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Congress Made Crucial Change to Vaccine Definition Weeks before COVID-19

The US government's definition of 'biological product' up until December 2019 may have prohibited the mRNA COVID-19 products from being labeled as vaccines.

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Without a quiet change to federal law just before the onset of COVID-19, the experimental, mRNA COVID jabs may never have been labelled as vaccines.

A previous article on LifeSiteNews.com described the major conflicts of interest observable during the process leading up to the U.S federal government's emergency use authorization of COVID-19 mRNA vaccines. In December 2019 (before reported outbreak of COVID-19), the U.S. federal government signed a contract with one COVID-19 vaccine maker, Moderna, which "stated 'mRNA coronavirus vaccine candidates [are] developed and jointly owned" by both Moderna and the U.S. federal government, the article explains.

This article discusses the additional significant fact that, also in December of 2019, the U.S. federal government changed the definition of "biological product" in federal laws governing vaccine labeling, emergency use authorization, and approval. The U.S. federal government labels vaccines as "biological products."

A thorough discussion of the significance of the change of the U.S. federal law cannot be provided here due to the technical, scientific, and pharmaceutical terminology and descriptions required. A basic summary is as follows: without the December 2019 change to U.S. law defining "biological product," the mRNA COVID-19 vaccines may have been required to be labeled as something other than a vaccine.

Stated slightly differently, the U.S. federal government's definition of "biological product" which was used up until a few weeks before the reported outbreak of COVID-19 may have prohibited the mRNA COVID-19 products from being labeled as vaccines.

It would probably be much more difficult for governments and/or employers to mandate receiving coronavirus mRNA substances labeled as drugs or other non-vaccine products. Guilt-tripping physicians, nurses, and others into receiving and supporting mRNA COVID-19 substances with the potential false accusation of "anti-vaxxer" would also be out of the question if the substances were not labeled as vaccines.

New definition of 'biological product' weeks before COVID

It should be noted that to become approved in the United States, vaccine manufacturers are required to submit a "Biologic License Application" to the U.S. federal government. (Page 2) U.S. federal law has vaccines included in the category of "biological products."

Prior to the 2019 change to U.S. federal law, the legal definition of biological product was as follows:

> The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, **protein (except any chemically synthesized polypeptide)**, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. (emphasis added)

The December 2019 change to the definition of "biological product" is found in the Further Consolidated Appropriations Act, 2020, and is as follows:

> **SEC. 605. BIOLOGICAL PRODUCT DEFINITION.**
>
> Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended by striking "(except any chemically synthesized polypeptide)."

Thus, prior to the 2019 change which was made soon before the reported outbreak of COVID-19, "*any* chemically synthesized polypeptide" would not be regulated by the FDA as a "biological product." This could be interpreted to mean that if a supposed "vaccine" was a "chemically synthesized polypeptide," then apparently it would not be regulated as a biological product.

But chemicals labeled as "vaccines" require biologic product license applications; thus, it seems that according to the previous definition of "biological product," any chemical entity that is a chemically synthesized polypeptide could not be labeled as a vaccine.

The significance of this change is that the mRNA COVID-19 vaccines chemically synthesize the SARS-CoV-2 "Spike" (also known as the "S") protein. (As of the time of this writing in August 2021), both mRNA COVID-19 vaccines which were given "emergency use authorization" by the FDA are "nucleoside modified" which means that they are "chemically modified" and programmed to synthesize the SARS-CoV-2 S protein.

Thus, the wording of the previous definition of "biological product" seems to suggest that the mRNA COVID-19 "vaccines" could not legally be labeled as vaccines. That would be a major problem for public health officials and "vaccine" makers.

COVID vaccines and 'chemically synthesized' mRNA

Without getting overly technical, it should be noted that COVID-19 mRNA vaccines are the first products which use the technique of "synthetic" or "chemically synthesized" mRNA to be given emergency use authorization by the FDA. (Pages 748-749)

After injected into humans, the chemically synthesized mRNA COVID-19 vaccines synthesize – or "produce" – a protein which is similar to the "spike" or "S" protein of SARS-CoV-2. Proteins "contain one or more polypeptides." Thus, the synthesis of the "S" protein is also described as "polypeptide synthesis."

A more specific explanation of the chemical synthesis of COVID-19 mRNA vaccines from the scientific literature is as follows:

> The chemical components of mRNA vaccines are pleasantly unremarkable, consisting primarily of RNA plus "water, salt, sugar, and fat," with two notable exceptions. The first is the lipid nanoparticles that encapsulate the mRNA and facilitate its delivery, which are excellently reviewed elsewhere. **The second is the non-natural RNA nucleobase N1-methylpseudouridine (m1Ψ**; Figure 1b), **which enhances** immune evasion and **protein production**. (Page 748, emphasis added)

For this article, it is important to know that a chemical component of COVID-19 mRNA vaccines is N1-methylpseudouridine. The chemical N1-methylpseudouridine "enhances...protein production." "Protein production" may also be stated as "protein synthesis" or "polypeptide synthesis." Another way to state this is that N1-methylpseudouridine is a chemical which participates in the polypeptide synthesis of the "S" protein necessary for the mRNA COVID-19 vaccines.

This means, then, that the "S" protein necessary for the COVID-19 mRNA vaccines could be accurately described as a "chemically synthesized polypeptide."

Now, refer to the definition of "biological product" before the December 2019 change to U.S. federal law. The law previously excluded "any chemically synthesized polypeptide" from the definition of "biological product." That definition, then, would seemingly exclude the COVID-19 mRNA vaccines from being labeled as a "biological product."

But since "vaccines" require a Biologic License Application, then it would seem that with the previous definition of "biological product," COVID-19 mRNA "vaccines" could not be labeled as vaccines.

More evidence of a falsified pandemic?

It is unknown if the legal definition of "biological product" was amended by Congress to remove "except any chemically synthesized polypeptide" to permit foreseen chemically synthesized COVID-19 mRNA substances to be labeled as "vaccines."

However, the fact that this significant change was made on page 595 of a 716-page law which is normally used for appropriating U.S. federal funding suggests the possibility of an attempt at being conspicuous.

The aforementioned change to U.S. federal law is also relevant to discussions in previous articles which described updates to U.S. federal laws made soon before COVID-19 suggesting the possibility that COVID-19 may be some sort of falsified pandemic exercise.

Specifically, the timing of the change – before COVID in December of 2019 – along with the apparent hurried status – burying the change on page 595 of a U.S. federal funding act – again suggests the possibility that COVID-19 may be a falsified pandemic exercise which U.S. federal government public health officials and politicians were preparing for by attempting to legally protect themselves with several significant changes to laws, strategies, and plans governing and regulating public health "emerging threats," pandemics, vaccines, or related subjects.

It is also worth repeating that the U.S. federal government partially owns an mRNA COVID-19 vaccine, and soon before their imposition onto Americans, the U.S. federal government seemingly ensured COVID-19 mRNA vaccines would be legal.

Of course, the timing and apparent conspicuousness of the 2019 change to the U.S. federal law which seemingly ensured that COVID-19 mRNA vaccines could legally be labeled as "vaccines" could merely be a coincidence. If keeping track of the large number of major coincidences regarding the COVID-19 pandemic, though, the reasonable person might at least be cautious of anything certain persons and entities communicate regarding the COVID-19 pandemic.

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