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FDA Overhaul Needed for New Vaccines and mRNA Therapies

Promise or Peril: COVID-19 mRNA Vaccine Issues Series (Part 1)

The regulations the FDA cobbled together for mRNA vaccine approval has set the stage for adverse events related to genetic therapies using this new technology.

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The pandemic has ended, but the introduction of the COVID-19 vaccines, which use mRNA technology, signifies the start of a new era in modern medicine. The lagging regulatory framework that the FDA cobbled together specifically for mRNA vaccine approval has set the stage for adverse events related to genetic therapies using this new technology. In this series, we reveal emerging concerns about mRNA injections related to the lipid nanoparticles, spike protein, and vaccine contamination as public documents are released.

ummary of Series Key Facts

- According to a Securities and Exchange Commission filing by Moderna in June 2020, "Currently, mRNA is considered a gene therapy product by the Food and Drug Administration (FDA)."

- The FDA created new guidance, released in June 2020, for gene therapy products to be marketed as vaccines against COVID-19. They weren't put through the same testing requirements as other RNA therapeutics. The new vaccines also weren't required to go through human biodistribution studies.

- Had mRNA vaccines been held to the same regulatory standards required for novel therapeutics, the following three issues would likely have been identified prior to authorization for human use:

  The lipid nanoparticle (LNP) shell that's used to deliver the mRNA has inflammatory potential and can cluster with other LNPs or fall apart, allowing the mRNA inside to fall out and circulate freely in the bloodstream.

  The spike protein coded by the mRNA and its S1 subunit has been found in the blood following vaccination. Both the spike protein and the S1 subunit are associated with inflammation and clotting.

Contamination during the manufacturing process can cause impurities in the vaccine, such as mRNA fragments and bacterial plasmids. Testing by pharma before authorization found impurities—have these issues been fixed?

- Despite the promising potential of mRNA therapeutics, did the COVID-19 pandemic emergency provide reasonable justification for the suspension of typical regulatory requirements?

- Should these vaccines have been recommended only for the highest-risk individuals pending further human testing? Should vaccine information sheets have included all known risks to allow for full and complete informed consent?

- Were mandates unethical given the lack of standard pre-authorization safety testing?

- All of these questions are relevant given the development of new mRNA vaccines against influenza and respiratory syncytial virus. What regulatory framework will apply going forward? Will these newer mRNA vaccines be subject to stricter oversight aligned with, to borrow Moderna's wording, "genetic therapy" or the lagging framework used for COVID-19 mRNA vaccines?

When a new vaccine is developed for humans, it's subject to rigorous safety testing—first in animals, then in humans. That's what normally happens. To illustrate what actually happened with the mRNA vaccines, it'll help to use an analogy. Let’s say the COVID-19 vaccine was the first bioengineered egg to be tested by the FDA for safe human consumption. The egg "shell" is the LNP capsule that carries the genetically modified "contents," the mRNA and spike protein.

The FDA decided to relax its regulations and only test the LNP shell in animals and bypassed testing of the contents (mRNA and spike protein) in animals or humans. This testing would have determined how the body responds to the new technology (biodistribution study).

In other words, the FDA approved the first-ever mRNA "vaccine" to be injected into the human body without checking the biodistribution of the "contents" (the mRNA and spike protein) for human safety. It only checked the LNP "shell" on animals before giving its stamp of approval. Even the limited LNP testing data is alarming.

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Despite this lack of adequate safety testing for the first mRNA "vaccine" used in humans, the FDA granted authorization and assured the public with authoritative certainty that the entire product was safe. As serious adverse events unfolded at an unprecedented rate, the FDA doubled down on its safety claims, requiring no additional studies.

The limited data we do have is concerning because it shows that the LNP spreads throughout the body instead of just staying in one place. This limited level of testing isn't permitted for the approval of other drugs.

The European version of the U.S. FDA—the European Medicines Agency (EMA), was more open than the FDA regarding the limited data available. The EMA shared many details about how the LNP (the "shell") spreads throughout the body. It also expressed concerns about impurities in the vaccines during manufacturing. This series will discuss these issues thoroughly, including excerpts from EMA reports. The Pfizer report submitted to the FDA, which we'll also cover, was only available after a Freedom of Information Act request,

a legal mechanism to compel disclosure. Why is there such reluctance to share testing data?

Relaxed Regulations for COVID mRNA Vaccines

Before a new drug or vaccine is approved by a health authority, it must understand how the body will process the drug.

Typically, a nonclinical pharmacokinetics study report is submitted to the FDA to explain how the drug is released, absorbed, distributed, metabolized, and excreted from the body. This is called a biodistribution study.

However, during the COVID-19 pandemic, the FDA modified its typical approval process for new vaccines in response to the public health emergency. The new "nonbinding recommendations" for the pharmaceutical industry issued in June 2020 relaxed the rules for mRNA vaccine approval compared to what's typically required for "gene therapy."

The new FDA guidance, titled "Development and Licensure of Vaccines to Prevent COVID-19," allowed companies to present data collected from other development platforms. In other words, studies that were conducted on other products were permitted to support the application for emergency use of the mRNA vaccines:

> "COVID-19 vaccine development may be accelerated based on knowledge gained from similar products manufactured with the same well-characterized platform technology, to the extent legally and scientifically permissible.

"In some cases, it may not be necessary to perform nonclinical safety studies prior to FIH [first in human] clinical trials because adequate information to characterize product safety may be available from other sources. For example, if the COVID-19 vaccine candidate is made using a platform technology utilized to manufacture a licensed vaccine or other previously studied investigational vaccines and is sufficiently characterized, it may be possible to use toxicology data (e.g., data from repeat dose toxicity studies, biodistribution studies) and clinical data accrued with other products using the same

platform to support FIH clinical trials for that COVID-19 vaccine candidate." The request for biodistribution studies is written in very general terms, without sufficient specificity for a novel therapeutic such as the COVID-19 mRNA vaccines:

> "Biodistribution studies in an animal species should be considered if the vaccine construct is novel in nature and there are no existing biodistribution data from the platform technology. These studies should be conducted if there is a likelihood of altered infectivity and tissue tropism or if a novel route of administration and formulation is to be used."

While the FDA authorized these products under these relaxed rules, other scientists have suggested that more specificity was needed. For example, a review by mRNA researcher Pieter Vervaeke and colleagues states: "The rapid rise of mRNA therapeutics has resulted in a regulatory framework that is somewhat lagging." They explain further in the abstract that a "multi-layered approach" should be used to understand what the new products do in vivo (in the human body).

"Biodistribution studies for RNA therapeutics should encompass both the RNA molecule(s), the individual components of the carrier, the combined RNA-carrier drug, and the produced protein," they said.

In other words, test the shell of the egg and the contents.

As we'll demonstrate, adhering to such guidelines would have been very helpful prior to authorization for human use. However, to our knowledge, none of the current COVID-19 mRNA vaccines have ever been through such biodistribution studies to evaluate the RNA molecule and its encoded spike protein. Only the LNP carrier capsule has been studied in this manner, and only in animals, not humans.

FDA Review of Pfizer Biodistribution Study

Based on the FDA's modified rules for mRNA vaccines, the agency reviewed Pfizer's BNT162b2 LNP carrier biodistribution study report in November 2020 to understand how the mRNA vaccine

would work. The report was marked as "approved" on Nov. 9, 2020 (pdf).

As will be presented here and in Part 2, this report was widely adopted by the European Medicines Agency, the Australian Therapeutic Goods Administration, and the Japanese government.

However, the LNP is only the carrier of the vaccine mRNA (the "shell" of the "egg"), it isn't the key active ingredient of the mRNA vaccine (the contents of the "egg").

The inside of the "egg" was replaced with a substitute—the mRNA carried in the LNP study was coded for luciferase, not the same spike-protein encoding that mRNA used in the vaccine. Finally, two of the lipids used in the LNP molecule hadn't previously been authorized for use in humans. Thus, novel lipids were being developed to carry a novel vaccine for a mass vaccination campaign, yet no human biodistribution studies were solicited.

The FDA typically requires human studies early in drug development, and as few as six healthy volunteers would have been required. Given that our bodies manufacture the spike protein once the vaccine is injected, human studies should have been done to evaluate the production, distribution, and metabolism of the mRNA and spike protein throughout the body.

While not ideal, animal studies do reveal helpful information. The biodistribution study report submitted by Pfizer used radioactive labeling to tag the LNPs in the vaccine administered to 21 male and 21 female rats. This allowed the scientists to track and quantify the amount of vaccine reaching various organs over 48 hours following injection.

The rats were injected with 50 micrograms of mRNA vaccine. After 15 minutes, in addition to having a relatively high mRNA concentration at the injection site, the vaccine began to disperse to different organs throughout the body, reaching the liver and spleen first.

After an hour, the concentration of the vaccine in the liver and spleen increased further, and it reached the adrenal glands and bone marrow.

After 24 hours, the researchers examined the distribution of the mRNA vaccine in the rats and found that in addition to the highest level being at the injection site, the next highest levels were in the spleen, liver, adrenal glands, ovaries, bone marrow, lymph nodes, kidneys, muscles, and heart, in order of the concentration. The liver reading was 24.288 at 48 hours. This number can be found in both the Australian and Japanese reports, which will be discussed in Part 2 of this series.

Figure 1: Rat Biodistribution Study Data in an FDA Report

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Table 1 **Mean (Sexes-Combined) Concentration and Recovery of Total Radioactivity in Whole Blood, Plasma and Tissues Following Single Intramuscular Administration of [^{3}H]-08-A01-C01 to Wistar Han Rats**

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as total lipid concentration (µg lipid equiv/g (mL)) and % of administered dose

Sample	Total Lipid Concentration (µg lipid equiv/g (or mL))							% of Administered Dose						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181	-	-	-	-	-	-	-
Adrenal glands	0.271	1.484	2.719	2.888	6.803	13.772	18.209	0.001	0.007	0.010	0.015	0.035	0.066	0.106
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365	0.000	0.001	0.001	0.001	0.001	0.002	0.002
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687	-	-	-	-	-	-	-
Bone marrow (femur)	0.479	0.960	1.237	1.236	1.836	2.492	3.771	-	-	-	-	-	-	-
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068	0.007	0.013	0.020	0.016	0.011	0.010	0.009
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112	0.000	0.001	0.001	0.002	0.002	0.002	0.003
Heart	0.282	1.029	1.402	0.987	0.790	0.451	0.546	0.018	0.056	0.084	0.060	0.042	0.027	0.030
Injection site	128.253	393.810	311.177	338.039	212.760	194.855	164.929	19.851	52.620	31.574	28.383	21.862	29.126	24.625
Kidneys	0.391	1.161	2.046	0.924	0.590	0.426	0.425	0.050	0.124	0.211	0.109	0.075	0.054	0.057
Large intestine	0.013	0.048	0.093	0.287	0.649	1.104	1.338	0.008	0.025	0.065	0.192	0.405	0.692	0.762
Liver	0.737	4.625	10.972	16.547	26.544	19.240	24.288	0.602	2.871	7.330	11.863	18.050	15.439	16.155
Lung	0.492	1.210	1.834	1.497	1.151	1.039	1.093	0.052	0.101	0.178	0.169	0.122	0.101	0.101
Lymph node (man)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	-	-	-	-	-	-	-
Lymph node (mes)	0.050	0.146	0.530	0.489	0.689	0.985	1.366	-	-	-	-	-	-	-
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	-	-	-	-	-	-	-
Ovaries (females)	0.104	1.339	1.638	2.341	3.088	5.240	12.261	0.001	0.009	0.008	0.016	0.025	0.037	0.095
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014	0.015	0.015	0.011	0.019
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001	0.001	0.000	0.000	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002	0.003	0.003	0.004	0.003
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008	0.008	0.005	0.006	0.009
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	-	-	-	-	-	-	-

- =Partial tissue taken therefore not applicable

FDA-CBER-2021-5683-0013984

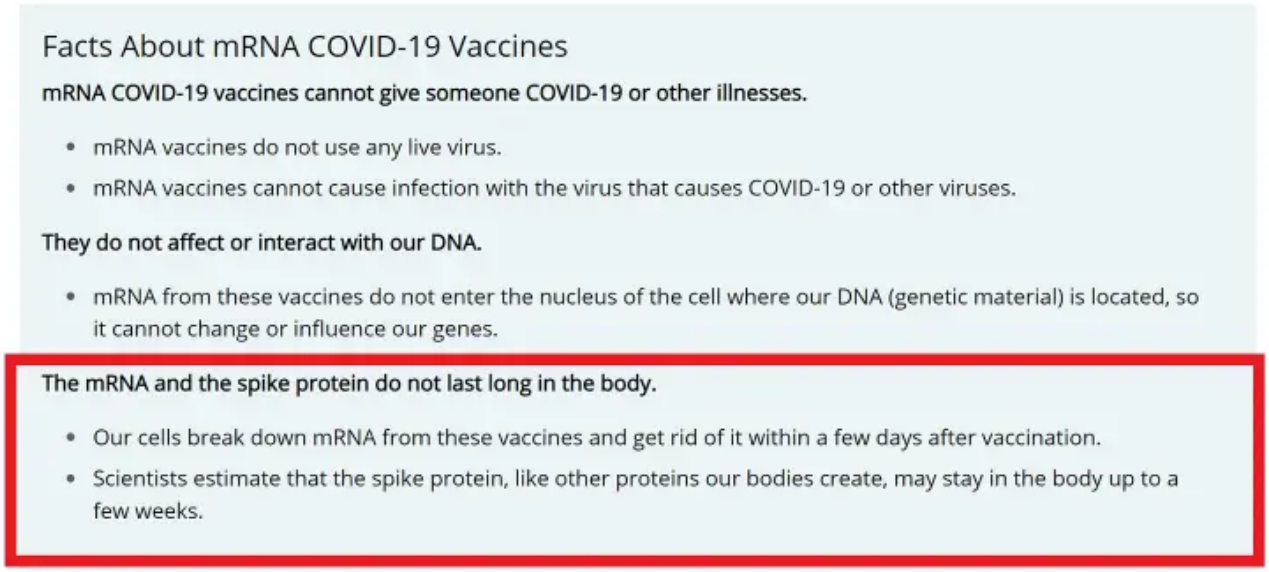
Rat biodistribution study data in an FDA report from November 2020. (Source: FDA-CBER-2021-5683-0013976)

CDC's Silent Removal of Reassuring Message

After issuing authorization, the U.S. Centers for Disease Control and Prevention (CDC) sought to calm fears about toxicity and claimed that the mRNA is broken down and removed from the body quickly, while the spike protein may take longer to clear.

Yet these claims (see below in the red box), which were stated on the CDC website on July 15, 2022, have been quietly removed. Does the CDC, therefore, acknowledge that evidence is lacking to support these claims?

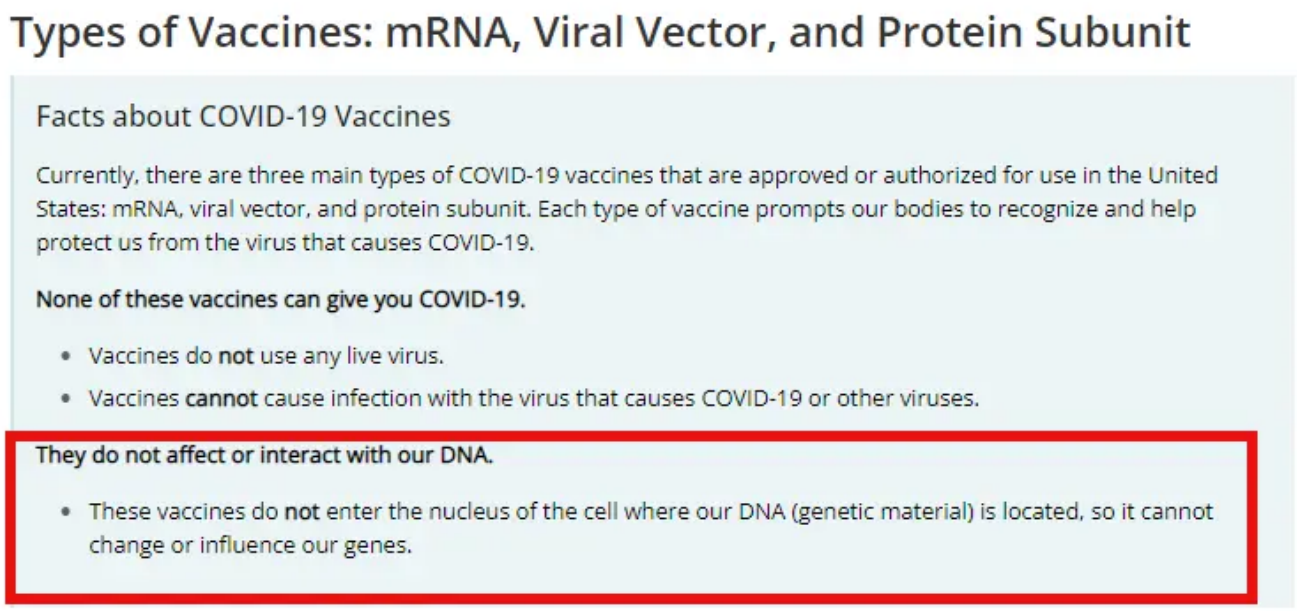
Figure 2a: CDC Reassurance That mRNA and Spike Protein Disintegrate Quickly



The CDC provides reassurance that mRNA and spike protein disintegrate quickly in the body on July 15, 2022. (Source:cdc.gov web archive)

Sometime after July 2022, the CDC updated this web page to reassure the public that the mRNA vaccine doesn't integrate into the human genome, with no mention of how long the spike protein and mRNA will last in the body.

Figure 2b: CDC Reassurance That mRNA Doesn't Enter the Cell Nucleus



The CDC provides reassurance that mRNA and two other types of vaccines don't integrate into the human genome. (Source:cdc.gov)

Why did the CDC change the messaging on its website to focus on DNA integration instead of how long mRNA and spike protein last in the body?

> *Next: A closer look at the reports from health authorities in Australia, Japan, and Europe provides insight into why the CDC may have withdrawn the claim that the mRNA is broken down quickly and that spike protein doesn't linger in the body. The EMA reports show where the LNP shell and mRNA travel throughout the body.*

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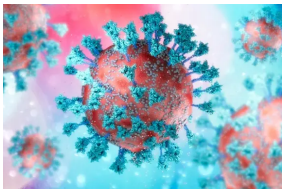

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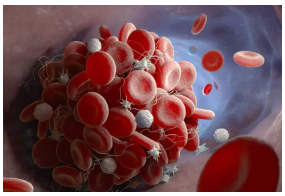

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