WA Premier tells Port Hedland council 'stick to knitting' after anti-COVID vaccine motion passes

By Charlie McLean and Jessica Shackleton

ABC Pilbara Public Health

Mon 14 Oct 2024 at 8:22pm

In short:

A majority of councillors in Port Hedland, in WA's north-west, have voted in favour of a motion calling for an "immediate suspension" of mRNA COVID-19 vaccines.

The motion cited unverified claims that Pfizer and Moderna vaccines are contaminated with DNA fragments.

What's next?

The motion also called for council administrators to write to the Prime Minister and national health authorities over the issue.

The Western Australia Premier has told a council in the state's north to "stick to its knitting" after it passed a motion urging state and federal governments to suspend some COVID-19 vaccinations.

The Town of Port Hedland held a special council meeting on Friday and has instructed its chief executive to write to authorities nationwide to immediately stop the use of Pfizer and Moderna vaccines.

The council motion was centred on an unverified study from Canada in 2023 which found "high levels of residual plasmid DNA present in the Pfizer and Moderna COVID-19 modified mRNA vaccine".

The Canadian study claims to confirm earlier findings by US molecular biologist Dr Philip Buckhaultz, but those findings have been debunked by fact-checking organisation AAP FactCheck.

Premier Roger Cook said the Port Hedland council had gone "off the rails" by spreading the unverified claim.

"The Town of Port Hedland should stick to its knitting," the Premier said.

"It should stay focused on the services and people of that community.

"It's another example of that council lacking the focus on the issues which matter to their constituents ... making sure they look after the people, not get distracted by these silly ideological debates."

The Town of Port Hedland councillor who put forward the motion, Adrian McRae, ran as a candidate for the Great Australia Party, which campaigned against vaccine mandates at the 2022 federal election.

He made headlines earlier this year over his appearance on Russian state television endorsing the transparency of Vladimir Putin's election victory.

Cr McRae agreed that weighing in on national vaccine policy was not the council's job, but said state and federal governments had failed to take

community concerns about the safety of COVID vaccines seriously.

Councillor Adrian McRae made international headlines in March after appearing on Russian state television endorsing Vladimir Putin. *(ABC News: Charlie Mc Lean)*

Vote doesn't represent community, says Mayor

Mayor Peter Carter and councillor Ambika Rebello were the only two councillors to vote against the motion, which passed 5-2.

"It's not the place for local government to do this sort of work," Cr Carter said.

"They're saying, 'well, it's for the community', well, the community is 17,000 people and we had 50 odd people in the gallery. That does not represent the whole community."

The motion also asked the council's administrators to write to the Prime Minister and national health authorities drawing attention to the issue.

The council's administration warned proceeding with the letter was almost certain to result in extreme reputational and financial impact.

Port Hedland's Mayor said the motion wasn't a good look for the town, which is home to the country's most valuable export terminals. *(ABC News: Charlie Mc Lean)*

Cr Carter said the motion was not a good look for the town.

"You're trying to build relationships with the state government, the federal government," he said.

> **"We're a very important town and this motion that was put forward ... it shouldn't have even been there."**

Cr Carter has faced his own controversies in recent years, including corruption allegations over his personal business dealings, inappropriate comments about a woman's mental health, and is engaged in defamation action against a fellow councillor.

Editor's note 21/10/2024: This article has been updated to provide additional information about claims surrounding COVID-19 vaccines.

Tuesday, 15th October 2024

s22

s22

Document 2

[redacted]

Port Hedland Council carries vaccine contamination motion

Albany Advertiser, Other, 14/10/2024, Cain Andrews

Port Hedland Council has voted to call for the immediate suspension of Moderna and Pfizer COVID vaccines at a special council meeting. on Friday night (October 11). [...] The town's chief executive is also tasked with sending a letter to WA Health Minister Amber-Jade Sanderson and Commonwealth Health Minister Mark Butler requesting public responses to the claims of alleged DNA contamination in Pfizer and Moderna vaccines.

Also reported by: North West Telegraph (Online), Augusta-Margaret River Times (Online), West Australian (Online), South Western Times (Online), Busselton Dunsborough Times (Online), Countryman (Online), Albany Advertiser (Online), Geraldton Guardian (Online), Narrogin Observer (Online), Manjimup-Bridgetown Times (Online), Harvey-Waroona Reporter (Online), Pilbara News (Online), Great Southern Herald (Online), Broome Advertiser (Online), Augusta-Margaret River Times (Online), West Australian (Online)

Read More

s22

[redacted]

s22

Document 2

s22

Document 2

WA Premier tells Port Hedland council 'stick to knitting' after anti-COVID vaccine motion passes

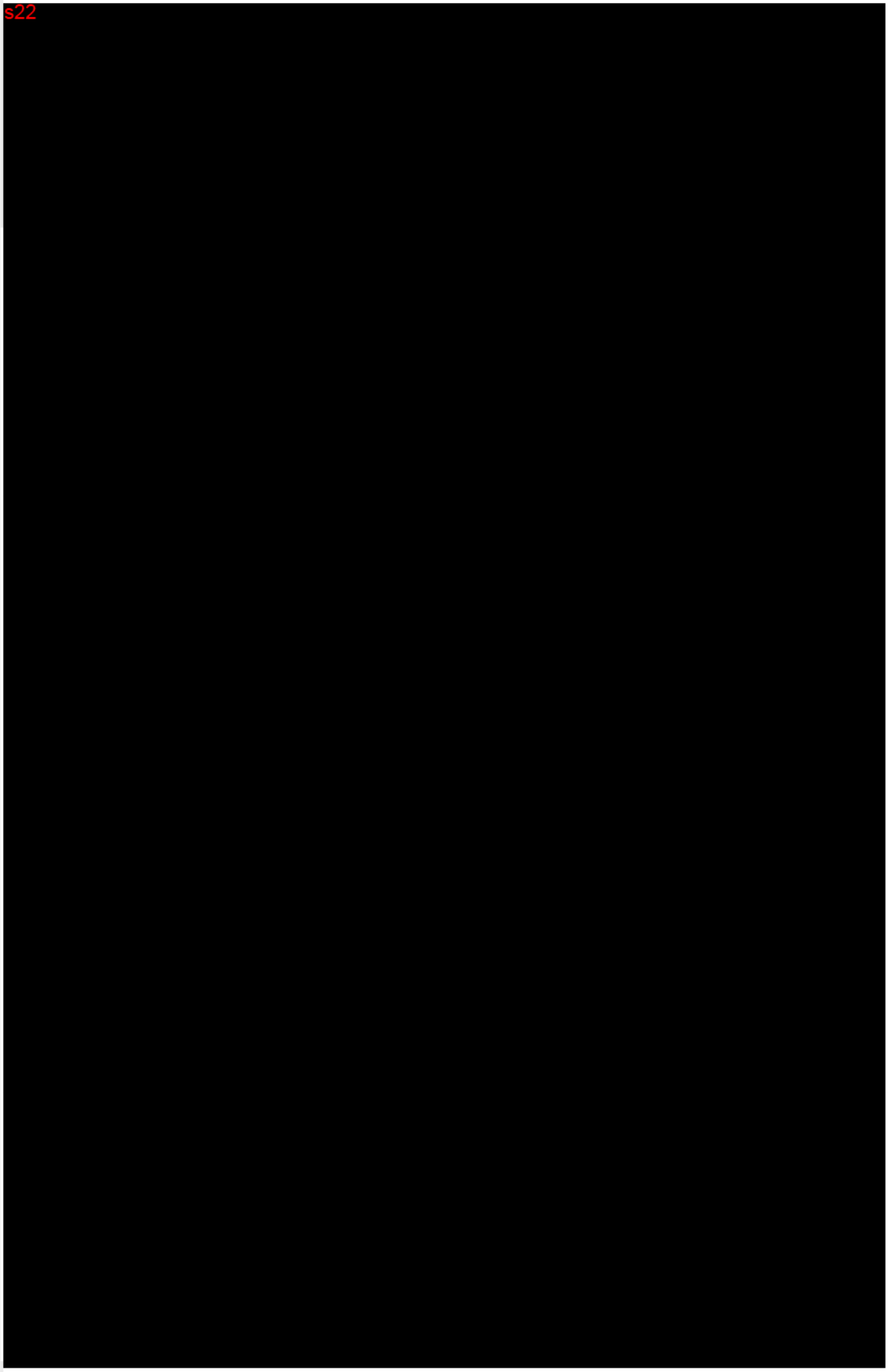
Document 2

ABC Online, Other, 14/10/2024, Charlie Mclean & Jessica Shackleton

The Western Australia Premier has told a council in the state's north to "stick to its knitting" after it passed a motion urging state and federal governments to suspend some COVID-19 vaccinations. [...] The DNA argument surfaced during the pandemic and has been discredited by several international bodies and the Australian Department of Health and Aged Care.

Read More

s22



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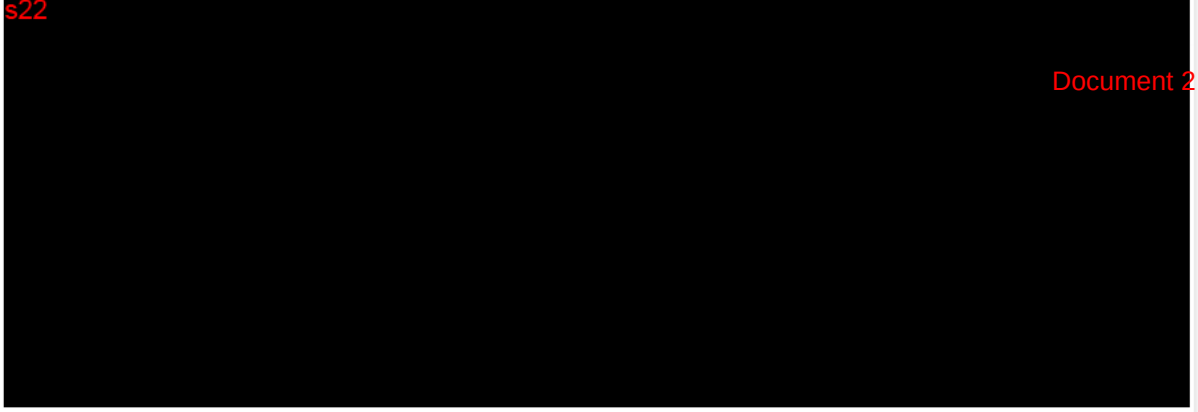


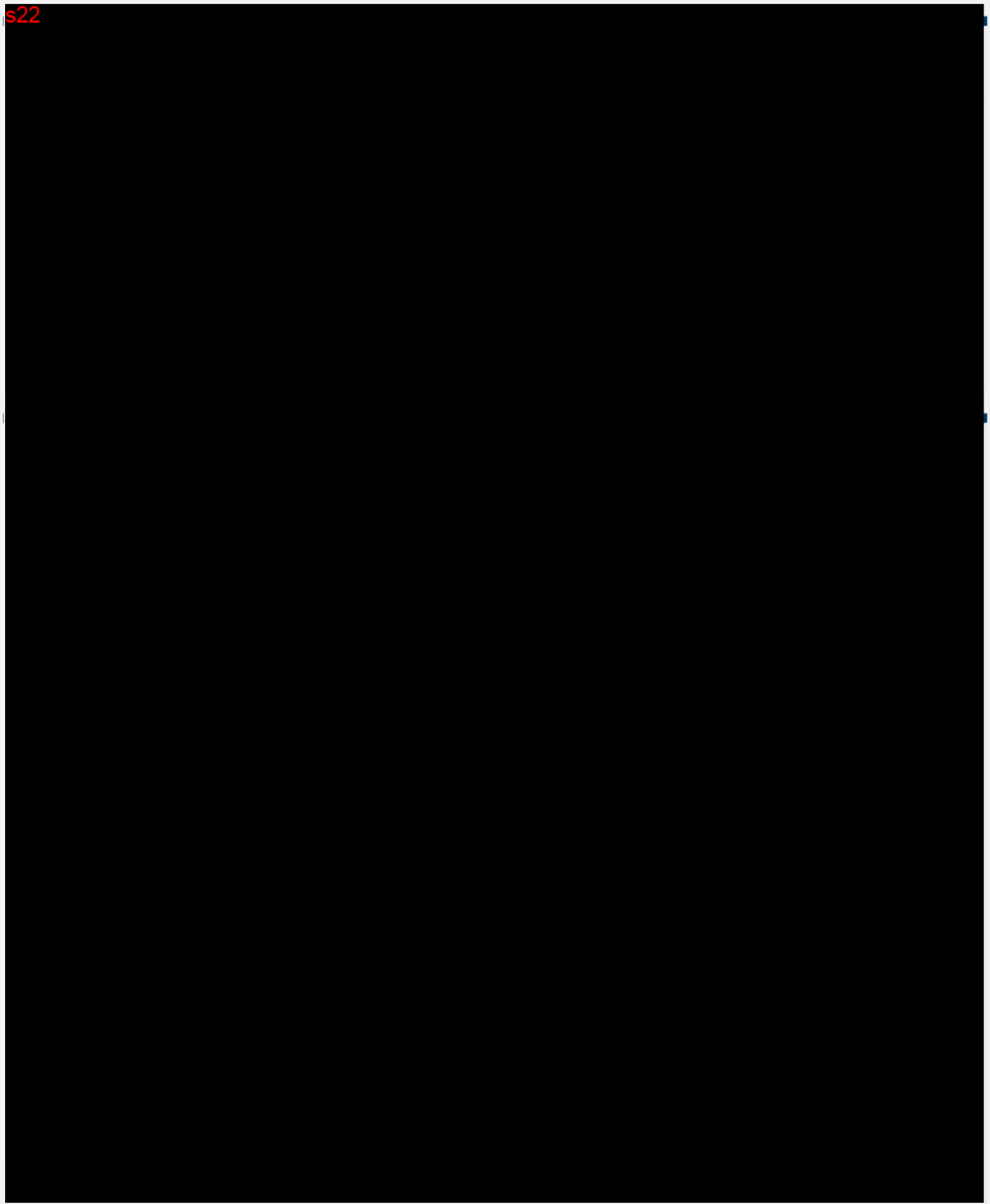
6PR, Afternoons, 14/10/2024, Julie-anne Sprague

The WA Premier has slammed the Port Hedland Council for passing a motion calling for the immediate suspension of COVID-19 vaccines. The motion, tabled by controversial councillor Adrian McRae, is based on a report from a Canadian virologist claiming DNA contamination in the Pfizer and Moderna vaccines can lead to cancer or altered DNA. The report has been debunked by the Therapeutic Goods Administration.

Play Now

Back to Top

s22



s22

Document 2

From: s22
To: s22
Cc: KERR, Lisa; s22
Subject: URGENT: For Input: DRAFT statement for publishing - DNA contamination in mRNA vaccines [SEC=OFFICIAL]
Date: Wednesday, 9 October 2024 5:58:46 PM
Attachments: image001.png

Dear s22 and s22 (s22 and s22),

Lisa has put together a draft statement (for publication), to address enquiries related to DNA contamination in mRNA vaccines (please see TRIM document D24-4291794)
The aim of this publication is so we can refer any future enquiries regarding this subject directly to this statement.

Please review and provide any input with track changes by **10am Thursday 10th October (tomorrow)**. Just to note, we will be seeking input from Tox, PVB and our legal team before it goes out.

Thank you!!

Kind regards

s22

Laboratories Business Operations Section

Medical Devices and Product Quality Division | Health Products Regulation Group
Laboratories Branch
Australian Government Department of Health and Aged Care
T: s22 | E: s22@health.gov.au
Location: TGA, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable and are creating confusion.

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce deaths and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see:
www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports that have been circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are causing the spread of misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—and mRNA which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in COVID-19 vaccines.
- Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method to test residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies used samples that were well past their use by date. Some samples had been opened and used. These samples were not suitable for testing.
- It is unknown where the vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means they may not have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, or accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. These types of accreditation ensures that the results laboratories produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after digestion and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also

independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety
To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for lifetime treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

From:	s22
To:	s22
Cc:	KERR, Lisa; s22
Subject:	RE: URGENT: For Input: DRAFT statement for publishing - DNA contamination in mRNA vaccines [SEC=OFFICIAL]
Date:	Thursday, 10 October 2024 10:05:38 AM
Attachments:	image001.png

Hi all,

We have added some comments to the document for Lisa's consideration.

Thanks

s22

From: s22 @health.gov.au>
Sent: Wednesday, October 9, 2024 5:59 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
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Thank you!!

Kind regards

s22

Laboratories Business Operations Section

Medical Devices and Product Quality Division | Health Products Regulation Group
Laboratories Branch

Australian Government Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted]@health.gov.au
Location: TGA, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From:	s22
To:	s22
Cc:	KERR, Lisa; s22
Subject:	RE: URGENT: For Input: DRAFT statement for publishing - DNA contamination in mRNA vaccines [SEC=OFFICIAL]
Date:	Thursday, 10 October 2024 9:44:58 AM
Attachments:	image001.png

Hi All,

I have provided my feedback using track changes and comments in the TRIM document. It is now checked into TRIM.

Please let me know if anything else is needed.

Regards

s22

From: s22 @health.gov.au>
Sent: Wednesday, October 9, 2024 5:59 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
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Document 7

From: [redacted]
To: HENDERSON, Nick; DUFFY, Tracey
Cc: KERR, Lisa; [redacted] LARTER, Claire; [redacted] AWLER, Tony
Subject: FW: URGENT: All 537 Australian Councils to Receive DNA Contamination Report [SEC=OFFICIAL]
Date: Monday, 14 October 2024 8:39:55 AM
Attachments: image001.png

FYI

[redacted] (Ms/ she/ her)

[redacted] to Deputy Secretary Professor Anthony Lawler

Health Products Regulation Group
Australian Government Department of Health and Aged Care
[redacted] | [redacted] @health.gov.au

This email comes to you from Ngunnawal Country
Location 27 Scherger Drive Fairbairn Level 2

I may send emails out of hours at a time that suits me. I look forward to receiv ng your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Austra ia and their continu ng connection to land sea and community. We pay our respects to them and their cu tures and to all Elders both past and present.

From: [redacted] @Health gov au>
Sent: Monday, October 14, 2024 8:34 AM
To: [redacted] @health gov au>; LAWLER, Tony <Anthony LAWLER@Health gov au>
Subject: FW: URGENT: All 537 Australian Councils to Receive DNA Contamination Report [SEC=OFFICIAL]

For information only.

From: [redacted] @yahoo com au>
Sent: Sunday, October 13, 2024 7:45 PM
To: Minister Butler <Minister Butler@Health gov au>; Minister Sanderson <minister sanderson@dpc wa gov au>; COMLEY, Blair <Blair COMLEY@Health gov au>; andrew robertson_Contact <andrew robertson@health wa gov au>; webservices@pmc gov au; premier@dpc wa gov au
Subject: URGENT: All 537 Australian Councils to Receive DNA Contamination Report

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

All 537 Australian Councils to Receive DNA Contamination report

JULIAN GILLESPIE
OCT 13

READ IN APP

good Substack Folk,

.. this pic is the TLDR

Credit @Jikkyleaks

---

but let me begin by asking ..

.. (please excuse the French)

How do you *piss off* 537 Australian Councils and their over 5,000 Councillors?

first .. you, as part of the Canberra Mob, lock down all their districts in 2020, 2021, and 2022

second .. being the Canberra Mob, you don t ask permission .. you don t pick up the phone to a single Council .. no, being the Canberra Mob, you just pay off all the State and Territory governments to tell the Councils and their Councillors to *heel* .. to *shut up* .. to *obey* .. *obey* the ***experts*** in Canberra .. the Canberra Mob

third .. being the Canberra Mob, orders are sent .. *coerce* .. *coercion* .. *coercing* all the residents of local Council districts to receive experimental gene therapies .. which the Canberra Mob do not tell anyone, are also GMOs

fourth .. you, as the Canberra Mob, send ***more*** orders .. mandate .. mandates .. mandating that a significant number of residents in every Council district **MUST** receive the experimental gene therapies if they want to keep their jobs .. if they want to see Grand Ma & Grand Pa .. while again, not telling anyone the vile vials contain GMOs

.. then later

.. after they forced these liquids into the bodies of over 20 million Australians

.. into the residents of your local Council district

.. the same Canberra Mob learn ***their*** needles contained grotesque amounts of synthetic DNA contamination

synthetic DNA contamination injected ..

---

into the Children of your local area

.. into the Babies born in your local area

Trillions of cancer causing fragments in every shot

.. Trillions of cancer causing fragments multiplied by the over 63 million doses the Canberra Mob *caused* to be injected into the residents of every local Council district across the country

after telling everyone ***they*** .. and only ***they*** .. were **the** health experts

.. but then, a group of ***honest*** experts look .. really look .. at what was in those 63 million shots and find a ***sh*t ton*** of DNA contamination

.. then .. when that Canberra Mob learn about this grotesque DNA contamination from this group of experts, that Canberra Mob says

---

.. NOTHING

---

that, good Substack Folk, is soon going to be the realisation of over 5,000 Australian Councillors

.. soon to learn that Tony Albanese was fully briefed on Australia s DNA contamination crisis by Russell Broadbent MP and others, critical health information impacting all of Australia s local government residents

---

.. and Tony

Don of the Canberra Mob, currently

.. said .. nothing

.. is saying

nothing

---

that, good Substack Folk, is how you *piss off* 537 Councils and their over 5,000 Councillors

---

the ire

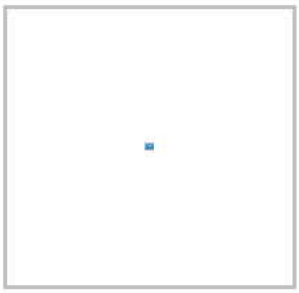
the understandable anger

.. in others, rage

.. a sense of utter betrayal, good Substack Folk, is soon to manifest variously in over 5,000 Australian Councillors, after the successful efforts of Councillor Adrian McRae in Port Hedland Council on Friday night, in helping his neighbouring Councillor colleagues *near and far* to all understand ..

Tony Albanese went MIA on the DNA

.. where's Tony?



.. enter Adrian McRae

Adrian McRae is no slouch .. now a successful industrialist in WA mining after starting with next-to-nothing, Adrian was earlier in the sciences as a specialist in horse medicine, dentistry no less, US qualified years ago, so he is no Johnny-come-lately for those unaware .. a very talented man

having seen the correspondence by Russell Broadbent MP to Tony .. the Prime Minister .. and especially the Science Summary contained in the letter of the 25th of September, Adrian knew more needed to be done

but first he contacted Dr David Speicher to ensure he was clearly understanding the true ramifications of Dr Speicher's DNA contamination findings .. then Councillor McRae made contact with several of the co-signatories and authors of the Science Summary to verify and clearly understand that the consequences, as stated, truly do represent a ***clear and present danger*** to all Australians

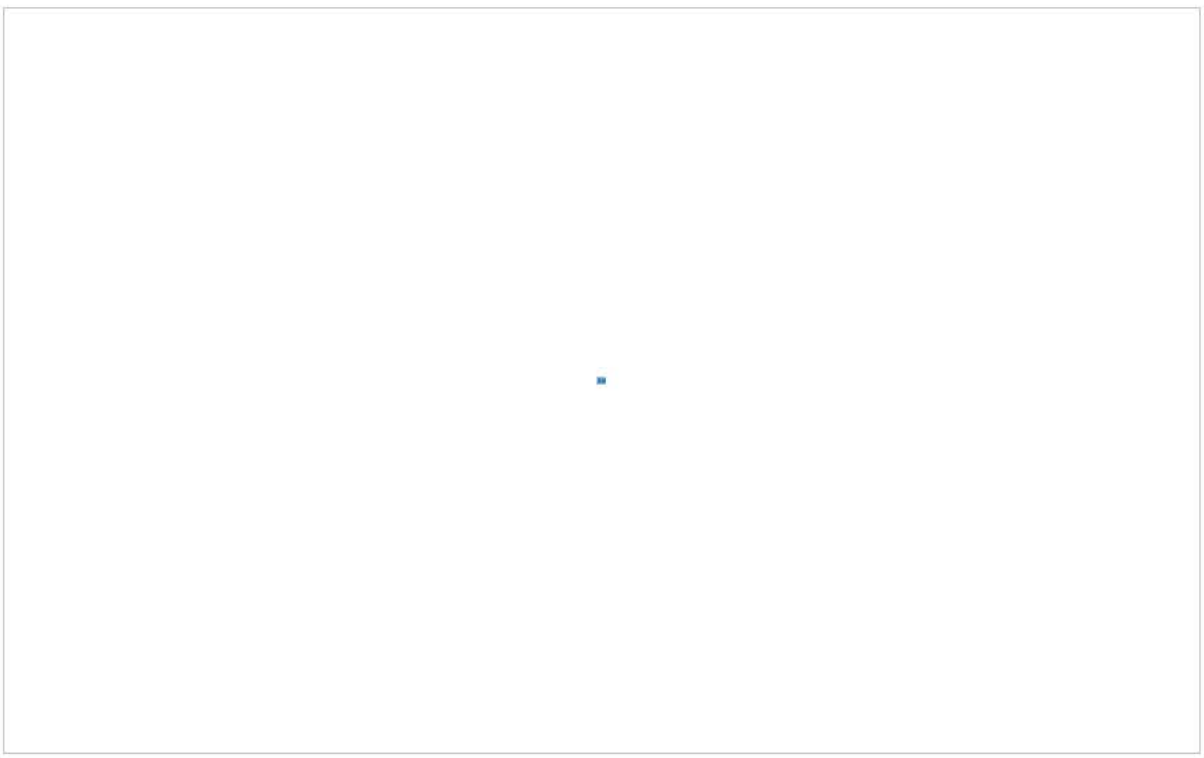
.. a threat that has unfortunately begun to materialise

armed with a thorough understanding of the situation **all** Australians now face .. whether vaxxed or unvaxxed .. as any rapid deterioration in the health of Australians impacts **all** Australians .. Councillor McRae knew the Special Meeting needed more than the Science Summary and contamination findings for getting the message understood in terms we can all understand .. and which the Councillors present needed for thoroughly understanding, so the urgency and purpose of the extensively documented Substantive Motion would become as clear as day

.. that required a Professor of renown who knows their stuff .. we shall return this part later

.. the meeting

video of the entire Special Meeting will be made available on the Port Hedland Council website in coming days HERE .. but for now the meeting can be seen here on Rumble .. thank you **Courage is The Cure**

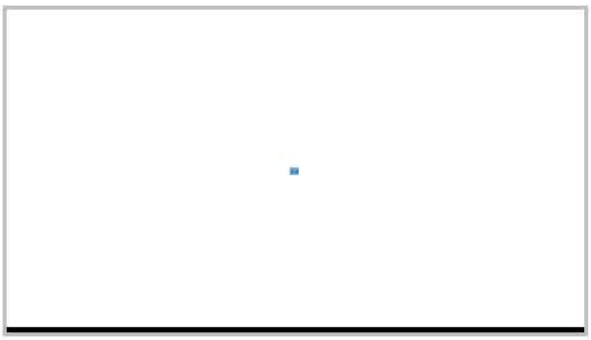


.. and it was a long one - at over 2 hours and 40 minutes - especially for you east coast Folk who stayed up burning the midnight oil

.. the speech for Australia

for mine, and to assist everyone here with *getting to the nub* of Adrian's concern and why this meeting had to go ahead urgently, I have extracted Councillor McRae's speech in support of the Motion .. a little over 10 minutes

.. Albanese .. take notes



.. **but wait** .. let s roll it back a little .. Adrian mentioned Angus Dalgleish

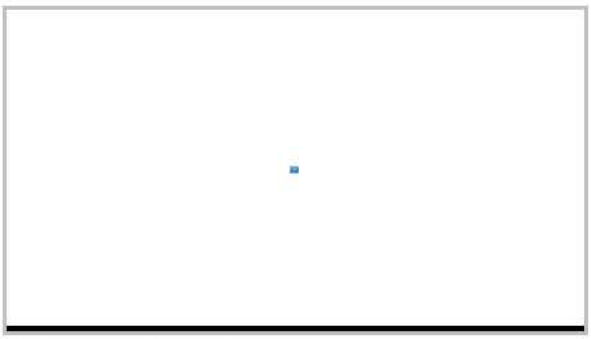
before Councillor McRae delivered this extraordinary speech the meeting was closed to the attending public and online audience for nearly 30 minutes, as Mayor Carter called a *Confidential Session* so Councillors could watch a certain video Councillor McRae had brought along

.. so, what was that video all about?

.. enter Professor Angus Dalgleish

Professor Dalgleish, as the ***lead*** co-signatory of Mr Broadbent s letter of the 25th, stepped-up to break-down the Science Summary that letter contains, for the benefit of Port Hedland Councillors and the attending public

here is what the Councillors were watching during that *Confidential Session* .. an address by Professor Dalgleish



.. I watch this testimony from Professor Dalgleish and here again and again and *again*

---

cancer

cancer

CANCER

---

this is the nature of the elephant in the room Councillor McRae has now - with the successful passing of the Motion - called upon all Australian Councils to see has been shown to the Prime Minister .. Tony .. weeks ago now .. about which Tony and the Canberra Mob are saying nothing

---

nada

zero

zip

.. a high-def version of Prof Dalgleish s video is available HERE

.. next steps

let s get into some of the detail of what the Motion succeeded in achieving for happening next

.. in short, the CEO of Port Hedland is now required to undertake the following:

> **(A)** Deliver the letter seen at **Annexure 1** to the Prime Minister, endorsing the letters of The Honorable Russell Broadbent MP dated 20 and 25 September 2024, in which Council repeats the call for an immediate suspension of the Pfizer and Moderna COVID-19 products under the same terms as expressed by Mr. Broadbent.
>
> **(B)** That Council forthwith circulate to all registered health practitioners and medical clinics operating within the Port Hedland Local Government Area a copy of the letter appearing at **Annexure 2**, to inform all local health practitioners of the report by Dr. Speicher and the findings of the Science Summary attached to Mr. Broadbent s letter of 25 September 2024. The Council strongly urges practitioners to share this information with patients contemplating receiving any Pfizer or Moderna COVID-19 vaccines. The goal is to ensure patients can provide legally valid informed consent. Copies of the letters from Mr. Broadbent MP and Town of Port Hedland to the Prime Minister will be attached.
>
> **(C)** That Council forthwith circulate to all other Australian Local Government Councils and Shires a copy of the letter appearing at **Annexure 3**. This letter will inform all Councils and Shires. about the findings of Dr. Speicher s report and the Science Summary, urging them to share the information with health practitioners and clinics in their areas to facilitate informed consent for their residents.
>
> The letter will attach the letters from Mr. Broadbent MP and the Council's letter to the Prime Minister, urging all other Australian Local Government Councils and Shires to consider sending similar correspondence to the Prime Minister.
>
> **(D)** Contact the Department of Health, Western Australia, and formally present Dr. Speicher s report, the letters from Mr. Broadbent MP, and the Council's letter to the Prime Minister, using a copy of the letter appearing at **Annexure 4**, requesting a public response and advice on steps the Department recommends for patients contemplating the receipt of any further Covid-19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.
>
> **(E)** Contact the Minister for Health of Western Australia, Amber-Jade Sanderson, to formally present Dr. Speicher s report, the letters from Mr. Broadbent MP, Council's letter to the Prime Minister, and Council s letter to all Australian Local Government Councils and Shires, using copy of the letter appearing at **Annexure 5**, seeking the Minister s public response and recommended actions for patients contemplating the receipt of any further Covid-19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.
>
> **(F)** Contact the Commonwealth Department of Health and Aged Care, specifically Deputy Health Secretary Professor Lawler and Health Secretary Blair Comley, presenting Dr. Speicher s report, the letters from Mr. Broadbent MP, Council's letter to the Prime Minister, and Council s letter to all Australian Local Government Councils and Shires, using copy of the letter appearing at **Annexure 6**, requesting a formal and public response from both officials, and recommended actions for patients contemplating the receipt of any further Covid-19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.
>
> **(G)** Contact the Commonwealth Minister for Health and Aged Care, Mark Butler, presenting Dr. Speicher s report, the letters from Mr. Broadbent MP, Council's letter to the Prime Minister, and Council s letter to all Australian Local Government Councils and Shires, using copy of the letter appearing at **Annexure 7**, requesting a formal and public response from Minister Butler, and recommended actions for patients contemplating the receipt of any further Covid-19 vaccines by Pfizer and Moderna, and advice on steps for public health and advice for medical practitioners.

.. all of the Annexures can be viewed HERE

.. but but but .. wait a minute

.. during the Special Meeting those annexures were **amended** to include additional paragraphs for heading-off the canned BS excuses from the TGA and Health Department when asked about this contamination

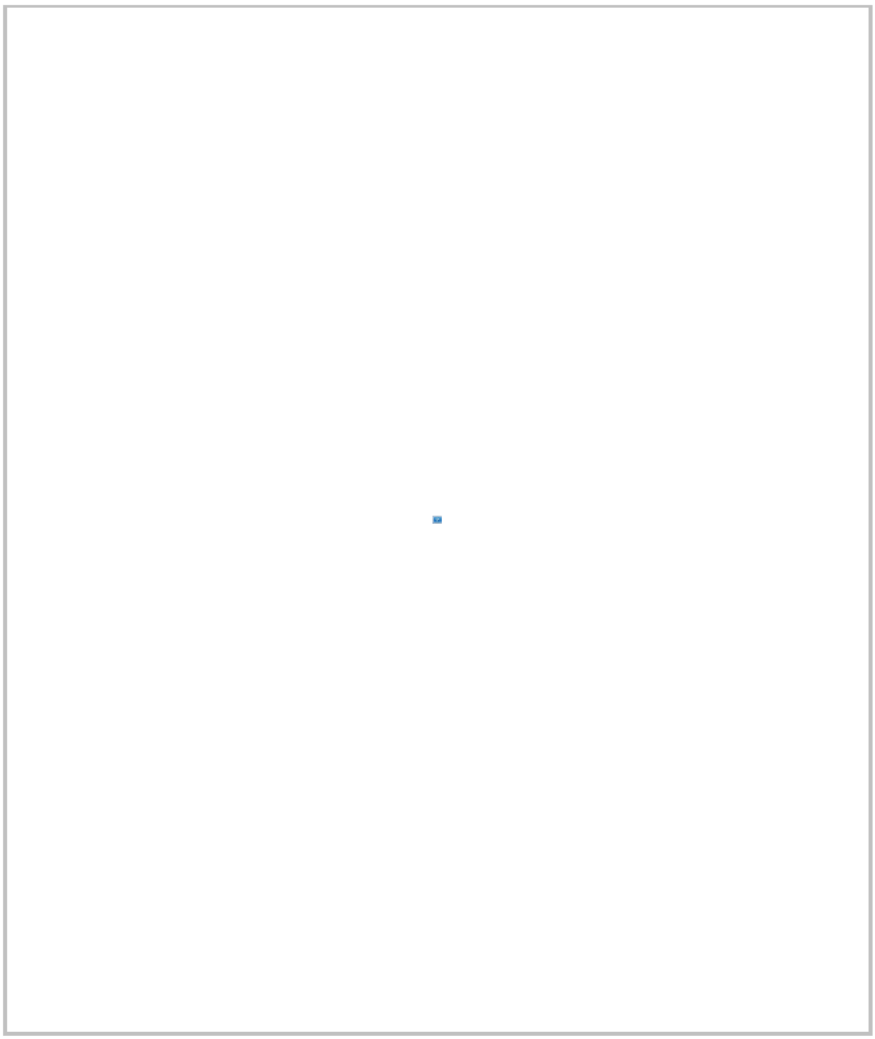
.. the same canned BS they recently flicked back at Rebekah Barnett when she asked the TGA to comment on the report of Dr Speicher

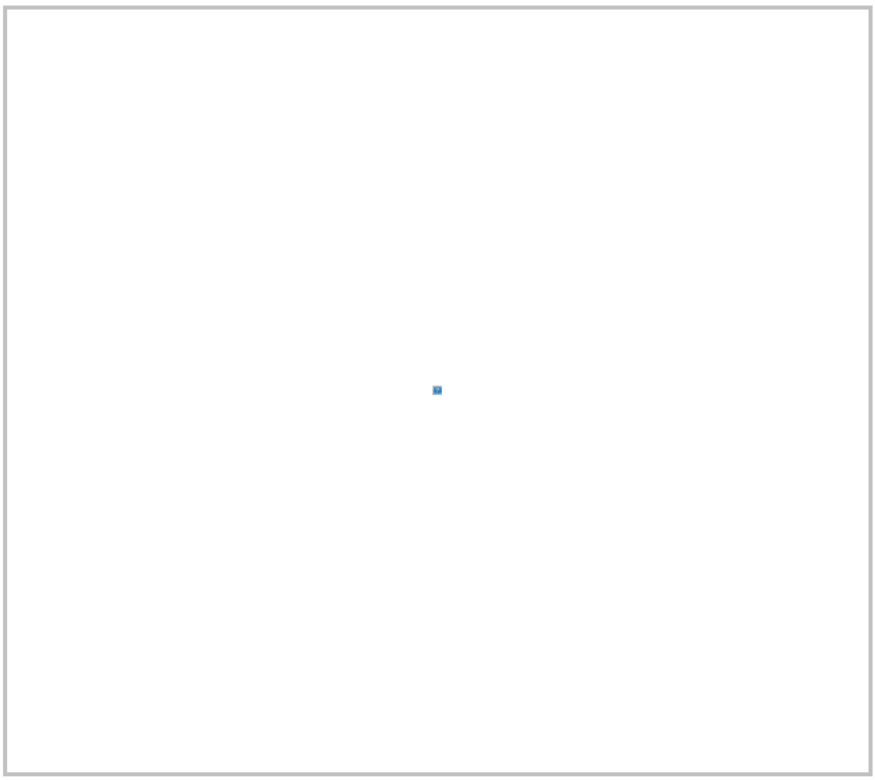
.. well, that BS don t fly no more, and here s why

read the text in RED below to appreciate the problem the TGA has .. and as a consequence, the rest of Australia now has, because of the TGA s incompetence .. or perhaps, intentional acts of deception

.. this RED text in amended **Annexure 1** is common throughout the rest

---





.. a copy of amended Annexure 1 with functional hyperlinks is here

Annexure 1 Amendment Letter To The Austr...

37.6KB · PDF file

Download

---

so you can see what the TGA has not been doing

.. it has not really been testing for DNA contamination

---

instead, these mugs have been using a test for DNA contamination which Moderna told them didn t work

.. yeah, you just read that right

.. yet somehow when Dr David Speicher produces world leading test methods that reveal the synthetic DNA contamination hidden in the LNPs, these mugs at the TGA instead start waving their hands in the air to misdirect everyone with outdated guidelines for validating test processes

---

yet the TGA never followed the same guidelines

the TGA instead has all along been using a test method

Moderna said was rubbish

yet the TGA has the hide to try .. try .. and soy Dr David Speicher's work is rubbish

and not to be relied upon

.. when the only ones performing shyster science are the TGA ..

.. and they know we know it

Councillor Adrian McRae also cottoned on to the grift and BS flowing out of the TGA as spruiked by their media/propaganda department

and Adrian McRae broke this all down at the Special Meeting last Friday, and the Councillors there understood we have a lying TGA that has been caught out .. thus why they agreed to Councillor McRae s mini motion calling for the amendments to get the text in RED inserted above

these last moment amendments were super important, because now all this material is being sent to all 537 Australian Councils, they will all know too what BS ***to not accept*** from the lying and deceitful TGA, which is in nothing but damage control now

---

they've been caught out

---

special *thanks* go to Australia s most intrepid independent investigative journalist, Rebekah Barnett, because it was she who put in the right FOI application with the TGA, that saw them fumble with their black marker redactions, and leave just enough pages exposed for the world to see they are purposefully using the exact DNA contamination test that one of the manufacturers told them not to use

as Hoody and John Larter would say ..

You just couldn t make this stuff up

---

ok .. that s about it for now Folks

I together with Councillor Blanco will be following-up with the Port Hedland CEO to ensure all the letters detailed in Annexures 1 through 7 above get sent properly, and don t end up in some mailbag by the side of the road, or lost to spam folders .. we will keep you apprised

I must admit to labouring under a shell shocking hangover yesterday after tippling a few into the wee hours Friday night with Councillor McRae and Councillor for Karratha, Brenton Johannsen, who did the long drive up to attend the Special Meeting, noting the urgency of the Motion s information, so he came to lend a hand and his voice in support

as too do we hope soon over 5,000 other Councillors will do across Australia .. get revved up if not down right angry as well .. probably enough to tell this Canberra Mob too, that Tony ol boy better get to quickly doing something

yes .. as Angus Dalgleish has made it clear .. we have already entered a health crisis and the Canberra Mob has to get off its collective ass*s and start fixing this mess they have made .. if we are to survive, as a country

thank you .. please share widely, and restack if you can

Buy Me a Coffee$

Jules On The Beach is free today. But if you enjoyed this post, you can tell Jules On The Beach that their writing is valuable by pledging a future subscription. You won't be charged unless they enable payments.

Pledge your support

LIKE COMMENT RESTACK

From: KERR, Lisa
To: s22
Cc: LARTER, Claire; VUCKOVIC, George; s22
Subject: RE: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 6:12:00 PM
Attachments: image002.png
image003.png

Thanks s22 – I've reviewed and accepted almost all of the changes.

s22 and Claire – there are comments in there for you both.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 5:06 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
Subject: RE: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa

Thanks for sending through.

s22 in our comms team has reviewed and provided some comments, suggested edits and structural changes. s22 has alerted the Health media team that this is coming.

Back to you for review and further progression up the line.

Regards
s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 16, 2024 2:08 PM
To: s22 @health.gov.au>
Cc: LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>
Subject: For review : D24-4291794 : DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22

As discussed, the draft statement is attached. It has AS cleared input from Toxicology and input from Claire Larter, SEB BSS and the Laboratories. May you please have a comms specialist review? This has not been past a FAS yet.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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------< Content Manager Record Information >------

Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

From: [redacted]
To: KERR, Lisa
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:26:15 AM

No further changes from me. Its really good!

[redacted]

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>
Cc: [redacted]@Health.gov.au>; [redacted]@health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi all,

Attached is a copy of the draft web statement. I'm about to send it up for clearance. May you please review and let me know if any of it needs to be changed? Ideally I would hope it gets published today….. I would also like to use some of it for a media response due at 2 pm today….Please don't amend the TRIM version – use the attached doc.

FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: s22
To: KERR, Lisa; s22
Cc: s22
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:00:01 AM

Good morning Lisa,

I have read the statement, and it reads very well. No further changes from me.

Regards

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi all,

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FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: s22
To: KERR, Lisa; s22
Cc: s22
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 10:52:57 AM
Attachments: image002.png

Hi Lisa,

I think it adequately represents our position.

s22
Biotherapeutics
Laboratories Branch MDPQD HPRG
s22
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
TGA Tindal Lane, Fairbairn ACT www.tga.gov.au
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: s22
To: s22 KERR, Lisa; s22
Cc: s22
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:29:32 AM

Good morning, Lisa,

No changes from me either.

Kind regards,
s22

From: s22 @health.gov.au>
Sent: Thursday, October 17, 2024 8:00 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Good morning Lisa,

I have read the statement, and it reads very well. No further changes from me.

Regards

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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published today….. I would also like to use some of it for a media response due at 2 pm today….Please don't amend the TRIM version – use the attached doc.

FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: s22
To: KERR, Lisa
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:29:31 AM

Thanks Lisa I should have said it reads great too!

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 9:28 AM
To: s22 @health.gov.au>
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22 – Sample number done, but the sentence with fetal comes from Tox and has been past Comms. Once it is cleared I can ask s22 as it bothered me too.

From: s22 @health.gov.au>
Sent: Thursday, October 17, 2024 9:20 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Subject: RE: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa – only minor suggestions (sorry if it seems picky!)

Page 2
Issues with samples:
Some of these studies use a very small sample number

Page 3
female fertility, foetal

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:42 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi all,

Attached is a copy of the draft web statement. I'm about to send it up for clearance. May you

please review and let me know if any of it needs to be changed? Ideally I would hope it gets published today….. I would also like to use some of it for a media response due at 2 pm today….Please don't amend the TRIM version – use the attached doc.

FYI this has input from SEB Tox and BSS, Pharmacovigilance Branch and our TGA Comms team.

Lisa

From: KERR, Lisa
To: s22
Cc: s22
VUCKOVIC, George
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date: Wednesday, 16 October 2024 3:46:13 PM
Attachments: image003.png
image004.png
image005.png

Thanks s22 – got it. I'm primarily concerned with allaying fears in the public that this is actually something to worry about when it isn't - and that we all agree on what can be said.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

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From: s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 3:12 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>
Subject: FW: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good afternoon Lisa,

Just chiming in to give a bit of clarity on the statements that were provided by the Tox section.

We agree with comments raised by BSS that the original dot point on the role of integrases should be deleted. There are papers implying that other enzymes/mechanisms are involved in

integrating SARS-CoV-2 sequences into the DNA of human cells (see Zhang et al 2021).

The comments and changes that were added by the Tox section were dot points regarding: (i) limits for residual DNA; (ii) the lack of evidence of adverse effects; and (iii) a recommendation to delete the statement on human exposure to foreign DNA.

The first dot point on limits for residual DNA is based verbatim on a previous response provided by the section.

> *"The limit for residual DNA in biological medicines is 10 ng/dose, as recommended by the WHO, US FDA and other regulatory agencies. The safe use of medicines produced by biotechnology in millions of patients for over 40 years demonstrates that residual DNA presents a very low safety risk. There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer."*

Its inclusion was intended to convey that the 10 ng/dose limit is effective at safeguarding against genomic integration (and cancers), evident by the long history of safe use of biotechnology products (including the more recent experiences with mRNA vaccines). There are several published papers that describe an improbable risk of oncogenicity from integration of host cell DNA from biological products, but they are considerably old (e.g. Krause & Lewis, 1998; Yang et al., 2010). In the event that some aspects of the statement are too speculative, we can also omit the following sentence *"There has been no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer."*

We would also like to take this opportunity to simplify the statement on adverse developmental effects, which we will update once the document is checked back into TRIM.

> Original:
> ~~No adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in the combined reproductive and development study in animals administered 200 times the clinical dose of vaccine.~~
>
> Amendment:
> In safety studies (combined reproductive and developmental study in animals), no adverse effects (e.g. impaired male or female fertility, fetal deaths, birth defects, developmental delays) have been noted in in animals administered 200 times the clinical dose of vaccine.

I hope this clarification has cleared up any confusion.

Kind regards,

s22 [redacted]

[redacted] – Toxicology Section
Scientific Evaluation Branch
Medicines Registration Division | HPRG
Australian Government, Department of Health and Aged Care
T: +s22 [redacted] | E: s22 [redacted]@health.gov.au | Location: Melbourne
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country

throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Wednesday, October 16, 2024 11:14 AM
To: KERR, Lisa <
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Thanks for this.

With regard to adding the comment about plasmid DNA entering the human genome, I would be uncomfortable with that as I am unaware of studies which have tested this and so personally I have no experience in the matter.

I note however that s22 has added a comment about their being no evidence of mRNA vaccines or biological medicines resulting in integration of residual DNA into human DNA genome or causing cancer. In this case s22 may be better placed to advise.

Regarding the intergrase dot point in the document, I recommend removal of that comment entirely. I don't believe it is correct and don't believe it adds anything, particularly in light of s22 comment.

Hope is helpful, happy to discuss.

Cheers

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Wednesday, October 16, 2024 6:29 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Thanks for looking at the document – may you please check it in as Claire Larter needs to work on it now.

So from your comments below I take it that if I change the sentence to something like "there is no evidence that plasmid DNA has entered the human genome" that would sit better with you? I've looped s22 into this as it appears that BSS and Tox have different views? Should I

arrange a meeting for us all to discuss?

I also wanted to play devils advocate a little and ask BSS if you were asked by a member of the public who has received a recombinant protein therapeutic good if the products you have approved have altered the human genome, have caused cancer or have lead to transgenic babies - what would you say?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
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From: s22 [redacted] @health.gov.au>
Sent: Tuesday, October 15, 2024 6:08 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Thanks for the call.

I have added some comments, I did rearrange the opening paragraph, I apologise if this is presumptuous on my part.

As noted, you may wish to consider the inclusion of viral gene therapies as examples of products which use high levels of DNA starting material. These are more analogous to the mRNA vaccines in that, for the one I am particularly similar with, large amounts of plasmid DNA are used in production which must be purified away from the therapeutic, in this case the viral vector. They also have the potential to package non-target sequences and be administered to patients. Note

that these do not have as long usage experience as some of the other examples.

Also as noted I do not believe the statement about integrases to be correct. As described below other mechanisms of DNA integration are possible, I would expect these to be rare events particularly in vivo with the cascade of circumstances required.

Hope is helpful.

Cheers

s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Tuesday, October 15, 2024 4:45 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22

Just had a very interesting chat with s22 about all of this – with regards to the specific circumstances that I'm referring to – eg minute amounts of highly fragmented bacterial plasmid. We agreed that to integrate, there would need to be a series of highly improbably events to line up. s22 has kindly agreed to provide some input into the draft statement.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s22 [redacted] @health.gov.au>
Sent: Tuesday, October 15, 2024 2:40 PM
To: s22 [redacted] @health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi s22 [redacted]

Thanks, with regard to the integration issue, foreign DNA can integrate into chromosomal DNA in the absence of an integrase in mammalian cells. This comes from the DNA damage/repair literature where breaks in DNA are repaired through processes called non-homologous end joining or homologous recombination. Exogenous DNA can potentially be incorporated using these processes.

Hope is helpful.

Cheers

s22 [redacted]

From: s22 [redacted] @health.gov.au>
Sent: Tuesday, October 15, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Hi Lisa,

Confirm BSS does evaluate residual host cell DNA as part of the premarket assessment of recombinant products. The accepted limit as mentioned is 10ng/dose and the method is usually qPCR via EP **2.6.35. Quantification and characterisation of residual host-cell DNA**, see attached.

In regard to the statement re DNA integration and the need for integrase suggest this may need to be softened as understand, although unlikely, there are alternative mechanisms for DNA integration. s22 [redacted] may have some additional thoughts/comments re this.

s22 [redacted]
Biological Science Section
Scientific Evaluation Branch

Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted]@health.gov.au

Location: Fairbairn ACT
PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Monday, October 14, 2024 10:41 AM
To: s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; PENGILLEY, Andrew <Andrew.pengilley@health.gov.au>; s22 [redacted]@health.gov.au>
Cc: s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>
Subject: Web statement to address DNA contamination misinformation [SEC=OFFICIAL]

Good morning colleagues,

Laboratories Branch is fielding increasing numbers of allegations about residual DNA contamination in the mRNA COVID vaccines. The latest items are attached (please review these if you haven't already). In response we are drafting a web statement about this misinformation. As can be seen in the attached email, there is a campaign starting up to send a study performed by a Canadian scientist to councils around Australia. We have already responded to an enquiry from one State on this matter. I would like the statement to go on the website in the next couple of days, so your earliest response would be appreciated. Tracey Duffy and Tony Lawler both agree this is an appropriate action to take (happy to hear your views/experiences).

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The mRNA is different from recombinant proteins because the DNA is encapsulated in the LNPs. The residual DNA:

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- Causes cancer
- Has/could result in transgenic babies

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Could you please review the draft web statement (D24-4291794) and make any additions, amendments or suggestions in the document via Track Changes?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

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From:	KERR, Lisa
To:	DUFFY, Tracey; s22
Cc:	s22 VUCKOVIC, George; LARTER, Claire; s22 HENDERSON, Nick; LAWLER, Tony
Subject:	Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date:	Thursday, 17 October 2024 2:09:39 PM
Attachments:	[D24-4399772] Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.DOCX image002.png

Good afternoon,

The comments from Tracey, Nick and Tony have been worked through. The latest clean copy is attached and here: D24-4399772

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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From:	KERR, Lisa
To:	LARTER, Claire; DUFFY, Tracey; s22
Cc:	s22 VUCKOVIC, George; s22 HENDERSON, Nick; LAWLER, Tony
Subject:	RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date:	Thursday, 17 October 2024 3:44:25 PM
Attachments:	image002.png image003.png

Thanks Claire,

Will take a look.

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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From: LARTER, Claire <Claire.Larter@health.gov.au>
Sent: Thursday, October 17, 2024 3:44 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]

Hi Lisa,

I suggested a minor edit in the safety section, and a comment in the first section as I think there

may have been some text missing.

Kind regards,
Claire

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 2:10 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]

Good afternoon,

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Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
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From: s22
To: s22 LAWLER, Tony; DUFFY, Tracey; KERR, Lisa
Cc: s22 VUCKOVIC, George; LARTER, Claire; s22 HENDERSON, Nick; s22 s22
Subject: RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 3:52:03 PM
Attachments: image001.png
image002.png

Thanks s22 /Tracey

No suggested changes from me

Rgds
s22

From: s22 @Health.gov.au>
Sent: Thursday, October 17, 2024 2:59 PM
To: s22 @Health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 @health.gov.au>; s22 s22 @health.gov.au>
Subject: RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]

Good Afternoon s22

Following on from Tracey's phone call, Tracey has asked me to share the Draft Statement - Addressing misinformation about DNA in the mRNA vaccines.

Please note that Tony's flight is scheduled to land around 6pm, he will then provide final clearance when possible.

s22
to Tracey Duffy, First Assistant Secretary

Medical Devices & Product Quality Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
P: +s22

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 2:10 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]

Good afternoon,

The comments from Tracey, Nick and Tony have been worked through. The latest clean copy is attached and here: D24-4399772

Kind regards,

Lisa

Lisa Kerr **PSM PhD MBA (Dr/she/her)**
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

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From: s22
To: KERR, Lisa
Cc: s22
Subject: RE: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Friday, 18 October 2024 2:14:21 PM
Attachments: image001.png
image002.png
image004.gif
image005.png
image006.png

Thanks Lisa.

I've now published the statement: https://www.tga.gov.au/news/media-releases/addressing-misinformation-about-excessive-dna-mrna-vaccines

Regards,

s22

, Web publishing
Web Experience Section | HPRG Digital Transformation Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: 27 Scherger Drive Canberra Airport, ACT 2609
PO Box 100, Woden ACT 2606, Australia

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From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 1:34 PM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: For publishing : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi s22

I understand you are expecting the attached statement for publishing on the website – please find below Tony's clearance. Please note that there is a link and a date to be inserted – both are highlighted.

Would you please let me know once it is live?

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
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Medical Devices and Product Quality Division
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From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Friday, October 18, 2024 1:22 PM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Thanks Lisa
Looks great!
No further changes from me
T

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Friday, October 18, 2024 11:14 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Cc: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Tony,

Final statement attached as promised.

Lisa

------< Content Manager Record Information >------

Record Number: D24-4399772
Title: Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

Document 19

From:	KERR, Lisa
To:	s22 LARTER, Claire; PENGILLEY, Andrew; s22
Cc:	s22
Subject:	Web statement to address DNA contamination misinformation [SEC=OFFICIAL]
Date:	Monday, 14 October 2024 10:41:27 AM
Attachments:	241009 - LOD to Min. Butler Re DNA.pdf FW URGENT All 537 Australian Councils to Receive DNA Contamination Report SECOFFICIAL.msg Science Summary Consequences of DNA.docx image002.png

Good morning colleagues,

Laboratories Branch is fielding increasing numbers of allegations about residual DNA contamination in the mRNA COVID vaccines. The latest items are attached (please review these if you haven't already). In response we are drafting a web statement about this misinformation. As can be seen in the attached email, there is a campaign starting up to send a study performed by a Canadian scientist to councils around Australia. We have already responded to an enquiry from one State on this matter. I would like the statement to go on the website in the next couple of days, so your earliest response would be appreciated. Tracey Duffy and Tony Lawler both agree this is an appropriate action to take (happy to hear your views/experiences).

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PJ O'Brien & Associates
PO Box 916
The Junction
NSW 2291

9 October 2024

U R G E N T

Minister for Health
Parliament House
Canberra
ACT 2600

BY EMAIL ONLY:
minister.butler@health.gov.au

Attention: The Hon. Mark Butler MP

Dear Minister Butler

Urgent Request for Suspension of Pfizer and Moderna COVID-19 Vaccines Due to Synthetic DNA Contamination

1. We write to you on behalf of Dr. Julian Fidge to urgently address the significant health and safety risks posed by the synthetic DNA contamination discovered in Pfizer and Moderna's COVID-19 vaccines. These findings, documented in the 9 September 2024 report by Dr. David Speicher, commissioned by our firm with provenance and chain of custody evidenced, reveal contamination levels that grossly exceed the regulatory limits set by the Therapeutic Goods Administration (**TGA**), posing unacceptable risks to the Australian population.

2. We understand that you are already familiar with the findings of Dr. Speicher's report, as they have been brought to the attention of the Prime Minister in letters from Mr. Russell Broadbent MP dated 20 and 25 September 2024, which included a Science Summary prepared by a coalition of eminent scientists. This Science Summary attached to the letter of 25 September details the well-established risks posed by synthetic DNA contamination and highlights the urgent need to act.

Findings of Dr. Speicher and Public Health Risks

3. Dr. Speicher's report confirms that both Pfizer's and Moderna's COVID-19 products contain excessive amounts of synthetic DNA, with contamination levels ranging from 7 to 145 times the allowable limit of 10 nanograms per dose. These findings represent an extraordinary public health risk, further corroborated by international studies in Germany, Canada, and the United States, that have similarly identified contamination in Pfizer and Moderna vaccines.

4. The contamination includes Simian Virus 40 (SV40) sequences in Pfizer's products, a viral sequence long known to present significant risks of cancer through insertional mutagenesis. It is well-established in scientific literature that as few as 3-to-10 SV40 fragments are enough to integrate foreign DNA into human cells, significantly increasing the risk of cancer. Dr. Speicher's findings indicate that a single dose of Pfizer's vaccine may contain as many as 575 billion SV40 fragments. Such contamination cannot be dismissed, especially given that 24 trillion synthetic DNA fragments could be present in just one shot, which drastically heightens the risk of serious long-term health consequences for the more than 20 million Australians who have received these products.

Legal Issues: Genetically Modified Organisms (GMOs)

5. As you may be aware, these findings further support claims currently before the Federal Court that Pfizer's and Moderna's COVID-19 vaccines are genetically modified organisms (**GMO**) under the *Gene Technology Act 2000* (Cth). Neither company has obtained the necessary licenses to deal with GMOs in Australia. The fact that this contamination represents unlicensed GMOs only compounds the gravity of the situation. The synthetic DNA contamination in both companies' vaccines constitutes another form of GMO that would have been prohibited from importation and licensed use in Australia, given the well-documented risks outlined in the scientific literature.

6. The Science Summary elaborates on these risks and provides substantial evidence that synthetic DNA contamination of this magnitude represents a serious threat to human health and life.

Failure of the TGA to Act and the Need for Immediate Ministerial Leadership

7. The TGA has failed to adequately address these safety issues. It has sought to dismiss Dr. Speicher's findings on the basis that they do not comply with ICH Q2(R2)

guidelines. However, these guidelines are inapplicable to synthetic DNA contamination in modRNA platforms, which is the technology used in both Pfizer's and Moderna's vaccines. Furthermore, the TGA's internal processes, as revealed by FOI 5286, are inadequate, as they only test for fragments of plasmid DNA, such as the Kanamycin Resistance Gene (Kan Gene), rather than addressing the full scope of the synthetic DNA contamination. The bulk of this contamination - fragments under 200 base pairs - has gone untested by the TGA, yet these fragments have been shown by Dr. Speicher and other labs abroad to constitute the majority of the contamination.

8. Moderna and Pfizer cannot rely on the TGA's failures to shield themselves from liability. It is clear that the TGA has not employed the appropriate methods to detect the full extent of the synthetic DNA contamination, and the onus now falls on your office to act in the best interests of the Australian public.

Call to Action

9. In light of this alarming evidence, it is incumbent upon you as Minister for Health to take immediate action to suspend the use of Pfizer's and Moderna's COVID-19 products. The widespread and severe contamination identified in Dr. Speicher's report presents ***clear and present dangers*** to public health, which includes our family members, children, and likely ourselves.

10. The TGA's paralysis in this matter leaves Australia's population vulnerable to further harm, and it is now your responsibility to lead the national response.

11. Furthermore, we call upon you to:

    a. Immediately suspend the distribution and administration of Pfizer and Moderna COVID-19 products until further testing can be conducted by independent laboratories using the methods outlined by Dr. Speicher.

    b. Ensure that the TGA and other relevant agencies secure a sufficient quantity of vials for independent testing, to verify the contamination's pervasiveness and assess the impact on the Australian population.

    c. Initiate a public health campaign to inform Australians about the contamination and advise those who have received these vaccines, particularly those who have experienced adverse effects or whose loved ones have died unexpectedly after vaccination.

12. Finally, we urge you to involve the Office of the Gene Technology Regulator (OGTR) to confirm whether the presence of synthetic DNA in these products contravenes Australia's GMO laws and ensure that any future vaccine imports adhere to all necessary legal and regulatory standards.

Conclusion

13. Minister, the evidence before you is irrefutable and demands an immediate response. The lives and health of millions of Australians are potentially at risk. We ask that you take immediate, decisive action to mitigate any further harm and to ensure that the public is informed of the potential dangers associated with these products. The eminent scientists who contributed to the Science Summary attached to Mr. Broadbent's letter stand ready to assist your office in any scientific or public health investigations moving forward.

14. We look forward to your urgent response and confirmation that steps are being taken to safeguard the public.

Yours faithfully

Peter O'Brien
Principal
PJ O'Brien & Associates
pj@pjob.com.au
+41 411 045 456

Katie Ashby-Koppens
Lawyer
PJ O'Brien & Associates
katie@pjob.com.au
+61 435 791 200

CC:
Blair Comley PSM
Secretary of Health
blair.comley@health.gov.au

Professor Anthony Lawler
Deputy Secretary
Department of Health and Aged Care
anthony.lawler@health.gov.au

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

---

[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

---

[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.

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

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

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

Australian Government

Department of Health and Aged Care

Ref No: MC24-015695

Mr Peter O'Brien and Ms Katie Ashby-Koppens
PJ O'Brien & Associates
pj@pjob.com.au

Dear Mr O'Brien and Ms Ashby-Koppens

Thank you for your correspondence of 9 October 2024 to the Minister for Health and Aged Care, the Hon Mark Butler MP, regarding your request to suspend the use of Pfizer and Moderna COVID-19 vaccines. The Minister has asked me to reply.

The Therapeutic Goods Administration (TGA) is aware of the report you commissioned from Dr David Speicher that claims the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. The TGA has released a media statement to assure the Australian public that the COVID-19 mRNA vaccines are safe and do not contain excessive amounts of DNA. The statement can be found on the TGA's website: www.tga.gov.au/news/media-releases/addressing-misinformation-about-excessive-dna-mrna-vaccines. This statement addresses many of the concerns you have raised in your letter. I have also attached published letters from the United States Food and Drug Administration and the Paul Erlich Institute in Germany responding to residual DNA allegations.

We note that Dr Speicher used both pPCR and fluorometry, and that only the fluorometry results have received attention. We are also aware that Dr Speicher attempted to reduce the crosstalk from mRNA in the fluorometry test using RNAse. It is likely that there is still crosstalk from small fragments of mRNA after digestion with the RNAse, and therefore it is important to know if Dr Speicher validated the method to demonstrate that the RNAse has indeed reduced interference in the test. This would need to be written in alignment with *ICH Q2 (R2) Validation of Analytical Methods*, or another similar guideline, to ensure robustness and reliability of the method.

The plasmids used in production of the mRNA vaccines are commonly used in the manufacture of biotechnology-based medicines. In line with the internationally recognised guidance, residual plasmid DNA is considered a lower risk as it is fully characterised, is not from a human cell line, and contains no oncogenes. Some of these plasmids contain smaller sequences of the SV40 virus. They do not encode proteins and have not been shown to pose a safety risk. Similarly, smaller residual DNA fragments of 200 base pairs or less are smaller than a functional gene. There is currently no evidence that residual DNA is associated with any adverse event.

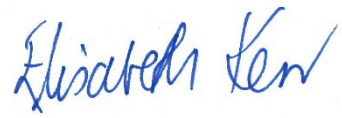
You have noted that there are claims currently before the Federal Court regarding the assertion that the Pfizer and Moderna mRNA vaccines are allegedly genetically modified organisms (GMOs). The Office of the Gene Technology Regulator has definitively declared that this assertion is not the case (www.ogtr.gov.au/resources/publications/addressing-misinformation-regulation-mrna-vaccines). We are aware that Dr Fidge's claim in the Federal Court of Australia was dismissed in March 2024, and publicly available information indicates that Dr Fidge's appeal was withdrawn and finalised in August 2024. There does not appear to be any other cases related to this topic currently before the Federal Court.

Thank you for providing the Science Summary. While the article presents an interesting perspective, it lacks the necessary rigor and supporting evidence to substantiate many of its claims. Many key statements are presented without proper citations, making it difficult to assess their validity. Additionally, some points appear to selectively draw from the literature potentially misrepresenting the broader consensus or ignoring conflicting data. Therefore, it is difficult to draw a balanced conclusion from this document.

Real-world evidence has demonstrated that COVID-19 vaccines significantly reduce the risk of severe disease, hospitalisation and death from infection with SARS-CoV-2. Evidence from the more than 13 billion doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

Thank you for writing on this matter.

Yours sincerely



Lisa Kerr PSM PhD MBA
Assistant Secretary
Laboratories Branch
Health Products Regulation Group
7 November 2024

Encl (2)

cc: Minister Butler

U.S. FOOD & DRUG ADMINISTRATION

December 14, 2023

Joseph A. Ladapo, MD, PhD
State Surgeon General
Florida Department of Health
4052 Bald Cypress Way, Bin A-00
Tallahassee, FL 32399-1710

Dear Dr. Ladapo,

This is in response to your letter of December 6, 2023, regarding the mRNA COVID-19 vaccines. In your letter, you raise the concern that SV40 promoter/enhancer DNA is present in these vaccines and that this raises safety concerns.[1] **We would like to make clear that based on a thorough assessment of the entire manufacturing process, FDA is confident in the quality, safety, and effectiveness of the COVID-19 vaccines.** The agency's benefit-risk assessment and ongoing safety surveillance demonstrate that the benefits of their use outweigh their risks. Additionally, with over a billion doses of the mRNA vaccines administered, no safety concerns related to residual DNA have been identified. Responses to each of your three specific questions follow below:

1. **In response to the question regarding potential genotoxicity of the mRNA COVID-19 vaccines:** No SV40 proteins are encoded for or are present in the vaccines. On first principle, it is quite implausible that the residual small DNA fragments located in the cytosol could find their way into the nucleus through the nuclear membrane present in intact cells and then be incorporated into chromosomal DNA.[2] Additionally, studies have been conducted in animals using the modified mRNA and lipid nanoparticle together that constitute the vaccine, including the minute quantities of residual DNA fragments left over after DNAse treatment during manufacturing, and demonstrate no evidence for genotoxicity from the vaccine.[3] Pharmacovigilance data in hundreds of millions of individuals also indicate no evidence indicative of genotoxicity.

2. **Regarding whether FDA considers the lipid nanoparticle delivery system in setting the safe levels of DNA in the mRNA vaccine:** The agency has taken into account the totality of the mRNA COVID-19 vaccine product, including the lipid nanoparticles, as it reviewed the manufacturers' specifications for residual DNA fragments present. Any contamination with residual DNA fragments is monitored routinely as a product specification.

3. **Regarding concern for possible integration of the residual DNA fragments into reproductive cells:** Please see the response to the first question above regarding the implausibility that the minute amounts of small DNA fragments present could find their way into the nucleus of these cells. Additionally, reproductive toxicology studies have been conducted to evaluate the mRNA COVID-19 vaccines and have found no concerns.

[1] In your letter, you raise questions, citing to the 2007 Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications. This guidance was developed for DNA vaccines themselves, not for DNA as a contaminant in other vaccines, and is not applicable to the mRNA COVID-19 vaccines.
[2] The Nuclear Envelope and Traffic between the Nucleus and Cytoplasm - The Cell - NCBI Bookshelf (nih.gov);
[3] https://www.fda.gov/media/151733/download?attachment; https://www.fda.gov/media/155931/download?attachment

Perpetuating references to this information about residual DNA without placing it within the context of the manufacturing process is misleading. Therefore, we hope the following general explanation of the manufacturing process for these vaccines will be helpful.

The starting material for the manufacture of the mRNA portion is a DNA template. As part of the purification process during production, the mRNA is treated with DNAse to digest residual DNA. There are internationally agreed upon recommendations for the quantity of residual DNA present in all biological products, including the mRNA vaccines.[4] The specification for the COVID-19 mRNA vaccines for residual DNA following DNAse treatment results in the presence of DNA fragments at a quantity that is less than three orders of magnitude lower than the quantity of the RNA dose by weight. This has been determined (and continues to be determined during production of lots) with a validated quantitative PCR assay.

No SV40 proteins are encoded by the nucleotide sequences present in the mRNA vaccines. The treatment of the products with DNAase also fragments any residual DNA template that might be present after other manufacturing steps. Thus, as noted above, following manufacture of the mRNA COVID-19 vaccines, no DNA encoding SV40 proteins is present in the residual DNA remaining in the products.

Additionally, animal studies with the mRNA delivery technology done over the past decade show no evidence of genotoxicity. Moreover, we now have access to global surveillance data on over one billion doses of the mRNA vaccines that have been given, and there is nothing to indicate harm to the genome, such as increased rates of cancers.

FDA takes its responsibility for ensuring the safety, effectiveness and manufacturing quality of all vaccines licensed in the U.S., including the mRNA COVID-19 vaccines, very seriously. We stand firmly behind our regulatory decision making with the authorizations and approvals of the COVID-19 vaccines, which have a highly favorable safety profile, and which have saved, and continue to save, many lives.

The challenge we continue to face is the ongoing proliferation of misinformation and disinformation about these vaccines which results in vaccine hesitancy that lowers vaccine uptake. Given the dramatic reduction in the risk of death, hospitalization and serious illness afforded by the vaccines, lower vaccine uptake is contributing to the continued death and serious illness toll of COVID-19.

We hope the information provided addresses your concerns and those of your constituents.

Sincerely,

Peter Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and Research

[4] WHO (World Health Organization) Meeting Report Study group on cell substrates for production of biologicals. June 11 and 12, 2007; 1–30; FDA Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications | FDA. U.S. Department of Health and Human Services, Food and Drug Administration Center for Biologics Evaluation and Research, February, 2010.

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Langen, 22.12.2023

Information for Healthcare Professionals

TESTING OF COVID-19 mRNA VACCINES

Methodology for Testing COVID-19 mRNA Vaccines for Alleged Contaminants

Due to a large number of inquiries from healthcare professionals, the Paul-Ehrlich-Institut would like to provide information on the current developments regarding alleged contaminants in vaccines. This information should also serve to inform both unsettled patients and those willing to vaccinate.

A large share of the data and studies on suspected contamination of COVID-19 mRNA vaccines circulating in the public are based on methodological deficiencies. There is also the issue of potentially improper storage of the vaccine doses tested. Experimental determinations, e.g. to test for residual third-party DNA in vaccine doses available on the market, must meet the following criteria in order to produce scientifically valid results:
(i) They must not be taken using samples from expired (expiration date exceeded) vaccine vials or from opened or improperly stored vaccine vials.
(ii) The methodology used to determine the amount of residual DNA must be demonstrably suitable and comprehensible – in particular, test interference should be ruled out by the presence of lipid nanoparticles in the vaccine vials (which cannot be guaranteed when tested on the final vaccine vial).
(iii) The method used must be validated to provide reliable and verifiable results.

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In the frequently cited preprint publications by McKernan et al. (April 2023)[1] and Speicher et al. (October 2023)[2], there is a lack of sufficient information as to whether the aforementioned conditions have been met, as well as information on the comprehensibility of the chosen methodology. Method validation is essential to ensure that reliable and reproducible results are achieved at all times with the implementation of the method used, regardless of the person performing it, and that the method is suitable for its intended purpose. Manufacturers comply with the above-mentioned conditions for obtaining scientifically tenable measurement results in residual DNA determinations.

Part of the plasmid DNA serves as a template for the production of the COVID-19 mRNA vaccines. After transcribing the relevant DNA sequence into mRNA, the plasmid DNA is then comminuted by means of enzymatic digestion with DNase and depleted via the purification process to obtain the active substance (mRNA). However, a residual amount of plasmid DNA is present in small amounts that are considered harmless below a threshold specified in the marketing authorisation. To date, there is no evidence to suggest that any adverse events could be associated with residual DNA levels in authorised COVID-19 mRNA vaccines.

The Paul-Ehrlich-Institut would like to explicitly state that no DNA from cells of animal origin is used in the production of COVID-19 mRNA vaccines. Exclusively plasmid DNA of bacterial origin is used in the production process. Possible risks that could arise from residual animal cell DNA are a potential tumourigenicity due to the transmission of proto-oncogenes and potential DNA infectivity due to the transmission of completely functional viral genes. These risks are not present with DNA of bacterial origin. In this context, the WHO guideline "Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks" and the US FDA guideline "Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications" are not used for the production of mRNA vaccines. This is due to the fact that both guidelines explicitly refer to cells of animal origin, not to

[1] McKernan Kevin, Helbert Yvonne, Kane Liam T, McLaughlin Stephen (April 2023): Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose.
[2] Speicher David J, Rose Jessica, Gutschi L. Maria, Wiseman David M, McKernan Kevin (October 2023): DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events.

bacterial cell substrates. Bacterial cells are expressly excluded from the guidelines.

Irrespective of this, the regulatory principle applies that as few contaminants as possible should be present in a vaccine and even theoretical risks should be reduced as far as possible. Therefore, very conservative limits for residual DNA have been set for the authorised COVID-19 mRNA vaccines and they may not be exceeded. Both residual bacterial genomic DNA and residual plasmid DNA are tested in the course of the production process. The fragmentation of plasmid DNA via DNase treatment of the mRNA, as it is done in the authorised COVID-19 mRNA vaccine products, provides additional safety, because even if complete and functional genes were contained, they would be almost completely degraded by DNase digestion during production and thus rendered harmless. This is because small DNA fragments are considered harmless as they cannot code for functional proteins (FDA Guidance for Industry (2010): "Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications").

The testing for residual DNA is not part of the official experimental OMCL (Official Medicines Control Laboratory) testing for batch release. Experimental OMCL testing of samples of each authorised vaccine batch includes the product-specific laboratory efficacy (potency) and safety parameters identified as relevant based on the evaluation of the vaccines in the authorisation process. The decision regarding the parameters to be reviewed is made in parallel with and based on the content of the benefit-risk assessment of each vaccine candidate as part of the authorisation process. This decision is the responsibility of the OCABR (Official Control Authority Batch Release) network and is based on a scientific consensus of the official experts. They identify and determine within an official procedure the product-specific critical test procedures, test parameters, and release criteria to be reviewed in the laboratory that are relevant to the efficacy and safety of an authorised vaccine product. The decision is evidence-based and scientifically substantiated as it is based on data and findings collected as part of the development process and reviewed in the authorisation process.

In addition to the experimental testing of the specified efficacy and safety parameters by the official testing laboratories (OMCL), testing of the manufacturing documentation (Lot Release Protocol, LRP) is also part of the scope of the official batch release. The OMCL checks the results of the experimental batch tests carried out by the manufacturer with regard to whether all

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critical parameters specified in the marketing authorisation and their thresholds (specifications) have been complied with. The analytical methods used by manufacturers to determine residual amounts of DNA in COVID-19 mRNA active substances are described in the authorisation dossiers of the authorised mRNA vaccine products. Their validity is checked in accordance with guidelines from ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and proven on the basis of the data provided. Each batch of the vaccine product Comirnaty is tested for residual DNA and the results are part of the manufacturer's batch release protocol, which is independently assessed by the authorities as part of the official batch testing process (OCABR). When it comes to federal batch release in Germany, the test data collected by the manufacturer using a defined and validated method are cross-checked by the Paul-Ehrlich-Institut before the Institute carries out a federal batch release for Germany.

Residual plasmid DNA quantities are deliberately tested on the active substance of the COVID-19 mRNA vaccines (drug substance) and not on the final product (drug product). This is the only way to rule out possible test interference by lipid nanoparticles (LNPs), which are only present in the final product. In the production steps between the production of the active ingredient and the production of the final product, no more DNA can enter the process or the product. This means that no increase in the DNA content per vaccine dose is possible during the production of the final vaccine doses from the active ingredient. Testing the residual DNA on the active substance is therefore more sensitive and representative of the DNA content of the final vaccine product.

From: DUFFY, Tracey
To: KERR, Lisa; HENDERSON, Nick
Cc: s22 LAWLER, Tony; s22 LARTER, Claire; VUCKOVIC, George; s22
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:19:39 AM
Attachments: image001.png

Thanks – I have had a quick look and provided some comments/questions in the TRIM file to try and tighten our points.

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 8:56 AM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
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Would you both please provide clearance for publication (or amendments…)

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:38:43 AM
Attachments: image001.png

Ok I've had a go at fixing/responding….

From: DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Sent: Thursday, October 17, 2024 9:20 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
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Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)

Assistant Secretary | Laboratories Branch
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Cc: s22 LARTER, Claire; VUCKOVIC, George; s22
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:49:35 AM
Attachments: image001.png
image001.png

Hi
Is the intent to get this online today? I will have TRIM access in a few hours and can have a look at it then.
Thansk
T

Sent from Workspace ONE Boxer
On 17 October 2024 at 6:38:43 am GMT+8, KERR, Lisa <Lisa.Kerr@health.gov.au> wrote:

> Ok I've had a go at fixing/responding….
>
> ---
>
> **From:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>
> **Sent:** Thursday, October 17, 2024 9:20 AM
> **To:** KERR, Lisa <Lisa.Kerr@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
> **Subject:** RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
>
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>
> ---
>
> **From:** KERR, Lisa <Lisa.Kerr@health.gov.au>
> **Sent:** Thursday, October 17, 2024 8:56 AM
> **To:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
> **Cc:** s22 @health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>
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Good morning Nick and Tracey,
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Would you both please provide clearance for publication (or amendments…)
Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

------< Content Manager Record Information >------

Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

[SEC=OFFICIAL]

From: KERR, Lisa
To: LAWLER, Tony; DUFFY, Tracey; HENDERSON, Nick
Cc: s22 [redacted] LARTER, Claire; VUCKOVIC, George; s22 [redacted]
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 9:55:11 AM
Attachments: image004.png
[D24-4291794] DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.DOCX

Hi Tony – e copy attached

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Sent: Thursday, October 17, 2024 9:50 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

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------< Content Manager Record Information >------

Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines -

October 2024

[SEC=OFFICIAL]

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, ~~we believe they are invalid~~the results are not robust or reliable and are creating confusion.

Commented [TD1]: Can we have another word?

Commented [TD2R1]: Or way of referring to the invalidity?

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce deaths and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports that have been circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are causing the spread of misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry that is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—and mRNA which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in COVID-19 vaccines.
- Methods for testing medicines are evaluated and approved by regulatory authorities, who require evidence that the methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method to test residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies used samples that were well past their use by date. Some samples had been opened and used. These samples were not suitable for testing.
- It is unknown where the vials were sourced or their location, custody or temperature before or during testing. Regulatory testing is conducted within tightly controlled frameworks that ensure traceability and certainty about the integrity and provenance of test samples.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification which is required by laboratories to perform approved testing for pharmaceutical companies, nor do they appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. Laboratories with these types of accreditation ensures that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies, and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after digestion and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also

independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety
To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for lifetime treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

From: LAWLER, Tony
To: HENDERSON, Nick; KERR, Lisa; DUFFY, Tracey
Cc: s22 [redacted] LARTER, Claire; VUCKOVIC, George; s22 [redacted]
Subject: Re: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 10:24:16 AM
Attachments: image001.png
DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024NH_TL.docx

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Thanks very much, this is great. Some corrections and comments from me in the attached (fortunately 25 people failed to board the plane!)
T

From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Thursday, October 17, 2024 10:05 AM
To: KERR, Lisa <Lisa.Kerr@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>
Subject: RE: For clearance: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]

Hi Lisa

This looks good. Minor comment in TRIM version and attachment for me

Nick

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 9:55 AM
To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
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> **Subject:** For clearance: DRAFT Statement - Addressing misinformation about DNA in the

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------< Content Manager Record Information >------
Record Number: D24-4291794
Title: DRAFT Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024

[SEC=OFFICIAL]

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, ~~we believe they are invalid~~the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Commented [TD1]: Can we have another word?

Commented [TD2R1]: Or way of referring to the invalidity?

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death~~s~~ and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports ~~that have been~~ circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to ~~causing~~ the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which ~~that~~ is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in ~~COVID-19 vaccines~~these tests.
- Methods for testing medicines are evaluated and approved by regulatory authorities, which~~e~~ require evidence that thosee methods are suitable for the intended purpose. The guideline used by the TGA and other regulators to assess the performance of test methods is *ICH Q2(R2) Validation of Analytical Procedures*, developed by the

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to ~~test~~ measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
  - ~~It is unknown~~ where the vials were sourced
  - ~~or~~ their location, custody or temperature before or during testing.
- Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated and results can be relied upon. Processes that do not ~~that~~ ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.~~.~~
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done when testing vaccines. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. This means that they appear not to have either Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies.~~,~~ N~~n~~or do the laboratories~~y~~ appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. ~~Laboratories with t~~These types of laboratory accreditation ensure~~s~~ that the results they produce are robust and reliable.

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Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after ~~digestion~~processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

Commented [TL3]: Too strong?

Commented [HN4]: Can we say they "appear" not to have, if we acknowledge their accreditation status is unknown? Should we change wording to say "this means they may not have either GMP etc"

Commented [TL5R4]: Could we say instead "there is no evidence that…"?

Commented [TL6]: Is "processing" a more accessible term than "digestion"?

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product.

Commented [TL7]: Can we strengthen this to say not just that we have tested, but that they have met those stringent limits?

The quality limits ensure that there is less than 10 ng present per dose – or less than one ten billionth of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome or causing cancer. This includes products such as insulin, which are injected multiple times a day for life-long~~time~~ treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Commented [TL8]: Would be good to have here our standard line of "over
x million doses and significant real world evidence has shown the risk/benefit ratio for vaccines remains overwhelmingly positive" or similar (don't have the words with me, sorry)

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

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Many of our concerns are listed below [link to the heading at bottom of report – Concerns with these studies].

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- Some laboratories have chosen to report DNA levels using a test called fluorometry, which is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in these tests.
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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This provides performance criteria that a test method must meet to demonstrate that its results are reliable and accurate. Using these criteria, the fluorometry method used in the quoted tests to measure residual DNA does not meet the requirement for specificity. Specificity means the ability for the test to measure the substance of interest (in this case DNA) without measuring other similar substances (such as mRNA).

- The physical reference materials were not adequately defined.

Issues with samples:

- Some of these studies use a very small sample number, for example only three vials. The studies also used samples that were well past their use by date. Some samples had already been opened and used. These samples were not suitable for testing.
- The provenance of the samples is also not clear. This means that significant information is not known about the vials used:
    - where the vials were sourced
    - their location, custody, or temperature before or during testing.

  Regulatory testing is conducted within tightly controlled frameworks to ensure that test samples cannot be manipulated, and results can be relied upon. Processes that do not ensure traceability and certainty about the integrity and provenance of test samples impact the reliability of findings.
- Vaccine vials are required to be shipped via 'cold chain' where the temperature must be within a specified range and monitored during transportation. Vials shipped to Australia must adhere to these requirements and the TGA checks that this is done. However, the samples used in these studies were not kept in cold chain and usually did not have temperature loggers with them.

Laboratory status:

- The accreditation status of the laboratories is unknown. There is no evidence that these laboratories have Good Manufacturing Practice (GMP) certification, which is required by laboratories to perform approved testing for pharmaceutical companies. Nor do the laboratories appear to have accreditation to the international standard *ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories*. These types of accreditations ensure that the results they produce are robust and reliable.

Biotechnology medicines have been available since the 1980s

DNA is an approved starting material for many biotechnology products. This includes recombinant proteins such as insulin, growth factors, cancer medicines, autoimmune therapies and other vaccines, as well as mRNA vaccines such as Comirnaty and Spikevax.

Residual DNA may be present in very small quantities in the mRNA COVID-19 vaccines and other biotechnology products. Residual DNA is the amount of DNA remaining after processing and purification of the medicine and is present as small fragments. Products that use DNA as a starting material have strict limits on the amount of residual DNA which can be present in the final medicine.

Medicines produced by biotechnology have been used by millions of patients for over 40 years. In that time, medicines containing residual DNA quantities under the required limits have presented a very low risk to human safety.

The ability of the manufacturer to minimise amounts of residual DNA and reliably test for it during the manufacturing process is rigorously evaluated by the TGA and other international regulators prior to approval.

The manufacturing protocol and test results must be provided to the TGA for each batch of vaccine released in Australia. Every final batch of the mRNA COVID-19 vaccines released in Australia has met the regulatory requirements for residual DNA concentration. To date, the TGA has also independently tested 27 batches of COVID-19 mRNA vaccines by qPCR to confirm the residual DNA concentration in the final product. The vaccines met the required limits for residual DNA.

The quality limits ensure that there is less than 10 ng present per dose – or less than ten billionths of a gram in each dose. These limits are used by the TGA, the World Health Organization, the United States Food and Drug Administration and other international regulatory agencies.

Residual DNA in Biotechnology Products – safety

To date, neither the TGA nor any international regulator has established a causal link between COVID-19 vaccines and any type of cancer.

There has been no evidence of mRNA vaccines or biological medicines used in Australia resulting in integration of residual DNA into human DNA genome. This includes products such as insulin, which are injected multiple times a day for life-long treatments.

Furthermore, in the combined reproductive and development animal studies using 200-times the clinical dose of mRNA vaccines, there were no adverse effects on male or female fertility, fetal deaths, birth defects, or developmental delays.

Evidence from the more than 13 billion vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The benefits of the approved vaccines far outweigh the possible risks.

From: LARTER, Claire
To: KERR, Lisa; DUFFY, Tracey; s22 [redacted]
Cc: s22 [redacted] VUCKOVIC, George; s22 [redacted]; HENDERSON, Nick; LAWLER, Tony
Subject: RE: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]
Date: Thursday, 17 October 2024 3:43:41 PM
Attachments: D24-4399772 Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 - PB edit.docx
image001.png

Hi Lisa,

I suggested a minor edit in the safety section, and a comment in the first section as I think there may have been some text missing.

Kind regards,
Claire

From: KERR, Lisa <Lisa.Kerr@health.gov.au>
Sent: Thursday, October 17, 2024 2:10 PM
To: DUFFY, Tracey <Tracey.Duffy@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>
Cc: s22 [redacted]@health.gov.au>; s22 [redacted]@Health.gov.au>; s22 [redacted]@Health.gov.au>; VUCKOVIC, George <George.VUCKOVIC@Health.gov.au>; LARTER, Claire <Claire.Larter@health.gov.au>; s22 [redacted]@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>
Subject: Web statement - Addressing misinformation about DNA in the mRNA vaccines [SEC=OFFICIAL]

Good afternoon,

The comments from Tracey, Nick and Tony have been worked through. The latest clean copy is attached and here: D24-4399772

Kind regards,

Lisa

Lisa Kerr PSM PhD MBA (Dr/she/her)
Assistant Secretary | Laboratories Branch
Medical Devices and Product Quality Division
T: +61 2 6289 2132 | E: Lisa.Kerr@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100, Woden ACT 2606
www.tga.gov.au

I may send emails out of hours at a time that suits me.. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and

their cultures, and to all Elders both past and present.

DRAFT Statement
Addressing misinformation about excessive DNA in the mRNA vaccines

The Therapeutic Goods Administration (TGA) is aware of misinformation in recent media and online reports that claim the COVID-19 mRNA vaccines are contaminated with excessive levels of DNA. This is not the case.

These reports are based on studies conducted by a small number of laboratories that have attempted to investigate the amount of DNA in COVID-19 vaccines.

While the TGA welcomes and constantly reviews the latest scientific evidence about the safety of vaccines and other biotechnology products, these recent studies fail to apply the required scientific rigor expected in pharmaceutical testing. As such, the results are not robust or reliable, and are creating confusion and concern regarding the safety of vaccines.

Many of our concerns are listed at [link to the heading at bottom of report – Concerns with these studies].

Commented [LC1]: I think there may be some text missing here?

Should the sentence read 'Many of our concerns with these studies are listed below' (with the link to the section on 'below'

The TGA reassures the public that all COVID-19 vaccines approved in Australia have been rigorously assessed and meet our high standards for safety, quality, and efficacy.

Vaccination against COVID-19 is one of the most effective ways to reduce the risk of death and severe illness from infection. The protective benefits of vaccination far outweigh the potential risks. This statement from medicine regulators around the world provides more information on the good safety profile of COVID-19 vaccines.

For more information on how we approve and regulate COVID-19 vaccines, see: www.tga.gov.au/products/covid-19/covid-19-vaccines

This statement represents the TGA's views on the scientific evidence as at [DATE]

Misinformation alleging DNA contamination in the COVID 19 vaccines

Some laboratories have attempted to investigate the amount of DNA in COVID-19 vaccines. This has led to a number of incorrect media and online reports circulated on social media about the safety of mRNA COVID-19 vaccines. These reports are based on studies that currently fall short of the scientific rigor expected in pharmaceutical testing and are contributing to the spread of vaccine misinformation.

Concerns with these studies include:

Selective reporting and method validation

- Some laboratories have chosen to report DNA levels using a test called fluorometry, which is known to overestimate DNA levels in the presence of mRNA. This is because the fluorescent dye used in this test binds to both DNA—which may be present in minute amounts—**and** mRNA, which is the main ingredient in the COVID-19 vaccines. This leads to incorrect DNA levels being reported in these tests.
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From:	KERR, Lisa
To:	LAWLER, Tony
Cc:	DUFFY, Tracey; HENDERSON, Nick; s22 [redacted]
Subject:	For clearance : D24-4399772 : Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024 [SEC=OFFICIAL]
Date:	Friday, 18 October 2024 11:14:33 AM
Attachments:	Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.DOCX Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024.tr5

Hi Tony,

Final statement attached as promised.

Lisa

------< Content Manager Record Information >------

Record Number: D24-4399772
Title: Final Statement - Addressing misinformation about DNA in the mRNA vaccines - October 2024