Internal emails reveal TGA fails to grasp mRNA vaccine science

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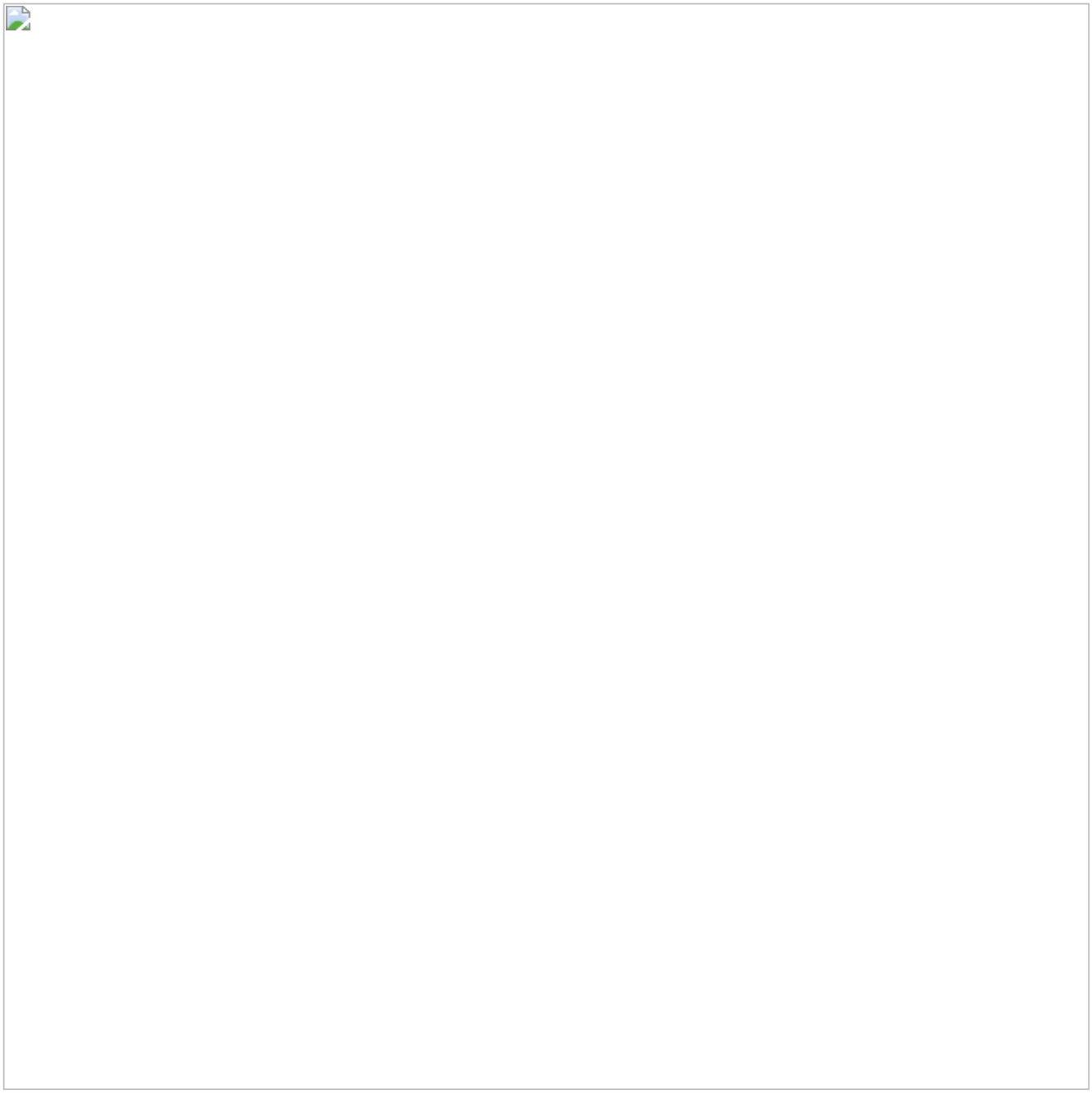


A Freedom of Information (FOI) request has uncovered emails from the Therapeutic Goods Administration (TGA), revealing internal discussions about “DNA contamination” risks in the COVID-19 mRNA vaccines.

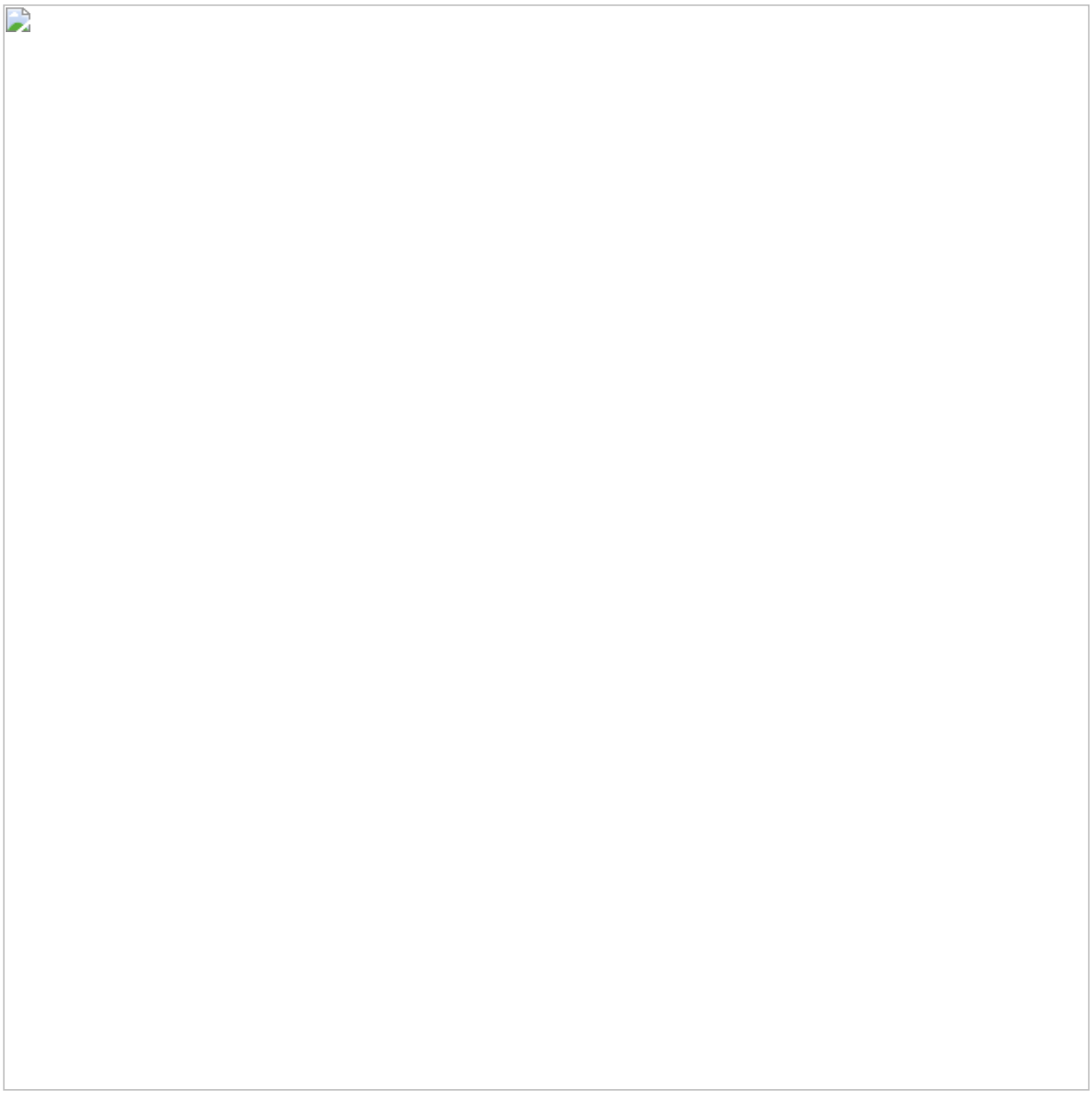
The disclosure relates to the TGA's announcement in October, which tried to quash “misinformation” about the potential for residual DNA to integrate into the human genome.

For months the TGA worked to counter studies by independent scientists, including Canadian virologist David Speicher, who reported that plasmid DNA in Australian vaccine vials exceeded safety limits by up to 145 times.

The correspondence revealed that the TGA was woefully unprepared to handle the complexities of the science, even as it publicly downplayed the dangers.

TGA's allegations of "misinformation" addressed in a recent talk in Perth.

In the emails, staffers discussed the risks of foreign DNA in the vaccines. "Foreign DNA can integrate into chromosomal DNA" admitted one staffer, who mentioned several ways that exogenous DNA can integrate into the host genome.



This has already been demonstrated in ovarian cancer cell lines by Kevin McKernan, and in epithelial stem cells from colon tissue by Phillip Buckhaults.

The communications also revealed awareness of the 'SV40 enhancer' region in Pfizer's vaccine, which enhances the transport of plasmid DNA to the cell's nucleus. Staffers noted that this event was considered "low probability."

- It contains a bacterial *ori* (origin of replication) to facilitate replication in bacterial cells. This *ori* would not be recognised in human cells.
- The plasmid also contains a SV40 promoter and f1 *ori* region (not shown in plasmid map presented by Sponsor but found in BLAST and reported in Speicher & McKernan papers). This is used in pCMV-Tag vectors for selection in mammalian cells. The SV40 enhancer region can promote nuclear transport of DNA. Risk that this will happen is low due to low level of DNA. Risk if does happen, low as integration events have low probability. The *ori* is not used for replication.

Another issue that emerges from the emails is the TGA's apparent failure to grasp the unique risks posed by residual DNA encapsulated in lipid nanoparticles (LNPs).

LNPs are the key to delivering genetic material inside cells, but the TGA seemed to be relying on an outdated regulatory framework, one that was designed for "naked DNA" rather than DNA carried within LNPs.

As many experts have pointed out, the presence of LNPs changes the risk dynamics of residual DNA. "The regulatory limit is just not relevant to mRNA vaccines that have lipid-nanoparticles," said Buckhaults in an earlier interview.

Moreover, the TGA seems to insist that because the DNA fragments are small (<200 base pairs), it must mean they pose less risk. However, the opposite is true.

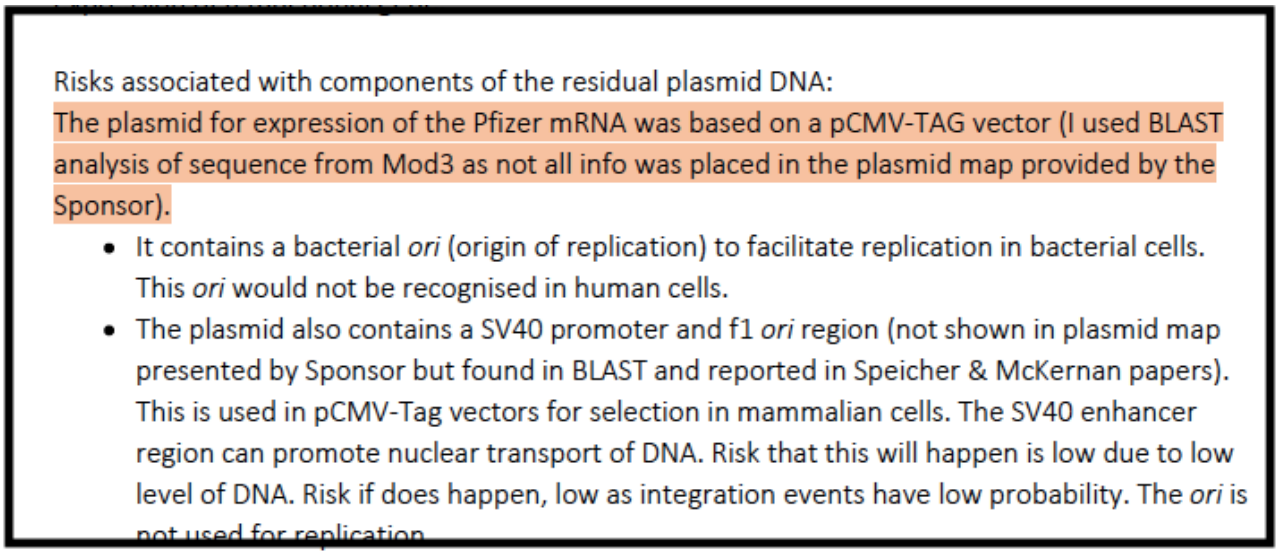
Therefore, a significant margin of safety exists with a limit of 10 ng/day. However, further considerations regarding safety are presented below.
The limit of 10 ng/dose was based on intact DNA. The safety margins are expanded further when the DNA is fragmented to <200 bp (FDA Guidance for Industry, 2010; and paper yet to get). Fragmentation of the DNA below the size of a functional gene such as this reduces the risk of expression of a functional gene.

Buckhaults explained that using enzymes to chop up the plasmid DNA into billions of tiny pieces, may actually *increase* the hazard for genome modification.

"Because instead of having one big piece, you've got, like, a bazillion little pieces. They've turned a shotgun slug into buckshot pellets," explained Buckhaults.

Finally, one of the TGA staffers made a novel admission that independent scientists in the field were not expecting.

Researchers Kevin McKernan and Jessica Rose both point to the reference of a "CMV promoter" in Pfizer's plasmid DNA, a gene sequence not previously identified in vaccine lots.



Risks associated with components of the residual plasmid DNA:
The plasmid for expression of the Pfizer mRNA was based on a pCMV-TAG vector (I used BLAST analysis of sequence from Mod3 as not all info was placed in the plasmid map provided by the Sponsor).

- It contains a bacterial *ori* (origin of replication) to facilitate replication in bacterial cells. This *ori* would not be recognised in human cells.
- The plasmid also contains a SV40 promoter and f1 *ori* region (not shown in plasmid map presented by Sponsor but found in BLAST and reported in Speicher & McKernan papers). This is used in pCMV-Tag vectors for selection in mammalian cells. The SV40 enhancer region can promote nuclear transport of DNA. Risk that this will happen is low due to low level of DNA. Risk if does happen, low as integration events have low probability. The *ori* is not used for replication

The CMV (Cytomegalovirus) promoter ensures efficient transcription of the desired gene, but could theoretically activate unwanted gene expression if integrated into human cells.

McKernan, who is currently testing human cancer samples, recently **reported finding this gene segment in a tumour biopsy from a cancer patient** who had received four Pfizer mRNA injections.

“We held off submitting this for publication as [we] couldn’t believe they would actually have a different plasmid in some vials,” McKernan said, initially suspecting his finding was due to lab contamination.

“[We] went back to purify the DNA in another lab to rule out lab contamination,” added McKernan, who expects to confirm the results of his biopsy sequencing soon.

I won’t detail every shortcoming in the emails, but it’s striking that by October 2024, the TGA was only beginning to fully engage with safety concerns—years after the vaccines had already been administered to millions of people.

The FOI emails reveal uncertainty among staff about the complexities of mRNA technology, highlighting an agency still struggling to fully understand the science.

Rather than addressing knowledge gaps before provisionally approving the vaccines, the TGA is now scrambling to consult internal experts to counter narratives and uphold its public stance of "safe and effective."

One staffer, focused on cooling public rhetoric wrote, “I’m primarily concerned with allaying fears in the public that this is actually something to worry about, when it isn’t.”

While it’s reasonable for public health bodies to avoid creating unnecessary panic, transparency about both known and unknown risks is crucial when uncertainty persists — something the TGA has failed to deliver.

As public awareness of this issue grows, so does the understanding that the TGA has not been transparent or thorough in investigating mRNA vaccine safety.

In its rush to reassure the public, the FOI emails reveal an unsettling truth.

The TGA overlooked critical safety aspects of the vaccines, leading many to conclude that its focus has been more on controlling its narrative than on prioritising the safety of the people it is meant to protect.