Moderna's Non-clinical Summary for Spikevax - Evidence of Scientific and Regulatory Fraud

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Journalist Article

In my previous article, I reviewed Pfizer's BNT162 non-clinical summary obtained via a successful freedom of information lawsuit by Judicial Watch[1]. Recently, an analogous set of materials became available for Moderna's SPIKEVAX. Non-clinical testing is part of the drug or vaccine development process during which the product is tested in cell lines and animals. The FDA Guidance documents for gene therapy platforms available prior to 2020 are 2013 (nonclinical Guidance[3]) and 2015 (clinical Guidance[4]), however, the FDA has been

publishing guidance documents for cellular and gene therapies starting in 1998[5]. Therefore, an extensive body of regulatory knowledge regarding non-clinical and clinical testing requirements for this product class has been available for the past 20+ years. These materials documented many serious risks, including death, potential to promote cancer, uncontrollable expression of proteins, genotoxicity, reproductive harm, and potential for transmission through "shedding," among many others. The manufacturers and regulators both were expected to anticipate these risks and design testing programs to exclude or fully characterize them.

The package of materials obtained from HHS contained 699 pages of studies and test results that were supposedly used by the FDA to clear Moderna's mRNA platform-based mRNA-1273 (Moderna's Covid-19 vaccine, or SPIKEVAX).

I am commenting primarily on the scope and regulatory completeness of the package, as the full reports of the studies themselves are still not available and/or irrelevant to the product, as will be discussed below.

Findings:

1. **Moderna's nonclinical summary contains mostly irrelevant materials.**
2. **Moderna claims that the active substance mRNAs of Spikevax does not need to be studied for toxicity and can be replaced with any other mRNA without further testing.**
3. **Moderna's nonclinical program consisted of studies of other unapproved mRNAs and only one non-GLP toxicology study of mRNA-1273 (active substance of SPIKEVAX).**
4. **There are two separate Investigational New Drug numbers for mRNA-1273: one held by Moderna, the other – by DMID (NIH), representing a serious conflict of interest.**
5. **The vaccine-induced antibody-enhanced disease was identified as a serious risk and was not excluded by Moderna due to absence of positive control and unvalidated methods used.**
6. **FDA and Moderna lied about reproductive toxicology studies in public disclosures and product labeling.**

Finding 1: Moderna's nonclinical summary contains mostly irrelevant materials and three different versions of the Module 2.4.

While 699 pages long, most of the nonclinical package contains largely irrelevant materials. Approximately 80% of materials included in the package are for other mRNA products unrelated to Sars-Cov-2 or covid illness. The entire package is haphazardly organized, possibly on purpose, to make it harder to read and interpret. Approximately 400 pages of the materials belong to one biodistribution study in rats, conducted at the Charles River facility in Canada, for an irrelevant test article, mRNA -1674. This product is a construct of 6 different mRNAs studied for cytomegalovirus in 2017 and never approved for market. This study demonstrated distribution of the lipid nanoparticles throughout the entire body and in all major organ systems (discussed in Finding 2). The study protocol, report, and amendments are copied numerous times and included both at the beginning and the end of the HHS package for an unknown reason. Were they trying to meet a word count minimum?

Sandwiched between the numerous copies of the same irrelevant study, I found "ModernaTX, Inc. 2.4 Nonclinical Overview" for mRNA-1273 with the Investigational New Drug

application reference IND#19745. Module 2.4 is a standard part of the New Drug Application and is supposed to contain the summaries of nonclinical studies.

There are three separate versions of Module 2.4 included, and many sections appear to be missing. It is not clear why multiple versions are included, and there is no explanation provided as to which version specifically was used for the approval of SPIKEVAX by the FDA. Module 2.4 starts on p. FDA-CBER-2021-4379-0001130 and continues to p.-0001160, the second and third copies start on 0001462 and up to -0001548. Hereafter, I will refer to the last numerical sequence of the page stamp. The three copies of Module 2.4 appear to be a similar version of the same overview document; however, they contain somewhat different set of statements and studies referenced.

The description of the finished supplied product differs between the two versions (differences in red):

- Version 1 (p. -0001466): "mRNA-1273 is provided as a sterile liquid for injection at a concentration of 5 mg/mL in 20 mM trometamol (Tris) buffer containing 87 mg/mL sucrose and 10.7 mM sodium acetate, at pH 7.5."
- Version 2 (p. -0001499): "The mRNA-1273 Drug Product is provided as a sterile suspension for injection at a concentration of 20 mg/mL in 20 mM Tris buffer containing 87 g/L sucrose and 4.3 mM acetate, at pH 7.5."

It appears from reading section 2.4.1.2 Test Material (p.-0001499) that Version 2 of the drug product had been used for manufacturing the Lot AMPDP-200005, which was used for nonclinical studies. There is no explanation given for why the drug product in Version 1 is different, and no comparability testing studies between the two product specifications are provided. Curiously, the approved Moderna SPIKEVAX label does not contain any information regarding the concentration of the product supplied in the vials[6].

Finally, all documents are poorly and often incompetently written. There are numerous hypothetical statements unsupported by any data, proposed theories, admissions of using unvalidated assays, and repetitive paragraphs throughout. Quite shockingly, this represents the entire safety toxicology assessment for an extremely novel product that has gotten injected into millions of arms worldwide.

Finding 2: Moderna claims that the active substance mRNAs of SPIKEVAX does not need to be studied for toxicity and can be replaced with any other mRNA without further testing.

The deception Moderna (and Pfizer and Janssen) has implemented, likely with full complicity of the FDA, is their assertion that all product risks are associated with the lipid nanoparticle delivery platform (LNP), and the mRNA "payload" does not need to be studied via standard safety toxicology tests. On p. – 0001499, it is stated:

"*The distribution, toxicity, and genotoxicity associated with mRNA vaccines formulated in LNPs are driven primarily by the composition of the LNPs and, to a lesser extent, by the biologic activity of the antigen(s) encoded by the mRNA. Therefore, the distribution study, Good Laboratory Practice (GLP)-compliant toxicology studies, and in vivo GLP-compliant genotoxicity study conducted with mRNA vaccines that encode various antigens developed*

genotoxicity study conducted with mRNA vaccines that encode various antigens developed with the Sponsor's mRNA? based platform using SM?102-containing LNPs are considered supportive, and BLA-enabling for mRNA-1273."

The company is claiming that the active drug substance of a novel medicine does not need to be tested for toxicity. This is analogous to claiming that a truck carrying food and a truck carrying explosives are the same thing. Ignore the cargo, focus on the vehicle. The claim is preposterous – the mRNAs and LNPs separately and together are entirely novel chemical entities, each requiring its own Investigational New Drug (IND) application and data dossier filed with the regulators, and studies with one mRNA are no substitute for all others.

For example, for Pfizer's mRNA product, the European Medicines Agency reviewers have issued the following opinion:

"The modified mRNA in the COVID-19 mRNA Vaccine is a chemical active substance that has not been previously authorized (sic) in medicinal products in the European Union. From a chemical structure point of view, the modified mRNA is not related to any other authorized substances. It is not structurally related as a salt, ester, ether, isomer, mixture of isomers, complex, or derivative of an already approved active substance in the European Union.

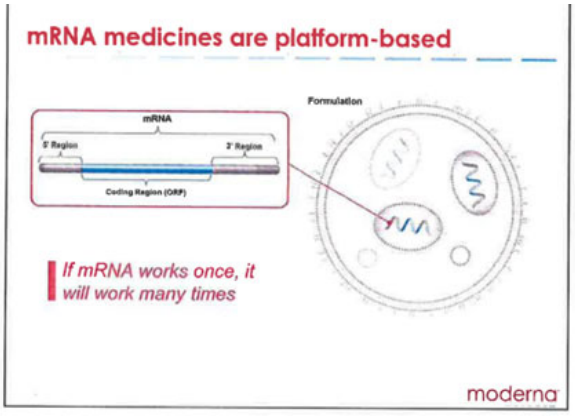
The modified mRNA is not an active metabolite of any active substance(s) approved in the European Union. The modified mRNA is not a pro-drug for any existing agent. The administration of the applied active substance does not expose patients to the same therapeutic moiety as already authorized active substance(s) in the European Union.

A justification for these claims is provided in accordance with the "Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances" (EMA/CHMP/QWP/104223/2015), COVID-19 mRNA Vaccine is therefore classified as a New Active Substance and considered to be new in itself."[8]

In other words, this chemical entity is ENTIRELY NOVEL. Nothing similar has been approved for market before. The reviewers specifically stated that "modified RNA" and not just the lipid envelope constitute the new chemical entity. All new chemical entities must undergo rigorous safety testing before they are approved as medicinal products in the United States, European Union, and the rest of the world.

Furthermore, the manufacturer's claim is not supported by any real data, no studies are cited showing that all toxicity of the product resides with the lipid envelope and none with the "payload" of the type and sequence of mRNA delivered to various tissues and organs. In addition, even though some components of the lipid envelope, such as cholesterol and DSPC, may not be considered novel chemical entities, they are used in an entirely novel two-part construct.

It is also not a matter of a mistake or rushing new technology to market under "crisis" conditions. This scientifically fraudulent strategy was not only premeditated, it was also never really concealed. As an example, in a 2018 PowerPoint presentation from JP Morgan conference filled with data-free cartoons and grandiose statements, Moderna's CEO Stephane Bencel made the following statement:



"If mRNA works once, it will work many times" describes the deception practiced by the manufacturers, FDA, CDC, NIH, every government health authority, and mainstream media talking head who participated in it.

Imagine Ford Motor Company claiming that its crash testing program should be contained to the vehicle's tires and that one test is sufficient for all vehicle models. After all, both F150 and Taurus have tires, what's in between the tires "worked once and will work again," and therefore, it is inconsequential to safety, does not need to be separately tested, and can be replaced at the manufacturer's will with any new variation. This is the claim that Moderna, Pfizer, Janssen, and other manufacturers of the gene therapy "platforms" have utilized. Unlike Ford's products, theirs have NEVER WORKED as none of their mRNA-based gene therapy products have ever been approved for any indication. The fact that the regulators did not object to this argument raises an even greater alarm. There is no question of incompetence or mistake. If this represents the current "gold standard" of pharmaceutical regulatory science, I have very bad news regarding the safety of the entire supply of new medicines in the US and the world.

Finding 3: Moderna's nonclinical program consisted of studies of irrelevant unapproved mRNAs and included only one toxicology study of mRNA-1273 (active substance of SPIKEVAX).

Briefly, a typical non-clinical program for a novel product might include:

- **Pharmacology:** studies on the primary and secondary modes of action. In the case when claims made about disease prevention, these would include desired immunogenicity, as well as demonstration of lack of undesired off-target autoimmunity and disease enhancement.
- **Pharmacokinetics**: how the drug is distributed through the body, with concentrations in major organ classes, as well as characterized time-course of the biodistribution.
- **Safety Pharmacology and Toxicology**: toxicities associated with the drug to major organs or tissues must be excluded and/or well characterized.

- **Other toxicology studies** such as carcinogenicity, genotoxicity, drug interactions, reproductive toxicology, specific population toxicities, etc.

Note that the more novel the product, the more extensive safety/toxicity evaluations apply.

Among three different versions of Module 2.4 included, I was able to identify approximately 29 unique studies. Only 10 of these were done with the correct test article (mRNA-1273): 9 pharmacology ("efficacy") and only one toxicology ("safety"). All of these were non-GLP studies, i.e., research experiments conducted without validation standards acceptable for regulatory approval. The other 20 studies, including all Pharmacokinetics and almost all Toxicology studies, were done with incorrect test articles (a variety of unapproved experimental mRNAs unrelated to SPIKEVAX or covid illness). There were 4 in-vitro and 2 in-vivo genotoxicity studies for the SM-102 lipid and PEG2000DMG only. The in-vivo genotoxicity studies included an irrelevant mRNA-1706 and a luciferase mRNA. Reproductive toxicology assessment conducted on rats is discussed below (Finding 6).

Pharmacokinetics (Biodistribution) were not studied with the SPIKEVAX mRNA-1273. Instead, Moderna included a set of studies with another, unrelated mRNA-1647, a construct of 6 different mRNAs which was in development for cytomegalovirus in 2017 in a non-GLP compliant study. This product has not been approved for market, and its current development status is unknown. Moderna claimed that the LNP formulation was the same as in SPIKEVAX, and therefore the study with mRNA-1674 was “supportive of” the development of SPIKEVAX. This claim is dishonest. While the kinetics of the product may be studied this way, the toxicities may not! We do not know what happens with the organs and tissues when the delivered mRNA starts expressing spike proteins in those cells. This is a crucial safety-related issue, and both the manufacturer and the regulator were aware of it yet chose to ignore it.

The study demonstrated that the LNPs did not remain in the vaccination site exclusively but were distributed in all organs analyzed, except the kidney. High concentrations were observed in lymph nodes and spleen and persisted in those organs at 3 days after the injection. The study was stopped before full clearance could be observed, therefore, no knowledge exists on the full-time course of the biodistribution. Other organs where vaccine product was detected included bone marrow, brain, eye, heart, small intestine, liver, lung, stomach, and testes. Given that the LNPs and mRNA-1647 were detected in all these issues, it is reasonable to assume that the LNPs carrying mRNA-1273 likewise would distribute in the same way, and therefore, the spike protein would be expressed by the cells in those critical organ systems with unpredictable and possibly catastrophic effects. Neither Moderna nor FDA wanted to evaluate this matter any further.

No metabolism, excretion, pharmacokinetic drug interactions, or any other pharmacokinetic studies for mRNA-1273 were conducted. There were no safety pharmacology assessments for any organ classes such as cardiovascular, CNS, liver, spleen, etc.

There was only one toxicology study included in the entire package related to the correct test article (mRNA-1273). The study, however, was non-GLP compliant and was not completed at the time the documents were submitted to the FDA. This study is titled "5 weeks (2 doses) repeat immunogenicity and toxicity study" and was conducted in rats. This study is described very briefly and refers to full reports in Module 2.6.2, which is not included in the HHS package. The summary of the results includes the following statement on safety observations: "There were no mRNA-1273-related effects on body weight. mRNA-1273-related clinical signs were observed on Day 1 and Day 22, starting at the 30 µg/dose. Clinical signs consisting of transient dose-dependent injection site edema with or without hindlimb impairment were observed at approximately 24 hours post dose and generally resolved within

impairment were observed at approximately 24 hours post-dose and generally resolved within 7 days after dose administration. mRNA-1273-related clinical pathology changes associated with inflammation, including increased neutrophils, eosinophils, and/or globulin, were observed starting at the 30 µg/dose. Other mild mRNA-1273-related changes observed at 30, 60, and/or 100 µg/dose consisted of decreased red cell mass, reticulocytes, and lymphocytes and increased creatinine, triglyceride, cholesterol, and/or glucose. In general, these changes are consistent with the results from the previous GLP rat toxicity studies conducted with the Sponsor's SM-102 LNP".

Found in a separate part of the data package, an updated paragraph on this study results reads that:

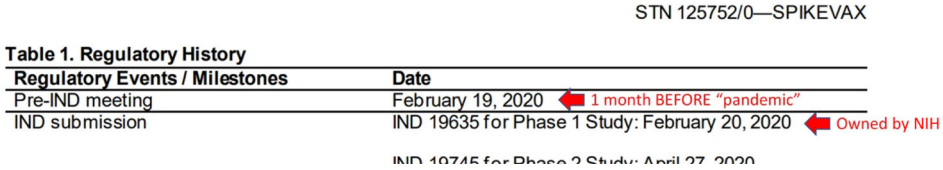
"Post-mortem test article-related and generally dose-dependent changes in organ weights and macroscopic and microscopic findings were observed at ≥ 8.9 µg/dose. Organ weight increases were observed in the spleen, liver, and adrenal gland. Organ weight changes were generally reversing by the end of the 2-week recovery period. Macroscopic changes included skin thickening at the injection site and enlarged lymph nodes. Injection site changes completely recovered, and lymph node changes were recovering by the end of the 2-week recovery period. Microscopic changes included mixed cell inflammation at the injection site; increased cellularity and mixed cell inflammation in the inguinal, iliac, and popliteal lymph nodes; decreased cellularity in the splenic periarteriolar lymphoid sheath; increased myeloid cellularity in the bone marrow; and hepatocyte vacuolation and Kupffer cell hypertrophy in the liver. Microscopic changes were generally reversing by the end of the 2-week recovery period."

These markers are indicative of possible tissue damage, systemic inflammation, and potential severe safety issues, and they are also dose dependent. Statements like "lymph node changes were recovering" are an admission that the product is associated with a potentially serious safety signal which was still ongoing when the study was terminated. Moderna, however, noted these and simply moved on, deciding to forgo any further evaluation of these effects.

Finding 4: There are two separate Investigational New Drug numbers for mRNA-1273: one held by Moderna, the other – by DMID (NIH), representing a serious conflict of interest.

Moderna's documents state that "A letter from DMID [Division of Microbiology and Infectious Diseases at NIH] authorizing the US Food and Drug Administration (FDA) to refer to IND#19635 to support review of this IND [Moderna's own IND# 19745] is provided in Module 1.4" (module is not included in the HHS package of documents).

The FDA's January 30, 2022 "Summary Basis for Regulatory Action SPIKEVAX" document[9] reveals the following timeline for Moderna's product:



STN 125752/0—SPIKEVAX

Table 1. Regulatory History

Regulatory Events / Milestones	Date
Pre-IND meeting	February 19, 2020 ← 1 month BEFORE "pandemic"
IND submission	IND 19635 for Phase 1 Study: February 20, 2020 ← Owned by NIH
	IND 19745 for Phase 2 Study: April 27, 2020

	IND 19745 for Phase 2 Study: April 27, 2020
Fast Track designation granted	May 11, 2020
Pre-BLA meeting	April 28, 2021, Clinical July 1, 2021, CMC/Regulatory
BLA 125752/0 submission	August 24, 2021
BLA filed	October 14, 2021
Mid-Cycle communication	The Applicant cancelled
Late-Cycle meeting	The Applicant cancelled
Action Due Date	April 24, 2022

According to this timeline, the product has two sponsors/owners (holders of the Investigational New Drug application[10] packages), one of whom is the NIH's division organizationally reporting to Anthony Fauci. The date of the pre-IND meeting for SPIKEVAX is February 19, 2020, the IND submission for NIH IND is the following day, February 20, while Moderna's own IND was submitted on April 27, 2020. To recall, according to the CDC, as of January 11, 2020, Chinese health authorities said they've identified more than 40 human infections as part of this outbreak that was first reported on December 31. The World Health Organization announced the preliminary identification of the novel coronavirus on January 9. The record of Wuhan-Hu-1 includes sequence data, annotation, and metadata from this virus isolated from a patient approximately two weeks prior.

This raises several questions that warrant further investigation:

- How was it possible for the NIH/Moderna to have the pre-IND meeting for a Phase 1 human clinical trial scheduled with the FDA for a vaccine product a month before the covid pandemic was declared? Preparation for a pre-IND meeting is typically a several months long, expensive, and labor-consuming process.
- How was it possible to have all materials prepared and the entire non-clinical testing process completed for this specific product related to a very specific virus which was only isolated and sequenced (so we were told) by January 9, 2020?
- What is the precise commercial and legal arrangement between Moderna and NIH regarding SPIKEVAX? Ownership of the IND is both legal and commercial matter, which in the case of public-private partnership must be transparently disclosed.
- Does NIH financially benefit from sales of Moderna product? Who at NIH specifically?
- Does forcing vaccination with the Moderna product via mandates, government-funded media campaigns, and perverse government financial incentives to schools, healthcare system, and employers represent a significant conflict of interest for the NIH as a financial beneficiary of these actions?
- Does concealing important safety information (see Section 6) by a financially interested party (NIH and Moderna) represent a conspiracy by the pharma-government cartel do defraud the public?

Additionally, it is interesting to note that immediately after the pre-IND meeting with the FDA, an extremely heavy volume of orders for Moderna stock began to be placed in the public markets. It would warrant an additional investigation into the investors that were able to predict the spectacular future of the previously poorly performing stock with such timely precision.

Finding 5: Vaccine-induced antibody-enhanced disease was identified as a serious risk and was not excluded by Moderna due to absence of positive control and unvalidated research methods used.

Prior to 2020, Moderna had not been able to bring any products to market. Its entire product development history was marked by numerous failures despite millions of dollars and lengthy time spent in development. Notably, its mRNA-based vaccines were associated with the antibody-enhancement (ADE) phenomenon. One such example includes Moderna's preclinical study of mRNA-based zika vaccine in which vaccinated mice all "uniformly [suffered from] lethal infection and severe disease due to antibody enhancement…"[11]. The scientists were able to develop a vaccine type (IgEsig-prM-E FL) that generated protection against Zika and "resulted in significantly less morbidity and mortality," although all versions of the vaccine unequivocally led to some level of ADE. (By day 5, survival rate for mice vaccinated with IgEsig-prM-E FL dropped to 80%, meaning 20% of the vaccinated mice had died thanks to ADE induced by the vaccine.)

The Primary Pharmacology section for SPIKEVAX included 9 studies evaluating immunogenicity, protection from viral replication (declared mechanism of action), and to evaluate potential for vaccine-associated enhanced respiratory disease. These studies included the correct test article (mRNA-1273), however, all were non-GLP compliant. The results of these studies are briefly summarized in the text of the document package, however, the study reports are not provided. On p.-000150, Moderna claims that "there were no established animal models" for SARS-Cov-2 virus due to its extreme novelty. In the next sentence, it appears that despite the extreme novelty of the virus, conveniently, Dr. Ralph Baric at the University of North Caroline at Chapel Hill possessed an already mouse-adapted SARS-Cov-2 virus strain and provided it for some of the Moderna's studies. Elsewhere, on p.-0001468, the company states, correctly, that the EDR concern was triggered by preclinical work on SARS-CoV and MERS-CoV vaccines, among others – so it seems the company is contradicting its own statements about lack of preclinical models of SARS. While discussing the ERD risk, Moderna also waives off their own results with the statement of invalidity of the assays and methods they have used: "As SARS-CoV-2 neutralization assays are, to this point, still highly variable and in the process of being further developed, optimized and validated, study measurements should not be considered a strong predictor of clinical outcomes, especially in the absence of results from a positive control that has demonstrated disease enhancement".

Clearly, both Moderna and FDA knew about disease enhancement and were aware of numerous examples of this dangerous phenomenon, including Moderna's own zika vaccine product of the same type. Yet, the FDA did not question Moderna's scientifically dishonest "studies" that dismissed this extremely significant risk without a proper study design.

Finding 6: FDA and Moderna lied about reproductive toxicology studies in public disclosures and product labeling.

Let's review the results that Moderna provided to the FDA and what FDA, in turn, communicated to the healthcare providers and public.

Moderna conducted Reproductive Toxicology study in pregnant and lactating rats using human dose of 100 mcg mRNA-1273 (described on p. -0001150). The full study report was not included in the package. However, in the narrative summary of the findings, Moderna wrote:

"High IgG antibodies to SARS-CoV-2 S-2P were also observed in GD 21 F1 fetuses and LD 21 F1 pups, indicating strong transfer of antibodies from dam to fetus and from dam to pup."

Safety assessments in the study appear to be very limited, however, the following findings are described by Moderna:

The mothers lost fur after vaccine administration, and it persisted for several days. No information on when it was fully resolved since the study was terminated before this could be assessed.

In the pups, the following skeletal malformations were observed:

"In the F1 generation [rat pups], there were no mRNA-1273-related effects or changes in the following parameters: mortality, body weight, clinical observations, macroscopic observations, gross pathology, external or visceral malformations or variations, skeletal malformations, and mean number of ossification sites per fetus per litter. mRNA-1273-related variations in skeletal examination included statistically significant increases in the number of F1 rats with 1 or more wavy ribs and 1 or more rib nodules. Wavy ribs appeared in 6 fetuses and 4 litters with a fetal prevalence of 4.03% and a litter prevalence of 18.2%. Rib nodules appeared in 5 of those 6 fetuses."

Moderna even tied the skeletal malformations to the days when toxicity was observed in the mothers: "Maternal toxicity in the form of clinical observations was observed for 5 days following the last dose (GD 13), correlating with the most sensitive period for rib development in rats (GDs 14 to 17)" …. and proceeded to wave off this finding as unrelated to the vaccine.

The FDA then lied on Moderna's behalf in the Basis for Regulatory Action Summary document[12] (Section 4: Non-clinical Reproductive Toxicology, p.14):

"*No vaccine-related fetal malformations or variations and no adverse effect on postnatal development were observed in the study. Immunoglobulin G (IgG) responses to the pre-fusion stabilized spike protein antigen following immunization were observed in maternal samples and F1 generation rats indicating transfer of antibodies from mother to fetus and from mother to nursing pups*"

from mother to nursing pups.

In summary, the vaccine-derived antibodies transfer from mother to child. It was never assessed by Moderna whether the LNPs, mRNA, and spike proteins transfer as well, but it is reasonable to assume that they do due to the mechanism of action of these products. This should have been tested, and risks to the child should have been assessed, as the baby's major metabolizing organs, such as the liver, are very small. Any "overdoses" or uncontrolled expression of toxins such as spike protein could pose serious life-threatening risks. This was never disclosed to the pregnant and breastfeeding women who were being bullied and coerced into these experimental injections. The FDA/CDC did not request to exclude pregnant and lactating women from the population for whom the vaccine should be recommended until such studies could be completed. The FDA then lied and reported "no skeletal malformations" in the non-clinical study in rat pups, despite this being clearly reported by Moderna and even statistically and temporally associated with the pregnant rats experiencing clinical signs of vaccine-induced toxicity. Even if the FDA's "expert opinion" was that it is not related – we should ask the question, why are they concealing the critical safety-related information from public and making the product look better than the manufacturer has admitted? The FDA they did not have any objective scientific evidence, excluding the skeletal malformations being related to the vaccine. Thus, the information should have been disclosed fully in the label of this experimental and poorly tested product, not hidden from public for over a year, and then disclosed only under a court order.

What Nonclinical Safety Data Did the FDA Ultimately Use for The Approval Decision?

Pharmaceutical manufacturers are inherently biased by having vested commercial interests in their products. This bias may lead them to cut corners in safety testing. For this reason, in the United States and globally, we have government regulatory agencies such as the FDA entrusted with setting the standards and evaluation of testing of medicines before they reach the market. The agencies are endowed with multi-billion-dollar budgets, and FDA alone employs approximately 19,000 world-class trained specialists in biology, chemistry, pharmacology, toxicology, and other relevant sciences. It should be quite straightforward for the FDA reviewers to see through the blatant fraud, omissions, use of inadequate study designs, and general lack of scientific rigor. The fact that over half of the package contains non-GLP studies for ~~irrelevant, unapproved, and previously failed~~ chemical entities alone should have been sufficient reason to not approve this product. Prior to 2020, it certainly would.

In FDA's published "Summary Basis for Regulatory Action SPIKEVAX" document from January 30, 2022, Section 4 "Nonclinical Pharmacology/Toxicology" summarizes which parts of Moderna's nonsensical nonclinical package was considered by the agency when approving the product. The summary is a 1-pager.

It appears that the FDA based their decision that the product is safe to administer to thousands of otherwise healthy humans on 2 studies in rats: the Reproductive Toxicology study (Finding 6 above) and the Repeat Dose Toxicity study (Finding 3 above). The rest of the 700-page package was deemed "other supportive studies." The FDA noted that they were conducted in "five vaccines formulated in SM-102 lipid particles containing mRNAs

conducted in five vaccines formulated in SM-102 lipid particles containing mRNAs encoding various viral glycoprotein antigens" but neglects to mention that these were five unapproved and previously failed products.

The venerable regulators, therefore, concluded that using novel unapproved mRNAs in support of another unapproved novel mRNA was acceptable! The circular logic is astonishing. The regulators that allow (and personally promote) the use of failed experiments in support of another new experiment directly on the unsuspecting public are a dangerous failure themselves. The FDA, pharma, and all other perpetrators of this fraud must be urgently stopped and investigated.

References:

[1] https://www.judicialwatch.org/documents/jw-v-hhs-fda-pfizer-biontech-vaccine-prod-3-02418/

[2] https://home.solari.com/review-of-pfizers-non-clinical-program-by-sasha-latypova/

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/preclinical-assessment-investigational-cellular-and-gene-therapy-products

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[6] https://assets.ctfassets.net/qjie68e5s6cv/5z3Eh7GEIURixd7wmKA3RW/3b781794281d5ab4893a20077c47f5bf/Spike PI-Final_1.31.22.pdf

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[8] Assessment report on the claim of new active substance (NAS) status of 5'capped mRNA encoding full-length SRAS-CoV-2 Spike protein contained in COVID-19 mRNA Vaccine BioNTech, Nov 11, 2020.

[9] https://www.fda.gov/media/155931/download

[10] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5388441/figure/F3/

[12] https://www.fda.gov/media/155931/download

References

Reproductive Toxicology for Moderna and Pfizer Vaccines

Fraud FDA Investigation mRNA Vaccines

Comments (11)

What do you think?

0/3000

Publish

B

bonnie

Jul. 21, 2022, 11:43 p.m.

How can I ever trust the industry again? This is beyond unacceptable. My children and grandchildren are already lost to us as they believed in our regulators and scientists, followed the mandates and abandoned their parents who chose to study the science. No punishment will ever be enough for what they have done to defraud humanity. Thank you Sasha for your thorough report. I hope this report is the turning point to force the reform of the regulatory agencies.

Reply

tonylin

Jul. 17, 2022, 10:01 p.m.

Wonder where did you get that IND 19635 is from NIH:
"One of whom is the NIH's division organizationally reporting to Anthony Fauci"
Could you share related documents?

Show more (1) Reply

T

tzontzose

Jul. 12, 2022, 8:11 p.m.

Looking forward to your blogs.

Reply

dalesaran

Jul. 12, 2022, 5:42 p.m.

Ma'am, you willing to put this into something more formal? Like a declaration or affidavit?
I'm an attorney currently suing the government over vaccine mandates, including for some of the reasons you outline.

Show more (1) Reply

S

sebastianhallen57

Jul. 7, 2022, 6:37 a.m.

Statistical process control (SPC) combines rigorous time series analysis methods with a graphical presentation of data, often yielding insights into the data more quickly and in a way more understandable to lay decision-makers.

SPC and its primary tool—the control chart—provide researchers and practitioners with a better understanding and communication of data from healthcare improvement efforts. [1]
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1758030/pdf/v012p00458.pdf

No statistical/mathematical tool tests a hypothesis given a single observation.
You made good analogies, Sasha. Thank you.

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peteryim

Jul. 6, 2022, 3:17 p.m.

I think it is an uphill argument as to why this agency continues to exist.

Reply

sonia_elijah

Jul. 6, 2022, 12:23 p.m.

Excellent report Sasha! Well done on exposing both scientific and regulatory fraud. Regulatory reform is a must if there's ever to be any trust in the FDA again.

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