccines. Matrivax Inc. Boston USA
12. West Nile virus vaccine vaccines. Prof. John Morrey, Utah State University
13. SARS vaccines, Dr Dale Barnard, Utah State University
14. RSV vaccines. Dr Kerry Empey, University of Pittsburg
15. Nanoparticulate universal influenza vaccines, Prof. Anton Middleberg, University of Adelaide
16. Peste De Petiti Ruminants vaccine, Dr Attilio Pini, Istituto Zooprofilattico Sperimentale Abruzzo e Molise, Termaon Italy
17. Rabies vaccine, Dr Mahfoud Brahimi, Algerier
18. Burkholderia pseudomallei vaccines, Dr Lisa Morici, Tulane University, New Orleans
19. Alzheimer's vaccines. Prof. Michael Agadjanyan, Institute of Molecular Medicine, and UCI Mind, California
20. Oncocerca vaccine, Prof. David Abraham, Jefferson Medical College, Philadelphia
21. Staphlococcal and filovirus vaccines. Dr Javad Aman, Integrated Biotherapeutics, Gaithersburg, USA
22. Malaria vaccines, Dr Holger Spiegel, Fraunhofer Institute, Germany
23. Horse vaccines for equine herpes, equine influenza and Japanese encephalitis, Dr Baldev Gulati, National Research Centre on Equines, Haryana, India
24. TB vaccines, Dr Jamie Triccas, University of Sydney and Dr Angelo Izzo, Colorado State University, Fort Collins
25. Influenza, anthrax and malaria vaccines, Dr Vidadi Yusibov, Fraunhofer USA Center for Molecular Biotechnology, Wilmington, Delaware.
26. Cancer vaccines, Dr Chris Weir, University of Sydney.
27. Gram negative vaccines, Dr Alan Cross, University of Maryland
28. Malaria vaccines, Dr Hermann Bujardlab, University of Heidelberg

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29. Herpes Simplex vaccine, Dr Jan-Ake Liljeqvist, Simplex, Sweden
30. TLR agonists. Dr Deepak Salunke, Panjab University, Chandigarh, India

MEDIA PRESENTATIONS

1. The FIELD study in type 2 diabetes. February 2000 Live interviews with ABC Radio, 2CA. Recorded television interviews: Prime, Win, ABC television. Articles: The Canberra Times, The Chronicle
2. Neural networks in the prediction of renal transplant outcomes. April 2000.Live interviews with ABC radio and 2CA. Recorded television interviews: Prime, Win, ABC television. Article: The Canberra Times)
3. Managing diabetes in the workplace. Nov 2000. Live interview with Damien Morgan Radio 2CA.
4. Can Canberra sustain a biotech boom? 14 Nov 2000 Article. The Canberra Times.
5. New diabetes trials to be conducted at the Canberra Hospital. Dec 2000.Live interviews with ABC national radio. Recorded television interview: Win television, Article: The Chronicle
6. New drugs for type 2 diabetes. March 2001 Recorded television interview: Prime, Win television
7. The NHSC to conduct a trial of a novel cancer diagnostic test, C-Test. Oct 2001. Recorded television interview: Channels 2, 7, 9, 10 National broadcast
8. The DREAM study: preventing the development of type 2 diabetes. Recorded television interview: Win television. Oct 2001.
9. The 2001 Canberra Region Annual Scientific meeting. Recorded television interview: Win television. Oct 2001.
10. Diabetes week, Tasmania. August 2002. Live radio interview. ABC Radio.
11. Mapping of the mouse genome. Dec 2002. ABC National television and radio.
12. Diabetes study, an ACT coup. May 2003. Interview ABC Radio, Article Canberra Times, Chronicle, Canberra Doctor.
13. Development of a novel vaccine. Article Canberra Times, July 2003
14. Obesity in Australians has reached Aussie mice. July 2003. Interview ABC regional radio, WIN television, ABC television, the Canberra Times, BBC Radio.
15. Virally-mediated obesity. Interview, New Idea. 2004
16. Implications for Tasmania of the rising incidence of diabetes. Article. Sunday Examiner. May 2004
17. Prospects for islet cell transplantation. Television interview. National broadcast. Channel 7. March 2005
18. Stories on bioterrorism vaccines. Channel 7, radio, Advertiser, Messenger. Sept 2005
19. Between 2005 and 2014 I have made multiple television, radio and newspaper appearances as expert spokesperson on vaccine related issues, particularly influenza vaccines, most particularly during the 2009 'swine flu' pandemic
20. Advertiser newspaper story. Flinders trialling Hep B vaccine. Feb 2014
21. Chanel 7 Today Tonight program. Ebola outbreak. Oct. 2014.
22. Chanel 10 news. Ebola vaccines. Oct. 2014.
23. Multiple media sources. Alzheimer's vaccine breakthrough. August 2016.
24. Multiple media sources. COVID-19 vaccines. March 2020 to present.
25. Multiple media sources. Origins of COVID-19 vaccines. March 2020 to present.

ORAL PRESENTATIONS (International and National Meetings)

1994

1. Whole blood interferon gamma responses to glutamic acid decarboxylase in normal subjects. Plenary. 13th International Immunology and Diabetes Workshop, Chantilly, France.

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2. Diurnal rhythms in human cytokine production. Poster presentation, 3rd International Conference on Cytokines, Florence, Italy.
3. Seminar, Biotechnology Research Institute, Kaneka Corporation, Osaka, Japan.
4. Seminar, Department of Endocrinology, Odense University Hospital, Denmark.
5. Seminar, Department of Immunology, Erasmus University, Rotterdam.

1995

6. Poster Presentation, Keystone Symposium on Control and Manipulation of the Immune Response, Taos, New Mexico, USA.
7. Poster Presentation, 1st Immunology of Diabetes Society Congress, Orvieto, Italy.
8. Seminar, Barbara Davis Center for Childhood Diabetes, Denver, USA.
9. Seminar, Department of Endocrinology, St. Bartholomews Hospital, London
10. Seminar, Picower Institute for Medical Research, New York, USA
11. Seminar, Roche Milano Ricerche Laboratories, Milan, Italy.
12. Seminar, DNAX Research Laboratories, Palo Alto, California, USA.
13. Seminar, Department of Theoretical Biology, Los Alamos National Laboratories, New Mexico, USA
14. Seminar, Hopital Necker, INSERM 25, Paris, France.

1996

15. Poster presentation, 2nd Immunology of Diabetes Society Congress, Canberra. Nov 1996

1999

16. Evidence from twins for acquired cellular immune hyperactivity in Type 1 Diabetes. Symposium presentation. 4th Immunology of Diabetes Society Congress, Fuigi, Italy
17. Circadian rhythmicity in macrophage migration inhibitory factor and its relationship to circadian rhythms of the human immune response. Seminar. Picower Institute Annual Scientific Retreat, New York
18. Circadian rhythmicity in the IFN-©/IL-10 ratio: a dynamic disequilibrium in the Th1/Th2 balance. Poster Presentation, Keystone Meeting on Immune Regulation, Keystone, USA.
19. GAD responsiveness and T-cell hyper-reactivity in the type 1 diabetic twin of identical pairs. Poster Presentation, The 4th International Diabetes Federation WPR Congress, Sydney.
20. Seminar, Picower Institute for Medical Research, New York, USA.
21. Seminar, Department of Cellular Biology, University of Rome, Italy.
22. Seminar, Dept. Molecular Medicine, Karolinska Institute, Stockholm.
23. Seminar, Inflammation Research Group, Astra-Zeneca, Stockholm.

2000

24. The relationship between cortisol and macrophage inhibitory factor (MIF); a novel model of endocrine-immune interaction. Symposium presentation. International Congress of Endocrinology, Sydney.
25. Human trials to prevent in type 1 diabetes. Seminar, Bioinformatics Centre, National University of Singapore.

2001

26. Fas ligand-fas interaction plays a critical role in b-cell death in type 1 diabetes. Symposium presentation. 5th Immunology of Diabetes Society Congress, Chennai, India Feb 2001 (prize for best abstract).
27. Seminar, Hospital Univ. Germans Trias i Pujol, Barcelona, Spain. Jan 2001.

2002

28. Potential gene targets in human disease. Plenary. FANTOM2 (Functional Annotation of the Mouse) Meeting. RIKEN Genomic Sciences Center, Yokohama, Japan
29. Temporal compartmentalisation of the immune response. Plenary. 6th Latin American Congress of Immunology and 3th Cuban Immunology Congress, Havana, Cuba.

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30. Computational modelling and prediction systems in clinical and experimental immunology. Symposium. 6th Latin American Congress of Immunology and 3th Cuban Immunology Congress, Havana, Cuba.
31. Pathogenesis of type 1 diabetes: dominant pathway of beta cell apoptosis and prevention of immune mediated beta cell destruction. Symposium. 6th Latin American Congress of Immunology and 3th Cuban Immunology Congress, Havana, Cuba.
32. Pathogenic mechanisms in type 1 diabetes. Seminar, University of Florida, Gainesville, Florida.
33. The DESIRE project: towards prevention of type 1 diabetes. Seminar, Juvenile Diabetes Research Foundation, New York.
34. The Combined Use of Genomics, Computational Modeling and Prediction Systems in Immunology Research. Seminar, Sanger Institute, Cambridge, UK.
35. Fas is the dominant mediator of b-cell apoptosis in the presence of insulitis: a major controversy resolved. Poster, Immunology of Diabetes Society Congress, Copper Mountain, USA.
36. Diabetes mediated by b-cell specific transgene expression: a novel model of non-immune diabetes. Poster, Immunology of Diabetes Society Congress, Copper Mountain, USA.
37. Prevention of autoimmune diabetes through immunostimulation with Q fever complement fixing antigen. Poster, Immunology of Diabetes Society Congress, Copper Mountain, USA.
38. Computational Modeling and Prediction Systems in Human Immunology. Invited Plenary. Novartis Symposium on Immunoinformatics, London UK.

2003

39. Immunoinformatics: use of artificial intelligence tools to accelerate immunology research. Invited Plenary Speaker, World Science Festival 2003 & International Dialogue to Celebrate Golden Jubilee of DNA Double Helix Discovery, New Dehli, India.
40. Immunoinformatics and modelling of human MHC class I antigen Invited Seminar. All India Institute of Medical Science, Ansari Nagar, New Dehli, India.
41. Immuno-GRID. Invited plenary. Life Sciences Grid Mini-symposium at Global Grid Forum 7, Tokyo Japan.
42. Computational Modelling Systems in Human Immunology Research. Invited Seminar. RIKEN Institute, Yokohama, Japan
43. Relevant pathways of ®-cell apoptosis in human type 1 (autoimmune) diabetes. Invited Seminar. RIKEN Institute, Yokohama, Japan
44. Pathogenesis of type 1 diabetes; how close are we to a cure. Invited Seminar, Dept Molecular Biomedicine, CINVESTAV-IPN, Mexico City.
45. Highly potent and nontoxic polysaccharide adjuvants based on gamma inulin efficiently boost humoral and cellular responses to protein subunit vaccines. Biotechnology Havana 2003. Cuba. Nov 2003.

2004

46. "The power of integrated informatic and molecular approaches to transform diabetes discovery" Immunology of Diabetes Society Congress, Cambridge, UK March 2004.
47. Invited Speaker and Discussion Panel Member, First International Immunoinformatics Meeting, Yokohama, Japan. Feb 2004.
48. Invited Speaker, Immunoinformatics Workshop, Medical Bioinformatics Conference, Singapore, March 2004.
49. Invited Speaker, 2nd International Workshop in Vaccine Adjuvants and GlycoCongugates (Adjuvant 2004), Cuba.

2005

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50. The IIMMS Distinguished Speaker Award Lecture: "Immunoinformatics: Past, Present and Future". 2nd International Immunoinformatics Symposium. March 7-9, 2005, Boston, USA
51. Invited Speaker, Federation of Immunology Societies of Asia Congress, April 2005, Hanghzou, China.
52. Invited Speaker, "Adjuvants for therapeutic hepatitis B vaccines" Immunotherapeutic Approaches in Hepatitis Congress, Varedero, Cuba April 2005.
53. Invited Speaker and Workshop convenor, ESF Marie Network – Myelin Structure and its role in Autoimmunity II, May 2005, Potenza, Italy. April 2005
54. Invited seminar "Why has it been so difficult to develop human-approved adjuvants with the ability to stimulate both antibody and cellular immune responses?" RIKEN Institute, Yokohama, Japan. June 2005
55. Invited Speaker, "Strategies for improved vaccine design", Japanese Chem-Bio Informatics Society Congress, Yokohama August 2005
56. Invited Speaker, Saitama Medical School Genomics Institute, Tokyo, Japan August 2005
57. Invited Speaker, Kitasato Institute, Tokyo, Japan. August 2005

2006

58. Invited Speaker and Symposia Chair, International Congress of Immunogenomics and Immunomics (BCII2006) Hungary

2007

59. Invited Speaker and Symposia Chair, World Vaccine Congress, Singapore, June 2007
60. Invited Speaker, Carbohydrate Moieties as Vaccine Candidates, National Institute of Health Workshop, Bethesda, Sept 2007

2008

61. Invited Speaker, Vaccines Development Forum, Las Vegas, April 2008
62. Invited Speaker, Phacilitate Vaccine Forum, Geneva, May 2008
63. Invited Speaker, Immunopotentiators in Modern Vaccines, Jamaica, May 2008
64. Seminar, Centre for Disease Control (CDC), Atlanta, May 2008
65. Invited Speaker and Symposia Chair, World Vaccine Congress, Singapore, June 2008
66. Invited Speaker, World Vaccine Congress, Sydney, Australia Oct 2008
67. Invited Speaker and Symposia Chair, 2nd Vaccines Asia Congress, Beijing, China Nov 2008

2009

68. Invited Speaker, 8th Asia Pacific Congress of Medical Virology, Hong Kong. Feb 2009
69. Invited Speaker and Panellist, World Vaccine Congress, Washington DC. April 2009
70. Invited Speaker, "Integrating informatic and molecular approaches" Symposium, ESA Annual Scientific Meeting, Adelaide, Aug 2009
71. Invited speaker, 3rd Vaccines Renaissance Congress, Providence, Rhode Island, Oct 2009
72. Invited speaker, National Institutes of Health (NIH) Adjuvant Development Workshop, Washington, DC, USA Oct 2009
73. Invited Speaker and Panellist, Influenza Congress USA 2009, Washington DC. Nov 2009

2010

74. Invited Speaker, Vaccines & Biologics Summit 2010, Kuala Lumpur, Malaysia, June 2010
75. Invited Speaker, World Influenza Congress Asia, Singapore. June 2010
76. Invited speaker, 4th Vaccines Renaissance Congress, Providence, Rhode Island, Oct 2010
77. Invited speaker, National Institutes of Health (NIH) Adjuvant Development Workshop, Washington, DC, USA Oct 2010

2011

78. Invited Speaker, Vaccine Technology and Innovation World, New Delhi, India, March 2011
79. Invited Speaker and Panellist, Oxford Global Vaccine Congress, London April 2011

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80. Invited Speaker and Panellist, World Vaccine Congress, Washington DC. April 2011
81. Invited Speaker "Vaccination for Type 1 diabetes prevention" Endocrine Society of Australia symposia on "Endocrine-Immune Interactions". ESA Annual Scientific Meeting, Perth, Aug 2011
82. Invited Speaker, Carbohydrate Moieties as Vaccine Candidates, National Institute of Health Workshop, Bethesda, Oct 2011
83. Invited speaker, 5th Vaccines Renaissance Congress, Providence, Rhode Island, Oct 2011
84. Invited speaker, National Institutes of Health (NIH) Adjuvant Development Workshop, Seattle, USA Oct 2011

2012

85. Seminar, Barbara Davis Diabetes Center, University of Colorado, Denver, USA March 2012
86. Invited speaker, AVID Meeting, Brisbane Australia, May 2-4, 2012
87. Keynote speaker "Modern vaccine design and development" and Vaccine Symposia chair, BioPharma Australasia Convention 2012, Sydney, 23-24 August 2012
88. Invited speaker, National Institutes of Health (NIH) Adjuvant Development Workshop, Washington, USA Oct 2011
89. Invited Speaker, Oklahoma Medical Research Institute, Oklahoma City, Oct 2012
90. Invited Speaker, Department of Immunology, Stanford University, Oct 2012
91. Invited Speaker, World Vaccine Congress, Lyon France, Oct17-18, 2012

2013

92. Invited keynote speaker, member advisory committee and session chairman, IBC's 4th Annual Vaccine Development & Production Summit, Durham, North Carolina June 3-5, 2013
93. Invited keynote speaker, Influenza workshop, World Vaccine Congress-Asia, Singapore, June 17-20, 2013
94. Invited keynote speaker, 3rd International Conference on Vaccines & Vaccination, Las Vegas, USA. July 29-31, 2013
95. Invited keynote speaker, CHI Novel Vaccines : Innovations & Adjuvants meeting, Boston, USA, August 13 - 15, 2013.
96. Keynote address, Alstrom's Europe Annual Scientific Workshop, Milan, Italy Sept 2013
97. Invited Seminar, Padua University, Padua, Italy, Sept 2013
98. Keynote address, Vaccine World CIS/CEE, Moscow, Russia, 7-9 Nov 2013

2014

99. Invited speaker, "New Technologies, New Vaccines", Delaware, USA 23-26 March 2014
100. Invited speaker, "World Vaccine Congress", Washington, USA 23-26 March 2014
101. Guest Seminar, University of Texas Medical Branch, Galveston, USA
102. Guest Seminar, Tulane University, New Orleans, USA
103. Invited speaker, 5th International NanoBio Conference and NanoBio Australia 2014, Brisbane, 6-10 July
104. Meeting President and Opening Keynote Address, Vaccines 2014, Valencia, Spain 24-26 Sept

2015

105. Invited speaker, United States–Australia Biomedical Research Partnership, Canberra, 13 July 2015
106. Meeting President and Opening Keynote Address, Asia Pacific Global Summit and Expo on Vaccines & Vaccination July 27-29, 2015 Brisbane, Australia
107. Invited Speaker, 8th International Society of Vaccines (ISV) Conference, 19-22 Oct 2015. Seoul, South Korea
108. Speaker, National Institutes of Health (NIH) Adjuvant Development and Discovery Workshop, Bethesda, USA Oct 2015
109. Invited speaker, 8th Vaccines Renaissance Congress, Providence, Rhode Island, Oct 2015

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110. Speaker selected from abstracts. Vaccines Against Antigenically Variable Viruses Symposium (VAAVV 2015), Ames, Iowa, USA. Oct 2015

2016

111. Invited Speaker, World Vaccine Congress, Washington DC, 29 March 2016
112. Seminar, National Institutes of Health, Bethesda, USA 1 April 2016
113. Invited Speaker, Peter MacCallum Cancer Centre Research Seminar Series, Melbourne, Sept 15, 2016
114. Speaker, National Institutes of Health (NIH) Adjuvant Development and Discovery Workshop, Bethesda, USA, Oct 2016
115. Session Chair, Mechanisms of Immune Efficacy, 2016 International Society for Vaccines (ISV) Congress, Boston, USA, 2-6 Oct 2016
116. Invited speaker "Adjuvants play a critical role in universal influenza vaccine design", 2016 International Society for Vaccines (ISV) Congress, Boston, USA, 2-6 Oct 2016
117. Invited speaker, "Vaccines for prevention or treatment: from influenza to Alzheimer's disease", Emerging Therapeutics Summit 2016, Melbourne, 23 - 25 Nov 2016
118. Opening Plenary Speaker, "Alzheimers and other unorthodox vaccines" New Horizons conference, Sydney, 21-22 Nov 2016.
119. Keynote speaker, "Design of a universal influenza vaccine", DNA- and RNA-Based Vaccines Symposium, Eleventh Annual ImVacS: Immunization and Vaccine Summit, Boston USA, 6 Dec 2016

2017

120. Invited Keynote Speaker, "Developing the first vaccine to prevent Alzheimer's disease", Vaccine Innovation Forum 2017, April 26-27, Shanghai, China.
121. Invited Seminar, "Next generation vaccine design; faster, smarter, and safer", Infection and Immunity Seminar Series, University of Sydney, July 2017
122. Invited keynote, "Vaccine adjuvants in cancer and other immunotherapy applications", Cambridge Health Institute Twelfth Annual Meeting on Advances in Vaccine Technologies, Boston August 29-30, 2017
123. Invited speaker, "Why haven't Alzheimer's vaccines succeeded yet?" World Vaccine Congress, Barcelona, Spain, Oct 2017
124. Invited speaker, "Development of proprietary polysaccharide vaccine adjuvants that meet the needs of humans and animals when concerning Influenza, West Nile and other re-emerged viruses" 3rd Veterinary Vaccine Co-conference, Barcelona, Spain, Oct 2017
125. Invited keynote, "Molecular modelling for enhanced vaccine design"2017 International Conference on BioNano Innovation, Brisbane, 24-27 September 2017
126. Co-chair, session on "Systems Vaccinology and Computational Vaccinology", International Society of Vaccines Congress, Paris, Oct 6-8, 2017
127. Invited keynote, "Innovations in vaccine design", RMIT University Drug Delivery Symposium, Melbourne, 27 November 2017
128. Chairman and Keynote address, NIH Workshop, Immune System Engineering For Targeted Tolerance in Type 1 Diabetes, Bethesda USA Nov 2017
129. Keynote, National Institutes of Health (NIH) Adjuvant Development and Discovery Workshop, Bethesda, USA, Nov 2017
130. Invited Seminar, UniSA, Adelaide, November 2017

2018

131. Chairman and Keynote address, NIH Blue Ribbon Panel on Vaccine Adjuvants, Rockville, USA. April 2018
132. Invited speaker, "Development of an universal influenza vaccine, 7th Australasian Vaccines & Immunotherapeutics Development Meeting 2018", Melbourne May 2018
133. Invited speaker "Use of Adjuvants in Allergy Vaccines", FOCIS Annual Meeting, San Francisco, June 2018

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134. Speaker selected from abstracts, International Society of Vaccines Congress, Atlanta, October 2018
135. Invited speaker "Leveraging Emerging Technologies Including Machine Learning & Deep Sequencing for Clinical Development of Cancer Vaccines & Other Immuno-therapeutics " and panel member "Governance, Bureaucracy, Ethics & Cultivating Innovation - What More Needs to be Done to Cultivate Cutting Edge Research in Australia" BioConnections Australia, Melbourne, Nov 2018
136. Invited speaker "Deep Sequencing, Machine Learning & In Silico Modelling for Development of Cancer Vaccines & Other Immuno-therapeutics" AI, Machine Learning & Robotics in Health, Melbourne, Nov 2018

2019

137. Short talk on adjuvants, NIH delegation visit to CPLB, a joint venture between Novavax and Cadila Pharmaceuticals, Ahmedabad, India, April 2019
138. Short talk on adjuvants, NIH delegation visit to Zydus Cadila, April 2019
139. Invited Speaker, "Moving Novel Adjuvants into Phase 1 Clinical Trials", DBT-NIAID Vaccine Adjuvant Science Collaborative Training Workshop, Delhi. India, April 2019
140. Keynote plenary speaker, SPARC International Workshop at Panjab University, Chandigarh. India, April 2019
141. Invited seminar, IIT Ropar, Ropar, India. April 2019
142. Invited seminar, NIPER Mohali, India. April 2019
143. Invited seminar, CSIR-IMTECH, India. April 2019
144. Invited seminar, Scripps Institute Florida, Jupiter, Florida. July 2019
145. Invited seminar, Cleveland Clinic, Cleveland, USA, July 2019
146. Invited Plenary Speaker, "Adjuvants for all occasions", Vaccines R&D-2019, Boston, USA. Nov 2019
147. Chair and Invited Speaker, Cleveland Clinic Research and Innovation Symposium, Port St Lucie, Florida, Nov 21-22, 2019

2020

148. Invited talk, ACIS virtual symposium – Viruses are colloids– how can colloid science impact Covid-19 and beyond? RMIT, Melbourne 30 July 2020
149. Invited talk, "The race to develop COVID-19 vaccines and treatments", Research Reconnect Series, Oracle, Aug 2020
150. Invited speaker, "Progress in the development of COVID-19 vaccines" Integrated Strategies to Combat the Pandemic COVID-19 Workshop, Department of Biochemistry, School of Life Sciences, Central University of Rajasthan, India. 20 August 2020
151. Invited speaker, Panjab University, Chandigarh
152. Invited speaker, "The race to develop a COVID-19 vaccine". Webinar Series on COVID-19 specific Events, VACCINE & IMMUNIZATION: COVID-19, Biotechnology Society of Nepal, 13 Sept 2020
153. Webinar Panelist, The Race to Develop COVID-19 Vaccines and Treatments, Oracle Corporation Sep 10, 2020
154. Invited seminar, "Progress in development of COVID-19 countermeasures" COVID19 forum, Peter Doherty Institute for Infection and Immunity, Melbourne 16 Sept 2020
155. Panel member, "Taming COVID-19 Vaccines, Anti-Virals & Anti-Infammatories", Citibank , 11 Sept 2020
156. Invited speaker, "COVID-19 vaccines", Innovate Health Conference Sept 2020
157. Invited talk, IMAPAC's Corona360 In-Conversation Live Moderated Interview on SARS-CoV-2 Vaccine Development Challenges.
158. Panel member, Addressing barriers to uptake: Adherence, misinformation, & anti-Science, PSWC2020, 4-6 Oct 2020

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159. Plenary Panel member, Bridging infectious disease vaccines and cancer immunotherapy, World Vaccine Congress Europe Oct 2020
160. Invited speaker, COVID Innovation Symposium, Waters Corporation, Nov 2020
161. Invited speaker, "Covax-19®, a pandemic vaccine for all occasions" Vaccine World Asia Congress 2020, Nov 3, 2020
162. Invited talk, V International Agrotechnological Summit, Kazakh National Agrarian Research University, 3 Dec 2020
163. Invited keynote, "Covid-19 vaccines", The Canadian COVID Collaboration: Community-led solutions for this pandemic, Public online meeting. 9 Dec 2020
164. PANEL: COVID-19 vaccine development, World Vaccine and Immunotherapy Congress (Dec 1st - 3rd, 2020)

2021

165. Invited keynote, "Update on COVID-19 vaccines", International conference of Biotechnology Society of Nepal (ICBSN 2021), Nepal 12-14 Feb, 2021
166. Invited keynote," COVID-19 vaccines, how soon, how much, how effective?" Biologics Manufacturing Japan & Vaccine World Japan 2021 (3-4 February, 2021).
167. "Covid-19 vaccine development", WHO COVID-19 Vaccine research forum, March 2021
168. Invited talk, "Advax adjuvant", NIH Adjuvant Working Group, March 2021
169. 1st International Conference on COVID-19: "COVID-19Vaccines & Beyond" April 10, 2021. University of Health Sciences Lahore Pakistan.
170. Invited keynote, "Latest Developments in Vaccine Adjuvants", 2021 Global COVID-19 Vaccine Research and Development Summit, 17 May 2021, China
171. Invited speaker, "COVID-19 Vaccine Development Plan and Supply Chain Management Challenges in Global Market", 10th Biologics Manufacturing Korea 2021, 23-24 June, 2021
172. Invited keynote speaker, The Origins of Covid-19", PDA Aseptic Processing of Biopharmaceuticals conference Oct. 19-21, 2021
173. Invited keynote speaker, Live-Moderated Interview – "The COVID-19 Vaccine Development Landscape in APAC Region", IMAPAC Singapore, 11 August 2021
174. Invited keynote speaker, Role of Adjuvants in Vaccine Design, IVI's 20th International Vaccinology Course, Sept 2021
175. Invited keynote speaker, "Covid-19 vaccines", Global Conference on Vaccines Research and Development (Vaccines Conference-2021) August 26-27, 2021
176. Invited seminar. "Next generation vaccines for COVID-19 variants of concern". Nepal Biotechnology Society, 26 July 2021
177. Invited keynote speaker, "Covid-19 vaccines", 9th Annual Biologics World Taiwan 8 Sept 2021

PUBLICATIONS

ORIGINAL RESEARCH PAPERS

1. **Petrovsky** N, McNair P and Harrison LC. Circadian rhythmicity of interferon-gamma production in antigen-stimulated whole blood. Chronobiologia 1994, 21: 293-300. (Times Cited 21)
2. **Petrovsky N** and Harrison LC. Cytokine-based human whole blood assays for the detection of antigen-reactive T cells. J. Immunol. Methods 1995, 184: 219-229. (IF2.46) (Times Cited 32)
3. **Petrovsky N** and Harrison LC. TH1 and Th2. Swinging to a hormonal rhythm. Immunology Today. 1995 16: 605-606. (Times Cited 12)

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4. **Petrovsky N**, Bonnevie-Nielsen V, Kyvik KO, Beck-Nielsen H, Green A, Harrison LC. Evidence for the viral aetiology of IDDM. J. Autoimmunity 1997, 25: 251-252 (IF1.917) (Times Cited 4)
5. **Petrovsky N** and Harrison LC. HLA class II-associated polymorphism of interferon-gamma production: implications for HLA-disease association. Hum. Immunol. 1997, 53:12-16. (IF 2.664) (Times Cited 20)
6. **Petrovsky N**. Danazol in the treatment of a systemic lupus erythematosus (SLE)-like illness associated with deficiency of the fourth component of complement. Aust. NZ J. Med. 1997, 27: 189. (IF 3.59)
7. **Petrovsky N**, and Harrison LC. Diurnal rhythmicity of human cytokine production: a dynamic disequilibrium in T helper cell type 1/T helper cell type 2 balance? J. Immunol. 1997, 158:5163-5168. (IF 6.486) (Times Cited 61)
8. Daniel S, Brusic V, Caillat-Zucman S, **Petrovsky N**, Harrison L, Riganelli D, Sinigaglia F, Gallazzi F, Hammer, J, van Endert PM. Relationship between peptide selectivities of human transporters associated with antigen processing and HLA class I molecules. J Immunol. 1998, 15;161(2):617-24. (IF 6.486) (Times Cited 46)
9. **Petrovsky N**, McNair P and Harrison LC. Diurnal rhythms of pro-inflammatory cytokines: Regulation by plasma cortisol and therapeutic implications. Cytokine 1998, 10: 307-312. (IF 1.986) (Times Cited 51)
10. Brusic V, van Endert P, Zeleznikow J, Daniel S, Hammer J and **Petrovsky N** A neural network model approach to the study of human TAP transporter. In Silico Biology 1999, 1: 109-121. (Times Cited 1)
11. Brusic B, Zeleznikow J, **Petrovsky N**. Molecular Immunology Databases and Data Repositories. J. Immunol. Methods 2000, 238: 17-28. (IF2.46) (Times Cited 10)
12. **Petrovsky N** and Bucala R. Macrophage Migration Inhibitory Factor (MIF): A Critical Neurohumoral Mediator. Annals N Y Acad Sci 2000, 917: 665-671. (IF 1.26) (Times Cited 4)
13. Brusic B, Bucci K, Schönbach C, **Petrovsky N**, Zeleznikov J and Kazura J. Efficient Discovery of Immune Response Targets by Cyclical Refinement of QSAR Models of Peptide Binding. Journal of Molecular Graphics and Modelling 2001, 19, 405-411. (IF 3.036) (Times Cited 12)
14. **Petrovsky N**. Towards a unified model of neuroendocrine-immune interaction. Immunol Cell Biol 2001, 79, 350-357. (IF 2.618) (Times Cited 32)
15. **Petrovsky N**, Silva D, Socha L, Slattery R, Charlton B. The role of Fas ligand in beta cell destruction in autoimmune diabetes of NOD mice. Annal N Y Acad Sci 2002, 958, 204-8 (IF 1.789) (Times Cited 10)
16. **Petrovsky N**, Tam S, Brusic V, Russ G, Socha L, Bajic V. Use of artificial neural networks in improving renal transplantation outcomes. Graft 2002, 4, 6-13. (Times Cited 1)
17. Tran HA, **Petrovsky N**, Field AJ. Severe diabetic retinopathy: a rare complication of acromegaly. Internal Medicine Journal 2002. 32, 52-55 (IF 3.59) (Times Cited 3)
18. Isidori AM, Kaltsas GA, Korbonits M , Pyle M , Gueorguiev M , Meinhardt A, Metz C, **Petrovsky N**, Popovic V, Bucala R and Grossman AB. Response of serum macrophage migration inhibitory factor (MIF) levels to stimulation or suppression of the hypothalamo-pituitary-adrenal axis in normal subjects and in patients with cushing's disease. J. Clin Endocrinol. Metab. 2002. 87,1834-40. (IF 5.778) (Times Cited 17)

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19. Yu K, **Petrovsky N**, Schönbach C, Koh JLY and Brusic V. Methods for prediction of peptide binding to MHC molecules: a comparative study. Molecular Medicine. 2002. 8:137-48. (IF 3.576) (Times Cited 17)

20. Brusic V, **Petrovsky N**, Zhang G and Bajic VB. Prediction of promiscuous peptides that bind HLA class I molecules. Immunol. Cell Biol. 2002 80:280-5. (IF 2.618) (Times Cited 14)

21. **Petrovsky N**, Bonnevie-Nielsen V, Kyvik KO, Beck-Nielsen H, Green A, Harrison LC. Evidence from twins for acquired cellular immune hyperactivity in type 1 diabetes. Immunology. 2002 106:584-589. (IF 2.965) (Times Cited 3)

22. Tran HA, **Petrovsky N**. Pregnancy-associated osteoporosis with hypercalcaemia. Intern Med J. 2002 32:481-5. (IF 3.59) (Times Cited 3)

23. Y. Okazaki, Y. Furuno, et al. Analysis of the Mouse Transcriptome based upon Functional Annotation of 60,770 full length cDNAs. Nature 2002 420:563-73. (IF 32.182) (Times Cited 332)

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25. Silva D, Charlton B, Cowden W, **Petrovsky N.** Prevention of autoimmune diabetes through immunostimulation with Q fever complement fixing antigen. Ann NY Acad Sci. 2003 1005:423-30.

26. Socha L, Silva D, Lesage S, Goodnow C, **Petrovsky N** The role of endoplasmic reticulum stress in non-immune diabetes: NOD.k iHEL, a novel model of ®-cell death. Ann NY Acad Sci. 2003 1005:178-83.

27. Silva D, Socha L, Charlton B, Cowden W, **Petrovsky N**. Autoimmune diabetes in the NOD mouse: An essential role of Fas-FasL signalling in beta cell apoptosis. Ann NY Acad Sci. 2003 1005:161-5

28. Nagashima T, Silva S, Socha L, **Petrovsky N**, Suzuki H, Kasukawa T, Kurochkin I, Konagaya A, Laboratory of Genome Exploration Research Group and Schönbach C. Inferring higher functional information for RIKEN mouse full-length cDNA clones with FACTS. Genome Res. 2003 13: 1520-1533. (IF 10.382)

29. Brusic V, Pillai RS, Silva DH, **Petrovsky N**, Schönbach C. Cytokine-related genes identified from the RIKEN full-length mouse cDNA dataset. Genome Res. 2003 13: 1307-1317. (IF 10.382)

30. Brusic V, Millot M, **Petrovsky N**, Gendel SM, Gigonzac S, Stelman SJ. Allergen Databases. Allergy. 2003 58:1093-100. (IF 3.496)

31. Brusic V, **Petrovsky N**, Gendel SM, Millot M, Gigonzac S, Stelman SJ. Computational Tools for the Study of Allergens. Allergy. 2003 58:1083-92. (IF 3.496)

32. Brusic V and **Petrovsky N**. Bioinformatics for Characterisation of Allergens, Allergenicity and Allergic Cross-Reactivity. Trends in Immunology. 2003 24:225-8. (IF 13.075)

33. Silva D, **Petrovsky N***, Socha L, Slattery R, Gatenby P, Charlton B. Mechanisms of accelerated immune-mediated diabetes resulting from islet beta-cell expression of a FAS ligand transgene. J. Immunol 2003 170:4996-5002. (*corresponding author) (IF 6.486)

34. **Petrovsky N**, Schonbach C, Brusic V. Bioinformatic strategies for better understanding of immune function. In Silico Biol. 2003. 411

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42. Tran HA, Silva D, **Petrovsky N**. Potential pitfalls of using HbA1c as the sole measure of glycaemic control. Clinical Diabetes 2004 22:141-43.
43. Brusic V, Bajic V, **Petrovsky N**. Computational Methods for Prediction of T-cell epitopes – a framework for modeling, testing and applications. Methods 2004 34:436-43.
44. **Petrovsky N** and Brusic V. Virtual Models of the HLA Class I Antigen Processing Pathway. Methods 2004 34:429-35.
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48. Tran HA, Chua YJ and **Petrovsky N**. Diabetes-related dyslipidaemia. Pathology 2004 36:576-9.
49. Shadabi F, Cox RJ, Sharma D, **Petrovsky N**. A hybrid decision tree artificial neural networks ensemble approach for kidney transplantation outcomes prediction. Lecture Notes in Artificial Intelligence 2004 3215: 566-572.
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51. Silva D, **Petrovsky N**. Identification of key beta cell gene signaling pathways involved in type 1 diabetes. Ann NY Acad Sci. 2004 1037:203-7

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