

Review of: "mRNA: vaccine or gene therapy? Regulatory issues."

Karen Manoutcharian¹

¹ Universidad Nacional Autónoma de México

Potential competing interests: No potential competing interests to declare.

In the current study, the author accurately outlined the legal/regulatory issues related to recently licensed Covid-19 mRNA vaccines. Although the conclusions and concerns are clearly right on, there are still several critical scientific issues that require clarification. Perhaps the most important: the initial promise and the milestone in success for these vaccines were their capability to protect against infection: these vaccines are not able to do it. Furthermore, the decision to give emergency use authorization has been made on highly questionable trial data where among thousands of vaccinated people a handful of them got infected while among non-vaccinated the numbers were about 15-20. Importantly, the rate of exposure to the virus, both in initial and later studies, never has been considered. Therefore, we should avoid confusion and clearly should separate commercial "success" from vaccine efficacy in terms of purely scientific criteria and definitions. Finally, the mRNA is just a vaccine delivery vehicle, more precisely is a kind of business "project" lacking any novel/new idea-based component and could not replace the promising vaccine immunogen itself. Therefore, there is not any sound scientific argument to be optimist regarding the possible success of these vaccines targeting both the pathogens bearing high mutation rate and cancer.