# A Physician's Open Letter to Fellow-Catholics on COVID-19 Vaccines and Treatments

Gwyneth Spaeder

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## Part I: A review the history and data on mRNA vaccines

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*"There is no pathophysiologic or historical reason to believe that a new, previously unseen side effect from either of the mRNA COVID-19 vaccines will suddenly occur months to years after it has been given" -- Dr. Gwyneth Spaeder*

The public debate over COVID vaccines, their efficacy and their morality has been seriously distorted by disinformation, often passed along the internet and social media by well-intended individuals.

I should like to offer answers to some Frequently Asked Questions and present constructive criticism on the incomplete or incorrect assertions and conclusions I frequently hear. I write as a physician who has spent the last 20 months working with COVID patients and their families. I write specifically as a paediatrician who has watched children lose parents and grandparents, months of education, and sometimes their own health to this virus.

I write also as a mother who has tried to balance my vocational call as wife and mother with my duty to my patients; to reconcile what I know to be scientifically valid with my desire to return my family life to normal, and to continue to work with my husband to raise our children in the Catholic faith, using the challenges of this historical moment to emphasise that Catholicism honours both faith and reason.

Did the 2020 Note from the Congregation for the Doctrine of the Faith on the morality of using some anti-COVID-19 vaccines rely on incomplete data?

To date, the most authoritative Catholic statement on COVID vaccines is the 2020 Note from the Congregation for the Doctrine of the Faith concerning the use of some COVID-19 vaccines. It is sometimes claimed that, at the time the Note was written, there was incomplete data on both the nature of the design and of the components used in the mRNA vaccines produced by Pfizer and Moderna. It is understandable that many people had questions regarding the use of mRNA technology when these vaccines were first granted Emergency Use Authorisation.

It was not a lack of data, however, but a lack of familiarity with the involved science among the general public, that created these concerns. A brief biology review is in order here, as much of the initial concern I have heard from parents of patients, as well as from friends, was due to the mistaken fear that injecting mRNA into our muscles could somehow change our own unique genome. This simply cannot happen.

Messenger RNA, or mRNA, is a molecule that tells our body how to make proteins. Once the protein is made, the mRNA is degraded and passes out of the body with other waste products. This process only occurs in one direction. There is never a chance of modification of the vaccine recipient's own genome as the process of transcription and translation by which proteins are made only moves forward: DNA to RNA to protein. It cannot work in reverse. (The exception to this involves reverse transcriptase enzymes, such as contained in HIV, a retro-virus, but are decidedly not present in the mRNA vaccines.)

This process is entirely different from what is known as gene therapy, in which there is a targeted insertion of DNA directly into the nuclear genome in order to permanently change the genetic code for a therapeutic purpose. The mRNA vaccines are working "downstream" of DNA as I described above and therefore cannot alter the vaccine recipient's genome.

As for the components of the Pfizer and Moderna vaccines, they are known, published and freely available for review by anyone who wishes to investigate. In fact, these are some of the "cleanest" vaccines ever made, lacking many of the preservatives that have (incorrectly) concerned many people about other, older vaccines.

**Are these mRNA vaccines safe and effective?**

One of the first questions I often hear concerning these vaccines involves the speed at which they were developed. I understand why the timeline could be construed as suspect, given our common experience of rushed-function-leading-to-poor-outcome. I can confidently assure those who query me on this point that three important facts should allay their concerns.

First, most medical research (especially pharmaceutical research) proceeds at a glacial pace because of paperwork and competition. The filling out, filing, submitting, reviewing, correcting, re-submitting and waiting-for-a-response-before-moving-onto-the-next-step that is a reality for every researcher was expedited in this instance due to the urgency of the situation.

Moreover, a specific research team is (almost always) competing for time and attention (physical resources, funding and slots on review board schedules) with other teams investigating other medical issues. These factors in the typical development that lead to delay of approval were all cleared away when the decision was made to prioritise COVID-19 therapies and vaccines. This meant that the mRNA vaccines could be safely brought to the public in a shorter-than-usual time frame. The actual science was not short-cut: The studies on safety and efficacy for both Pfizer and Moderna were enormous studies with plenty of power to support their conclusions.

Second, mRNA technology is not new. This technology has been studied and pursued as a possible therapeutic agent since the 1970s and several pharmaceutical companies have been working with it in cancer therapeutics since the late 1990s. What previously

limited its successful application in vaccine medicine involves technicalities about the rapidity with which it degrades in the body. That characteristic should be reassuring to anyone concerned about long-term safety. It was only when discoveries were made in the 1990s about the use of certain lipid (fat) particles as delivery and stabilising agents that mRNA vaccines became feasible.

The Pfizer and Moderna COVID-19 vaccines use mRNA to "teach" our bodies how to make COVID-19 spike proteins. These are proteins that stick up from the surface of the viruses and help it to enter and infect cells. They're also the part that our immune system reacts to. The mRNA vaccine contains the instructions for this very specific type of protein, and since it is only a small part of the virus, there is no risk of actual infection.

The mRNA is degraded once it has delivered its instructions — it can't replicate on its own because we don't have the specific DNA to make more of it. The protein can't replicate on its own once the mRNA is gone. And the protein will be gone, too, once the immune system learns to recognise it and eliminate it.

Third, in the history of vaccine science, no side effects have been detected after the first eight weeks of use in the general population. When the polio vaccine was first developed in the 1950s, there were rare cases of paralysis that occurred within four weeks of someone having received the oral live polio vaccine (which is no longer used in the United States).

The yellow fever vaccine has a few very rare side effects (brain stem swelling in young children, organ failure in older individuals) that can occur within one week of vaccination. The influenza vaccine is rarely associated with Guillain-Barre syndrome, which can develop within eight weeks of vaccination. That we are now approaching a year of global distribution of these COVID vaccines to billions of individuals with no newly emerging long-term negative effects should be reassuring. There has been a very small risk of myocarditis, or inflammation of the heart muscle, following

administration of the both the Moderna and Pfizer COVID vaccines. However, that risk was identified within weeks of widespread distribution, occurs within days of receiving the vaccine, is mild and self-limited, and remains lower than the risk of myocarditis from an actual COVID-19 infection.

There is no pathophysiologic or historical reason to believe that a new, previously unseen side effect from either of the mRNA COVID-19 vaccines will suddenly occur months to years after it has been given.

The COVID19 pandemic has created a historical experience that many of us have never encountered before, namely living through an evolving medical crisis in real-time. Recommendations that change over time and newly applied scientific discoveries are understandably challenging for many to accept. Fortunately, a large part of physician training involves learning how to critically assess and interpret data so as to be able to best help the individual patient. Trusting your chosen physician has never been so important.

## Part II: A look at COVID-19 vaccine immunity, safety and morality

*"There are many reasons to be concerned about the way public officials and governmental leaders around the globe have addressed the COVID-19 pandemic. Morally serious people should continue to be alert to challenges to authentic human freedom. Catholics have no reason, however, to fear the safety, efficacy, or morality of the mRNA COVID-19 vaccines." Dr. Gwyneth Spaeder M.D.*

As a physician who has treated paediatric patients over the course of the coronavirus pandemic, I've fielded numerous concerns about COVID-19 that are based on misinformation. In Part One of this Frequently Asked Questions, I reviewed the science behind mRNA technology and presented research on their efficacy. In Part Two, I seek to shed light on the medical expectations related to immunity and examine moral aspects of COVID-19 vaccination.

### Do Moderna and Pfizer COVID-19 vaccines actually provide immunity?

It is frequently said, or implied, that the Moderna and Pfizer COVID-19 vaccines do not provide immunity or decrease the risk of spread of disease. Yet this is precisely what they do. The outcomes of both the initial Moderna and Pfizer trials (both randomised controlled trials involving 30,000-40,000 persons) showed remarkable efficacy in preventing COVID-19 disease: 95% for Pfizer and 94.1% for Moderna in the Phase III trial publications.

We currently know that the Pfizer and Moderna vaccines have slightly less efficacy against the Delta variant, but even as that variant surged across the world, hospitalisations and deaths were vastly higher amongst unvaccinated individuals. How long the vaccine-induced antibody response and subsequent immunological protection lasts, or will provide protection against future variants is a matter of ongoing study, but the same is true of the immunological response to natural COVID-19 infection.

The use of the term “immunity” is part of what is at issue here. The CDC/WHO definition of a vaccine changed in early September 2021 from a pharmaceutical that provides “immunity” to one that provides “protection.”

Why the change? Because it was becoming apparent that the colloquial use of the term “immunity” was very different from the scientific use. So while the medical field uses “immunity” to refer to the immune system being activated to fight an infection to various degrees, the general public was interpreting “immunity” to mean zero chance of infection (what medicine calls sterilising immunity, something that very few vaccines actually achieve).

The Pfizer COVID-19 vaccine does not provide sterilising immunity, but it certainly activates the immune system to fight the virus upon exposure, thereby providing “protection.” The word change, then, while providing bait for those looking to discredit the vaccine and its supporters, indicated nothing about the data supporting its efficacy.

The circulating claim that vaccinated individuals “can become infected and infect others more easily than the unvaccinated” has no scientific basis whatsoever. Unvaccinated individuals are 6.1 times more likely to contract COVID-19 than their vaccinated counterparts. And while vaccinated individuals can still spread the COVID-19 virus to others, there is good data to show that the levels of nasal virus are lower and drop faster in vaccinated persons compared to unvaccinated. (When looking at data regarding this question, it is important to remember that there is a difference between the Alpha strain and Delta strain of COVID-19, such that the benefits of the vaccine for Delta in regards to transmission are less robust than they were for Alpha, but still far outstrip no vaccine protection at all.) To suggest that having received the vaccine increases the risk of transmission to others, then, is illogical: If a vaccinated individual is less likely to contract COVID-19 and has a smaller nasal viral load for a shorter period of time, it is not

mathematically or biologically possible for the vaccinated to be spreading the virus faster.

**What about the calculus over the risks and benefits of the vaccines?**

Any medical intervention must be analysed in terms of its potential risks and benefits before being approved for use; this is especially true for vaccines, as they are (typically) given to healthy individuals to prevent possible future harm, rather than to persons already ill and requiring treatment of their disease. The need for convincing data on vaccine safety and efficacy is precisely why pharmacologic products proceed through a very defined set of studies prior to receiving approval for widespread use: Phase I trials simply look at the safety profile of the new drug. If Phase I results are acceptable, Phase II trials begin to assess efficacy in a targeted population. It is only after those two phases are completed successfully that a Phase III trial is initiated — these are the large-scale trials that try to confirm both safety and efficacy across the intended population that will be receiving the new medicine. As mentioned earlier, there are varying degrees of statistical strength to the data coming from Phase III trials based on the study design. Large, randomised, placebo-controlled trials, such as the trials conducted for the mRNA vaccines, carry the most statistical weight.

The criticism one hears that the Congregation for the Doctrine of the Faith did not consider the risk/benefit ratio of these vaccines before issuing its 2020 Note is unfounded. The Note focuses on the question of receiving vaccines that have any connection to foetal cell lines (which I address more fully in the next section), and correctly points out that an assessment of the data supporting safety and efficacy is beyond CDF's purview.

It may be helpful to point out some social media landmines to be avoided here. Infovax is an Italian anti-vaccine propaganda site; there are countless more such sites spreading falsehoods in multiple languages.

Assertions one reads, such as "more people are dying from the COVID vaccine than from COVID itself," should be supported by more than a reference to a Twitter post; in fact, any statistical claim should be supported by reproducible and validated data systems. But be careful to understand the data systems themselves!

Particularly frustrating to me are repeated claims from some Catholics that are based on a distorted VAERS data. One example being that "in nine months these vaccines have caused more deaths than in 30 years of other vaccines." VAERS (Vaccine Adverse Event Reporting System) accepts data input from anyone. If anyone believes they are experiencing a negative vaccine reaction, they can input that into VAERS (got flu vaccine on Monday and left big toe hurts on Tuesday). The CDC, the FDA, or other regulatory agencies can then look for a "signal" — are a lot of people suddenly reporting that their left big toe hurts? — and investigate if warranted. Most likely it will turn out that a few people happened to stub their toes the day after receiving their flu shots (i.e., correlation does not equal causation).

The salient fact about VAERS is that, for non-professionals, there is no way to sort rubbish from valid concerns before an investigation is done. And since anyone can contribute, it is not hard to imagine that in an age of vaccine controversy like ours, many will input nonsense (intentionally or not) that creates false signals. People are mortal beings and tragedies happen. If someone is convinced the COVID vaccine is dangerous and hears that her second cousin on her sister-in-law's side died two weeks after receiving her COVID vaccine (although it was in a car collision), that person can go list that second cousin as "deceased following COVID vaccination." When you are vaccinating millions of individuals in a short period of time, there are going to be deaths that coincidentally occur in close temporal proximity to those individuals receiving their COVID-19 vaccine. The vaccine is no more the cause of those deaths than drinking coffee before leaving for work causes the

inevitable morning traffic jam; one just temporally precedes the other.

**What about foetal cell lines and moral cooperation?**

The CDF's 2020 Note addressed the morality of receiving a COVID vaccine that had any connection to foetal cell lines that may have been obtained from an abortion. The cell line at issue in these vaccines is HEK293, which came from either an abortion or a miscarriage that occurred in 1973. The generational descendants of this original cell line are used ubiquitously in pharmaceutical research, touching everything from Tylenol and Sudafed to antibiotics and chemotherapy drugs.

The sanctity of human life from conception to natural death is an absolute norm in Catholic moral teaching, and so all Catholics must take reasonable steps to avoid cooperation with the evil of abortion and should encourage alternate means of drug testing and development. That being said, the question of the morality of receiving either the Pfizer or Moderna COVID-19 vaccines within the context of a devastating pandemic has been consistently described, by orthodox theologians of excellent repute, as an example of passive material cooperation and as such, is a morally licit decision.

The claim heard recently, that there is a Pfizer whistleblower who has released "shocking" emails showing that the Pfizer COVID vaccine actually contains foetal cells, is concerning, then, because if true, it could potentially change the moral calculus of receiving these vaccines. However, the whistleblower never actually makes that claim, nor is the claim true.

What she says is that she found internal emails from Pfizer employees discussing the fact that some individuals would have ethical concerns about a vaccine that had even a remote connection to foetal cell lines. The emails confirm what has been known for over a year: The Pfizer COVID-19 vaccine does not contain foetal cells. The HEK293 cell line was used in laboratory

testing to determine if the proposed mRNA could in fact induce antibody production against the spike protein. The ongoing manufacturing or production of the Pfizer COVID-19 vaccine that is currently in distribution does not require or use foetal cell lines.

**Do the vaccines pose dangers to pregnant women?**

Pregnant women and children were not included in the original Phase III trials of either the Moderna or Pfizer COVID-19 vaccines. This was to be expected. Medical research involving these two populations always lags behind other populations, because it is inherently riskier to test a new product on a pregnant woman or young child than on a healthy (non-pregnant) adult. In fact, many of the medications routinely used in pregnant women and children have never been specifically studied in those populations — this kind of use is called "off-label" usage.

Examples of medications that are used this way in children include numerous antibiotics, pain medications and anti-seizure drugs. Similar lists can be created for medications that women may use during pregnancy. However, as it became clearer that infection with COVID-19 during pregnancy increased the risk of poor outcomes both for the mother and her child, there was increased interest in giving COVID vaccines to pregnant women even if they had not been specifically studied in that population.

Initial reassurance about the safety of receiving the vaccine while pregnant came from the fact that, while not part of the study design, 57 women discovered they were pregnant during the course of the Pfizer, Moderna and J+J phase III trials combined. (Pregnant women with COVID-19 infection have a higher rate of ICU admission and mechanical ventilation than non-pregnant women with COVID-19. Pregnant women with COVID-19 are also more likely to die or have their newborns admitted to the Neonatal ICU than pregnant women without COVID-19.) There was no difference in miscarriage rates or pregnancy course between women in the control group versus women who received the vaccine. This

unintended small study has now been replicated in a larger observational trial and there was again no difference in risk of miscarriage between those who received the vaccine while pregnant and those who did not. Over the past 9-10 months since the COVID-19 mRNA vaccines became available, hundreds of thousands of pregnant women have received the vaccines and safety data monitoring systems have not detected any increased risk to these women or their unborn children.

There are certainly women who have received the COVID vaccine and later suffered a miscarriage. That is undeniably tragic and the loss to those families should not be minimised, but the relevant question in the vaccine discussion is whether miscarriage is occurring at a higher rate in vaccinated women than unvaccinated women. Miscarriage is very, very common. If millions of women are immunised, there are going to be women who miscarry after vaccination (again, correlation does not equal causation). Without referencing background rates of miscarriage it is simply not possible to draw any meaningful conclusions.

**Are there secret components in the vaccines that are being withheld from the public for commercial reasons?**

The vaccine ingredients are not trade secrets. They are published and readily available to anyone who wants to know them.

Compared to most other vaccines, there are relatively few components to these mRNA vaccines. And while some of the components may sound concerning (4-hyroxybutyl or mono-basic potassium phosphate), it is important to remember that life is built from chemicals. Many items we consume daily sound far different if described by their chemical names: “The boy drank dihydrogen oxide because he had eaten too much sodium chloride” versus “The boy drank water because he had eaten too much salt.”

I have heard it said, sometimes sarcastically and sometimes in all seriousness, that there are components in these vaccines that will

allow for "tracking" of individuals who receive them. One such theory involved a component called graphene.

Graphene oxide is an artificially manufactured form of carbon being looked at for potential antibacterial and antiviral properties, among other uses. While there are early studies looking at its potential utility in vaccine science (none of these studies have reached human subject trials), it is not an ingredient in any of the available COVID-19 vaccines. Claims to the contrary have been thoroughly debunked, and the fact that this rumour continues to circulate is evidence of how easy it is to spread scientific-sounding misinformation online.

**What about alternative prophylactic treatments and alternative effective therapies?**

I often hear that we do not need these vaccines because there are effective treatments that cure patients. While we all wish this to be the case, it is simply not true. There are treatment protocols developed over the past 20 months that improve outcomes, but they are not those typically cited online and in social media.

There is considerable anecdotal evidence suggesting benefits from Hydroxychloroquine and Ivermectin, for example, but no large scale, rigorous scientific studies to support their use. The kind of studies one considers in order to draw conclusions matters. There are ranked standards for evidence; the gold-standard is the randomised, controlled trial. The "plasma treatment" advocated for by Dr. Giuseppe De Donno did look promising for a while, and an article in the New England Journal of Medicine in February of this year suggested it was worth looking into, but within a few months a meta-analysis (which combines data from several different large studies) published by Cochrane concluded there was no benefit in moderate to severe disease and uncertain benefit in illness that was mild or without symptoms.

Hydroxychloroquine and Ivermectin are not being "systematically boycotted" by the WHO or the CDC, as some charge. Both

organisations have strongly recommended against the use of the medications in patients with acute COVID-19 infection because there is no evidence that they work to decrease mortality or hospitalisation length. Hydroxychloroquine, for example, was examined in the RECOVERY trial, a randomised control trial; the results of that study not only showed no decrease in mortality, but an increase in the length of hospital stay, intubation/ventilation, and death in patients who received the drug. That particular trial involved more seriously ill, hospitalised patients, but another trial looked at the use of Hydroxychloroquine in individuals who were COVID-19 positive but either asymptomatic or well enough to stay at home. The results showed no benefit in virology clearance or time to clinical improvement.

As emotionally persuasive as anecdotal evidence can be, national and global health organisations cannot make recommendations on medical therapies based on personal stories of positive outcomes; the scientific community depends not on individual cases of apparent recovery after the use of Hydroxychloroquine but on the results of randomised controlled studies involving close to 5,000 patients. It is for this reason that the FDA revoked its emergency-use authorisation for Hydroxychloroquine as a treatment for acute COVID-19 infection in June of 2020.

The Ivermectin results are similarly unconvincing. Ivermectin is a highly effective medicine in certain types of parasitic infections. But numerous individual studies as well as several meta-analyses have shown no consistent benefit to the use of this drug in treating or preventing infection with COVID-19. Perhaps most convincingly, a large meta-analysis published in July 2021 was retracted by the authors a month later after claims of significant fraudulent data undermined the conclusions of the original paper. While some medical providers continue to express frustration that their hospital systems are restricting the use of Ivermectin for COVID-19 patients outside of ongoing clinical trials, this does not mean that governmental agencies are conspiring to prevent sick people from

receiving necessary medicine. It simply means that the available evidence does not support the use of this drug for the treatment of this particular illness at this time.

## A Concluding Thought

Catholics around the world are looking to voices of authority for guidance on questions of morality and the COVID-19 pandemic. The Catholic Church has a long tradition of leadership in medical science. From Gregor Mendel to St. Gianna Beretta Molla, Catholic scientists and physicians have demonstrated that effective and faithful health care must embrace a rigorous scientific method and not fear where well-designed and executed research will lead. Those who speak about the COVID-19 pandemic and the mRNA vaccines must follow this example. Ours is a faith that should never shy away from scientific discovery, as all truths about our bodies and our health can only point us closer to the God who created us.

There are many reasons to be concerned about the way public officials and governmental leaders around the globe have addressed the COVID-19 pandemic. Morally serious people should continue to be alert to challenges to authentic human freedom. Catholics have no reason, however, to fear the safety, efficacy, or morality of the mRNA COVID-19 vaccines. These vaccines should be viewed as an example of how dedicated medical professionals can use their God-given talents to help bring an end to the immense suffering caused by this virus.

*Gwyneth Spaeder Dr. Gwyneth Spaeder is a Paediatrician in Raleigh, NC. She attended the University of Dallas. She received her medical degree from The Johns Hopkins School of Medicine where she also completed her Paediatric Residency.*