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Pfizer Used Dangerous Assumptions, Rather Than Research, to Guess at Outcomes

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Global Research, August 03, 2022
DailyClout 1 August 2022
Theme: Science and Medicine

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At the launch of widespread mass inoculation of the public with Pfizer's mRNA vaccine, BNT162b2, media, physicians' spokespeople, and government officials communicated widely that the injected drug would be retained at the injection site muscle tissue and in local lymph nodes. The components were supposed to be metabolized in a day or so, leaving only induced SARS CoV-2 Spike antigen to evoke a therapeutic immune response. A short pulse of drug effect would be followed, they claimed, by limited production of Spike antigen.

However, newly released internal Pfizer documents show that this is not true. In fact, the injection causes widespread distribution of the material in tissues and this distribution persists for at least two days, and probably much longer. These facts are the exact opposite of what was publicized.

A cluster of FDA-released Pfizer documents — "*Final Report: A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats*" [see this], *2.4 NONCLINICAL OVERVIEW* [see this], "*MODULE 2.6.5. PHARMACOKINETICS TABULATED SUMMARY*" [see this] and the heavily redacted report "*R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODERNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION*" [see this] — all examine tissue distribution of Pfizer's mRNA vaccine BNT162b2. These documents will be addressed in this report.

Pfizer Study 185350, "*Final Report: A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rat*", is one of 21 preclinical Prizer studies involving mice, rats and rhesus macaque non-human primates. Study No. 185350 (Sponsor Reference ALC-NC-0552) was summarized in Pfizer's "2.4 Nonclinical Overview" and was separately published as a Final Report dated September 24, 2020.

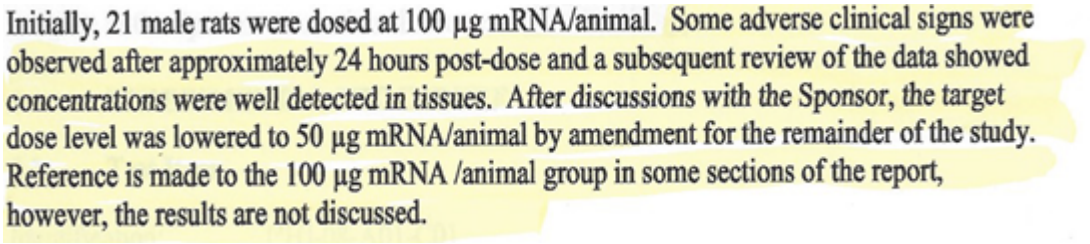
Contained in that document is the following identification of the source:

> Test Facility Study No. 185350 REDACTED
>
> SPONSOR: Acuitas,
>
> 6190 Agronomy Road,
>
> Ste. 402,
>
> Vancouver, V6T 1Z3 Canada
>
> Sponsor Reference No. ALC-NC-0552

This study was made up of 42 male and 21 female Wistar Han rats. These rats were injected with 50 or 100 micrograms of BNT162b2 mRNA/LNP (lipid nanoparticle) product labelled with a radioactive tracer material, 3H. Then the rats were sacrificed at intervals of 0.25 hours (15 minutes); 1 hour; 2 hours; 4 hours; 8 hours; and then at 1 and 2 days.

The results of 21 male and 21 female sacrificed rats are presented.

The 100-microgram dose was associated with loss of weight and apparent toxicity in two animals. Unfortunately, the full results of the 100-microgram dose were not presented at all. [see this, p. 11.]


Initially, 21 male rats were dosed at 100 µg mRNA/animal. Some adverse clinical signs were observed after approximately 24 hours post-dose and a subsequent review of the data showed concentrations were well detected in tissues. After discussions with the Sponsor, the target dose level was lowered to 50 µg mRNA/animal by amendment for the remainder of the study. Reference is made to the 100 µg mRNA /animal group in some sections of the report, however, the results are not discussed.

This is very important. The 100 microgram dose was considered too toxic to continue to use in the experiment, so the dosage was cut in half. 100 micrograms is the amount in the Moderna injections.

The 50 microgram dose was not safe. One female rat in the 50-microgram dose exhibited piloerection and hunched posture. [see this, p.19.]

The injection did not stay at the injection site, as we were promised it would. Rather, following injection, the drug was persistent at the injection site, with a third of the dose remaining in muscle tissue for two days in males, and a sixth of the dose remained in females for the same duration.

Timepoint (h)	Injection site (µg equiv lipid/g)		Injection site (% dose)	
	Male	Female	Male	Female
0.25	219.940	36.566	32.887	6.815
1	587.670	199.950	68.829	36.411
2	529.210	93.144	39.053	24.094
4	619.850	56.227	47.710	9.056
8	299.590	125.930	18.731	24.993
24	267.170	122.540	31.957	26.295
48	268.770	61.088	32.823	16.426

But it did not all stay in the deltoid muscle. From the injection site in the deltoid muscle, mRNA/ Lipid Nanoparticles appeared in blood and plasma fifteen minutes after injection and persisted for the entire duration of the two-day study.

Timepoint (h)	Blood (µg equiv lipid/g)		Plasma (µg equiv lipid/mL)		Blood:plasma ratio	
	Male	Female	Male	Female	Male	Female
0.25	3.003	0.936	6.035	1.894	0.48	1.15
1	2.809	5.928	5.379	10.884	0.49	0.54
2	4.028	6.773	8.714	9.091	0.46	0.64
4	3.400	2.698	8.755	4.251	0.42	0.60
8	2.000	0.628	3.573	1.147	0.56	0.55
24	1.274	0.544	2.621	0.945	0.49	0.57
48	0.535	0.305	1.085	0.524	0.50	0.58

On page 20 of "*Final Report: A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rat*," the authors note that widespread distribution to "most tissues" occurs by the time of first analysis at 15 minutes after injection.

There was greater accumulation in blood when compared to plasma, and males generally had higher concentrations than females with lower blood to plasma ratios. No explanation for these differences was offered.

The major tissues that contained the drug concentration, aside from muscle at the injection site, were identified as being the liver, spleen, adrenal glands, and ovaries. The drug persisted in tissues throughout the duration of the study. The meaning and potential implications of the persistence in tissues was not addressed. [see this, p. 21]

Timepoint (h)	Values expressed as µg equiv lipid/g)						
	Liver		Spleen		Adrenal glands		Ovaries
	Male	Female	Male	Female	Male	Female	Female
0.25	1.151	0.323	0.354	°0.313	0.302	°0.240	°0.104
1	4.006	5.244	2.140	2.801	0.580	2.388	1.339
2	9.574	12.370	5.255	10.213	1.206	4.232	1.638
4	18.525	14.569	8.945	11.646	2.569	3.206	2.341
8	27.916	25.172	24.434	19.747	6.387	7.218	3.088
24	23.360	15.119	22.819	17.341	19.948	7.595	5.240
48	18.164	30.411	19.550	27.155	21.476	14.942	12.261

°Mean includes results calculated from data less than 30 cpm above background

Timepoint (h)	Liver		Spleen		Adrenal glands		Ovaries
	Male	Female	Male	Female	Male	Female	Female
0.25	0.995	0.209	0.014	°0.011	0.001	°0.001	°0.001
1	2.834	2.907	0.087	0.098	0.002	0.012	0.009
2	7.629	7.030	0.232	0.418	0.005	0.015	0.008
4	15.027	8.699	0.351	0.419	0.012	0.018	0.016
8	21.519	14.580	1.118	0.845	0.026	0.043	0.025
24	19.901	10.977	0.957	0.685	0.083	0.049	0.037
48	13.953	18.357	0.914	1.146	0.104	0.108	0.095

°Mean includes results calculated from data less than 30 cpm above background

Top: highest mean concentrations. Bottom: equivalent % dose.

The next two tables present the overall tissue distribution data from this study. It is reasonable to conclude, thus, that BNT162b2 is distributed throughout the body and persists for at least two days, the duration of the study. [see this, pp. 7-8] Tissue specimens were harvested but, unfortunately, no microscopic analysis of these specimens is presented at all, so potential damage to various organs was not evaluated.

BNT162b2
2.6.5 Pharmacokinetics Tabulated Summary

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 185350

Species (Strain):	Rat (Wistar Han)
Sex/Number of Animals:	Male and female/3 animals/sex/timepoint (21 animals/sex total for the 50 µg dose)
Feeding Condition:	Fed ad libitum
Method of Administration:	Intramuscular injection
Dose:	50 µg [^{3}H]-08-A01-C0 (lot # NC-0552-1)
Number of Doses:	1
Detection:	Radioactivity quantitation using liquid scintillation counting
Sampling Time (hour):	0.25, 1, 2, 4, 8, 24, and 48 hours post-injection

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined)							% of administered dose (males and females combined)						
	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	1.48	2.72	2.89	6.80	13.8	18.2	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	1.24	1.24	1.84	2.49	3.77	--	--	--	--	--	--	--
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	1.03	1.40	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	394	311	338	213	195	165	19.9	52.6	31.6	28.4	21.9	29.1	24.6
Kidneys	0.391	1.16	2.05	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	1.10	1.34	0.008	0.025	0.065	0.192	0.405	0.692	0.762
Liver	0.737	4.63	11.0	16.5	26.5	19.2	24.3	0.602	2.87	7.33	11.9	18.1	15.4	16.2
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09	0.052	0.101	0.178	0.169	0.122	0.101	0.101

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 185350

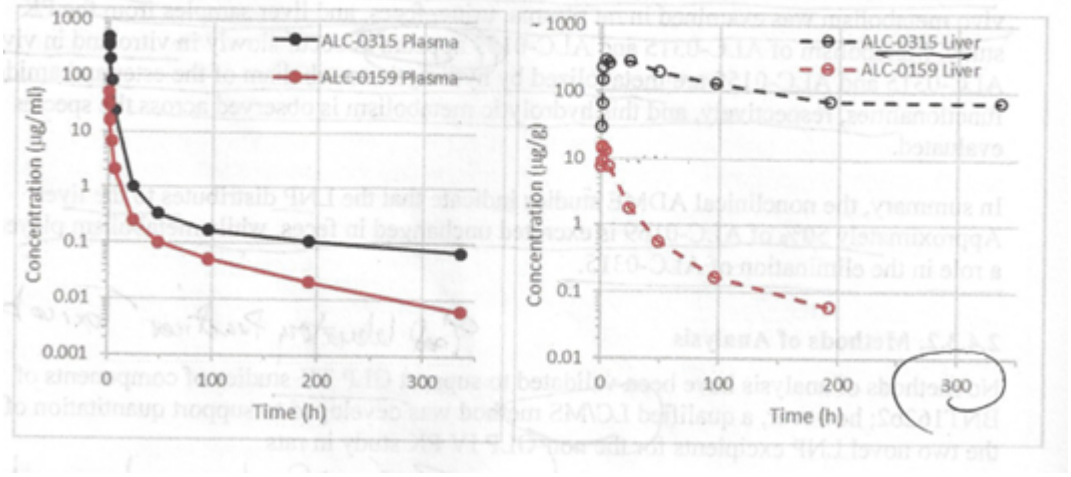
Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							% of Administered Dose (males and females combined)						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--	--	--	--	--	--	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--	--	--	--	--	--	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--	--	--	--	--	--	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	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	--	--	--	--	--	--	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024	0.130	0.319	0.543	0.776	0.906	0.835
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001	0.002	0.002	0.003	0.001	0.001	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013	0.093	0.325	0.385	0.982	0.821	1.03
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006	0.019	0.034	0.030	0.040	0.037	0.039
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007	0.010	0.017	0.030	0.034	0.074	0.074
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004	0.007	0.010	0.012	0.008	0.007	0.008
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000	0.001	0.001	0.001	0.001	0.001	0.001
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002	0.011	0.015	0.008	0.016	0.018	0.022
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--	--	--	--	--	--	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--	--	--	--	--	--	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--	--	--	--	--	--	--

A separate pharmacokinetic study, "PF-07302048," looked at the persistence of the LNP (lipid nanoparticle) transport vessel with a test mRNA inside consisting of LNP coating wrapped around Luciferase mRNA, Figure 2.4.3-1 below. ["*R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODRNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION"*, see this]

The object of this study was to follow the LNP vessel in plasma and liver, and then measure transcription of mRNA inside target organs to validate the delivery model using the bioluminescent properties of Luciferase to identify transcription of the mRNA in target tissues. [see this]

From this study, we learn that the two measured components of the lipid nanoparticle coating, ALC-0315 [(4-hydroxybutyl) azanediyl]di(hexane-6, 1-diyl) bis (2-hexyldecanooate)] and ALC-0159 (2-[2-(polyethylene glycol)-2000]-N, N-ditetradecylacetamide) are detectable in plasma after 300 hours – that is to say, 12.5 days – which fact raises the issue of how long the contents of the LNP vessel with the mRNA inside persists, and what the implications are of prolonged occupation of host cells by this material. In this study, the BNT162b2 was injected intravenously, accelerating the dissemination of drug. [*2.4 NONCLINICAL OVERVIEW*, see this, p.16]

Figure 2.4.3-1. Plasma and Liver Concentrations of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg



This study of the biodistribution of the LNP coating containing Luciferase mRNA found that not only was the mRNA transcribed, but the LNP "vessel" components ALC-0315 and ALC-0159 were retained in the liver and in the plasma for at least 12.5 days. The fate of the Luciferase mRNA was not discussed.

With respect to degradation of the mRNA component, we learn from "*2.4 Nonclinical Overview"* that Pfizer/Acuitas did not study at all the degradation of the synthetic mRNA in BNT162b2. Similarly, there was no analysis by Pfizer of protein products from BNT162b2 provided. [see this, p.20]

The protein encoded by the RNA in BNT162b2 is expected to be proteolytically degraded like other endogenous proteins. RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. Therefore, no RNA or protein metabolism or excretion studies will be conducted.

Several serious questions are raised by these results:

1. How long does the BNT162b2 mRNA persist in human tissues? Where does it go in the host cell? How long does it persist inside the cell? What proteins does it produce, and for how long?
2. Is there any possibility that the BNT162b2 mRNA can be transcribed into DNA, then incorporate into the host genome? If this happens what are the implications?
3. What are the toxicities from the lipid nanoparticle coating?
4. Was Pfizer obligated to answer these questions prior to human testing?
5. Doesn't proper informed consent require answers to these questions?

Fortunately, answers to these important questions are beginning to appear:

1a. Duration of mRNA in tissues:

In a July 19, 2022, article, the essayist Joomi reviews the topic of how long BNT162 b2 containing mRNA stabilized by a synthetic nucleotide 1N-methyl pseudouridine persists in human tissues. [see this]

A January 2022 human lymph node biopsy study from Stanford University found that the

mRNA from both Pfizer and Moderna persists for at least two months, which was the duration of the study. [see this]

1b. Proteins produced from BNT162b2 mRNA:

Spike protein is produced after the mRNA is transcribed, and has been found in vivo for at least four months after inoculation. [see this]

Proteins transcribed from the mRNA have not been completely characterized yet. SARS-CoV-2-like Spike protein has been identified as long as four months after inoculation with LNP/mRNA in human exosomes. Toxicity of Spike protein has been described and is reviewed in the essay "We're still being misled about how long the mRNA vaccines last in the body." [see this]

2. What is the fate of BNT162b2 mRNA?

We were informed that "RNA is required for protein synthesis, does not integrate into the genome, is transiently expressed, and is metabolized and is eliminated by the body's natural mechanisms and, therefore is considered safe." [*Alberer, M. et al. Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomized, prospective, first-in-human phase 1 clinical trial. Lancet 90, 1511-1520 (2017).*] [*Sahin, U. e al. Personalized RNA mutanome vaccines mobilize poly-specific therapeutic immunity against cancer. Nature 547, 222-226 (2017).*]

However, Alden, et. al., reporting in *Current Issues in Molecular Biology* 2022, 44, 1115-1126, found BNT162b2 mRNA is reverse transcribed into host DNA beginning six hours after contact with BNT162b2:

> "In the BNT162b2 toxicity report, no genotoxicity nor carcinogenicity studies have been provided. Our study shows that BNT162b2 can be reverse transcribed to DNA in liver cell line Huh7, and this may give rise to the concern if BNT162b2-derived DNA may be integrated into the host genome and affect the integrity of genomic DNA, which may potentially mediate genotoxic side effects. At this stage, we do not know if DNA reverse transcribed from BNT162b2 is integrated into the cell genome. Further studies are needed to demonstrate the effect of BNT162b2 on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as tissues from human subjects who received BNT162b2 vaccination." [see this]

This study did not identify DNA transcribed from BNT162b2 mRNA in the host genome following transcription.

However, Zhang et. al., working at Massachusetts Institute of Technology, demonstrated fragments of SARS-CoV-2 mRNA integrated in host DNA in "Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues," published in 2021 in *PNAS,* vol. 118, no. 21:

> "We show here that SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of the infected cell and be expressed as chimeric transcripts fusing viral with cellular sequences. Importantly, such chimeric transcripts are detected in patient-derived tissues." [see this]

So, scientists are getting close to knowing whether BNT162b2, with its synthetic mRNA, is

translated into host DNA and is now a permanent part of human genetic material. If so, the next step is to determine what the implications are.

3. What are the toxicities from the lipid nanoparticle coating?

More research is required to understand the implications of LNP concentration in various organ tissues. It is thought that the PEG component (the polyethylene glycol that coats the LNP) is responsible for anaphylaxis, an often rapid-onset major physiologic event that requires emergency treatment.

4. Was Pfizer obligated to answer these questions prior to human testing?

5. Doesn't proper informed consent require answers to these questions?

The answers to questions 4 and 5 are "yes," and the reasons should be obvious now. Basic information about functioning of this mRNA product, BNT162b2, was not known at the time of mass inoculation; and, therefore, a proper risk, benefits and complications discussion was compromised by lack of information. Informed consent is not possible in such a situation.

In conclusion, many negatively consequential shortcuts were made in the development of BNT162b2.

Many omissions in basic research evaluation of BNT162b2 were kept hidden, and there was outright misinformation regarding some of the work that was done.

Assumptions rather than actual research to determine where BNT162b2 goes, what it does, and how long it lasts were made that proved to be false and constitute intentional mis/dis/mal information. We were told that the prodrug, BNT162b2, consisting of a lipid nanoparticle coating of synthetic messenger ribonucleic acid (modRNA), would be deposited in muscle tissue at the injection site and would be migrate to local lymphatics prior to rapid degradation producing Spike antigens for a limited period of time that would produce a desired immune response.

However, Pfizer in its very early Phase 1 trial with mice, rats, and rhesus non-human primates learned that the LNP/mRNA is rapidly disseminated throughout the body and remained in tissues for as long as it was studied, 48 hours for BNT162b2 and 12.5 days for the LNP/Luciferase mRNA test product.

No effort was expended to determine what proteins are produced by the modRNA, what their physiological actions are and how long they are produced as well as what toxicities and adverse events might be anticipated with widespread usage of the LNP/mRNA prodrug.

FOIA requests for internal documents from federal health care agencies, independent review board members, approximately 140 clinical investigators and Pfizer personnel should be made.

Billions of doses were administered to billions of people. The scale of this potentially massive medical misstep is large.

Ten months to develop novel gene therapy for a novel virus is well short of the five to 10 years usually required to develop, test and refine such a product. After billions of doses have been given to children and adults around the world, possibly altering the course of

human evolution, the public is now seeing the unfortunate consequences of cutting corners.

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