

JUNE 18, 2025

The myth about Popeye's super strength coming from a miscalculation of iron content in spinach is a classic example of how errors and misinformation can spread. highlighting the importance of accurate data and critical thinking in science. Not one but three similar miscalculations occurred with mRNA vaccine reach and strength.

First Both Moderna and Pfizer EUA authorised Process 2 product potency considerably exceeds safe pyrogenic threshold established in their respective pivotal clinical trials, in Pfizer by 1700%. There were two Pfizer and Moderna processes; Process 1, a trial “mock up” and Process 2 “upscale”. Pfizer is described later; Moderna published their findings about the two processes in December 2020. The image below shows how much more potent Process 2(b) is than Process 1 (a)

*“UNITED STATES SECURITIES AND EXCHANGE COMMISSION ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2020”<sup>1</sup>*

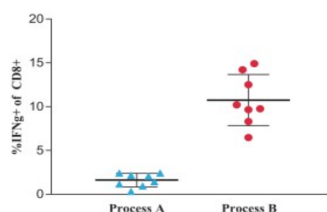
*mRNA manufacturing process: Improving pharmacology*

Our platform creates mRNA using a cell-free approach called *in vitro* transcription in which an RNA polymerase enzyme binds to and transcribes a DNA template, adding the nucleotides encoded by the DNA to the growing RNA strand. Following transcription, we employ proprietary purification techniques to ensure that our mRNA is free from undesired synthesis components and impurities that could activate the immune system in an indiscriminate manner. Applying our understanding of the basic science underlying each step in the manufacturing process, we have designed proprietary manufacturing processes to impart desirable pharmacologic features, for example increasing potency in a vaccine. Using a model antigen injected intramuscularly in mice at a 3 microgram (µg) mRNA dose, the figure below shows the significant improvement in CD8 T cell response we have achieved through mRNA manufacturing process science and engineering as evidenced by Process B.

16

Table of Contents

Manufacturing process changes to tune immune response in mouse study



Second Biodistribution expectation was that product remained in the arm. That was not the case - see *Nonclinical Evaluation Report BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATY™) Submission No: PM-2020-05461-1-2 Sponsor: Pfizer Australia Pty Ltd January 2021*

*Table 4-2. Mean concentration of radioactivity (sexes combined) in tissue and blood following a single IM dose of 50 µg mRNA/rat p45<sup>2</sup>*. This is examined later,

Third an important signal of a significant AESI – lymphadenopathy - was missed because clear and unarguable evidence of excessive Process 2 product potency was recorded in the Pfizer booster trial disguised as third dose booster reactogenicity instead of product reactogenicity. The booster report also refers to but dismisses a cardiac event now known to be closely linked to process 2 Pfizer. The two signals in the Pfizer booster report – cardiac and blood/lymphatic disorder – examined later - have come to typify the lack of mRNA product /platform safety. Neither safety nor efficacy in the Pfizer authorised product were properly examined; Process 2 was only tested in 306, not 43,800, people. There is a plausible mechanism of harm, **endotoxins** from manufacture Process 2. Evidence shows no enhanced immunological benefit from enhanced potency which is a safety risk.

The Covid mRNA programme must be paused to re-examine and reconsider the evidence base for mRNA platform safety and efficacy to evaluate a true risk /benefit profile now pandemic conditions have passed.

<sup>1</sup> <https://www.sec.gov/Archives/edgar/data/1682852/000168285221000006/mrna-20201231.htm>

<sup>2</sup> <https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf>

## FIRST MISCALCULATION – PROCESS 2 POTENCY GREATLY EXCEEDED PROCESS 1 POTENCY BUT THIS WAS NOT RECOGNISED

### Relevant Regulatory History

20 November 2020

FDA published

*"Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum"*<sup>3</sup>.

The meeting records two processes of manufacture on P 47. The following excerpt from p47 very is important. It states a requirement for future reporting on "release" or "commercial", "upscale" DP (Drug Product) and DS (Drug Substance ) potency

*"All stability studies of the DS and DP lots are ongoing and will continue to be monitored. Data will be submitted to the EUA as they become available. The analytical procedures developed and used for the release and stability monitoring of BNT162b2 DS and DP include tests to ensure their identity, purity, quality, and **potency**."*

"Potency" is considered a crucial factor; FDA was obviously concerned that P2 potency should be similar to P1.

In the screen shot of p47 below, Drug Substance (DS, active substance) comments are light green; drug product (DP, the vaccine finished product ) comments orange; combined DS and DP comments are dark pink. These emphasise potency in terms of efficacy not in terms of reactogenicity, which does not correspond to immunogenicity in the authorized Pfizer product

*Reactogenicity Correlates Only Weakly with Humoral Immunogenicity after COVID-19 Vaccination with BNT162b2 mRNA (Comirnaty®)*<sup>4</sup>

5.4. Chemistry, Manufacturing, and Control (CMC) Information

The manufacturing process for the BNT162b2 drug substance (DS) consists of two major steps: (b) (4). The BNT162b2 drug product (DP) is manufactured by mixing the modRNA DS with lipids during lipid particle (LNP) formulation followed by fill/finish. To support the EUA request, in-process, release, and characterization data for a minimum of three process performance qualification (PPQ) DS batches for each DS manufacturing facility were provided. Certificates of Analysis (CoAs) for a minimum of three GMP commercial-scale DP lots from each DP manufacturing node were requested from the Sponsor to demonstrate DP process performance and consistency. DP data from four manufacturing nodes were available during the EUA review. In addition, to support vaccine supply and availability, data from two additional nodes will be submitted to the EUA between December 17 and December 23, 2020. Once authorized, the Sponsor will submit the CoAs of DP lots to be distributed under EUA for review at least 48 hours prior to lot distribution.

The DS manufacturing process underwent changes during vaccine development. (b) (4)

A comprehensive analytical comparability assessment has been performed and the submitted data support the comparability of (b) (4) with (b) (4) for the manufacture of BNT162b2 DS. (b) (4)

For DP, the manufacturing process was changed from a Classical process to an Upscale process involving an increase in batch size (capable of accommodating larger RNA input) to meet commercial need. A comparison of available DP batch release data and an in-depth analytical comparability assessment between six representative Classical process DP batches and one Upscale process DP batch support the use of the Upscale process for DP manufacture under emergency use. A more comprehensive comparability assessment encompassing additional lots from multiple DP manufacturing nodes is ongoing and the results will be provided to the EUA upon completion of the study.

Stability studies have been designed to support the use of vaccine under the EUA. All available stability data generated using the BNT162b2 DS and DP lots support the emergency deployment of the Pfizer-BioNTech COVID-19 Vaccine. All stability studies of the DS and DP lots are ongoing and will continue to be monitored. Data will be submitted to the EUA as they become available.

The analytical procedures developed and used for the release and stability monitoring of BNT162b2 DS and DP include tests to ensure their identity, purity, quality, and potency. The assays are appropriate and acceptable to be used for the control of DS/DP quality. All analytical procedures used for the release of emergency supply DS and DP have been adequately

47

<sup>3</sup> <https://www.fda.gov/media/144416/download>

<sup>4</sup> <https://www.mdpi.com/2076-393X/9/10/1063>

Page 6 of the Booster trial report sets out the Process 1 trial data cut off November 14<sup>th</sup>, 2020, and the safety summary to that date. By reference to p47 above, this safety data derives only from P1 “classical” manufacturing method, not the P2 “upscale” version.

22 August 2024

VRBPAC authorized these 2 same products Moderna and Pfizer using the FDA’s “strain change rule”<sup>5</sup> under which updated vaccines are not considered new vaccines. Because the changes are limited to the version or versions of the virus that are being targeted, the manufacturers are not required to conduct new safety or effectiveness studies.

The original sin of Pfizer and Moderna excessive potency overtopping the safe pyrogenic threshold has therefore been passed down to the third and fourth generation **without scrutiny**.

The evidence of Pfizer excessive reactogenicity is in the FDA Medical Professional leaflet<sup>6</sup> taken from the August 22<sup>nd</sup> FDA News Release

*FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants*<sup>7</sup>

The leaflet describes various Pfizer clinical trials. It notes (p12) that in the pivotal C4591001 trial involving 21,900 people taking 2 doses of product - 43,800 doses – there were significant unsolicited adverse events – non serious

*“The higher frequency of reported unsolicited non-serious adverse events among Pfizer-BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset. **From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced** with notably more cases in the **Pfizer-BioNTech COVID-19 Vaccine group (64)** vs. the placebo group (6), which is plausibly related to vaccination.”*

Lymphadenopathy was an AESI at that time. Due to this frequency – 0.3% in vaccinated and 0.1% in placebo – it was graded “uncommon”.

However, the booster trial reported on p24 shows a wholly different reactogenicity 1700% greater than the pivotal trial

#### *“Unsolicited Adverse Events*

*Overall, the 306 participants who received a first booster dose, had a median follow-up time of 2.6 months after the booster dose to the cutoff date (June 17, 2021). In an analysis of all unsolicited adverse events reported following the first booster dose, through 1 month after the booster dose, in participants 18 through 55 years of age (N=306), those assessed as adverse reactions not already captured by solicited local and systemic reactions were **lymphadenopathy (n=16, 5.2%)**, nausea (n=2, 0.7%), decreased appetite (n=1, 0.3%), rash (n=1, 0.3%), and pain in extremity (n=1, 0.3%).”*

Such a substantial rate uplift is not easily explained by the same product absent a cumulative increase between doses 1 and 2, which is not present. It was verifiably a different product; product used in booster trial was solely Process 2 not Process 1. In the report on

*“Vaccines and Related Biological Products Advisory Committee Meeting September 17, 2021”*<sup>8</sup>

---

<sup>5</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC4947948/>

<sup>6</sup> <https://www.fda.gov/media/167211/download?attachment>

<sup>7</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-and-authorizes-updated-mrna-covid-19-vaccines-better-protect-against-currently>

<sup>8</sup> <https://www.fda.gov/media/152176/download>

A cohort of 306 people, from pivotal main trial C4591001 received their first dose of Process 2 as described on page 5 below:

Solicited and unsolicited safety data from booster recipients (12 Phase 1 participants 65 through 85 years of age and 306 Phase 2 participants 18 through 55 years of age) were reviewed and compared to labeled safety data from the reactogenicity subset (N=2700) of recipients of the 2-dose primary series. Safety following the booster dose was assessed for a median of 2.6 months among both Phase 1 and Phase 2/3 study participants. Reported frequencies and severities of local and systemic solicited adverse reactions following the booster dose were not substantially different from those following Dose 2 of the primary series. Reported frequencies and severities of solicited adverse reactions following the booster dose were lower among the 12 Phase 1 participants 65 through 85 years of age compared with the 306 Phase 3 participants 18 through 55 years of age, similar to age group-related differences in reactogenicity associated with the primary series. Lymphadenopathy (16/306; 5.2%) was the most common unsolicited adverse event (AE); all events of lymphadenopathy occurred within 3 days of vaccination. No other adverse events of clinical interest (i.e., myocarditis, pericarditis, Bell's Palsy, appendicitis) were reported following the booster dose. The incidence post-booster dose was substantially higher than the rate reported among adults after any of the 2 doses of the primary series (83/21,926; 0.4%). However, most (n=15) were mild to moderate in severity and lasted between 2 to 8 days. Two cases of mild lymphadenopathy were reported as ongoing and resolving at the time of last assessment. No deaths were reported following the booster dose, and one nonfatal serious adverse event (acute myocardial infarction 2 months after the booster dose, assessed as unrelated to study vaccination) was reported.

This booster report also mentions a myocardial infarction deemed not to be product related. Furthermore, this booster product which is Process 2 "upscale" product - was not evaluated for efficacy as shown on p4.

On page 4 the report states that booster Process 2 product type, which had now been in distribution for over 10 months, was compared with a small group that had also with the 306 received 2 doses of the "prototype" - Process 1 - but then received a third booster dose of the same Process 1 "prototype" not the upscale Process 2.

and formulated in lipid particles (LNPs). The approved regimen is a 2-dose primary vaccination series administered 3 weeks apart. During clinical development, the vaccine, containing mRNA, was called BNT162b2.

On August 25, 2021, Pfizer submitted a supplement to their Biologics License Application (BLA) for COMIRNATY seeking approval for administration of a booster dose approximately 6 months after primary series. To support the need for a booster dose, the submission referenced several observational studies that suggest waning of protection in the setting of the current Delta variant surge among individuals who previously received a 2-dose series.

This BLA supplement includes safety and immunogenicity data assessed against the reference strain (wild-type) from approximately 300 immunocompetent adults 18 through 55 years of age enrolled in an ongoing Phase 2/3 study (C4591001) who completed the primary vaccination series consisting of two doses of BNT162b2 administered intramuscularly (IM) and who received a BNT162b2 booster dose approximately 6 months after completion of the 2-dose primary series. Efficacy was not evaluated for Phase 3 BNT162b2 booster group participants. Supportive data from the Phase 1 portion of this study in participants 18 through 55 years of age (N=11) and 65 through 85 years of age (N=12) who had received a 30 µg BNT162b2 prototype vaccine approximately 7 to 9 months after their second dose were also included and consisted of safety data and immunogenicity data evaluating neutralizing antibody titers elicited by the booster dose against the reference strain (wild-type) of SARS-CoV-2 and variants of concern (VOCs).

The effectiveness of the booster dose is based on immunobridging analyses from the Phase 3 group of participants 18 through 55 years of age comparing 50% neutralizing antibody titers against the reference strain at 1 month after the booster dose to those observed at 1 month post-primary series among participants without evidence of prior SARS-CoV-2 infection. Immunobridging analyses included hypothesis testing for:

- geometric mean titers (GMTs) of SARS-CoV-2 neutralizing antibodies at 1 month after the

The European Medical Agency Comirnaty Booster Variation lists the three batches used for the Booster trial and they are all Process 2 Batches

EMA/497785/2021 Committee for Medicinal Products for Human Use (CHMP) Assessment report COMIRNATY Common Name: COVID-19 mRNA vaccine (nucleoside-modified) Procedure No. EMEA/H/C/005735/II/0067 Marketing authorisation holder (MAH): BioNTech Manufacturing GmbH<sup>9</sup>

P27 of the EMA report

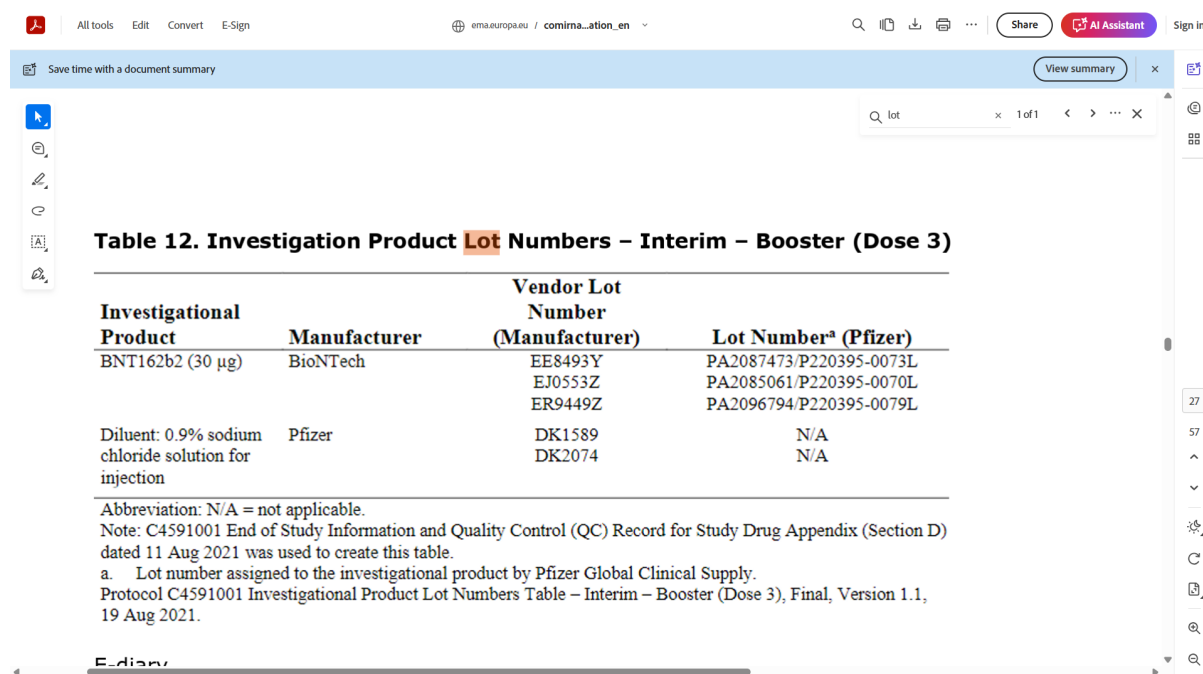


Table 12. Investigation Product Lot Numbers – Interim – Booster (Dose 3)

Investigational Product	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number <sup>a</sup> (Pfizer)
BNT162b2 (30 µg)	BioNTech	EE8493Y EJ0553Z ER9449Z	PA2087473/P220395-0073L PA2085061/P220395-0070L PA2096794/P220395-0079L
Diluent: 0.9% sodium chloride solution for injection	Pfizer	DK1589 DK2074	N/A N/A

Abbreviation: N/A = not applicable.  
 Note: C4591001 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 11 Aug 2021 was used to create this table.  
 a. Lot number assigned to the investigational product by Pfizer Global Clinical Supply.  
 Protocol C4591001 Investigational Product Lot Numbers Table – Interim – Booster (Dose 3), Final, Version 1.1, 19 Aug 2021.

These three batches EJ0553, EE8593 and ER9449 were authorized by UK MHRA Regulator; EJ0553 was the first ever batch authorized in the world on 2<sup>nd</sup> December 2020<sup>10</sup>

EJ0553 and EE8493 drug substance was cultured in Andover, Mass. The batches are representative of the commercial product deployed in the USA under EUA. The 5.2% Lymphadenopathy reactogenicity rate derives therefore from the first dose of upscale /commercial product not the third dose, as misleadingly set out in the Booster report.

If this same higher rate 5.2% had applied to the prototype product used in pivotal trial C4591001 doses 1 and 2, there would have been between 1021 and (63 x 17) = 1071 lymphadenopathy reactions in the vaccine cohort, and the trial would have had to be halted.

There is a plausible reason for this increased reactogenicity – endotoxin. The P2 type was manufactured in Escherichia coli as described in the UK Public Assessment Report<sup>11</sup>.

*"The DNA template from which the RNA is transcribed is critical for the fidelity of the mRNA. The manufacture of the DNA template has been described. It is manufactured through fermentation in an established and well-controlled Escherichia coli cell line, extracted and purified."*

The problems of cleaning and filtering active substance for endotoxins are long recognised and well known-

<sup>9</sup> [https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0067-epar-assessment-report-variation\\_en.pdf](https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-ii-0067-epar-assessment-report-variation_en.pdf)

<sup>10</sup> <https://web.archive.org/web/20201203150911/https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/conditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine>

<sup>11</sup> <https://web.archive.org/web/20201216233459/https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine>



## SECOND MISCALCULATION – BIODISTRIBUTION

The Australian Therapeutic Goods Agency published a report in which Pfizer set out a table of LNP bodily distribution in rats after intramuscular injection, noting that Pfizer has erroneously equated mass with volume in the measure and they are entirely different p45. These findings bear on the lymphadenopathy results from the clinical trial using endotoxin cultured product. The table presented below states

*Draining lymph nodes to the site of injection should have been collected and analysed for radioactivity, given the increased size of draining lymph nodes seen in other nonclinical studies after dosing.*

V9 the authorised active substance was tested in rats.

The narrative also tells us that biodistribution was significant

*Slow but significant distribution of lipid nanoparticles from the site of injection with major uptake into liver. Minor distribution in spleen, adrenal glands and ovaries over 48 h.*

*Mean blood:plasma ratios of 0.5-0.6 indicating nanoparticles mainly present in plasma fraction of blood with peak concentrations in plasma at approx. 2 h post-dose.*

### Total Lipid Concentration (µg lipid equiv/g (or mL)

PDF

All tools

Edit

Convert

E-Sign

tg.gov.au / foi-2389-06

Save

Search

AI Assistant

Sign in

Save time with a document summary

View summary

Sample	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.037	0.100	0.126	0.128	0.093	0.084	0.181
Adrenal glands	0.27	1.48	2.72	2.89	6.80	13.77	18.21
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687
Bone marrow (femur)	0.48	0.96	1.24	1.24	1.84	2.49	3.77
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068
Eyes	0.010	0.033	0.052	0.067	0.059	0.091	0.112
Heart	0.28	1.03	1.40	0.99	0.79	0.45	0.55
Injection site	128.3	395.8	311.2	338.0	212.8	194.9	164.9
Kidneys	0.39	1.16	2.05	0.92	0.59	0.43	0.41
Large intestine	0.013	0.048	0.09	0.29	0.65	1.10	1.34
Liver	0.74	4.62	10.87	16.55	26.54	19.24	18.28
Lung	0.49	1.21	1.83	1.50	1.15	1.04	1.09
Lymph node (axillary)	0.044	0.189	0.290	0.408	0.334	0.554	0.727
Lymph node (mesenteric)	0.050	0.146	0.230	0.489	0.489	0.985	1.066
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192
Ovaries (bilateral)	0.104	1.84	1.44	2.34	3.09	2.54	12.26
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599
Parathyroid gland	0.339	0.645	0.868	0.864	0.405	0.478	0.694
Prostate (male)	0.061	0.091	0.128	0.157	0.150	0.183	0.170
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264
Skin	0.013	0.208	0.159	0.140	0.119	0.157	0.253
Small intestine	0.030	0.221	0.476	0.879	1.279	1.302	1.472
Spinal cord	0.043	0.097	0.169	0.288	0.106	0.085	0.112
Spleen	0.33	2.47	7.73	10.80	22.09	20.88	33.88
Stomach	0.017	0.045	0.115	0.144	0.268	0.152	0.215
Testes (male)	0.031	0.042	0.079	0.129	0.146	0.304	0.320
Thymus	0.088	0.243	0.340	0.355	0.196	0.207	0.331
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.009
Uterus (female)	0.043	0.203	0.305	0.140	0.287	0.389	0.454
Whole blood	1.97	4.37	5.40	3.05	1.31	0.91	0.42
Plasma	3.16	8.13	8.98	4.50	2.36	1.78	0.81
Blood:plasma ratio	0.615	0.515	0.550	0.610	0.555	0.530	0.540

- Mean total radioactivity was greatest at the injection site followed by the liver with much lower total recovery in spleen, adrenal glands and ovaries (Table 4-2). The total radioactivity recovery was less than 100% at all time-points (range = 20 - 60%) probably due to difficulty in collecting entirety of injection site samples and the presence of radioactivity in the carcass, faeces and urine, which were not analysed.
- The tissue distribution pattern was similar in 100 µg mRNA/animal dose group as noted above for 50 µg mRNA/animal dose, with highest distribution into liver, adrenal glands and spleen.
- Draining lymph nodes to the site of injection should have been collected and analysed for radioactivity, given the increased size of draining lymph nodes seen in other nonclinical studies after dosing.

Conclusions

- Slow but significant distribution of lipid nanoparticles from the site of injection with major uptake into liver.
- Minor distribution in spleen, adrenal glands and ovaries over 48 h.
- Mean blood:plasma ratios of 0.5-0.6 indicating nanoparticles mainly present in plasma fraction of blood with peak concentrations in plasma at approx. 2 h post-dose.

## THIRD MISCALCULATION – LYMHADENOPATHY SIGNAL IN ENDOTOXIN BASED PRODUCT WITH UNCERTAIN BIODISTRIBUTION

<sup>12</sup> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/bacterial-endotoxinspyrogens>

The Pfizer biodistribution study shows that LNPs travel widely, but that study was passive as it did not include the active substance encased in the LNP. The distribution pattern shows the product can potentially act as if it were an intrathecal or epidural administration.

The TGA Australia studied Pfizer Moderna and Astra Zeneca doses and concluded that their endotoxin content was within internationally safe limits<sup>13</sup>. All being under 5EU/ml. This is a false flag. The part table is shown below; this applies to intramuscular product that does not stray from the local draining lymph node. However as shown the product does travel widely throughout the body and the masked endotoxin behaved more like these other much more sensitive measurements.

On this page:

Conclusion

	418911	6	< 5.0
--	--------	---	-------

Table 4 Pfizer (Comirnaty) Endotoxin test results (EU/mL).

	AUST R	Number of Batches*	Results
COMIRNATY	346290	80	< 5.0
	377110	2	< 5.0
	377111	15	< 5.0
	393433	2	< 5.0
	394890	5	< 5.0
	400874	9	< 5.0
	419330	4	< 5.0
	419332	1	< 5.0
	419371	1	< 5.0
* Batch numbers tested may not reflect total number of batches released in Australia. Some batches:			
<ul style="list-style-type: none"><li>• may have been tested and redirected to other markets;</li><li>• sent for method development purposes; and or,</li><li>• further consignments of the same batch.</li></ul>			

Conclusion

All batches of mRNA vaccines tested for residual DNA content in the TGA Laboratories were found to

Back to top

The FDA has published extensive data about the safe limits for endotoxin<sup>14</sup>. The limits in cases of contact with lymphatic system, the cardiovascular system the intraocular environment, the cerebrospinal region all require much lower levels for safe administration, all of which advice refers to devices but is directly applicable to these products and their operation.

#### 11. What are the endotoxins limits for medical devices?

*The Center for Devices and Radiological Health (CDRH) has adopted the USP Endotoxin Reference Standard and limits for medical device extracts expressed in EU/mL. USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices provides the limits for medical devices within its scope. The endotoxins limit for a medical device is dependent on the intended use of the device and what the device contacts (e.g., blood, the cardiovascular system, cerebrospinal fluid, intrathecal routes of administration, permanently implanted devices, and devices implanted subcutaneously).*[\[27\]](#)

<sup>13</sup> <https://www.tga.gov.au/resources/publication/tga-laboratory-testing-reports/summary-report-residual-dna-and-endotoxin-covid-19-mrna-vaccines-conducted-tga-laboratories>

<sup>14</sup> [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-pyrogen-and-endotoxins-testing-questions-and-answers#\\_Toc315937931](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-pyrogen-and-endotoxins-testing-questions-and-answers#_Toc315937931)



For medical devices, using the extraction volume recommendations described below, the limit is 0.5 EU/mL or 20 EU/device for products that directly or indirectly contact the cardiovascular system and lymphatic system. For devices in contact with cerebrospinal fluid, the limit is 0.06 EU/mL or 2.15 EU/device. For devices that are in direct or indirect contact with the intraocular environment, a lower endotoxins limit may apply. Please contact the appropriate review division for specific recommendations.

The process of preparing an eluate/extract for testing may vary from device to device. Some medical devices can be flushed, some may have to be immersed, while others may need disassembly. Unless otherwise directed by another compendial standard, our recommended rinse volumes include the following: (1) each of the 10 test units should be rinsed with 40 mL of non-pyrogenic water; (2) for unusually small or large devices, the surface area of the device that contacts the patient may be used as an adjustment factor in selecting the rinse or extract volume. The endotoxins limit can be adjusted accordingly. In any case, the rinse/extract procedure should not result in a greater dilution of endotoxin than recommended in USP <85>. For inhibition/enhancement testing, both the rinse/extract solution and the device eluate/extract should be tested.

Examples of medical devices with testing or interference challenges include devices that are coated with anticoagulant, contain heavy metals, or that have particulates. In these situations, treatments for interferences can include digestion, dilution, and addition of buffers, centrifugation, or filtration.

During the same surgical procedure or placement in the same surgical site, multiple units of the same device from one manufacturer should generally meet the same endotoxins limit as a single device administered during the procedure. In instances where multiple units of the same device are known or intended for use in a single procedure, manufacturers should justify any deviation from the overall endotoxins limit identified in this guidance.

When a manufacturer of medical devices plans to use LAL testing that deviates significantly from this guidance or recognized standard, a premarket notification (510(k)) under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act) or a premarket approval application (PMA) supplement under section 515 of the Act should be submitted. Significant deviations include, but are not necessarily limited to: higher endotoxin concentration release criteria, sampling from fewer than three (3) lots for inhibition/enhancement testing, lesser sensitivity to endotoxins, and a device rinsing protocol resulting in greater dilution of endotoxins than that recommended in this guidance."

Confirmatory signal detection for lymphadenopathy from UK and Europe

IN Quarter 3 of 2022 UK MHRA published a paper entitled

"Impact of COVID-19 vaccine reports on disproportionality analyses for other vaccines Type of paper: For Advice"<sup>15</sup>

The paper presented a table of signals from the covid vaccines and one of them was "necrotic lymphadenopathy"

---

<sup>15</sup> [https://assets.publishing.service.gov.uk/media/65f06d57133c220011cd38ce/FOI\\_22-1232\\_PDF\\_attachment\\_\\_2\\_.pdf](https://assets.publishing.service.gov.uk/media/65f06d57133c220011cd38ce/FOI_22-1232_PDF_attachment__2_.pdf)

assets public... / FOI\_22...ment\_2 Save

Share AI Assistant Sign in

Save time with a document summary View summary x

Whilst the majority of vaccine-event pairs did not differ substantially between RRR and PRR, 25% of pairs had an absolute difference of 1.5 or more and 10% of 3.5 or more. A more detailed evaluation of individual vaccine-event pairs with the highest difference between RRR and PRR revealed the following examples:

Vaccine	Event	n	rr	pr	ebgm
CHADOX1 NCOV-19	Thrombosis with thrombocytopenia syndrome	17	2.24	43.5	1.83
CHADOX1 NCOV-19	Heparin-induced thrombocytopenia	15	2.24	38.5	1.79
TOZINAMERAN	Device defective	9	3.32	44.1	2.01
TOZINAMERAN	Liquid product physical issue	12	3.06	27.8	2.09

OFFICIAL – SENSITIVE COMMERCIAL CHM/PEAG/2022/3<sup>rd</sup> MEETING

CHADOX1 NCOV-19	Cerebral mass effect	10	2.24	26.1	1.65
TOZINAMERAN	Necrotic lymphadenopathy	1	3.32	20.9	1.52

Results for the datamining run that combined drugs and vaccines showed more concordance between the RRR and PRR, persistent differences remained for 15% of vaccine-event pairs.

4. DISCUSSION

Current reports for COVID-19 vaccines make up a large proportion of the UK's spontaneous

This is a sign of malignancy and possibly cancer, The same effect was identified in Netherlands by Lareb the Signal detection Agency, which published 2 papers on lymphadenopathy . The second paper in 2024, *Prolonged duration of COVID-19 vaccine-induced lymphadenopathy*<sup>16</sup> , sets out evidence from over 17,000 reports of lymphadenopathy from the Netherlands alone, showing high frequency after the first dose and reducing numbers but increased intensity of reaction the more doses were administered

Within the 18,986 reports on lymphadenopathy following COVID-19 vaccination, we identified 67 cases with prolonged duration of 6 months or more. These reports contained a total of 73 lymphadenopathy-related MedDRA preferred terms (PT) since some patients developed lymphadenopathy at multiple sites. All cases were reported by consumers or other non-health care professionals. The most frequently reported COVID-19 vaccine brand was BioNTech/Pfizer (66%), followed by Moderna (22%), AstraZeneca (8%), Janssen (3%), and unspecified brand (2%). Most cases were reported for the primary series (85%; 55% for the first vaccination and 30% for the second). Only 15% of cases was reported for the booster vaccination.

IN 61 of 67 case cases the cause of the prolonged lymphadenopathy was unknown, but the signal again is one linked with malignancy.

So, this confirms the position that the process 2 product begins reacting in an excessively potent manner form the first dose, and that reactogenicity is plausibly linked with and cause by endotoxin contamination from the product manufacture ; and that potency was never properly evaluated for its effects on safety.

## CONCLUSION

The evidence presented makes the case to pause the mRNA vaccines while regulatory error is rectified and proper rigour applied to testing the product potency for safety and efficacy, as the historical record shows possible connections between contamination and several areas of the body disproportionately affected by the products/

<sup>16</sup> <https://www.lareb.nl/Knowledge/FilePreview?id=50729&p=33578>

