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COVID-19 Injection Campaign Violates Bioethics Laws. Dr. Robert Malone

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Safety data analysis and reporting in clinical trials of the COVID jabs appear to have been manipulated in at least some cases. One method for manipulating randomized clinical trial safety data is to only analyze the "per protocol" treatment group (those who completed all doses and were fully compliant with the study design) as opposed to "intent to treat" which would include all patients that have signed informed consent

For example, if a participant only accepted one dose and trial protocol called for two, under a "per protocol" analysis, adverse events they experienced would be dismissed and not included in the safety analysis. This is a classic way to manipulate safety data in clinical research, and it's usually forbidden

Since the COVID shots only have emergency use authorization, they are experimental products and, as such, they are not authorized for marketing

Bioethics are written into federal law. As an experimental trial participant, you have the right to receive full disclosure of any adverse event risks. Full disclosure of risks is not being done, and in fact is being suppressed

Adverse event risks must also be communicated in a way that you can comprehend what the risks are, and the acceptance of an experimental product must be fully voluntary and uncoerced. Enticement is strictly forbidden

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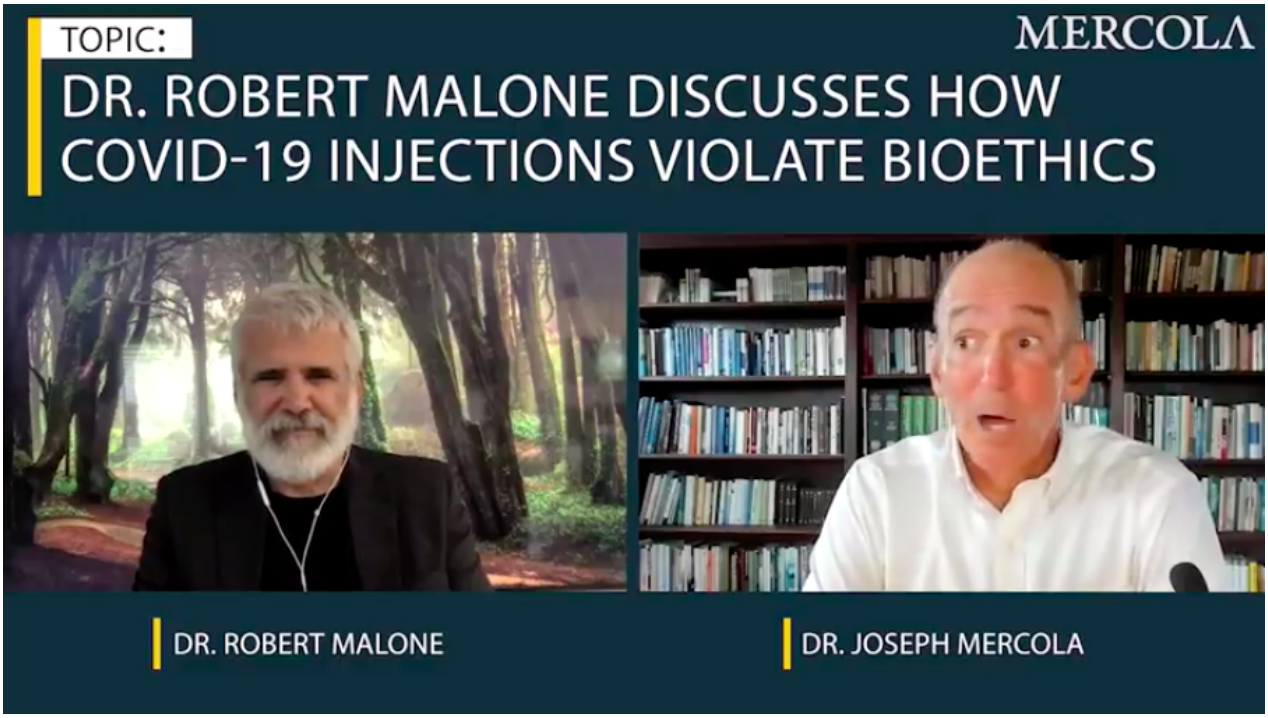

Watch the video here.

As the inventor of the messenger RNA (mRNA) vaccine platform, **Dr. Robert Malone** is one of the most qualified individuals to opine on the benefits and potential risks of this technology.

His background includes a medical degree from Northwestern University, a master's degree from Salk Institute, a bachelor's degree in biochemistry from UC Davis, a Giannini fellowship in pathology and a post-graduate fellowship in global clinical research at Harvard.

He taught pathology to medical students for about a decade at the University of Maryland and the University of California Davis, and then became an associate professor of surgery at Uniformed Services, University of the Health Sciences, where he launched a major research institute focused on breast cancer and high-throughput screening in genomics for breast cancer.

After that, he helped found a company called Inovio, which has brought forth a number of gene therapy discoveries, including vaccines, and the use of pulsed electrical fields as a delivery method. After 9/11, a colleague at the University of Maryland's department of business and economic development connected him with Dynport Vaccine Company, a startup that had received a DoD contract to manage its biodefense products.

> *"That's when I transitioned from being more of an academic to the advanced development world of clinical research, regulatory affairs, project management, compliance, quality assurance — all of that stuff that goes into actually making a product,"* Malone explains.
>
> *"It was a huge epiphany that the world really didn't need more academic thought leaders and [that] I was wasting my time focusing on that. What the world really needed was that people understood the underlying technology and the discovery research world, but also understood advanced development, which is that drug development is a highly-regulated world. And there aren't very many of those.*

> *So, I set out to become really expert in that latter part and worked with the government, particularly in biodefense and vaccine development, for a couple of decades. And that brings me to the present.*
>
> *I've captured a couple of billion dollars in grants and contracts for companies that I've worked with, and clients from the government, from BARDA* [Biomedical Advanced Research and Development Authority], *from the Department of Defense and others."*

COVID-19 'Vaccines' Are Gene Therapy

I've been accused of falsely stating that these COVID shots are not vaccines but gene modifying interventions. However, even Malone agrees with this statement, and as the inventor of the technology, he should know. He points out that in Germany, by law you cannot refer to this technology as a genetic vaccine or gene therapy vaccine. "The German government has specifically outlawed the use of gene therapy-based vaccine as a term," he says.

With his background, and having received the COVID shot himself, he can hardly be called an "anti-vaxxer" and/or someone who doesn't believe in gene therapies. Yet, he recently went public with concerns about the safety of rolling out this kind of technology on a mass scale, and the unethical ways in which they're being promoted.

As has become the trend, he was immediately censored. Wikileaks even went so far as to erase him from the historical section of the mRNA vaccine page and his own personal Wikipedia page was removed. All references to Malone inventing the mRNA technology were removed and attributed to a variety of institutions instead.

Blowing the Whistle

Malone's public involvement with the COVID jab issue began with a short essay[1] reflecting on the bioethics of the current campaign to get a needle in every arm. This essay grew out of a conversation he'd had with a Canadian physician. Malone's essay catalyzed an interview with Bret Weinstein in June 2021 on the DarkHorse Podcast.

This isn't the first time Malone has spoken out against unethical behavior in science. He was also a whistleblower in the Jesse Gelsinger death case,[2] back in 1999. Gelsinger was a young man who had a rare metabolic disorder called ornithine transcarbamylase deficiency syndrome (OTCD), where dangerous amounts of ammonia build up in your blood.

He'd been diagnosed at the age of 2, and was managing his condition with a regimen of nearly 50 drugs a day. At 17, Gelsinger signed up for an investigational gene therapy. Like the COVID shots, the therapy involved injecting a gene attached to an adenovirus, which would be integrated into his DNA to permanently produce an enzyme that prevents ammonia buildup.

Gelsinger was the 18th person to receive the gene therapy, and while the others had only experienced mild side effects, Gelsinger had a severe response after scientists at the University of Pennsylvania administered adenoviruses doses that were far above what had been approved by the corresponding safety committee.

Gelsinger became disoriented and developed jaundice and acute inflammation, followed by

a rare blood clotting disorder and multi-organ failure. He was dead within days. Even a decade later, Gelsinger's death is still considered the biggest setback for gene therapy.[3]

> *"When the Jesse Gelsinger events happened, I also had long been a deep insider in the gene therapy space, so I had specific knowledge of what had happened at Penn — the ethical transgressions, shall we say, that occurred — and had awareness, again, just like now, of the technology,"* Malone says. *"So, I was able to make sense of things that otherwise were obscure for journalists and even other scientists."*

After speaking out about the ethical transgressions that contributed to Gelsinger's death (dosing which exceeded approved levels), Malone became a "persona non-grata" in the gene therapy community. In other words, he was blacklisted by his peers and prevented from participating in gene therapy research.

> *"That's part of why I went in a different direction with my career and focused on government work and biodefense, supporting the Department of Defense,"* Malone says. *"The lesson learned for me is that I'm able to be resilient, together with my wife's support.*
>
> *Another key lesson was that your friends will support you through times of crisis if you behave with integrity and maintain your friendships and treat people with respect. I also had a lot of support for having spoken out and taken an ethical high road on that and not compromised myself …*
>
> *It's part of why I'm comfortable [speaking out now]. People tell me that I come across as balanced and calm. But yes, this is a little bit frightening and once again, [I'm] putting my career on the line. But once again many of my colleagues in the government are grateful that I'm speaking this way. They are not able to have a voice because of their jobs and government policies about speaking out."*

Public Responses to Censorship Make a Difference

As explained by Malone, he's been heavily censored since his three-hour interview with Brett Weinstein. LinkedIn even deleted his account. However, LinkedIn users all around the world canceled their accounts in protest and wrote the company, explaining their cancellations were in protest of Malone being censored.

The social media uproar culminated in a major news article in a mainstream Italian paper, which appears to have pushed LinkedIn over the edge. LinkedIn eventually reinstated Malone's account and even sent him a letter of apology.

> *"I don't think I've ever heard of a company writing a letter of apology after delisting and deleting somebody,"* he says. *"My sins were 'profound,'"* he says sarcastically, *"They were that I outed the chairman of the board of directors of Reuters who is also sitting on the board of Pfizer, for cross-posting the Wall Street Journal article on vaccine toxicity risks, and well, basically for complaining about censorship.*
>
> *So, they sent me my list of sins with six different posts that were to pretty much anybody's eye innocuous, which I then took and cross-posted onto Twitter. So, that revealed the absurdity of that … The note [of apology] that I received basically said, 'Look, we don't have the expertise to censor you, but if you cross the line, we have the*

right to summarily delete you again and so mind your manners.'"

The Repurposing of Drugs to Combat Pandemics

In recent years, Malone has been involved in yet another startup company (Atheric Pharmaceuticals), in collaboration with the DoD, that focused on repurposing drugs to combat Zika infection. That company went bankrupt for lack of investor interest in repurposing drugs for treating infectious diseases.

When the COVID-19 outbreak began, he got a call from a colleague who works in the intelligence community in Wuhan, China, who urged him to put together a team to investigate the possibility of repurposing old drugs against COVID.

His team is currently about to enter clinical trials for a number of licensed off-patent drugs. That said, his biggest contribution so far is probably his commentary on the bioethics of what is going on.

"Both my wife and I are deeply ethical people," he says. *"We're high school sweethearts. We try really hard to live ethical lives and to help our fellow man as well as the animals in our lives. So that's just the place we come from. It's bedrock. We're not rich people.*

I recall a long telephone call with the Canadian physician that poured his heart out about the situation in Canada that he's encountering, both with vaccine administration in primary practice, and also in administering alternative therapies to outpatients, which generally have no therapies available.

I mean, the position is a bit shocking — in the emergency rooms all across the world. Basically, you go to the ER and if your O2 sets are down, pushing towards 80, they say, 'Well, go [home] and come back when your lips are blue.' And that's the essence of it. They don't really offer anything.

So many physicians, including this gentleman in Canada, have been seeking alternative strategies and they've tested and administered these various agents. We've heard of fluvoxamine, ivermectin, hydroxychloroquine. There are many, many others now, including those that we're working with (famotidine and celecoxib) that seem to have therapeutic benefit when administered early to shut down this hyperinflammatory response.

So, he shared this and the stories of multiple reports of vaccine adverse events that in his clinical judgment were clearly vaccine related, some of them quite serious, and that the Canadian government would summarily dispose of those as non-related even though in his clinical judgment, they clearly were related.

He spoke about the enticement of children in Canada with ice cream and the willingness of the Canadian government to administer vaccine to children without their parents or guardians consent after enticing them with ice cream cones, and some of the other things that I just found shocking …

It mirrors what we're seeing across the world, where governments are taking liberties with people's health and their rights without real legislative authorization to do so in most cases."

Core Bioethical Principles Are Being Violated

Malone and his wife Jill are both trained in bioethics, so after listening to this Canadian colleague, he decided he could help by writing a lay press opinion piece about the bioethics of experimental vaccines under emergency use authorization.

> *"I have intimate knowledge of not only the emergency use authorization legislation, the FDA policies behind it, I even know the people that wrote it,"* Malone says.
>
> *"So, we dove in, refreshed our memories on the whole history of the modern bioethics construct that briefly runs from Nuremberg Trials to the Nuremberg Code, to Helsinki Accord, to the Belmont Report in the United States, and to the common rule that exists in the code of federal regulations."*

In summary, since the COVID shots only have emergency use authorization status, they are experimental products, and as such, they are not authorized for marketing. The core bioethical principles that apply therefore involve three key components:

1. Bioethics are written into federal law — As an experimental trial participant, which is what everyone is at the moment who accepts a COVID shot, you have the right to receive full disclosure of any adverse event risks. Based on that disclosure, you then have the right to decide whether you want to participate.

Adverse event risk disclosure should be provided at the level of detail disclosed in any drug package insert. However, the COVID shots have no such insert or detailed disclosure, and adverse event reports are even being suppressed and censored from the public.

Instead, as explained by the FDA,[4] since the COVID shots are not yet licensed,[5] rather than providing a package insert, the FDA directs health care providers to access a lengthy, online "fact sheet" that lists both clinical trial adverse events and ongoing updates of adverse events reported after EUA administration to the public.

A shorter, separate, online fact sheet with far less information in it is available for patients — but, provider or patient, you still have to know where to look up each of the three EUA vaccines separately on the FDA website to access those fact sheets.[6]

2. Adverse event risks must be communicated in a way that you can comprehend what the risks are — This means the disclosure must be written in eighth grade language. In clinical trials, researchers must actually verify participants' comprehension of the risks.

3. The acceptance of an experimental product must be fully voluntary and uncoerced — enticement is forbidden. "I argue that all of this public messaging that we've all been bombarded with … constitutes coercion," Malone says.

"The most egregious example of this that I've ever seen, is the federal government identifying 12 people … and labeling them as the dirty dozen, [saying] that they are responsible for causing death because they are disseminating what the government has determined to be misleading information about vaccines. This is mind boggling to me and to most of my colleagues."

How Falsehoods Are Getting Top Billing

As you probably know, I am on that "disinformation dozen" list. The irony of this situation is that government officials are really the ones contributing to the deaths by not adhering to bioethical principles that are enshrined in law. It's a classic case of 1984 Orwellian doublespeak.

As I mention in the interview, the "misinformation dozen" list is the creation of the Center for Countering Digital Hate (CCDH), a shady organization funded by dark money that sprung up less than two years ago.

> *"Yeah, you don't even have to go to dark money. It's out in the open. There's this Trusted News Initiative led by the BBC. They announced … last fall that they have integrated Big Tech, Big Media and new media, Facebook, Google, Microsoft, et cetera, into an organization that was intended to control false narratives relating to elections, but they decided to turn it on what they perceived as false narratives for vaccines,"* Malone says.
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> *"As if that wasn't enough, the Wellcome Trust and the Bill & Melinda Gates Foundation have announced initiatives where they're making block grants to Facebook, which is then funding these new pop-up fact-checker organizations … [that] are employing methods to smear people and to ban information …*
>
> *What happens is these fact-checker organizations will make their pseudo fact check, like what I experienced with Reuters — which was transparently false, their fact check — and then the media will recycle the fact check. So that moves up in the Google ranking and they're citing themselves. That's what's going on. And it's sponsored by the likes of Wellcome Trust and Bill & Melinda Gates Foundation and they're quite proud of it."*

Why Target Children and Pregnant Women?

Considering the unknown risks involved, why are governments and vaccine makers pushing so hard for children and pregnant women to participate in this experiment? Both have an extremely low risk for complications from COVID-19, which makes adverse effects of the vaccine all the more unacceptable, if not all together intolerable.

There's the appearance that there was manipulation of safety data analysis and reporting in the Phase 1, 2, 3 clinical trials … by focusing on patients who had completed the study per protocol, as opposed to those that entered the study as intended to treat. [If] you've only accepted one dose of vaccine under those clinical trial protocols and you have an adverse event … that information about the adverse event … is lost. It's not included in the safety analysis. This is a classic way to manipulate safety data in clinical research, and it's strictly forbidden. ~ Dr. Robert Malone

Making matters worse, there's no process in place to capture all side effects. Somehow, this was left out, and there's evidence to suggest this was done intentionally.

> *"I think it's important for the listenership to recognize that what we have is still an emerging understanding of what the adverse events are,"* Malone says. *"I could tell you the story of how the cardiotoxicity adverse event was recognized, and it was not*

through official channels. There is [also] the appearance that the CDC is deliberately under-reporting adverse events to the public.

And there's the appearance that there was manipulation of safety data analysis and reporting in the Phase 1, 2, 3 clinical trials for some of these products by focusing on patients who had completed the study per protocol, as opposed to those that entered the study as intended to treat.

That's a subtle distinction, but what it means is that if you've only accepted one dose of vaccine under those clinical trial protocols and you have an adverse event, and you decide to drop it out, or they gently suggest that you shouldn't take the second dose, that information about the adverse events that you received — which would have made you at even higher risk for the second dose — is lost. It's not included in the safety analysis.

This is a classic way to manipulate safety data in clinical research, and it's strictly forbidden. So, the FDA is onto that trick. Normally, if I was to do that, I would get slapped down immediately. Why they allow these large drug companies to do this (if, in fact they did) — and you can't claim that Pfizer didn't know what they were doing — is beyond me.

Now that we know about the adverse events associated with the cardiotoxicity in adolescents and the damage to the heart and the deaths associated with that, people can start to do calculations based on official CDC data, [but] those data are flawed.

They probably under-report the true adverse event rate by about a 100-fold if you're relying on the various historic analysis information. But you can look at those data. And if you're a data scientist, you can do the calculations that the CDC is not doing and not disclosing to us about risk benefit.

The ones that I've seen done by well-trained and highly experienced specialists, people that work for the insurance industry that do this for a living … come out literally upside down."

If the clinical trials did not include patients dropped after Dose 1 in the safety analysis, this would indicate a "per protocol" safety analysis was performed, and therefore that the safety data analyses leading to the emergency use authorizations were not based on rigorous safety assessments.

Multiple patients claiming to have been included in COVID-19 clinical trials have also reported on social media that their reports were excluded from final safety analyses, although this cannot be verified.

Risks Significantly Outweigh Benefits

A study[7] posted July 7, 2021, which looked at deaths occurring in children in the U.K. during the first 12 months of the pandemic, found 99.995% of children diagnosed with COVID-19 survived.

By July 19, 2021, in the United States, a total of 335 children under 18 had died with a COVID-19 diagnosis on their death certificate.[8] An analysis by Marty Makary and colleagues

at Johns Hopkins, together with FAIR Health, showed none of the children under 18 who died and were diagnosed with COVID-19 between April and August 2020 were free of preexisting medical conditions such as cancer.[9]

Now, while the average healthy child has a minuscule chance of dying from COVID-19, and their risk of developing heart inflammation from the COVID jab is also quite low, the risk associated with the injection is still significantly greater than any risk associated with the natural infection. As explained by Malone:

> *"That ratio comes out suggesting that there will be more lives lost to receipt of the 'vaccine' in a universal vaccine campaign than there would be if all those kids were infected by SARS-CoV-2. This upside-down ratio appears to extend or very close to equivalent at least up to the age of 30.*
>
> *So, we're in a position where the data that we have are admittedly flawed. Is that by intent or what? From my standpoint, the data are the data, so I can't smoke out what somebody within health and human services intended to do, but I can look at the data, and others can.*
>
> *And the data absolutely do not support a positive risk-benefit ratio for vaccination of infants through young adults, based on any normal criteria. So then why are they doing this crazy stuff? It seems to all be wrapped around the axle of the need to justify universal vaccination.*
>
> *I argue that this is actually a mid-century policy that goes back to the '50s and the '60s polio vaccine campaign, when the government and world health authorities established a position that it was OK to lie, to withhold information about risk for vaccines, because to have the full spectrum of information about the risks of vaccines would cause people to not accept the vaccine.*
>
> *So, 'Shut up, we know it's best for you and don't question us' is a firmly authoritarian position. It is intrinsically authoritarian and paternalistic. It's exactly the kind of stuff that George Orwell wrote about in his book '1984.' It was a warning … of how governments and authoritarian structures will behave and do behave."*

Denial of Vaccine Dangers Has Been Federal Policy Since 1984

Ironically, Malone points out that in the 1984 Federal Register,[10] it's stated that posting information into the federal register about vaccine risks that jeopardizes vaccine I uptake shall be suppressed.

> *"So, it's a clear federal policy going back to 1984,"* Malone says. *"This is the way they're going to handle things. And they're going to handle it with the noble lie of saying, 'No, there are no risks and what we're doing is fully justified' …*
>
> *I don't think we have to go to imagining some grand conspiracy at Davos between certain individuals. I think this is an emergent phenomena of the intersection of old-school thinking about information management and new-school capabilities and technologies.*
>
> *I think the CDC, HHS, WHO, and Wellcome Trust or Bill & Melinda Gates foundation,*

etcetera, have just grossly misread the population, certainly in the United States. And so now we're in a position where before, according to Del Bigtree, there was about 1% to 2% of people that self-identified as anti-vaxxers, and we're now [above] 40%. Clearly, about 40 to 50% of the population are just dug in. They're not going to accept these vaccines.

The White House now finds it necessary to have a special group to identify and target 12 American citizens for what they believe to be vaccine disinformation, and to make a big public press announcement about it. Don't they have anything else to do? It seems like the world has got bigger problems than Dr. Mercola, but what do I know?

The whole thing is mind-bending. And a lot of people, including many Europeans, are really lit up over this. They remember. European intellectuals are very aware of the dynamics that happened in Germany in the 1930s … I think this could be a turning point in a lot of things."

The Powers That Be Have Been Given Free Reign

While Malone is not interested in speculating about the intentions behind all this malfeasance, he's intimately familiar with the power of Big Pharma to manipulate governments. As detailed in other articles, several of the COVID injection makers have a rich history of illegal activity and unethical behavior, and now they have been given free reign to do as they please.

They're been completely absolved from liability if and when something goes wrong with these injections, and governments are enticing and bullying citizens to participate in Big Pharma's experiment.

"If you give that kind of liberty and power to a global multinational and absolve them of any accountability, they will serve their stockholders," Malone says. "They are not geared to serving the rest of us, whatever they may say in their press releases.

That's just how big pharma behaves, and we've chosen this model. Messaging having to do with alternative treatments and the importance of wellness, those are not consistent with the 'Take this pill, pay your price and shut up' kind of business model.

Personally, I think that Mr. Gates and his foundation have done enormous irreparable harm to world health community through his actions and his own personal biases. He has really distorted global public health. At some point, there will be books written about this, and I'm sure an enormous number of Ph.D. theses will be granted. But meanwhile, we all have to live with it."

The National Vaccine Information Center (NVIC) recently posted more than 50 video presentations from the pay-for-view Fifth International Public Conference on Vaccination held online October 16 to 18, 2020, and made them available to everyone for free.

The conference's theme was "Protecting Health and Autonomy in the 21st Century" and it featured physicians, scientists and other health professionals, human rights activists, faith community leaders, constitutional and civil rights attorneys, authors and parents of vaccine injured children talking about vaccine science, policy, law and ethics and infectious diseases, including coronavirus and COVID-19 vaccines.

In December 2020, a U.K. company published false and misleading information about NVIC and its conference, which prompted NVIC to open up the whole conference for free viewing. The conference has everything you need to educate yourself and protect your personal freedoms and liberties with respect to your health.

Don't miss out on this incredible opportunity. I was a speaker at this empowering conference and urge you to watch these video presentations before they're censored and taken away by the technocratic elite.

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Notes

[1] Trial Site News May 30, 2021

[2] sciencehistory.org June 4, 2019

[3] Indian Journal of Pharmaceutical Science Sep-Oct 2009; 71(5): 488-498

[4] Research Square July 7, 2021 DOI: 10.21203/rs.3.rs-689684/v1

[5, 6] Wall Street Journal July 19, 2021

[7] FDA Emergency Use Authorization for Vaccines Explained November 20, 2020

[8] FDA Licensed Vaccines July 16, 2021

[9] FDA COVID-19 Vaccines July 20, 2021

[10] Federal Register Vol. 49, No. 107 June 1, 1984 pp 23006-007 (PDF)

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