MRNA, GENE THERAPIES AND BIOMANUFACTURING FRAUD

Are covid vaccines gene therapies?

Response to a reader's question

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This is a short post. One of my readers asked me this question based on the recent publication from Yale researchers who found spike protein expressed after covid mRNA injection for up to 700 days post injection. That means “permanent” spike expression is induced by these shots in some people. The question was, paraphrasing, does this evidence mean that covid vaxxes are gene therapies?

My answer:

First thing everyone should be aware of - there is no legal definition of what is a vaccine. Meaning there is no composition of matter or chemical design of a substance that is defined in law or regulatory standards. There never was. Vaccines are NOT regulated based on product substance or design or any product-related feature. Instead, once a chemical substance is declared a “infectious disease vaccine”, no

matter what that chemical composition contains, is simply put into regulation-free and liability-free category.

The main problem with this is that the FDA (based on current US law) plays word games, calling the same technology different things solely based on arbitrarily proposed uses of the technology.

The FDA of course knew mRNA vaxxes are exactly the same technology as gene therapies, and they knew it was going to be deadly, disabling and sterilizing and causing cancer and other adverse events, and also produce indefinite spike expression in some people, because this type of technology has been in development for a long time. The 2015 FDA Guidance for gene therapies lists the examples of risks they already knew by then:

II. BACKGROUND

The design of early-phase clinical trials of CGT products often differs from the design of clinical trials for other types of pharmaceutical products. Differences in trial design are necessitated by the distinctive features of these products, and also may reflect previous clinical experience.

Early experiences with CGT products indicate that some CGT products may pose substantial risks to subjects. These experiences include multi-organ failure and death of a subject who received a GT product for ornithine transcarbamylase deficiency (Ref. 4), late-onset T-cell leukemia in subjects who received a GT product for X-linked severe combined immunodeficiency (X-SCID) (Ref. 5), and development of tumors in the brain and spinal cord of a patient who received intrathecal allogeneic stem cells for ataxia telangiectasia (Ref. 6). These events illustrate that the nature of the risks of CGT products can be different from those typically associated with other types of pharmaceuticals.

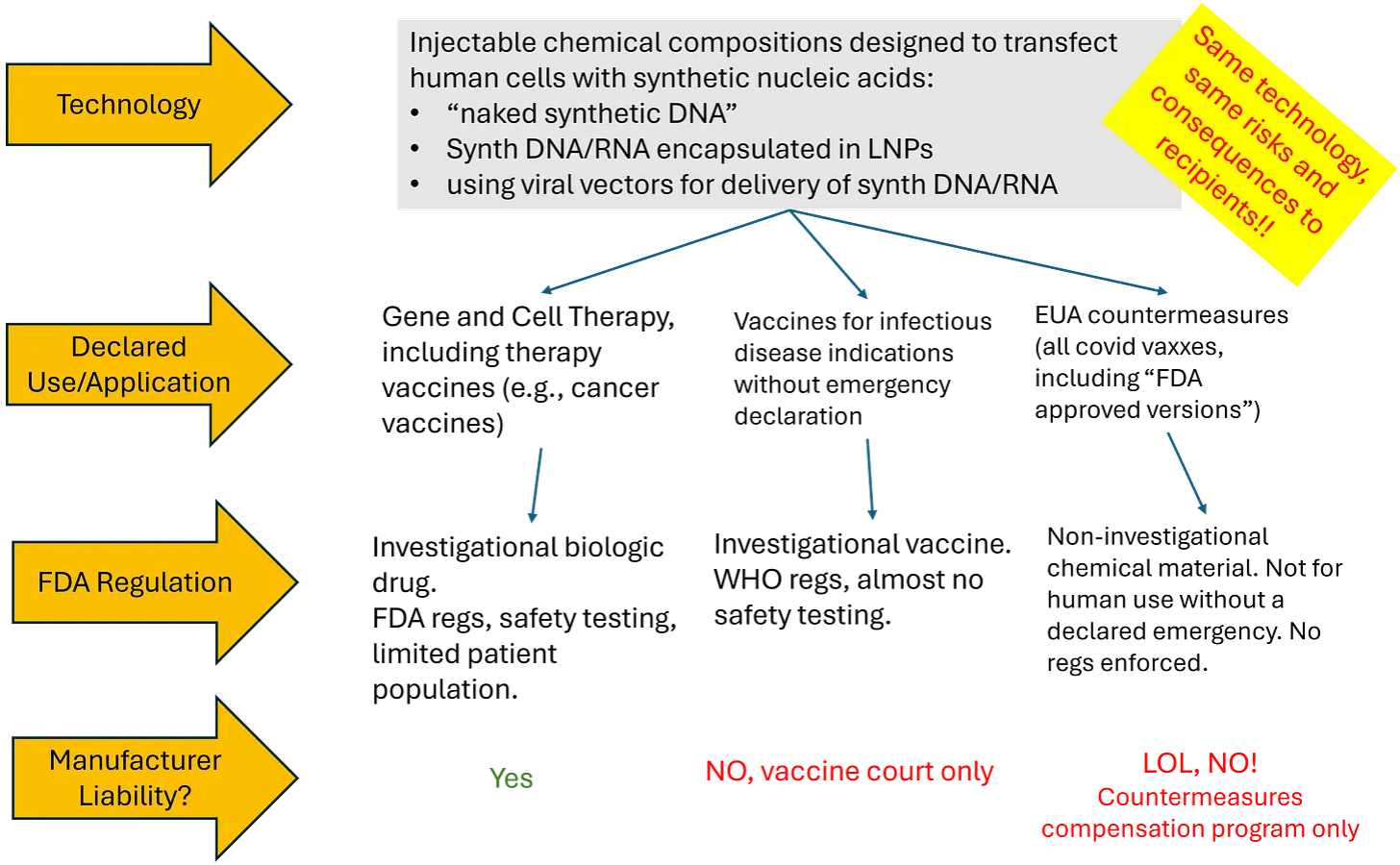
Features of some CGT products that may contribute to their risks include the potential for prolonged biological activity after a single administration, a high potential for immunogenicity, or the need for relatively invasive procedures to administer the product. Unlike many small molecule pharmaceuticals, the logistics and feasibility of manufacturing a CGT product sometimes influence the design of the clinical trials. In addition, the preclinical data generated for CGT products may not always be as informative as for small molecule pharmaceuticals, particularly since it usually is not feasible to conduct traditional preclinical pharmacokinetic (PK) studies with CGT products.

The FDA are the competent authority, they document their knowledge in Industry Guidance documents, and therefore, "we didn't know" doesn't fly as defense for them. They knew very well if this is injected into billions of people, millions will be killed and many more millions will suffer permanent disability. They didn’t make any mistakes. Their actions were deliberate and pre-planned.

The FDA misused and abused federal law and their authority.

The FDA uses word games to pretend these risks do not apply to covid vaxxes. The current law allows them to simply declare something a "gene therapy" or "vaccine" or "countermeasure", and then use entirely different statutory/regulatory frameworks for the **same technology injected into people** on this basis. These are 3 categories of use/application, not different technologies.

I made this highly simplified table to illustrate how this works in the currently twisted and abused regulatory framework:



An analogy for this would be designating the same make and model of a vehicle as "fleet" vs "personal use" and then pretending that for fleet use no safety regulations or testing of the vehicle itself, as it comes from the same manufacturing line, is applicable, or some major categories of it are not applicable. This is the case with "gene therapy" vs. vaccine/countermeasure is even worse than my car example, because the same chemical cocktail is injected into the person. The risks and

consequences for the person subjected to it are always the same. The only thing that is “changing” - risks, consequences, liabilities, costs are being removed and profits boosted for the manufacturers. For the person who gets injected the risk of death and injury remains the same, but instead of being informed about it (as they would be if offered gene therapy), they are now being lied to and told it’s 100% safe!

Regarding the technology itself (mRNA in lipid nanoparticle [LNP], or DNA in adenoviral vector) - both of these are what is known as "transfection" technologies. The purpose of the product design is to deliver various chemical cargo inside the cellular membranes, and often into the nucleus (this will happen with or without extra features like SV40 if it gets into the dividing cells). The LNPs will deliver the cargo attached to them into the cells, i.e. transfect the cells, and this is the principle behind all "gene therapy" products. The LNP platform or adenovirus platform are just 2 different types of "cargo trucks", the LNP being particularly effective in hacking the cells. The fact that it is a transfection tech is documented very widely in the science literature and in regulatory documents.

A truck is a truck, there is no hiding of the fact. As I said above, the FDA simply uses their declaratory authority to say that when we drive this truck on this street, it's not a truck anymore, and vehicle safety regulations no longer apply.

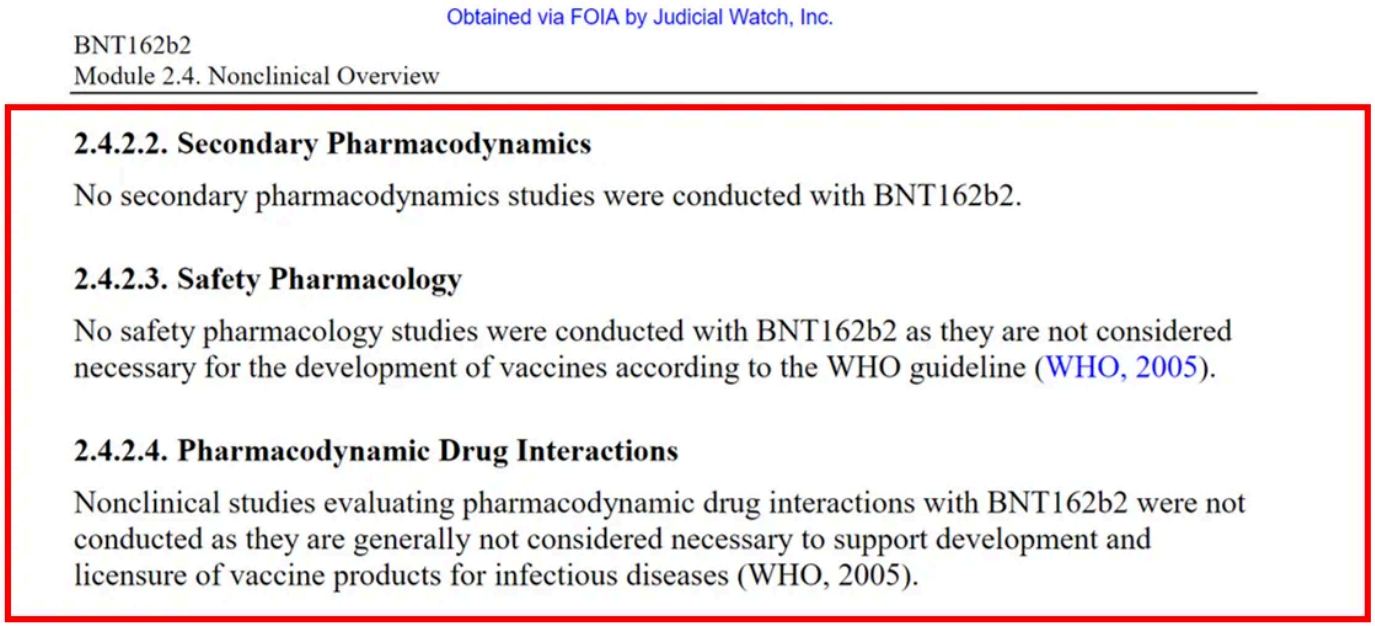
When the FDA declares an LNP based product a "gene therapy" (a synthetic biologic drug) - some rules apply for testing them, albeit the FDA is now also waiving many of

these rules based on "ultra rare/orphan" disease indications. While the regulations are waived, the patient population is also highly narrowed (some indications have <1000 people in the world eligible, and so in this case, the waiving of regs can be viewed as a logical tradeoff. Gene therapies cannot be mandated. Informed consent applies to gene therapies. And finally, manufacturers do face liability and that's the best compliance enforcement one can hope for.

Despite rampant corruption and fraud in pharma/FDA, gene therapies still have requirements for safety studies that are completely not required for the vaccine designation of the same technology/product composition. Specifically, genotoxicity and carcinogenicity studies apply to gene therapy designation and do not apply at all to vaccine designation, regardless of the technology used. This is based on WHO 2005 guidance for vaccines, which does not take into account vaccine design or ingredients at all! The FDA miraculously follows this nonsense and accepts WHO guidelines without WHO having any jurisdiction or Congressional authority for regulating the interstate commerce of pharmaceuticals in the US!

Based on this, regardless of how many independent science studies show that the spike is being expressed for 700+ days, or aggressive cancers develop all over the body, or even that the product integrates into the genome of some of the cells - the FDA does not have any statutory requirement to take these studies into account and they can continue authorizing the product! Here is the screenshot from Pfizer's FOIAed

documentation from 2022 showing that the genotox, carcinogenicity and safety pharmacology studies are not required for **ALL vaccines** (not only mRNA ones):



2.4.2.2. Secondary Pharmacodynamics

No secondary pharmacodynamics studies were conducted with BNT162b2.

2.4.2.3. Safety Pharmacology

No safety pharmacology studies were conducted with BNT162b2 as they are not considered necessary for the development of vaccines according to the WHO guideline (WHO, 2005).

2.4.2.4. Pharmacodynamic Drug Interactions

Nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted as they are generally not considered necessary to support development and licensure of vaccine products for infectious diseases (WHO, 2005).

2.4.4.4. Genotoxicity

No genotoxicity studies are planned for BNT162b2 as the components of the vaccine construct are lipids and RNA and are not expected to have genotoxic potential (WHO, 2005).

2.4.4.5. Carcinogenicity

Carcinogenicity studies with BNT162b2 have not been conducted as the components of the vaccine construct are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential. Carcinogenicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005).

That's why we have seen in the past 4 years that no matter what adverse event data presented to them, the FDA always says that "covid vaccines are safe and effective". It's not because they don't know that these things are killing millions of people, **it's only because the law permits them to disregard this knowledge.** And they are evil people using bad law as a cover to injure and kill with impunity, that's of course the main reason.

As an example, here is an article from pharma industry press, calling LNP platforms "gene therapy" (correctly).

https://endpts.com/exclusive-crispr-delivery-startup-spotlight-therapeutics-shuts-down/

Quote: "Ironically, Spotlight was one of the few companies devoted to CRISPR's biggest technical bottleneck: delivering it to the right part of the body. **Most gene editing companies are packaging the genetic blueprints for CRISPR treatments into the viral vectors used by more traditional gene therapy companies or in the lipid nanoparticles popularized by the Covid-19 vaccines**. "

Update 2/28: Katherine Watt just published an in-depth analysis of the biologics regulations since 1944, describing how they are designed to deceive the consumers that these substances are regulated like drugs (they are not). This explains why vaccines do not have legal product definition - unlike drugs, there is no definable "identity" for these products:

> 1938 FDCA, Section 505(d) authorized the Secretary of Agriculture (later Federal Security Agency Administrator, later Health, Education and Welfare Secretary) to issue orders refusing to permit new non-biological drugs to enter interstate commerce on several grounds.
>
> The manufacturing-related grounds to deny permission for distribution were:
>
> "upon finding...that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its **identity, strength, quality and purity**."

> 1944 PHSA, Section 351(d) authorized the Federal Security Agency Administrator (formerly Treasury Secretary, later HEW Secretary) to issue "licenses for the maintenance of establishments" to "propagate or manufacture" any biological product designated as a "virus, therapeutic serum, toxin, antitoxin or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound)."
>
> The manufacturing-related standards for issuing licenses were:
>
> > "upon a showing that the establishment and the products for which a license is desired meet standards designed to insure the **continued safety, purity, and potency** of such products..."
>
> The most important word in the FDCA section is **identity**, and that's the most crucial omission from the PHSA section.
>
> Biological products are not legally required to be identifiable or identified.
>
> Without an identified, identifiable, stable product, it is not practically or theoretically possible to insure qualities, properties, characteristics or attributes of propagation materials and methods, or to insure attributes that could inhere in a product itself, such as safety, purity or potency, in initial or in continued form.

Art for today: Still Life with Daisies, oil on panel, 9x12 in.

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