

mRNA Covid Shots Should Be Labeled 'Gene Therapy Products,' Peer-Reviewed Study Warns

Reminder: Hidden In Plain Sight - "mRNA "Vaccines" Are Gene Therapy. May cause Undesirable Side Effects That Could Delay Or Prevent Their Regulatory Approval", BioNTech SEC Filing, 2021



LIONESS OF JUDAH MINISTRY
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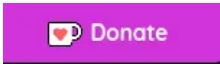
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Frank Bergman August 6, 2023

An explosive peer-reviewed study has warned that mRNA Covid shots are being incorrectly classified in an effort to bypass regulations for public use.

Researchers behind a study published in the renowned International Journal of Molecular Sciences are urging regulatory agencies to consider the safety issues associated with the rapid approval of COVID-19 vaccines.

They are calling on federal government agencies to correctly classify messenger RNA (mRNA) shots as gene therapy products (GTPs).

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COVID-19 vaccines in the form of a rolling review.

A [rolling review](#) is a regulatory tool typically used during a public health emergency to speed up the assessment of data for medicines or vaccines.

It allows data to be reviewed as it becomes available, without the complete data package or specific controls.

This process led to broad and continuous biodistribution of mRNA COVID-19 vaccines that were not thoroughly studied.

The shots have been rolled out for public use despite yielding tests with non-compliant results regarding purity, quality, and batch homogeneity.

Manufacturers are now planning to replace classic vaccines with mRNA shots using the same process.

The replacement will start with influenza vaccines with others to follow.

Currently, the U.S. Centers for Disease Control and Prevention (CDC) defines a "[vaccine](#)" as a preparation used to stimulate the body's immune response against diseases.

However, the agency's definition was changed in 2021 over concerns it didn't apply to Covid shots.

A vaccine must contain an antigen to trigger the body's natural immune response.

Pfizer and Moderna's mRNA vaccines do [not contain antigens](#).

The active substance used to elicit an immune response in these vaccines is the mRNA—a [form of nucleic acid](#) and the [genetic material of the SARS-CoV-2 virus](#) that provides instructions to the body for producing antigens—spike proteins.

In other words, the mRNA is not the substance causing active immunization.

Instead, the mRNA must be translated into protein by the cells of the person vaccinated.

That person's immune system must produce its own antigens to trigger an immune response.

The U.S. Food and Drug Administration (FDA) states that [gene therapy](#) seeks to “modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use.”

Moderna's [Q2 2020 filing](#) with the Securities and Exchange Commission (SEC) acknowledged that mRNA is “considered a gene therapy product by the FDA.”

In addition, BioNTech founder Ugur Sahin stated in a 2014 article that “one would expect the classification of an mRNA drug to be a biologic, gene therapy, or somatic cell therapy.”

According to the FDA, mRNA vaccines are comparable to the [TypeIA of prodrugs](#).

TypeIA is substances that, after administration, are converted in the body into pharmacologically active drugs.

This “prodrug property” could suggest that additional controls should be applied in addition to those required for vaccines.

However, neither the FDA nor the European Medicines Agency (EMA) have referenced these qualifications for mRNA COVID-19 vaccines.

“With a conventional vaccine, you have the antigen, and you inject it into a person, and that is the thing that your immune system looks at and says, ‘ah ha,’ we need to make antibodies, T-cells, and other immune system components to what’s being injected,” said [Dr. David Wiseman](#), a research scientist with a background in pharmacy, pharmacology, and experimental pathology, said in response to the study’s findings.

“The prime reaction of an mRNA vaccine is that it instructs the body how to make the antigen of interest.

“So, it’s similar to a prodrug, which is converted inside the body via metabolism and enzymes into the desired drug effect.

“The substance you’re injecting isn’t doing the final action; it leads to the thing that does the final action.

“With a prodrug, the molecule you inject does not get changed into the final molecule of the antigen, it simply provides instructions because it’s gene therapy.”

Wiseman said the FDA and EMA guidance and regulations that discuss gene therapy all define gene therapies “more or less” the same way.

However, a number of years ago, the FDA decided to exclude vaccines for infectious diseases from its various guidance for unknown reasons, including vaccines made from gene therapy technology.

Vaccines, in essence, were given their “own set of rules.”

However, the FDA can “change or exclude whatever they want from regulatory guidance, but it doesn’t change the biologic definition of the product,” said Wiseman.

“Since Pfizer and Moderna COVID-19 vaccines meet the definition of gene therapy, they should be handled according to gene therapy guidelines.”

Source: [slaynews.com](https://www.slaynews.com)

The Truth About "Safe and Effective" mRNA "Vaccines" Hidden In Plain Sight

mRNA "Vaccines" Are Gene Therapy. May cause Undesirable Side Effects That Could Delay Or Prevent Their Regulatory Approval According To BioNTech SEC Filing

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