Review of: "mRNA: vaccine or gene therapy? The safety issues of regulation"

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Helene Banoun addresses a timely and important issue, namely what is the regulatory status of mRNA based therapeutics, is it to be considered gene therapy or not. What is left out of the discussion, and could be included, that on average the development, testing, and regulatory trajectory of a given vaccine is 10-15 years. In times of COVID-19, this would mean that the first vaccines could come to the market in 2030-2035. I disagree with the opening statement of the abstract that vaccines escape some of the controls required for (other) human drugs. (I also wouldn't use the word " escape"). It would be strange that the regulatory authorities such as FDA and EMA are of such an opinion, because they ultimately can approve (or not) any new drug, being a vaccine or any other medicine.

The subject as such is important, but it not little-known as stated in the first line of the introduction is well known.

Maybe one aspect could be added to the discussion. The mRNA technology in general (in the sense of modified RNA; in the current version of the manuscript it is unclear whether mRNA stands for messenger RNA or for modified RNA, modRNA is used once) was and is being developed as a novel form of gene therapy. And indeed, the success of mRNA vaccines for COVID-19 has spurred research into wider application, including cancer vaccines. The notation "vaccine" is not needed, a cancer vaccine also falls within the definition of a vaccine, as are vaccines against addiction. Vaccination also includes the administration of antibodies, that is passive vaccination.

In some countries, and the USA and France are used as an example, the military were involved in management of the unprecedented global health crisis. This certainly was not the case in the majority of countries.