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VIA EMAIL AND FEDERAL EXPRESS

Wilson Bryan, MD
Director, Office Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave WO71-3103
Silver Spring, MD 20993-0002
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Re: Oversight of COVID-19 Vaccines by OTAT

Dear Dr. Bryan:

We write on behalf of Informed Consent Action Network (“**ICAN**”) to inquire as to why the Office of Tissues and Advanced Therapies (“**OTAT**”) is not overseeing the development, authorization/licensing, and use of mRNA and viral vector COVID-19 vaccines.

As Dr. David Wiseman noted in his comments at the June 10, 2022 Cellular, Tissue and Gene Therapies Advisory Committee (“**CTGTAC**”) meeting,¹ both Pfizer’s and Moderna’s mRNA COVID-19 vaccines meet the FDA’s definition of a “Human gene therapy product”² in that both contain nucleic acids. Both products therefore fall under OTAT’s purview, since “OTAT-regulated products include gene therapy.”³ In fact, Moderna expected that its vaccine would be regulated as a gene therapy product by the FDA, disclosing in its SEC filings that “Currently, mRNA is considered a gene therapy product by the FDA.”⁴ Similarly, BioNTech has

¹ <https://www.youtube.com/watch?v=Eo2BXnGienc&t=11547s>

² “Human gene therapy product: FDA generally considers human gene therapy products to include all products that mediate their effects by transcription or translation of transferred genetic material or by specifically altering host (human) genetic sequences. Some examples of gene therapy products include **nucleic acids** (e.g., plasmids, in vitro transcribed **ribonucleic acid** (RNA)), genetically modified microorganisms (e.g., viruses, bacteria, fungi), engineered site-specific nucleases used for human genome editing, and ex vivo genetically modified human cells. Gene therapy products meet the definition of ‘biological product’ in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. 262(i)) when such products are applicable to the prevention, treatment, or cure of a disease or condition of human beings.” <https://www.fda.gov/media/113768/download> at 30 (footnote omitted) (emphasis added).

³ <https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/otat-learn>.

⁴ <https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm>.

stated in its SEC filings that, “mRNA therapies have been classified as gene therapy medicinal products.”⁵

While OTAT regulates products involving infectious diseases and vaccines and is presently conducting “7 COVID-related research projects,”⁶ we are not aware of OTAT’s involvement with COVID-19 vaccines.

Notably, at CTGTAC’s September 2-3, 2021 meeting, Dr. Rosa Sherfat gave a presentation on “Toxicity Risks of Adeno-associated Virus (AAV) Vectors for Gene Therapy (GT),” in which adverse events similar to those seen from COVID-19 vaccines were discussed, including, for example, thrombocytopenia.⁷

Given the foregoing, as well as OTAT’s responsibility for regulating “gene therapy” products, as well as “tumor vaccines,”⁸ and its mission, which includes “ensuring safety of individuals,”⁹ why is the OTAT not handling review and authorization/licensure of COVID-19 mRNA and viral vector vaccines? We look forward to your prompt response.

Very truly yours,

A handwritten signature in blue ink, appearing to read 'A. Siri', with a stylized flourish at the end.

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.

⁵ <https://investors.biontech.de/static-files/ab71fa6c-64dd-43e4-bf0f-bbecd5a0694d>.

⁶ <https://www.fda.gov/media/156771/download> at 6, 11 (indicating OTAT regulates “Non-viral vectors (e.g., plasmids)” and “Replication-deficient viral vectors (e.g., adenovirus, adeno-associated virus, lentivirus)”).

⁷ <https://www.fda.gov/media/151969/download> at 2, 7.

⁸ <https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/otat-learn>.

⁹ *Id.* at 4.