Russell Broadbent MP
Member for Monash

25 September 2024

The Hon Anthony Albanese MP
Prime Minister
Parliament House
CANBERRA ACT 2600

By email: parliament@pm.gov.au

Dear Prime Minister

I refer to my letter of 20 September 2024 calling on the government to immediately suspend the use of Pfizer and Moderna Covid-19 products due to the evidence of significant synthetic DNA contamination, as detailed in Dr. David Speicher's report.

Unlike the Thalidomide tragedy, which resulted in over 10,000 victims globally, the Covid-19 vaccines have been administered to more than 20 million Australians, totalling over 63 million doses. The contamination detected in these vaccines, if not addressed, presents a substantial risk, with the potential for these dangers - such as genomic integration and potential long-term health impacts - to multiply with each additional dose administered. Immediate action through a suspension of these products is critical to mitigate further risk.

To assist in adopting a precautionary approach and minimizing further harm, I enclose a Science Summary created and endorsed by eminent Australian and international scientists and medical experts. The summary reinforces the known and potential dangers of DNA contamination and highlights the need for an urgent and independent investigation. As advised by the co-signatories, the Department of Health and Aged Care has produced no evidence to demonstrate why the detected DNA contamination will not produce the dire adverse health outcomes detailed in the Science Summary.

Additionally, I have reason to believe that multiple attempts by prominent scientists to warn the TGA of these risks have been disregarded since early 2021, raising serious questions about the agency's ability to protect the health and well-being of Australians.

Finally, I draw your attention to the Biosecurity Act 2015, which may now be relevant. Given the contamination evidence, I recommend the Minister for Agriculture initiate a Biosecurity Import Risk Analysis of these products, potentially leading to the suspension of these products due to the risks they pose to human health.

I gratefully acknowledge the assistance of the 52 co-signatories below in the preparation of this letter and reiterate my call seeking your urgent action to ensure the safety of all Australians.

Yours sincerely

Russell Broadbent MP
Member for Monash

Prof Angus Dalgleish
MD FRACP FRCP FRCPath FMedSci
Principal of the Institute of Cancer Vaccines and Immunotherapy
London, United Kingdom

Emeritus Prof Wendy Hoy
Professor of Medicine, FAA AO FRACP
MBBS(H1) BScMed (H1)
University of Queensland

Emeritus Professor Robert Clancy
AM FRS(N) BSc(Med) MB BS PhD DSc
FRACP FRCP(A) FRCP(C)
University of Newcastle, Australia

Prof Alexandra Henrion Caude
Geneticist, Director of Research INSERM
French National Institute of Health and Medical Research
Paris, France

Prof Sucharit Bhakdi MD
Chair em., Department of Medical Microbiology and Hygiene
Johannes-Gutenberg University Mainz, Germany

Kevin McKernan
BSc
Research Director (fmr)
Human Genome Project

Prof Ian Brighthope
Director, The World of Wellness International
Advisor, The Aligned Council of Australia

Prof Gigi Foster
Co-Director, Australians for Science and Freedom
University of New South Wales

Prof Robyn Cosford
MBBS(Hons), DipNutr, Dip Hom, FACNEM
FASLM, Professor of Nutritional and Environmental Medicine
Chair, Director Children's Health Defense

Prof Bonnie Mallard PhD
Professor of Immunogenetics
Governor General Innovation Awardee
Department Pathobiology
University of Guelph
Canada

Professor Augusto Zimmermann
PhD (Mon.), LLM summa cum laude
LLB (Hons.), CIArb, DipEd.
Sheridan College, Western Australia
The University of Notre Dame Australia

Prof Brendan Vote
Director, Tasmanian Eye Institute Ltd
Clinical Professor
University of Tasmania

Prof Gabriel Moens AM
Emeritus Professor of Law
The University of Queensland

Professor Paul Frijters PhD
Professor of Economics MBSC
Emeritus Professor London School of Economics

A/Prof Byram W. Bridle
Immunology and Virology
Department of Pathobiology
University of Guelph
Canada

A/Prof Peter Parry
MBBS, PhD, FRANZCP, Cert. Child & Adolesc. Psychiatry
University of Queensland

A/Prof D Jonathan Gilthorpe
BSc (Hons), PhD, Docent
Senior Lecturer
Umeå University, Sweden

A/Prof Michael Sladden
MBChB, MAE, MRCP, FACD, FRACGP
MRCGP, Consultant Dermatologist
Associate Professor Medicine and Dermatology
University of Tasmania

A/Prof Mark Jones
Biostatistician
Institute for Evidence-Based Healthcare
Faculty of Health Sciences & Medicine
Bond University

Dr Tess Lawrie
MBBCh, PhD
Director, Evidence-based Medicine Consultancy Ltd, EbMCsquared CIC

Dr Jessica Rose, PhD
Applied Mathematics,
Immunology, Computational Biology
Biochemistry, Molecular Biology

Dr Christopher Neil
MBBS, FRACP, PhD
Cardiologist
President, Australian Medical Professionals Society

Dr Jeyanthi Kunadhasan
MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)

Dr David J. Speicher
Virologist, PhD DTM
Senior Research Associate
University of Guelph
Canada

Dr Angela Jeanes
BSc(Hons), PhD

Dr Julie Sladden
MBBS(Hons), BMedSci
PGDipMedEd

Dr Astrid Lefringhausen
PhD Molecular Biology and Biochemistry
Specialised in Virology and Immunology
Board of Directors CHD Australia

Dr Luke McLindon
MBBS FRACGP FRANZCOG
Obstetrician & Gynaecologist
Advanced Laparoscopy/Endometriosis/Infertility

Dr Conny Turni
BSc, Hons, PhD
Senior Research Fellow
Microbiology Research
QAAFI
University of Queensland

Dr Nicholas J. Hudson, PhD
Senior lecturer in Metabolic Biochemistry
University of Queensland

Dr Andrew Madry
BSc PhD

Dr Kylie O'Brien PhD
Dr Kylie O'Brien PhD, MPH, BAppSc(Chin Med)
BSc(Optom), Grad Cert Tertiary Education
Consultant in Integrative Medicine
Consultant in Higher Education

Dr Phillip Altman
BPharm(Hons), MSc, PhD
Clinical Trial and Regulatory Affairs Consultant

Dr Nicole Delépine
Paediatric Oncologist
Chief of Paediatric Oncologist Department (Retd)
Hospital Garches, France

Dr Duncan Syme
MBBS FRACGP DROGG Dip Practical

Dr Christopher Milburn MD
Family & ER Medicine
Canada

Dr Andrew McIntyre
Consultant Gastroenterologist
FRACP MBBS(Hons)

Dr Monique O'Connor
MBBS FRANZCP

Dr Paul Oosterhuis
MBBS FANZCA (retired)

Dr Judy Wilyman PhD
Master of Population Health

Dr Melissa McCann
BPharm MBBS FRACGP

Dr Julian Fidge
BPharm, Grad Dip App Sc (Comp Sc)
MBBS, FRACGP, MMed (Pain Mgt)

Dr Geoff Pain
PhD. B.Sc.(Hons.)
Grad Dipl Business Management

Christof Plothe DO
BSC.(OST), HONS

Kara Thomas
BNurs, GCertNurs, MInt&CommDev

Jason Strecker
BCompSci, DipEd

Ros Nealon-Cook
BPsychSc(H1), BCompSc(H1)

Peter Fam
LLB, Human Rights Lawyer, Principal Partner
MAATs Methods

William D H Parry
Lawyer
LLB/LP, B.BehavSci(Psych), D.Bus

Tony Nikolic
Director
Ashley, Francina, Leonard & Associates

Katie Ashby-Koppens
Lawyer
PJ O'Brien & Associates

Julian Gillespie
LLB, BJuris

Science Summary

Consequences of Synthetic DNA Contamination

Executive Summary: Excessive synthetic foreign DNA encapsulated in lipid nanoparticles can integrate into human cells, potentially leading to genomic instability, cancers, immune system disruption, and adverse hereditary effects.

The synthetic DNA contamination is present as both whole plasmid (circular) DNA and fragmented (linear) forms of the same plasmid DNA leftover from the production process.

The TGA has long recognised this must be filtered out before final products are injected into Humans because of known risks of integration into the Human genome, and severe diseases, as explained below.

This DNA contamination has been shown to be encapsulated in, and protected by, the Lipid Nanoparticles (LNPs) within the products, which together form **LNP-modDNA complexes**.

The LNP-modDNA complexes transfer their cargo of synthetic DNA throughout the Human body as follows:

a) The LNP-modDNA complex transfers the whole (circular) and fragmented (linear) DNA from the injection site throughout the Human body, bio-distributing to virtually all organs via the bloodstream.

b) The LNP-modDNA complex then transfers the whole (circular) and fragmented (linear) DNA across cell membranes of cells of affected organs, delivering the synthetic DNA into the cytoplasm of cells.

c) The synthetic DNA is then further transferred from the cytoplasm into the cell nucleus where natural Human DNA is located.

The presence of synthetic DNA in the cytoplasm alone induces cancer[1].

The TGA limit of 10 nanograms *per dose* was made with the long out-dated understanding that any DNA contamination would be "naked" or "free" DNA, ***not being encapsulated*** in protective LNPs. Naked DNA is readily "mopped up" by our immune system when detected

[1] He *et al*: *Cytoplasmic DNAs: Sources, sensing, and roles in the development of lung inflammatory diseases and cancer* Front. Immunol., 12 April 2023; Kwon *et al*: *The Cytosolic DNA-Sensing cGAS–STING Pathway in Cancer* Cancer Discov (2020) 10 (1): 26–39.

in the blood. Synthetic DNA cloaked in LNPs is transferred throughout the Human body undetected.

Crucially, naked DNA has no ability to cross cell membranes and enter cells.

In contrast, synthetic DNA encapsulated in LNPs possess a high ***transfection*** efficiency, meaning, the LNP-modDNA complexes are efficient at delivering synthetic DNA into Human cells.

Once within the cytoplasm synthetic DNA gains entry to the nucleus during cell division, when the protective nuclear envelope temporarily breaks down, or *much* more easily, with the assistance of Simian Virus 40 (SV40) genetic sequences long known to assist entry into the nucleus, even when cells are not undergoing cell division[2]. The Pfizer product contains these SV40 sequences.

The scientific literature is abundant on the subject of transfection of plasmid DNA encapsulated in LNPs into mammalian cells[3], and the subsequent localization into the cell nucleus, showing ***transgene*** expression in all major organs including the heart, lung, liver, spleen, kidney, brain, testis, and ovaries.

The chromosomal integration of plasmid DNA into the natural DNA of mammalian cells was demonstrated as early as 1982[4].

The integration of plasmid DNA demonstrated in 1982 shares multiple features with the synthetic DNA discovered in the Moderna and Pfizer Covid products.

The introduction of foreign or modified genes (DNA) into mammalian cells using this and similar techniques has since become commonplace in experimental research and in biotechnology. The methodology is referred to as ***transfection***, and organisms modified in this manner as ***transgenic***. Stable integration can occur with both linear and circular plasmid DNA[5].

In this context, further consideration must be given to the previously published study by Aldén *et al*[6] (2022), who detected DNA ***copies*** of the spike protein gene in a Human liver cells exposed to the Pfizer product. Aldén *et al's* findings are now supported by the discoveries by

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[2] Dean *et al*: *Sequence Requirements for Plasmid Nuclear Import* Experimental Cell Research Volume 253, Issue 2, 15 December 1999, Pages 713-722.

[3] Kulkarni *et al*: *Design of lipid nanoparticles for in vitro and in vivo delivery of plasmid DNA* Nanomedicine 2017 May;13(4):1377-1387; Scalzo *et al*: *Ionizable Lipid Nanoparticle-Mediated Delivery of Plasmid DNA in Cardiomyocytes*. Int J Nanomedicine. 2022;17:2865-2881

[4] Southern *et al*: *Transformation of mammalian cells to antibiotic resistance with a bacterial gene under control of the SV40 early region promoter*. J. Mol. Appl. Genet. 1 (1982), 327–41.

[5] Stuchbury *et al*: *Optimizing the generation of stable neuronal cell lines via pre-transfection restriction enzyme digestion of plasmid DNA*. Cytotechnology 62 (2010), 189–94.

[6] Aldén *et al*.: *Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line*. Curr. Issues Mol. Biol. 44 (2022), 1115–1126.

McKernan *et al* 2023, Speicher *et al* 2023, Konig et al 2024, and the Australian DNA contamination report of Dr Speicher that the Pfizer and Moderna products contain *substantial* amounts of synthetic DNA. In other words there is a *definite possibility* of cellular uptake of this DNA contamination.

Further, preliminary results returned by the former research director for the Human Genome Project, Kevin McKernan, working with cancer researcher Professor Ulrike Kämmerer, has confirmed the synthetic DNA contamination from Pfizer's Covid vaccine not only crossed into cells, but it also survived multiple cell divisions.

This is suggestive that the contaminant DNA is able to transfect (enter) the cell nucleus, and that it integrated with Human DNA. Further analysis is ongoing with details available here.

When genomic integration of foreign DNA occurs at the wrong place within the genome, it frequently induces malignant diseases, cancers, especially leukaemia[7].

Oocytes – immature ovum - can be transfected with synthetic DNA at certain stages of maturation[8], and so can sperm-producing cells within the testes[9]. The offspring of such treatment were shown to be *transgenic*.

It can therefore not be ruled out that persons injected with mRNA vaccines that also contain synthetic DNA will subsequently give rise to *transgenic* children. DNA insertion into germline cells might also interfere with early intrauterine development and thereby induce miscarriages or malformations.

In the study by Wang *et al*[10], significant plasmid DNA transfection into cells was observed after intramuscular injection followed by electroporation (electric field applied to promote transfection/entry of plasmid DNA into cells) – up to a 34 fold increase.

While electroporation did increase the cellular uptake of the injected DNA, it was likely much less effective in this regard than the LNPs contained in the Pfizer and Moderna products would be[11], due to the extensive bio-distribution LNPs achieve throughout the Human body, enabling ***magnitudes more*** synthetic DNA to be presented to ***magnitudes more*** cell varieties, which

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[7] Staal *et al*.: *Sola dosis facit venenum. Leukemia in gene therapy trials: a question of vectors, inserts and dosage? Leukemia* 22 (2008), 1849–1852.

[8] Laurema et al.: *Transfection of oocytes and other types of ovarian cells in rabbits after direct injection into uterine arteries of adenoviruses and plasmid/liposomes*. Gene Ther. 10 (2003), 580–4.

[9] Dhup *et al*: *Transgenesis via permanent integration of genes in repopulating spermatogonial cells in vivo*. Nat. Methods 5 (2008), 601–3.

[10] Wang *et al*.: *Detection of integration of plasmid DNA into host genomic DNA following intramuscular injection and electroporation*. Gene Ther. 11 (2004), 711–21.

[11] Tanaka *et al*: *Improvement of mRNA Delivery Efficiency to a T Cell Line by Modulating PEG-Lipid Content and Phospholipid Components of Lipid Nanoparticles*. Pharmaceutics. 2021 Dec; 13(12): 2097.

DNA is then aided by the transfection properties of the LNPs, for cellular entry throughout the Human body.

Accordingly, it must be expected that there will be chromosomal integration of the contaminating synthetic DNA within Human recipients of the Pfizer and Moderna products containing DNA contaminants.

The SV40 promoter sequences found in the Pfizer product also includes an internal ***origin of replication*** that can potentially cause ***copies*** of the synthetic DNA to be made inside Human cells.

This replication would require either the SV40 virus itself, which already infects a minority of Humans, or replication by the Human BK or JC polyomaviruses[12]. Any additional copies of the synthetic DNA generated would amplify the risk of genomic integration with Human DNA and increase the risk of malignant tumours (cancers) associated[13] with the SV40 virus.

Genetic sequences of SV40 have long been known to facilitate entry into the nucleus and facilitate integration with Human genes, with SV40 genetic sequences long suspected and implicated[14] in the explosion of cancers after having contaminated Polio vaccines last century.

The SV40 promoter sequence in the Pfizer product has long been known to ***bind*** to tumor suppressor p53[15], known as the *Guardian of the Genome*. Contaminated Pfizer doses containing billions of SV40 molecules act as decoys by binding to p53, leaving insufficient p53 to protect against cancers.

Three Australian vials evidenced synthetic DNA contamination ranging between 78ng to 1,460ng ***per dose***.

The TGA ***limit*** is 10ng ***per dose***.

A Pfizer dose containing 500ng of synthetic DNA would contain approximately 2.4 - 24 Trillion[16] synthetic DNA molecules. An adult Human has approximately 37 Trillion cells.

Within this range a recipient would receive between ~60 Billion and 575 Billion SV40 molecules.

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[12] DeCaprio *et al*: *A cornucopia of human polyomaviruses*. Nat. Rev. Microbiol. 11 (2013), 264–76; I. Hussain et al.: *Human BK and JC polyomaviruses: Molecular insights and prevalence in Asia*. Virus Res. 278 (2020), 197860.

[13] Rotondo *et al*.: *Association Between Simian Virus 40 and Human Tumors*. Front. Oncol. 9 (2019), 670.

[14] Fisher *et al*: *Cancer risk associated with simian virus 40 contaminated polio vaccine* Anticancer Res. 1999 May-Jun;19(3B):2173-80.

[15] Draymen *et al*: *p53 elevation in human cells halt SV40 infection by inhibiting T-ag expression* Oncotarget. 2016 Aug 16.

[16] Assuming DNA molecules ranging in lengths 200 to 20 base pairs.

Only 3-10 copies of this synthetic DNA containing the SV40 enhancer are needed to be inserted into a single cell for the risk of insertional mutagenesis (cancers) to exist[17]. The remaining synthetic DNA fragments numbering in the Trillions also threaten or have likely produced severe disease. Studies must begin immediately.

Lastly, identification of the synthetic DNA contamination has also identified other adulterations requiring further study, including: Double stranded synthetic RNA (dsRNA); synthetic RNA:DNA hybrids; and an undisclosed *reverse* Open Reading Frame (ORF) closely related to genetic sequences for producing the spidroin (spider) proteins (MsSp1) known to cause blood clots. Each of these further adulterations are known causes of severe disease.

Summary & Further Peer Reviewed References

The following list of peer reviewed literature supports the following statements made in respect of the excessive DNA contamination detected in the Pfizer and Moderna products, ***exacerbated by repeated doses,*** which is associated with, and may result in:

a) Extended duration of synthetic spike protein production for an unknown period of time, possibly years;

b) Promotion of antibiotic resistance within the Human host and throughout communities;

c) Replication of the synthetic (whole plasmid) DNA within the Human host;

d) Genomic insertion of the synthetic DNA into natural Human chromosomal DNA;

e) Genomic integration inducing malignant/cancerous diseases;

f) Inactivation of the p53 leading to the proliferation of tumors;

g) Presence of synthetic DNA in cytoplasm inducing malignant/cancerous diseases;

h) Transfection into Oocytes and sperm-producing cells leading to:

   i. Altered transgenic offspring;

   ii. Interference with early intrauterine development;

   iii. Induction of miscarriages and malformations.

[17] Dean *et al*: *Sequence Requirements for Plasmid Nuclear Import* Experimental Cell Research Volume 253, Issue 2, 15 December 1999, Pages 713-722.

Liu *et al* 2021: Gene Therapy with Plasmid DNA

Haraguchi *et al* 2022: Transfected plasmid DNA is incorporated into the nucleus via nuclear envelope reformation at telophas

Zhu *et al* 2022: Multi-step screening of DNA/lipid nanoparticles and co-delivery with siRNA to enhance and prolong gene expression

Moreau *et al* 1985: The SV40 72 base repair repeat has a striking effect on gene expression both in SV40 and other chimeric recombinants

Prasad *et al* 2005: The role of plasmid constructs containing the SV40 DNA nuclear-targeting sequence in cationic lipid-mediated DNA delivery

Miller *et al* 2008: Cell-specific nuclear import of plasmid DNA in smooth muscle requires tissue-specific transcription factors and DNA sequences

Young *et al* 2003 Effect of a DNA nuclear targeting sequence on gene transfer and expression of plasmids in the intact vasculature

Escriou *et al* 1998: Cationic lipid-mediated gene transfer: analysis of cellular uptake and nuclear import of plasmid DNA

Zanta *et al* 1999: Gene delivery: A single nuclear localization signal peptide is sufficient to carry DNA to the cell nucleus

Tseng *et al* 1999: Mitosis enhances transgene expression of plasmid delivered by cationic liposome

Hwang *et al* 2001: Liver-targeted gene transfer into a human hepatoblastoma cell line and in vivo by sterylglucoside-containing cationic liposome

Hong *et al* 1997: Stabilization of cationic liposome-plasmid DNA complexes by polyamines and poly(ethylene glycol)-phospholipid conjugates for efficient in vivo gene delivery

Uyechi *et al* 2001: Mechanism of lipoplex gene delivery in mouse lung: binding and internalization of fluorescent lipid and DNA components

Li *et al* 1997: In vivo gene transfer via intravenous administration of cationic lipid-protamine-DNA (LPD) complexes

Liu *et al* 1997: Factors controlling the efficiency of cationic lipid-mediated transfection in vivo via intravenous administration

Sakurai *et al* 2001: Interaction between DNA-cationic liposome complexes and erythrocytes is an important factor in systemic gene transfer via the intravenous route in mice: the role of the neutral helper lipid

Zhang *et al* 1998: Vector-specific complementation profiles of two independent primary defects in cystic fibrosis airways

Kariko *et al* 1998: Phosphate-enhanced transfection of cationic lipid-complexed mRNA and plasmid DNA

Midoux *et al* 2009: Chemical vectors for gene delivery: a current review on polymers, peptides and lipids containing histidine or imidazole as nucleic acids carriers