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VIA FEDEX AND EMAIL

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Re: Alarming Reports of DNA Contamination in Pfizer's COVID-19 Vaccines

Dear Secretary Becerra, Commissioner Califf, Principal Deputy Commissioner Woodcock, and Drs. Marks and Shimabukuro:

We write on behalf of Informed Consent Action Network ("**ICAN**") regarding alarming reports of DNA contamination in Pfizer's COVID-19 vaccines. There is a critical need for the Food and Drug Administration ("**FDA**") to investigate this issue and publish its findings forthwith.

I. The Manufacturing Process of the Vaccine on the Market Is Different Than the Vaccine Tested in the Clinical Trials

Josh Guetzkow, PhD, MA published in the July 2022 issue of *The BMJ* that, according to Pfizer's Study C4591001 Protocol,[1] Pfizer used manufacturing "Process 1" for its clinical trials but switched to "Process 2" in order to upscale production.[2] This is significant because, as explained in a recent preprint by molecular virologist and clinical epidemiologist David J. Speicher, PhD, DTM, *et al*.:

> Production of modRNA used in the original Pfizer randomized clinical trial (RCT) utilized a PCR-generated DNA template (Process 1). To generate billions of vaccine doses, this DNA was cloned into a bacterial plasmid vector for amplification in *Escherichia coli* before linearization (Process 2), expanding the size and complexity of potential residual DNA and introducing sequences not present in the Process 1 template.[3]

This change in processing may explain the contamination.

II. The Vaccine Contains Plasmid DNA in Levels That Exceed FDA and EMA Guidelines

As first reported by scientist and genomics expert Kevin McKernan at the June 15, 2023 VRBPAC meeting, Mr. McKernan's lab found DNA contamination in mRNA COVID-19 vaccines well in excess of that allowed by FDA and EMA guidelines.[4] The level detected was 18-70 fold over the EMA limit of 330ng DNA/mg of RNA[5] and it exceeded the FDA limit of

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[1] Fernando P. Polack et al., *Safety and efficacy of the BNT162B2 mRNA COVID-19 vaccine*, 383 N Engl J Med2603–2615 (Dec. 31, 2020), https://www nejm.org/doi/full/10.1056/nejmoa2034577.

[2] Josh A Guetzkow & Retsef Levi, *Effect of mRNA Vaccine Manufacturing Processes on Efficacy and Safety Still an Open Question*, BMJ (May 13, 2023), https://www.bmj.com/content/378/bmj.o1731/rr-2 (responding to Jennifer Black, *Covid-19: Researchers Face Wait for Patient Level Data from Pfizer And Moderna Vaccine Trials*, BMJ (July 12, 2022), https://www.bmj.com/content/378/bmj.o1731).

[3] David J. Speicher et al., *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*, OSF Preprints (Oct. 19, 2023), https://osf.io/mjc97/.

[4] FDA, *182nd Meeting of Vaccines and Related Biological Products Advisory Committee*, YouTube (Jun. 15, 2023), https://www.youtube.com/watch?v=gBOyPREXGh8&t=17924s.

[5] Kevin McKernan et al., *Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose*, OSF Preprints 12 (Apr. 10, 2023), https://osf.io/b9t7m/ (citing Josephson, Filip, *Rapporteur's Rolling Review Assessment Report EMEA/H/C/005735/RR*, Committee for Medicinal Products for Human Use 78 (Nov. 19, 2020), available at https://icandecide.org/wp-content/uploads/2023/11/Rapporteurs-Rolling-Review-Report-Quality-COVID-19-mRNA-Vaccine-BioNTec-1.pdf).

10ng/dose in vaccines.[6] McKernan's research is summarized in his paper released in April 2023.[7]

Philip Buckhaults, PhD, a cancer genomics researcher at the University of South Carolina, replicated these findings and testified about them before the South Carolina Senate on September 12, 2023.[8] In his testimony, Dr. Buckhaults stated that "[t]he Pfizer mRNA vaccine is contaminated with the plasmid DNA vector that was used as the template for in vitro transcription reaction."[9] Dr. Buckhaults estimates that there are 200 billion pieces of this plasmid DNA in each dose of the vaccine.[10] He notes that the amount of DNA in the vials he tested has in some cases exceeded the FDA's limits.

However, there is cause for concern even where the amounts have not exceeded the limit; crucially, those DNA limits are not the appropriate measure because they pertain to vaccines with recombinant proteins or attenuated viruses which would contain "naked DNA." Dr. Buckhaults explained that, with regard to those types of vaccines, this is "not a problem" because the DNA "gets chewed up immediately … and there's no real mechanism for it to get inside the cells."[11] However, as Dr. Buckhaults observes, that regulatory limit is inappropriate and inapplicable to the COVID-19 vaccines because, here, "everything [in the COVID-19 vaccines] is encapsulated in this lipid nanoparticle [and] it's basically packaged in a synthetic virus able to dump its contents into a cell."[12] In other words, any quantity of DNA in the COVID-19 vaccines is a "far more serious issue" given the design of the vaccines. Thus, adherence to those older standards is not sufficient to guarantee safety.[13]

The third lab to confirm these contamination findings was the Magdeburg Molecular Detections laboratory in Germany, which tested five sealed batches of the BNT162b2 vaccine, all of which contained plasmids between 83 to 354 times above the EMA limit.[14] Dr. Jürgen O. Kirchner wrote of these findings in his September 16, 2023 letter to the German Minister of Health.[15]

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[6] McKernan, *supra* note 5 (citing Li Sheng-Fowler, Andrew M. Lewis & Keith Peden, *Issues Associated with Residual Cell-substrate DNA in Viral Vaccines*, 37(3) Biologicals 190–195 (June 2009), https://www.sciencedirect.com/science/article/abs/pii/S1045105609000293?via%3Dihub); *see also* Harry Yang, *Establishing Acceptable Limits of Residual DNA*, 67 PDA J. Pharma. Sci. & Tech. 155-163 (Mar. 2013), https://journal.pda.org/content/67/2/155.long.

[7] McKernan *supra* note 5.

[8] South Carolina Legislature (Sept. 12, 2023), https://www.scstatehouse.gov/video/archives.php (select "Tuesday, September 12, 2023 10:00am Senate Medical Affairs Committee -- Senate Medical Affairs Committee" at 3:35:00).

[9] *Id*. at 3:38:45.

[10] *Id*. at 3:49:05.

[11] *Id.* at 3:51:25.

[12] *Id.* at 3:52:23.

[13] *Id.* at 3:50:56.

[14] Letter from Dr. Jürgen O. Kirchner to Prof. Dr. Karl Lauterbach at 9 (Sept. 16, 2023), https://www.genimpfstoffe.com/wp-content/uploads/2023/09/Verblindet-Fax-BMG-Lauterbach-16.-Sept-2023-1.pdf

[15] *Id.*

Dr. David Speicher's study found the following results regarding residual DNA limits:

> These data demonstrate the presence of billions to hundreds of billions of DNA molecules per dose in these vaccines. Using fluorometry all vaccines exceed the guidelines for residual DNA set by FDA and WHO of 10 ng/dose by 188 – 509-fold.[16]

III. The Vaccine Contains Simian Virus 40 Enhancers

On October 19, 2023, it was revealed that Health Canada had independently confirmed the presence of Simian Virus 40 ("**SV40**") DNA sequence in the Pfizer vaccine.[17] After Mr. McKernan and Dr. Buckhaults publicly raised the issue of the presence of SV40 enhancers in the vaccines earlier this year, Health Canada stated that "it was possible for Health Canada to confirm the presence of the enhancer based on the plasmid DNA sequence submitted by Pfizer against the published SV40 enhancer sequence."[18]

As Mr. McKernan noted during his presentation to VRBPAC, "The Pfizer vaccines specifically have this SV40 promoter, which was not disclosed in the expression vector map that was given to … the EMA, but the expression vector has a 344 base pair promoter with a nuclear localization signal known as this SV40 promoter."[19]

The work of David Dean, Ph.D., at the University of Rochester shows that SV40 provides a unique key that allows entry to the nucleus:

> [W]e have demonstrated that portions of the 72 bp SV40 enhancer are required for the nuclear entry of plasmid DNA in all eukaryotic cells tested to date; plasmids not containing this sequence remain in the cytoplasm until cell division, whereas plasmids containing the enhancer migrate to the nucleus within several hours.[20]

IV. The Effects of DNA Contamination on Human Recipients Are Unclear

There have long been concerns over the presence of DNA in vaccines. In fact, Moderna's patent for its COVID-19 vaccine specifically mentions that it chose to avoid the "direct injection of genetically engineered DNA" because with it "comes potential problems, including the

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[16] David J. Speicher et al., *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*, OSF Preprints (Oct. 19, 2023), https://osf.io/mjc97/.

[17] Matthew Horwood, *Health Canada Confirms Undisclosed Presence of DNA Sequence in Pfizer Shot*, The Epoch Times (Oct. 19, 2023), https://www.theepochtimes.com/world/exclusive-health-canada-confirms-undisclosed-presence-of-dna-sequence-in-pfizer-shot-5513277.

[18] *Id.*

[19] FDA, *182nd Meeting of Vaccines and Related Biological Products Advisory Committee*, YouTube (Jun. 15, 2023), https://www.youtube.com/live/gBOyPREXGh8?si=aDPw7J5WQOJ_89p4&t=18001.

[20] https://www.urmc.rochester.edu/labs/dean/projects/nuclear-targeting-of-plasmids-and-protein-dna-comp.aspx.

possibility of insertional mutagenesis, which could lead to the activation of oncogenes or the inhibition of tumor suppressor genes."[21]

According to Dr. Buckhaults, the plasmid DNA vectors found in the Pfizer vaccine "could be the cause of some of the rare but serious side effects like death from cardiac arrest."[22] Specifically, "The DNA can and **likely will** integrate into the genomes of transfected cells. There is a **very real hazard** for genome modification of long-lived somatic cells, which could cause sustained autoimmune attack towards that tissue."[23] Crucially, he notes that the genome modification is also a "very real theoretical risk of future cancer, in some people" because, "depending on where in the genome this foreign piece of DNA lands, it can interrupt a tumor suppressor or activate an oncogene."[24]

V. Conclusion

ICAN is aware that this serious issue has been brought to FDA and the response was as follows: "With over a billion doses of the mRNA vaccines administered, no safety concerns related to the sequence of, or amount of, residual DNA have been identified. With regard to the FDA-approved mRNA vaccines, available scientific evidence supports the conclusion that they are safe and effective."[25] This response, however, is inadequate, particularly in light of the above.

Therefore, we ask that the FDA immediately take the following actions:

- Determine if DNA contamination is present in Pfizer's COVID-19 vaccine and make public the results as Health Canada has;
- If there is DNA in Pfizer's COVID-19 vaccine, disclose what potential safety concerns might exist and should be studied;[26]

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[21] https://patents.google.com/patent/US10933127B2/en.

[22] South Carolina Legislature s*upra* note 8 at 3:38:44.

[23] *Id.* (emphasis added).

[24] *Id.* at 3:41:11.

[25] https://www.theepochtimes.com/article/fda-responds-after-being-urged-to-recall-pfizers-vaccine-over-dna-fragments-5519632.

[26] This is consistent with the WHO's Guidelines which state: "Further, … **a DNA sequence homology check of the plasmid with the international databases** (e.g. the National Center for Biotechnology Information, National Institute for Health, USA, and/or other international nucleotide databases) **should be performed to investigate the presence of unintended sequences of biological significance such as those encoding cellular growth functions or alternative and unanticipated reading frames. The identity of the plasmid after transfection into the bacterial cell to be used for production should be confirmed in addition to the phenotype of the cell**. Representative restriction enzyme maps may be useful. Rearrangements of the plasmid within the host bacterial cell are not acceptable." World Health Organization, WHO Technical Report Series No 941, 2007: Guidelines for Assuring the Quality and Nonclinical Safety Evaluation of DNA Vaccines 65 (2007), https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-for-assuring-the-quality-and-non-clinical-safety-evaluation-of-dna-vaccines70ee1b3e-88a6-40af-8989-fbff8304a377.pdf?sfvrsn=521ee591_1&download=true (emphasis added).

- Sequence DNA samples from the stem cells of vaccinated individuals to determine if genome modification has occurred—as urged by Dr. Buckhaults;[27] and

- Determine if any existing contamination meets the definition of "adulteration" pursuant to 21 U.S.C. § 351.

ICAN respectfully requests a response forthwith detailing the precise steps FDA is taking to investigate these troubling findings regarding DNA contamination in Pfizer's COVID-19 vaccines and, if no steps are being taken, an explanation for FDA's refusal to do so.

Very truly yours,

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[27]South Carolina Legislature s*upra* note 8 at 3:44:35.