How are the COVID vaccines different from other vaccines on the market?

The COVID vaccines are mRNA (messenger RNA) vaccines, which are completely new. No mRNA vaccine has ever been licensed for human use before. There are no other therapies or prophylactics on the market that use the same approach, despite a handful of efforts.

Traditional vaccines introduce pieces of a virus ("live" or inert), as well as adjuvants such as aluminum and mercury, to stimulate an immune reaction. The new mRNA vaccine is completely different. It actually injects (transfects) molecules of synthetic genetic material from non-human sources into our cells. Once in the cells, the genetic material interacts with our transfer RNA (tRNA) to make a foreign protein that supposedly teaches the body to destroy the virus being coded for. Note that these newly created proteins are not regulated by our own DNA, and are thus completely foreign to our cells. What they are fully capable of doing is unknown.

This process is, in effect, genetic modification. Its purpose is to insert foreign genetic material into our own DNA to alter its expression. Again, this process has never been used in other vaccines.

The Moderna vaccine is given in two doses, 28 days apart. The Pfizer vaccine will require two shots, three weeks apart.

The Pfizer and Moderna vaccines also include the traditional toxic adjuvants.

What are safety concerns?

Antibody Dependent Enhancement: "Exaggerated Immune Reaction"

A major concern being voiced by scientists and physicians (including the ex-Pfizer head of respiratory research Dr. Michael Yeadon and the lung specialist and former head of the German public health department Dr. Wolfgang Wodarg) has to do with the potential for antibody-dependent enhancement (ADE), a phenomenon documented in humans, non-human primates, and ferrets in connection with the coronaviruses linked to SARS and MERS. In ADE, vaccines can cause antibodies present in a person's body to act like a Trojan horse for wild viruses.

In the case of individuals receiving COVID-19 vaccines, ADE could not only end up enhancing disease severity but could also lead to organ damage. Of concern, COVID-19 vaccine trials are not designed to detect ADE. It is not known what proportion of the U.S. population might suffer pathogenic priming or ADE after receiving a COVID-19 vaccine, but the estimated 15 to 24 million Americans who already have an autoimmune disease could be particularly susceptible. The CDC has indicated that individuals with high-risk medical conditions—individuals excluded from the Phase I trials—are one of the proposed groups for early vaccination.

The Risks of Genetic Modification

The vaccine trials have not ruled out whether the new genetic material they will insert into human bodies are homologous (the same) as other genetic sequences in the body. If homologous sequences are present, the body will be "taught" to attack itself.

If this seems an unlikely occurrence, consider these facts. A <u>BLAST search</u> is a way to search the compiled genetic data bank for all human and microbial sequences. A BLAST search for one of the sequences (called the Rd-Rp sequence) being used in the RT/PCR tests (which are being used to diagnose the presence of the coronavirus) reveals that there are 99 human chromosomes with a 100 percent sequence identity match. Another sequence (called the Orflab sequence) being used in the PCR test returns 90 with a 100 percent sequence identity match to human chromosomes.

In addition, doing a BLAST search reveals 92 microbes identical to the Or1ab sequence and 100 microbes identical to the RdRp sequence. These sequences are being used in the PCR tests because they are identified as being part of the coronavirus. It's logical to assume that these genetic sequences — as well as others —are in the vaccines as well. The response could be either an acute inflammatory response or, later in life, the development of an autoimmune disease.

(Side note: That the PCR tests are searching for genetic sequences innate in the human body means that the PCR testing for the SARS CoV2 virus has no scientific validity as it is not testing for any sequence that is UNIQUE to any virus. This explains why so many people test positive and have few or no symptoms of illness).

Infertility

The vaccinations are expected to produce antibodies against spike proteins of SARS-CoV-2. However, spike proteins also contain syncytin-homologous proteins, which are essential for the formation of the placenta in mammals such as humans. It has not been ruled out that a vaccine against SARS-CoV-2 could trigger an immune reaction against syncytin-1. Such an immune reaction would cause infertility of indefinite duration in vaccinated women. The trials are too short in duration to assess this outcome, and were not designed to assess this outcome.

PEG

The mRNA vaccines from Pfizer and Moderna contain polyethylene glycol (PEG). The reason is that the mRNA molecule is vulnerable to destruction. To protect the fragile mRNA strands while they are being inserted into our DNA, they are coated with PEGylated lipid nanoparticles. This coating hides the mRNA from our immune system, which ordinarily would kill any foreign material injected into the body. PEGylated lipid nanoparticles have been used in several drugs for years. Because of their effect on immune system balance, several studies have shown them to induce allergies and autoimmune diseases. Additionally, PEGylated lipid nanoparticles have been shown to trigger their own immune reactions, and to cause damage to the liver.

PEG is not only a potential <u>allergen</u>, it is also a suspected <u>carcinogen</u>. Moderna's 2018 <u>corporate</u> <u>prospectus</u> acknowledges that "there can be no assurance that our LNPs (lipid nanoparticles) will not have undesired effects," including reactions that "could lead to significant adverse events."

Media outlets are <u>reporting</u> that two individuals who received the Pfizer-BioNTech <u>COVID-19</u> mRNA vaccine developed severe anaphylactic reactions following the injection.

<u>Reuters</u> reported on Dec. 10 that an investigation into the <u>anaphylactic reactions</u> has identified PEG as the likely culprit. It was also reported that PEG is not in other types of vaccines.

According to these <u>news reports</u>, documents published by the two companies showed that people with a history of severe allergic reactions were excluded from the clinical trials. Therefore, this life-threatening adverse safety signal did not appear in their clinical trial safety data.

Although the FDA has labeled PEG as "biologically inert/inactive," investigators are now questioning its <u>biocompatibility</u> and warning about PEGylated particles' promotion of tumor growth and adverse immune responses that include "probably underdiagnosed" lifethreatening <u>anaphylaxis</u>. These undesirable responses have, on occasion, halted clinical trials. As a result, some scientists argue that it is time to develop alternatives <u>to replace PEG</u>.

American and Dutch researchers declared in 2013:

"[T]he accumulating evidence documenting the detrimental effects of PEG on drug delivery make it imperative that scientists in this field break their dependence on PEGylation."

A 2016 study in Analytical Chemistry <u>reported</u> detectable and sometimes high levels of anti-PEG antibodies (including first-line-of-defense IgM antibodies and later stage IgG antibodies) in approximately 72% of contemporary human samples and about 56% of historical specimens from the 1970s through the 1990s. Of the 72% with PEG IgG antibodies, 8% had anti-PEG IgG antibodies > 500ng/ml., which is considered extremely elevated. Extrapolated to the U.S. population of 330 million who may receive this vaccine, 16.6 million may have antibody levels associated with adverse effects.

The researchers confessed that the results were entirely unexpected. The authors concluded that: The population's <u>increased exposure</u> to PEG-containing products makes it "natural to assume" that anti-PEG antibodies will continue to be widespread."

Moderna documents and publications indicate that the company is well aware of safety risks associated with PEG and other aspects of its mRNA technology. In the corporate prospectus supporting Moderna's stock market launch in late 2018, the company was frank that its technical approach has numerous risks.

Specifically, Moderna acknowledged the potential for its proprietary lipid nanoparticles (LNPs) and PEG to produce "systemic side effects," given the scientific literature's documentation of these types of side effects for other LNPs. In comments not generally seen by the public, Moderna stated (p. 33):

[T]here can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: immune reactions, infusion reactions, complement reactions, opsonization reactions, reactions, antibody reactions . . . or reactions to the PEG from some lipids or PEG otherwise associated with the LNP. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our clinical trials.

Addressing the efficacy side of the equation, a mid-2019 study by authors who "are or have been employees of Moderna, Inc. and receive salary and stock options from Moderna, Inc." further admitted that anti-PEG antibodies "present <u>significant challenges</u> to the clinical efficacy of PEGylated therapeutics and will require strategies to overcome [their] effects."

Cancer Risk

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) is the U.S. Food and Drug Administration's (FDA) internal panel that licenses new vaccines as "safe and effective," and that approved the Pfizer vaccine for emergency use.

In a 2012 VRBPAC meeting, panelists voted unanimously to allow use of human **tumor** cells in vaccines. The FDA allows both <u>human fetal cells</u> and adult human tumor cells in vaccines. Both types have cancer risks. While both Pfizer and <u>Moderna</u> tested their mRNA vaccine using fetal cells, there are no fetal cells, cell debris or DNA in their final products.

However, according to company documents, Johnson and Johnson (Janssen) and Altimmune's COVID vaccines are manufactured in the human fetal cell line PER-C6, and thus the final vaccine products will contain cellular debris and DNA fragments from these cells. Researchers harvested these cell lines from the eyeball of an 18-week-old human fetus aborted in 1985, and then rendered them immortal by making them cancerous.

The <u>AstraZeneca</u>, Cansino, Gamayela, Vaxart, LongComm and Upitt vaccines are manufactured in the human fetal cell line HEK293, and thus the final vaccine products will contain cellular debris and DNA fragments from the fetal HEK-293 cell line. Scientists harvested this cell line from the kidney of a female Dutch fetus legally aborted in 1973 and then immortalized the cells by rendering them cancerous.

According to FDA's "The Pink Sheet" dated Nov. 29, 1999, for two decades the agency has been acutely aware of the inherent risks of using immortalized cell lines for vaccine development. The FDA Center for Biologics Evaluation and Research Director Dr. Peter Patriarca explained that continuous cell lines are used for their ability to self-propagate, making them an ideal substrate on which to grow viruses. "The worst thing we are concerned about is ... malignancy, because some of these continuous cells have the potential for growing tumors in laboratory animals."

Patriarca further conceded that "the technology to make these vaccines actually exceeds the science and technology to understand how these vaccines work and to predict how they will

work." This dire "black box" conundrum that Patriarca described in 1999 is even more acute today with the urgent pressure to develop COVID vaccines before manufacturers have tested them in animals or subjected them to long-term safety studies.

Risk Reduction

Moderna announced an effectiveness rate of 94.5 percent for its vaccine. How did the company come to that number?

It's called risk reduction. Moderna's trial included 30,000 total participants, so approximately 15,000 participants were in each section of the trial (the vaccine section and the placebo section). Moderna reports that in the "vaccine" arm of the trial, only five people (0.03 percent) got symptoms on Day 14 (Note: The trial was designed only to assess symptoms on Day 14 after receiving the vaccine or the placebo – not whether the vaccine prevented infectivity or transmission.)

In the "placebo" arm, 90 people (0.6 percent) got symptoms on Day 14. Therefore, the actual symptom-reduction benefit of this injected drug is 0.57 percent (0.6 percent minus .03 percent equals .57 percent).

Where did they get the headline of 94.7 percent reduction, passing the magic threshold of 90 percent for fast-track approval? They added five (from five vaccine participants who had symptoms) to 90 (90 placebo participants who had symptoms) to get 95. Ninety is 94.7 percent of 95, so with the magic of risk reduction, we have a successful "vaccine" trial.

Pfizer's effectiveness rate was reported as both 90 percent and 95 percent. These numbers were calculated in the same way at Moderna's number. Astonishingly, all drugs' effective rates are calculated in this way, rather than in absolute numbers. Again, the absolute number for the Moderna trial indicates that the experimental vaccine — subjected to no long-term studies — was only .57 percent more effective than the placebo at reducing or preventing symptoms of illness at Day 14 after injection. It's unclear whether the symptoms that were reported had anything to do with COVID or with side-effects of the vaccine.

About the Trials

The <u>studies</u> are *not* designed to detect a reduction in outcomes such as severe illness, hospitalization or death. For individuals who develop severe symptoms, the vaccine is not a remedy.

Participants in every Covid-19 vaccine trial have reported <u>adverse reactions</u> including high fever, chills, muscle pains and headaches. Some have even reported <u>severe reactions</u> that required <u>hospitalization</u> and invasive treatment. According to the FDA, potential long-term effects may include Guillain-Barré syndrome, brain swelling, muscle weakness and paralysis, convulsions and seizures, stroke, narcolepsy, shock, heart attack, autoimmune disease, arthritis and joint pain, multisystem inflammatory syndrome in children, and <u>death</u>. Again, some <u>UK health workers</u> have experienced anaphylactic shock after receiving one dose of the approved vaccine.

The vaccines aren't designed to prevent COVID. An FDA Pfizer briefing <u>paper</u> published December 10, 2020, revealed 43 percent more suspected cases of Covid-19 in the vaccinated group than in the placebo group within seven days of vaccination. They will also not end restrictions. Dr. Anthony Fauci of the National Institutes of Health acknowledges that the vaccines may prevent symptoms but <u>will not block spread</u> of the virus, so vaccine recipients will still need to wear masks, practice social distancing and avoid crowds.

Given these issues, is the vaccine even necessary? According to the CDC's current best <u>estimate</u>, the "infection fatality rate" (IFR) for Covid-19 is less than 1 percent for people age 69 and younger, including a .003 percent IFR for children and adolescents.

Vaccine Makers Can't Be Held Liable for Injuries or Death

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was signed into law by United States President Ronald Reagan as part of a larger health bill on November 14, 1986. NCVIA's purpose was to eliminate the potential financial liability of vaccine manufacturers due to vaccine injury claims to ensure a stable market supply of vaccines. By 1985, vaccine makers were having trouble getting insurance coverage because of risks associated with the DPT vaccine, so they appealed to Congress for help. This act is the result. Therefore, if you or anyone you know is injured or killed by the vaccine, you or they or family members can't sue the manufacturer.

No Long-Term Safety Studies

Absolutely no long-term safety studies have been conducted on any of these vaccines. The following numbers come from the FDA's Vaccines and Related Biological Products Advisory Committee in its meeting on Dec. 10 to review the Pfizer vaccine:

Less than 2.1 percent of the safety study cohort had been followed for more than three months as of the Nov. 14 cutoff date. This is inadequate to determine any long-term effects of the vaccine. If the manufacturers allow vaccination of the placebo group after six months, longer follow up of the early cohorts will be lost.

Only 2.1 percent and 1.8 percent of the study cohort included patients 75 years old and older with pre-existing medical conditions, for the vaccinated and the placebo groups, respectively. There were only 41 total African Americans older than 75 in both arms of the Pfizer vaccine study. These are insufficient samples on which to base broad recommendations for these very important and vulnerable segments of the population.

Even pro-vaccine doctors are expressing serious doubts:

In November 2020, Dr. Peter Jay Hotez said of the new mRNA vaccines: "I worry about innovation at the expense of practicality because they [the mRNA vaccines] are weighted toward technology platforms that have never made it to licensure before."

Hotez is a major proponent of vaccines and is a Professor of Pediatrics and Molecular Virology & Microbiology at Baylor College of Medicine, where he is also Director of the Texas Children's Hospital Center for Vaccine Development.

Michal Linial, PhD is a Professor of Biochemistry. Because of her research and forecasts on COVID-19, Dr. Linial has been widely quoted in the media. She recently stated, "I won't be taking it [the mRNA vaccine] immediately – probably not for at least the coming year. We have to wait and see whether it really works. We will have a safety profile for only a certain number of months, so if there is a long-term effect after two years, we cannot know." (Is "two years" really sufficient time to assess a "long-term effect"?)

It's also worth noting that Moderna's preliminary safety data suggested that patients in the mRNA-1273 trial were more likely to experience systemic adverse events -- clinical-trial lingo for "difficult side effects" -- after a second dose of the vaccine. Again, vaccine-trial candidates are screened for any chronic health issues, such as asthma, allergies, autoimmune diseases — they are the healthiest people in the population at large. How will people who do have chronic issues, even mild ones such as allergies, respond to these vaccines?

Moderna and Pfizer History

Moderna has never successfully produced a medicine of any kind. Established in 2010, it has never brought a product to market, nor gotten any of its nine or so vaccine candidates approved for use by the FDA. It has also never brought a product to the third and final phase of a clinical trial. Moderna's scientific approach to vaccine development has never been successfully implemented in humans.

The company's insiders have made high-profile exits from their stock positions. The CEO, chief financial officer, chief technical officer, president, and chief medical officer of Moderna have sold tens of millions of dollars of the company's stock over the last five months in a slew of pre-planned trades. Could this be a sign they don't have confidence that the company's future stock price will be higher than what it is now?

Pfizer was ordered to pay the largest health care fraud settlement in history in 2009. The company had to pay \$2.3 billion to resolve criminal and civil allegations that the company illegally promoted uses of four of its drugs, including the painkiller Bextra, according to the U.S. Department of Justice. At the FDA's request, Pfizer pulled Bextra off the market in April 2005 because its risks, including a rare, sometimes fatal, skin reaction, outweighed its benefits.

The FDA

We would all like to trust that governmental agencies act with integrity and transparency. We would especially hope that the FDA, entrusted to examine and review pharmaceutical products, has the highest standards of integrity. However, over time, such agencies – including and especially the FDA – have acted in ways that do not engender trust. A whole separate paper could be written on the dangerous drugs they approved that had to be recalled. Here are sample quotes from people who have insider experience with the FDA.

"If the American people knew some of the things that went on at the FDA, they'd never take anything but Bayer aspirin." — Len Lutwalk, FDA scientist

"The FDA, by spinelessly knuckling under to every whim of the drug companies, has thrown away its high reputation, and in doing so, forfeited our trust." — Drummond Rennie, deputy editor of the Journal of American Medical Association

"[The] honest employee fears the dishonest employee. There is also irrefutable evidence that managers at CDER (Center for Drug Evaluation and Research of the FDA) have placed the nation at risk by corrupting the evaluation of drugs and by interfering with our ability to ensure the safety and efficacy of drugs. While I was at FDA, drug reviewers were clearly told not to question drug companies and that our job was to approve drugs ... If we asked questions that could delay or prevent a drug's approval — which of course was our job as drug reviewers — management would reprimand us, reassign us, hold secret meetings about us or worse ... When you are able to dig in, if you found issues that would make you turn down a drug, you could be pressured to reverse your decision, or the review would then be handed off to someone who would simply copy and paste whatever claims the company made in the summary document ... I believe I also have documentation of falsification of documents, fraud, perjury and widespread racketeering, including witnesses tampering and witness retaliation." — Ronald Kavanagh, Ph.D., pharmacist who reviewed medications for the FDA from 1998 to 2008

FDA Plans to Monitor COVID Vaccine Injuries

The FDA is formulating its surveillance methodologies for tracking injuries from the COVID vaccines. The following list of possible "Adverse Event Outcomes" from the vaccines is from a presentation that's on the FDA website.

In addition, <u>CNBC reports</u> that the FDA's staff recommends monitoring people who get either the Pfizer or Moderna vaccines for possible cases of Bell's palsy, saying it's not necessarily a side effect but worth watching out for after a handful of trial participants got the condition, which causes half the face to droop.

Please note: One of the other "adverse outcomes" they'll be tracking is death.

FDA Safety Surveillance of COVID-19 Vaccines: <u>DRAFT</u> Working list of possible adverse event outcomes ***Subject to change***

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease

- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

What can I do to prevent this vaccine from being mandated?

Continue to get informed. Follow what is happening with business and school mandates, state mandates, etc. Become a part-time activist, learn how to email and call your state reps, make phone calls, sign petitions, go to protests.

There are a number of dedicated people and non-profits fighting this battle. They depend on our support. Follow them on social media, re-post and publicize their work, donate money if you can.

Childrens Health Defense, Bobby Kennedy's group www.childrenshealthdefense.org

Informed Consent Action Network, www.icandecide.org

National Vaccine Information www.nvic.org

Del Bigtree, the Highwire https://thehighwire.com/

For political action and lobbying: www.standforhealthfreedom.com

New York city area, Autism Action Network, <u>www.autismactionnetwork.org</u>

If you are in Columbia County, NY, join a local real life network of activists

www.doweneedthis.org email: info@doweneedthis.org