To Drs. Anthony F.,
Francis Collins,
Emily Erbelding
Gary Gibbons,
Amy Wernimont and
All other NIH, FDA, CDC directors and
Various science journalists

Date: February 3, 2021

RE: Potential fatal flaw in COVID vaccine “neutralizing antibody” paradigm (Whistleblower concerns) Version 1.0 (short summary).

Dear Dr. Fauci, Dr. Erbelding, and Dr. Collins,

Dr. Erbelding, thank you for your email response to my email of September, 2020 (I have included references from your October, 2020 email to me as Appendix B). I am not an infectious disease expert but I do think you missed the main point of my initial email. My main question was how do COVID “neutralizing antibodies” from the blood traverse the “blood lung barrier”? I cannot emphasize enough the importance of the questions I raise because if I am correct, the beneficial effect of the vaccines will be much shorter than currently imagined.

As I understand it, the current paradigm for how the Influenza and COVID vaccines work is that neutralizing antibodies generated in the blood then traverse the blood lung barrier and once in the alveolar epithelial area, the antibodies “neutralize” potential viral particles before the alveolar epithelial cells can be infected.

I raised the question because I found no active transport system for antibodies crossing this blood lung barrier from the blood side into the alveolar side. I raised the question because the blood brain barrier size limit for molecules is typically no greater than 500 Daltons and so I questioned how IgG antibodies that are 150,000 Daltons in size can cross the blood lung barrier. If in fact this question was previously overlooked and never properly investigated, the hypothesis for how all respiratory viral vaccines work is suspect.

Analogies have weaknesses but also draw the mind to relevant points. Let's imagine that we are inspectors for life-vests and we realize they only work for 10 minutes; if the defective life vests are released for public use, aren't we liable for potential future passenger deaths if cruise ships sink? If the life-vests are released without knowledge that it is potentially defective, then there is no negligence; but when the inspectors are informed of a potentially fatal defect in the life-vests and yet no action is taken and no one is warned, is there negligence now?

If during my response, I state a point as a fact, it is purely for explanatory reasons and so please fact check all my points. I am not an infectious disease expert so please investigate any facts I present. I do not want to be sued by the very large biotech companies for these "whistleblower concerns" that I urgently raise.

Here is the scenario. If the COVID vaccines are only effective for a few weeks from the point of the last vaccine shot, are we potentially risking people's lives who believe they have protection for a much longer time frame?

If sufficient COVID-19 "neutralizing antibodies" truly cannot cross the blood lung barrier, then the current paradigm for how respiratory viral vaccines work is potentially fatally flawed and there is no working hypothesis. A hypothesis or theory is useful because it helps predict what will happen next. A hypothesis is testable. The current "replication crisis" in science is in play for this issue. What if the results of the vaccine clinical trials are repeatable in the short term, but because of a

potentially incorrect paradigm, the results will only show up temporarily? The current good COVID vaccine clinical study results are even more misleading because the results can be replicated. But, my alternate hypothesis for the good results predicts that the good results will be short term. Both hypotheses are testable. The test to determine which hypothesis is correct has not been performed. I will also forward this email to all the authors I can find who are addressing the current “replication crisis” in science. If my concerns are correct, this will be the most classic case of a “false positive” in the history of medicine. Once my concerns are heard, it will be virtually impossible to argue, as a scientist, that the additional test I am requesting should not be performed. I am not saying I am correct. I am stating that the next course of action as a scientist is not debatable; that next step is the additional clinical trial to determine which hypothesis is correct.

Without a correct paradigm, wrong predictions can be made about how long the vaccines are effective for. Since the current hypothesis relies on antibodies traversing the blood lung barrier and since this may not occur, I propose an alternate hypothesis for why the COVID vaccine clinical trials currently demonstrate good short-term results.

Activation of the innate immune system often results in production of cytokines including various interferons. It is well known that RNA, which is typically intracellular, can activate the innate immune system when RNA is found outside cells and result in formation of interferons. COVID vaccines have included mRNA injection in two studies, the Pfizer clinical trial and the Moderna clinical trial. RNA injection also results in formation of the COVID antigen and foreign antigen is also well known to activate the innate immune system which also can result in the formation of interferons. The fact that mRNA injection into the human body causes activation of the innate immune system and production of interferons and other cytokines is well-known. Patients also have symptoms typical of cytokines such as muscle aches and fever/chills. I have included 8 references.

So, the alternate hypothesis for why the COVID mRNA vaccine clinical trials had good results is that each injection of foreign material activates the innate immune system with subsequent production of interferons within the human body and that interferons interfere with virus propagation in the human body, including the COVID 19 virus. I can provide hundreds to thousands of references showing how interferons interfere with virus propagation.

Other facts also support the alternate hypothesis. Approximately 20 million Americans have tested positive for COVID-19 in 2020. At least 18 million Americans recovered within a week or so and the development of COVID-19 IgG antibodies take at least 2 weeks from good exposure, so COVID-19 “neutralizing antibodies” could not have played a significant role in the recovery of 18 million Americans recovering from COVID-19. The “neutralizing antibody” paradigm cannot be invoked for how the majority of Americans who were infected with COVID recovered before the formation of any IgG antibodies.

The lung is a balloon mostly filled with air and the balloon membrane can effectively prevent even most water molecules from crossing from the blood into the lung. A water molecule weight is 18 Daltons. An antibody molecule weight is 150,000 Daltons. This is the blood lung barrier. If the blood lung barrier can slow down water from crossing from the blood into the alveolar space, why would it let an antibody molecule which is MUCH larger, easily cross? So, two huge facts. 18 million Americans recovered without a COVID-19 neutralizing antibody present. Even if COVID-19 antibodies were present in the blood, it is not very likely these antibodies can cross the blood lung barrier and be present in the alveolar space, which is where COVID-19 is infecting alveolar epithelial cells and for the neutralizing antibody to have a chance at preventing an initial lung infection, the antibody needs to be present here.

To review, 18 million Americans recovered in a week or so without antibodies. Isn’t the mechanism behind this incredible recovery of so many people relevant? Any

curiosity? They all just “healed?” No further questions? Maybe the innate immune system even without antibodies is much more potent than previously thought? In the COVID vaccine clinical trials, for the vaccine group about 10 people were infected with COVID and in the control group about 200 were infected and this is why the vaccine was touted to be “95% effective”. When the average person believes that 40,000 people were recruited for the vaccine clinical trials, and the clinical trials are touted as 95% effective, many people can be misled into thinking that 20,000 were prevented from being infected with COVID, which was not the case.

I don’t think the vaccine study researchers realized that the innate immune system activation could also prevent virus propagation. RNA injection can cause stimulation of the innate immune system. Let’s imagine, the first COVID vaccine mRNA injection (1st activation) stimulates the innate immune system. Then, the body converts the mRNA into a foreign COVID-19 antigen (2nd activation) which AGAIN stimulates the innate immune system. Then, later, a vaccine booster of mRNA (3rd activation) is injected into the same patient which again stimulates the innate immune system. Then, that mRNA becomes foreign COVID-19 antigen (4th activation) and yet again stimulates the innate immune system. So, maybe the 200 people that didn’t get infected in the COVID-19 vaccine trial, maybe the protective effect of the vaccine was NOT due to the “neutralizing antibody” theory but due to activating of the innate immune system FOUR times? Remember, the innate immune system healed 18 million Americans in a week without antibodies. Isn’t it very likely that this alternate hypothesis is correct? That activation of the innate immune system (with generation of interferon which creates a cellular environment that makes viral propagation more difficult) is more likely the reason that 190 less patients in the vaccine group were infected with COVID?

The innate immune system can heal 18,000,000 Americans in a week or so in the year 2020 (without antibodies), but the innate immune system can’t prevent 200 Americans from being infected with COVID in the vaccine clinical study? Let me put it another way.

The innate immune system can heal 18,000,000 Americans in a week or so in the year 2020 (without antibodies), but the innate immune system can't prevent 0.001% of 18,000,000 Americans from being infected with COVID in the vaccine clinical study?

The alternate hypothesis is that injection of mRNA and the subsequent formation of foreign antigen in the body are both innate immune system activating events and that activation of the innate immune system results in production of various interferons which then interfere with virus propagation. We now have two competing hypotheses. To try to discover which hypothesis is correct, we can add a very simple but crucial control to the clinical trials. The COVID vaccine clinical trials can be repeated with an addition control group of 20,000 patients and this control group can be given 4 influenza vaccine shots over the time span of the clinical study. The influenza vaccine will create only influenza neutralizing antibodies but also activate the innate immune system creating interferons. Clearly, no COVID-19 "neutralizing antibodies" will be formed in this group and clearly the innate immune system will be activated and if this Influenza vaccine control group shows similar clinical results as the COVID vaccine group, then doesn't that definitively show that the current "neutralizing antibody" paradigm is in deep trouble and that the concerns of the potentially fatal flaw in the "neutralizing antibody" paradigm are still an issue? If even without a "COVID neutralizing antibody", the Influenza vaccine group has much less COVID infections than the placebo control group, then we have powerful additional support for the alternate hypothesis.

Doesn't this add tremendous strength to the alternate hypothesis, that the current good vaccine clinical trial results are due to activation of the innate immune system and not the "neutralizing antibody" paradigm? If that is the case, then like any good medicine, activating the innate immune system is BEST used when a patient is ACTUALLY infected with the virus. Activating the innate immune system can cause many other issues. Isn't this the much more scientific approach, to recall the

COVID-19 vaccine and redo the clinical trial with the appropriate crucial controls? It is not without excellent reasons that this request is made.

The alternate hypothesis on how the vaccine shows good clinical data (activation of the innate immune system and production of protective interferons) also explains how every American who recovered from COVID actually recovered. Isn't it true that the more data that is encompassed by a hypothesis, the more likely the hypothesis is to be correct? The current "neutralizing antibody" paradigm can't explain the 18 million Americans that recovered from COVID because "neutralizing antibodies" weren't even present when the majority of American's had actually already recovered. The alternate hypothesis on how the vaccine shows good clinical data doesn't have an obvious flaw and encompasses much more data. The current "neutralizing antibody" paradigm has a potentially fatal flaw in that the question of how the "neutralizing antibody" actually finds its way into the lung was apparently not properly researched and investigated and the current hypothesis doesn't even attempt to explain how 18 million Americans recovered from COVID in 2020.

The Influenza vaccine industry borrowed the "neutralizing antibody" paradigm from other successful vaccines but every system is different just like the treatment of every cancer is different and the flu vaccine industry appears to have overlooked the question of how these "neutralizing antibodies" actually find their way into the lung alveolar area. The COVID vaccine industry adopted this "neutralizing antibody" paradigm from the flu vaccine industry, which happened to be sloppy in their research. Now, we are in the position of having to question and investigate their potentially colossal faulty assumptions. The alternate hypothesis explains the good results from COVID vaccine clinical studies and the alternate hypothesis can also be invoked to explain how 18 million Americans recovered from COVID in a week to 10 days, whereas the current paradigm can say nothing about how 18 million Americans who recovered from COVID since IgG "neutralizing antibodies" formed after almost everyone had recovered.

Repeating the COVID vaccine clinical trials with a proper crucial control that helps clarify which hypothesis is correct is of paramount importance because if the current “neutralizing antibody” paradigm is correct, the “life vests” may work for the necessary amount of time whereas if the alternate hypothesis is correct, then the duration of the “protection” provided by the vaccine will be much shorter, possibly just a few weeks after the last vaccination shot.

Version 2.0 (Dr. Erbelding's attempt to respond to my email describing the fatal flaw in the COVID vaccine paradigm)

On a recent CBS News podcast, Dr. Fauci you stated, "You know, I love the Brits, they're great scientists, but they just took the data from Pfizer's company and instead of scrutinizing it really, really carefully, they said, 'OK, let's approve it, that's it,' and they went with it." The Brits didn't have the information I provided you in my first email to you (Appendix A) that described a potentially fundamental flaw in your "neutralizing antibody" paradigm. You had this information, and yet you didn't bring this issue to the FDA panel that approved the COVID vaccine.

I carefully disclosed all the issues with the current paradigm to you. The current paradigm for how a COVID-19 vaccine works is that a COVID antigen injected intramuscularly results in COVID neutralizing antibodies forming in the blood and these neutralizing antibodies make their way into the lung alveolus where the neutralizing antibodies can bind to COVID virus particles BEFORE the virus infects lung alveolar epithelial cells. No one considered the Blood Lung Barrier and what transport system the antibodies would use to cross this very significant barrier. I brought this potential fatal flaw in logic to your attention in a very concerned email that included many NIH directors and I mentioned that I thought it was serious enough that I sent certified letters to a 100 U.S. Senators.

I felt I explained this potentially fatal flaw in the current vaccine paradigm but Dr. Erbelding's email response to me didn't appear to acknowledge the issue. I will try to explain my position in many more versions, so there is less miscommunication.

Let's look at Pfizer and Moderna's data really, "really carefully and really, really scrutinize it". The current paradigm in a nutshell is that COVID-19 vaccines result in production of specific "neutralizing antibodies" that bind to the virus and prevent it from infecting lung cells. The email I wrote that Dr. Erbelding replied to (Appendix A), points out a potentially colossal fatal flaw in the current "neutralizing antibody"

paradigm for respiratory virus vaccines since it appears that the question of how antibodies from the blood pass through the blood lung barrier has not been properly addressed and researched. Please remember, the blood lung barrier is impermeable enough to prevent our lungs from being flooded with H20 and while a water molecule weight is 18 Daltons, an antibody molecule weighs 8000 times more (IgG antibody molecule weight, 150,000 Daltons).

Dr. Emily Erbelding, in her email response to me (dated October 28, 2020, Appendix B), did provide me with one reference from 33 or so years ago that described a "passive" transudation of antibody from the blood to nasal mucosa. That article also described needing a fairly high blood antibody titer to be able to barely detect antibodies on the nasal mucosa. I will quote from Dr. Erbelding's October 28, 2020 email to me,

"Investigators found evidence of reduced viral replication and an increase in antibodies to the antigen in the candidate vaccine in BAL fluid [1, 2, 3, 4] (antibodies from blood plasma cross the blood-air interface and enter the BAL fluid through a process called transudation; secretion from the airway tissues and the immune response localized in the lung also play a role [5])."

The author of that one study Dr. Erbelding referenced never explained the "process called transudation" except to state multiple times that it was a "passive transudation" process. There was no description of an active transport system for IgG antibodies from the capillary through the blood-gas-barrier into the alveolar epithelial space. The reference for that author is, "Wagner, D.K., Clements, M.L., Reimer, C.B., et. al. 1987. Analysis of immunoglobulin G antibody responses after administration of live and inactivated influenza A vaccine indicates that nasal wash immunoglobulin G is a transudate from serum. Journal of Clinical Microbiology; 25 (3): 559-562."

For the time being (since no one can provide a reference showing an active transport mechanism for IgG antibodies across the blood lung barrier), let's assume COVID-19 specific antibodies can't actually diffuse across the blood lung barrier in sufficient quantity to actually "neutralize" COVID-19 virus particles. I propose an alternate hypothesis for why Pfizer and Moderna's clinical trials were effective. 20 million Americans were COVID-19 positive as of January, 2021. At least 18 million of those Americans recovered or well on their way to recovery by a week or two of when their illness started. Antibodies take at least 2 weeks from good exposure to mount a good response. Even in your clinical trials, you waited 4 weeks before attempting to even detect "neutralizing" COVID antibodies in the blood. So, again, my point. At least 18 million Americans recovered from COVID-19 with barely a COVID-19 antibody in sight. Can we agree that the human body still healed 18 million Americans? It follows that "neutralizing antibodies" had little to do with their recovery.

Now, addressing the Pfizer and Moderna Clinical trials. The clinical trials are potentially fatally flawed and not properly tested. The premise is, that "neutralizing antibody" can actually travel through the blood lung barrier and be present within the alveolar space at a sufficient concentration to "neutralize" COVID-19 particles before they can infect epithelial cells. The vaccine supposedly prevented about 200 people from being infected? Since I just explained the significant barrier to antibodies crossing the blood lung barrier, (as a reference point, the uninfected blood brain barrier size limit for molecules that can cross the blood brain barrier is about 500 Daltons and antibodies are 150,000 Daltons) since the paradigm relies on a "neutralizing antibody" and since those antibodies would have to cross the uninfected blood lung barrier and since there is not a single research citation showing an active transport system for antibodies crossing the blood lung barrier from the capillary side, the current hypothesis of "neutralizing antibodies" in the Pfizer and Moderna clinical trials, has not been properly investigated.

I described 18 million Americans having recovered from COVID-19 in about a week or so. Clearly COVID-19 antibodies weren't present (since antibodies take at least 2 weeks from good exposure to reach a "therapeutic" level. Clearly we need to call the system that improved these 18 million American's something with the word "immune" and also "system" so I'll refer to it as the "immune system without antibodies" (ISWA), or more familiarly known as the innate immune system. The innate immune system can be activated by foreign antigens. A large "vaccine" injection of mRNA can also activate the innate immune system. There were 4 activations of the innate immune system during the clinical trial period which was about 4 or 5 months. Isn't it possible that the innate immune system without antibodies which undoubtedly healed 18 million Americans in a week or so was also activated 4 times by the "COVID-19 vaccine" and that activation of the innate immune system without antibodies is the mechanism by which the Pfizer and Moderna clinical trials achieved good results?

Now, we unequivocally have two hypotheses for how the current COVID vaccine clinical trials achieved such good results. The current "neutralizing antibody" paradigm, which potentially has a colossal fatal flaw in the form of not having a final path for the antibody to reach the lung alveolus; and the alternate hypothesis which has a huge advantage in that it can also be invoked to explain how 18 million Americans recovered.

The current paradigm is potentially devastatingly flawed and the alternate hypothesis is simple and straightforward. It is imperative to have more data which can help rule-in or rule-out each paradigm. This is important for many reasons but most critically to better understand the duration of protection provided by the COVID vaccine. The current paradigm predicts the vaccine may be protective for a year or two. The alternate hypothesis would anticipate protection for at best a couple of months after the last vaccine injection, if mRNA used and at best a few weeks if COVID antigen used as the vaccine.

A recall of the currently FDA approved COVID vaccines and a repeat clinical trial to obtain additional data to help determine if the current paradigm is accurate or if the alternate hypothesis is a more credible theory is imperative since the prediction of duration of protective action for the vaccine between the two paradigms is vastly different. The COVID vaccine clinical trial can be repeated with an extra critical control arm consisting of 20,000 patients who are given 4 influenza vaccine shots during the course of the clinical trial. If the Influenza vaccine control group has similar poor results with the placebo, then there is more evidence to show that the COVID “neutralizing antibody” is finding its way into the lung alveolus and “neutralizing” COVID virus particles. If the Influenza vaccine control group has very good clinical results, similar to the COVID vaccine group, then since the influenza vaccine control group does not produce COVID “neutralizing antibodies”, but the influenza vaccine group still does activate the innate immune system which results in interferon generation, then there is much more evidence that the alternate hypothesis is the correct one.

Remember, the “immune system without antibodies” that I am invoking in the alternate hypothesis healed at least 18 million Americans in a week or so, and the current paradigm of “neutralizing antibody” for how the COVID-19 vaccine works only helped less than 200 people and even those might have been helped by the innate immune system and NOT the “neutralizing antibody”.

Once a paradigm is suspect, if another alternate hypothesis is offered that makes more sense, the controls have to be planned to rule in or rule out the new hypothesis. The scientific approach is to require Pfizer and Moderna to add this extra critical control to their repeat clinical study. Remember, the “immune system without antibodies” actually healed 18 million Americans in a week or so. At best, the current “neutralizing antibody” paradigm in the COVID vaccine clinical trials only prevented 200 patients from acquiring COVID. Also, that is at best. Because it is highly probable those 200 patients or so were also mostly helped by the “immune system without antibodies”.

To put it into a geographical representation, 18 million Americans recovered via the innate immune system versus 200 Americans that didn't get infected in the COVID vaccine clinical trials; what is more impressive, the diameter of earth or 600 feet? To make the contrast even more stark, 20 million Americans tested positive; but there is a good chance that 60 million Americans actually had COVID but went untested. Now, the analogy is the diameter of the earth compared to someone's front yard (200 feet). Which is more impressive?

This is potentially a classic Type 1 error, or a "false positive" finding. The companies unluckily conclude that something is a fact. In this case, consider a vaccine clinical study where researchers compare the COVID vaccine with a placebo. If the patients who are given the COVID vaccine get better results than the patients given the placebo but there are TWO separate pathways activated by the COVID vaccine, it may appear that the COVID vaccine pathway ONE (development of neutralizing antibodies) is effective, but in fact the conclusion is incorrect and it is in fact the COVID vaccine activating pathway TWO (Innate immune system) that is responsible for the better results.

Type 1 errors classically occur because of a short clinical trial duration or a small sample size. What is interesting in the COVID clinical trials is that the researchers did exactly this. A true sample size of 200 COVID infected patients (the actual number of infected patients was a very small number in both the vaccine and placebo arms of the study) in their study compared to the number of actual patients recruited for the study (40,000), shows poor judgment and shortening the duration of the trial exacerbated this issue. But the true reason for the possible Type 1 error, if in fact a Type 1 error occurred, is because the researchers may not have acknowledged that there may be an alternate mechanism activated by the vaccine that was responsible for the good clinical results. It is especially disconcerting because attempting to minimize activation of the innate immune system is one of the most significant issues facing mRNA vaccines (References 1-8), and so it is virtually

unthinkable that they were not aware of this issue. But, wanting to believe that the "neutralizing antibody" was the reason for the good results was so strong (classic case of confirmation bias), that ironically, the very issue the mRNA vaccine researchers were combating prior to commercializing mRNA vaccines (inadvertent activation of the innate immune system), may have potentially been the very reason their mRNA vaccines worked so well in reducing virus propagation.

Many research fields are in a crisis of confidence as it becomes more apparent that many research findings cannot be replicated. According to on survey in Nature, more than 50% of researchers think there is a "significant crisis". "Two-thirds of researchers who responded to the survey by this journal (Nature) said that current levels of reproducibility are a major problem." Nature, E Button, K. S., Ioannidis, J. P. A., Mokrysz, C., Nosek, B. A., Flint, J., Robinson, E. S. J. & Munafo, M. R. (2013). Power failure: why small sample size undermines the reliability of neuroscience. Nature Reviews. Neuroscience 14, 365–376. Editorial, May 25, 2016.

Your "true" sample size in your clinical COVID vaccine study are the actual patients that were infected with COVID on both the control and the vaccine side (total true sample size of well less than 300). Small sample sizes can exacerbate the issue of "false positives".

I am claiming as my hypothetical "study" 20 million Americans who were COVID infected. I "confirmed" that 99.99% of patients in my "study" had no COVID antibodies prior to their infection. I then confirmed that all 20 million Americans were COVID positive. I followed their progress and guarantee that 70% to 90% had recovered or were well on their way to recovery by Day7 of their respective illness. I "checked" all 20 million Americans for COVID antibodies in their blood at Day 7 and found very little to barely detectable COVID antibodies at Day 7. What do you think of the power of "my study"? Did I effectively much more impressively show that COVID neutralizing antibodies were not significantly involved in the recovery of at

least 18 million Americans? Now, aren't we curious how these 18 million Americans recovered? Without that amazing antibody present?

The current COVID-19 vaccine companies have described good clinical results. The companies describe clinical results that are about 95 percent effective. As an example, in the Pfizer clinical trial, the placebo group had approximately 200 infected patients. The vaccine group only had about 10 infected patients. The audacity of man. Which is more impressive? The recovery of 18 million or so Americans in a week? Or the prevention of 190 infections with a COVID-19 vaccine? 18 million Americans were healed by the human body using the innate immune system (without antibodies). 190 infections were prevented by a COVID-19 vaccine that produced a “neutralizing antibody”. But, “neutralizing antibodies” have to cross this huge obstacle course of a barrier (the blood lung barrier) before the antibodies are able to “neutralize” any virus particles. The good clinical results in the Pfizer COVID-19 vaccine clinical trials may purely be the result of activation of the innate immune system that also healed 18 million Americans within a week and not the effect of the “neutralizing antibodies” which would have to traverse the blood lung barrier. Once a hypothesis has a potentially fatal flaw, an alternate hypothesis is proposed and then the next step is to formulate an appropriate clinical trial design with proper critical controls to help answer the question. The question is, are the Pfizer COVID-19 vaccine clinical trial results good because of 1) activation of the innate immune system or 2) the effectiveness of COVID-19 “neutralizing antibodies”? The simple addition of one proper control group will point scientists in the right direction. Add a control group using an Influenza vaccine in 20,000 volunteers. The influenza vaccine will result in “non-neutralizing antibodies” against COVID since influenza antigens are very different from COVID-19 antigens. To be fair, the influenza vaccine control group must be given the influenza vaccine 4 times to match the 4 times the innate immune system is activated with 2 mRNA COVID vaccine shots. If this flu vaccine control group has very good clinical results and the flu vaccine prevents COVID-19 infections or reduces the severity, then clearly the

"neutralizing antibody" argument falls apart and Pfizer's good clinical results are much more likely due to the multiple activations of the innate immune system.

Let's follow the science. The science is that the term "blood lung barrier" has been around a very long time. The science is that there is not a single publication that describes an active transport system for transporting IgG antibodies from the blood through the blood lung barrier into the alveolus where COVID-19 is infecting alveolar epithelial cells and where most of the damage in the lung is being inflicted. The science is that without an active transport system, the larger the size of a molecule, the more difficult it is for the larger molecule to cross barriers via passive diffusion (and antibodies are some of the largest molecules in the blood). The science is that the "immune system without antibodies" healed 18 million Americans. This is "the science". And science always allows for debate and discussion and new hypothesis and ongoing research. Do we really want to keep exposing Americans to the COVID-19 vaccine, knowing that the "neutralizing antibody" paradigm is potentially fatally flawed and doesn't include a real pathway for the antibodies to go from the blood (where the antibody is generated) through the blood lung barrier, into the alveolus where the virus is infecting lung cells? Yet, the COVID vaccine clinical trials seem to have good data. With a potentially severely flawed paradigm, there currently isn't a working hypothesis for why the clinical data came out so well. Pushing the vaccine on the American people without a valid hypothesis is not science. There is an alternate hypothesis. If in fact it is not the neutralizing antibodies, then it means the COVID-19 vaccine may only prevent infections for a short time and that the benefit will wane within a few weeks of the last vaccine injection and that inducing unnecessary antibodies may cause significant permanent side effects for a segment of the population. The current COVID vaccine clinical trials activate the innate immune system FOUR times when someone isn't actually infected. If in fact the alternate hypothesis is correct and it is the "immune system without antibodies", then the effect of the vaccine will only last a few weeks after the injection; interesting isn't it that the flu vaccine requires one shot but the COVID-19 vaccine requires two shots spaced a month apart and that the flu vaccine studies

usually extend a year and that the COVID-19 vaccine studies only last a few months? Isn't it interesting how the design of the COVID-19 vaccine trial unwittingly really promotes a good clinical result if in fact it is just activation of the "immune system without antibodies"? Isn't open mindedness a very important trait for a good scientist that wants to be thorough and not take short cuts? Isn't this a most persuasive argument for repeating the COVID vaccine clinical trials with the appropriate critical controls?

Dr. Fauci, you might have to answer a million questions by reporters and scientists about what you knew before my email and your thoughts after my email of September 27, 2020. Millions of small businesses went bankrupt in the past six months. You made general statements that once we achieved the goal of "herd immunity" for 70 to 80% of the population, the country could resume normal activity. "Herd immunity" cannot exist if there aren't enough "neutralizing antibodies" in the lung. What if we never reach "herd immunity"? Should the country stay closed forever? If the concept of "herd immunity" isn't based on real science, then what was the basis of your recommendations? Everyone will wonder why the recommendations were made. I informed you of the potentially fatal flaw in the "neutralizing antibody" paradigm and yet you continued to talk publicly about "herd immunity" and seemingly disregarded the email I sent you. How can there be "herd immunity" via the vaccine if "neutralizing antibodies" are not able to accumulate sufficiently in the alveolus via passive diffusion? Dr. Erbelding's October, 2020 email response (Appendix B) to my email quoted a 33-year old paper, to discredit the issues I raised. Without a mechanism for IgG antibodies to cross from the blood through the Blood-Lung-Barrier, how can there be sufficient "neutralizing antibodies" in the lung to prevent a COVID infection? The article that Dr. Erbelding quoted was a one-word explanation for how IgG antibodies cross from the blood onto the surface of nasal mucosa, the word was "transudation". One word is like "abracadabra". In science, generally we prefer a bit more explanation than one word. Even Wagner, the author of that 33-year old paper, described it as a "passive transudation". That is the only paper that Dr. Erbelding quoted me that shows how an IgG antibody might

cross the blood lung barrier, yet that author (Wagner) described a passive process which greatly reduces the chances of “neutralizing antibodies” crossing the blood gas barrier in any significant fashion. The mechanism of IgG antibodies passing from the blood into the alveolus is “passive transudation”? Since Wagner did not actual refer to the blood lung barrier, may I also invoke “passive transudation” as a mechanism whereby IgG antibodies pass from the blood into the brain through the blood-brain barrier? After my email of September 27, 2020 (Appendix A), what did you understand “herd immunity” from a vaccine to be and how did you continue to make public statements regarding the “goal posts” of herd immunity? After this email, how will you explain your goal posts of “herd immunity”?

The FDA just approved Pfizer's and Moderna's COVID-19 vaccines. 20 million Americans have thus far been tested positive for COVID-19, and well over 90% of patients have recovered or were well on their way to recovery by one week from the start of their respective illnesses. It can be safely assumed that 18 million Americans have recovered or were clearly on the road to recovery within one week of their COVID-19 infection start date. COVID-19 antibodies were not present in 99.9 percent of these 18 million Americans, since it is well known that antibody generation requires at least two weeks. The difficulty of antibodies passing through the blood lung barrier has been thoroughly discussed in other parts of this letter repetitively. In the COVID-19 vaccine clinical trials, 20,000 patients received the COVID-19 vaccine and 20,000 patients received a placebo. In the vaccine group, there were about 10 infections. In the control group, there were about 200 infections. 190 less patients were infected in the COVID-19 vaccine group. 95% efficacy sounds very impressive. 190 less patients being infected sounds miniscule. Especially when compared to the 18 million Americans who recovered within a week or so of their infection using the immune system without the presence of COVID-19 antibodies.

If the current paradigm is incorrect, they planned their clinical trials incorrectly. The current paradigm describes a "neutralizing antibody" formed in the blood following the vaccination and then the COVID-19 antibody neutralizing the virus in the alveolus of the lung. The scientific community never seemed to have asked how IgG antibodies in the blood pass through the blood lung barrier (BLB) which the antibody must do in order to "neutralize" the virus in the alveolus, otherwise the virus can infect the alveolar epithelial cell. Since the newly formed COVID-19 antibody is unlikely to be able to reach the alveolus in a significant concentration if it is only relying on "passive transudation", then the COVID-19 vaccine results in COVID-19 antibodies which aren't able to reach the alveolus, how would this COVID-19

vaccine prevent 190 people from being infected relative to the control group? Once it is realized that it is not the “neutralizing antibody” in the lung that helped 18 million Americans recover in a week since COVID-19 “neutralizing antibodies” were not present for these 18 million Americans, then it is imperative to know how these 18 million Americans recovered in a week, apparently without too much difficulty for the most part. It is the innate immune system that healed these 18 million Americans, particularly, the decreased global protein production from the phosphorylation of eIF2α and the efficiency of the ribonucleases that cut up the COVID RNA. Interferons produce an “antiviral state” by ultimately phosphorylating eIF2α and decreasing viral RNA translation into viral proteins. Now, which is more impressive? 18 million Americans recovering from COVID in about a week or so from their respective COVID infection date? Or 190 less Americans that were infected with COVID due to the vaccine? But even more pointedly, why are the COVID vaccine companies so certain that it was the “neutralizing antibody” that prevented these 190 Americans from being infected with COVID? Isn’t it much more likely that the vaccine injection activated the innate immune system? Interferons are an integral part of the innate immune system. Clearly the vaccine injection induced fever and malaise and muscle aches in many patients (all signs and symptoms of cytokine generation). Clearly the vaccine injection is activating the innate immune system. The production of interferons creates an “anti-viral” state in the body by signaling cells to reduce protein production. Yet it is so apparent that the companies were not aware of this paradigm because they could have easily added a control to show this. If they added one other group of 20,000 patients and used the “FLU” vaccine as another positive control, the flu vaccine would not create a COVID neutralizing antibody and yet the flu vaccine would also activate the innate immune system and create interferons and produce fever and muscle ache and this group would also have a much reduced COVID infection rate. The only explanation would be the activation of the innate immune system since the FLU “neutralizing antibody” would not neutralize a COVID virus particle.

Version 5.0 (“antibodies pass through the blood lung barrier by passing through the blood lung barrier”)

I am quoting your email reply to me dated October 28, 2020. “Preclinical animal studies of SARS-CoV-2 candidate vaccines have evaluated viral titers and the level of neutralizing antibodies in bronchoalveolar lavage (BAL) fluid collected from the lower respiratory tract. Investigators found evidence of reduced viral replication and an increase in antibodies to the antigen in the candidate vaccine in BAL fluid [1, 2, 3, 4]” Of the 4 articles, only the 1st reference mentioned antibodies in BAL, Yu, J., Tostanoski, L.H., Peter, L., et. al. 2020. DNA vaccine protection against SARS-CoV 2 in rhesus macaques. Science; 369 (6505): 806-811. BAL IgG for the 100 ug dose showed AUC of 5 to 8 range. But fascinatingly, the Humoral IgG ranged from AUC of 4 to 5. There was actually an orders of magnitude larger level of neutralizing antibody found in BAL fluid compared to humoral levels. There was no mention of the amount of fluid used to perform the BAL in the procedural steps to determine BAL IgG levels. The reason why I mention this is simple. The lung is mostly air. For example, if there is salt on the desk, what is the concentration of salt on the desk? The amount of fluid that is used determines the concentration, does it not? If 5 cc of fluid is used to dissolve the salt on the desk versus if 10 cc of fluid is used to dissolve the salt, wouldn’t the concentration be different by 2 times? So, because the IgG in BAL was on average AUC of 6 and the humoral average AUC was 4, that is approximately a 100 times greater level of antibody concentration in BAL versus plasma. How much saline they used in performing the broncho-alveolar lavage to determine the level of IgG antibody in the BAL samples is not mentioned. It is critical to know this piece of information. If in fact that lung accumulated up to a hundred times concentration of neutralizing IgG antibody compared to plasma, there must be a very strong active transport system, that has yet to be described and published. Because, if purely due to passive diffusion, the IgG antibody in the BAL sample would not be greater than the serum values of IgG antibody. The one article (Wagner) that you quoted from 33 years ago to show the mechanism for antibodies

moving across membranes only mentions “transudation” and the article describes “transudation” as a passive diffusion process and shows that an antibody blood level of AUC 8 results in barely “detectable” levels on nasal mucosa, which would be less than an AUC of 1. Is it possible your authors (Tostanoski) miscalculated the data? I am extremely curious as to how much fluid the authors used during the BAL procedure to determine a BAL IgG level of 6 when the humoral IgG concentration was much lower.

You referred to an article by Wagner from 1987. His study tried to determine specific IgG levels on nasal mucosa and if the specific IgG source was local or from serum. I quote directly, “In this study, we showed that the concentration gradient of influenza HA antibody from sera to nasal washes was similar in our two vaccine groups and that a $\log_2$ titer of 8.4 (approximately 1:350) was required before HA specific IgG was detected in nasal washes.” Journal of Clinical Microbiology, march, 1987, p. 561. He did not pose any mechanism but distinctly states that “nasal wash antibody appeared to be mainly derived from the serum by a process of passive transudation”. He also states “others have suggested a transudate from serum down a concentration gradient”. Both statements indicate a passive diffusion powered by a concentration gradient and not an “active” transport mechanism. Also, he states that a $\log_2$ titer of 8.4 in serum is necessary before IgG HA antibody becomes detectable. I do not interpret “detectable” antibodies as a sufficient level or concentration of antibody to prevent infection.

Here is another article. “The mechanism, however, by which IgG may cross epithelial barriers to function in mucosal secretions remains unknown.” J Exp Med. 2002 Aug 5; 196(3): 303–310. Receptor-mediated Immunoglobulin G Transport Across Mucosal Barriers in Adult Life Functional Expression of FcRn in the Mammalian Lung.

Here’s another one. “An isolated perfused rat lung model was used to examine IgG transport across pulmonary epithelium from airspace to perfusate. …. Pulmonary

epithelium expresses functional FcRn providing an absorption pathway potentially important for highly potent Fcgamma-fusion proteins but unlikely to be of quantitative significance for the systemic delivery of inhaled therapeutic monoclonal IgGs." Expression and Transport Functionality of FcRn within Rat Alveolar Epithelium: A Study in Primary Cell Culture and in the Isolated Perfused Lung. March 2006 Pharmaceutical Research 23(2):270-9. This paper discusses IgG transport via a FcRn that binds and transports IgG, but this is from airspace to perfusate, note that the reverse direction is needed for transport of IgG from serum to airspace. Note also that the authors state that the quantitative significance is unlikely in the opposite direction, regardless.

There are a few papers that describe using alveolar epithelial cell FcRn (neonatal Fc receptor) to transport molecules conjugated to Fc from the airway lumen across the epithelial cell barrier into blood. Oral and pulmonary delivery of FSH–Fc fusion proteins via neonatal Fc receptor-mediated transcytosis S.C. Low, S.L. Nunes, A.J. Bitonti, J.A. Dumont Human Reproduction, Volume 20, Issue 7, July 2005, Pages 1805–1813. But over and over again, these papers describe IgG transport from the airway lumen into the blood and not the reverse direction. For your COVID-19 neutralizing antibody that is created in the blood (after an intramuscular injection of vaccine), the neutralizing antibody would have to cross the blood gas barrier in the reverse direction, from the basal surface of the epithelial cell to the apical surface. Has that ever been described?

Dr. Erbelding, once you agree that your vaccines activate the innate immune system, the debate is a matter of which has more effect, interferon molecules or COVID-19 specific neutralizing antibodies, which are both produced away from the lung and have to make their way into the lung. However many molecules of antibody you want to let through the blood lung barrier, you will have to let in a lot more interferon molecules, since interferon molecules are much smaller. Since you do not have a known mechanism for IgG antibody transport across the blood lung barrier, and if you want to invoke "transudation" based on one paper that describes

“transudation” as a passive process, why can I not invoke “transudation” and passive diffusion for interferons crossing the blood lung barrier. Since interferon molecules are about 20,000 Daltons in size and IgG molecules are about 150,000 Daltons in size, there would be an approximately 15 times greater passive diffusion of interferon molecules than antibody molecules across the blood lung barrier. Once in the alveolar area, which do you think would have a stronger effect on viral replication, antibodies or interferon molecules? For every virus particle, at least several antibody molecules would be required to “neutralize” a single virus particle since IgG antibodies are 9 nm long and COVID-19 virus particles are around 100 nm in diameter. Compare that to interferon molecules which activate PKR enzymes which then phosphorylate eIF2 and result in decreased cellular protein production which reduces the chances of viral propagation within a cell. An antibody at best has a one to one ratio of neutralizing virus particles. Interferon uses an enzymatic pathway to activate PKR which phosphorylates eIF2 and decreases viral propagation. An antibody has to be at the exact right position and has a short window of time to bind to the virus particle before the virus infects a cell. An interferon molecule creates a local area of decreased protein production and timing and positional requirements are not nearly as stringent in hindering virus propagation. I understand the immune system is complex. You are attributing the decrease in viral propagation in the lungs following COVID-19 vaccines to IgG antibodies that cross the blood lung barrier. Clearly that is what the COVID-19 vaccine companies are also attributing the improved clinical course to. I am attributing the decrease in viral propagation in the lungs following COVID-19 vaccines to activation of the innate immune system. The COVID-19 vaccine researchers apparently overlooked this fact; they could have easily added the proper critical control for this in their clinical study but they did not. The bolus of mRNA (COVID-19 vaccine) injected into patients will without a doubt cause local activation of the innate immune system and the production of local cytokines and interferon molecules associated with the innate immune system will spread throughout the body (fever and malaise is evidence of this) and even into the lung alveoli where these cytokines result in activation of PKR which results in phosphorylation of eIF2

and a dramatic reduction in viral RNA translation. If in fact the FDA or these companies were aware that this was likely, why wouldn't they add a simple control? On top of a normal saline injection control group, one could also have added a control group using an Influenza vaccine which also activates the innate immune system as evidenced by the production of fever and malaise and yet produces an antibody that cannot neutralize COVID-19. Yes, this means that the flu vaccine industry is also in need of a working paradigm. The Influenza vaccine industry also has this same "neutralizing antibody" paradigm that is potentially fatally flawed. Currently, there is zero evidence that the alternate hypothesis is incorrect and that the current paradigm of "neutralizing antibody" in the lung is the main player in viral propagation reduction in the lung. Isn't this extremely relevant scientific questioning and challenging of the current paradigm and sufficient information to recall the COVID vaccines and re-do the COVID vaccine clinical trials with the proper critical controls?

Is there any reason you can imagine, not to repeat these trials with the correct added control groups? Interferons were named for their ability to "interfere" with viral replication by protecting cells from virus infections, and clearly injecting a bolus of mRNA or foreign antigen into muscle can induce local interferon production that can spread all over the body. Why is this so relevant? If the alternate hypothesis is correct and injection of COVID-19 antigen or mRNA resulted in activation of the innate immune system and that was why there was less COVID virus propagation in the lung, that also means that there is no memory, in the sense of the adaptive immune response and specific antibodies. The innate immune system does not have "memory" in the sense we understand that specific antibodies have memory. The "memory" that the innate immune system has is much more impressive. The contention that the immune system needs some kind of work-out or "priming" to be more effective only applies to the adaptive immune system and specific antibody generation. The innate immune system operates on fundamental factors that are different from SELF and NON-SELF. The adaptive immune response (antibodies) sense subtle differences in pathogens and require "priming". The innate immune

system senses marked differences in SELF from NON-SELF and this is built-in and doesn't have to be re-learned in every person as evidenced by the built-in PRR (pattern recognition receptors) that are activated by PAMPs (pathogen associated molecular patterns).

What then would be the point of a COVID-19 vaccination? It would be protective only for a few weeks. To find out what the CEO of Moderna said regarding a short lived effect of the vaccine, just google this phrase, "Moderna CEO and nightmare". The half-life of typical IgG antibodies is about 21 days. But, COVID "neutralizing antibodies" are imbued with extra-ordinary powers? Regardless, if the good results are due to innate immune system activation, it is unlikely the protective effect of the vaccine will last more than a few weeks after the COVID antigen disappears from the human system.

I just can't help but wonder what happened to "the science". If in fact the COVID vaccination clinical results appeared favorable because of activation of the innate immune system, it is not likely to prevent infection more than a few weeks. My contention is that the innate immune system activation which is non-specific and general (due to foreign COVID antigen or mRNA being injected intramuscularly) is by far the single most important reason for improved clinical results post challenge in COVID-19 vaccine clinical studies and the addition of a control using influenza vaccine shots is an excellent way to show whether the current paradigm or the alternate hypothesis is likely to be more accurate.

Again, 20 million Americans tested positive for COVID-19 in 2020. Within a week, 90 percent or 18 million Americans had recovered or were well on their way to recovery although antibodies form after 2 weeks from good exposure. So, 18 million Americans recovered without a significant level of COVID-19 antibodies in their system and most likely due to the innate immune system activation. But for certain, COVID-19 specific antibodies were not involved in these 18 million Americans recovering since a good concentration of antibodies take at least 2 weeks from good

exposure. So, why would I be impressed with a COVID vaccine clinical trial of 40,000 when only 200 or so Americans contracted COVID-19 with or without the vaccine? The innate immune system healed 18 million Americans this year and what is impressive about COVID-19 specific antibodies that possibly prevented 190 Americans from developing COVID-19 illness. In the COVID vaccine clinical trials, what if it was the innate immune system activation (which is the same system that healed 18 million Americans) that actually helped the 200 patients in the study and NOT the "emperor's new clothes" antibodies. Doesn't it make sense to do this simple additional control with the influenza vaccine to see if in fact activation of the innate immune system is actually what was protective in the COVID vaccine clinical trial? Weighing in on the side of the alternate hypothesis are 18 million Americans (who got better without antibodies) and weighing in for the side of the current "neutralizing antibody" paradigm are a couple of hundred Americans (who you think didn't get COVID because of neutralizing antibodies).

In the September email to you (Appendix A), the main concern was "how do antibodies cross the blood gas barrier?" You quoted a paper from 33 years ago which seems like ancient history since I was a junior in college then. The one paper (Wagner) that was quoted was from 33 years ago and the paper 1) did not state a mechanism for antibodies crossing the epithelial barrier, 2) referred only to nasal mucosa, 3) mentioned "passive transudation" as opposed to an active transport mechanism, 4) described needing a serum antibody concentration of 8.4 and then the antibodies from the blood could come "down a concentration gradient" to be detectable on the nasal mucosal surface, which does not sound like a therapeutic level. The one paper cited to address the potentially fatal flaw concerns actually seems to support the alternate hypothesis and not the current "neutralizing antibody" paradigm. Then, wouldn't it seem appropriate that the FDA scientists that approved the current COVID-19 vaccines be alerted to this serious issue regarding the generally accepted paradigm of how vaccines prevent future infection? If in fact the current paradigm of how vaccines work is that a "neutralizing antibody" binds to the virus pathogen but with regards to respiratory viral illness, the neutralizing antibody

would have to be in the alveolus and the blood gas barrier was not considered and the whole paradigm is in question, wouldn't it be most appropriate to alert the FDA to this alarming situation? Wouldn't the FDA scientists be shocked to know that no one knows if COVID-19 neutralizing antibodies actually cross the blood lung barrier in a significant concentration? Wouldn't not informing the FDA scientists who approved COVID-19 vaccines be the exact opposite of "transparency?"

Risk versus benefit. R/B. The ratio of Risk/Benefit becomes much larger if the benefit is significantly decreased. The FDA and CDC and other health organizations that determined that the R/B ratio was adequate based their assessment on assuming that COVID-19 antibodies were able to be present in the alveolus and "neutralize" COVID-19 virus particles. For argument's sake, let's assume that R/B ratio was 1.0 and that the FDA was willing to approve the vaccines based on this number. If suddenly, the FDA is given information that the benefit of the vaccines is much less, than the R/B ratio becomes much higher than 1.0.

Quoting The Motley Fool article (Jan 12, 2021) authored by Keith Speights, "Moderna CEO Stephane Bancel alluded to a 'nightmare scenario' in his comments at an event last week. In that scenario, COVID-19 vaccines only provide protection against infection by the novel coronavirus for at most a couple of months." If the alternate hypothesis is correct and "neutralizing antibodies" have very little do with the rate of COVID infection and the recovery from COVID, and since there is a potentially "fatal flaw" in the current paradigm (the Blood Lung Barrier is in fact a Barrier), and if in fact the good clinical results from the COVID vaccine are due to activation of the innate immune system, then the effects of the COVID vaccine may last only a few weeks after the injections are discontinued, a "nightmare scenario" for Moderna, but not for America. Americans will be spared all the side effects of vaccines and all the other potential serious issues that can occur with vaccines.

Dr. Erbelding, in addressing the concerns I raised regarding the potentially fatal flaw in the current “neutralizing antibody” paradigm, you provided a one-word mechanism “transudation” from a 33 year old paper that also does not elucidate that mechanism of “transudation” but states that a specific antibody in the blood was detected on “nasal mucosal” surfaces. So, it’s not clear whether you are agreeing that antibodies can’t cross the blood lung barrier in significant amounts or not. If in fact you are agreeing, then the R/B ratio must be re-evaluated because most benefits of activating the innate immune system are short lived and there is no hypothesis that you are presenting to show that the innate immune system has “memory” in the sense that COVID-19 vaccines result in COVID-19 “neutralizing antibodies” that are specific to COVID-19 and have memory. The “adaptive immune system”, or “neutralizing antibody” generation, improves with “exposure” or “training” and this is the system that is often thought to have “memory”. If you believe another arm of the immune system improves with “training” or “exposure”, aside from the adaptive immune response, then a hypothesis need to be formulated, pathways delineated, experiments planned, and data submitted so other scientists can add input to any conclusions drawn. Given that scenario, I would suggest that comparing any newly minted hypothesis, to the clinical course of a 6-month old human infant, that does not generate much antibodies and does not have a history of exposure to viral illnesses (being only 6 months old), yet when exposed to Influenza or COVID, the infant almost always easily handles the respiratory viral infection. To describe any arm of the innate immune system as requiring “training” or “exposure”, one would have to have excellent research and well delineated pathways to show that this “training” is helpful for the innate immune system and the “gold standard” would be how easily a 6-month old human infant handles the respiratory virus using its innate immune system without “exposure” or “training”. Clearly, human infants handle respiratory viruses well and without antibodies (and no, I am not advising we perform research experiments on infants). The innate immune system is not understood to need “training” or “exposure” to be quicker or faster or better at handling viruses. Of course, 6-month old human infants handling COVID is another data point that is not

well explained with the “neutralizing antibody” paradigm but supports the “alternate hypothesis”.

Dr. Erbelding, the current hypothesis of “neutralizing antibodies” is potentially fatally flawed. I’m sure you agree that there is no need to invoke some other speculative long-term benefit without a testable hypothesis at this time. To be more precise, there is never a need to invoke a speculative benefit without a testable hypothesis.

This is how ironic these COVID-19 vaccine studies are if the effects of the COVID-19 vaccine intramuscularly are NOT due to COVID-19 antibodies that are able to cross the blood lung barrier and be present in the alveolus to bind COVID-19 virus particles. If in fact these COVID-19 vaccine studies resulted in good clinical results because of an activation of the innate immune system, which generally is known NOT to have the kind of memory that specifically generated antibodies have, then the good clinical results are also only going to last as long as the innate immune system is activated (order of weeks). Most flu vaccines have been only administered once per year. COVID-19 vaccines have been administered twice. Both times the mRNA vaccine was injected, it also caused production of foreign antigens that each time AGAIN stimulated the innate immune system.

With a potentially fatal flaw in the “neutralizing antibody” paradigm, without a well thought out paradigm, is it appropriate to encourage 300 million Americans to receive the COVID vaccine? Wouldn’t it be more appropriate to try to first measure the actual level of COVID-19 neutralizing antibodies in the lung in these studies? Science progresses because of open debate, transparency and fairly addressing other scientists’ reasonable concerns, even if the concern is exposing a potentially “fatal flaw” in the paradigm. If in fact I present a concern with the current paradigm that generally implies that “neutralizing antibodies” are present in the alveolus and can “neutralize” COVID-19 particles before the COVID-19 virus is able to infect alveolar epithelial cells, and I bring this concern up because I can’t find any scientific articles that address this issue, and I share with you that I understand the blood

brain barrier generally has a barrier limit of molecules weighing less than 500 Daltons and so I can't understand how an antibody that weighs 150,000 Daltons would be able to cross the blood lung barrier, isn't that a very legitimate reasonable scientific concern? Wouldn't it be more scientific to address this concern than to bury the concerns that are raised?

For the sake of argument, if the R/B ratio for the COVID-19 Vaccine is 1.0, and the vaccine is assumed to have a benefit for 1 year, if the benefit is only 4 weeks, the R/B ratio is 10.0. That is a much worse R/B ratio. Typically flu vaccines have anywhere between a 10% to 90% benefit. The flu vaccine benefit studies are usually performed over a year. If in fact the alternate hypothesis is correct and even the flu vaccine clinical benefits are mostly from the activation of the innate immune system which generally would be of benefit for possibly a few weeks, then if the exact same flu vaccine study R/B ratio is assessed over a year and R/B ratio is assessed over 4 months, the flu vaccine study would show much more impressive results if the study only lasted 4 months. The flu vaccine study would suddenly go from an average of 50% benefit to over 90% benefit since most of the benefit of activation of the innate immune system would be during the actual activation of the innate immune system, a much shorter time than a year. Please remember that the flu vaccine was only given once. COVID-19 vaccines are given twice. And the mRNA produces "foreign antigen" that each time activates the innate immune system again. Compare activation of the innate immune system once during a one-year study with the flu vaccine and activation of the innate immune system 4 times in 4 months with your COVID-19 vaccine study. Clearly your study will look more impressive. Didn't anyone wonder why Pfizer and Moderna both got such amazing results, better than the flu shot ever achieved over the past 40 years? The lack of scientific curiosity is deafening. And Astrazenica had slightly less good clinical results? They only injected the COVID antigen twice, correct? So Astrazenica only activated the innate immune system twice, of course less efficacy against viruses, if the alternate hypothesis is correct. And most recently, J&J's

COVID vaccine efficacy of 66%? Only one injection of COVID antigen so only one activation of the innate immune system.

Purely hypothetical, but what happens if you inspect life-vests and you find that these life-vests actually absorb water and have little ability to increase buoyancy and work for only about 10 minutes but you approve the life-vests to be used on cruise ships. If the ship sinks and you are the inspector of these very short working life vests, are you guilty of these passengers' deaths? If this COVID vaccine short-term benefit is purely due to activation of the innate immune system and NOT due to "neutralizing antibodies", then when elderly patients receive this "COVID Vaccine" that only has a short-term effect and these elderly patients are more lax about their activities believing they are "protected" for "two years", did you harm them, if they are infected with COVID after the vaccine and then pass away? I'm raising a HUGE RED FLAG about the benefits of these COVID vaccines and I have EXCELLENT rational arguments demonstrating the potential "fatal flaw" in your "neutralizing antibody" paradigm, and if you ignore this information, are you now the inspector of the defective life vests that realized that there was a fatal flaw with the life vests, but then for political reasons, let the ship continue with the defective life vests?

In the tradition of scientific openness and in the spirit of providing transparency to the American people, isn't it necessary for you to state what you understand to be the paradigm for how these vaccines prevent infection? If you include in your hypothesis a "neutralizing antibody" point, please provide data showing the detection of COVID-19 antibodies in the lung and the mechanism for IgG antibodies crossing the blood lung barrier. You did cite a 33-year old article showing a specific antibody in the blood that was then "detectable" on nasal mucosa. "Detectable" is far from therapeutic and the author Wagner using the word "transudation" does not count as a mechanism for IgG antibody transport across the blood lung barrier. If you provided a paper showing an "antibody channel" in both the capillary endothelium and an "antibody channel" in the alveolar epithelium, that is a potential mechanism. But as a response to my concerns about not being able to find any scientific articles

discussing a mechanism for the passage of antibodies across the blood lung barrier, providing a one-word mechanism “Transudation” from a 33-year old article that does not further elaborate on that word, except to say that antibodies were “detectable” on the nasal mucosa surface, is far from an adequate response. It is a response I might expect from a medical student, but not from a scientist at the top of his/her respective organization. If this is the level of science that is allowing hundreds of millions of Americans to be vaccinated with a COVID-19 vaccine, then the American people have every right to be concerned. I am certain if you provide these concerns to the scientists at the FDA who have approved these COVID-19 vaccines, they will agree that these concerns are real and that there is not a currently valid hypothesis for how respiratory vaccines work. I am not disputing your 14 other articles that show benefit. I am just proposing a very valid alternate hypothesis for how your COVID-19 vaccine clinical trials and studies are resulting in less viral propagation in the lung and if this alternate hypothesis is correct, then the effect is temporary at best and in that situation, the Risk/Benefit ratio completely changes and whatever R/B ratio was used to approve respiratory vaccines in the past, this R/B ratio is at least 10 times as high and so not even close to the ratio number necessary for approval (a “nightmare scenario”).

The blood lung barrier is not a term that I coined. “Albumin is normally found in lavage fluid at a concentration of ~8-10% of that in blood, whereas the concentration of serum proteins of 100 kDa in lavage fluid is 1% of their concentrations in blood and that of 10 kDa porteins is ~20-25% of that found in blood. Thus there is an inverse relationship between the molecular masses of serum proteins and their concentrations in lavage fluid”. The authors note in their abstract of this paper, “The specific pathways and regulatory mechanisms responsible for translocation of proteins across lung alveolar epithelium and regulation of the cognate receptors (e.g., 60-kDa albumin binding protein and IgG binding FcRn) expressed in alveolar epithelium need to be elucidated.” Kwang-Jin Kim et. al, Protein transport across the lung epithelial Barrier. Am J Physiol Lung Cell Mol Physiol 284, 2003; pg. L252.

IgG antibodies are 150,000 Daltons (8000 times heavier than a water molecule) which means that lavage fluid concentrations of IgG antibody based on simple passive diffusion would be less than 1 % of that found in blood, if Fick's law of diffusion is a straight line, which it is not. A curved line would indicate that lavage fluid concentrations of IgG might be less than 0.5% of the blood concentration. Dr. Erbelding, I am disappointed at the lack of thorough analysis you performed in assessing the potentially "fatal flaw" I raised for the industry's "neutralizing antibody" paradigm and also your lack of thoroughness in analyzing the only paper you cited (Wagner, 1987) showing a "mechanism" for antibody transport across the blood lung barrier. Are you still of the opinion that your email response to me is an appropriate response to the serious issues I raised in my email to Dr. Fauci and Dr. Collins on September 27, 2020?

A single word, "Transudation", is not an elucidation of the specific pathway or regulatory mechanism whereby IgG antibodies from the blood cross the blood gas barrier. IgG antibodies have a molecular weight of 150,000 Daltons. Without a specific mechanism and only relying on passive diffusion, one can safely estimate based on the inverse relationship line between molecular masses of serum proteins and their concentrations in lavage fluid, that IgG antibodies would have a lavage fluid concentration of less than 1% of their serum concentration. Even at an IgG lavage fluid concentration (antibodies in the lung) of 2% of IgG serum concentration, which would be grossly overestimating the IgG lavage fluid concentration, that would not be considered a therapeutic IgG level in the lung. If there was a specific mechanism or pathway for IgG antibodies to cross the blood gas barrier, I am fairly certain you would have cited it. I have yet to find a single citation that elucidates a pathway or mechanism for IgG antibodies to cross the blood gas barrier, aside from passive diffusion. Please note, we are not discussing a diseased state of the lung where neutrophils have released devastating enzymes causing lung white-out and breaches of the blood lung barrier, since vaccines are not typically given to individuals with active lung infections. Vaccines are given to healthy individuals. The Blood lung barrier is intact in healthy individuals. After formation of "neutralizing

antibodies" in these healthy patients, the antibodies face an intact blood lung barrier in their journey into the lung which is where they can "neutralize" COVID virus particles.

Is there a single citation to support the industry's main hypothesis of a COVID-19 neutralizing IgG antibody transport mechanism from the blood into the lung? Are you not able to provide a single citation that shows COVID-19 neutralizing IgG antibody in BAL fluid in a human study?

An important point to add. Let's pretend it is the year 1950 and you didn't have all that positive clinical research data about respiratory vaccines and that scientists and doctors were trying to come up with a paradigm for how vaccines might work for respiratory viral illness and in that time, I presented my arguments against antibodies neutralizing virus particles in the lung because of the blood lung barrier. Wouldn't it be true that no one would believe in that theory of neutralizing antibody in the lung neutralizing virus particles until there was research that showed a transport system or research that demonstrated significant antibodies on the other side of the blood gas barrier? You say you have all this data about how well COVID-19 vaccines work. First things first. So you agree that neutralizing COVID-19 antibodies in the blood have no obvious path through the blood lung barrier into the lung alveolar sac? If you really want to insist that your 33-year old article (Wagner) stating antibodies from the blood were found on the nasal mucosa and the author of that paper used a word "transudate" as an explanation for how that occurred, then if you really want to apply that to the blood lung barrier, why would I not have a right to apply that transudation "mechanism" to the blood brain barrier? Suddenly, any barrier in the body can be easily overcome by any large drug molecule with a single word, "transudation"?

Generally in science, a single word explanation does not even serve as an educated guess, much less a "mechanism" or "hypothesis". Are you letting go of the antibody neutralizing a virus particle in the lung as a reason why respiratory vaccines work in

the lung? If in fact you are letting go of this paradigm, you don't have a hypothesis as to why respiratory vaccines injected intramuscularly actually decrease virus propagation in the lung. NOT a single hypothesis. You just have good clinical data. You give a neutralizing COVID-19 vaccine intramuscularly. You wait a few weeks and you give another booster COVID-19 vaccine intramuscularly. You inoculate these mammals with COVID-19 into the lung. You never check for COVID-19 antibody in the lung. You do notice less viral propagation in the lung. Let's suppose you have this data but you don't have a hypothesis yet. Then, out of nowhere, you come up with one word, "transudation" to explain that you think it's antibodies in the blood that "transudate" into the lung alveolar sac. Since you know the blood lung barrier is quite formidable, you use this word "transudate" and now you've solved your one issue with your hypothesis. Do you really think other scientists and researchers would be convinced with a one-word mechanism of "transudation" to be persuaded that your hypothesis (antibodies being formed in the blood and migrating across the blood lung barrier to neutralize virus before the virus can infect alveolar epithelial cells) is true? Using "transudation" without a mechanism and without further explanation of "transudation", isn't this a little like the "emperor's new clothes"? I have never been able to use that phrase more appropriately than in this situation. Literally, "transudation" has no meaning aside from "crossing membranes" and there really is no explanation for how antibody molecules that are 150,000 Daltons in weight can cross the blood lung barrier. Your understanding of this and your actions may result in hundreds of millions of Americans being vaccinated with your COVID-19 vaccine and possibly tens of thousands and maybe more Americans developing potentially permanent serious side effects. If the tables were flipped and I was the one trying to argue that antibodies can get across the blood lung barrier, and the only explanation I had was "transudation", you would be extremely frustrated with me. Aren't we rigorous scientists, who believe in reality, who believe that if two facts are contradictory that only one can be correct, to whom I have explained in exceedingly thorough detail, why I don't think antibodies from the blood can cross the blood lung barrier in any significant amount?

You invoke “transudation” as a mechanism for enormous large molecules to cross the blood lung barrier because some scientist (Wagner) 33 years ago used that word. But since you want to invoke that word as proof that antibodies can cross the blood lung barrier, would you approve a grant for a company that was developing a new 150,000 Dalton brain antibiotic drug, although typically the blood brain barrier is truly a barrier for molecules greater than 500 Daltons in weight, as long as they reference “transudation” as the mechanism whereby their new drug crosses the blood brain barrier?

Your (and Dr. Fauci’s) grave mistake in reasoning may affect millions of Americans negatively. You are allowed mistakes in thinking “it’ll rain today”. No one counts on you for that and the farmer won’t sue you when you’re wrong about that statement. But, you and Dr. Fauci are Directors of Infectious Disease at the NIH. People expect more reasoning power when you are dealing with issues that directly impact billions of people.

The NIH has access to billions of dollars. If you, Dr. Erbelding, had simply said,

“very interesting, wow. Hmmm…. I can’t seem to find an article showing how antibodies cross the blood lung barrier. Ah, I found one… but it’s not very enlightening and it’s 33 years old, so that doesn’t help me much. And the author uses the word ‘transudation’ but then he says ‘passive transudation’ which says he doesn’t know of an active transport system. He could have just said, ‘passive diffusion’. Fascinating, did no one look into this? Really? I rarely ever have to make real decisions because most issues are vetted well before it ever hits my desk. I’m shocked but yes, of course, this is the very essence of our ‘neutralizing antibody’ theory for how vaccines work for respiratory viral disease. I’ll call the companies right away and see if their scientists are aware of this issue. I’ll allocate $1 million for this project and put my interns to work on it tomorrow. Thank you so much for raising those questions and I’ll update you when I find out more.”

But, sadly, you didn't. If in fact you both knew your reasoning was faulty and you both are in on this because of profits in your investments in these companies, shame on you both. You and Dr. Fauci will have plenty to answer for and a multitude of questions to answer from the average American that you want to stick the vaccine to, to fellow researchers, to your higher ups including Dr. Collins.

If hundreds of thousands of people all over the world suffer potentially permanent side effects, because of your lack of scientific curiosity and open-mindedness, how will you reconcile the lack of adding a proper critical control to the study, in light of this 70 plus page document? Because in every court of law where you and Dr. Fauci are sued for the side effects patients potentially needlessly suffered from the COVID vaccine, this detailed document will surface and your explanation of how antibodies cross the blood lung barrier, invoking the single word, "transudation", will not be acceptable. Everyone will look at you curiously and ask you to explain "transudation". And will you reply "transudation" is "transudation"?

Let's put the COVID-19 vaccine back where it belongs, in the arena of BASIC SCIENCE RESEARCH. This is how it works in science, is it not? If you don't have a hypothesis, you don't have anything to test. Again, your one word, "transudation", is NOT a hypothesis. Once we have a hypothesis and we test it and it seems to work and other people can verify our results and the theory and data are vetted and many bright minds can debate it, then as time goes, it becomes a theory that is accepted and moves out of the basic science arena and even becomes used as medication. The COVID-19 vaccine is not there. There is potentially a "fatal flaw" in the COVID vaccine paradigm. You seem to agree that the current paradigm has issues. You agree that you are borrowing the flu vaccine industry theory on how respiratory vaccines result in neutralizing antibody in the blood that then traverses the blood lung barrier and neutralizes viruses in the alveolar sac before those viruses can infect alveolar epithelial cells. You didn't vet the theory. You borrowed it. Dr. Fauci was annoyed at the British scientists for not being so thorough. Well, they didn't have the information I provided you and Dr. Fauci.

The Merriam-Webster medical dictionary definition of “transudation” is “the act or process of being transuded”. The definition of “transudate” is “a transuded substance”. The definition of “transude” is “to pass through a membrane or permeable substance”. So, the one word that you believe prevents a potential “fatal flaw” in the “neutralizing antibody” paradigm is “transudation” invoked by you. That one word, “transudation” is all that stands between the COVID vaccine having legitimacy or you recommending reversal of the FDA approval of the COVID vaccine. Since the one paper you described as having a mechanism showing how antibodies cross membranes is authored by Wagner (1987) and since he doesn’t shed much light on that word “transudation” except to imply that it’s a passive process, I looked up the word in a medical dictionary and it means to “pass through a membrane”. My explanation in my email of September 27, 2020, stated my concerns with the question of “how do neutralizing antibodies cross the blood lung barrier?” The exact quote from your email reply to me was (words in parenthesis below are mine),

“antibodies from blood plasma cross the blood-air interface (blood lung barrier) and enter the BAL fluid (lung) through a process called transudation”

or per Webster’s definition, I’ll replace the word “transudation” with Webster’s definition of “transudation” which is “passing through a membrane”, so now your email reply is,

“antibodies from blood plasma cross the blood-air interface (blood lung barrier) and enter the BAL fluid (lung) through a process called passing through a membrane”.

Or just a summary of your one sentence,

Antibodies pass through blood lung barriers through a process called passing through a membrane.

Almost sounds scientific. Your word “transudation” and your flawed understanding of the word “transudation” let the COVID vaccine be FDA approved.

Version 6.0 Vaccines Role in Herd Immunity

The public did not know that there will never be herd immunity. Herd immunity relies on specific COVID neutralizing antibodies preventing a COVID infection in the lung. That isn't possible if the "neutralizing antibody" has no clear path into the lung.

Yes, the elderly are at much higher risk. For those at risk, do we really think 6 feet is the answer? Maybe the correct answer is 60 feet or 600 feet or 6000 feet. Since there will never be herd immunity, what now? We need much more stringent measures for people at risk and everyone else has to be given freedom to live their lives. Without a "neutralizing antibody" in the lung, COVID infections cannot be prevented. If COVID infections cannot be prevented with a vaccination, vaccinations cannot contribute to "herd immunity". The goal post of "herd immunity" is not scientific if there is no path for the "neutralizing antibody" to enter the lung. There is no goal. If a "neutralizing antibody" can't pass through the blood lung barrier, there will never be "herd immunity" from mass vaccinations. If this is so important to your public policy, please state scientifically what you think "herd immunity" is and if it includes an individual being more resistant to infection, shouldn't you be able to explain scientifically how you believe an individual is more resistant to infection? If you can't, there is no "herd immunity". If you include "neutralizing antibody" in the lung as part of your scientific explanation, you need to provide references to show the transport mechanism that allows "neutralizing antibodies" in the blood to be transported across the blood lung barrier into the alveolus where the lung epithelial cells are being infected. If there is no possible way for an individual to become more resistant to infection, there will never be "herd immunity". Then, what excuse do you have to keep the economy closed? And aren't you providing misinformation to elderly people who receive vaccines and giving them a false sense of security which may increase their rates of COVID infection and death? Do you see how having a correct understanding of reality is what science is, and not one that is based on false hope?

Dr. Fauci, you continued to talk about “herd immunity” even after I sent my first email to you (the email that Dr. Erbelding responded to for you). You must have seen the data that I provided. Can you provide a definition of “herd immunity”? Doesn’t it mean resistance to COVID-19 infection due to a prior COVID-19 infection or a COVID-19 vaccine that in either case presumably generates specific “neutralizing antibodies” in that person? And that this “neutralizing antibody” drastically reduces the chance of COVID-19 infection which then reduces the rate of spread of COVID 19 within a community? But, if this “neutralizing antibody” can barely make its way into the lung, what does your “herd immunity” even mean?

If there is a village of 300 and COVID-19 infects every person and 30 people pass away, then if a COVID-19 wave comes the following year and infects every person again, very few people will die during the next wave. This is NOT “herd immunity”. That is a population that is able to handle COVID-19. The population of 300 prior to the first wave of COVID-19 and the population of 270 after the first wave of COVID 19 are distinctly different populations. But you see how the vaccine data can “look good” if it is given after the 30 people pass away since the 270 are much more capable of handling the virus even if they were never given the vaccine. I do not believe that you have a working theory for “herd immunity” if the only paper you can cite me for how IgG antibodies from the blood end up in the alveolus is a paper that is 33 years old.

Version 7.0 (One reality, two contradictory facts, both cannot be correct)

Consistency in any worldview is important. There is a reality. Within that reality, if two facts are contradictory, only ONE of those facts can be correct. Some paradigms are consistent within themselves but don't match reality. Not so helpful, but easy to make fun of. Other paradigms more closely match reality and are consistent within themselves. Isn't this what we strive for as scientists?

Will the human body listen to Dr. Fauci because of his 30-year history as NIH Director of infectious disease? Just because Dr. Fauci wants the human body to use the antibody to heal us from COVID-19 infections, does anyone really believe the human body will listen to him? The human body did not need to listen to him as it healed well over 18 million Americans without an antibody around (it could have been 60 million Americans).

Politicians like Cuomo who say mindless things like "every life is sacred", who advise the rest of us to "follow the science", who do not know a thing about science, looked to the infectious disease experts and their wrong negative perception was not corrected. Based on the prior email detailing the blood lung barrier issue, it would have been apparent to the average infectious disease expert that the "neutralizing antibody" paradigm was in trouble and that the vaccine might never be able to prevent COVID-19 infections if the neutralizing antibody cannot get into the lung. There is no apparent obvious path for the "neutralizing antibody" to travel from the blood where it is formed to the alveolus where the infections are occurring. It has been stated hundreds of times in this email and will be stated again; there is not a single published scientific paper in a reputable journal that describes an active transport system that transports IgG antibodies from the blood side of the blood gas barrier to the alveolar side of that barrier. If this concern ends up being correct, there can be no "herd immunity" from vaccines. "Herd immunity" relies upon "neutralizing antibodies" in the lung that prevent infection and the corollary is prevention of spread of infection to other individuals. The only reference Dr.

Erbelding provided was a 33 year old paper that described IgG antibodies going from the blood into the nasal mucosa as a “passive transudation”. A passive process would reduce the amount of antibody passing through the blood lung barrier to less than approximately 1% of the serum concentration, assuming simple laws of diffusion, which is a passive process. A “neutralizing antibody” level in the lung of less than 1% of serum concentration is highly unlikely to be able to prevent infection.

The country was advised to not return to “normal” until we reached this “goal post” of “herd immunity”. If it is agreed that currently it is unknown if there is an active transport system to move “neutralizing antibodies” across the blood gas barrier from the blood side to the alveolus side, there can be no prevention of COVID-19 infections based on vaccines, and since “herd immunity” relies on prevention of infections with the goal of preventing spread to other individuals, “herd immunity” isn’t possible if the “neutralizing antibodies” aren’t in the lung; the stark conclusion to draw would be that public policy was based on “faulty science”.

So we should never return to “normal” since we will never reach “herd immunity”?

If COVID-19 was as serious as Ebola, public policy in 2020 may have been appropriate. But within a few months of the covid pandemic, it was apparent that healthy young individuals could handle COVID-19 easily. Okay, let’s crunch some numbers. There were 300,000 COVID-19 deaths in 2020. Doctors and hospitals often misrepresent for profit, so let’s reduce this to 200,000. Also, since 60,000 influenza deaths normally occur in the U.S. annually but since COVID-19, no influenza deaths were reported, and a very safe assumption is that very few influenza deaths will be reported over the next 5 years, only subtracting two years of influenza annual deaths (120,000) is fair and now the number is 80,000 COVID deaths for the year 2020. Divide that by 12 months, and we are at 7,000 deaths a month from COVID in the year 2020. On average, 250,000 Americans die every month (300 million Americans die every 80 years). Adding COVID deaths, now it is 257,000 Americans that died every month in 2020, instead of 250,000. No one is

disputing that life is sacred. Yes, human lives are important. But that doesn't seem to be a huge jump, from 250,000 to 257,000.

Can we discuss whether 7000 5-year-old deaths is a more grave situation than 7000 75-year-olds? What 75 year old grandparent would not give their life for their 5-year old grandchild? Would we ever expect the reverse? I will say that if each year of human life is sacred, then a 5-year-old has 75 more sacred years of life to live. A 75-year-old has 5 more sacred years of life to live. So, isn't the conclusion that there are more sacred years of human life in a 5-year old versus a 75-year old? Cuomo's gift to America was an unwillingness to crunch the numbers from his one statement "every life is sacred". It truly set America back.

Keeping America closed based on "faulty science" definitely caused a lot of human misery too, based on the misrepresentation of the seriousness of COVID-19. The mortality rate for COVID-19 was thankfully much less than SARS CoV-1. Within a few months, it was apparent that COVID-19 had a mortality rate of at most 1% and possibly much less. SARS CoV-1 had a mortality rate approaching 9%, and much higher for the elderly. Lives are important and avoiding a lot of human misery is important too. Making statements such as "every life is sacred," prevents proper analysis. Would we really save ten 90-year-old lives by spending $200 million, which with the same amount of money could prevent hunger and suffering for 2 billion people? To say "every life is sacred" prevents appropriate analysis and prevents correct decision making which can lead to nonsensical public policy. Consistency again is important. When a statement like "every life is sacred" is made, shouldn't appropriate questions be asked as a follow up? The person who makes a statement like this, is likely to judge any follow up question and the hearer of this statement understands that asking follow-up questions puts the questioner or challenger of this statement into the unfortunate position where others believe the questioner does not believe every life is sacred. It is a most thoughtless statement for that reason. The first question to ask once a brainless statement like this is made is, if we had limited resources (which is reality) and we could only save one

person between two sacred lives, a 5-year-old healthy child or an 80-year-old semi senile grandfather, who would we use our limited resources on?

There were 300,000 COVID deaths last year (no adjustments will be made). Assuming average age at death last year from COVID was 76 and that typical age of death is 79. So, 300,000 deaths last year and since they would have on average lived 3 more years, multiplying the two, that is 900,000 human life years that were lost last year. Let's say my assumption of average age at death from COVID of 76 years old is incorrect so I'll change this assumption to average age of death for the 300,000 COVID deaths last year to 69 years old. Now, they had 10 more years to live. So, 300,000 COVID deaths in 2020 multiplied by 10 years of life is 3,000,000 human life years that were lost in 2020.

Let's crunch some other numbers. Take alcohol deaths. 100,000 alcohol related deaths in 2019. Average age I'll guess is 45. Then, they have 35 years more to live that they didn't live because they died early. So, each year in the US, we lose (35 years multiplied by 100,000 alcohol deaths) 3.5 million human life years to alcohol. If we close 1.7% of our economy (alcohol total revenue), we save 3.5 million human life years ANNUALLY. By trying to close 50% to 100% of our economy last year for COVID-19, let's say we saved 1,000,000 people who had 3 more years to live since COVID-19 is especially hard on the elderly, then we saved 3 million human life years.

(Yes, Governor Cuomo, life is sacred. Get rid of alcohol. You will save a lot more "sacred lives" if you get rid of alcohol in the U.S. than how you managed COVID-19. Your blanket statements about how every "life is sacred" shows that you're not doing the simple math to see if what you're saying actually makes any sense.)

I did tell you that my last email was sent out to 100 senators. I am taking this quite seriously, since we're dealing with millions of lives being affected. You are responsible for setting all this brainless activity in motion (Governor Cuomo

brainlessly brandishing his non-sense, claiming he is following “the science”) by the medical leadership’s lack of understanding of the complex relationship between humans and pathogens.

Since every life is sacred, and we should all do everything we can even if it only helps very little (mask wearing), and since we can save 3 million human life years by sacrificing only 1.6 percent (total alcohol revenue in U.S.) of our economy, are we all in agreement that we eliminate alcohol again in this country, Prohibition 2? I am sure my arguments will go right over Governor Cuomo’s head. Consistency within a paradigm that matches reality is FAR more useful than providing fake comfort. Your lack of reviewing my critical questions with an open mind back in September of 2020 had a butterfly effect that bankrupted many small businesses and restaurants and made life miserable for many American people.

Here’s a most interesting hypothetical analysis of the year 2010. Everyone knows at least a few friends that get the flu every year. Let’s say that’s 10 million Americans got the flu in 2010, a reasonable number. That’s only 1 in 30 of your friends. I’m going to guess that typically 95% of people under 50 who get the flu just sweat it out at home. But, let’s say 5 million (of the 10 million who got the flu) decide to go to the hospital this hypothetical year because they all of a sudden all panic. In the U.S., our elderly often pass away in nursing homes and hospitals. Nosocomial infections are a huge under-advertised problem for hospitals. Hospitals are also full of elderly patients who also happen to be sick which is why they are in the hospital. Now, this hypothetical year, 2010, 5 million young people who got the flu decided they needed to be admitted to hospitals. The rates of spread of flu in hospitals is now drastic and every hospital is fully contaminated with the influenza virus and huge numbers of in-patients (elderly who are admitted for other reasons but who clearly are also at high risk of dying from influenza if exposed) are suddenly all exposed to influenza and a “bad flu” year just became the flu year from hell. Typically 60,000 to 70,000 pass away of the flu annually, and typically elderly. But this hypothetical year, 300,000 elderly pass away of the flu because 5 million young

flu patients decided to go to the hospital and the number of elderly influenza deaths soared compared to previous years.

Interesting? Governor Cuomo and nursing homes. Dr. Fauci and hospitals? A Governor sending elderly COVID patients to nursing homes and a Director sending young COVID patients to hospitals? An infectious disease expert aware of the issues of nosocomial infections who absentmindedly sent young healthy COVID infected people into hospitals to infect the elderly sick who are the majority of hospital admissions? Did Dr. Fauci panic a bunch of young people who went to hospitals and spread COVID-19 even more, to the very people who are at greatest risk? The elderly who are sick? A Governor that rambles and an 80-year-old Director of Infectious Disease.

History repeats itself. In the SARS outbreak of 2003, about 9% of patients with SARS died. The mortality rate for the age group over 60 approached 50%. Among the seven coronaviruses that spread easily and infect humans, SARS-CoV-1 had by far the highest mortality rate at 9% and SARS-CoV-1 again taught us (just like influenza) that the elderly were at much higher risk. Within a few months, it became clear that COVID had a much lower mortality rate than 9% but that, similar to SARS CoV-1, the elderly had a high mortality rate. Some of the young non-medical people with agile brains seemed to have concluded this, as they even participated in "COVID parties". They would not have participated in SARS parties and definitely would not have had "Ebola parties". It was becoming fairly apparent that COVID was not nearly as fatal as SARS-CoV-1, but that the elderly were still at high risk, not unlike influenza. Publicly acknowledging these facts, that COVID had a much lower mortality rate than Ebola or SARS-CoV-1, but that the elderly were still at high risk and focusing on educating the public about these facts would probably have saved many more lives; but the continued non-stop negative news panicked many of the more easily frightened young healthy individuals who acquired COVID, who then went to ERs around the country and drastically increased the spread of COVID to those who were by far most at risk, the elderly who were already hospitalized for

other illnesses. No special knowledge of epidemiology or innate immune biochemical pathways was necessary to marshal America's medical staff correctly to avoid exposing our most vulnerable to our infected youth (who had an extremely low mortality rate from COVID). It would be extremely interesting to know how many deaths in hospitals were actually admitted with COVID versus the total number of hospital deaths due to COVID.

Please do not assume that I don't believe human life is sacred. I understand evolutionary biology well enough to know how incredible the human body is. And how precious every human is. And how marvelous the human body is. Yet, we didn't arrive here from the first primordial cell because of lack of pain and suffering. We all arrived here because of diversity in every generation from when we were one-celled life forms 4 billion years ago, past aquatic life, through the hundreds of millions of years of being mammals. Diversity saved us. That some people die of COVID-19 is sad and tragic. But we do have 250,000 deaths every month in the U.S., and those are all sad and tragic also. It is the human condition (and it's far from the plague). Dr. Fauci, would you rather we all be identical? Then a single virus could potentially wipe out humanity. Isn't it better that we are diverse and varied? Isn't the more appropriate way to put it is that our diversity in our human genome is what protected humanity from various pathogens? Isn't it more appropriate to appreciate the diversity of the ones who passed away from COVID 19, and some day in the future, it may be our turn also? I'm all for considering them heroes. I am in no way saying that those who died young of COVID-19 are inferior or bad or evil and that we are stuck in a "survival of the fittest" mode. Isn't the best way to save lives from COVID, a more accurate understanding of how 18 million Americans healed themselves in about a week (without antibodies by the way)? I am in no way saying we should not try to save more lives. Do not pretend to be on the moral high ground if you are not willing to completely back elimination of alcohol from the U.S., which would save more sacred and young lives than you are saving with your non-scientific recommendation to keep restaurants closed. But, you understand what I am saying. You're a doctor and you've studied medicine and

infectious disease. The average person does not have the same scientific background as you. So, shouldn't you have presented it the proper way? That it is very sad and tragic. That we are working on therapeutics. But that thank GOD it isn't Ebola or SARS-CoV-1 which we knew within 3 months. That it could have been SO MUCH WORSE. I'm really curious what you were thinking, Dr. Fauci. Didn't you watch all those pandemic movies? Did COVID-19 look anything like those movies? Truly, any respiratory viral disease that over 99% of human infants can handle easily cannot be a reason to shut down half our economy. And, to truly help those at risk, we face reality and not hide behind some fake hope of vaccines achieving "herd immunity" for us. Open-mindedness, ability to analyze the data correctly, isn't this what truly saves lives? Sending young healthy panicking COVID patients to hospitals full of elderly sick patients, does that save lives? If you are the inspector of life vests and you are aware that there is a high potential of the life vests being severely defective (and may only work for a few minutes), aren't you potentially putting many lives at risk? Am I the whistleblower trying to save lives and are you the one putting more human life at risk? You wouldn't go to a superstitious witch doctor to save lives, because a correct understanding of reality is always the safer bet. Let's approach this the scientific way.

The first primordial cell 4 billion years ago was able to handle the RNA viruses, if those early cells didn't figure it out, we wouldn't be here. Those cells used something like our ribonucleases that cut up RNA. Millions of people all over the world are recovering from COVID-19 and the main mechanism is this and does anyone talk about it? Why is it that you're always promoting vaccines and antibodies but never once mention the main enzyme which without, not one person on earth would have recovered from COVID-19? You were so focused on antibodies (for most of your life) and now everyone talks about antibodies partly because of your influence. Do you know what other strategy those first primordial cells used? They decreased protein production. Why? Because if the ribonucleases have more time to cut up the viral RNA before it becomes viral protein, then the cell wins the war. Did you really believe that if your precious

“neutralizing antibody” did not stop the virus from injecting its RNA into a lung epithelial cell, that the infected cell would have to die? Ribonucleases are the most abundant enzyme on earth. Ribonucleases are the most underappreciated enzyme on earth. Ribonucleases are the reason anyone and everyone who recovered from COVID recovered (I hope you know why the Pfizer vaccine has to be stored at such a low temperature). Ribonucleases are everywhere. Ribonucleases are on your phone, on your fingers, in the dust. Every cell on earth that has DNA is busy cutting up RNA with its ribonucleases. Every insect, every plant, almost every life form you have ever seen is all day every day busy using ribonucleases to cut up RNA, our own too. We cut up our own RNA and we cut up any viral RNA that happens to come in. Incredible isn’t it? The inefficiency was startling to me. For weeks, I could not comprehend the magnitude of this inefficiency. Yet, if cells didn’t do this, they would all die. But nevertheless the inefficiency is startling. EVERY CELL ON EARTH that has DNA including cockroaches, algae, plants, animals, humans, we all cut up RNA with ribonucleases nonstop. The inefficiency is startling. Yet, without it, we would all be dead, because RNA viruses would take over our cellular protein making processes.

Not a single complex feedback loop in our body would exist without ribonucleases to cut up RNA. For example, if my blood sugar goes to 180, I need insulin protein. That means I need to make insulin RNA, then I make insulin protein and my blood sugar goes to 100. But what happens if my cells were not cutting up RNA with ribonucleases? My insulin RNA wouldn’t be cut up. I would keep producing insulin protein since my insulin RNA was still available and my blood sugar would go to zero and I would be dead. Every feedback loop in our body needs an off signal. The main “off” for RNA is to cut it up with ribonucleases. You see how we need ribonucleases to turn off our RNA? Every feedback loop in human cells (all cells) needs an OFF mode. Cutting up the RNA with ribonucleases is that OFF mode. If the temperature in my room is 80, I want 30 minutes of cold air. I don’t want 3 weeks of cold air. But we aren’t creatures made of steel and plastic; we are made of fragile and degradable proteins and organic molecules. Our most important “off”

switch, our “universal” off switch for every RNA we ever transcribe from our DNA, is comprised of ribonucleases that degrade RNA.

So, RNA viruses put that first primordial DNA cell, our ancestor, on the path to complexity. Without the RNA virus, those primordial cells may not have had the urgency and need to cut up RNA with ribonuclease type enzymes. The RNA viruses actually put that first primordial cell using DNA as information 4 billion years ago that was our ancestor, on the path to complexity. Incredible, isn’t it? I’m not certain I am correct, but it does make a lot of sense, and I wasn’t around 4 billion years ago, so I’m only guessing. But, it seems to make sense. So, who or what created us? What put us on the path to complexity? RNA viruses. Did we humans evolve in the presence of sunlight? Yes. We need sunlight. Did we evolve in the presence of water? Yes. And we need water. Did we evolve in the presence of RNA viruses? Yes. And we need them.

We have 8 slightly different ribonucleases, maybe even more. Can they still mutate? We got here because of mutations and just because we’re sentient and conscious and super complex now does not mean we will stop mutating. So, yes of course our ribonucleases can still mutate. Is it possible that someone is genetically unlucky and they inherit 3 mutated defective ribonucleases from their mom and 4 mutated defective ribonucleases from their dad? Yes. Then they will only have one functional ribonuclease (and they will have other chronic illnesses). Will that create problems for them in handling RNA viruses? Yes, of course. Humans mainly handle RNA viruses such as COVID-19 with RIBONUCLEASES. And will those unlucky few who have so many defective ribonucleases also have other chronic illnesses? Yes, of course. And they will have trouble cutting up the RNA from RNA viruses such as COVID-19. What put those first primordial cells on the path to complexity that is now us? RNA viruses and because of these RNA viruses, the need for all cells that are DNA-based to constantly cut up RNA, the virus RNA and THEIR own RNA. If the cell is cutting up viral RNA with ribonucleases, the cell also has to cut up its own RNA. One might say that RNA viruses created humanity. And what does the RNA

virus do for us today? We evolved in the presence of sunlight and we need sunlight today. We evolved in the presence of RNA viruses, RNA viruses may have put us on the path to complexity, and RNA viruses may have a maintenance role in aiding humanity today. It is the circle of life. Just because as humans we evolved to this point, this level of complexity, this level of intelligence, this level of awareness, it is patently false that we will no longer have mutations within our genetic code. We will continue to undergo mutations, including mutations within our at least 8 separate ribonuclease genes. So, what role does the RNA virus play for humanity today? It helps keep our mutated ribonucleases to a minimum. Do we just leave those with defective ribonucleases to die? Absolutely not. But understanding why they die is the best way for us to develop therapeutics to help them, is it not? And understanding the human bodies mechanisms used to heal 18 million Americans from COVID-19 without an antibody helps us develop ways to facilitate the body, does it not? But, we don't shut down the country for them either. "Every life is sacred"? Remember the "bubble boy"? Wasn't his life sacred? Did we close down the country for that dejected boy? Again, to me human life is incredibly sacred. I am always amazed at the incredible complexity of all carbon-based life. But our response must be commensurate with the severity of the illness. 100% shutdown for an Ebola type virus (50% mortality for all) makes sense. From there, adjust accordingly, correct? In our next pandemic, the Director of Infectious Disease will know not to panic young healthy individuals who acquire the next respiratory virus (especially once we realize the total mortality rate is 1% or less and that the mortality rate is much higher for the elder, both facts very likely to be true) since panicked young infected patients who go to hospitals will drastically increase the spread of the "next" respiratory virus.

Don't you believe that public policy should match the severity of the pandemic? Do you really believe that teenagers would have had "Ebola parties"? And we all want to protect our elderly parents and grandparents who are over 65 and at higher risk, but there were many ways of doing that without trying to keep everyone at home.
Sending terrified young patients with COVID-19 to the hospital created a bigger

nightmare for the elderly sick, did it not? In the future, when politicians, scientists, and physicians look back at how COVID-19 was managed, without a doubt your recommendations will be analyzed and criticized and ultimately numbers will win; and they will adjust language so brainless politicians like Governor Cuomo can't make irresponsible statements that prevent proper problem solving and thought. Dr. Fauci, you disappointed America and in wanting to manage a pandemic once during your 30 year term, your negativity may have actually drastically increased the number of COVID deaths by panicking and thereby sending millions of young healthy COVID infected patients into hospitals full of our elderly sick; if this was the case, there was never a more classic case of a "self-fulfilling prophecy". If it is later determined that the true mortality rate even with your negativity was less than 1% overall and that the mortality rate drastically increased with age as with influenza and SARS CoV-1, the post-mortem on your job performance will conclusively show that your negativity and lack of leadership surely contributed substantially to the total death rate.

This is not eugenics. Eugenics is when an extremely dumb small-minded man with a thick mustache thinks he knows who should live and who should die. This is nature. I am not saying they should all die. I am saying a correct understanding of reality will help even those at risk of dying of COVID much more. I am saying we are not going to stop mutating as humans because we have reached this level of awareness and intelligence (not all of us).

This is a delicate matter and you needed to find a delicate way to present it to the public. Unfortunately, your fixation on antibodies prevented a proper analysis of the issues at hand. 20 million Americans test positive for COVID-19 last year and a very safe guess of 15 million recover within 10 days, well before IgG antibodies formed. You are ignoring how ridiculously large numbers of Americans healed without a significant IgG antibody presence. If you want to say that IgM antibodies are created early, well then let's see your active transport system for an IgM antibody that is 5 times larger than an IgG antibody across the blood lung barrier. As a gentle

reminder, the size limit for a molecule for passage through the blood brain barrier is approximately 500 Daltons. An IgG antibody is approximately 150,000 Daltons. An IgM molecule is 5 times larger than an IgG molecule. Let's not have you pretend that you think IgM molecules can also pass through the blood lung barrier by a process called "passing through the barrier". Your extremely serious case (maybe hopeless case) of confirmation bias prevented you from even assessing the potential fatal flaw in the current "neutralizing antibody" paradigm I emailed to you last year. You thought it was your "my precious" antibody that had to stop this virus. Even if it was unscientific. You did not mention Ribonucleases in any of your public appearances. You mentioned antibodies and vaccines thousands of times. But, the one molecule that we wouldn't be here without, that put us on the path to complexity, that was the main reason that everyone on earth who recovered from COVID actually recovered, did not get a mention, not even in passing. You are clearly showing favoritism to your "pet" antibody molecule. So. We got here after 4 billion years from the first primordial cell. We didn't need masks throughout. Suddenly we need all sorts of stuff. The truth? Can you handle the truth? Can you handle reality? Influenza has been killing 50 to 100,000 Americans a year for the past 80 years for sure. That's well over 4 million deaths. COVID-19 and influenza combined will be about the same number after the first few years since there is probably going to be a huge overlap in human vulnerability to these two viruses. Science will later show that the ones at risk should be 600 or 6000 feet away from the rest of us, not 6 feet. You see how science works? From a correct understanding of reality with a paradigm that doesn't ignore barriers. Inconsistencies are a huge red alert sign. If someone is death to me, truly 6 feet and two masks won't do it. I would want to be 6000 feet away from death. Isn't understanding reality more useful than having the potentially false hope of your vaccine that might actually cause more death?

You think we can achieve herd immunity. But you can't even define what it means or you won't put it down on paper. Because if you explain the actual mechanism of "herd immunity" in the human body, I will scientifically dissect it until there's nothing

left, not unlike your “neutralizing antibody” paradigm that you can’t let go of even when I’m presenting “real science” to you. Do you see, if you understand reality correctly and how the human body is resolving a COVID-19 infection, you can facilitate the human body to do a little better what the human body is already doing amazingly well. For example, not eating protein is probably going to help infinitely more than your vaccine, if it is shown your “neutralizing antibody” in fact can’t make it across the blood lung barrier into the lung. Starting with the correct paradigm is what would have allowed you to come up with better solutions.

Any pattern of behavior that is preserved in 99% of the population of 7 billion people on earth is preserved genetically because it provides a very significant advantage in survival. Every one of us, all 7 billion people on earth, when we were 2 years old and came down with a viral illness, 99% of us as infants, got fussy and ate much less. Why? Because we are descendants of human infants from 500,000 years ago that also did not eat much when infected with a virus. The human infants 500,000 years ago that liked to eat when infected with a respiratory virus were much more likely to die and because they died of the viral illness, are not our genetic ancestors. So, we are ALL descendants of those human infants from millions of years ago that DIDN’T like to eat much when infected with a virus because that behavior of reducing protein and calorie intake during a viral illness drastically improved the chances of overcoming a viral illness. I know the correct mechanism behind this, but it clearly appears that you do not, or you would have told the world by now. The world will want to know why you non-stop promoted antibodies and vaccines (despite my describing the potential fatal flaw with your “neutralizing antibodies” paradigm). Is it because you want to sell your vaccine every year to every American for the next 100 years?

Any public official who is in the position of approving billions of dollars for companies applying for grants for the last 30 years, I would have to question their motives. Most people in a democracy feel twinges of guilt when they are in a position of power for over 15 years and quietly leave the spotlight. Some stay for 30 years. Not because

they are competent and a seeker of truth. Again, it is only my opinion, but no one who was in a position of power for 30 years will be able to convince me that they did it for the American people. Because, if you are looking out for the American people, there are thousands of infectious disease experts who know much more than you do right now and even 15 years ago.

Version 8 (Personal plea to Dr. Collins)

Dr. Collins,

You probably will not remember me, but you were my genetics professor in medical school. I don't know the policies of the NIH. But, it seems to me incredibly non scientific and non-democratic to have a director of any division at the NIH for 30 straight years. Isn't there some kind of testing every few years? I am sure there are hundreds of infectious disease experts in the U.S. that are more qualified than Dr. Fauci currently. His ignoring of my grave concerns regarding the current paradigm for the vaccine is now putting millions of Americans at risk. Don't you agree that there are currently a minimum of hundreds of infectious disease experts that are more qualified than Dr. Fauci?

Let's imagine a "Scenario A" where my alternate hypotheses are not examined and researched, and the COVID-19 vaccine continues to be pushed onto the American people. In a fictitious country of 300 Americans, COVID-19 infects all 300 Americans. 30 people die. The other 270 Americans recover. Six months later, a COVID-19 vaccine is given to the 270 Americans who survived. The following year, all 270 Americans again infected with COVID but this time only 3 people die of COVID. The following years, COVID is still endemic but only 1-3 Americans die annually. The COVID-19 vaccine is now "proven" and every year all 270 Americans must be vaccinated to prevent another "pandemic". There will never be a scientist who can challenge the efficacy of this vaccine and even 30 years later, everyone will still receive the COVID-19 vaccination every year. COVID vaccines are mandated and the pharmaceutical industry makes $60 billion a year on both COVID and FLU vaccines.

Let's repeat this scenario and call it "Scenario B" but this time without a COVID-19 vaccine. In a country of 300 Americans, COVID-19 infects all 300 Americans. 30 people die. The other 270 Americans recover. Six months later, a COVID-19 vaccine is developed but a serious flaw is discovered and it is not rolled out. The following year, all 270 Americans again are all infected with COVID but only 3 people die. See, this is NOT "herd immunity". These people can definitely be infected again and again with COVID, but they can HANDLE it. The following years, COVID is still endemic but only 1-3 Americans die annually. COVID vaccines are not given to anyone and the pharmaceutical companies don't make the extra $60 billion a year on COVID and FLU vaccines.

Do you see how the population of 300 Americans before COVID (population before) and the population of 270 Americans after everyone was infected with COVID (population after) are different? If someone is infected with COVID and shakes it off like a mild flu, what are the chances that that same person if infected with COVID again will die from the second infection? Close to zero? Especially close to zero if they reduce protein and calorie intake during their illness.

Dr. Collins, do you see why you are the only one in a position to stop this potential madness or at least recommend revoking the COVID vaccine FDA approval until the proper critical ontrol that I have recommended is added to a repeat clinical trial? I don't know much about Dr. Fauci except from his interviews and I don't have any other information on him but just knowing that Dr. Fauci has been in his position for 30 years, doesn't he have too many financial reasons to want this "Scenario A" to play out? His lack of ability to assess rationally the issues I raised regarding the potential "fatal flaw" in his "neutralizing antibody" paradigm appears to be a hopeless case of confirmation bias. But, truly, do we really expect more open-mindedness from an Director who has held this same position for 30 years and is now 80 years old?

If in fact Dr. Fauci didn't heed my warning concerns and let the COVID vaccine be approved without vetting the concerns I raised, and if in fact there is not an active transport system for "neutralizing antibodies" to cross the blood lung barrier, then Dr. Fauci should do what he should have done over 15 years ago, resign from his position. He is the chief inspector of potentially defective life-vests and knowingly approved the potentially defective vests (in spite of my dire warning) and in essence was willing to put tens of thousands of lives at increased risk of death (if vaccinated people think they have protection from infection, they may alter their behavior and take increased risk), either from incompetency or corruption. Dr. Fauci, the NIH Director of Infectious Disease did not act like he knew what he was talking about. So, why is he in his position? He did not know that "herd immunity" would only be possible if his "neutralizing antibody" was in the lung to prevent an infection. When I brought up the potentially fatal flaw of there NOT being a clear path for his "neutralizing antibody" to cross the blood lung barrier into the lung alveolus, which is where the "neutralizing antibody" needs to be in order to prevent an infection, shouldn't he have immediately recognized the magnitude of this problem and the threat to his "herd immunity" paradigm? It's not like he's the Director of Community Service for some little town. With great power comes great responsibility and hard questions from people. His words and attitudes regarding Covid 19 meant a lot to Americans, because of his expertise in the field. Do I care what President Trump said about COVID? Not really, he isn't a scientist. Do I care about what Dr. Fauci says? Yes, he's the NIH Director of Infectious Disease.

If it is ultimately demonstrated that there is NOT an active transport system across the blood lung barrier for Dr. Fauci's vaccine derived "neutralizing antibody", this will be a very public demonstration of a medical paradigm shift (in the understanding of human respiratory viral infections and the cellular mechanisms responsible for recovery from viral infections) and a most egregious display of lack of scientific curiosity on Dr. Fauci's part. Again, it is hard to disparage Dr. Fauci too much for his lack of open-mindedness, he might be set in his ways and not open to challenging questions that disrupt his favored paradigm. But I will not apologize for being harsh

in questioning him for his incompetency. Too many important policy decisions were made based on his negativity and millions lost their jobs and their businesses and their life-savings due to his terribly negative portrayal of COVID-19. Later, many post-mortems will be performed on his job performance and I highly doubt they will be more generous than my assessment.

Also, based on what currently appears to be a more accurate understanding of the mechanisms the human body uses to actually recover from COVID-19, I have developed a therapeutic and I will apply for NIH grants. I doubt Dr. Fauci will be supportive since it is in direct competition with his favored “vaccine” approach. The current paradigm (neutralizing antibodies) does not even attempt to explain how the almost 20 million Americans (who tested positive for COVID in 2020) actually recovered. The alternate paradigm that I have not fully disclosed here also explains how the 20 million Americans recovered from COVID-19 last year. It is easier to facilitate what the human body is doing so well when there is a correct understanding of the biochemical reactions and mechanisms the human body actually used to heal 18+ million Americans from COVID in 2020. The “neutralizing antibody” paradigm can’t be invoked to explain the 18+ million Americans that recovered from COVID in 2020 because antibodies weren’t present for at least 2 week and antibodies don’t have a known path into the lung.

I will call the 18+ million Americans who recovered in 2020 in about a week to 10 days as “my research study” since no one else seems to want to claim it. Imagine if I did a blood test for COVID antibodies on each of these 18+ million Americans on day 1 of their respective illness, repeated a blood test for COVID antibodies on day 7 of their respective illness, noted that 90% were well on their way to recovery. Then, in “my research study”, I will have proved that “COVID neutralizing antibodies” were not a significant player in 18+ million Americans who recovered from COVID. But, that is in essence what happened. We are sure that 99.9% of Americans did not have COVID antibodies at the beginning of their illness or at day 7 of their illness. Dr. Fauci’s hopeless confirmation bias prevented him from seeing this glaring

inconsistency. When houses burn down, there is always ash present. But, did the ash stop the fire? If you sprinkle these ashes on an intact structure, will the house not burn down because of the ash? In fact, there aren't always antibodies after a COVID infection. The Stanford data actually showed that mild cases of COVID often had NO COVID antibodies form. Based on Dr. Fauci's "neutralizing antibody" paradigm, one would think that patients who developed a higher level of antibodies would have had an easier COVID course, when the Stanford data showed that patients who had a low or non-existent antibody level actually had a much milder COVID clinical course, in direct contrast with a "neutralizing antibody" paradigm.

Grant funding for my companies Phase 2 and Phase 3 FDA clinical trials would be proportionately more difficult to obtain for my proposals given that Dr. Fauci is so deeply entrenched in the current paradigm. Dr. Fauci was wrong about the usefulness of antibodies and vaccines for HIV and that embarrassment may have only increased his resolve that a COVID vaccine must be the answer for this pandemic. His conviction in the certainty of the current paradigm has led him to in effect disqualify my extremely serious letter to him describing the potential "fatal flaw" in the incumbent paradigm, the blood lung barrier, given that it might undermine his current paradigm. He in essence tried to dismiss the evidence I provided by using a single word "transudation" as a "mechanism" for how extremely large IgG antibodies cross the formidable blood lung barrier.

If 300 million Americans potentially must be vaccinated with the COVID vaccine annually for potentially decades, shouldn't the underlying paradigm be sufficiently solid so that a single surgeon can't stumble upon such a massive potential flaw in the paradigm? Isn't this the ultimate oversight, not having a path for the "neutralizing antibody" from the blood to traverse the blood lung barrier and so unable to be present in the alveolus where the virus is infecting the lung cell? If my concerns are correct, my heart-felt apologies to Dr. Erbelding if I was a bit harsh in this letter. But, if my concerns are correct, I will wish I had been much more critical of Dr. Fauci by a factor of a 100.

Dr. Collins, you will also be a part of medical history on this largest of stages, if it is later shown that there is no active transport mechanism for IgG antibodies to cross the blood lung barrier, there will be a paradigm shift in understanding how humans resolve respiratory viral infections. . . and Dr. Fauci and his “neutralizing antibody” will be nowhere in sight.

Dr. Collins. To not take action based on this 70+ page letter may also result in increased deaths from COVID-19. There is not a close doctor friend I have who has listened to this “alternate paradigm” compared to the “neutralizing antibody” paradigm who doesn’t share my concerns. Yet, they all firmly believe that I will not be able to influence the NIH or FDA sufficiently to have the FDA recall the COVID vaccines (the reason for 70 pages). Political pressure and scientists’ grant funding and resistance to change are often mentioned. I am more hopeful and apparently naively trust science and scientists more than I should. Please do not let me lose my faith in science and scientists. I trust that rational scientists will approach my grave concerns rationally and draw similar conclusions. I gave up religion because of science. I was always in the search for a more true understanding of reality and I was convinced that science was by far the most impressive tool. You are highly regarded and your assessment of my 70 page letter will definitely go far in persuading the FDA to recall the vaccine. Most scientists will agree that given this new information, requesting further research is rational and it will be hard for any group to find fault with a decision to recall the COVID vaccine and request an additional control in the next COVID vaccine clinical trial.

My hope is that the questions I have asked and the presentation of this issue was persuasive enough that the conclusion is foregone. I have had many discussions over the past 6 months with my mentor, Dr. Peter McDonnell (Director of Ophthalmology at Johns Hopkins), regarding this issue and he was as astounded as anyone else can be at the nature of the “false positives” provided by “neutralizing antibodies” generated from vaccines. Dr. McDonnell was at Johns Hopkins as a

medical student when the idea of bacteria potentially being responsible for duodenal ulcers first came to light and he remembers the closed-mindedness of the doctors at the time in response to those ideas. “Paradigm shifts in medicine happen one funeral at a time”, he explained to me many times recently as he quoted one of his mentors. With COVID-19, we do not have that amount of time. Our children are having their youth stolen with a misunderstanding of these respiratory viruses from our medical leadership. Small business owners are going belly-up in droves. We have all learned to download the latest software updates, although we have all experienced headaches from the process. Let’s download one of the best and brightest infectious disease experts into the NIH Director of infectious disease and allergy position. Let’s bring these concerns to the FDA so we can stop providing potentially defective life-vests which can end up actually harming or even killing more Americans.

You have been the Director of the NIH during the “replication crisis”. If my concerns are validated, research on respiratory vaccines will have been reproducible for the wrong reasons, even more misleading than the average “false positive” research results. If the results of these COVID vaccine clinical trials are not re-examined, in spite of the thorough rational discussion over these 70 pages, then the honest, hard working, insightful, truly truth-seeking researchers will be more discouraged and disheartened. I know your reputation is one of utmost integrity. Yes, I understand this will be difficult. But, when two-thirds of researchers believe that reproducibility in published claims is a major problem, don’t we have to make that sure our science reflects reality?

I am again stating that I am presenting my concerns. I would much appreciate if the U.S. government would provide me protection from lawsuits from these biotech companies and individuals for the concerns I present here. I liberally used the word “potential” and I state again that it is up to the reader to verify any facts that they believe I present here.

Again, however impressive this logic is in exposing a potentially massively flawed "neutralizing antibody" paradigm for respiratory viruses, the therapeutic I have discovered is many times more impressive and with the proper funding I can initiate Phase 2 clinical trials in a matter of a few short months. The government spent well over $20 billion on these COVID-19 vaccines that are relying on a potentially "fatally flawed" paradigm. With a $20 million grant, I can advance this new therapeutic to Phase 2 FDA trials within a few months and it can potentially treat every current and new strain of Influenza and every current and new strain of COVID. The government's return on their $20 billion investment into a COVID-19 solution will be a complete loss if it turns out that the blood lung barrier can prevent IgG "neutralizing antibodies" from crossing it and if it turns out that the good current COVID vaccine clinical trial results are due to activation of the innate immune system. But, with this addition $20 million in funding, there may be an inexpensive commercially available therapeutic for all strains of influenza and all strains of COVID within 6-8 months from time of funding. So, then, the $20 billion that the government allotted for a COVID-19 solution will have expanded to much less than $21 billion and the solution will potentially be a treatment for most respiratory viruses, even for future pandemics.

I love America. My parents' homeland is South Korea. I have learned that any homogenous society inherently limits challenging ideas and limits freedom to think even on a social level, often even without understanding that it is occurring. The diversity and celebration of diversity in America allowed my questioning nature to evolve and develop. I know that. If I have uncovered a massive flaw in the current respiratory vaccine paradigm, it is because of the diverse environment America provided for me. If I am wrong, then no foul. But I am certain that even if I am wrong, there will be scientific advancement because of the questions I have raised and a better understanding of the mechanisms behind respiratory vaccines. If my concerns actually expose a massive flaw, then I have benefited Americans and given back to the country that allowed this freedom of thought (and speech),

freedom to question and freedom to challenge established systems (I hope without getting myself killed or audited to death).

Dr. Collins, I look forward to meeting you in person (again),

Joseph Lee, M.D.
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www.lungvirus.com

p.s. (I am a huge “hitchens” fan, rip; I know you were a good friend to him) ©

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References

1. Jounai, Nao et al. “Recognition of damage-associated molecular patterns related to nucleic acids during inflammation and vaccination.” Frontiers in cellular and infection microbiology vol. 2 168. 8 Jan. 2013, doi:10.3389/fcimb.2012.00168

2. Roh, Jong Seong, and Dong Hyun Sohn. “Damage-Associated Molecular Patterns in Inflammatory Diseases.” Immune network vol. 18,4 e27. 13 Aug. 2018, doi:10.4110/in.2018.18.e27

3. Goulopoulou, Styliani et al. “Toll-like Receptors in the Vascular System: Sensing the Dangers Within.” Pharmacological reviews vol. 68,1 (2016): 142-67, doi:10.1124/pr.114.010090

4. Jensen, Søren, and Allan Randrup Thomsen. "Sensing of RNA Viruses: a Review of Innate Immune Receptors Involved in Recognizing RNA Virus Invasion." Journal of Virology, Feb 2012, 86 (6) 2900-2910; doi: 10.1128/JVI.05738-11

5. Ansel, K Mark. “RNA regulation of the immune system.” Immunological reviews vol. 253,1 (2013): 5-11. doi:10.1111/imr.12062

6. Enzo Maxim Scutigliani, Marjolein Kikkert. "Interaction of the innate immune system with positive-strand RNA virus replication organelles." Cytokine & Growth Factor Reviews, Volume 37, 2017, Pages 17-27, ISSN 1359-6101

7. Nelson, Jennifer et al. "Impact of mRNA chemistry and manufacturing process on innate immune activation". Science Advances 6. 26(2020), doi: 10.1126/sciadv.aaz6893

8. Pardi, N., Hogan, M., Porter, F. et al. "mRNA vaccines — a new era in vaccinology." Nat Rev Drug Discov 17, 261–279 (2018). https://doi.org/10.1038/nrd.2017.243

Appendix A (Dr. Lee September 2020 email to Dr. Fauci)

Joe Lee <josephlee@lungvirus.com>
To:anthony.fauci@nih.gov,execsec1@od.nih.gov,gary.gibbons@nih.g
ov Cc:amy.wernimont@nih.gov
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heal y@latimes.com
Sun, Sep 27, 2020 at 9:08 PM
To Drs. Anthony Fauci,
Francis Collins,
Gary Gibbons and
Amy Wernimont.

Dear Madam and Sirs,

The information contained in this email has also been sent to the President and all members of Congress by certified mail and email.

In one of the potentially largest blunders in the history of modern medicine, it appears that not a single researcher has EVER actually investigated and published HOW any neutralizing antibody (produced as a result of a vaccine for a respiratory virus) enters the lung.

If the questions posed below are indeed valid, then NOT a single COVID-19 vaccine produced by any company on earth will EVER work, but still with all the potential side effects of vaccines. It can never be ethical to provide the public with a vaccine that has little to no benefit, but all the side effects including seriously debilitating and potentially permanent issues. Imagine the potential avalanche of plaintiff lawsuits if it comes to light later that the questions posed here are in fact valid.

I am a practicing ophthalmologist in Los Angeles. I was a student of Dr. Francis Collins (Genetics) in medical school at the University of Michigan in 1989. I completed a refractive surgery fellowship under Dr. Peter McDonnell (1998, USC) who is currently the chair of the Ophthalmology Department at Johns Hopkins; he has been in regular contact with me regarding this issue for weeks and is equally stunned, amazed and appalled.

Please review ASAP.

Urgently,

Joseph Lee, M.D.
e signature
/joseph lee/

Contact:

Joseph Lee, M.D.
josephlee@lungvirus.com

COVID-19: HIGHLY SENSITIVE DATA

"Whistle-blower" concerns

Buena Park, CA - This is extremely CRITICAL information regarding any potential COVID-19 vaccine. There may be reason to believe that the current medical paradigm regarding development of a COVID-19 vaccine is based on false assumptions.

In basic terms, the lung is like an air-filled balloon. Red blood cells and antibodies exist on the outside of this balloon membrane and lung epithelial cells are on the inside of this membrane. The lungs cannot work effectively if filled with fluid so obviously this "balloon" lung membrane is fairly watertight. How large is a water molecule versus an antibody molecule? For perspective, an antibody molecule is 36 times larger than a water molecule. If the lung "balloon" membrane barrier can effectively prevent water molecules from passing through, why would that strong, tight barrier allow antibodies to easily pass through?

If a water molecule cannot easily pass from the blood side of the lung to the epithelial cell side of the lung where the infections from the covid virus are taking place, how would an antibody molecule be able to traverse this "blood lung barrier"? This barrier concept is NOT new.

Any upcoming COVID-19 vaccine assumes that a covid antibody formed in response to an intramuscular injection of a covid antigen results in a covid neutralizing antibody. For the antibody to neutralize a covid virus particle, the antibody must be at the site of the lung epithelial cell infection. HAS ANY RESEARCHER SHOWED HOW THE ANTIBODY PASSES THROUGH THE BLOOD LUNG BARRIER? I have not found a single published schematic showing the path of the antibody from the capillary to the alveolar epithelial cell surface. An antibody molecule is only effective if it can reach the surface region of the epithelial cells that are at risk for infection, which is on the OTHER side of the "blood lung barrier".

After consulting with many physicians and researchers regarding my findings, they unanimously have grave concerns regarding the astounding lack of vetting for the current antibody paradigm. Can a single researcher at any of these covid vaccine companies articulate how the “neutralizing” antibody reaches the lung epithelial cell space? Drugs are only approved when it is shown they achieve therapeutic levels at the site of action. Why would antibodies be exempt from this very basic principle?

It is highly unlikely that any COVID-19 vaccine researcher will be able to state a credible explanation that adequately addresses these grave concerns. No one disagrees that a neutralizing antibody in the blood will neutralize COVID in the blood. But the lung is the site of most of the devastation and it appears the neutralizing antibody has no path to the lung alveolar epithelial cell area. If the current medical paradigm is faulty, then very bright minds all over the world will re direct their efforts appropriately which can only help in the fight against COVID.

I can’t accept that millions of Americans and others around the world might be subjected to a COVID vaccine with little to no efficacy while risking harmful, even potentially permanent and dangerous side-effects. My oath as a physician to “do no harm” obligates me to warn the public of any potential risks. I want to emphasize that I have never been anti-vaccine, prior to this. This stark warning is strictly limited to respiratory virus vaccines.

My sincere hope is that scientists and physicians continue to value intellectual integrity. If the current medical paradigm on how our bodies heal from a respiratory virus is wrong, isn’t it better to know and fully vet the current paradigm?

Regarding liability for this letter and any facts presented, I encourage due diligence in efforts to evaluate any statements I have made. I offer, simply, my own opinion. My primary objective is to protect the health and well-being of the American people.

I clearly have much more information pertaining to this topic than can possibly be relayed in this notice. I am very willing to provide additional information, as requested.

Appendix B (Dr. Erbelding's references)

1. Yu, J., Tostanoski, L.H., Peter, L., et. al. 2020. DNA vaccine protection against SARS-CoV-2 in rhesus macaques. Science; 369 (6505): 806-811.
2. van Doremalen, N., Lambe, T., Spencer, A., et. al. 2020. ChAdOx1nCoV-19 vaccine prevents SARS-CoV-2 pneumonia in rhesus macaques. Nature.
3. Guebre-Xabier, M., Patel, N., Tian, J.H., et. al. 2020. NVX-CoV2373 vaccine protects cynomolgus macaque upper and lower airways against SARS-CoV-2 challenge. bioRxiv.
4. Wagner, D.K., Clements, M.L., Reimer, C.B., et. al. 1987. Analysis of immunoglobulin G antibody responses after administration of live and inactivated influenza A vaccine indicates that nasal wash immunoglobulin G is a transudate from serum. Journal of Clinical Microbiology; 25 (3): 559-562.
5. Jackson, L.A., Anderson, E.J., Rouphael, N.G., et. al. 2020. An mRNA vaccine against SARS-CoV-2 – preliminary report. The New England Journal of Medicine. 6. Anderson, E.J., Rouphael, N.G., Widge, A.T., et. al. 2020. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. The New England Journal of Medicine.
7. Keech, C., Albert, G., Cho, I., et. al. 2020. Phase 1-2 trial of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine. The New England Journal of Medicine.
8. Folegatti, P.M., Ewer, K.J., Aley, P.K., et. al. 2020. Safety and immunogenicity of the ChAdOx1nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomized controlled trial. The Lancet; 396 (10249): 467-478.
9. Sahin, U., Muik, A., Derhovanessian, E., et. al. 2020. COVID-19 vaccine BNT162b1 elicits human antibody and TH1 T cell responses. Nature.
10. Walsh, E.E., Frenck, R., Falsey, A.R., et. al. 2020. RNA-based COVID-19 vaccine BNT162b2 selected for a pivotal efficacy study. medRxiv.
11. Jones, B.E., Brown-Augsburger, P.L., Corbett, K.S., et. al. 2020. LY-CoV555, a rapidly isolated potent neutralizing antibody, provides protection in a non-human primate model of SARS-CoV-2 infection. bioRxiv.
12. Meredith Wadman. 2020. Eli Lilly reports promising first results for an antibody against COVID-19. Science.
13. Baum, A., Ajithdoss, D., Copin, R., et. al. 2020. REGN-CoV2 antibodies prevent and treat SARS-CoV-2 infection in rhesus macaques and hamsters. Science. 14. Matthew Herper. 2020. Regeneron's COVID-19 antibody may help non-hospitalized patients recover faster, early data show. Stat News.