Prior to the usage of the COVID gene based therapeutic in late December 2020, the singular scientific information presented to clinicians to assess its efficacy and safety was the Pfizer-BioNTech trial. It was published in arguably the highest impact medical profession journal in the United States. Every physician practicing in the U.S. is familiar with the New England Journal of Medicine and its reputation.
Polack FP, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med 2020: 383: 2603-15.

The two month interim trial results were made freely available to practitioners for their evaluation December 10th, 2020 before the biologic product became available. The data presented clearly showed that the risks of the experimental injection far outweighed any benefits to the trial participants. The results demonstrated 17 times as many significant adverse events compared to COVID cases prevented (no matter how mild) for those receiving the prodrug. Additionally, the data showed nearly twice as many *serious* harms as serious cases of COVID prevented in the experimental group when compared to control group. Based on those obvious results, the modified RNA treatment posed overall much greater risk than benefit. I should not have been advised to receive the injection based on these results.

Determining the safety and efficacy of any available therapeutic and ethically providing that information to patients is a core professional competency for safe medical practice in the community. These professional skills are a requirement of medical licensure and tested for with the first part of the United States Medical Licensing Examination.[1,2]
Food and Drug Administration. Communicating Risks and Benefits: An Evidence-Based User's Guide. August 2011
AHRQ. The SHARE Approach - Communicating Numbers to Your Patients: A Reference Guide for Health Care Providers

This care standard is taught, tested for and promoted because the physician is required to exercise independent and critical analysis of treatments regardless of the source of any new recommendation. This is specifically so the physician is not inappropriately influenced by predatory business interests or unknowledgeable public officials who could intentionally or unwittingly harm the public. The doctor reported here had a professional duty and social contract to act in my best interest with the professional assessment, advice and practice contested herein. This is regardless of any coercion the doctor may have been under by third parties and financial pressures. American College of Physicians Ethics Manual: Seventh Edition. January 2019
AMA Code of Medical Ethics, Chapter 2 Consent, Communication & Decision Making

The results of the Pfizer-BioNTech study were reported in a fashion that is *misinformative* to the untrained/nonprofessional reader.[3] That is, the "95% effective and protection" statements were *misleading* of the trial data.[4] This doctor should have quickly recognized this basic statistical flaw and that the risks actually outweighed the benefits. The doctor should not have recommended the gene based product for me on this basis. Unlike other therapeutics which become widely available, the ability to apply this professional skill was uniquely straightforward and simple in the case of this drug and represents and extremely low bar for professional competency.

Specifically, overestimating the benefit of the biological prodrug by acknowledging only relative risk and ignoring the potential harms to patients which were much more frequent,

misrepresenting those benefits and harms, and then advising me to receive the modRNA treatment all constitute a failure of community care standard. This doctor cannot ethically choose only a new easily demonstrable harmful “standard” while ignoring all well-established standards for safe medical practice.

This doctor’s behavior was inconsistent with professional medical standards documented above. The doctor made a clinical decision involving my care that was clearly inappropriate for the situation. This doctor’s poor clinical judgement to advise the injection put my safety at completely unnecessary risk, constituting patient endangerment. Moreover, by failing to communicate/disclose appropriate risk information regarding/misrepresenting the COVID gene based therapeutic, the doctor also denied me the inalienable right to exercise autonomy through proper informed consent or refusal. As the regulatory agency responsible for issuing this doctor’s license to practice medicine and ensuring compliance with community care standards, I am requesting a full investigation into this incident of medical incompetence which was followed by significant harm to me (including loss of trust in the medical community) as detailed in this complaint submission.

Additional sources supporting my complaint:

1. Biostatistics, Epidemiology/Population Health, & Interpretation of the Medical Literature. In: USMLE® Content Outline: A Joint Program of the Federation of State Medical Boards of the United States and NBME. 2024:37. https://www.usmle.org/sites/default/files/2022-01/USMLE_Content_Outline_0.pdf
2. Social Sciences. In: USMLE® Content Outline: A Joint Program of the Federation of State Medical Boards of the United States and NBME. 2024:39. https://www.usmle.org/sites/default/files/2022-01/USMLE_Content_Outline_0.pdf
3. Brown R B. (2022). Relative risk reduction: *Misinformative* measure in clinical trials and COVID-19 vaccine efficacy. Dialogues in health, 1, 100074. https://doi.org/10.1016/j.dialog.2022.100074
4. Stadel B. (2005). *Misleading* use of risk ratios. Lancet, 365(9467), 1281-1360.
5. Public Health Sciences: Epidemiology and Biostatistics. Tao L. ed. First Aid for the USMLE Step 1. McGraw Hill, 2022. 260. https://archive.org/details/fa-2022/mode/2up
6. Public Health Sciences: Ethics. Tao L. ed. First Aid for the USMLE Step 1. McGraw Hill, 2022. 268-269. https://archive.org/details/fa-2022/mode/2up
7. AAFP. Practice Guidelines. Shared Decision-Making: Guidelines From the National Institute for Health and Care Excellence. https://www.aafp.org/pubs/afp/issues/2022/0800/practice-guidelines-shared-decision-making.html
8. Fraiman J, et al. (2022). Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine, 40(40), 5798–5805. https://doi.org/10.1016/j.vaccine.2022.08.036
9. Principles of Biomedical Ethics: Eighth Edition. Oxford University Press. October 2019. https://global.oup.com/ushe/product/principles-of-biomedical-ethics-9780190640873?cc=us&lang=en&