The mRNA Story

Preamble

This detailed look at the use of mRNA in the Covid vaccines is written to help ensure everyone understands what was done by distributing an mRNA vaccine to hundreds of millions of people globally, and some of the potential consequences. This is not about any other Covid vaccines or vaccines in general. It's very important to understand exactly what happened with respect to these mRNA vaccines, to understand the potential long-term implications, and to understand the impact on other similar technologies under development, because mRNA is only the beginning…..

The single most important thing to understand is that mRNA technology has been around for more than 30 years in research and development but it **had never been used before in humans, ever**. If you don't remember anything else from reading this, please remember that this is a totally new, never before used technology that is very different from all the other approaches taken for vaccines and for therapeutics as well. It's not just different – its fundamentally different - not like "apples and oranges" different – it's more like apples and giraffes different.

So to recap, the mRNA vaccines used a completely and totally different technology that had never before been used in humans in any form.

When they develop new drugs, pharma companies are financially motivated to do three things; (1) minimize clinical trials needed, (2) only design trials that will demonstrate safety and efficacy using surrogate markers (3) stop any trials that are not generating the data they expect, and (4) hide and obfuscate.

A clinical trial is much like a jury trial – it's not always the case that the defendant is correctly proven either innocent or guilty – rather the finding made at the trial is based on the evidence presented. In some cases, important evidence can be suppressed, misrepresented or intentionally not presented, and sometimes evidence that doesn't find its way into the trial may have had a bearing on the case if it was able to be presented. Similarly in the case of clinical trials, pharma companies strive to generate data that would help them get their drug approved but it may not necessarily be data that will prove the efficacy or safety of the drug to treat of manage a specific disease. So drugs are approved on the basis of the trial evidence presented and on the basis of what data the FDA is asking for, but not necessarily the best data that could have been used.

During Covid all the rules were put aside – all the work done all through the years since the FDA came into existence in 1906 as a result of the passage of the Food Drug and Cosmetics act was suspended. Since its inception the FDA had been building and developing a strong regulatory process for pharmaceuticals and there seemed to be a lot of mutual respect between pharma companies and the FDA, and between FDA and the public. All the scientific capital and credibility that had been built up over all those years was lost in the 24 months immediately after the release of the Covid vaccines. FDA suspended its rules and decided that the emergency use authorization they were handing out trumped everything else. Trials that would normally be done to evaluate the biodistribution, cellular uptake, endosomal escape, translation rates, functional half-life and inactivation kinetics of synthetic mRNA, rates and duration of vaccine-induced antigen expression in different cell types, as well as potential interactions with the host genome were all bypassed. So instead of requiring safety and efficacy, they no longer cared about either. Covid vaccine development and production

more resembled the wild west where snake oil dealers ran wild, then it did modern times in a regulated environment. The pharma companies developing these "vaccines" called all the shots (pun intended).

Very little data had been made available from Pfizer and Moderna – they and FDA essentially conspired to keep a lid on their data and to allow them to avoid generating data so that these vaccines were allowed and forced to be distributed based on a very small amount of incomplete data. Recently through a freedom of information request the EMA (European Medicines Authority – Europe's FDA) was forced to release the submission package for the mRNA vaccines. This is the first time we have a full picture of what was done.

As has been reported in dozens of journal articles, hundreds of millions of people have been injected with these mRNA vaccines which were designed to prevent coronavirus infection, but instead caused a myriad of side effects including:

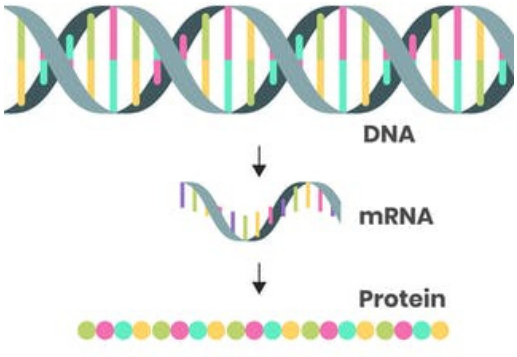
- Myocarditis and pericarditis
- Menstrual bleeding
- Various Neuropathies
- Thrombosis

In addition to exposing yourself to the risk of one of these or many other vaccine side-effects, most people who got vaccinated also got Covid afterward so the "vaccine" does not prevent infection. In fact a very large recent study by the Cleveland Clinic (one of the foremost research institutes in the world) concluded that not only does the (newer) bivalent vaccine not prevent coronavirus infection, it may actually make it **MORE** likely that one can get coronavirus infection! What they found was that the more doses of the vaccine you got, the greater the likelihood was that you would get re-infected. **So to reiterate, the Cleveland Clinic's large recent study demonstrated that rather than preventing infection, the bivalent vaccine actually does the opposite – it encourages infection! Let that sink in for a minute……**

As incredible as this may sound, their lack of efficacy is far from the worst part of the mRNA vaccines, so buckle-up boys and girls for this next bit. As it turns out, the question everyone should be asking right now is do you really know what was in the Covid injection you received? But first a little background to set the stage.

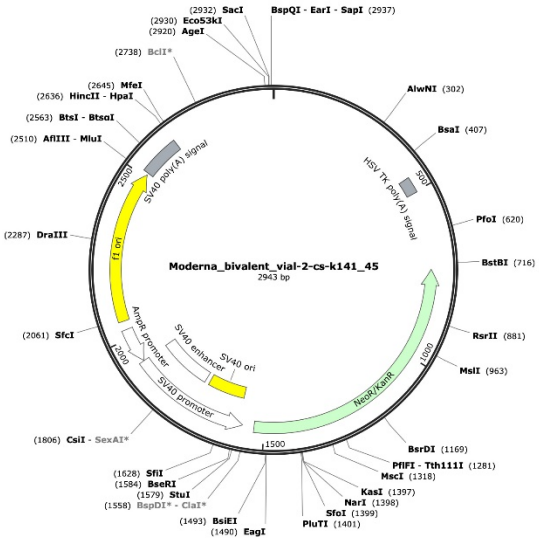
Background mRNA Information

I tried to make this as interesting and brief as possible but it is admittedly, unavoidably "dry" and drawn-out in spots – it's important to try and get through this though to have a good basis of understanding. By the way, part of the reason I know about this stuff is because I've done similar work myself in the past so I can provide something of a first-hand perspective.



mRNA is one species of nucleic acid - DNA is the most famous nucleic acid and so RNA is kind of the Robin to DNA's Batman. mRNA's role is to copy the code in your DNA to provide the roadmap for proteins to be made from the specific DNA sequence it has copied (the m stands for messenger). The diagram to the left shows this progression. Your DNA is forever but these mRNA copies are purposefully designed to be very short-lived – once the protein is made the RNA is digested - so mRNA is kind of like a secret note – once it's been read it is destroyed – think Mission Impossible; "this tape will self-destruct in 10 seconds". Having worked with RNA a lot I know it's so unstable that it's very hard to isolate it – even your skin has enzymes on the surface that can digest RNA so RNA gets digested early and often. In fact, if it stayed around, it would cause the protein its coding for to be over-produced and that's not good so its purposefully labile design is important for genetic regulation.

But mRNA's short life is not good if you are making an mRNA vaccine – in fact you can't make an mRNA vaccine out of natural mRNA, it won't work – you would never be able to keep it stable for even a few minutes after it's made. So the clever people who designed the vaccine had to first make stable mRNA – and to do that they had to add unnatural ribonucleotides to the RNA when it was made to make it "bullet proof". They also added a "tail" and the result was this non-natural mRNA is "invisible" to the digestion enzymes whose job it is to get rid of RNA.



Mass producing mRNA is also not easy – the RNA sequence for the spike protein is too big to make at large scale synthetically using a machine, so it has to make it in bacteria. To do that you first need to make a circular DNA called a plasmid which they constructed out of bits and bobs of DNA from phage, a monkey virus called Sv40, and a bunch of different bacterial genes. The Moderna plasmid is depicted at the left. They isolated this plasmid DNA from bacterial fermenters and then used the DNA to generate the RNA copies using phage enzymes while adding the un-natural ribonucleotide (it's called N1 methyl-pseudouridine – spelled just like it sounds – except for the silent p and the silent e…..) and the tails. One issue with the tails is their length – the lengths of the tails are variable and so the mRNA produced is of various lengths (not all the same).

The next issue to deal with is delivery – how do you get the mRNA where it needs to be inside the human body so it can create a spike protein in a location where the immune system recognizes it as foreign and generates antibodies (the immune response). This also is not easy and had never been done before either (see a pattern yet?). Ok so there has been a technology around for a long time and that had been used to deliver therapeutics, but never nucleic acids called lipid nanoparticles (LNP) – these are un-natural, large molecule lipids like polyethylene glycol (PEG) and others (it's all about surface tension and liquid-liquid interfaces but that's a story for another day). The idea is to create a "Trojan horse" the stuff inside of which can be hidden and protected. This is known as a non-targeted delivery system – sort of a "dumb" system that is designed to just avoid destruction and get taken up by cells indiscriminately.

History of mRNA Vaccines and Therapeutics

Let's digress for a minute and talk about the history of mRNA vaccines/therapeutics.

> **Perry Mason to defendant**: "*So you would have this court believe that there was this great technology out there (ie mRNA therapeutics) that was fully developed and ready to go but nobody was using it, and then when Covid came along, all of a sudden this great, fully developed technology was pulled out of a drawer, so it could save the day"?*
>
> *"Isn't it true that this technology has not been safety tested in humans? Isn't it true that there's no proof that the mRNA is translated correctly into spike protein? Isn't it true that there's no scientific evidence that the correct type of immune response will be elicited? Isn't it true that you are just taking advantage of a pandemic to introduce this half-baked technology?*
>
> **D.A Burger***: I object your honor - counsel is badgering this witness.*
>
> **Perry Mason***: No further questions, your honor.*

This is a great story line for a movie (in fact it is the story line for literally dozens of movies where the "antidote" is available in some scientist's refrigerator) but unfortunately, it's not reality.

The reality is that mRNA technology has been around for a very long time – more than 30 years. Over the course of that time many companies have been working diligently, spending lots of time and money to develop drugs using this technology but have not been successful mainly because of the safety issues associated with it – it's actually a very complex system to assemble. In fact, I found a great review article that was published right before Covid came on the scene (most pre-Covid articles are less biased and very useful – many of the articles published post-Covid are unfortunately very biased). This peer-reviewed publication is a very long, detailed review article published in August 2019 by researchers at Ghent University (one of the best places to learn about mRNA) and it painstakingly describes all of the mRNA work done to date (it cites more than 200 references), and then concludes;

> "*For prophylactic mRNA vaccines against infectious diseases, (pre-)clinical studies (in non-human primates) show accumulating evidence that mRNA vaccination is feasible, generally well-tolerated, and potentially beneficial over other traditional vaccine approaches. However, it is still waiting for a more extended clinical experience on how patients respond to mRNA vaccines, including more comparative research to select for the best suited mRNA platform and administration route, as well as to show clear therapeutic benefits over other vaccine strategies. Together, it is but a matter of time before we will be able to determine which of these mRNA vaccine candidates/strategies enable effective but safe immune responses in humans, hopefully leading to a new generation of vaccines."*
>
> *Rein Verbeke, Ine Lentacker, Stefaan C. De Smedt, Heleen Dewitte,*
> *Three decades of messenger RNA vaccine development,*
> *Nano Today, Volume 28,2019,100766,ISSN 1748-0132,*
> *https://doi.org/10.1016/j.nantod.2019.100766*

Ok so in August of 2019 some of the best minds on the subject concluded that mRNA technology, although promising, was still in the development stage and would require more data to determine the best platform administration route and comparison data – in other words it was not yet ready for prime time. That was in

August 2019….. August 2019…….. AUGUST 2019! Covid came on the scene in Nov 2019 and the first vaccine was out at end of 2020. So, after more than 30 years of work on mRNA, experts in August 2019 concluded there was still lots of work to be done. But miraculously, a mere year and a half later vaccines using mRNA technology had been designed, developed, tested, manufactured at large scale and were ready to be distributed worldwide to every human on the planet!

Heavy stuff – time for a break. From the 1944 Howard Hawks film To Have and Have Not – Lauren Bacall (Slim), Humphrey Bogart (Steve):

> ***Steve :*** *I got to get nursie out of here or she never will come to.*
>
> *[picks up Mme de Bursac who passed out from chloroform, Slim follows]*
>
> ***Slim :*** *What are you trying to do, guess her weight?*
>
> ***Steve :*** *She's heftier than you think.*
>
> *[lays her down on a bed]*
>
> ***Steve :*** *Better loosen her clothes.*
>
> ***Slim :*** *You've been doing all right.*
>
> *[Steve starts to loosen]*
>
> ***Slim :*** *Eh, maybe you'd better look after her husband.*
>
> ***Steve :*** *He's not going to run out on me.*
>
> ***Slim :*** *Neither is she.*
>
> ***"To Have and Have Not"*** *Scripts.com. STANDS4 LLC, 2023. Web. 15 Sep. 2023. <https://www.scripts.com/script/to_have_and_have_not_21975>.*

When Bogart looks at the beautiful woman in his arms who is out cold, he pauses and then looks her over again from head to toe for a few more seconds just as Bacall enters the room, and without missing a beat, she says in that patented, sarcastic Bacall voice "what are you trying to do, guess her weight" – fantastic! Interestingly, this movie is based on a book by Ernest Hemingway which was adapted into a movie script by William Faulkner – even though the two famous writers were rivals and didn't see eye-to-eye. Oh, by the way, this has absolutely nothing to do with mRNA piece – I just like the exchange between Bacall and Bogart and since I have your attention, I couldn't resist putting it in……

OK, break time is over - back to it:

mRNA Dosage

What about the dose of mRNA given – since this was the first time this technology was used, there was nothing to model on so how was the dose determined? Most people know that Moderna and Pfizer mRNA vaccines came out with very different doses even though they are essentially the same vaccine – why? Let's consider the rationale for setting dose - the idea is to mimic viral infection and present enough spike protein to the immunogenic B cells to generate an antibody response. Typically, when developing a new drug, pharma companies are required to do dose ranging and dose finding studies designed to both determine the optimal

dose, and to determine the "minimal effective dose". This is usually very important because FDA does not normally grant marketing approval to doses that are higher than necessary to achieve efficacy. Nobody really knows how much mRNA is enough to generate enough spike protein to do this or how long that spike protein needs to be around so the mRNA vaccine manufacturers likely overcompensated, essentially delivering as much mRNA as they could get away with in each dose. We now know that the spike protein mRNA from these vaccines stays around for at least 28 days! In fact, studies done recently have demonstrated that spike protein levels were ***lower*** in people who died from COVID compared to spike protein levels in vaccinated individuals! This is quite remarkable, as it suggests that spike protein levels get to higher levels after two jabs of the Pfizer vaccine than in people with *severe* COVID! Traditional vaccines present the antigen protein for a very short time and then again 6 months or a year later in a booster – there has never been a scenario where a foreign protein stays around for this long and so consequently nobody knows what effect this will have long term.

All the regulatory control that is present in human cells, the mRNA lability, limitations on amount of each protein translated, how and when and where this happens both in the body and the cells, is all the product of eons of evolutionary development – and this is for proteins that are supposed to be in humans! The mRNA vaccines have subverted these natural cellular regulatory roadblocks to overproduce a foreign protein from a virus in all different tissues throughout the body!

You can choose to believe that this great technology (the Antidote) was on the shelf and ready to go – it happens all the time in Sci-Fi movies so it must be possible. (No more anecdotes about antidotes).

Some Assembly Required

So, you go down to your local doctor's office, or CVS, or the guy with the station wagon who hangs out at the corner, and you get your Covid shot. What actually happens next inside your body? Well, the lipid nanoparticles (LNPs) containing the mRNA that are injected into your muscle tissue in your arm have no reason to hang around there – there's nothing to keep them there and there's lot of new, shiny objects around so they head off in all different directions and get gobbled up by all different types of cells. Some will end up in the blood stream via white blood cells and from there they will be brought to the four corners of your body. LNPs are actually very good delivery vehicles and are also very good at protecting their payload but they are not targeted delivery vehicles. When they get picked up (engulfed) by these cells they spill their guts into the cytoplasm of those cells – everything that was packaged inside the LNPs is now part of those cells. The mRNA starts being translated into protein and since it is non-natural it doesn't get degraded but instead gets translated again to make even more protein and this cycle repeats as long as that cell is alive. If this was the end of story things would be good – but unfortunately there's a lot more going on.

There are other issues associated with delivery of nucleic acid sequences like mRNA as vaccines in place of using the protein itself – one is that instead of delivering the actual viral protein, you are relying on your cells to make that viral protein. Remember back in high school biology class right before you started falling asleep, the teacher was talking about the triplet code? Three nucleotides together code for one amino acid (if you don't remember this you might already have been asleep – think instead about what was on the paper of the person you copied from on the test). But because the mRNA is "read" by the ribosomes to make protein, the protein that's made is dependent on the reading frame that's used (ie where the ribosome starts reading) – this is only an issue if there is more than one viable reading frame in the sequence you've injected. Unfortunately, in the case of the mRNA in the Covid vaccine it's been discovered that there are three viable reading frames; the correct one that generates spike protein, and two other open reading frames that could be translated into two different proteins. So, in addition to producing the covid spike protein inside your body, the vaccine injection

you got down at Pete's Bar and Covid Vaccine Parlor may also be directing your cells to make two additional unknown, foreign proteins. Again, since the mRNA is bullet-proof these unknown proteins will be made over and over in your cells and will be around to do whatever it is they do. Eventually your immune system will become tolerant of them and will no longer consider any of these non-human, non-viral proteins, (including the spike protein), to be foreign proteins.

In addition to all that, these mRNA sequences needed to go through what's called "codon optimization" – before your eyes roll back in your head, this is just a fancy term that just means the triplet code is a degenerative code and so the triplets mean different things in different situations (kind of like the word "tear", which could mean ripping something or it could refer to the moisture that comes from your eyes when you are crying). So, it's a tomayto-tomahto sort of thing – the virus reads it as tomayto, and the human cells see tomahto. To fix this issue, the developers of the vaccine had to normalize the virus code for human cells and so they had to make some changes to the mRNA sequence. Even though the spike protein mRNA in the vaccine ends up encoding the exact same sequence of amino acids that are in the spike protein, the actual sequence of letters in the mRNA were not the same as in the virus itself.

Additionally, the mRNA that human cells is translating is not normal human mRNA since it has the un-natural ribonucleotide pseudouridine and the triplicate code was modified as part of the codon optimization efforts. With all these modifications it's likely that the "reading" of the mRNA by the ribosomes is at best slowed, and at worst not done accurately. What I mean by this is that the reading done by ribosomes would be affected because it's not what they are used to seeing and this will likely result in errors being made (some errors will actually be the result of the ribosome having to slow down to translate – kind of like you would with if you were trying to makes heads or tails from somebody speaking a different language dialect.)

The Old Switcheroo

> ***Bugs:*** *It's true, Doc. I'm a rabbit, alright. Would you like to shoot me now or wait 'til you get home?*
>
> ***Daffy:*** *Shoot him now!!!! Shoot him now!!!!*
>
> ***Bugs:*** *You keep outta this! He doesn't have to shoot you now!*
>
> ***Daffy:*** *He does so have to shoot me now! (to Elmer) I demand that you shoot me now!*
>
> *[Elmer shoots him.]*
>
> ***Bugs****: Like they say, never send a duck to do a rabbit's job.*
>
> ***Daffy :*** *You're despicable.*
>
> ***Rabbit Seasoning, Warner Bros. (United States, 1952)***

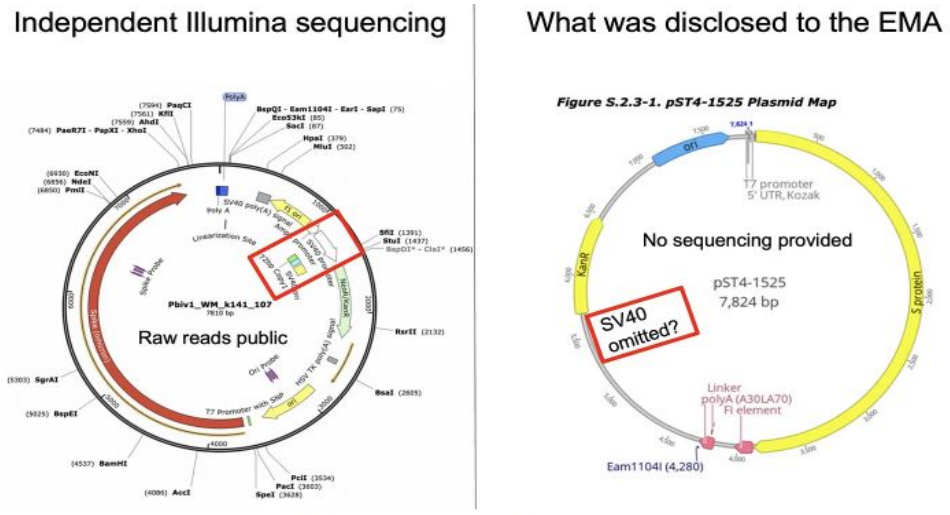
One of the things that happened under the cloak of darkness is that Pfizer did a switcheroo. When Pfizer first made their mRNA vaccine and then submitted the info to the FDA and EMA, they used synthetic (linear) DNA made on a machine. But when it came time to scale-up they had to switch to manufacturing the DNA as a plasmid in bacteria because they couldn't scale-up the machine-made DNA efficiently and quickly enough. So, all the vaccine efficacy and safety data that was broadcast to the world was based on the data generated using the synthetic DNA. Of course, everyone involved knew that this switch was going to have to happen and that the machine-made DNA was the prototype and then the actual DNA was the plasmid made in bacteria. The

problem is they are not equivalent and so there needed to be a cross-over study done to bridge between the two. Here's a quote from the paper that discovered this:

> *"The protocol amendment states that "each lot of 'Process 2'-manufactured BNT162b2 would be administered to approximately 250 participants 16 to 55 years of age" with comparative immunogenicity and safety analyses conducted with 250 randomly selected 'Process 1' batch recipients. To the best of our knowledge, there is no publicly available report on this comparison of 'Process 1' versus 'Process 2' doses."*

Apparently not satisfied to have only made one major change from their regulatory submission, Pfizer apparently made another very significant switcheroo – this time it was the actual sequence of the DNA plasmid itself. In its submission to the European Medicines Association, it described a plasmid DNA that contained a T7 promoter (T7 is a bacterial phage). We have since learned (more on how later) that the actual plasmid they used had a very different sequence and contained a promoter from SV40 which is a monkey virus. SV40 virus is controversial as it was found to have contaminated one type of polio vaccine, and is still debated to this day if whether that SV40 from the polio vaccine actually resulted in millions of cancers (a topic for another day).

I have worked with both the T7 promoter sequence, as well as the SV40 promoter and I can tell you from first-hand experience that the SV40 promoter is extremely effective at generating mRNA in mammalian cell systems. It's actually considered a "super promoter" and the sequence also contains a nuclear localization sequence (more on this later too). In any case the switcheroo from T7 (bacterial) to SV40 (mammalian) is very significant and if it was in the original submission, would have more than raised a few eyebrows.



The plasmid map that was derived with independent sequencing is on the left. The plasmid map disclosed to the EMA omitted the mention of SV40 components in the vaccine.

Antibodies

Why are anteaters so healthy – they're filled with ant-i-bodies!

It's time to take a small side-trip to talk about antibodies - specifically immunoglobulin subcategories (a favorite dinner-table subject across the country). There are 4 major subclasses of IgG antibodies called IgG 1-4. IgG1 and IgG3 are the most commonly found subclass followed by IgG2 – IgG4 is a very uncommon subclass of IgG and it is very rarely found in significant quantities in an immunologic reaction. In fact because of its nature (IgG4 are bi-specific as a result of the F(ab) arm exchange that created that subcategory), IgG4 antibodies are

generally not very good at binding antigens, they tend to block effector cell response, and in general are found most commonly in situations where there's prolonged exposure to an antigen. So you can think of IgG4 essentially as a "blocking" antibody because it tends to suppress or halt inflammation. It also has a role in a lot of different diseases including having a large role in some cancers.

There are now dozens of papers published on the antibody types found after mRNA vaccination. In general, they noted that several months after the second immunization with the Pfizer mRNA vaccine, SARS-CoV-2-specific antibodies were mainly composed of normally uncommon, non-neutralizing IgG4 antibodies. The population of IgG4 subcategory increases even more after a third mRNA vaccination and/or SARS-CoV-2 variant breakthrough infections. The induction of IgG4 antibodies is an infrequent event, but more than that it could be indicative of antigen tolerance (one example of induced immune tolerance is organ transplantation). What this means is that the vaccines could be building a tolerance for Covid proteins and if this is the case, any subsequent Covid-like infection would not be considered a threat by the immune system.

It's All Relative

> *There is an old joke: a man who is disliked by nearly everyone in his town dies — gladdened by his death, the townsfolk show up for the funeral. When asked by the presiding minister if anyone had a good word to say of him there was silence for a long time. The minister again asked; "surely someone can think of something good to say about him." Finally, an old man in the back rose and said "His brother was worse."*

OK so you think this is not too, too bad – You've been injected with a vaccine that doesn't actually prevent Covid, and the more injections you get the better chance of getting Covid, but you think "I can live with that". Also, the mRNA from the vaccine that was injected a couple of years ago was in your body churning out spike and two other proteins for months, and the primary antibody type may be preventing your immune system from doing its job. Not great, but in most cases not (yet) lethal – those extra toes that are growing can be hidden with thick socks and wide shoes, and the twitching and facial tics might go away in a few years.

But it gets worse ……. (If we were at a three-ring circus, at this point we would have finished looking in both side tents and are now ready to go into the center tent and see the main event.) One of the attractive features of mRNA as a template for making vaccine antigens in vivo is that mRNA is not DNA and so it does not integrate into your genome (if it did it would be considered gene therapy). As a matter of fact, that was one of the selling points for mRNA technology: don't worry, nothing to see here – its only mRNA and mRNA does not cause permanent changes. There are two problems with this rationale.

The first is that mRNA can be turned back into DNA by something called reverse transcriptase which is a viral enzyme and is not normally found in humans, but in the past few years there have been discoveries of reverse transcriptase activity in human cells (we won't go deeper into the weeds here, but it is an evolutionary by-product and turns out to be important). Recently a publication demonstrated that Covid vaccine mRNA could be reverse transcribed in human liver cells by this endogenous reverse transcriptase found naturally in human cells and especially in liver. The paper also pointed out through a number of other references that the tissue distribution of the covid vaccine was widespread and it has been found in most tissues in the body. Based on these two pieces of data the concern is that once reverse transcribed back to DNA, it would then integrate into

the genome and become a permanent part of your DNA, that of the person next to you, and the other billion or so people on the planet who received the Covid mRNA vaccines.

The Cracker Jacks Vaccine – There's a Different Surprise in Each Vial!

That's all interesting and horrifying but as incredible as that all sounds, we haven't gotten to the part where you need to buckle-up and make sure your trays are in the upright and locked position, and there are no sharp objects or high bridges nearby. Here's where the story goes from crazy to double extra stupid really crazy.

Remember the question we asked earlier; what was actually injected into all those people when they went to get the Covid mRNA vaccine? What was it that actually got injected into their bodies? Do you know what it was? Do we know what it can do?

If you are paying attention and you are a total nerd, you might have already figured this out. Remember the earlier discussion regarding T7 vs SV40 promoter – how do we know about that switcheroo and I said more about this later? Well guess what? It's later now, so here we go.

The big problem with calling the vaccines "just mRNA" is that they're not just mRNA! The Covid vaccines that many people got, don't only contain mRNA, but they also contain the original DNA that the bacteria used to make the mRNA (remember the plasmid DNA that was constructed). Let me say that again – the mRNA vaccines also contain double stranded DNA. What's even worse is that this contaminating double stranded DNA has also been packaged into those lipid nanoparticles (LNPs) and so have actually been injected with is a mixture of mRNA, and DNA (the correct, official scientific term for this is gemish, from the Yiddish – the correct response to which is Oy Gevalt, also from the Yiddish).

The presence of contaminating DNA in the vaccine vials was discovered as the result of some excellent work done by Kevin McKernan who wasn't looking for it, but came upon the presence of the contaminating DNA by chance and has since spent a lot of effort looking into it more deeply. His conclusions to date follow:

- The Pfizer vaccine has 1 replication competent plasmid per 350 mRNA molecules and equates to billions of antibiotic resistant plasmids injected per person per shot.
- These contaminating DNA plasmids, packaged into LNPs, can transfect and transform both mammalian and bacterial cells in the microbiome in anyone who received these vaccines
- Circular plasmids like those found to contaminate the covid vaccines are used for stable transfection and continued expression of genes in mammalian cells with the strong SV40 promoter. This could lead to prolonged spike expression in patients injected with these constructs even over that from the long-lived mRNA.
- Since the contaminating DNA plasmids have genes for neomycin or kanamycin, use of these antibiotics after vaccination with these plasmids could enable the selection of neomycin and kanamycin resistant bacteria in the gut microbiome. The administration of dual antibiotic resistance, high-copy number plasmids to billions of people could become a step backwards in the fight against antibiotic resistance.

From my point of view the presence of so much DNA in these vials, and the fact that there is variability from vial to vial with regard to the amount of DNA present, all points to a very concerning lack of controls during production. It also could be indicative of a total disregard for quality in that its possible (ie likely) that Pfizer and Moderna knew about the DNA contamination and chose to both ignore it and not tell anyone else. They were

able to hide behind the cloak of darkness that the EUA gave them and the fact that there would not be any lawsuits that would necessitate discovery that would reveal any of this.

So it's not just the spike protein, or the mRNA that's a problem – its also the fact that there is packaged DNA that can be integrated into your genome in the injection as well. At this point you may be thinking, there are so many issues, I'm losing track. Let's see if I have this straight – the Covid vaccine:

- Is not able to prevent coronavirus infection
- Can make coronavirus infection more likely especially after multiple injections
- Was made using mRNA technology that was not successfully developed for anything prior
- Has the ability to be turned into DNA that can integrate into cellular genomes
- Is heavily contaminated with DNA packed into LNPs that are designed to promote gene therapy
- Was manufactured with poor quality control standards based on significant vial-to-vial differences

Intermission

Before our heads explode, lets take a break and divert to a philosophical interlude. We humans believe we are superior to nature, that we can master and control nature, and that we are just around the corner from having the secret to everything – when in reality we are still light years away from being close to that (evidently, we are still "smarting" (pardon the pun) from losing access to the Tree of Knowledge in Eden). The idea that there is one overarching theory to explain "everything", that discovering the "God Particle" (the Higgs Boson), that sequencing the human genome would unlock all the secrets of human genetics, if you build the world's largest particle accelerator and then build a larger one, if you deploy the Hubble space telescope, then the larger Webb, and then the more advanced Euclid, if you uncover all these and many more secrets of the universe, you will be "all knowing." Harry Truman used to say: "its what you learn after you know it all that counts". We may think we are close to knowing it all when in reality we are a long way from that.

We humans also believe that we can use our believed, advanced state of knowledge to protect ourselves from everything – we can legislate away and vaccinate away anything bad. Because of this we have become vaccine crazy, and plan to make vaccines for everything and anything. So if you're fastidiously following the CDC's guidelines, you would have gotten more than 50 vaccinations by the time you are in high school. But the floodgates are only now opening wider – pharma companies see gold in vaccines especially those against infectious agents that shift and drift and would require yearly update boosters. Based on a law from the 1980s, pharma companies are protected from liability when it comes to vaccines so you have a situation where you have no risk at all – vaccines are the perfect product. Up until now vaccines took a while to develop because most antigen vaccines are made in eggs and so the process is slow. mRNA vaccines are a game changer – you can crank-out dozens of different vaccines in no time, and that's what's happening now. And by playing on people's hypochondriacal tendencies, it doesn't take long to make many people believe they need all these vaccines – even those that are against things for which we already have natural immunity, or even for things that it is very unlikely we will get and especially for things for which the vaccine side effects are more onerous than the disease symptoms. "What's the harm – just get a shot and you will be protected."

So we have a situation where we are trading natural immunity for man-made immunity – we are replacing what we had from nature's purposeful design, evolution and natural selection, and are replacing it with what we can make because we know better. The problem with this logic is; (1) our research and development efforts are all

biased by money – funding, eliminating liability, reducing competition – so we are not developing what's best for human beings, but instead what's best for individual companies, and (2) no matter how hard we try or how smart we think we are, we are not able to out-do nature. In the case of foreign agents like viruses, our natural immunity is incredible and we should stop trying to modify it or change it, or improve it, and especially stop trying to subvert it.

And I went to see the doctor of philosophy
With a poster of Rasputin and a beard down to his knee
He never did marry or see a B-Grade movie
He graded my performance, he said he could see through me
I spent four years prostrate to the higher mind
Got my paper and I was free

We go to the doctor, we go to the mountains
We look to the children, we drink from the fountain
Yeah, we go to the Bible, we go through the work out
We read up on revival, we stand up for the lookout
There's more than one answer to these questions
Pointing me in a crooked line
And the less I seek my source for some definitive
The closer I am to fine

Songwriters: Emily Ann Saliers Closer to Fine lyrics © Godhap Music

Amy and Emily of the Indigo Girls got it right with these lyrics – there is always more than one answer and always another question, and the less you believe there is something definitive that will solve everything and instead believe in the power of uncertainty, the closer you will be to fine. The biochemical and molecular biological systems that allow us to live, breathe and think are exquisitely and purposefully developed and regulated, and are the product of eons of evolution. They are also developed to take into account the multi-factorial nature of biological systems. We as humans have a tendency to look at large, complex biochemical systems and pick out one thing that we want to change to make it better. We usually do this though, without considering all the consequences that change can have throughout the body and on other biochemical systems to which it may be tied (some ties we may not know about). So our tendency is to try and "correct" or improve on nature – our arrogance leads us to believe we know better.

There's a very famous line in Shakespeare's Hamlet – "There are more things in heaven and Earth Horatio, than are dreamt in your philosophy." The line is said by Hamlet in response to Horatio's not believing in the possibility of ghosts. How can anyone believe in a soul but not believe in ghosts? Ok we've officially gotten very far off topic – if we continue it won't be long before we are talking about why the aborigines in Australia believe humans have multiple souls or how it's possible that the Einstein-Podolsky-Rosen paradox holds up for clouds of atoms…….

Intellectual humility is absolutely required to be successful in science, medicine and in public health – although this may seem counterintuitive, arrogance is actually antithetical to success. In medicine many patients complain that their doctors don't listen to them or don't believe their symptoms are real. In contrast humble healthcare professionals engage in shared decision-making, consider patient perspectives, and demonstrate

empathy, ultimately leading to better patient outcomes and increased trust between providers and patients. Displaying intellectual humility enhances credibility, reliability, and trustworthiness, positioning individuals as respected sources of information

As much as we don't want to admit it, there is no such thing as a free lunch – everything we do has a consequence – usually multiple consequences. You can't make a "simple change" to an organism and expect that not to have a myriad of effects, most off-target and many we may never know happened, may never be able to tie back to the original event, or could never predict. Up until we started messing with DNA and an individual's genetic makeup, all the therapeutic approaches we've had were reversible.

This is not to say we should not continue to try and improve living conditions for humans. In fact we have done that very well over the past century – the poverty rate continues to decline, access to clean water and food has improved tremendously, and most importantly access to information and energy sources. (End of philosophical interlude).

Back To the mRNA Story

When we last left our heroes, we were talking about so many things, so let's recap:

- Although mRNA technology has been around for more than 30 years, prior to the covid vaccines it had not been able to be used safely and effectively in humans for anything,
- Covid mRNA vaccines are the first use of mRNA technology in humans for anything EVER,
- Covid bi-valent (newer) vaccines do not prevent coronavirus transmission and multiple doses make it more likely that you will get Covid,
- mRNA in the Covid vaccines is packed into lipid nanoparticles to protect it,
- Lipid nanoparticles get transported to all four corners of the body in all tissues,
- In the Covid vaccine the mRNA used is made "bullet-proof" and so it doesn't degrade quickly,
- Modifications made to the natural mRNA sequence of the spike protein can cause translational mistakes,
- There are also two other open reading frames in the mRNA used and these could also be translated into other (non-spike) proteins,
- mRNA can be reverse transcribed back to DNA in human cells,
- Vaccine manufacturers had a "free pass" for the covid vaccines and so took short cuts and didn't do controlled studies,
- There is double stranded DNA also packaged into the lipid particles and it's possible this DNA can become integrated into the host cells genome,
- Based on data from 8 vials of covid vaccine tested, there are wide differences in the amount of contaminating DNA present indicating a lack of good vial to vial quality control.

Normally the developer of any new pharmaceutical is required to demonstrate that it is both safe and efficacious. In the case of mRNA covid vaccines, it appears that neither was demonstrated and so it seems all that was required to get past the FDA was that the vial labels were applied straight. Also, since Pfizer did its switcheroo, the process actually used to manufacture the distributed vaccine including the DNA vector used to create the mRNA was never tested at all. This was a fiasco on so many levels it's hard to fathom. I was going to

say they got a “get out of jail free card” but in reality, they got a card that gave them immunity (pun intended) from ever going to jail at all, and instead were allowed to “pass Go and collect” billions of dollars.

From Hitchcock’s 1946 masterpiece, Notorious – Alex Sebastian is a Nazi in exile and Madame Sebastian is his mother:

> *Alex: Mother, Mother.*
> *Mme. Sebastian: Why are you up so early?*
> *Alex: I need your help.*
> *Mme. Sebastian: Something is wrong?*
> *Alex: A great deal - Alicia.*
> *Mme. Sebastian: I have expected it. I knew. I knew. What is it? Mr. Devlin?*
> *Alex: [a high overhead shot] No.* ***I am married to an American agent.***
> *Mme. Sebastian: Yes, it is easy to see now. I knew but I didn't see. They picked her because of her father.*
> *Alex: I must have been insane, mad. Behaved like an idiot, to believe in her with her clinging kisses.*
> *Mme. Sebastian: Stop wallowing in your foul memories.*
> *Alex: Then what do I do? There's nothing to do. I'm done, finished. They'll find out.*
> *Mme. Sebastian: They won't find out.*
> *Alex: They'll find out what I'm married to. Look what they did to Emil Hupka, Emil who did nothing. And I've betrayed them, I've bungled and there's no excuse. I'd do the same myself - kill the fool that betrayed them.*
> *Mme. Sebastian: There's no need for them to find out.*
> *Alex: Mathis is very sharp.*
> *Mme. Sebastian: Yes. He dislikes you. But his criticism of your talents wouldn't go that far to imagine that you are married to an American agent.* ***You are protected by the enormity of your stupidity - for a time.***
>
> *Notorious, RKO Radio Pictures, 1946*

This is one of my absolute favorite movie lines of all time – in his 1946 film Notorious, Hitchcock sets this up – when the Nazi in exile who married an American spy asked his mother how he can prevent his colleagues from killing him when they find out what he did, his mother said you have nothing to worry about – “you are protected by the enormity of your stupidity”. Wow, what a line! She’s telling her son what he did was so colossally stupid, nobody would ever find out he did it since they would never believe anyone could possibly do something that stupid! What we are learning now about the covid vaccines is just the tip of the iceberg and there’s much more below the waterline that will still be coming out. My hope is that the enormity of the collective stupidity of the regulators, pharma companies and scientific community does not cause everyone to assume something could not possibly be so colossally F-ed-up….. because we lived through it and know that it actually happened (in the words of Chico Marx: “who are you going to believe, me or your own lying eyes”!)

What was done in forcing through the mRNA vaccines so quickly, and without consideration for any of the normal safety and efficacy parameters required for drug development, will either undo everything that was developed over time to prevent haphazard pharma development and will also set a very dangerous precedent, or it will cause such a backlash against regulators, pharmaceutical companies and the scientific community in general, that it will set pharmaceutical development back decades. There is no good scenario about what the future will look like.

Our Incredible Immune System

SULU: Captain, shields just snapped on. Something heading in at multiwarp speeds.
KIRK: Evasive maneuvers, Mister Sulu.
SPOCK: An extremely powerful bolt of energy, Captain.
KIRK: Full power to the shields, Mister Scott.
SCOTT: Giving them all we got.
KIRK: All hands, Red Alert. Phaser banks stand by. Photon torpedoes to Condition Red, Condition Red.
(The viewscreen fills with a ball of bright light.)
SULU: It's going to hit.
(Everyone gets thrown around a lot, and the lights go out for a short while.)
SCOTT: Shields still holding, sir.
KIRK: Good.
SPOCK: Temporarily, Captain. Our shields absorbed energy equivalent to ninety of our photon torpedoes.
KIRK: Ninety?
SPOCK: I may add, the energy used repulsing this first attack reduced our shielding power twenty percent.
UHURA: First attack, sir?
KIRK: I think we can expect others, Lieutenant.
SPOCK: We can resist three more such attacks. The fourth will shatter our shields completely.

CBS/Paramount Star Trek, The Changeling, Season 2 -Episode 3, 1967

If you haven't figured it out yet our immune systems are complicated, multi-faceted, multi-factorial, exquisitely balanced systems with redundancies and an amazing ability to change and adapt. The system has to recognize and discriminate to identify real threats and avoid autoimmune responses, it has to adapt its response to any newly identified threat and then it has to have a memory component to be able to respond again to the same threat without going through the whole process each time. The immune system as we currently understand it is incredible and after all the time and money spent on researching it, we still don't fully understand our immune systems (I don't think we're even as close as some think) and we may never fully and completely comprehend how it all works.

Our immune system is our shield and is analogous to the shields in Star Trek – it turns on when needed and is able to repel multiple different attacks but it requires a lot of energy and support. Its incredible to think about all the potential infections that could happen to us if not for our immune system. In fact, most people with healthy, strong immune systems are unlikely to die from any infectious agents and its really only those who are immunocompromised or have co-morbidities that put additional pressure on their immune systems, that are at risk. The Star Trek ship Enterprise would not have lasted one episode without its shields and we would not last a day without our immune system. We should be focused on what we can do to help support our immune system, to fuel our shields and not on changing or modifying it until we fully understand it.

In general, there are two classes of immune cells; B cells that cause the initial antibody response and T cells which work to kill infected cells. Both B cells and T cells also have a memory function so that they will recognize a foreign substance more quickly if they run into it again (usually this will result in the immune system preventing any of these subsequent infections from causing any symptoms.) A few months ago, a paper was

published that challenged our understanding of how antibodies are activated. Previously, it was believed that the antigens from, for example, viruses or vaccines would have to cross-bind a B-cell's receptors on the cell surface. That's what it says in all the textbooks. But researchers in Denmark and Germany have shown that even antigens that can only bind one receptor at a time are able to activate the B cells. This represents a very significant difference in our understanding of a very fundamental part of the immune process. If these researchers are correct, then we have been basing our previous decisions on immunotherapy, on a partly incorrect or incomplete fundamental assumption.

This is not unique – every day there are scientific papers published that share data challenging our understanding of every facet of this incredibly complex system. If we only have a partial, rudimentary or even incorrect understanding of how the immune system works, and we make decisions based on that limited understanding regarding modifications that we believe will improve the immune response, we risk making a wrong decision that could be both individually and communally catastrophic. Also, in our arrogance if we think our understanding is correct and complete, and we make decisions along the lines of those we made for the Covid mRNA vaccines, decisions that could result in mistakes, mistakes that might not be confined to a few people but rather mistakes that could be spread out and affect both large numbers of people as well as threaten to impact their offspring (or their ability to have offspring), either of which could be existential.

This is not to say we shouldn't be working to come up with new and improved therapeutic approaches to treat diseases involving the immune system. In fact, I believe the opposite - we should be doing this – but with humility and prudence. That means placebo controlled randomized double-blinded clinical trials with actual (not just surrogate) endpoints --- **always and everywhere, no matter what, no exceptions**. There is also the issue of the bias introduced by the pharmaceutical-regulatory complex. Right now pharmaceutical companies are required by their investors to deliver "blockbuster" new drugs regularly. Regulatory agencies are often staffed by people who want to get jobs at pharmaceutical companies after they retire from their government job. Together this makes for a very biased system and encourages cutting corners to get new drugs approved more quickly and sometimes without the proper rigor. In the end there will be backlash because people's distrust for new drugs and therapies will increase and that would be helpful to either side. What is needed is a prohibition on high level regulatory people joining pharma companies for a period of time (lets say 5 years) after leaving FDA, NIH, CDC or any other government employment.

There are a lot of things we can do to be healthier but making changes to our immune systems on a widespread basis, without understanding the long-term implications and especially the breadth of those would not only shorten our lives but could also be an existential threat to humanity - it could be catastrophic. So, because we were concerned about a pandemic and its effects on humanity, we very quickly at multi-warp speed (pun intended) and without the proper clinical trials, developed a vaccine that didn't work and that could have long term negative effects on our immune system. Instead of letting our immune system work to recognize and build protection against Covid, we thwarted it because we are smarter than our natural immune response (ie "we are the government and we're here to help").

Shields at full strength Mr Scott.

I'm giving her all we've got, Captain, she can't take anymore…..

OK So Everything Sucks – Now What?

So what do we do now – what are the next steps. Well since you asked, here are my recommendations:

- A lot of bad came out of covid but we need to leverage the opportunities it created. One of these is that covid exposed a lot of things going on "behind the scenes" that people didn't realize was happening. One of them is the fact that vaccines are treated differently than other FDA drugs – not only do they get a free ride with regard to potential liability, but they also have not been required to do real placebo-controlled trials. So going forward we need to:
    - Rescind the National Child Vaccine Injury Act of 1986 – supposed to make vaccines safer but did the opposite
    - Mandate that all vaccines demonstrate safety and efficacy through placebo-controlled trials with actual placebo – no more non-inferiority trials.
- Re-do the VAERS system completely – take it out of the control of the HHS
- NO MORE FAUCI's – we learned that Fauci was a mob boss with total control of NIH research budget and he used this to extort scientists to do what he wanted (and to not do what he didn't want done) – legal extortion. We need to establish both oversight by an inspector general and an independent review board to review all grant awards.
- Re-define CDC's mandate and scope. Make it clear that CDC is not authorized to create mandates or laws but only recommendations on which Congress can act. CDC scope should be limited to infectious and other communicable disease control (and not for example workplace health).
- Commission an actual study to review all the data to date on incidence of childhood diseases to establish a correlation (either positive or negative) with vaccine distribution. We have decades of data now and we need to determine if vaccines have had an effect on prevention of communicable diseases (even though most people believe a positive correlation exists, it does not – in fact no studies have demonstrated whether vaccines have been useful)
- Anything that is given to everybody (like vaccines) should be required to go through extensive testing – in fact it should be more rigorous than those drugs or vaccines that have limited distribution due to label claim limitations.
- Define all mRNA drug products as Nucleic Acid therapeutics and treat them the same way as a gene therapy product. Require any mRNA-based drug/vaccine to have no detectable double stranded DNA left after manufacturing.

The Bottom Line

Believe it or not after all the stuff you just read, and all the technical details and scientific jargon (like gemesh) you just learned, there are only two things you need to remember from all this:

1. **mRNA technology was never, ever, ever used before in any human drug product, ever. This was the first time it was used, the technology was not fully developed yet, and it was not controlled properly. mRNA vaccines are 180 degrees different from traditional vaccines. We have no idea what the long-term effects will be – we have nothing to which to compare it.**

2. **We (the human race) forced hundreds of millions of people to get injected with something about which we had very little data using a technology that had never been used before, made in a rush, cutting corners and with very low-quality standards. Cavalierly doing something like this is reckless and could end up being an existential threat, and should never, ever, ever happen again.**

So there you have it - that's the mRNA story – a still to be finished sci-fi thriller – and they all lived happily until the next pandemic. By the way I believe mRNA is just a dress rehearsal for the real thing – gene therapy.

Although it sounds good – simply replace a mutant gene with one that has the correct sequence - gene therapy, including gene modification (ie CRISPR) is really scary stuff because its permanent – you can't easily undo it. Any side effects it causes will be side effects you will have to live with (if you're lucky) for the rest of your life, but in the immortal words of the Joker, "I believe what doesn't kill you only makes you stranger". Gene therapy has been around for a long time, it was already tried in humans and although the initial trials done 15 years ago failed, there have been some limited early-stage successes recently. I am actually a proponent of gene therapy especially in cases in which it used to correct an actual gene mutation. What I'm against is the haphazard development, testing and deployment of anything that powerful, based on arrogance and ignorance, along the lines of what happened with the Covid vaccines, and its wide-spread dissemination. Gene therapy needs to only be used for good instead of evil (see Wives, Stepford). With the very heavy investments made by pharma companies and venture investors, it could be just waiting for the right crisis to be deployed on a wide-spread basis …… sound familiar? – Play it again Sam, we've seen this movie before.

What's the worst thing that could happen - I mean, it's only life after all, right?

Question Everything - Stay Skeptical my Friends……