Report Concerning Dr. Charles Hoffe and the Citation Issued July 19, 2023

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Background

I am Board Certified in Internal Medicine, Pulmonary Diseases, and Critical Care Medicine and am a former Associate Professor, Chief of the Critical Care Service, and Medical Director of the Trauma and Life Support Center at the University of Wisconsin. To date, I have published over 50 peer-reviewed papers, 17 book chapters, and served as senior editor of an award-winning textbook now published in its 2nd edition and translated into 7 languages. I have never had any malpractice claims or patient complaints.

I am also the founder and Medical Director of a private telehealth practice opened in February of 2022 called the Leading Edge Clinic (drpierrekory.com), which is solely focused on treating patients with COVID and its complications including “long haul” and post-COVID-mRNA vaccine injury syndromes.

I have led ICU’s in multiple COVID-19 hotspots throughout the pandemic, the first being Mount Sinai Beth Israel ICU in New York City during their initial surge in May 2020 for 5 straight weeks, I then travelled to other COVID-19 hotspots to run COVID ICU’s in Greenville, South Carolina and Milwaukee, WI during their surges. I have co-authored over ten influential papers on COVID-19 with the most impactful being a paper that was the first to support the diagnosis of early COVID-19 respiratory disease as an organizing pneumonia, thus explaining the critical response of the disease to corticosteroids. I have also published over 15 Op-Ed’s in major news outlets in the U.S and I write for a medical Blog called Medical Musings where I have almost 80,000 subscribers.

I also am the Co-Founder, President, and Chief Medical Officer of the Front Line COVID-19 Critical Care Alliance, a non-profit organization of critical care specialists led by Professor Paul Marik whose mission has been focused on the research and development of effective treatment protocols for COVID-19 using repurposed drugs.

I am most known for my U.S Senate Testimony calling attention to the critical need for corticosteroid use in hospitalized patients in May 2020 and then again in December of 2020 on the efficacy of ivermectin in early outpatient prevention and treatment of Covid. Most recently, based on my extensive research with the FLCCC, I became one of the most sought-after experts on the use of ivermectin. My book, “The War on Ivermectin” has achieved best seller status at times in multiple book categories on Amazon in the U.S, Canada, Australia, and the UK.

My CV attached as Appendix A.

A brief summary of accomplishments from my CV:
I have a BA in Mathematics from University of Colorado, Boulder in 1994
I have a MA in Public Health Administration from New York University, 1996
I have an MD from St. George's University, Grenada 2002

From 2008-2015 I was a Teaching Attending at Beth Israel Medical Center in New York City.
From 2012-2015, I served as the Program Director of the Pulmonary and Critical Care Fellowship at Beth Israsel Medical Center.
From 2015-2020 I was the Chief of the Critical Care Service at the University of Wisconsin where I also served as the Medical Director of the Trauma and Life Support Center.
Since 2020, I have been the President and Chief Medical Officer of the Front Line Covid-19 Critical Care Alliance
Since 2022, I have been the Chief Medical Officer of The Leading Edge Clinic

I was considered one of the world pioneers in the use of ultrasound by physicians in the diagnosis and treatment of critically ill patients. I helped develop and run the first national courses in Critical Care Ultrasonography in the U.S. and served as a Director of these courses with the American College of Chest Physicians for several years. I am also the senior editor of the most popular textbook in the field titled "Point of Care Ultrasound," a book that is now in its 2nd edition and that has been translated into 7 languages worldwide. I led over 100 courses nationally and internationally teaching physicians this now-standard skill in his specialty.

I was also one of the pioneers in the United States in the research, development, and teaching of performing therapeutic hypothermia to treat post-cardiac arrest patients. In 2005, my hospital was the first in New York City to begin regularly treating patients with therapeutic hypothermia. I then served as an expert panel member for New York City's Project Hypothermia, a collaborative project between the Fire Department of New York and Emergency Medical Services that created cooling protocols within a network of 44 regional hospitals along with a triage and transport system that directed patients to centers of excellence in hypothermia treatment, of which my hospital was one of the first.

I am known as a Master Educator and have won numerous departmental and divisional teaching awards in every hospital I have worked and I have delivered hundreds of courses and invited lectures throughout my career.

In collaboration with Professor Paul Marik, I also helped pioneered the research and treatment of septic shock patients with high doses of intravenous ascorbic acid. My work was the first to identify the critical relationship between the time of initiation of IV Vitamin C therapy and survival in septic shock patients, an aspect of the therapy that led to understanding all the failed randomized controlled trials that employed delayed therapy.

EXPERT OPINION

I acknowledge correspondence from you dated November 3, 2023, asking me to formulate an independent professional opinion concerning the safety and effectiveness of ivermectin as a treatment and prophylaxis for SARS-CoV-2 (Covid-19), as well as the science regarding Covid 19 vaccine "shedding".

You have asked me to comment on the opinion expressed by the "expert", Dr. Trevor Corneil, relied upon by the College concerning these issues in his report dated September 26, 2022, specifically in sections 6.4, 6.5 and 6.10 of his report.

I am aware of my duty to assist the panel and I am not an advocate for any party. I have prepared this report with this in mind and am happy to testify in any setting to address questions regarding the matter.

I attach as Appendix B, a copy of your letter of instruction, including the list of documents which I have reviewed in forming my opinion.

Further, you asked me to refer to paragraphs 3a and 3c of the Citation and paragraph d, and e. of the Particulars and the Joint Message so I could be informed about what the College and our government officials have had to say about these issues.

Response To Section 6.4 of Dr. Trevor Corneil Expert Opinion

My first comment on Dr. Corneil's report is that he carefully defines the following terms: "misleading", "incorrect", "inflammatory" and then judges Dr. Hoffe's statement in relation to meeting the definitions of each term above. He then follows each statement's characterization according to these terms with his opinion as to whether Dr. Hoffe's statements meet the College's "Prudence and Harm Prevention" standards.

Similarly, for the below expert report, understanding the arguments I put forth requires knowledge of the word "disinformation." The Oxford English dictionary definition is "*a form of propaganda involving the dissemination of false information with the deliberate intent to deceive or mislead.*"

Understanding my below expert opinion and how I arrived at it also requires the knowledge that disinformation has been long deployed by select corporations across a range of industries. In the article called "The Disinformation Playbook" written by the Union of Concerned Scientists, they write, "corporations manipulate science and scientists to distort the truth about their products, using a set of tactics made famous decades ago by the tobacco industry. We call these tactics the Disinformation Playbook."

An important point to understand about disinformation tactics is that corporations deploy them when "science emerges that is inconvenient to their interests." The Disinformation Playbook was first developed in the 1950's by the Tobacco Industry to scientifically counter the emerging reports of greatly increased incidences of cancers in smokers. They successfully used disinformation for 50 years until the Master Settlement in 1995 with the US Attorney Generals of 50 states.

As one of the world experts in the use of ivermectin in the prevention and treatment of Covid-19, my first review paper called "Review of the Emerging Evidence Demonstrating Efficacy of Ivermectin in the Prevention and Treatment of Covid-19" is one of the most popular published

scientific papers of the last 15 years with an altmetric score ranking it the 10th most popular paper out of the last 25 million papers published.
Based on my intensive study of the ivermectin evidence base, including in-vitro, in-vivo, clinical and epidemiological studies, the evidence for efficacy is overwhelming, with, as of today, January 10, 2023, results available from 100 controlled clinical trials, 47 of them randomized, with meta-analysis data finding statistically significant, large magnitude reductions in mortality, hospitalization, time to clinical recovery, and time to viral clearance.

However, Dr. Corneil, along with numerous public health agencies and professional societies across the world's advanced health economies consistently ignore or systematically dismiss and distort the evidence of efficacy based on the widespread "opinion" that the evidence base represents "low-quality" evidence that should not be relied on. This is a well-known Disinformation tactic called "the Diversion" where the pharmaceutical industry co-opts 3rd party agencies and organizations to "manufacture uncertainty where little or none exists."

The reasons for the Disinformation campaign against ivermectin are multiple. First is that knowledge of ivermectin's efficacy in both prevention and treatment would have led to the revocation of the EUA supporting the massive mRNA vaccine market and the global vaccination campaign and would also increase what public health authorities perceived as the #1 enemy in the pandemic, that of "vaccine hesitancy." A third reason is that knowledge of ivermectin's efficacy would greatly decrease profits from the competing, patented, highly profitable Covid medicines such as remdesivir, paxlovid, and molnupiravir.

From the article, "The Disinformation Playbook" they name and define five Disinformation tactics. The most prominent disinformation tactics deployed against ivermectin have been extensively documented in my book called "The War on Ivermectin." The tactics described from their 2017 article are as follows:

1) using fraudulent studies designed to achieve pre-determined results.
2) censoring the publication of positive studies in prominent medical journals
3) selectively publishing only negative studies in prominent medical journals
4) harassing scientists who speak out with results or views inconvenient for competitors of ivermectin.
5) using front groups and 3rd party organizations to "manufacture uncertainty where little or none exists."
6) Buying credibility through alliances with academia or professional societies
7) Manipulating government officials or processes to inappropriately influence policy.

For the purposes of this report, I will focus mostly on the first three tactics above which has led to widespread false beliefs regarding ivermectin.

Statement (d). Dr. Hoffe stated in an interview with Laura-Lynn Tyler Thompson, video of which was posted online on or around July 6, 2021, at 20:45 – 21:23:

"*...There are brilliant, very, very safe, very effective treatments for Covid, and for the medical authorities to tell them that they have to go home and do nothing is is utter negligence. ... And for people to say that it is it is safer to do nothing than to take something like ivermectin, which*

is unbelievably safe – I mean, in many countries, it's available without prescription, I mean it's safer than aspirin, it really is safer than aspirin, um, so it is absolutely absurd [inaudible] that this is being denied from people".

In Dr. Corneil's assessment of the accuracy of Dr. Hoffe's statement, he concludes the following in regard to the use of ivermectin to prevent or treat Covid-19:

1) Prior and current evidence strongly suggest that Ivermectin is neither a safe nor effective treatment or prophylaxis for COVID-19 illness. A meta-analysis published in April 2021 urged caution as available trials investigating the use of ivermectin for prophylaxis against COVID-19 exhibited a serious risk of bias and imprecision.141 A Cochrane systematic review conducted in July 2021 noted that the reliable evidence available did not support the use of ivermectin for treatment or prevention of COVID-19.142 Recently, a double blind randomized clinical trial of over 1400 patients observed that administering ivermectin did not prevent the occurrence of serious outcomes, hospitalizations or death from COVID-19.143 The World Health Organization issued a recommendation on March 31, 2021 against the use of ivermectin for patients with COVID-19, regardless of disease severity, except in the context of a clinical trial.144 On Oct. 19, 2021, Health Canada issued a public advisory not to use ivermectin to prevent or treat COVID-19.145

I will now explore the selective evidence that Dr. Corneil relied on to reach those conclusions.

IVERMECTIN IN THE PREVENTION OF COVID-19

a) Dr. Corneil writes, "A meta-analysis published in April 2021 urged caution as available trials investigating the use of ivermectin for **prophylaxis against COVID-19** exhibited a serious risk of bias and imprecision."
b) To support this statement he cites a meta-analysis in the BMJ from April of 2021 (Bartoszko et al) which included only 2 randomized controlled trials of ivermectin in prevention of Covid. He also cites a Cochrane review which included only one RCT that Bartoszko included.

The first observation I will make is that Dr. Corneil relied on only two RCT's only to form this opinion when there are 4 that have been conducted. Second, he appears unaware of the evidence showing that both the BMJ and Cochrane review of prophylaxis trials are examples of the disinformation tactic called "the Fake," i.e. "using fraudulent studies designed to achieve pre-determined results."

The most brazen evidence that these papers were attempts to reach a "pre-determined result" is that the BMJ paper was published three months before the Cochrane review and included two RCT's while Cochrane only included one. There were two available at the time of the Cochrane review, Seet et al and Shouman et al. Why would they ignore one of the RCT's?

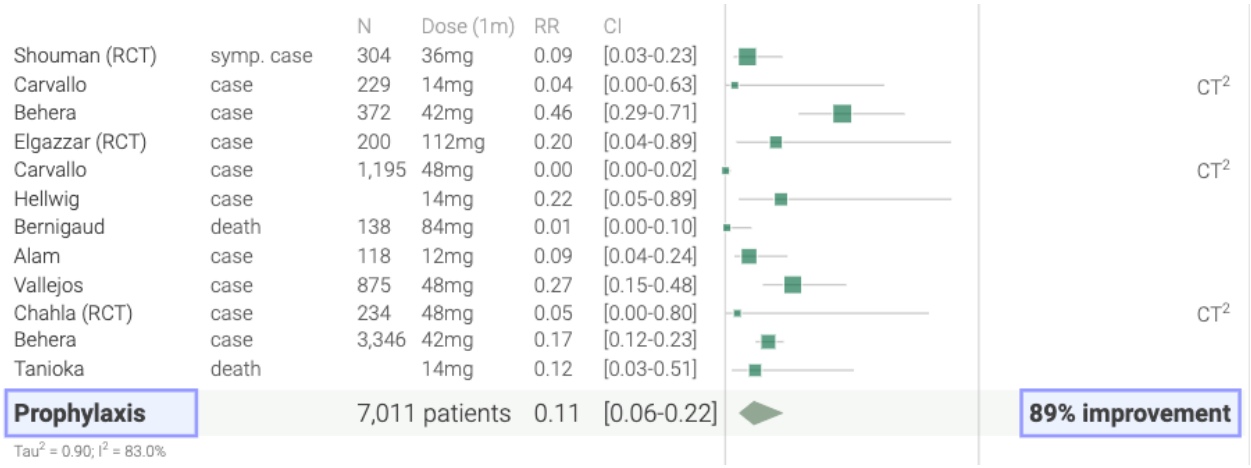
Further evidence of fraud (bolded) can be seen in the abstract of the Cochrane review which states:

We found one study. Mortality up to 28 days was the only outcome eligible for primary analysis. *We are uncertain whether ivermectin reduces or increases mortality compared to no treatment (0 participants died; 1 study, 304 participants; very low-certainty evidence). The study reported results for development of COVID-19 symptoms and adverse events up to 14 days that were included in a secondary analysis due to high risk of bias. No study reported SARS-CoV-2 infection, hospital admission, and quality of life up to 14 days.*

The first two sentences are provably false. First there was more than one RCT available which studied ivermectin in prevention.

Second, in the one study they included, the primary outcome was the development of Covid-19 symptoms, not mortality. Instead that paper reported that the incidence of Covid-19 symptoms was 7.4% in those prophylaxed with ivermectin and 58.4% with standard of care. This was a very large magnitude and highly statistically significant reduction in risk of developing Covid symptoms, yet Cochrane reported it as being negative for an incorrectly stated primary outcome of mortality. The large, statistically significant numerical reduction in risk of contracting Covid is not mentioned.

Similar evidence of fraudulently ignoring the evidence base for ivermectin as a prevention of Covid can be found in the WHO Living Guideline for ivermectin, published March 31, 2021 where they stated in Section 3.1, "**While ivermectin is also being investigated for prophylaxis, this guideline only addresses its role in the treatment of COVID-19".** I believe the College should ask themselves why the WHO, in the midst of a global pandemic, would refuse to look at the evidence base for ivermectin as a preventative? Especially since the evidence base at that time (screenshot taken March 31, 2021 from the internet archive of ivmmeta.com):



As you can see above, there were results from 3 RCT's available, all finding large magnitude, statistically significant reductions in the risk of getting Covid. Further, there were 7 other observational controlled trials (I excluded the "ecological" trials). I must note that the Elgazzar trial above was later retracted (this was a disinformation tactic which I am happy to provide

evidence of separately if asked), however, other RCT's finding similar benefits subsequently replaced his trial in the evidence base.

Why were observational controlled trials excluded from the BMJ, Cochrane, and WHO analyses?

I maintain that excluding OCT's is a form of disinformation in that OCT's can be done for little to no funds by independent investigators free of pharmaceutical conflicts of interests. The known and explicit bias of the massive funders of large RCT's are generally not present in OCT's. This is why the pharmaceutical industry and it's high-impact medical journals have increasingly avoided publishing OCT's in the last decade.

For support of my statement above that "Big Pharma" exerts immense influence of our most respected medical journals, I will reference the book written in 2001 by the former 20-year editor-in-chief of the New England Journal of Medicine (NEJM), Dr. Marcia Angell (she was also the first woman to serve in this role). The book is called *Drug Companies & Doctors: A Story of Corruption.*

A well-cited statement of Dr. Angell is

"*It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor."*

Dr. Relman, another former editor-in-chief of the NEJM said this in 2002:

"The medical profession is being bought by the pharmaceutical industry, not only in terms of the practice of medicine, but also in terms of teaching and research. The academic institutions of this country are allowing themselves to be the paid agents of the pharmaceutical industry. I think it's disgraceful."

Richard Horton, editor in chief of the Lancet said:

"The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and ***flagrant conflicts of interest****, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness"*

More damning is that there is no evidence to support this growing practice of systematically excluding OCT's from systematic reviews and meta-analyses. In fact, it is in violation of evidence based medicine (EBM) given that it willfully ignores decades of research which have found, on average, that OCT's and RCT's reach the same conclusions.

From the definitive Cochrane review on this topic, the authors conclude that "Factors other than study design *per se* need to be considered when exploring reasons for a lack of agreement between results of RCTs and observational studies." Further, prominent professional societies have issued policy statements to reverse this practice by concluding, from their analyses of controlled trial

designs, that "*observational studies should be considered in developing clinical practice guidelines and in making clinical decisions*." Lastly, until Covid, the WHO routinely relied on more diverse sources of data and trial designs to inform their treatment recommendations.

Further, another astonishing violation of EBM is the repeated insistence that "low quality" trials be ignored. The reality is that there is no published evidence that I am aware of that finds that "low quality" controlled trials reach different conclusions than "high quality" controlled trials. In fact, there is only one paper I know of which compared the conclusions of what current EBM grading systems determine is low quality and high quality. In that paper, they found that low-quality and high-quality trials also reach the same conclusions on average.

Thus, it is my strongly held, evidence-based opinion that the systematic ignoring of both OCT's and "low quality trials" are instead fraudulent efforts to create the myth that only "Big RCT's" that require massive funding can determine "scientific truth" or "scientific consensus."

In the below expert opinion, I will show provide extensive evidence that the bias of the funders of those "big RCT's" essentially determine the results of the RCT's and those results are then used to establish a fraudulent "scientific consensus." This occurs when the "real science" I described above reaches conclusions that are "inconvenient to the interests of the pharmaceutical industry." I suspect that many members of the Royal College of Physicians and Surgeons are unaware of how rife disinformation is, or of the studies I just presented regarding the soundness of non-RCT derived evidence.

In contrast to Dr. Corneil and the numerous professional society recommendations he cites, many independent experts like me have, in line with this knowledge of the equivalence of OCT findings and RCT findings and high quality and low quality trials, chosen to rely upon a "totality of the evidence standard" and include data from OCT's and supposed "lower quality" trials. This practice is the most adherent to the foundational principles of Evidence Based Medicine (EBM). Recall that in the 1980s, responding to the need to overturn entrenched dogmas with scientific evidence, Gordon Guyatt coined the term "evidence-based medicine," (EBM). Then in 1996, David L Sackett, published a widely cited article defining exactly what EBM was: the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

Notice how Sackett does not define current best evidence as "RCT's only":

"By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from **patient centered clinical research** into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.

Put differently, Sackett, proposed that three different considerations that needed to be weighted equally in evidence based clinical practice:

•Patient Values
•Clinical Expertise
•Relevant Research

In terms of relevant research, the summary analyses of the prevention trials found a highly statistically significant 88% reduction in your chance of getting Covid, far outperforming what we know now of the efficacy of the Covid mRNA vaccines. Yet, the agencies and societies across the world all ignored the OCT's and included only a subset of the RCT's, and in the case of Cochrane, mis-stated its findings and their importance. The WHO ignored the evidence base entirely in their ivermectin recommendation.

It is my professional opinion that these actions were willfully committed as a disinformation tactic to "arrive at a pre-determined result", which is to find that ivermectin is ineffective in preventing Covid-19 for the reasons I stated above.

In support of Dr. Hoffe's statement, the College should be aware that the evidence base for ivermectin in the prevention of Covid includes: 14 controlled trials including 18,799 subjects of which: 4 are RCT's, 2 are propensity score matched trials (PSM – which rival RCT's in accuracy), and 8 are OCT's. Each one of the 14 trials which studied ivermectin in prevention of Covid-19 found large benefits in reducing risk, and in 13 of the 14, the benefits were highly statistically significant.

In the RCT's alone:

i. Shouman et al: 91% reduction in the incidence of getting Covid, p<.001, 304 patients
ii. Chahla et al: 95% reduction in the incidence of getting Covid, p=.002, 234 patients
iii. Seet et al: 74% reduction in risk of getting Covid , p=.008, 1,236 patients
iv. Desort-Henin et al: 72% reduction in the incidence of Covid, p<.001, 399 patients).

In the propensity score matched trials:

i. Kerr et al:44.5% reduction in the incidence of Covid, 67% reduction in risk of hospitalization and 79% reduction in risk of death, p values all less than .001. Study included 6,068 patients.
ii. Morgenstern et al: 74% reduction in the incidence of Covid, 80% reduction in risk of hospitalization

In the observational controlled trials:

iii. Carvallo et al: 96.3% reduction in risk of Covid, p <.001, 229 patients
iv. Behera et al: 54% reduction in risk of Covid, p<.001, 372 patients
v. Carvallo et al: 100% reduction in risk of Covid, P,.001, 1,195 patients
vi. Bernigaud et al: 99% reduction in risk of Covid, p<.001, 3,131 patients
vii. Alam et al: 91% reduction in risk of Covid, p<.001, 118 patients
viii. Behera et al: 83% reduction in risk of Covid, p<.001, 3,346 patients
ix. Mondal et al: 87.9% reduction in risk of Covid, p=.006, 1,470 patients
x. Samajdar et al: 79.8% reduction in risk of Covid, p<.001, 245 patients

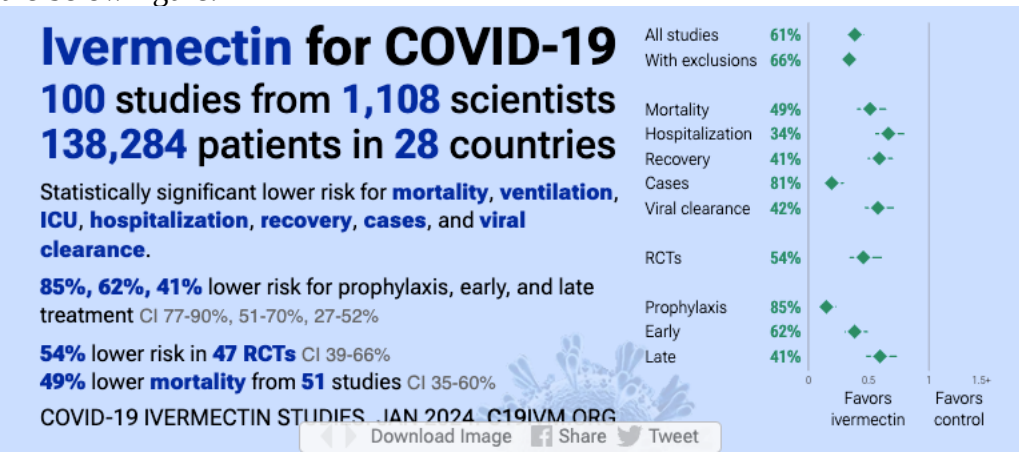
To summarize, as above, there are 4 RCT's, 2 PSM, and 8 OCT's. All but one, find that, like the RCT's, large, statistically significant reductions in the incidence of Covid occurred among treated patients. The largest trial by Kerr et al, of which I am a co-author, studied the results of a prospective prophylaxis program conducted by the City of Itajai in Brazil which included 133,051 patients. Both the non-propensity matched, and propensity-matched analyses found statistically significant, large reductions in the risk of not only getting Covid, but also in the risk of hospitalization and death.

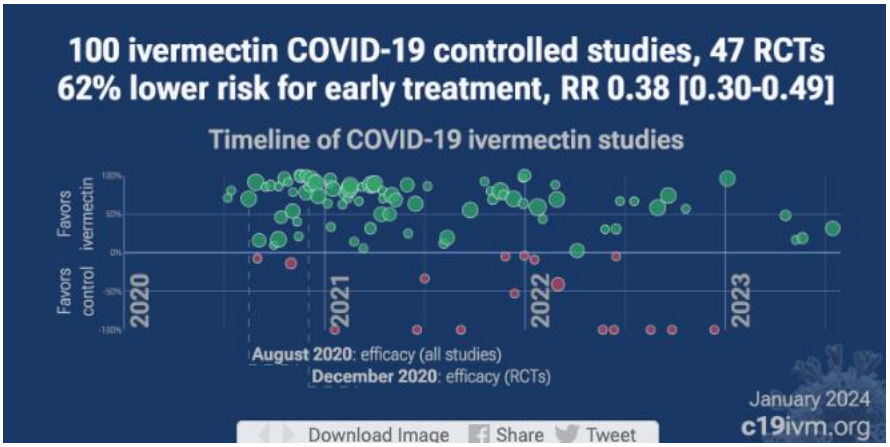
Thus, based on the totality of the highly consistent evidence base of 14 controlled trials all showing statistically significant efficacy and safety, I disagree with Dr. Corneil's statement above that "prior and current evidence strongly suggest that Ivermectin is neither a safe nor effective prophylaxis for COVID-19 illness." I instead find that Dr. Hoffe's statement is entirely accurate and not misleading, inaccurate, or in violation of the Prudence and Harm Reduction standards.

IVERMECTIN IN THE TREATMENT OF COVID-19

The main rationale that agencies and "experts" like Dr. Corneil use to reject extensive evidence in favor of the use of ivermectin in COVID-19 is to isolate a few negative studies and attempt to highlight them without acknowledging the substantial body of trials contributing data for a substantial meta-analysis. Of the 46 RCTs, Dr. Corneil simply cited one "negative" RCT (Bramante et al) and one Cochrane systematic review from July of 2021 (approximately two and a half years ago).

The overall tracking of the studies along with a real-time meta-analysis of not only ivermectin but also dozens of other Covid therapies using the same inclusion and meta-analysis protocol, can be found at c19early.com. The results for ivermectin as of today, January 10, 2023 are based on 100 controlled trials. Note the Forest plots showing the meta-analysis findings to the right in the below figure:





Further, in this *analysis*, Ivermectin was found to have been adopted in all or part of 22 countries (39 including non-government medical organizations).

Now, since Dr. Corneil cited only two studies to support his assertion that "Prior and current evidence strongly suggest that Ivermectin is neither a safe nor effective treatment or prophylaxis for COVID-19 illness," I think it is important that we carefully review the innumerable deficiencies, anomalies, and limitations of the two papers he cited to support the above statement.

1) Bramante et al was a "remote" phase 3, double-blind, randomized, placebo-controlled trial which included 1,431 patients. There are numerous critical and severe issues with this trial as below (click on link for the evidence of these issues):

CRITICAL	1. Ivermectin vs. placebo analysis - 61% lower hospitalization. 2. Severity mismatch for ivermectin treatment but not for any other medication or control
CRITICAL	3. ER results unreliable, not related to symptoms
CRITICAL	4. Mismatch with reported death and symptoms
CRITICAL	5. Ivermectin vs. placebo symptoms consistent with efficacy
CRITICAL	6. Multiple outcomes missing, including time to recovery
CRITICAL	7. Hypoxemia results unreliable but prioritized
CRITICAL	8. Adverse events suggest authentic ivermectin not taken
CRITICAL	9. Major event counts differ between paper and registry
CRITICAL	10. Baseline data differs between paper and registry
CRITICAL	11. Control group includes metformin, adjustment protocol violation
CRITICAL	12. Primary outcome changes
CRITICAL	13. All 7 secondary outcomes deleted
CRITICAL	14. Metformin/fluvoxamine conclusions opposite of Together Trial, but matching earlier studies on each team

CRITICAL	15. Author claims results from 596 researchers should be censored for false information
CRITICAL	16. Administration on an empty stomach
CRITICAL	17. Results delayed 6 months (including life-saving metformin results)
CRITICAL	18. Subject to participant fraud

SERIOUS	19. Fewer comorbidities for serious outcomes
SERIOUS	20. Control arm results very different between treatments
SERIOUS	21. COVID-19 specific symptoms hidden in appendix
SERIOUS	22. Authors claim placebo is not better than the treatments
SERIOUS	23. Incorrect claim that no treatment reduced severity
SERIOUS	24. False conclusion
SERIOUS	25. Trial outcomes modified
SERIOUS	26. Very high percentage of missing data
SERIOUS	27. Medication delivery varied significantly
SERIOUS	28. Treatment 3 days for ivermectin, 14 days for metformin and fluvoxamine
SERIOUS	29. SAP dated after trial
SERIOUS	30. Test requirement and delivery prohibits early treatment
SERIOUS	31. Conclusion modified by journal
SERIOUS	32. Symptom results contradictory
SERIOUS	33. Adherence very low
SERIOUS	34. Inconsistent blinding statements
SERIOUS	35. Author indicates a best guess can be used for onset
MAJOR	36. Ivermectin from source chosen has shown lower efficacy
MAJOR	37. Highest mean age for ivermectin, lowest for placebo
MAJOR	38. Adherence subgroups analysed but not reported
UNKNOWN	39. Maximum symptom duration not clear
UNKNOWN	40. No discontinuation due to hospitalization for ivermectin
COMMENT	41. Authors indicate up to 5 day delay in real-world usage

It is my opinion, the above actions by the investigators essentially prove that this trial was an example of the Disinformation tactic called “The Fix” whereby investigators conduct a trial with the intent of reaching pre-determined results, i.e. to show ivermectin does not work.

I find it troubling that Dr. Corneil would rely on a single RCT out of the 47 available to support his bold assertion that ivermectin is not effective against Covid-19. I must add here that the COVID-OUT study was not the only “Fix” within the ivermectin evidence base. Studies with similarly identified anomalies in the design and conduct of the trial include TOGEHER, Lopez-Vallejo, and the two ACTIV-6 trials but a discussion of their deficiencies are beyond the scope of this report. If interested, I refer you to the Chapter in my book called “The Big Six” (i.e. the 6

largest examples of "the Fake". However, in addition to citing that one RCT, Dr. Corneil also cited a Cochrane Review which, if possible, has even more glaring issues than the COVID-OUT RCT above.

Mmta-analyses have long been considered stronger evidence than a single study or small collection of studies. I am concerned that multiple supportive meta-analyses were ignored by Dr. Corneil such as Hariyonto et al, Babalola et al, Bryant et al, and Kory et al.

In addition, the ivermectin meta-analysis performed by the WHO, was ignored by Dr. Corneil.

In the WHO guideline, which has not been updated in over two and a half years, despite the evidence base now including 47 RCT's, they included 6 RCT's which studied mortality as an endpoint, and in those studies they reported 70 deaths per 1000 in the standard-of-care treated patients versus 14 deaths per 1000 in ivermectin treated patients, leading to a statistically significant **81% reduction in mortality.** The chart below is from the WHO guideline document:

Outcome Timeframe	Study results and measurements	Comparator Standard care	Intervention Ivermectin	Certainty of the Evidence (Quality of evidence)	Plain language summary
Mortality	Odds ratio 0.19 (CI 95% 0.09 – 0.36) Based on data from 1419 participants in 7 studies. [1] (Randomized controlled)	70 per 1000 Difference:	14 per 1000 **56 fewer per 1000** (CI 95% 63 fewer – 44 fewer)	Very low Due to serious risk of bias and very serious imprecision [2]	The effect of ivermectin on mortality is uncertain.

In the "Certainty of the Evidence" column, they graded the evidence as having "very serious imprecision." Know that the expert systematic reviewer team of Lawrie et al that has long worked for the WHO reached a different grading of the quality of evidence. More recently, they argue that "downgrading the quality of the evidence to this degree based on imprecision is incorrect when the treatment effect is so large, the outcome prevented is *death*, and the medicine is one of the safest, least expensive, and most widely available in the world."

Further, I along with many other ivermectin experts strongly disagree with this rationale put forward by the WHO guideline College for not recommending ivermectin:

*"Applying the agreed values and preferences, the GDG [Guideline Development Group] inferred that **almost all well-informed patients would want to receive ivermectin only in the context of a randomized clinical trial [emphasis mine]**, **given that the evidence left a very high degree of uncertainty in effect on mortality**, need for mechanical ventilation, need for hospitalization and other critical outcomes of interest and there was a possibility of harms, such as treatment-associated SAEs [serious adverse events]*."

Thus the WHO based their entire recommendation against ivermectin by arguing that critically ill patients and their loved ones would rather participate in a placebo-controlled trial instead of immediately being treated with one of the safest medicines in history (see next section) at a time that the WHO's best available evidence found an 81% chance of reducing their chances of dying. This is beyond absurd. I strongly disagree with how they apply and interpret such positive evidence and is not a misinformed opinion of their findings.

Dr. Corneil chose to cite only the Cochrane Review of ivermectin by Popp et al but again, I am concerned that he selectively relied on a single "supposedly negative" meta-analysis and ignored multiple supportive meta-analyse such as Hariyonto et al, Babalola et al, Bryant et al, and Kory et al. I believe he did so to best support his argument that ivermectin is ineffective. Yet I must ask the question as to why an "expert" would ignore such a huge evidence base in drawing conclusions?

Most troubling about the only review Dr. Corneil chose, is that Popp et al only selected 14 of the 31 published studies available at the time, rejecting large studies with positive effects on questionable grounds, such as:

- a demand that only studies with PCR testing be included even though availability and accuracy varied considerably, especially at the time;
- inconsistent rejection of comparators such as disallowing trials against hydroxychloroquine even though it has been determined by these same reviewers to without clinical effect and thus could properly serve as a control/comparator group;
- exclusion of combination therapies even though that is how it is actually used in practice. A principal criticism the Popp authors had of favorable studies was inclusion of those that used doxycycline in the intervention arm, complaining that the impacts of doxycycline could not be separately determined. Popp, ibid. at 32-33. While there may be some sense to this, given complications such as pneumonia, if doxycycline had a significant therapeutic impact on COVID-19 we would live in a better world
- In five of the included studies in the unfavorable Popp review, subjects only received a single dose, which could not have possibly reached therapeutic levels and are not valid studies. Subjects only received the FLCCC-recommended dosing in 5 of the 14 studies. Ibid. The study authors expressly state that they were aware of the dosing issue but did not have sufficient information to look at dose-response curves, yet included low-dose studies in the analysis in any event.
- Pre defined (and essentially arbitrary) time points for outcome measures (28 day mortality, infection within 14 days) resulted in further exclusions.
- High Risk of bias studies were rejected for "primary" analyses.

The inclusion policies thus excluded much of the available trials data yet, they still were not done whittling down the evidence base. Popp et al further fragmented the data by analyzing inpatient and outpatient data as separate comparisons, though the patients had the same disease and hospitalization criteria vary considerably according to local resource constraints.

More anomalous actions occurred when more than a year later, Popp et al released an updated version. They somehow managed to add new criteria so that 7 of the 14 studies they had included

the previous year were no longer eligible. Even though new trials were added, they ended up with fewer studies in 2022 than in 2021.

It is generally not good practice for a systematic review to modify its protocol between revisions—since it gives the impression of p-hacking taking place—but in an abundance of good faith, I will assume the authors had their reasons for this alteration.

However, we quickly uncover even more problems. The new criterion—that did much of the heavy lifting in terms of exclusions—was the "trial registration" criterion, specifically the requirement that a trial be prospectively registered:

2	**Trial registration**	Does the study report a trial registry number?	Check in the publication or study report	If study is not prospectively registered, **exclude** the study
		Is the study prospectively registered?	Check in the trials register the date of protocol submission and first posted. Prospective registration is defined as registration of a trial before enrolment of the first participant as defined by the WHO. It must be determined whether the registers registered (date first posted) without delay at this point in the pandemic. In case of doubt, check for the date first submitted or the authors must be asked for the submission date.	

They are quite clear that if the date of registration is not *before* the date of the enrollment of the first participant, the study should be excluded. In fact, on the basis of this criterion, they excluded several studies they had included in their 2021 edition of their systematic review. The excluded trials were: Abd-Elsalam, Biber, Chachar, Okumuş, and Shah Bukhari.

The problem is that, despite this clearly stated new exclusion criteria, they ignored it by including the 4 largest studies, ***all of which did not prospectively register their trial*** prior to enrolling the first patients. The four are TOGETHER, Vallejos, I-TECH. Kirti, and Gonzalez. By violating their own trial protocol this invalidates the systematic review since 2,582 of the 3,409 patients included did not qualify for inclusion.

Another disturbing anomaly within the Popp et al review is that they the authors stated *"*serious adverse events (SAE) including vision problems, neurotoxicity and liver damage can occur" ***though the cited source contains no such reports***. Moreover, the considerable literature on safety is ignored (see next section).

Finally, know that none of the positive meta-analyses arbitrarily excluded such a large portion of the evidence base. One expert systematic review group's critique of Popp et al's review, aptly titled their paper "The uses and abuses of systematic reviews."

Finally, beyond the 100 controlled trials, 47 of them RCT's, and the numerouspositive meta-analyses of the ivermectin evidence base, there are a number of health ministry reports of early treatment programs, all showing large reductions in hospitalization or death when ivermectin was used. See:

- **La Misiones, Argentina** – Health Ministry analyzed the data from 4,000 ivermectin treated patients and, compared to the rest of the population over the same time period, found a 75% reduction in need for hospital and an 88% reduction in death.
- **Uttar Pradesh, India** – Using a strategy of close surveillance combined with both ivermectin treatment of all positive cases and preventive treatment of all family contacts. On September 10, 2021, only 11 cases with no deaths were recorded in a population of 241 million..with 67 of their 75 districts having no active cases at the time.
- **The Brazilian city of Itajai** offerred ivermectin as prevention to the entire city's population with 133,051 (60%) agreeing to take ivermectin every two weeks for 6 months. Compared to the 45,716 city inhabitants that declined to use ivermectin, ivermectin users were 47% less likely to contract illness, had a 70% lower mortality rate, and a 67% lower hospitalization rate. By the end of the 6 month program, the citywide COVID mortality fell from 6.8% to 1.8%.
- **La Pampas, Argentina** – Health Ministry compared over 2,000 patients they treated early with ivermectin to over 12,000 without treatment and found that in patients over 40, rates of ICU admission and death both fell by 40%.
- **Peru** – A nationwide mass-distribution program called "Mega-Operación Tayta" (MOT), initiated at various times across 25 states of Peru in May 2020, led to a 74% drop in regional excess deaths within a month, with *each drop* beginning 11 days after each MOT region's varied start times
- **The Health Ministry of Sultan Kudarat** in the Phillipines launched an ivermectin drive and found that cases rapidly dropped by 86%. compared to nearby regions
- **In Japan,** the President of the Tokyo Medical Association recommended that all physicians start to use ivermectin as early treatment during their summer surge. They are now recording the lowest rate of COVID hospitalization in the pandemic.

Finally, 23 countries (39 including NGO's) have now given either partial or full approval for use in COVID, which encompasses 25% of the world's population.

Thus based on the large and consistently positive evidence base from RCT's , OCT's, and health ministry reports, I find Dr. Hoffe's statements on the efficacy of ivermectin to be fully supported by and consistent with the scientific evidence. I thus strongly disagree with Dr. Corneil's assessment of Dr. Hoffe's statement.

SAFETY OF IVERMECTIN

I strongly agree with Dr. Hoffe's statement that ivermectin is "*very, very safe, very effective treatments for Covid…" and that it is "unbelievably safe."*

Dr. Corneil instead finds that, *"Ivermectin, especially at high doses, can be dangerous for humans and may cause serious health problems such as vomiting, diarrhea, low blood pressure, allergic reactions, dizziness, seizures, coma and even death."*

Dr. Corneil's opinion characterizing Dr. Hoffe's statement as incorrect, misleading etc. is easily disproven with the available, extensive data on the nearly unparalleled safety of ivermectin in treatment of both Covid and the 40 years history of global use to treat parasitic diseases.

In response to Dr. Corneil's claim that ivermectin can cause low blood pressure, in this scoping review of the safety of ivermectin, the author states "A sudden and marked drop in blood pressure, severe skin reaction and liver injury have been mentioned in early safety reviews. The clinical experience accumulated over the years showed these severe adverse events are unequivocally extremely rare. The often-reiterated claim, even today, that ivermectin can be lethal in treated patients only rests on a one-page correspondence to the Lancet published in 1997. This claim is deemed to be unfounded as it has never been further substantiated until today and instead, 3 subsequent publications repeatedly showed this claim was either incorrect or methodologically inaccurate."

A number of reviews on the safety of ivermectin have been performed since the onset of the Covid pandemic. One group of toxicologists published a paper finding that "Ivermectin was generally well tolerated, with no associated CNS toxicity at doses up to 10 times the FDA-approved maximum dose of 200 µg/kg. All doses had a mydriatic effect like a placebo. The adverse experiences between ivermectin and placebo were similar and did not increase with the ivermectin dose."

Another safety review stated " The safety, availability, and cost of ivermectin are nearly unparalleled given its low incidence of important drug interactions along with only mild and rare side effects observed in almost 40 years of use and billions of doses administered."

Further, the safety of standard doses of ivermectin (0.2 mg/kg x 1–2 days) have a nearly unparalleled safety profile historically among medicines as evidenced by the following findings:

- **WHO Guidelines for Scabies**: "the majority of side effects are minor and transient"
- **Jacques Descotes, Toxicologist and Expert on Safety of Ivermectin:** "severe adverse events are unequivocally and exceedingly rare"
- **LiverTox Database**: Not considered toxic to the liver
- **Nephrotox Database:** Not considered toxic to the kidney
- **PneumoTox:** Not considered toxic to the lungs

Safety of High Dose Ivermectin - COVID-19 Studies

- Randomized controlled trial of ivermectin in COVID using 0.6mg/kg x 5 days reported no differences in side effects
- Randomized controlled trial, with 3 arms; one arm treated with 1.2 mg/kg x 5 days, and another treated with 6mg/kg x 5 days with no differences in side effects.
- A report by the State Health Minister on 3,000 patients in La Pampa, Argentina who were part of a "test and treat" program were given 6 mg/kg daily x 5 days. Liver function tests and significant side effects were closely monitored and none were reported as abnormal
- A report by the Health Minister in Misiones, Argentina, also using 0.6 mg/kg x 5 days with no significant adverse events reported.
-

Malaria Studies

- Ivermectin alone was safe and well-tolerated in macaques with repeated doses at 3 and 1.2 mg/kg x 7 days, with no signs of neurological, gastroenterological, or hematological complications.
- Study of "Efficacy and Safety of High dose ivermectin for Reducing Malaria Transmission" compared 0, 3 and 0.6 mg/kg x 3 days and found no differences in side effects.

Healthy Volunteers

- Report of a group of healthy adult subjects given up to 10 x standard dose, either 2-4 x the standard dose three times a week or 6–10 x standard dose once and found the doses generally well-tolerated.

Systematic Reviews

- A systematic review and meta-analysis of high dose ivermectin found no difference in side effects between dose of up to 0.4 mg/kg and higher doses (up to 0.8 mg/kg doses every 3 days)
- A comprehensive review of 350 articles by the famous French toxicologist Jacques Descotes was presented in March 2021. In this document, he states,

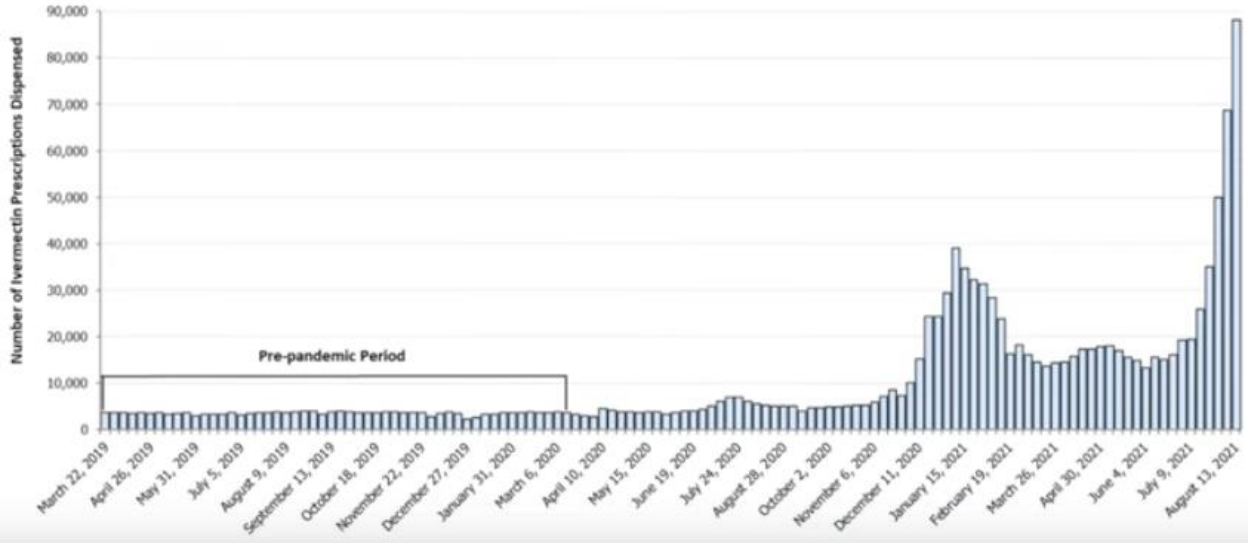
1. "Based on all the data presented above, the author of this report believes it is fair to say that ivermectin did not directly induce an excess of deaths in treated groups of human subjects. Statements, past or present, that ivermectin can kill patients, are therefore considered to be misleading as they do not take into account all the medical information that has been accumulated over the last decades."
2. "Only very few cases of accidental human overdose have been reported despite the wide availability of ivermectin as a veterinary and human medicine [Hall et al., 1985; Graeme et al., 2000; Deraemecker et al., 2014; Goossens et al., 2014]. Usually, moderate neurotoxic manifestations with rapid recovery after unspecific supportive measures were the predominating course of events. No accidental overdose including in infants and young children had a lethal outcome."

Case Series

1) A case series of 3 children with relapsed leukemia treated with high dose (1.0 mg/kg) ivermectin daily for between 2 weeks and 6 months reported no significant adverse events.

Further, Ivermectin is on the WHO's list of essential medicines, has been given nearly 4 billion times around the globe and is widely considered a safe drug. According to the WHO, it is safer than both aspirin and Tylenol. Its discoverers were honored with the Nobel Prize in 2015 for the drug's global and historic impacts in eradicating endemic parasitic infections in many parts of the world. There is good scientific evidence that the escalating doses required to maintain antiviral levels have been subjected to considerable testing and are in fact safe.

To better understand the overall safety signal in Covid it is useful to look at absolute numbers in data from the FDA Adverse Events Reporting System (FAERS). While poison control calls and FAERS each suffer from limitations, it is notable that reports for products containing ivermectin actually fell slightly in 2020 and 2021, despite greatly increased use and dosing (see below data demonstrating the massive rise in ivermectin prescriptions in the U.S), with a combined total of 503 adverse reports which was at an annual rate that is less than 2017-2019. Reports did not rise post-COVID-19, but actually fell.



Safety Comparisons with Other Treatment Options

VigiAccess™ Uppsala Monitoring Centre | WHO Collaborating Centre for International Drug Monitoring

Medicine	Year started reporting	Deaths	Adverse events
Tetanus vaccine	1968	34	16,729
Measles vaccine	1992	36	10,357
Acetaminophen (Tylenol)	1968	4,120	203,990
Ivermectin	**1992**	**26**	**7,380**
Paxlovid	2022	74	44,290
Tocilizumab	2005	1,313	69,709
COVID-19 vaccines	2021	26,013	5, 275 222
Remdesivir	2020	728	11,056

As per above table using data from the WHO's Vigiaccess surveillance database as of today January 12, 2023: there have been 16 deaths attributed to ivermectin *over a 30-year period*, while there have been 11,056 deaths attributed to Remdesivir though it was only approved by FDA on October 22, 2020 and given to far fewer patients. Remdesivir, which is considered the "standard of care," was approved contrary to WHO recommendations against its use and a significant body of literature finding its risks outweigh any benefit.

The level of side effects in such approved drugs is one of the reasons that the Nebraska Attorney General found that ivermectin prescribing was proper and his Opinion puts the ivermectin data into stark perspective by comparing them with far more numerous adverse events from Remdesivir's use in COVID-19.

Paxlovid is contraindicated if a patient is taking a significant list of other drugs and has a higher risk. Since its approval in 2022 it has already had 21,249 adverse event reports to Vigiaccess, which is three times the amount reported for ivermectin over the past 30 years. Molnupiravir has not shown high levels of effectiveness, shows 2,677 adverse events, and has not shown significant efficacy at reducing death rates. Studies are continually published showing poor safety and effectiveness, for example a recent study in Lancet showing that "Molnupiravir did not reduce the frequency of COVID-19-associated hospitalizations or death among high-risk vaccinated adults in the community." While these drugs may have a role to play in treatment, a

fair comparison shows that ivermectin is more effective and demonstrably safer than other available treatments and far safer than the one drug–Remdesivir–that the FDA initially approved for use against COVID.

Notably, there have been 100 studies with over 135,000 patients listed at https://c19ivm.org/ without a significant safety signal emerging.

Further, the principal investigator of the largest trial on ivermectin in Covid, Ed Mills, stated in March of 2022, during an NIH Collaboratory: "I would say that the safety analysis, you know, ivermectin does not appear to cause much of a safety concern. That argument that has been put forward by people I don't think holds very well at all."

The concluding sentence of Jacques Descotes review of the safety of ivermectin: "*the author of the present analysis of the available medical data concludes that the safety profile of ivermectin has so far been excellent in the majority of treated human patients so that ivermectin human toxicity cannot be claimed to be a serious cause for concern.*

Finally, in a meta-analysis of 11 RCT's in Covid, assessing 1533 participants, there was no significant difference between ivermectin and control in the risk of severe adverse events (aRR 1.65, 95% CI 0.44–6.09; $I^2 = 0\%$).

Thus, it is clear from the accumulated and published evidence that Dr. Hoffe's statement is highly scientifically accurate, unlike the conclusion of Dr. Corneil.

IVERMECTIN ACCESS:

Statement (e). In an interview presented by Quo Vadis ("QV TV"), video of which was posted online on or around October 2021, at 02:30:58 - 02:31:39, in response to the question, "what is the best approach with a doctor that is pro-vax uh, or will not prescribe ivermectin?", Dr. Hoffe stated:

"Yeah well now, no doctors are allowed to prescribe ivermectin in BC or Alberta. If you can find somebody [inaudible] in another province, they might, but most doctors will not because they're afraid of getting investigated by their college." Someone in the audience asked, "how do we buy it then?". Dr. Hoffe stated, "[inaudible] you can go to a feed store that sells stuff for livestock and tell them you've got a herd of sheep and you need ivermectin [laughter from the audience]. Someone from the audience stated, "that's a serious question". Dr. Hoffe stated, "Yeah, no, and I'm being serious. That's a serious [inaudible] you literally, the government is forcing people to use veterinary products".

The accuracy and soundness of Dr. Hoffe's statement regarding access to ivermectin can only be understood in the context of the Disinformation campaign I described at the beginning of this report.

I am a physician who has treated over a 1,000 Covid patients with ivermectin since October 2020 and am regularly in communication with a network of ivermectin experts and researchers globally.

I can attest that the ability of patients in many countries to access ivermectin became increasingly difficult. In the United States, I observed an abrupt change in my ability to prescribe ivermectin through retail pharmacies whereby suddenly pharmacists all over the country began to refuse to fill valid prescriptions. This change was most pronounced immediately following what I call "the Horse Dewormer PR Campaign" which began in late August of 2021 (Chapter 33, the "War on Ivermectin," Exhibit C). That sequence of actions and events led to the publication on Sept. 1, 2021 of a joint statement by the American Medical Association, the American Pharmacists Association, and the American Society of Health-System Pharmacists whereby they "strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial."

Other countries and regions, like in BC and Alberta went further, effectively threatening the licenses of physicians who prescribed ivermectin. Such actions effectively restricted the ability of acutely ill Covid patients to access what I have shown above, to be a life-saving drug. Physicians who were aware of the vast extent of data proving its life-saving efficacy were put into a difficult situation given that, As Dr. Hoffe correctly mentions, their governing bodies caused this "blockade" to happen.

Given that the Hippocratic Oath to which we physicians abide includes the statement, "I will do no harm or injustice to them (patients), such a mandate left few options for an ethical physician to navigate in the situation of a restriction of access to human forms of ivermectin..

Given his statement was made in October of 2021, prior to the availability of paxlovid or molnupiravir, it must be understood that there was no other treatment option available with demonstrated efficacy. So, a physician faced with caring for a patient with a potentially life-threatening illness could simply offer supportive care only and hope deterioration and death would not occur, or they could attempt to gain access to a life-saving therapy for their patient.

As a U.S citizen, I was in a much better position than Dr. Hoffe in that I found that our system of independent, small business, compounding pharmacies with rare exceptions, routinely filled my valid prescriptions.. Many of us early treatment experts began circulating lists of "safe pharmacies" that would fill our prescriptions and would not report us to regulatory bodies. Dr. Hoffe did not have that option.

In my book, The War on Ivermectin, Chapter XX, I included numerous testimonials sent to me of patients who rapidly recovered after taking animal versions of ivermectin, and further testimonials by family members who "snuck in" animal versions to treat patients in hospitals who also reported positive results.

Further, although we know that animal sources of ivermectin are not manufactured to the same quality standard as human versions, I am aware of only a handful of reports of adverse events related to use of animal versions, however I am not aware of any data showing that the human version was then better tolerated. Adverse effects can happen with the human version as well. One fact to be aware of is that the liquid formulations of animal ivermectin generally contain only three ingredients –1% ivermectin, 40% glycerol formal, and propylene glycol. Glycerin formal has excellent performance and is **harmless to human body** and has no toxic and side effects. **Propylene**

glycol is considered generally safe **by US and European authorities**. There is only one documented case of propylene glycol toxicity and was caused by excessive alcohol intake. Despite this knowledge, I agree that none of the animal products are manufactured to human standards nor are they tested in humans. Thus, there is a theoretical risk of harm to a human from using an animal product. However, I would maintain that the risk is likely a trivial one based on my knowledge of many physicians across the world who reported to me that they were forced to rely on prescribing animal versions due to lack of access to human version, and along with the many patients who reported to me that they prophylaxed with ivermectin on a weekly or biweekly basis throughout the pandemic.

Know that physicians, when making treatment decisions, must balance the risks and benefits of a particular treatment as well as a consideration of alternatives to the treatment. In the situation of having the responsibility to care for a patient with a potentially life-threatening disease, in a situation where your governmental regulatory agencies have restricted access to a very safe, life-saving treatment, I find it not only practical but admirable that a physician would attempt to guide patients with a route to accessing a medicine that could save their lives.

This is an extremely challenging ethical situation with no easy answers. Although I am glad I personally never had to recommend someone use an animal version of ivermectin, had I been in a situation like Dr. Hoffe and other doctors were in Alberta and BC, I personally would not have hesitated to recommend patients to get access to the animal version. It is the least worst option in my opinion. I have seen to many people die or become disabled from Covid infections. I know of no deaths or disability resulting from ivermectin. I remind the reader and the College that this situation was not created by Dr. Hoff and he attempted to provide the most sound guidance on how to navigate it. I again later lay blame at the feet of the pharmaceutical industry and public health agencies and professional societies who consistently chose not to critically or expertly assess the evidence for ivermectin like I have done above. It is they who should be litigated against and punished. Not Dr. Hoffe.

SHEDDING:

Statement (j). In an interview presented by QV TV, video of which was posted online on or around October 2021, at 02:03:56 – 02:05:12, in response to the interviewer asking, "Can you explain what shedding is and should we be concerned?", Dr. Hoffe stated:

"Yeah so shedding, shedding is an interesting one. There is something that comes out of the skin and the breath of vaccinated people that causes bleeding and clotting in other, in nonvaccinated people. And it has been reported all around the world, particularly in women, for some reason, I suppose because women have have menstrual cycle and that sort of thing. So it has caused [inaudible] miscarriages, it has caused [inaudible] very erratic and heavy periods, it has caused women who are post-menopausal to start bleeding again, and Pfizer, if you read the study design [inaudible] for Pfizer,it's page 67 and 68, they record that something is released from the skin and the breath of vaccinated people that can effect pregnant or breast-feeding women. They didn't say what it was. But it is, the effect has been noted around the world. So we

don't know exactly what they're shedding, but there is something that causes disease in nonvaccinated people".

Dr. Corneil's assessment of Dr. Hoffe's statement contained numerous ignorances and inaccuracies as follows:

First, Dr. Corneil's response reveals immediately that he is wholly ignorant of the definition of "shedding" in the context of a gene therapy. He instead relied on the definition used in context of a viral illness or traditional vaccine. When in the context of a gene therapy product, in this FDA document called "Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry" the FDA defines shedding as follows:

"*The release of viral or bacterial gene therapy products from the patient by any or all of the following routes: feces (feces); secretions (urine, saliva, nasopharyngeal fluids, etc.); or through the skin (pustules, lesions, sores).*"

Based on his written assessment of Dr. Hoffe's statement above, it appears that Dr. Corneil is unaware that the Covid mRNA "vaccines" are actually gene therapy products. To wit, ***gene therapy medicinal products*** (GMTPs or GTP's) are defined in the FDA's 2015 document on Gene Product Shedding Studies:

"Gene therapy products are all products that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms.

Also note that in this European Medicines Agency (EMA) document, the mRNA vaccines also meet their definition of gene therapy medicinal products (GMTP's).

So beyond not understanding that the Covid vaccines are gene therapy products and that all gene therapy products are at risk of being shed, Dr. Corneil also seems unaware that the FDA literally recommends shedding studies be done for all gene therapy products in both humans and animals, as per the FDA's 2015 document on Gene Product Shedding Studies.

So, the FDA knows there are real risks that a product of a gene therapy can be shed from one person to another. For instance, in this insert of the first ever approved gene therapy product called Luxterna, they warn:

- Shedding of LUXTURNA

  Transient and low level shedding of LUXTURNA may occur in patient tears. Advise patients and/or their caregivers on proper handling of waste material generated from dressing, tears, and nasal secretion, which may include storage of waste material in sealed bags prior to disposal. These handling precautions should be followed for up to 7 days following LUXTURNA administration.

Manufactured by:
Spark Therapeutics, Inc.
3737 Market Street
Philadelphia, PA 19104

US License #2056

So, its prescribing information specifies that Luxturna can be found in a patient's tears after injection and it hence for the first seven days after injection, care must be taken to avoid anyone else coming in contact with those tears to prevent unintended shedding of the product. Another similar gene therapy, Roctavian also was found to shed (e.g., into semen), and the FDA advises those who receive it to not donate semen or impregnate someone for at least 6 months after administration. Finally, Zolgensma, a gene therapy, utilizing a different virus was also found to shed for a month, and its package insert advises that during this time, to be careful of how feces from the patients are disposed of (so no one else is exposed to it).

Unfortunately, due to the fact the vaccines were developed at "warp speed," no shedding studies were done in humans. However, according to this paper, via a Pfizer document obtained by FOIA it was revealed that shedding of their mRNA vaccine was studied in the urine and feces of intra-muscular injected rats. Unfortunately, that document is no longer at the website referenced.

Now, in the case of the Covid vaccines, the "products" that are at risk of being shed from one person to another would be the spike protein and/or the components of the vaccine which include lipid nanoparticles, naked mRNA, and polyethlene glycol (PEG).

Another category of technology that the Covid mRNA "vaccines" fall under is "nanoparticle technology" given that the mRNA is delivered to the cell within lipid nanoparticles. Nanoparticles exist in both natural, biological forms (called exosomes) as well as synthetic ones such as in the lipid nanoparticles (LNP) of the mRNA vaccines. Importantly, synthetic mRNA vaccine LNPs have the same structure as the natural exosomes they seek to mimic.

From this paper in Molecular Therapy, they state:

Exosome-like nanovesicles (ELNVs) are biological nanostructures of 40–150 nm, are secreted by most types of cells and relay information between cells and organisms across all three kingdoms of life. Although earlier perceived to be cellular debris and hence undervalued, ELNVs are now acknowledged as crucial entities to regulate physiological functions of multicellular organisms in an intercellular transmission manner.

The most important fact to remember is that the smaller the size of an LNP or exosome, the more widely they distribute and the more easily they can enter the body.

Now, to prove that mRNA vaccine product shedding is occurring and can occur, I maintain that evidence for the following mechanisms is required:

1) The LNP's with mRNA or the produced spike protein would have to distribute widely in the body (so excretion from the lungs, urine sweat, breast milk etc could then be possible).
2) The spike protein would then have to be found in exosomes in sufficient quantities in body fluids or exhaled breath.
3) LNP's and/or spike protein containing exosomes would then have to be able to be absorbed into the body of someone nearby, with the most worrisome route being via inhaled breath.
4) Finally, typical vaccine adverse event symptoms would need to be documented in unvaccinated people (or vaccinated) after being closely exposed to other vaccinated people.

Before I go through the evidence for each of the above steps needed to "prove" that shedding of Covid vaccine mRNA is real, first know that Pfizer knew the risks of shedding because, in their trial protocol (I used Dr. Corneil's citation for the Pfizer trial protocol but it no longer exists there, instead the page says "access denied"):

1) they prohibited pregnant women or those breast feeding from receiving the vaccine (or future doses if they had already received one). I can only interpret this as meaning that Pfizer knew of a theoretical risk of a breast feeding mother could expose her child to the vaccine or a component of it.

2) Stated it needed to be reported if a pregnant women (e.g., a healthcare worker in the trials) was exposed to the intervention by inhalation or skin contact from someone who had been vaccinated.

3) Stated it needed to be reported if someone in the previous category (not vaccinated but exposed to someone who was) then was in close proximity to their wife and their wife was pregnant

The above exclusion criteria indicate that Pfizer was following the existing standards that the FDA stipulates for gene therapies, i.e. they need to be evaluated for shedding before being given to humans (and furthermore be subsequently tested in humans).

Now, lets go through the evidence supporting the dynamics required to transmit an mRNA vaccine product from a vaccinated person to another.

Shedding Condition #1

"*The LNP's with mRNA or the produced spike protein would have to distribute widely in the body (so excretion from the lungs, urine sweat, breast milk etc could then be possible).*"

Evidence:

Dr. Corneil dismisses the possibility of the above by stating "the vaccine stays in the arm." This is a false statement. From a recently leaked EMA letter, we now know the synthetic LNP's containing vaccine mRNA are distributed widely in the body. Second, from a Japanese FOIA'ed document of the lipid nanoparticle biodistribution data for Pfizer's vaccines, it is clear the LNP's distribute widely. In addition, the Therapeutics Goods Administrations (TGA) of Australia's evaluation report on Pfizer's nonclinical biodistribution study alarmingly revealed that the lipid nanoparticles which encase the mRNA, travel to the liver, spleen, brain, eyes, bone marrow, adrenal glands, **ovaries and testes**– nearly every organ tissue.

Shedding Condition #2

"The spike protein would have to be found in exosomes in sufficient quantities in body fluids or exhaled breath."

Evidence:

One study found that significant amounts of spike protein containing exosomes (which circulate in the bloodstream) increase rapidly after vaccination (and then decline) and appear to be one of the primary means responsible for the vaccine antibody response.

In addition, significant amounts of RNA containing exosomes can be found in breath, and those exosomes (which derive from the lungs) vary depending upon on the disease state someone has (see this 2013 paper, this 2020 paper and this 2021 paper—since this is a new field of research, each paper is more sophisticated than the preceding one).

Another concern is from another study which found that vaccine mRNA is present from day one and persists in the bloodstream for at least 2 weeks after injection; its concentration starts to decrease after 4 days. Note this is much longer than was claimed by the manufacturers on the basis of brief studies in rats.

From the conclusion:
In conclusion, we showed that BNT162b2 vaccine mRNA remains in the systemic circulation of vaccinated individuals for at least 2 weeks, during which it likely retains its ability to induce S-protein expression in susceptible cells and tissues.

Another study found that vaccination with mRNA and translation of the mRNA induces the production of exosomes carrying the spike protein and circulating in the blood 14 days after injection and **up to 4 months after**.

Another group similarly found that the spike protein concentration rapidly increases in blood after vaccination (within 1 to 3 days) and persists in the bloodstream for more than a week.

Although they report that the spike is completely eliminated within 1 month a more recently published study which looked much more carefully, found spike protein circulating in the blood up to 187 days after vaccination (after which they stopped testing and finished their study).

The spike protein has a high (heparin dependent) affinity for binding to the surface of exosomes.

Long COVID (and more severe acute COVID as well as Long Vax) is characterized by the presence of spike protein studded exosomes (see this paper and this paper). Additionally, they also showed exosomes from COVID patients are highly inflammatory (and potentially clot forming) and are taken up by the lung cells.

The most detailed study (and imaging) of spike protein containing exosomes can be found in this paper (which also found that spike protein containing exosomes can circulate a year after COVID infection). For example, this research team reported that the spike protein persists for a long time in free form: full-length spike is detected up to day 15, with a peak at 62 pg/mL. After the 2nd dose, free spike is no longer detected as *it would be* bound to antibodies (but the study did not look for antibody-spike immune complexes**).**

A table from this paper on spikeopathy summarizes the studies showing persistence of spike protein and other vaccine components as below:

Table 1. Studies demonstrating persistence of vector-based vaccine constituents and/or derivative spike protein.

Author	Constituents/Tissue Type/Assay Technique	Duration Measured
Animal		
Pfizer (Japanese MoH) 2020 [46]	Radiolabelled LNP in plasma and tissues	140 h–14 days
Human		
Ogata et al. (2021) [52]	Spike protein and S1 subunit (assay)	3 days
Bansal et al. (2021) [57]	Spike Protein	4 months
Fertig et al. (2022) [50]	LNPs and mRNA	15 days
Röltgen et al. (2022) [53]	mRNA and Spike Protein in ipsilateral lymph nodes; 2–7 days post dose in blood	60 days
Yamamoto et al. (2022) [58]	Spike Protein in skin	3 months
Yonker et al. (2023) [54]	Spike Protein in blood	1–19 days *in cases of myocarditis*
Castruita et al. (2023) [51]	mRNA in plasma	28 days

Clinical and pathologic evidence are available as well: a case report of an autopsy done in a man who died of multifocal necrotizing encephalitis three weeks after the vaccine found vaccine spike in numerous organs (heart, brain, muscles, germinal centers etc.). Further, they emphasized the finding of high concentrations in the walls of capillaries.

Finally, a team led by the esteemed senior German Pathologist Arne Burkhart, stained autopsy specimens for the presence of spike protein. He has presented their findings in multiple invited lectures and reported that out of the first 50 autopsies performed at the request of families who suspected their loved one's death was due to the vaccine, in 80% of cases spike induced organ damage was determined to be the proximate cause of death.

Shedding Condition #3

"*LNP's and/or spike protein containing exosomes would then have to be able to be absorbed into the body of someone nearby, with the most worrisome route being via inhaled breath."*

Evidence that LNP's from vaccinated people can be transmitted to and subsequently enter our bodies can be found in this this review of nanoparticles (i.e LNPs/exosomes):

As far as the exposure of humans to NPs is concerned, they can enter the body through inhalation, ingestion, skin uptake, injection, or implantation. It is also interesting to note that NP uptake could be intentional or non-intentional. Some exposures are unintentional, such as pulmonary inhalation of NPs in the environment or at manufacturing sites."

The below figure from the above paper illustrates the various routes of absorption and dissemination of nano particles throughout the body:

Figure 1

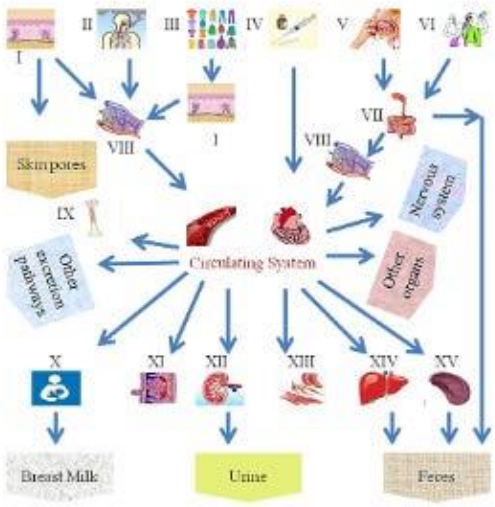


FIGURE 1. Scheme of the different exposure routes of nanoparticles in the human body. (I) Skin, (II) inhalation, (III) fabric, (VI) intravenous injection, (V) food intake, (VI) water intake, (VII) gastrointestinal tract, (VIII) lymph, (IX) bone marrow, (X) breast milk, (XI) placenta, (XII) kidney, (XIII) muscles, (XIV) liver, and (XV) spleen.

In a paper from 1999 they state that nanoparticles (NPs) can cross the biological barriers shielding various parts of the human body, such as the blood-testes barrier and enter the testes in animal models.

In this review of nanoparticles (i.e LNPs/exosomes) they state:

"As far as the exposure of humans to NPs is concerned, they can enter the body through inhalation, ingestion, skin uptake, injection, or implantation. It is also interesting to note that NP uptake could be intentional or non-intentional.

In another review paper on nanoparticles they state: *"these ultrafine particles are capable of entering the body through skin pores, debilitated tissues, injection, olfactory, respiratory and intestinal tracts. These uptake routes of NPs may be intentional or unintentional. Their entry may lead to various diversified adverse biological effects. Until a clearer picture emerges, the limited data available suggest that* ***caution must be exercised when potential exposures to NPs are encountered. These nanosized particles are likely to increase unnecessary infinite toxicological effects on animals and environment; although their toxicological effects associated with human exposure are still unknown.***

Further, there is a large and growing body of research in the development of a "LNP nanoparticle therapeutics" (i.e. using LNP's to deliver drugs and/or corrective genes). Currently, therapeutic nanoparticles have been successfully administered: transdermally, transfollicularly, intranasally, via inhalation and then excreted via urine, feces, saliva, breast milk, exhaled breath, sweat, and transcutaneously (here, here, here).

I believe the inhalation route to present the highest risk of absorbing shed gene therapy-based vaccine products. The findings in this paper from 2005 are support that likelihood:
When inhaled, specific sizes of NSPs (nano-sized particles, i.e. LNP's/exosomes) are efficiently deposited by diffusional mechanisms in all regions of the respiratory tract. The small size facilitates uptake into cells and transcytose across epithelial and endothelial cells into the blood and lymph circulation to reach potentially sensitive target sites such as bone marrow, lymph nodes, spleen, and heart.

This randomized, double-blind controlled trial in *The Lancet* found that in humans, liposomal DNA gene therapy loaded nanoparticles administered locally by nebulization transfected airway cells. This was validated by the fact the cystic fibrosis patients treated in this manner experienced a stabilization of lung function, while the placebo group experienced a decline.

Clinical trials for influenza prevention have shown the efficacy and safety of inhaled mRNA vaccines. This study reported 3 clinical trials that used aerosol as the route of administration. In 2022, this study showed that exosomes were effective via nebulization therapy in COVID-19 patients. Finally, extracellular vesicles by inhalation (ongoing trial against Alzheimer's disease) is being studied.

Lastly, a 2023 peer-reviewed study found that unvaccinated individuals who were around COVID-19 vaccinated individuals developed an immune response to the spike protein. Although the authors hypothesize that "antibodies" were transferred, I disagree based on the above, I maintain that the children were exposed to spike and then made antibodies. I am unaware of data showing that humoral (antibody) immunity can be transferred to children outside of the womb.

Shedding Condition #4

"Documentation of typical Covid mRNA vaccine adverse event symptoms in unvaccinated people after exposure to Covid mRNA vaccinated people."

I will first begin with the evidence for placental shedding/transmission of LNP's.

Animal studies clearly indicate that nanoparticles can transit through ordinary placental transcellular transport. In this paper, they report that in animal models "nanoparticles can readily pass through the placental barrier" and, more disturbingly, "that NP's less than 240 nm have transplacental activity in an ex vivo human placental perfusion model." It is worth noting that the LNP's in the Covid mRNA vaccines range from 100-400nm in size. Further, in one mouse study, they developed a PEG-ylated LNP similar to the COVID mRNA vaccines that could get to the uterus as a therapeutic delivery mechanism. Apparently, they succeeded given the study

conclusion: *"These LNPs may provide a platform for in utero mRNA delivery for protein replacement and gene editing."*

There are significant amounts of data showing risks of the Covid mRNA vaccines to fetuses in pregnancy. Let's start, again, with this document obtained by FOIA from Pfizer and the FDA:

3. RESULTS

Of the 673 case reports identified in the search, 458 involved BNT162b2 exposure during pregnancy (mother/fetus) and 215 involved exposure during breast-feeding.

- In 210 out of the 458 cases, maternal exposure (PTs Maternal exposure timing unspecified, Maternal exposure during pregnancy, Maternal exposure before pregnancy,

  Exposure during pregnancy) was reported either with no associated AEs or with AE off-label use/product use issue for either the mother or the baby.

- Among the remaining 248 cases, the most commonly reported AEs were product use issue (83), off-label use (81), pain (including but not limited to vaccination site pain/pain/pain in extremity)(101), headache (57), abortion spontaneous (51), fatigue (43), pyrexia (26), chills (24), myalgia (23), nausea (22), arthralgia (16), dizziness (15), malaise (12), lymphadenopathy (11) and asthenia (11).

To summarize the above, Pfizer received 458 reports of mothers "exposed' to the vaccine while pregnant. In 248 (54%) reports, an adverse event was reported. 53 of the 248 adverse events involved spontaneous abortion, which they then "excluded" 17 due to having comorbidities or history of spontaneous abortion, an exclusion which I disagree with.

For instance, there is an unacceptable amount of spontaneous abortion reports within 1-10 days of the vaccine, and then a large number where the temporal association is left quite vague, i.e. "received vaccination in first trimester and abortion occurred at 6 weeks." This suggests vaccination occurred right before the spontaneous abortion (given that the average time that women realize they are pregnant is at 5.5 weeks from conception). Take some time to peruse the below list of events:

NT162b2
umulative Review from Pharmacovigilance Database

- There were 53 reports of spontaneous abortion (51)/ abortion (1)/ abortion missed (1) following BNT162b2 vaccination. Of these reports, 4 cases were COVID-19 positive (including suspected), and 13 cases had relevant medical history of endometriosis (1), abortion spontaneous (10), polycystic ovaries (1), menstruation irregular (1). These cases were therefore excluded from the review. One patient had a medical history of COVID-19 (unknown if ongoing) and was excluded from the review. The remaining 39 cases are summarized in Table 1.

Table 1. Summary of Patients with Outcome of Pregnancy – Abortion spontaneous

Age	Medical History	Outcome of Pregnancy
40 years	Not provided	The patient was unaware of her pregnancy at the time of vaccination. Suspected abortion occurred at 6 weeks of pregnancy.
37 years	Not provided	Patient received vaccine during first trimester (1-12 weeks) on 19 Jan 2021 and suffered spontaneous abortion on 3 Feb 2021.
33 years	Not provided	Patient received first dose of vaccine during first trimester (1-12 weeks). Abortion occurred at 3 weeks of pregnancy.
32 years	Not provided	Patient was vaccinated during first trimester (1-12 weeks) on 23 Dec 2020 and suffered a spontaneous abortion on 06 Jan 2021.
39 years	Asthma / Eosinophilic oesophagitis	Patient received vaccination at gestation of 6 weeks and spontaneous abortion occurred 11 days post vaccination.
31 years	Not provided	Patient experienced spontaneous abortion 8 days after receiving 2nd vaccine at 6 weeks pregnant.
35 years	Asthma / Gastrooesophageal reflux disease	Patient experienced missed abortion in the 7th week of pregnancy on an unspecified date with outcome of unknown.
33 years	Pregnancy	The patient was unaware of her pregnancy at the time of vaccination, which occurred at gestational age of approximately 3 weeks. Spontaneous abortion occurred at gestational age of 6 weeks.
34 years	Pregnancy	Patient was 3 weeks pregnant at the time of the first vaccination, without knowing she was pregnant. She found out she was pregnant one week after the vaccination. She then had a spontaneous abortion in week 6 of pregnancy.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy Spontaneous abortion, gestational age unknown.
34 years	Continuous positive airway pressure / Overweight / Sleep apnoea syndrome	Patient reported that she was unknowingly pregnant upon receiving COVID-19 vaccine dose 1. Spontaneous abortion occurred at 4 weeks of pregnancy.
Unknown	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 5 weeks of gestation.
37 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 6 weeks of pregnancy.
31 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 5 weeks of gestation.
32 years	Not provided	Patient received her first vaccine dose at 3 weeks of pregnancy and experienced spontaneous abortion about 5-6 days before her second dose.

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3NT162b2
Cumulative Review from Pharmacovigilance Database

Table 1. Summary of Patients with Outcome of Pregnancy – Abortion spontaneous

Age	Medical History	Outcome of Pregnancy
23 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 1 month of pregnancy.
29 years	Pregnancy	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 4-5 weeks of gestation.
34 years	Not provided	The patient experienced spontaneous abortion at a routine OBGYN visit, gestational age unknown.
38 years	Not provided	Patient had spontaneous abortion at 12 weeks after receiving the second dose of vaccine.
29 years	Anxiety/Seasonal allergy	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 6 weeks of gestation.
41 years	Pregnancy	Patient was vaccinated during first trimester (6 weeks, also reported 1-12 weeks). Spontaneous abortion was diagnosed on 09 Jan 2021 (17 days after vaccination administration).
32 years	Pregnancy	The patient had spontaneous abortion at 5.5 weeks, which was conceived 3 days after receiving the vaccine.
36 years	Allergy to animal/Food allergy/Seasonal allergy	The patient was unaware of her pregnancy at the time of vaccination. Spontaneous abortion occurred during 5th week of pregnancy.
30 years	Clinical trial participant	Patient was vaccinated during first trimester (1-12 weeks). Spontaneous abortion occurred 1 week after first dose.
26 years	Not provided	Patient was vaccinated during first trimester (1-12 weeks). Spontaneous abortion occurred 1 day after vaccination.
28 years	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
25 years	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
Unknown	Not provided	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion, gestational age unknown.
34 years	Not provided	Patient received vaccine at 4 weeks 5 days of pregnancy. Spontaneous abortion occurred during Week 8 of gestation.
29 years	Pregnancy	Patient experienced spontaneous abortion 10 days after first dose of vaccine during first trimester of pregnancy.
21 years	Not provided	Patient was vaccinated during first-trimester (1-12 weeks) and experienced spontaneous abortion after 12 days.
30 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred at 11 weeks of pregnancy.
36 years	Coronavirus test negative/Deep vein thrombosis	Patient received vaccine at an unspecified time during pregnancy. Spontaneous abortion occurred at 4 weeks of pregnancy.
39 years	Drug hypersensitivity	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred during Week 8 of gestation
26 years	Not provided	Patient received vaccine during first trimester of pregnancy. Spontaneous abortion occurred after 5 weeks of pregnancy.
Unknown	Not provided	Spontaneous abortion occurred 3 days post first dose of BNT162b2.
Unknown	Not provided	Miscarriage after receiving both doses of COVID-19 vaccine

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Beyond the above, there is an enormous amount of data showing the toxicity in menstruation and pregnancy as follows:

One team of researchers performed a survey study of the impacts of vaccination on menstruation and were quickly deluged with 140,000 reports. Published in Science, they found that 42% of women reported menstrual abnormalities related to the vaccine.

From this article by investigative reporter Sonia Elijah, she reports on data obtained from a Freedom of Information Act request for the EU's Periodic Safety Update Report #3 (PSUR #3), covering the 6-month period of 19 December 2021 through to 18 June 2022, which recently became available on the Austrian Politics and Science blog, tkp. Here is an excerpt:

The pregnancy cases (cumulative clinical trial data)

The pregnancy cases arising from the cumulative clinical trial data in PSUR# 3, originated from Pfizer's phase 1/2/3 clinical trial through to June 2022. Even though pregnant women were excluded from Pfizer's pivotal trial, some of the female participants became pregnant.

As part of the approval letter for the emergency use of COMIRNATY (marketing name for Pfizer-BioNTech mRNA vaccine), the World Health Organisation (WHO) requested that BioNTech, the marketing authorisation holder, monitor their outcomes.
There were 697 pregnancy cumulative cases reported, which comprised of 597 mother cases and 100 baby/foetal cases. '*431 cases reported exposure to vaccine in utero without the occurrence of any clinical event'* in the mother cases. The following is a breakdown of the 166 mother cases which did report adverse clinical events. The numbers in brackets reflect the number of frequently reported events.

- ~ 1/5 of all mother cases reported serious adverse events (139)
- spontaneous abortions (46)
- Pre-eclampsia (7)
- Cephalo-pelvic disproportion (6)
- Abortion missed, Foetal death, postpartum haemorrhage, premature separation of placenta (4 each)
- Abortion threatened, ectopic pregnancy, gestational hypertension, premature delivery, premature labour (3 each)
- Abortion incomplete, hyperemesis gravidarum, maternal exposure via partner during pregnancy, miscarriage of partner, uterine disorder (2 each)
- COVID-19 (9)
- Anaemia (2)

From the list above, it's note-worthy to point out that "maternal exposure via partner during pregnancy" and "miscarriage of partner" refers to cases of women being **indirectly exposed to BNT162b2 by their vaccinated partners**. This importantly relates to vaccine shedding, which we know from their clinical trial protocol that Pfizer's was aware could happen. According to Pfizer's own clinical trial protocol, cases of pregnant women who were **indirectly exposed** to the vaccine by their partners (who participated in the trial) were classified as 'Exposure During Pregnancy' and immediately reported to Pfizer Safety on the Vaccine Serious Adverse Event Form within 24 hours of the investigator's awareness. The pregnancy was to be followed up by the investigator with Pfizer Safety being notified of the outcome.

The baby/foetal cases (cumulative clinical trial data)

What's disturbing is that a staggering 98 out of the 100 baby/foetal cases were reported as serious. The screenshots below reflect their appalling outcomes.

- Hundred (100) baby/foetal cases, 98 serious and 2 non-serious. Cases are classified according to pregnancy outcome.
    - Pregnancy outcome: Live birth with congenital anomaly: Thirty-one (31) of these cases reported 39 congenital anomalies that were coded to the PTs Atrial septal defect (4), Ankyloglossia congenital, Hypoxic-ischaemic encephalopathy, Neonatal hypotension, Trisomy 21 (2 each), Cleft lip, Coma neonatal, Congenital rubella syndrome, Congenital skin dimples, Congenital skin disorder, Craniosynostosis, DiGeorge's syndrome, Gnathoschisis, Microcephaly, Neonatal pneumothorax, Neonatal intestinal perforation, Neonatal seizure, Nervous system disorder, Newborn persistent pulmonary hypertension, Osteochondrodysplasia, Patent ductus arteriosus,

Polydactyly, Pyelonephritis acute, Renal failure neonatal, Renal tubular necrosis, Sepsis neonatal, Sex chromosome abnormality, Syndactyly, Thanatophoric dwarfism, Thrombocytopenia neonatal, Ventricular septal defect, Vesicoureteric reflux (1 each).

For the 68 baby/foetal cases showing 'live birth without congenital anomaly,' the serious adverse event outcomes can be read in the screenshot below.

- Pregnancy outcome: Live birth without congenital anomaly: Sixty-eight (68) cases reported live birth babies without congenital anomaly. Of these 68 cases, information regarding trimester of exposure was available in 40 cases. Of these 40 cases, in 23 cases, foetus was exposed during the 3rd trimester, in 14 cases foetus was exposed during the 2nd trimester, and in 3 cases exposure occurred during the 1st trimester. The frequently reported events (>1 occurrence) in these 68 cases were coded to PTs Jaundice neonatal (11), Foetal distress syndrome (8), Premature baby (6), Neonatal pneumonia, Neonatal respiratory distress, Bronchiolitis, Neonatal respiratory distress syndrome, Hyperbilirubinaemia neonatal (3 each), Foetal hypokinesia, Neonatal tachypnoea, Dehydration, Gastroenteritis, Patent ductus arteriosus, Anaemia neonatal, Sepsis neonatal, Hypoglycaemia neonatal, Meconium aspiration syndrome (2 each). In all these 68 cases, there was limited information regarding the mother's obstetric history, which precluded meaningful causality assessment.

Table 69. Post-Authorisation Data: Pregnancy Outcome during the Reporting Interval[a]

Pregnancy outcome	Prospective cases 1032 (28.3% of pregnancy cases)					Retrospective cases 866 (23.8% of pregnancy cases)				
	Timing of exposure in pregnancy					Timing of exposure in pregnancy				
	Before conception	1st trimester	After 1st trimester	During all pregnancy	Unknown	Before conception	1st trimester	After 1st trimester	During all pregnancy	Unknown
Ectopic pregnancy	0	1	0	0	0	0	1	0	0	1
Spontaneous abortion	0	14	1	0	25	0	149	13	0	281
Elective termination (foetal defects)	0	0	0	0	2	0	10	3	0	24
Elective termination (no foetal defects or unknown)	0	0	0	0	1	0	4	2	0	2
Stillbirth with foetal defects	0	0	0	0	0	0	4	7	0	15
Stillbirth without foetal defects	0	1	2	0	2	0	3	10	0	13
Live birth with congenital anomaly	0	14	2	0	10	0	5	10	0	11
Live birth without congenital anomaly	0	100	240	0	617	0	29	89	0	180
Total	***0***	***130***	***245***	***0***	***657***	***0***	***205***	***134***	***0***	***527***

a. 19 December 2021 through 18 June 2022.

Significantly, a third of the pregnancy outcomes provided during the reporting period were negative.
Spontaneous abortion: 483
Live birth with congenital abnormalities: 52
Still birth with foetal defects: 26
Elective termination (because of foetal defects): 39
Out of the 3642 pregnancy cases, 322 were classified as baby/foetal cases and 3320 were mother cases.

The baby/fetal cases (post-authorization data)

90% of the 322 baby/fetal cases were classified as serious. There were 39 cases of 'live birth with congenital anomaly.' The screenshots below, show the frightening range of those defects.

- Three hundred twenty-two (322) baby/foetal cases, 283 serious and 39 non-serious. Cases are classified according to pregnancy outcome.
  - Pregnancy outcome: Live birth with congenital anomaly: Thirty-nine (39) of these cases reported 72 congenital anomalies that were coded to the PTs Foetal malformation (4), Atrial septal defect, Congenital anomaly, Ventricular septal defect (3 each), Congenital cystic lung, Congenital hydronephrosis, Congenital skin dimples, Exomphalos, Foetal cardiac disorder, Foetal chromosome abnormality, Foetal growth restriction, Kidney malformation, Pulmonary valve stenosis congenital (2 each), Anal atresia, Ankyloglossia congenital, Arnold-Chiari malformation, Cleft lip, Cleft palate, Cloacal exstrophy, Congenital amputation, Congenital foot malformation, Congenital haematological disorder, Congenital hand malformation, Congenital heart valve disorder, Congenital musculoskeletal disorder, Congenital musculoskeletal disorder of limbs, Congenital musculoskeletal disorder of spine, Congenital oral malformation, Cryptorchism, Double outlet right ventricle, Dysmorphism, Enlarged foetal cisterna magna, Fallot's tetralogy, Foetal arrhythmia, Foetal growth abnormality, Growth retardation, Heart disease congenital, Heart valve incompetence, Hepatic cytolysis,

Hypospadias, Meningomyelocele, Neonatal deafness, Neonatal infection, Polydactyly, Pulmonary artery stenosis congenital, Pulmonary sequestration, Renal aplasia, Renal disorder, Renal dysplasia, Renal failure, Renal fusion anomaly, Renal hypertrophy, Spina bifida, VACTERL syndrome (1 each). Of these 39 cases,

There were 37 cases of spontaneous abortion in the baby cases with reported events of 'Foetal growth restriction (18) congenital anomaly (8), Foetal heart rate abnormal (3), Cytogenetic abnormality Foetal vascular malperfusion (2 each).'

In 4 cases the mother had an underlying medical history but for the remaining 33 cases, the report states, 'there was limited information regarding obstetric history or co-suspect medications of the mother, which precluded meaningful causality assessment.'

There were 23 cases of reported elective termination of pregnancy. **22 out of the 23 cases** '**reported elective termination due to foetal defects**.' There were a further 21 cases of still births, with just over 70% of those cases reporting foetal defects.

In stark contrast to the damning data, the report concludes: '**There were no safety signals regarding use in pregnant/lactation women that emerged from the review of these cases**..'

Furthermore, throughout the 'Use in Pregnant/Lactating Women' section in PSUR #3, the following dismissive and recurring statement is made, ""There was limited information regarding mother's obstetric history, which precluded meaningful assessment."

Beyond the European data, Thorpe et al recently published a study finding unprecedented signals of harm of the Covid-19 mRNA vaccines from the VAERS database using a CDC established method for detecting vaccine danger signals called "the proportional reporting ratio" (PRR). The CDC states that a **PRR of two or greater** is a safety signal "that requires further study."

The two figures below show the PRR's for eleven menstrual and pregnancy related outcomes. The first on the left calculates it by number of doses given and the second to the right by number of persons vaccinated. The magnitude of the PRR's are unprecedented. Depending on comparator method, having "abnormal menses" ranges from an **RR of 298 to 4927 (i.e. well over the threshold of 2)**. With miscarriages, the PRR ranges from 15-57.

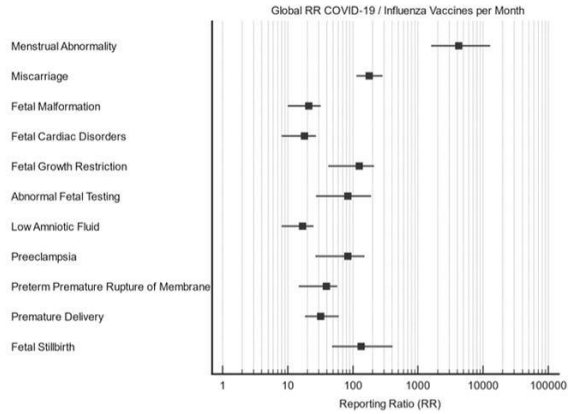


Figure 2. Global Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Month.

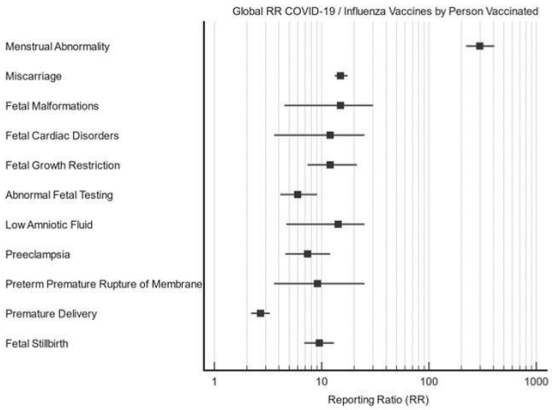


Figure 3. Global Reporting Ratios (RRs) for COVID-19 vs. Influenza Vaccination by Persons Vaccinated

Note the conclusion by this team of authors: "These results necessitate a worldwide moratorium on the use of COVID-19 vaccines in pregnancy."

Evidence of Shedding via Breast Milk

This study found that the vaccine mRNA was found in the milk of 1/10 women studied (4/40) in the first week after vaccination with mRNA vaccine (either after dose 1 or dose 2). Amounts can reach 2 ng/mL of milk.

Although the authors did not think this represented a "significant" amount, in Banoun's masterful review paper on shedding, she explains:

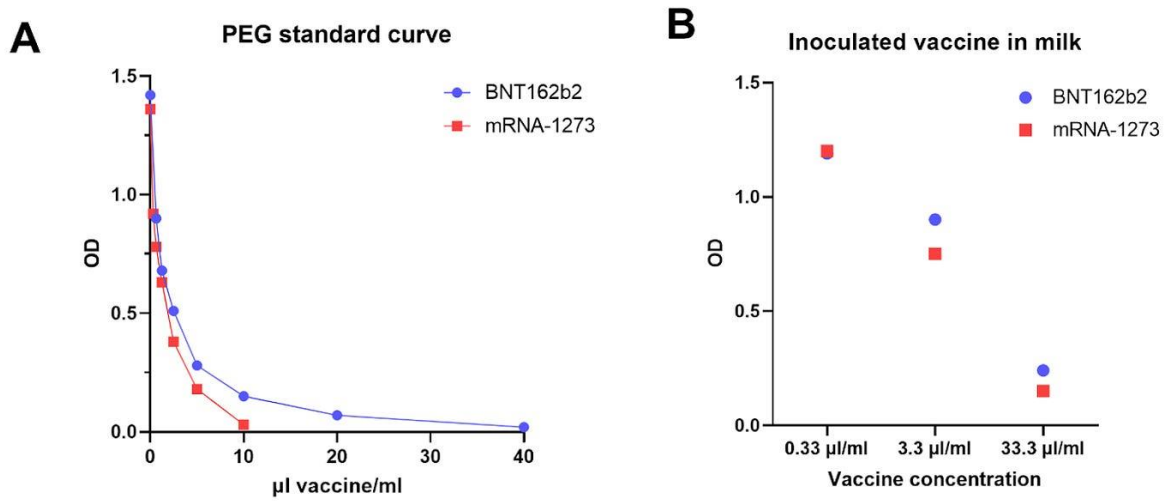
This amount may seem small compared to the 30 micrograms of mRNA injected with the vaccine, but it can be enough to produce a significant amount of spike. Indeed, an infant makes several feedings per day, for approximately 240 to 360 mL per day and a total over a week of 1680 to 2,520 mL in the first week. ***The newborn, weighing between 2 and 5 kg, could therefore be exposed to a dose of 5 µg of mRNA in its first week. This seems disproportionate compared to the 10 µg injected into children aged 5 to 11*** *years who weigh approximately 18 to 35 kg*

respectively [39]. The method used in the latter study is more sensitive than that of Golan et al. who did not find mRNA in milk [40].

This study in the Lancet reported on the breast milk of 11 women who were vaccinated with mRNA within 6 months of delivery. They found trace amounts of mRNA in 7 samples from 5 different participants at various times up to 48 hours post vaccination. The vaccine mRNA appeared in higher concentrations in the extracellular vesicles (i.e. exosomes/nanoparticles) than in whole milk. Their conclusion:
"Our findings demonstrate that the COVID-19 vaccine mRNA is not confined to the injection site but spreads systemically and is packaged into breast milk extracellular vesicles."

Another study found PEG (a component of the mRNA vaccine) as well as Covid vaccine mRNA in breast milk as shown below.

Supplementary data:



The authors write "Of note, PEGylated proteins concentration is higher in mRNA-1273 compared to BNT-162b2 **which also stand in line with mRNA concentration** in each vaccine (ready for administration vaccines were used)." So, a dose-response relationship was found which is particularly damning - the more you give, the more you find in breast milk).

So, we know mRNA can be transmitted (shed) to breastfed babies in breast milk. I used to dismiss the importance of this finding by reasoning that the stomach acid of the baby would destroy the mRNA it and render it inert. But then I found these papers (here, here, and here), which stated:

It has been known for some years that mRNA encapsulated in extracellular vesicles is protected from gastric juices and can transfect intestinal cells. A recent review by Melnik and Schmitz confirms that milk EVs survive the extreme conditions of the gastrointestinal tract, are

internalized by endocytosis, are bioavailable, reach the bloodstream, and penetrate peripheral tissue cells. Beyond integration into the genome, other concerns should arise such as provoking an "immunogenic" reaction to mRNA.

Clinical evidence suggesting that the mRNA and/or spike in breast milk can survive in the stomach and cause illness in the baby lies in the below list from an eight-page confidential document of reports made to Pfizer by lactating women who were vaccinated. Pfizer was aware of and tracking adverse events in babies "exposed" to the mother's vaccination via breast milk. Pfizer observed what was graded as non-severe adverse events (AEs) in a whopping 20% of the 215 lactating women reporting "exposure" to the vaccine.

The report also documents 10 ***serious*** AEs, including facial paralysis (not listed under "serious" interestingly), lymphadenopathy (swelling of lymph nodes that could be associated with cancer), and blurred vision. Note these are all side effects of the vaccines reported by adults. Among infants, reports included skin exfoliation, rashes, swollen skin, and unspecified sickness. That is a very high percentage of serious AEs in babies for any therapy.

Table 2. Number of Adverse Events Reported in Infants with 'Exposure via Lactation'

Preferred Term	Number of Events
Rhinorrhoea	1
Roseola	1
Skin exfoliation	1
Vision blurred	1

There were 10 SAEs reporting with the PT Exposure via lactation. Six of these SAEs were reported in infants.

- A 15-month old infant with medical history of vomiting experienced skin exfoliation and infant irritability while being breastfed (latency <7 days). The outcome of the event 'skin exfoliation' was not recovered and outcome of event 'infant irritability' was unknown. No causality was reported by the physician.
- A 9-month old infant with a medical history of meningococcal vaccine and no history of allergies, asthma, eczema or anaphylaxis experienced rash and urticaria a day after exposure via lactation. The outcome of the events was 'resolved' and event did not happen after the second day. No causality assessment was provided.
- A day after the mother received vaccination, a baby developed a rash after breastfeeding. At the time of the report, the event was 'not recovered. A causality assessment was not provided.
- An 8-month old infant experienced angioedema one day after his mother received vaccination. The event was considered non-serious by health authority and the outcome at the time of the report was unknown. No causality was provided.
- There were 2 cases reporting 'illness' after exposure via breast milk'. In the first case, a 6-month old infant developed an unspecified sickness 2 days post mother's vaccination. The outcome of the event sickness was recovered, and no causality assessment was provided. The second case, a 3-month old infant developed an unspecified illness and required hospitalization for 6 days post exposure via breast milk (>7 days latency). The event outcome was reported as 'recovering' and no causality assessment was provided.

Again from the article by investigative reporter Sonia Elijah, she reports on data obtained from a Freedom of Information Act request for the EU's Periodic Safety Update Report #3 (PSUR #3), covering the 6-month period of 19 December 2021 through to 18 June 2022, which recently became available on the Austrian Politics and Science blog, tkp. She discovered that Pfizer **documented numerous cases of strokes, convulsions, and respiratory failure among nursing babies.**

16.3.3.1.16. Respiratory AESIs

Search criteria - HLTs (All Path) Lower respiratory tract infections NEC; Respiratory failures (excl neonatal); Viral lower respiratory tract infections OR PTs Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Respiratory disorder.

Upon review, 4 cases were determined to be non-contributory and were not included in the discussion since these cases involved exposures to the vaccine during the mother's pregnancy or through breastfeeding.[99]

It is important to note that upon further review of PSUR #1, something extremely disturbing surfaced – adverse events were reported for breast-fed babies, indirectly exposed to the Pfizer-BioNTech mRNA shot, by their vaccinated mothers. The screenshot below is taken from page 165 of PSUR #1.

16.3.3.1.16. Stroke

- Search Criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents; Cerebrovascular venous and sinus thrombosis (Primary Path).
  - Upon review, 2 PM cases were determined to be non-contributory and are not included in the discussion since these 2 cases involved babies who were indirectly exposed to BNT162b2 (trans-mammary route).

The fact that 2 cases from the post-marketing (PM) data involved babies who were indirectly exposed to the Pfizer-BioNTech mRNA vaccine (BNT162b2) **via the trans-mammary route** (through the breast milk) and consequently suffered a **stroke** (central nervous system haemorrhages and cerebrovascular accidents), is shocking.

Then, on page 149 (screenshot below), 3 more cases of babies suffering from neurological adverse events, for example, convulsions, from being indirectly exposed to the vaccine via their vaccinated mothers' breast milk, were recorded.

16.3.3.1.10. Neurological AESIs (including demyelination)

- Search Criteria: SMQ Convulsions (Narrow and Broad) OR SMQ Demyelination (Narrow and Broad) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Neuropathy peripheral; Polyneuropathy.
  - Upon review, 3 PM cases were determined to be non-contributory and are not included in the discussion since these 3 cases involved babies who were indirectly exposed to BNT162b2 (trans-mammary route).

From the analysis of booster doses (> 2 dose primary series), a staggering 455 cases were recorded during the 6-month reporting interval (1 from the clinical trial data and 454 recorded from the post-marketing data) involved babies whose cases "**were excluded due to indirect exposure (transplacental/transmammary) to BNT162b2**" as below:

Analysis of Booster Doses

Search criteria: Dose number equal to 3 or Dose number equal to 4 OR Dose Description containing the word "BOOSTER" OR LLT equal to BOOSTER.

The search yielded 119,601 cases (491 CT cases and 119,110 PM cases).

Upon review,

– 455 cases (1 CT and 454 PM) involving babies were excluded due to indirect exposure (transplacental/transmammary) to BNT162b2.

A further example, shown in the screenshot below taken from page 239, reports 4 cases (babies) suffering from respiratory adverse events of special interest (AESI), which were "determined to be non-contributory and were not included in the discussion since these cases involved **exposures to the vaccine during the mother's pregnancy or through breastfeeding**."

16.3.3.1.16. Respiratory AESIs

Search criteria - HLTs (All Path) Lower respiratory tract infections NEC; Respiratory failures (excl neonatal); Viral lower respiratory tract infections OR PTs Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Respiratory disorder.

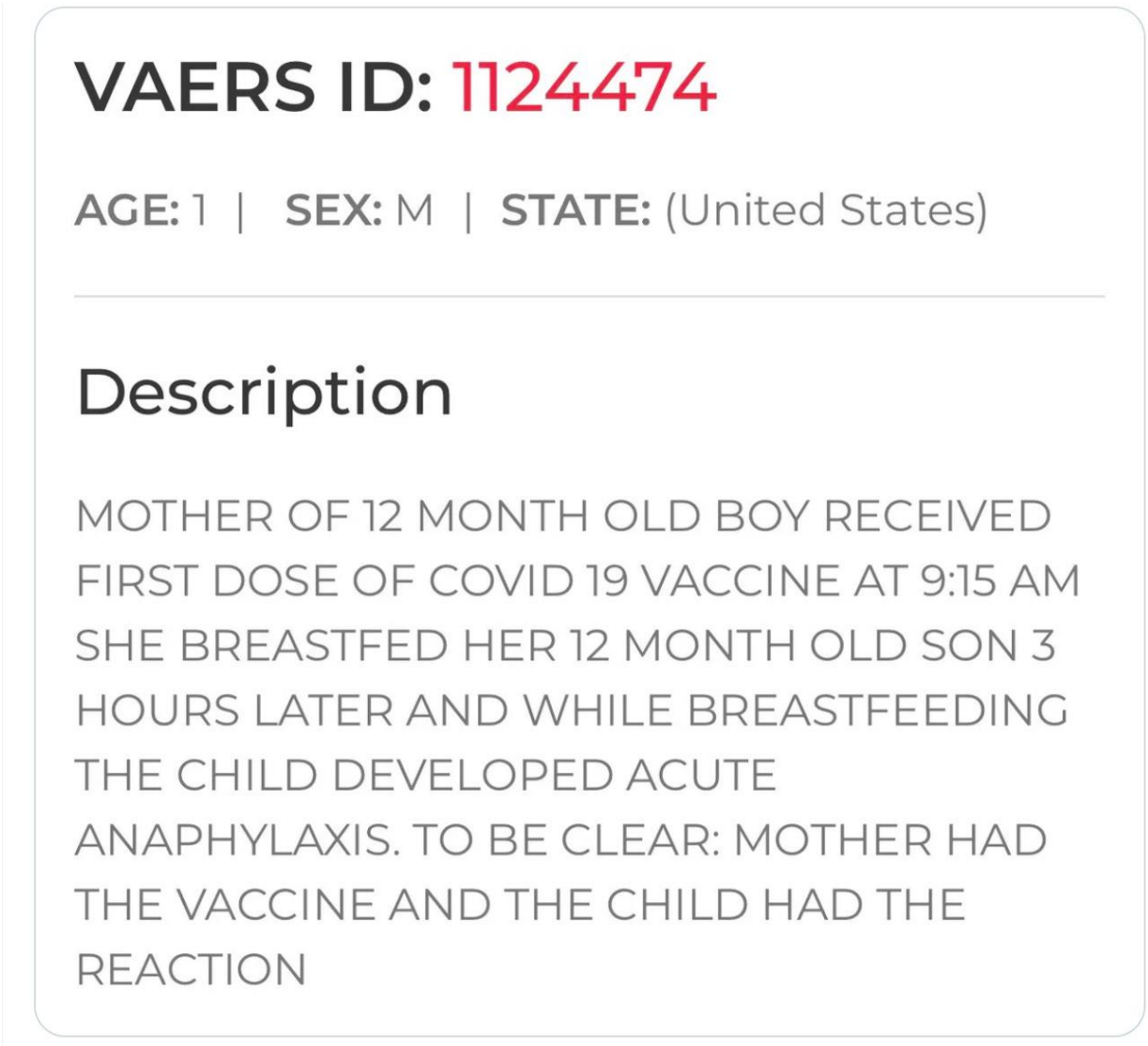
Upon review, 4 cases were determined to be non-contributory and were not included in the discussion since these cases involved exposures to the vaccine during the mother's pregnancy or through breastfeeding.[99]

In both PSUR reports the same reason is given by Pfizer/BioNTech for why these cases "are not included in the discussion" because they "**were determined to be non-contributory**" since they involved babies "**who were indirectly exposed to BNT162b2**."

This is clearly an admission that babies can be "indirectly exposed", i.e evidence that shedding between mother and baby occurs.

Given the gravity of this important safety signal affecting nursing babies, to brush over the fact that these infants' adverse event cases were non-contributory because they were indirectly exposed to the vaccine via breast milk is unconscionable.

More evidence: A study published a year ago in JAMA revealed that 3.5% of women reported a decrease in breast milk supply and **1.2% reported "issues with their breastmilk-fed infant after vaccination."** Here is one vivid VAERS entry which could represent spike or the LNP in breast milk:



VAERS ID: 1124474

AGE: 1 | SEX: M | STATE: (United States)

Description

MOTHER OF 12 MONTH OLD BOY RECEIVED FIRST DOSE OF COVID 19 VACCINE AT 9:15 AM SHE BREASTFED HER 12 MONTH OLD SON 3 HOURS LATER AND WHILE BREASTFEEDING THE CHILD DEVELOPED ACUTE ANAPHYLAXIS. TO BE CLEAR: MOTHER HAD THE VACCINE AND THE CHILD HAD THE REACTION

Elijah did a more recent investigative report on Pfizer's Pregnancy and Lactation Review which had just been released in April per court-order by the FDA, 2 years after it was signed off, and she again found reports of similar damning adverse events, such as spontaneous abortions and preterm delivery of foetuses after **exposure to the vaccine trans-placentally or trans-mammary** (through the breast milk) after their mothers were vaccinated. Adverse events such as facial paralysis and lymphadenopathy were also reported in infants, indirectly exposed through the breast milk of their vaccinated mothers.

Again from the paper published in the *Journal of American Physicians and Surgeons* by Thorp et al., they discovered an astonishing volume of global adverse event counts for COVID-19 vaccines reported over 18 months, *compared to 282 months for influenza vaccines*, (see screenshot of Table 1 below).

Table 1. Global Adverse Events (AEs): COVID Vaccines; Influenze Vaccines

Adverse Event (AE)	AE Count (COVID; influenza)	AE/month (COVID; influenza)	AE/billion doses (COVID; influenza)	AE/billion persons (COVID; influenza)
Menstrual abnormality	12,843; 65	714; 0.221	1,060; 0.985	2460; 8.43
Miscarriage	3,338; 325	185; 1.11	277; 4.92	638; 42.2
Chromosomal Abnormalities	10; 0	0.556; 0.00	0.829; 0.00	1.91; 0.00
Malformation	22; 2	1.22; 0.0068	1.82; 0.0303	4.21; 0.259
Cystic Hygroma	8; 0	0.444; 0.00	0.663; 0.00	1.53; 0.00
Fetal Cardiac Disorders	18; 2	1.00; 0.0068	1.49; 0.0303	3.44; 0.259
Fetal Arrhythmia	5; 0	0.278; 0.00	0.414; 0.00	0.956; 0.00
Fetal Cardiac Arrest	20; 0	1.11; 0.00	1.66; 0.00	3.82; 0.00
Malperfusion	12; 0	0.667; 0.00	0.994; 0.00	2.29; 0.00
Growth Anomaly	188; 24	10.4; 0.0816	15.6; 0.364	35.9; 3.11
Abnormal Fetal Surveillance	178; 45	9.89; 0.153	14.7; 0.682	34.0; 5.84
Placental Thrombosis	6; 0	0.333; 0.00	0.497; 0.00	1.15; 0.00
Stillbirth	402; 62	22.3; 0.218	33.3; 0.970	76.9; 8.3
Low amniotic fluid	17; 1	0.944; 0.00340	1.41; 0.0152	3.25; 0.130
Preeclampsia	133; 28	7.39; 0.0952	11.0; 0.424	25.4; 3.63
Preterm Delivery	384; 212	21.3; 0.721	31.8; 3.21	73.4; 27.5
PPROM	45; 9	2.50; 0.0306	3.73; 0.136	8.60; 1.17
Premature Baby Death	10; 0	0.556; 0.00	0.829; 0.00	1.91; 0.00

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Lastly, via personal communication with the Principal Investigator Dr. Sue Peters, a study was performed where a group of unvaccinated women were exposed to recently vaccinated women and the authors have disclosed to me that 70% of women developed menstrual irregularities subsequent to the exposure. For more details on the study, I refer you to Dr. Peters at sp@suepeters.com. I believe her study, along with all the above data, would most definitively support the scientific and clinical accuracy of the comments on shedding made by Dr. Hoffe.

Conclusion

In light of all the evidence I have presented on the science and impacts of shedding, I believe that much of Dr. Corneil's professed expert opinion should be called into question when he makes such easily disprovable assertions so emphatically. For instance, he wrote:

" there is no biological mechanism for viral shedding or release of any vaccine component to occur with these vaccines."

From the above highly referenced series of papers, this statement is 100% false. Further, his characterization of Dr. Hoffe's statement on shedding risks as being inaccurate and in violation of both the Prudence and Harm Prevention standards is driven by demonstrable and unconscionable ignorance of the topic.

Another statement of Dr. Corneil's regarded Pfizer's clinical trial protocol as follows:

"*There was significant media interest in, mischaracterization and misrepresentation of the Pfizer Comirnaty clinical trial protocol which included on pages 67 and 68, a standard exclusion criterion involving female study participants found to be pregnant while being exposed to or having been exposed to virus or an attenuated virus following inhalation or skin exposure182.* ***This criterion is not relevant to non-viral based vaccines including mRNA COVID-19 vaccines and does not speak to or corroborate COVID-19 viral shedding or shedding of any other component of the Pfizer Comirnaty COVID-19 mRNA vaccine****.*

I instead will argue that the exclusion criteria was appropriate and consistent with those of a gene based therapy.

From the evidence I have presented, it is clear that shedding phenomenon is real and has adverse impacts in not only breastfed babies but most convincingly on menstruation as accurately discussed by Dr. Hoffe. Shedding is real. Pfizer knew shedding was real, and the section of the protocol with such "shedding exposures" as exclusions is perfectly in line with precautions taken around gene-based nanoparticle technology.

Again, Pfizer knew that shedding was a possibility given that they specifically excluded people "exposed" to the vaccine via inhalation (not subtle) or skin contact. Starting on p. 67 of the protocol the investigator is **instructed to report** various "environmental exposures."

1)A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception."

2) "A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact."
3) "A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception."
4) "A female is found to be breastfeeding while being exposed or having been exposed to study intervention (ie, environmental exposure). An example of environmental exposure during breastfeeding is a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention by inhalation or skin contact."

From this expert review of shedding of mRNA vaccines which has been peer-reviewed and published, the author's interpretation of these exclusion criteria directly contradicts Dr. Corneil as follows:

The protocol for the Pfizer Phase I/II/III trial of COVID-19 mRNA vaccines (which began in May 2020) mentions the possibility of passage of the study product through inhalation or skin contact and passage through semen from a man exposed through inhalation or skin contact and passage through breast milk; the possibility of an adverse vaccine reaction from these exposures is also mentioned [15]. Pfizer's data clearly indicate that a pregnant woman may be exposed to "the intervention studied due to environmental exposure."

Environmental exposure can occur through "inhalation or skin contact." Examples of environmental exposure during pregnancy include: A female family member or health care provider reports that she is pregnant after being exposed to the study intervention through inhalation or skin contact. A male family member or health care provider who was exposed to the study intervention by inhalation or skin contact subsequently exposes his female partner before or around the time of conception.

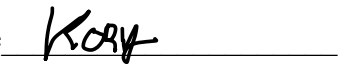
The author further interprets the section as follows:
This clearly means that any contact, including sexual contact with someone who has received the vaccines, exposes those who have not received the vaccines to the "intervention", i.e. mRNA. Exposure during breastfeeding had also to be immediately notified during the trial: it is assumed that the investigator is concerned that a breastfeeding mother could transmit the experimental mRNA to her baby if she received the vaccines directly or if she is "exposed to the study intervention by inhalation or skin contact."

I understand in some small way as to how Dr. Corneil's misinterpretation occurred. I believe it is partly due to the fact that the protocol was written in what I maintain was a deliberately obfuscating way (i.e. they purposely use the word "exposed" in two different connotations, such as in exclusion #4 where they describe receiving the intervention (i.e. the vaccine) as having been "exposed" to it, but then they also use exposed in the context of "environmental exposure."

Finally, I am seriously troubled by the fact that Dr. Corneil, either willfully or through ignorance would so erroneously accuse Dr. Hoffe of violating both Prudence and Harm Prevention standards with such easily disprovable data and arguments. I have provided extensive evidence which directly contradicts Dr. Corneil's opinion on Dr. Hoffe's statements on ivermectin's efficacy in

prevention and treatment of Covid as well as Dr. Corneil's opinion on Dr. Hoffe's statements on shedding. It is my opinion that Dr. Corneil's numerous false accusations that Dr. Hoffe violated practice standards threatens the livelihood of Dr. Hoffe by restricting or revoking his license to practice medicine. It is my belief that such behavior violates the *CMA Code of Ethics and Professionalism* and thus I encourage the College to investigate Dr. Corneil for his damaging behavior to a colleague.

Name: Pierre Kory, MD, MPA

Signature 

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