

Why Is the Associated Press Lying About Gene Therapy Shots?

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The notion that the COVID shots are a form of gene therapy is so risky for Big Pharma's bottom line, they're going to great lengths to make sure people don't think of them that way

The Associated Press published a "fact check" in which they argued that COVID shots are not gene therapy because they do not alter your genes

The AP misled readers by focusing on just one part of the FDA's definition of a gene therapy — the part about modifying expression of a gene. But the full definition also includes the words "or to alter the biological properties of living cells," which is precisely what the COVID shots do

When the mRNA shots were rolled out in 2021, they did not meet the U.S. Centers for Disease Control and Prevention's definition of a vaccine. They only met the FDA's definition of a gene therapy

The only reason COVID shots meet the CDC's definition of a vaccine now is because they changed the definition to prevent "COVID-19 deniers" from saying that "COVID-19 vaccines are not vaccines per CDC's own definition"

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While the COVID-19 shots are referred to as "vaccines," they do not meet the classical definition of a vaccine. Health authorities actually had to change the definition to accommodate the COVID shots and shut down the argument that, as experimental gene therapies, they may be riskier than traditional vaccines.

Meanwhile, based on the U.S. Food and Drug Administration's definition of "gene therapy" they're clearly gene therapies, and both Moderna and BioNTech acknowledge this. Despite

that, the notion that the COVID shots are a form of gene therapy is so risky for Big Pharma's bottom line,¹ they're going to great lengths to make sure people don't think of them that way.

Most recently, The Associated Press (AP) tried to debunk the idea that COVID shots are gene therapy, but as you'll see, they're either lying to protect the industry, or have gotten so inept they don't know how to do investigative journalism anymore. Either way, it doesn't reflect well on their credibility.

AP Lies About COVID Shots Not Being Gene Therapy

AP, at the end of December 2022, published a "fact check" titled "No, COVID-19 Vaccines Aren't Gene Therapy," in which they argued:²

"The COVID-19 vaccines do not change a person's genes, as gene therapy does ... The shots from Pfizer and Moderna use messenger RNA, or mRNA, to instruct the body to create a protein from the coronavirus. The Johnson & Johnson vaccine, meanwhile, uses a modified adenovirus to trigger an immune response ...

In recent days, social media posts have shared a claim that the vaccines are 'gene therapy' — which involves modifying a person's genes to treat or cure a disease, according to the U.S. Food and Drug Administration."³

The Definition of Gene Therapy

The FDA defined gene therapy in July 2018 and has not changed it since. Per the FDA's website as of this writing:⁴

"Human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use. Gene therapy is a technique that modifies a person's genes to treat or cure disease ..."

Here's where AP went wrong. They only used ONE part of the FDA's definition of a gene therapy — the part about modifying expression of a gene — in its debunking attempt. But the full definition also includes the words "or to alter the biological properties of living cells," which is precisely what the COVID shots do.

The mRNA in the COVID jab are molecules that contain genetic instructions for making various proteins. mRNA COVID shots deliver synthetic mRNA with a genetic code that instructs your cells to produce a modified form of the SARS-CoV-2 spike protein.

In other words, they "alter the biological properties of living cells for therapeutic use." Whether they modify your DNA is irrelevant. Note the word "or" in the FDA's definition. It means it can be one OR the other. They don't have to alter gene expression in order to still qualify as gene therapy, at least not per the FDA's definition.

Yes, the COVID Jabs Are Gene Therapies Per Definition

Moderna's November 2018 Securities and Exchange Commission (SEC) registration statement⁵ also confirms that its mRNA injections are defined as gene therapy, clearly

stating that “mRNA is considered a gene therapy product by the FDA.”

[In] the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products ... ~ BioNTech SEC Registration

The September 2019 SEC filing for BioNTech (its mRNA technology is used in the Pfizer vaccine) is equally clear, stating on page 21:⁶

“... in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products ...”

So, in the U.S. and Europe, mRNA therapies, as a group, are classified as “gene therapy medicinal products.”⁷ There’s simply no way around this. Yet to this day, mainstream media tries to “debunk” the reality of the COVID jab.

Definition of Vaccine Was Changed to Fool You

In 2018, Moderna acknowledged that mRNA technology was of a “novel and unprecedented nature,”⁸ yet for the past three years, we’ve been told that it’s just a newer, faster way to make vaccines.

The fact of the matter is that when the mRNA shots were rolled out in early 2021, they didn’t meet the U.S. Centers for Disease Control and Prevention’s definition of a vaccine. They only met the FDA’s definition of a gene therapy. And the only reason they meet the CDC’s definition of a vaccine now is because the CDC changed their definition.⁹

All the way up until the end of October 2021, the CDC defined a vaccine as “a product that stimulates a person’s immune system to produce immunity to a specific disease, protecting the person from that disease.” Immunity, in turn, was defined as “Protection from an infectious disease,” meaning that “If you are immune to a disease, you can be exposed to it without becoming infected.”

The new definition¹⁰ of “vaccine” is: “A preparation that is used to stimulate the body’s immune response against diseases.” So, a “vaccine” went from being something that produces protective immunity, to simply stimulating an immune response. The key words “to produce immunity” were eliminated from the equation.

This makes the COVID shots fit the description, as they do not make you immune against COVID-19 and weren’t designed to prevent infection in the first place.

Internal CDC correspondence¹¹ obtained through Freedom of Information Act (FOIA) requests also conclusively prove the reason for the change was simply to shut down arguments by “right-wing COVID-19 pandemic deniers” that “COVID-19 vaccines are not vaccines per CDC’s own definition.”

FDA Knew COVID Jabs Were Risky Territory

The FDA’s guidance for the human gene therapy products industry,¹² published in January 2020, also classified mRNA injections as gene therapy. Importantly, in this document the FDA stressed that gene therapy products that carry microRNA or cytokines can have

“unknown pleiotropic effects, including altered expression of host (human) genes that could result in unpredictable and undesirable outcomes.”

While the COVID jab certainly produces undesirable outcomes, [negative consequences were not unpredicted](#). Early on, a number of scientists who had looked into the shots’ mechanisms of action warned about the possibility of severe adverse outcomes, including impairment of the immune system, neurological dysfunction and cancer. Today, a wide array of data and statistics prove those early concerns were valid.

Risk-Benefit Analysis Decimates Safety Claims

For example, a risk-benefit analysis¹³ looking at the impact of booster mandates for university students concluded that between 22,000 and 30,000 previously uninfected adults (aged 18 to 29) must be boosted to prevent one COVID-19 hospitalization.

Meanwhile, for each hospitalization prevented, the jab will cause 18 to 98 serious adverse events, including 1.7 to 3 “booster-associated myocarditis cases in males, and 1,373 to 3,234 cases of grade ≥ 3 reactogenicity which interferes with daily activities.” According to the authors, mandating a third COVID shot for university students will result in “a net expected harm.”

The authors also stress that “Given the high prevalence of post-infection immunity, this risk-benefit profile is even less favorable.” They go on to state that “University booster mandates are unethical because:”¹⁴

- “1) no formal risk-benefit assessment exists for this age group;
- 2) vaccine mandates may result in a net expected harm to individual young people;
- 3) mandates are not proportionate: expected harms are not outweighed by public health benefits given the modest and transient effectiveness of vaccines against transmission;
- 4) U.S. mandates violate the reciprocity principle because rare serious vaccine-related harms will not be reliably compensated due to gaps in current vaccine injury schemes; and
- 5) mandates create wider social harms. We consider counter-arguments such as a desire for socialization and safety and show that such arguments lack scientific and/or ethical support.”

Government Study Also Highlights COVID Jab Problems

A small observational study^{15,16} led by neurology researchers at the National Institutes of Health brought equally bad news, as they found “a variety of neuropathic symptoms” occurring within three to four weeks of COVID injection:

“We studied 23 patients (92% female; median age 40 years) reporting new neuropathic symptoms beginning within 1 month after SARS-CoV-2 vaccination. 100% reported sensory symptoms comprising severe face and/or limb paresthesias, and 61% had orthostasis, heat intolerance and palpitations ...

Together, 52% (12/23) of patients had objective evidence of small-fiber peripheral neuropathy ... This observational study suggests that a variety of neuropathic symptoms may manifest after SARS-CoV-2 vaccinations and in some patients might be an immune-mediated process.”

FDA and CDC Refuse to Release Key Safety Analyses

Isn't it curious that the FDA, CDC, NIH and mainstream media refuse to admit there are risks, even though the NIH's own research shows it? In all likelihood, the FDA's and CDC's data collection on the shots also reveal there are significant problems, as both agencies are stonewalling attempts to get key safety analyses released. As reported by The Epoch Times back in the summer of 2022:¹⁷

“According to operating procedures laid out by the agency and its partner in January 2021¹⁸ and February 2022,¹⁹ the FDA would perform data mining ‘at least biweekly’ to identify adverse events ‘reported more frequently than expected following vaccination with COVID-19 vaccines.’ The agency would perform the mining on data from the Vaccine Adverse Event Reporting System (VAERS).

In a recent response, the FDA records office told The Epoch Times that it would not provide any of the analyses, even in redacted form. The agency cited an exemption to the Freedom of Information Act that lets the government withhold inter-agency and intra-agency memorandums and letters ‘that would not be available by law to a party other than an agency in litigation with the agency.’

The agency also pointed to the Code of Federal Regulations, which says that ‘all communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable ...’

It's not clear why the FDA could not produce copies of the analyses with non-factual information redacted.”

According to the VAERS standard operating procedures cited above, the CDC is also required to perform data mining analyses using Proportional Reporting Ratio (PRR) data mining. PRR²⁰ measures how common an adverse event is for a specific drug compared to all the other drugs in the database.

When The Epoch Times asked the CDC to release its results, it too refused. According to The Epoch Times,²¹ the CDC “has also twice provided false information when responding to questions.” First, they claimed that no PRR analyses were done and that data mining was outside their purview.

Some time later, they admitted the agency did perform PRRs starting in February 2021, only to later backtrack, saying they only started doing PRRs in March 2022. The Epoch Times cites several papers in which the FDA and/or CDC claim their data mining efforts have come up empty handed.

But if that's true, why the reluctance to release the data? Don't they want us to be reassured that these shots are as safe as they claim them to be? Why sit on exculpatory

evidence? Unless, of course, the data proves the FDA and CDC are lying.

Was No-Test Drug Approval the Plan All Along?

While I cannot prove it, I suspect Operation Warp Speed — devised in the spring of 2020 by a dozen top officials from then-President Trump’s health and defense departments to expedite the development of a COVID 19 vaccine²² — may have been intended to normalize the approval of gene therapy drugs without the proper testing.

Before the COVID shots were given emergency use authorization, no mRNA gene therapy had ever made it to market, despite more than 20 years’ worth of research and development. That tells you something about how difficult it is to get these products right, to make sure they work and are safe.

With the FDA’s implementation of a “[Future Framework](#)” scheme in June 2022 to speed up the delivery of COVID boosters,²³ the regulatory obstacles for gene therapies, especially the stringent safety requirements, were brushed aside. Now, the FDA can and will authorize reformulated COVID shots without human trials.^{24,25,26}

The FDA basically rewrote the rules on the fly, deciding that mRNA gene therapies are equivalent to conventional influenza vaccines and can be updated and released without testing.

The idea is that the safety of the mRNA COVID shots has already been proven by the original shots, which they claim have harmed or killed no one. Hence, safety is a given, and the effectiveness of reformulated boosters can be assessed simply by checking the antibody levels in a few mice, which is what Pfizer and Moderna did.

In reality, however, millions of people around the world have been [harmed and killed by the original shots](#), the [human trials for those shots were riddled with fraud](#), antibody levels tell us nothing about the jab’s ability to protect against infection, and the two technologies (conventional flu vaccines and mRNA gene therapy) have no common ground.

Beware of Future mRNA Injections

I have no doubt this “Future Framework” will also, over time, be widened to include other vaccines and drugs that drug makers may want to tinker with. Already, there are mRNA shots in the pipeline against herpes, malaria, influenza, [respiratory syncytial virus \(RSV\)](#), sickle cell disease, HIV, Epstein-Barr and cancer,^{27,28} and vaccine makers have received fast-track approval designation for at least some of these shots.²⁹

Eventually, this fast-tracking trend may even lower standards for drug trials in general, which historically have required at least 10 years of multiphase testing.³⁰ The dangers of this trend really cannot be overstated — especially when we’re talking about gene-based products.

So, to circle back to where we started, hopefully you can now see how the AP and other media are misleading you in their “fact checks” by focusing on just one aspect of the FDA’s gene therapy definition (the DNA-altering part), while ignoring the fact that COVID shots DO

meet the complete definition, and ARE classified as gene therapy, as acknowledged by BioNTech and Moderna in their SEC filings.

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Notes

^{1, 5, 8} [Moderna's SEC Form S-1 Registration Statement](#)

² [AP December 23, 2022](#)

^{3, 4} [FDA Gene Therapy Definition](#)

⁶ [US SEC BioNTech 2019](#)

⁷ [SWF Institute January 25, 2021](#)

^{9, 11} [Pulse Stubstack November 9, 2021](#)

¹⁰ [CDC Immunizations: The Basics, Definition of Terms](#)

¹² [FDA Guidance for Industry January 2020](#)

^{13, 14} [SSRN September 12, 2022](#)

¹⁵ [medRxiv May 17, 2022](#)

¹⁶ [Trial Site News September 1, 2022](#)

^{17, 21} [Epoch Times September 10, 2022](#)

¹⁸ [VAERS Standard Operating Procedures January 2021](#)

¹⁹ [VAERS Standard Operating Procedures February 2022](#)

²⁰ [All About Pharmacovigilance PRR](#)

²² [Politico January 17, 2021](#)

²³ [FDA Briefing Document June 28, 2022](#)

²⁴ [The Defender June 27, 2022](#)

²⁵ [The Epoch Times June 28, 2022 \(Archived\)](#)

²⁶ [New York Times June 27, 2022 \(Archived\)](#)

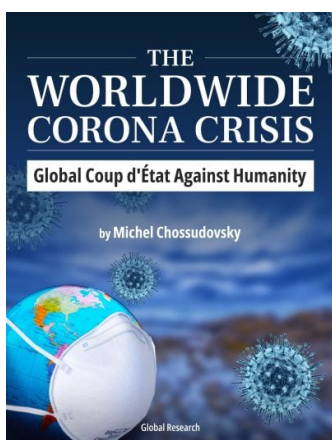
²⁷ [MIT Technology Review February 5, 2021](#)

²⁸ [Nature Biotechnology 2022; 40: 840-854](#)

²⁹ [FDA News August 5, 2021](#)

³⁰ [Phrma.org Biopharmaceutical research and Development](#)

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