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Senate Medical Affairs Committee
POB 142, Gressette Bldg. 412
Attn: Research Director
Columbia, SC 29202

To the Senate Medical Affairs Committee:

We write to you today regarding the Pandemic Preparedness Listening Session hosted by the Senate Medical Affairs Committee on September 12th. During the session, the Committee heard remarks pertaining to the Pfizer-BioNTech messenger RNA (mRNA) COVID-19 vaccine, incorrectly stating that the vaccine contains plasmid DNA that could potentially impact a person's DNA and be a theoretical cancer risk. There is no evidence to support these claims and they provide the risk of being misconstrued by either Committee members and/or the public at large.

The Pfizer-BioNTech COVID-19 vaccine has been reviewed by multiple regulatory authorities and advisory bodies globally and has met all safety and quality control guidelines. The U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and other authorities worldwide approved our COVID-19 vaccine with established specifications for development and manufacturing.

The validated method for assessment of residual DNA has shown that the Pfizer-BioNTech COVID-19 vaccine meets the requirements of the World Health Organization (WHO) and the FDA for biological products. Vaccine batches are only certified and released if the criteria, during quality control testing, are met using the validated and approved method. With respect to the Pfizer-BioNTech COVID-19 vaccine, no signs of DNA mutation or COVID-19 vaccine-induced cancer have been reported to date.

It is important to note that similar quality standards regarding residual DNA are applied to other vaccines. Small amounts of residual DNA can be found in several approved vaccines, including influenza and hepatitis vaccines, which have been administered globally for more than 30 years.

Since its initial authorization for use in December 2020, the Pfizer-BioNTech COVID-19 vaccine has been administered to more than 1.5 billion people, has demonstrated a favorable safety profile in all age groups, and has helped protect against severe COVID-19 outcomes, including hospitalization and death.

Sincerely,

A handwritten signature in black ink, appearing to read 'Annaliesa Anderson'.

Annaliesa Anderson, Ph.D.

Additional Resources:

- WHO guidance on residual DNA: [WHO Study Group on Cell Substrates for Production of Biologicals](#)
- FDA guidance: [Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications | FDA](#)
- Example of licensed flu vaccine (Flucelvax) package insert citing residual DNA levels below the WHO guidelines of <10 ng/dose: [download \(fda.gov\)](#)