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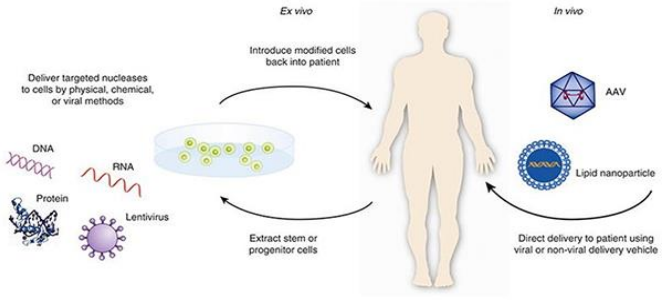
The FDA's definition of gene therapy elaborates:

> "Gene therapies can work by several mechanisms: replacing a disease-causing gene with a healthy copy of the gene; inactivating a disease-causing gene that is not functioning properly; **introducing a new or modified gene into the body** to help treat a disease." [Emphasis added.]



https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

Volume 13 of the October 2014 issue of *Nature* mentions:

> **"mRNA-based therapeutics — developing a new class of drugs"** and notes the FDA definition of gene therapy, "… modification of the genetic material of living cells. **Cells may be modified *ex vivo* for subsequent administration to humans or may be altered *in vivo* by gene therapy given directly to the subject**…Recombinant DNA materials used to transfer genetic material for such therapy are considered components of gene therapy." [Emphasis added.]

What Did Moderna Say About mRNA?

Moderna sued Pfizer-BioNTech in August 2022 for patent infringement over the mRNA technology platform. Note the term "platform." Given that both Pfizer and Moderna are using an mRNA platform for their COVID-19 "vaccines," consider the following from Moderna's June 30, 2020, quarterly report:

Moderna emphasizes:

> "No mRNA drug has been approved in this new potential class of medicines and may never be approved as a result of efforts by others or us. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines."

Moderna affirms:

> "***mRNA is considered a gene therapy product by the FDA…***because no product in which mRNA is the primary active ingredient has been approved, the regulatory pathway for approval is uncertain." [Emphasis added.]
>
> "**The number and design of the clinical trials and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products, or may require safety testing like gene therapy products**." [Emphasis added.]

CONCLUSION

- **Pfizer's COVID-19 mRNA platform product failed to protect from disease or prevent transmission of the SARS-CoV-2 virus and continues to cause harms, including death, as a "vaccine."**
- **Why was Pfizer's mRNA product not correctly categorized as gene therapy for the purpose of the FDA approval process?**
- **Why has it not been halted given its catastrophic health outcomes?**

You be the judge.