FDA is using the COVID-19 Vaccines as a "Platform Technology" for mRNA Vaccine Trials.

This shows shocking idiocy and malfeasance on the part of the FDA, as well as complete regulatory capture.

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Sep 28

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There was a World Health Organization (WHO) consultation in April, 2021 (Sept, 2022 online publication ahead of Dec, 2022 print) whereby US government officials laid out strategies for the process of future mRNA vaccine approvals by the FDA. A summary of this meeting has just been published online, ahead of print. So, we no longer have to speculate about what the FDA has decided about considering future mRNA vaccines and using the past pre-clinical data package as the foundation for these vaccines as being a “platform” technology.

The 2021 WHO informal consultation on regulatory considerations discussed these issues. Dr Keith Peden (Center for Biologics Evaluation and Research (CBER), Food and Drug Administration presented the FDA’s experience and position on licensure of new

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Emerg Microbes Infect 2022 Dec;11(1):384-391. doi: 10.1080/22221751.2022.2026742.

From the World Health Organization article:

My comments are in parentheses ( ) within the text below.

> ## Regulatory perspectives
>
> Dr Keith Peden (Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), USA) presented the **FDA's experience with mRNA vaccines, including product and Chemistry, Manufacturing and Controls (CMC) issues, potency determination, pre-clinical studies, efficacy assessment (what to monitor and what assays to use), evaluation of possible vaccine-enhanced disease, and the question of whether or not mRNA can be viewed as a platform technology.**
>
> **He commented that whether the individual LNP component should be evaluated separately or as the vaccine is an individual NRA's decision. CBER decided only the product should be tested** (*this means only the final formulation - for example, with the COVID-19 vaccine, only the final spike protein mRNA formulated as injected would need to be evaluated. No separate testing of the individual components, which is inconsistent with standard regulatory practice. The shocking implications of this are discussed below*).
>
> **The issue of whether mRNA vaccines are a platform technology and what the implications would be if so, has been discussed at the FDA** (*this means the vaccines would be like the flu- VERY limited pre-clinical and clinical would need to be done for full licensure*).
>
> This has implications, e.g., what testing would be required for a new mRNA that expresses a new antigen using the same LNP and manufacturing process? What pre-clinical studies would be required, and which could be dispensed with based on data from similar products? Could the vaccine development process be streamlined?
>
> *(He goes on)*
>
> CBER has determined that this is in flux, and **has not required that biodistribution studies be performed on a new vaccine if studies with another vaccine using the same manufacturing process and same LNP have already been done**. (*WOW. This is*

> *over the top malfeasance. With all this new mRNA vaccine and mRNA clinical trials being conducted - CBER DID NOT REQUIRE NEW BIO DISTRIBUTION STUDIES*!)
>
> It is expected that modifications to the manufacturing process, and likely the encapsulating lipids will occur in the future. (*as **future companies will have to face an onslaught of new requirements, such as addressing the stability of the mRNA in these vaccines, it will be almost impossible to now move away from this manufacturing process and LNP. This functionally provides a monopoly for the current companies, and an associated cash cow in perpetuity**).*

Highlights:

CBER decided that going forward, with new mRNA vaccine trials, ONLY the product (the final formulation) should be tested as long as **same manufacturing process and LNP are used. This is despite the fact that CBER did not do complete biodistribution or toxicity studies on these products, as discovered in the FOIA Japanese pre-clinical package and the US court ordered document release.**

Essentially, CBER has completely bypassed the issues of these vaccines not having a complete pre-clinical evaluation, and in April 2021 decided that new mRNA vaccines in development will not have to comply with the norms for vaccine development. That is all mRNA vaccines in the future, as long as don't vary from what has already been done, *will be like processed like the the influenza model, with only the "payload" to be tested.*

Finally, CBER has determined that bio-distribution studies on new mRNA vaccines using this "platform technology" will not have to be redone, even though they were not properly evaluated in the first place. This is over the top idiocy. New products will be allowed to proceed with human testing without having a complete pre-clincial data package - as what was submitted to the FDA was cobbled together from previous studies is incomplete. For instance, a reporter gene (luciferase) instead of the spike protein was used for toxicity and bio-distribution studies, and the LEAST sensitive assay to detect protein expression was used in the studies. As a consequence, the biodistribution data which the FDA is relying on is a gross underestimate of the true bio-distribution of transgene protein expression. The bio-distribution studies were done using techniques that were not able to differentiate bio-distribution in tissues. Instead,

whole animal imaging was used, which is essentially a parlor trick, and is absolutely not quantitative. Good for pictures on the cover of Rolling Stone, but not for actual bio-distribution analysis. This was the specific problem which I called Dr. Peter Marks about last fall, and which he assured me had been addressed in the full data package submitted by Pfizer. Just for the record, he lied to me.

What this all means is that using these flawed pre-clinical trials to support a platform technology was PLANNED from the beginning. By not focussing on the payload of the vaccines, but instead relying on the generic formulations prior to initiating clinical trials, this has allowed CBER (and Moderna, and Pfizer/BioNTech) to transfer these highly flawed pre-clinical data packages to all upcoming mRNA vaccine trials for new vaccine products!

The implications of this are enormous. First, it is complete regulatory failure as well as yet more evidence of regulatory capture. Second, that this “pandemic” has been exploited to drive approval of a mRNA platform technology -whereby only TWO companies will be allowed to compete (those that completed the two approved pre-clinical packages).

We know now that the pseudouridine-containing mRNA does not break down for months. But rather, it stays in the body producing protein. This is not natural mRNA by any stretch of the imagination, and it does not behave like natural mRNA. This technology, as currently practiced by Moderna and Pfizer/BioNTech, employs a novel polymeric biomolecule, the properties of which have not been well characterized. The protein levels being produced by these vaccines is not known, the duration of protein production isn’t known, and the biodistribution of protein production is not known. And the FDA and other global regulatory authorities are all comfortable with this?? As an example of one of the dangers with not knowing the protein levels, distribution and duration of transgene expression, we know from many prior immune tolerance studies that too much antigen (protein in this case), can cause “tolerance.” That is essentially where the immune system stops seeing the threat. These vaccines could easily drive up tolerance against a virus. We know from multiple peer reviewed papers from top global laboratories that they are driving “immune imprinting” or “original antigenic sin” problems- in human beings (not just mice). This is not theoretical. It is real, and being exacerbated by the “booster vaccines” (FDA terminology) or “new vaccines” (US White

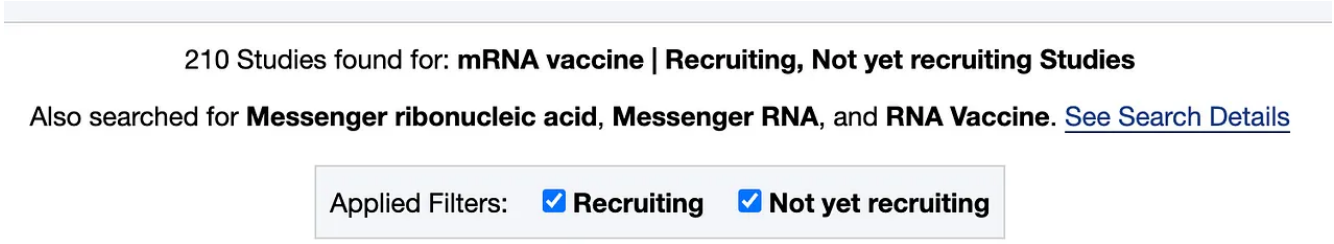
House terminology).

In the future, as companies will have to face an onslaught of new requirements, such as addressing the stability of the mRNA in these vaccines, it will be almost impossible to now move away from this manufacturing process and LNP. This will become the platform technology because of the shortsighted position taken by the FDA/CBER.

Another issue is that this synthetic mRNA (pseudouridine was substituted for uridine) is that it is immunosuppressive. Having this mRNA in the body suppresses not only the ability to fight off latent DNA viruses such as shingles, EBV and CMV, it is likely to also suppress the ability of the immune system to detect cancer.

In the future, CBER will have to come to terms with the fact that the pre-clinical trials were completely inadequate, and yet they now have 50+ mRNA vaccine trials currently enrolling and over 150 more on the way based on that highly flawed pre-clinical data package. A quick search at clinicaltrials.gov yields documents the problem that they have created.

Currently a search on mRNA vaccine yields many, many results of clinical trials that have evidently used the incomplete data package from the COVID-19 vaccines as "platform technology." At least 50 of these mRNA vaccine clinical trials are currently enrolling.



The FDA/CBER has allowed this to happen without any Congressional knowledge. This is a gross oversight. The Department of Justice and the US Congress need to demand answers now.

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"When a knowledge system importantly loses integrity, ceasing to provide the kinds of trusted knowledge expected of it, we can label this epistemic corruption. Epistemic corruption often occurs because the system has been co-opted for interests at odds with some of the central goals thought to lie behind it. There is now abundant evidence that the involvement of pharmaceutical companies corrupts medical science." - Sergio Sismondo, Department of Philosophy, Queen's University, Kingston, ON, Canada

https://euphoricrecall.substack.com/p/not-exactly-beacons-of-morality

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Brien Writes Brien's Newsletter Sep 28 ❤ Liked by Robert W Malone MD, MS

The silence of political leaders on this entire topic is the real crime against humanity. This is prima facie evidence that our system of constitutional rights and the rule of law has completely collapsed. We the people have been left alone to deal with this. I ask myself

every day how political leaders can fail to even mention medical ethics, medical freedom and proper regulatory oversight in their speeches, platforms and in all the millions they spend on tv ads and public messaging. It is a staggering development and is true of both parties in the US and most parties globally, with just a few notable exceptions(eg, Italy). I don't have an answer and don't know what it's going to take to change this situation, other than to keep praying.

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25 replies

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