

Coalition For Informed Choice

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In 2019, CFIC asked Dr. Lawrence Palevsky to analyze the manufacturing data of vaccines marketed in the US and mandated for schools. In his 12-page, April 8, 2019 report, he determined that all the vaccines contained components of blood in the final injectable products. That document is available from CFIC.

With the new COVID vaccines, people who are religiously opposed to injectable blood products want to know if they must abstain from those vaccines for the same reasons. CFIC commissioned Irina Dzyubinsky to perform the analysis. Her report (below) concludes that the COVID vaccines do contain blood components.

The COVID vaccines currently approved and authorized by the FDA (including EUA) are created using 2 different methods depending on the vaccine manufacturer.

The J&J vaccine uses adenoviral vectors carrying the COVID virus while Pfizer and Moderna vaccines use mRNA encapsulated in lipid nanoparticles carrying the COVID spike protein.

The J&J vaccine manufacturing process requires the use of cell culture medium for mass production of the virus being generated using adenoviral replication of the COVID genome and thus, there could be no question that this vaccine violates the blood principle cited in religious exemptions.

The mRNA vaccines manufactured by Pfizer and Moderna are massmanufactured using a cell-free system called in-vitro transcription (IVT), which is an enzyme-based process that "translates" a DNA template into mRNA. However, while the vaccine itself is technically produced synthetically, the DNA template used for mRNA translation is done either using synthetic DNA or cDNA. Both types of DNA templates can be used in mass production of the vaccines, but when cDNA template is used for mRNA IVT, the vaccines using the cDNA template violate the blood principle of religious exemptions.

To create a cDNA template, harvesting cells for their DNA from cells grown in cell culture medium is required. cDNA templates can be created using either insect cells or mammalian cells and, in both cases, require the use of blood-like products in their synthesis. Therefore, mRNA vaccines using this technology inherently contain blood products and are thus in violation of the blood principle cited in religious exemptions.

Additionally, there's also the question of the lipid nanoparticles or liposomes used to encapsulate the mRNA for passage into cells and how these liposomes are made. Literature and patents related to the Pfizer COVID mRNA vaccine cite that the lipids used to encapsulate the mRNA are synthesized using cellular technology.

Liposomes are vesicles comprising a lipid bilayer membrane. Liposomes comprise a liquid inner volume, preferably an aqueous inner volume. The lipid membrane of the liposome may comprise components such as, but not limited to, fats, oils, waxes, cholesterol, sterols, monoglycerides, diglycerides, phospholipids, glycolipids, steroids, proteins, and other membrane-associated components.

All of this means that cell and blood components are part of the lipid nanoparticles encapsulating the mRNA used in the vaccine. Moreover, there's also indication that in order for the mRNA vaccine to elicit a stronger immune response additional ingredients are added to the lipid nanoparticle containing the mRNA including components of antigen presenting cells such as dendritic cells.

Dendritic cells are a type of phagocytic cells belonging to the class of antigen presenting cells. These cells are derived from hematopoietic bone marrow progenitor cells and act as antigen-presenting cells and activate helper T cells and killer T cells as well as B cells. Thus, dendritic cells can actively induce a T cellor B cell-related immune response. BioNTech uses splenic immature dendritic cells, which are incubated with liposome formulations and peripheral blood lymphocytes.

Separately, the process to generate immature dendritic cells requires the use of peripheral blood mononuclear cells to generate purified CD14 positive mononuclear cells that are then used to generate immature dendritic cells after 5-day cultivation in cell culture medium with granulocyte-macrophage colony-stimulating factor (GM-CSF). GM-CSF is a substance that helps make more white blood cells, especially granulocytes, macrophages, and cells that become platelets. It is a cytokine that is a type of hematopoietic (blood-forming) agent.

As you can see, before the mRNA vaccines can be manufactured synthetically, the steps required to create the components that go into the mRNA creation use multiple processes that require cellular and blood products. Therefore, the claim that Pfizer and Moderna vaccines are devoid of blood components cannot be made and injection of these vaccines violate the blood principle cited in religious exemption applications.

**In summary**, any injectable classified as a vaccine by the FDA, whether it's an attenuated, live or dead virus, gene therapy—or mRNA-based—is considered a biologic and requires a biologics license for distribution. The reason for that is

that any type of vaccine will inherently contain biologic components that are by their very nature can never be devoid of cellular or blood components. No matter the purification or manufacturing method, some of the ingredients that comprise the final vaccine are blood-related components.

As this relates to the COVID mRNA vaccines, there is information posted that claims that the mRNA vaccine technology is fully synthetic and thus is devoid of blood components. This, in fact, is not the case and is erroneous.

While the mRNA can be made synthetically through an in-vitro transcription method using enzymes to cleave the cDNA into the mRNA, that is not the final product that makes up the injectable vaccine. The generated mRNA has to be encapsulated in a lipid in order for the cells to take up the mRNA, digest it, and provide the translation for the cell to make the spike proteins from that mRNA. If the mRNA was not encapsulated in a lipid, then the cells would see it as an antigen and either destroy it or create antibodies against the mRNA instead of the spike protein for which it codes.

Therefore, the final vaccine product must contain the lipid-encapsulated mRNA in order for the vaccine to do what it is intended to do and that in itself makes all the COVID mRNA vaccines a biologic containing blood components.

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