Question for written answer E-000355/2024
to the Commission
Rule 138
Virginie Joron (ID)

Subject: Lobbies calling for mRNA vaccines not to be classified as gene therapy

On 17 January 2024, BioNTech and Moderna lobbyists hosted a lunch in the European Parliament with Members[1] to discuss the forthcoming revision of the pharmaceutical legislation.

Their main objective was to change the legislation's definition of 'gene therapy'. At present, mRNA vaccines (like the COVID-19 vaccine) are to be classified as gene therapy. However, they felt that only products that modified the genome should be classified as gene therapy.

1. Do EMA and the Commission classify Comirnaty and Spikevax mRNA vaccines as gene therapy? If so, what are the corresponding regulatory consequences?

2. Has EMA carried out DNA integration assessments[2]or is it going to request them from independent laboratories?

3. What is the Commission's position on this opaque lobbying without debate?

Submitted:2.2.2024

[1] https://www.kangaroogroup.de/next-events/

[2] https://www.floridahealth.gov/_documents/newsroom/press-releases/2024/01/20240103-halt-use-covid19-mrna-vaccines.pr.pdf, 3 January 2024: 'The FDA's response does not provide data or evidence that the DNA integration assessments they recommended themselves have been performed.' 'DNA integration could theoretically [...] transform a healthy cell into a cancerous cell.'*DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada:Exploratory dose response relationship with serious adverse events,*David J. Speicher, Jessica Rose, L. Maria Gutschi, David Wiseman, Kevin McKernan, http://tinyurl.com/2s3npu8m: 'All products tested exceeded the guidelines for residual DNA set by the FDA and WHO of 10 ng/dose by 188 –509-fold.'