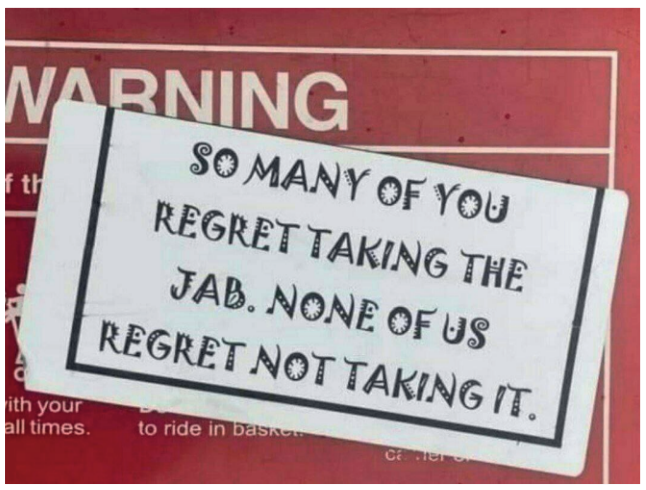

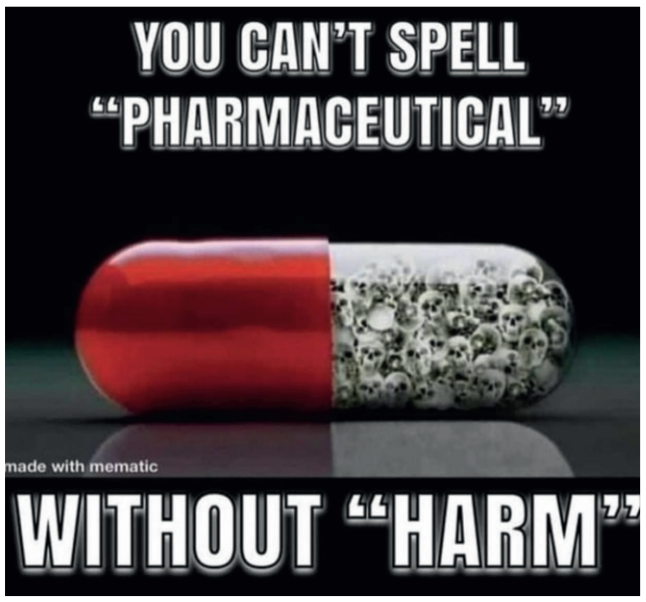

What the Leaked EMA Emails & Docs Reveal: Major Concerns with Pfizer C-19 Vaccine Batch Integrity and The Race to Authorize

by bobwidlefish, aug 2022, LINK

"Trial Site News recently were able to review leaked internal emails from the European Medicines Agency (EMA) and meeting report between the agency and Pfizer. The EMA oversees the evaluation and supervision of medicinal products for the European Union. Like other regulatory health bodies, its main responsibility is to protect and promote public health. Snapshots of internal EMA email correspondence; a November 26, 2020, PowerPoint presentation from a pivotal meeting between Pfizer and the agency, as well as a confidential 43-page Pfizer report were provided by an anonymous source because of their trust in Trial Site's commitment to transparency, accessibility, and accountability in furtherance of a highly ethical, quality-focused and public health-centric biomedical research industry.

Regulatory agencies, like the EMA, the Food and Drug Administration (FDA) in the U.S. and

the UK's Medicines and Healthcare products Regulatory Agency (MHRA) are chartered to make decisions based to better the public. External influences such as political or media pressure are not meant to be a driving factor in their decision-making, however, when it came to pandemic conditions and the fast-tracked conditional marketing authorization of the Covid-19 vaccines (particularly for the mRNA-based vaccines produced by Pfizer-BioNTech and Moderna), it appears the latter won the day.

The time period of the email correspondence in question stretches from November 10 – 25, 2020, just weeks before the EMA granted CMA (conditional marketing authorization) for the Pfizer-BioNTech Covdid-19 vaccine on December 21, 2020. The FDA granted EUA (emergency use authorization) for this vaccine on December 11 with the MHRA making it first to the finish line on December 2. Here this author uses the term 'finish line,' as the emails do reveal an intense, almost competitive-like rush to authorize the Covid-19 vaccines, as quickly as possible. Understandably, the world was gripped by a pandemic at the time, where there was immense impetus to authorize a vaccine to protect people from the novel coronavirus.
[…]

Cavaleri's email speaks to the extent of how politics (and the US government) was driving the FDA's regulatory process, making sure it was going at 'warp speed'. And of course, on that note Trump's Operation Warp Speed was to ensure all vaccine development records would be shattered. The intentions were undoubtedly good given the outbreak of the worst pandemic in a century. […]

In a November 19 email, Wathion reveals a 'rather tense' TC (teleconference call) with the European Commissioner (Ursula von der Leyen) which was 'at times even a bit unpleasant.' This reflects the mounting pressure which the EMA staff were under to issue CMA quickly following an EUA granted by the FDA/MHRA for the Pfizer-BioNTech vaccine. Von der Leyen is implicated in potentially being responsible for this tense environment with 'a delay of several weeks…not easily acceptable for the EC [European Commission].'

In early 2022, Trial Sites News reported how von der Leyen was embroiled in scandal when a group of independent MEPs demanded her immediate resignation and full disclosure of a series of private text messages between her and Pfizer's CEO, Albert Bourla. Only a small portion of these texts were ever disclosed. Of the ones that were, they revealed her negotiating portions of a European-wide vaccine deal, unilaterally with Bourla via a series of texts! Clearly standard protocols in Europe were thrown out the window in favor of expediency and this seemingly was tied to a unified competitive pressure on all three regulatory agencies.

Wathion lays bare his reflections after this particular TC, and shockingly writes how 'the political fall-out seems to be too high even if the "technical" level at the MSs [Member States] could defend such a delay in order to make the outcome of the scientific review as robust as possible.' Put another way the continuous broadcast of science first appeared as a cover for politics first. […]"

Read full article by Sonia Elijah, LINK