IN THE MATTER OF the CITATION to appear further amended and dated July 19, 2023 pursuant to Section 38 of the *Health Professions Act*, RSBC 1996, c 183

BETWEEN

COLLEGE OF PHYSICIANS AND SURGEONS OF BRITISH COLUMBIA (the "College")

APPLICANT

AND

DR. CHARLES HOFFE ("Dr. Hoffe")

RESPONDENT

APPLICATION RESPONSE OF DR. HOFFE

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Part 1: FACTUAL BASIS

Overview

- 1. In its <u>Application</u>, the College seeks an order that the panel take judicial notice of statements made by public health and government officials or the institutions they represent as constituting fact ("Notice Facts") (page 8/80 para 23). These statements are not proven, often constitute hearsay, and are contradictory to statements made by these same individuals and institutions, the COVID-19 vaccine manufacturers, and other credible sources of information, including qualified experts in the field.
- 2. No affidavit evidence has been filed by the College in support of their Application.
- 3. To say that the volume of public health guidance documentation relied upon by the College to support their Application is enormous, is an understatement. The various Government departments regularly publish lengthy articles and guidance on their respective websites that contain numerous links to other webpages within and outside their own department, which then again contain numerous links to other public health statements and so on and so on. There really is not an end to the links on each page taking one to yet another page. The sheer volume of this information makes it very difficult for the average citizen or legal or medical professional to wade through.
- 4. Some of the Notice Facts the College seeks judicial notice of are overly broad, vague, and in at least one instance contradictory, making it inappropriate to take judicial notice of them.
- 5. The public health and government officials that the College relies upon to support their Application have admitted that the evidence pertaining to the Notice Facts continues to evolve and change and has done so since the beginning of 2020 at an ever-increasing pace, again making it inappropriate to take judicial notice of the Notice Facts.
- 6. Although the College alleges that the facts that they seek judicial notice of are generally accepted by the profession, the evidence demonstrates that what many professionals may have believed at one point in time, has changed as new information has emerged.
- 7. To support its application, the College relies upon various statements made by public health authorities and government officials, or courts who have taken judicial notice of those statements as fact when the opposing party failed to present credible admissible evidence, including expert evidence, to the contrary Many of these cases were decided when significantly less information was available to public health and government officials responsible for making these statements. In a number of these cases, the court took judicial notice of facts that have subsequently been proven wrong, or that public health and government officials have admitted were wrong.
- 8. The College has referenced 53 Court decisions which they argue supports its Application. A careful review of these authorities makes it clear that they do not support taking judicial notice of the Notice Facts in the circumstances of this disciplinary hearing.

- 9. The majority of the authorities referred to by the College are family law cases where there was a dispute between parents as to whether or not the best interests of a particular child indicated that they should be vaccinated with a Covid 19 vaccine, and in some instances, vaccines on the regular childhood vaccination schedule. In only 3 of these cases did an opposing party even attempt to tender expert evidence to contradict the facts that the opposing party sought judicial notice of.
- 10. In <u>B.C.J.B. v. E.-R.R.R. 2022 ONCJ 500</u> the Court declined to take judicial notice of the COVID-19 vaccines and instead elected to decide the matter based upon expert evidence presented to the Court. In <u>O.M.S. v. E.J.S. 2023 SKCA 8</u> the Court of Appeal determined the Chambers Judge took judicial notice of the safety and efficacy of the COVID-19 vaccines in error when the parties presented conflicting expert evidence. In <u>C.M. v. S.L.S. 2022 ONCJ 206</u> the Court determined that the experts presented by the parent opposing the vaccine were not qualified to opine on the matters in issue. In the remaining cases, the party opposing the judicial notice application were unsuccessful because they failed to present the Court with sufficient admissible evidence to the contrary.
- 11. Of the remaining non-family law cases cited by the College, only 3 of those involved attempted to present expert evidence to challenge the application for judicial notice. Where the evidence presented was admissible, the Court declined to take judicial notice and rendered its decision based upon the evidence presented by the parties in the hearing.
- 12. In Kodheir v. Canada 2022 FC 44, the opposing party attempted to tender expert opinion from an emergency room physician and biostatistician who the Court found were not qualified to provide expert evidence on the matters in issue. In B.C. General Employees' Union v. BC Safety Authority (Technical Safety BC) 2023 CanLII 76193 (BC LA) the labour arbitrator declined to take judicial notice and instead allowed the opposing party to present qualified expert opinion evidence on the matters in issue. In College of Physicians and Surgeons of Ontario v. Trozzi 2023 ONPSDT 22 they disqualified one of Dr. Trozzi's experts on the basis of that they were not qualified to opine on the issues in question, and found that Dr. Trozzi's remaining expert, was only qualified by counsel to provide evidence on two very narrow points. The panel held his evidence did not address the scope of Dr. Trozzi's misstatements and accordingly declined to give weight to his opinion and instead preferred the opinion of the College's 3 expert witnesses. In the other 3 disciplinary hearing decisions referred to by the College the physician did not contest the charges in the citation.
- 13. There are no authorities provided by the College involving a disciplinary hearing of a physician where the panel decided to take judicial notice where the physician submitted qualified expert evidence that pertained directly to the facts that the College sought judicial notice of.
- 14. It is clear from a review of the authorities that the Courts across the country are not unanimous on whether it is appropriate to take judicial notice of statements made by public health and government officials and the institutions they represent about facts similar to the Notice Facts.

- 15. One thing that all of the Court decisions do agree upon however, is that if a party wishes to challenge a judicial notice application of this nature, they are entitled to do so provided they submit compelling evidence, including expert evidence, to directly challenge those facts.
- 16. The College admits that Dr. Hoffe must have the opportunity to respond and show that the alleged facts in question are not sufficiently notorious or beyond reasonable dispute to warrant judicial notice (<u>Application</u> page 53/80 paragraph 81).
- 17. Dr. Hoffe has delivered 8 expert reports to the College (the "Expert Evidence") containing evidence that the College admits directly challenges the "facts" the College says are notorious (Application page 3 paragraph 5).
- 18. The qualifications and credentials of Dr. Hoffe's experts from Canada, the United States and the United Kingdom are extensive. They present data to support their conclusions, often supported by peer reviewed literature and research as well as from the vaccine manufacturers themselves. Dr. Hoffe will also present evidence from the very public health and government guidance that the College relies upon, which will demonstrate that these individuals and institutions have regularly changed their mind as to what they say the facts are about the Notice Facts, and that they often disagree with and contradict each other and even themselves. The evidence will also show that these same public health officials concede that the evidence is emerging and rapidly evolving over time and that they are monitoring the situation. They have made a committment to advise the public when new information becomes available. Dr. Hoffe will also present evidence from documentation created by the COVID-19 vaccine manufacturers, and other reputable organizations, some of whom have been relied upon by the College, which also contradict many of the Notice Facts (collectively, the "Evidence").
- 19. The College indicated to the panel and counsel for Dr. Hoffe in a March 8, 2024 email that if their application for judicial notice is not successful, instead of having one expert witness, namely Dr. Corneil as previously indicated, they intend to call 2-3 witnesses, one expert, and "about 6 rebuttal experts". In their Application the College says that they will need to prepare numerous rebuttal reports resulting in the hearing being significantly longer (Application, page 5, para 14). In counsel's email, they advise that instead of requiring 2 weeks for the disciplinary hearing, they "guess 4-5 weeks for the evidentiary portion of this hearing" will be required.
- 20. While one would assume that the College had already garnered the evidence they believed was necessary to prove the charges set out in the Citation before the Citation was issued on February 11, 2022. The fact that the College now says they will need several additional lay and expert witnesses requiring more than double the time for hearing previously scheduled to provide the evidence necessary to prove the allegations in the citation, strongly supports the argument that the Notice Facts are not facts that are notorious, nor capable of immediate and accurate demonstration by resort to readily accessible sources of indisputable accuracy.

- 21. At the prehearing conference on February 26, 2024, a member of the panel asked counsel for the College whether the College's expert Dr. Corneil provided evidence concerning the Notice Facts in his report. Counsel for the College conceded that he did. It is thus not necessary, or reasonable, to take judicial notice of facts that the College has already tendered expert evidence in an attempt to prove those facts at the hearing.
- 22. The College complains that if the panel does not take judicial notice of their alleged facts the hearing will be significantly longer with increased time substantially devoted to a detailed hearing of evidence on various particular scientific issues including the opinion expressed by Mr. McKernan on the risks posed by the recent admission by Health Canada that the vaccines are contaminated with DNA and Simian Virus 40. (Application, page 5, paragraph 14)
- 23. The College essentially argues that the convenience gained by having less witnesses and a shorter hearing should be preferred over having a fair hearing where they actually have prove the allegations and address the compelling contrary evidence (Application, page 5, paragraph 15).
- 24. The College admits that the panel is going to be asked to determine whether misconduct has occurred (Application paragraph 16). The misconduct that is alleged is that Dr. Hoffe made statements that contradict what the College says are "universal facts" about these topics. Yet the College argues that judicial notice should be taken as this will focus the hearing away from general topics not specific to this dispute. As Notice Fact 4 indicates, the College is seeking judicial notice of the fact that vaccines are generally safe and have a low risk of harmful effects. These are broad assertions. They seek to discipline Dr. Hoffe for making statements about specific side effects of the COVID-19 vaccines. Dr. Hoffe has presented credible expert evidence and statements made by Health Canada, NACI, the BC CDC and other public health officials that challenge the veracity of the Notice Facts that demonstrate a fair and proper hearing is required to determine the facts.
- 25. Contrary to the College's submission, allowing Dr. Hoffe to present evidence to challenge the evidence presented by the College through their expert Dr. Trevor Corneil, does not turn the disciplinary hearing into Royal Commission of Inquiry into the government's public health response, or a general inquiry into the nature of the COVID-19 pandemic (Application page 4, para 9 and page 5, para 11). The College alleges facts that are broad and far reaching. Dr. Hoffe is entitled to present evidence to challenge the facts alleged by the College in order present full answer and defence to the charges in the Citation.
- 26. The College is fully aware of Dr. Hoffe's evidence after having been in possession of his expert reports for nearly 2 months.
- 27. While the College has referenced very select excerpts of the evidence from Dr. Hoffe's expert reports in its Application, the references are often taken out of context, and omit the relevant facts and opinion.
- 28. The College complains that if Dr. Hoffe is permitted to tender the Evidence that there is a risk that their Notice Facts may not be accepted, and the panel would then need to

adjudicate the facts (Application page 5 para 13). That is the very purpose of the disciplinary hearing. The principles of procedural fairness and natural justice require an opportunity for both parties to tender all relevant evidence, that may be tested under cross examination, so that the panel can determine what the facts are and thereafter render a fair and just decision based upon all of the evidence, not only the untested evidence proffered by one party.

- 29. The College complains that if the panel does not take judicial notice of their version of the facts, they will "need to prepare numerous rebuttal reports to address various issues raised by Dr. Hoffe's experts". Dr. Hoffe's expert witnesses present evidence that directly challenge the facts alleged by the College through their expert witness Dr. Trevor Corneil in support of the charges contained in the Citation. There should be no need for the College to retain numerous additional witnesses if Dr. Corneil has presented the evidence necessary to support the issuance of the Citation. (Application, page 5, paragraph 14).
- 30. The College says that "a quick visit to Health Canada's website" will verify their version of the facts and therefore should be accepted without challenge (Application page 5, para 13). The evidence clearly demonstrates that Health Canada has made many statements about the issues raised in the Citation over the last 4 years, and has often changed its position as to what it says the facts are and admits the facts are still changing and more information is expected in the future.
- 31. While any party would be content to have a trier of fact accept their version of the facts without having to prove them and without allowing the opposing party an opportunity to challenge them, that would be procedurally unfair, especially in the context of a disciplinary hearing where a higher standard of procedural fairness is required because the potential consequences are so severe.
- 32. While the College claims that preventing Dr. Hoffe from presenting his own evidence to challenge the facts alleged by the College would promote efficiency and public confidence in the administration of justice, Dr. Hoffe maintains the opposite is true. It would effectively prevent Dr. Hoffe from being able to defend himself against the charges in a fair an impartial hearing where both parties present evidence to the panel that is tested by cross examination. To allow the College's application in the face of significant credible evidence, from 8 qualified experts, along with other evidence from public health and government and the manufacturers themselves which directly challenge the Notice Facts, taking judicial notice would amount to a breach of procedural fairness and would bring the administration of justice into disrepute.
- 33. Dr. Hoffe however, is prepared to agree that certain portions of the facts alleged in the Notice Facts, are indeed facts, not on the basis of judicial notice, but on the basis of the evidence presented:
 - (a) Notice Fact (4) "The [COVID-19] vaccines do not prevent infection, reinfection or transmission."; and
 - (b) Notice Fact (6) "Health Canada has approved COVID vaccines."

The Evidence Pertaining to the "Notice Facts" the College Seeks Judicial Notice of

- 34. Dr. Hoffe's expert witnesses provide qualified expert opinion and fact evidence that directly challenge the Notice Facts. The full reports of these expert witnesses are also relied upon by Dr. Hoffe as part of his Response to the Application and have previously been provided to counsel for the panel and to counsel for the College. The reports themselves, provide clear, convincing and cogent evidence that directly challenge the veracity of the Notice Facts and demonstrate that judicial notice should not be taken of them.
- 35. The expert witnesses relied upon by Dr. Hoffe include the following experts (with a brief description of their areas of practice and expertise provided. A full description of their qualifications can be found in their respective reports):
 - (a) Kevin McKernan, genomist, and Team Leader for Research & Development for the Human Genome Project, and has over 59,000 citations 's publications in the genomics field and has issued dozens of patents related to DNA and RNA purification and DNAs, the founder of 3 genomics companies has been awarded over \$30 million in National Institute of Health grants for genomics, Beverly, Massachusetts
 - (b) <u>Dr. Jessica Rose</u>, researcher with advanced degrees in applied mathematics, immunology, computational biology, molecular biology and biochemistry, computational and data science analyst, Ontario
 - (c) <u>Dr. Eric Payne</u>, qualified Pediatric Neurologist and Clinical Researcher specializing in neuro- critical care, epilepsy, and neuro- inflammation, with a Master of Public Health from Harvard University where he gained expertise in epidemiology and statistics. He served 6 years as a Staff consultant at the Mayo Clinic in Rochester Minnesota where he gained additional expertise in neuro- inflammation in clinical trials, Alberta
 - (d) <u>Dr. Pierre Kory</u>, BA in mathematics, MA in public health administration, and an MD, served as program directory of the pulmonary and critical care Fellowship at Beth Israel Medical Centre, was the Chief of the Critical Care Service at the University of Wisconsin where he also served as the Medical Director of the Trauma and Life Support Centre, President and Chief Medical Officer of the Front Line Covid 19 Critical Care Alliance, and Chief Medical Officer of the Leading Edge Clinic, Saint Augustine, Florida
 - (e) Dr. Claire Craig, medical practitioner with a specialty in diagnostic pathology, and a fellow of the Royal College of Pathologists 2009, is cochair of the Health Advisory and Recovery Team, a body of UK doctors, scientists, statisticians, psychologists, ethicists and other professionals who focus on research into Covid 19 in the United Kingdom, from 2016-2019, was the Clinical Lead for Pathology on the cancer arm of the 100,000 Genomes Project: Genomics England LTD, London

- (f) <u>Dr. Steven Pelech</u>, PhD and postdoctoral training in the area biochemistry, on the faculty of the University of British Columbia as a professor in the Department of Medicine for over 35 years at Vancouver, British Columbia;
- Dr. James Thorp, obstetrician and gynecologist, clinical professor Department of Obstetrics & Gynecology, Florida State University College of Medicine at Pensacola Regional campus December 2003-2015, Voluntary re-certification for ObGyn and Maternal Fetal Medicine, American Board of Abstract tricks and Gynecology 2011-2023, was a Fellow of American College of OB/Gyn, and was rated in the top 15% of 1403 to reviewers and 1998 of Obstetrics and Gynecology, a regular reviewer of the American Journal of Obstetrics and Gynecology, the Journal of Maternal Fetal Medicine, New England Journal of Medicine in the Journal of the American Medical Association, Gulf Breeze, Florida
- 36. Dr. Peter McCullough, cardiologist, epidemiologist and board-certified in internal medicine and cardiovascular disease, with a certification in clinical lipidology (previously echocardiography). Dr. McCullough participates in the maintenance of certification programs by the American Board of Internal Medicine for both Internal Medicine and Cardiovascular Diseases. He practices internal medicine and clinical cardiology as well as teaches, conducts research, and is an active scholar and medicine with roles as an author and former editor-in-chief of 2 peer-reviewed journals as well as editorialist and reviewer at dozens of major medical journals and textbooks. He has led clinical, education, research and program operations at major academic centres (Penry Ford Hospital, Oakland University William Beaumont School of Medicine, Baylor University Medicine Centre, as well as academically oriented community health systems. He frequently lectures and advises on internal medicine, nephrology and cardiology to leading institutions worldwide. He has extensively published his research on subjects in addition to Covid 19, having more than 1000 related scientific publications. He served as the chairman or as a member of more than 20 randomized trials of drugs, devices and clinical strategies, and sponsors have included pharmaceutical manufacturers, biotechnology companies and the National Institutes of Health. He is a fellow of the American College of Cardiology, the American Park Association, the American College of Chest Positions, the National Lipid Association, the Cardiorenal Society of America and the National Kidney Foundation. He holds a Masters Degree in Public Health in the field of epidemiology., Texas.
- 37. The College has provided a list of particulars by letter dated July 28, 2022 concerning the allegations in the Citation, that are referred to in part at pages 6 to 8 in paragraph 18 of the Application (the "Particulars Letter"). The College says that the statements are unprofessional, misleading, incorrect or inflammatory. The Particulars letter is attached to this Response as <u>Appendix 1</u>.
- 38. The Particulars Letter advises that the statements that the College is referring to in the Citation are about the safety and efficacy of the Covid-19 vaccines and the safety and efficacy of alternative treatments for Covid-19 such as Ivermectin and can be summarized as follows:

- (a) the Covid 19 vaccines were experimental (Application page 6, paragraph 18 (1)(i));
- (b) we have no idea what the long-term safety consequences might be (Application page 6, paragraph 18 (1)(i));
- (c) the spike proteins generated from the Covid 19 vaccine concentrate in the ovaries (Application page 6, paragraph 18 (1)(ii));
- (d) that after vaccination many women notice disruption to their menstrual periods or they become erratic or heavy (Application page 6, paragraph 18 (1)(ii);
- (e) we have no idea what the fertility consequences will be (Application page 6, paragraph 18 (1)(ii));
- (f) in children, myocarditis is a huge safety problem, in that it causes permanent damage to the heart muscle because heart muscles cannot regenerate (Application page 6, paragraph 18 (1)(iii));
- (g) with myocarditis and clotting, the damage is cumulative so this is a very serious patient safety issue (Application page 6, paragraph 18 (1)(iii), and paragraph c. of the Particulars Letter)
- (h) women were experiencing miscarriages postvaccination (Application page 6, paragraph 18 (1)(iv))
- (i) women have antibodies to the placenta (Application page 6, paragraph 18 (1)(iv))
- (j) there is a very high chance of causing permanent infertility in women (Application pages 6 and 7, paragraph 18 (1)(iv))
- (k) 62% of his patients that he tested with a d-dimer blood test had evidence of microscopic clotting (Application page 7, paragraph 18 (1)(v))
- (l) vaccine injuries are massively understated and that studies have shown that less than 1% of vaccine injuries ever get reported (Application page 7, paragraph 18 (1)(vi))
- (m) the other safety issue is sudden-death, from strokes; and that the risk of sudden-death from a Covid 19 vaccination is 5 times higher than dying from Covid itself (Application page 7, paragraph 18 (1)(vii))
- (n) In young people, a Covid vaccines are more than 100 times more likely to cause death than Covid itself (Application page 7, paragraph 18 (1)(vii))

- (o) when asked about shedding and whether there was concern, Dr. Hoffe stated that "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 non-vaccinated people. It is has negative impacts upon women including affecting their menstrual cycles and causing miscarriages as was noted in the Pfizer study at page 67 and 68 (Application page 7, paragraph 18 (1)(viii) and paragraph j. of the Particulars Letter)
- (p) the Covid vaccines are much more dangerous to children than Covid ((Application page 7, paragraph 18 (2)(i))
- (q) ivermectin is a very safe and effective treatment for Covid 19 ((Application page 7, paragraph 18 (3)(i))
- (r) You can go to a feed store that sells medication for livestock and tell them you have a herd of sheep and you need ivermectin. I am being serious, the government is forcing people to use veterinary products because they are prohibiting doctors from prescribing it.
- 39. The College claims that the statements of Dr. Hoffe are misleading, incorrect or inflammatory because they contradict facts notorious within British Columbia and Canada or because they are readily and authoritatively demonstrable by resort to governmental sources. (Application page 8, paragraph 19).
- 40. Dr. Hoffe will present below the evidence that supports the veracity of the statements referenced above, or at the very least, calls into serious question the accuracy of the public health statements that claim otherwise.

Notice Fact (1) "The Covid virus kills or causes other serious effects

- 41. Dr. Eric Payne, pediatric neurologist and clinical researcher in Alberta, provides facts in his report from the Alberta and Canadian Government's own data that shows the risk for severe disease and deaths from Covid 19 is extremely skewed to those above 70 years of age, especially those with multiple comorbidities. As of May 13, 2022, only 2.8% of all COVID-19 related deaths in Canada occurred in those under 50 years of age. (Report of Dr. Payne, paragraph 43).
- 42. Dr. Payne also confirms at paragraphs 44 of his report that the CDC data confirms the following about infection and mortality rates for Covid 19:

0-19 years of age	0.000003% infection fatality rate	99.997% survival rate
20-49	0.0002% infection fatality rate	99.98% survival rate
50-69	0.005%	99.5% survival rate
70+	0.054%	94.6% survival rate

- 43. Dr. Payne points out that it is important to remember that 30-50% of all Covid 19 deaths are people who died with, and not from, Covid 19. (at paragraph 49). In support of this fact Dr. Payne points to the government of Ontario indicating that only half of the previously reported hospitalizations are actually due to Covid 19 and the CDC recently corrected reporting errors in its overall Covid 19 death count, reducing it by 72,722 deaths, that were previously attributed to Covid 19, including 416 pediatric deaths. The CDC's correction of its faulty statistics cut their estimates of death in children by 24% (paragraph 50). Dr. Bonnie Henry made similar admissions on behalf of the province of British Columbia with respect to overestimating Covid 19 hospitalizations by 46%. (Affidavit #1 Dr. Hoffe, page 7, paragraph 31 "XXX")
- 44. Dr. Payne confirms that the Alberta statistics show that there were a total of 588,691 confirmed PCR positive cases (which is a massive underrepresentation of total cases), 27,488 total hospitalizations with/from COVID, 4,097 total ICU hospitalizations with/from COVID, and 4,621 deaths with/from COVID. Therefore, among ~ 4.5 M Albertans, 0.61% were hospitalized, 0.091% required ICU admission, and 0.1% died (paragraph 41).
- 45. Dr. Steven Pelech, PhD in biochemistry, a member of the faculty of University of British Columbia and Professor in the Department of Medicine confirms in his report that the average age of persons that died of Covid 19 in Canada was approximately 84 years, compared to about 82 years for all-cause mortality. He states that the BC statistics confirm that there was no major increase in all cause mortality in the first year of the Covid 19 pandemic, when the virus was more virulent, and there were no specific medications for its treatment or vaccination for its prevention. Most of the excess all cause mortality in 2022 in BC cannot be attributed to the virus. Dr. Pelech points out that it is important to understand that there were fewer deaths from other infectious diseases such as the flu and RSV during the first 2 ½ years of the Covid 19 pandemic, and about one half of the deaths ascribed to Covid 19 were in people that died with Covid 19, but actually may have died due to their comorbidities. He notes that Canadian researcher and scientist Denis Rancourt has concluded that there was no increase in all cause mortality in the US in 2020, especially when compared to 2017. This is true in Canada and elsewhere. (Report of Dr. Pelech, pages 149 150, paragraph 298).
- 46. Dr. Pelech also confirms that given that close to 90% of around 40 million Canadians have had Covid 19 at least once, and 35,079 deaths have been attributed to the disease, its average rate of lethality is close to 1 in 1000, with it being closer to 1 in 100,000 for those from 0 to 25 years of age, and 1 in 200 for those over 65 years of age. He notes that this is a far cry from the average lethality estimates by public health officials that range from 1% to 4%. (Pages 81-83, paragraph 159).
- 47. Dr. Clare Craig notes that "[t]he average age of a Canadian Covid death is higher than the normal life expectancy. In 2019, over 80-year-olds accounted for 51.1% of deaths. Over 80-year-olds account for 69% of Covid labelled deaths (Report of Dr. Craig, page 6, lines 146-148)
- 48. So while the College seeks judicial notice of the statement "the Covid virus kills or causes other serious effects", it is important to note that the projections and statistics provided by

the BC and Canadian government are of some questionable reliability given subsequent significant revisions by those governments to correct errors in overestimating harms related to Covid 19. The data shows that the prevalence of severe outcomes is heavily skewed to those over 70 years of age with multiple comorbidities and that there was no access mortality in 2020, and any excess mortality seen in 2021 and beyond, cannot likely be attributed to the virus.

Notice Fact (2) "The virus does not discriminate"

- 49. The College is asking the panel to take judicial notice of the statement "The virus does not discriminate." It is unclear if this is a reference to infection, transmission, or severity of outcomes, and if this statement is intended to apply to people of all ages of all health conditions. One assumes the College is referring to SARS-CoV-2 but this is not specifically stated.
- 50. The evidence provided by the expert witnesses, , prove that the virus does discriminate in terms of who is more likely to get infected, and the severity of outcomes if one is infected, as noted above with respect to Notice Fact (1).
- 51. Dr. James Thorp, obstetrician and gynecologist, confirms in his report that studies conducted throughout the pandemic have shown that pregnant women are at no greater risk of severe Covid 19 disease and death than their nonpregnant peers (Report of Dr. Thorp, page 1 lines 41-45)
- 52. Dr. Thorp points to a May 2021 study of approximately 11,000 pregnant and nonpregnant women, all hospitalized for Covid 19 viral pneumonia, which found the mortality rate among hospitalized pregnant women was significantly lower than their non-pregnant hospitalized peers (0.8% versus 3.5%). This also held true among the subset admitted to ICU where 3.5% of pregnant patients died, compared to 14.9% of nonpregnant patients. (Page 2, lines 46-51)
- 53. Dr. Peter McCullough opines that while Covid 19 could be a fatal disease for elderly and individuals with other comorbidities, in the summer of 2021, it was well documented and known that there was a very low mortality rate for persons less than 70 years of age (Report of Dr. McCullough, page 33, line 635-639)
- 54. Dr. Craig illustrates that the susceptibility rate for Covid 19 was about 10% throughout each wave and variant of the virus (Report of Dr. Craig, page 15, lines 330-343).
- 55. The Saskatchewan Court of Appeal recently noted one of the experts called on behalf of the father in a family law case opined that Covid 19 has a diverse range of clinical presentations that range from asymptomatic infections to severe and fatal disease and that the presentation of symptoms is variable with an increasing severity of illness associated with older age and/or underlying health complications. This conclusion, and the actual real world government data contradicts Notice Fact 2 that seeks judicial notice of the statement "the virus does not discriminate." (O.M.S. v. E.J.S. 2023 SKCA 8) at para 83.

Notice Fact (3) "Vaccines work"

- 56. The College is asking the panel to take judicial notice that "Vaccines work". (Application page 9/80, paragraph 3).
- 57. The word "vaccines" is not defined by the College. It is not clear if the College is seeking judicial notice of this statement with respect to all vaccines approved by Health Canada or simply with respect to the COVID-19 vaccines that were approved by Health Canada. Some of the case authorities the College seeks to rely upon are in the family law context where the Court was dealing with vaccines on the regular childhood vaccination schedule and some dealt with COVID -19 vaccines, and some dealt with both. It is not clear if this statement is intended to apply to the AstraZeneca or Johnson & Johnson COVID-19 vaccines that were approved by Health Canada and promoted as such by public health and government officials as being safe and effective but were later removed from the market due to serious adverse effects from those vaccines, including death.
- 58. Also, the word "work" is not defined. It is not clear what the College means by this term because the College also seeks judicial notice of the statement "vaccines do not prevent infection, reinfection or transmission... "(Application page 9/80 Notice Fact (5)).
- 59. Dr. Hoffe's expert witnesses provide qualified expert opinion and fact evidence that directly challenge this statement.
- 60. Dr. McCullough indicates in his report that it was evident that the COVID-19 vaccines were progressively losing efficacy over the prevention of COVID-19 and, in widely vaccinated countries, up to 80% of COVID-19 cases were in the previously vaccinated, implying the vaccines were becoming obsolete with antigenic escape or resistance to variants (e.g. Delta) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain. (Report of Dr. Peter McCullough page 41, Lines 807-823
- 61. Dr. McCullough indicated in his report that it was increasingly known that vaccine efficacy was waning rapidly and that natural immunity was protective against disease. As mentioned previously, Francis Collins emailed colleagues at the NIH including Anthony Fauci on September 16, 2021: "Interesting and pretty compelling evidence that VE [Vaccine Efficacy] is falling 5 6 months post vaccination for both infection and hospitalization for those over 65. Even for those 3 4 months out there is a trend towards worsening VE." Previously, in late August and early September, Humetrix had been telling the CDC and FDA that: "...findings show a very significant decrease in VE ... for Pfizer or Moderna." "73% of Covid-19 cases occurred in fully vaccinated individuals." Further, "Prior Covid-19 infection has a major protective effect against breakthrough hospitalization."
- 62. Dr. Payne confirms in his report that with respect to the Omicron SARS-CoV-2 mutations, which began affecting Canadians in mid-December 2021, the publicly available data since that time has shown that it is the fully vaccinated who have been more likely to get COVID-19 compared to the unvaccinated. (Page 6). In fact, publicly available provincial statistics from Alberta, Ontario, and British Columbia, revealed that even proportionally by vaccination status, the fully vaccinated were in fact MORE likely to catch the Omicron

- variant, than those who were unvaccinated (Appendix A, Figures 1-4). (Report of Dr. Payne page 6, paragraphs 20 and 21)
- 63. Dr. Payne confirms that the Ontario statistics show that by mid-December 2021 and January 2022, the fully vaccinated occupied the vast majority of Covid cases (page 37, Appendix A)
- 64. Similarly, Dr. Payne points out that the BC CDC statistics for the period to March 13 to April 30, 2022 show that vaccinated individuals accounted for 93% of Covid 19 related deaths, an increase of 226% since March 13. This included 76% who had received 3 injections, and 15% would receive 2 injections. The triple and double vaccinated accounted for 85% of Covid 19 cases, 82% of hospitalizations with/from Covid 19, and 85% of critical care Covid related admissions. The triple vaccinated accounted for 66% of cases, 63% of hospitalizations 57% of critical care. (Page 39, Appendix 1, Figure 4).
- 65. Dr. Payne also points to the US CDC data which demonstrated negative vaccine effectiveness vs. omicron over time across all age groups including children (page 40, Appendix 1, figure 6).
- Or. Payne provides numerous examples of data from a variety of countries including the United Kingdom, Scotland, Denmark, Sweden, and Israel, that clearly show the effectiveness of the vaccines waned progressively over 4-6 months following immunization. (page 7, paragraphs 24, 26, 28, 32 and 37).
- 67. Dr. Jessica Rose confirms that the clinical trials initially run by Pfizer are moot because the placebo participants were unblinded and subsequently injected with the Covid 19 vaccines. Moreover, the products that were administered to the public were not produced using the same modified mRNA synthesis procedure as for the products used in the clinical trials. (Report of Dr. Jessica Rose, page 25).
- 68. Dr. Rose confirms that the animal studies were done after Phase I and phase II studies were done on humans, not before (page 30, last paragraph).
- 69. Kevin McKernan, genomist, confirms that the Covid 19 vaccines do not stop transmission and evidence is mounting that the vaccinated have a higher rate of Covid 19 (Report of Kevin McKernan, page 2, paragraph 9)
- 70. The College references a decision of <u>Parmar v. Tribe Management Inc. 2022 BCSC 1675</u> to support their request that the panel take judicial notice of the fact the statement that "Vaccines work". "vaccines work... they reduce severity of symptoms and bad outcomes."(<u>Application</u> page 5, para 13, page 9, para (3)). The College misquotes the Justice, resulting in a misleading representation of what the Court said. The College quotes from paragraph 109 of the decision at follows:

"vaccines work...they reduce the severity of symptoms and bad outcomes"

The Court's actual statement is as follows (with the College's omission underlined):

In addition, courts have taken judicial notice of the fact that vaccines work. While they do not prevent infection, reinfection, or transmission, they reduce the severity of symptoms and bad outcomes

- 71. This panel will recall that our public health and government officials repeatedly told the public when the vaccines were first being rolled out, that a person vaccinated with one dose of the vaccine would not contract or transmit Covid 19.
- 72. The same public health and government officials later told the public that 2 doses of the vaccine were needed to achieve this result.
- 73. The same public health and government officials on December 3, 2021 told the public that the efficacy of the vaccines waned after a few months and regular booster doses were required every 3 to 6 months. (Affidavit #1 Dr. Hoffe, page 6, paragraph 25, exhibit "U")
- 74. Dr. Theresa Tam, Chief Public Health Officer for Canada, recently confirmed on September 12, 2023 that the efficacy of Covid-19 vaccination wanes after 6 months. (Affidavit #1 Dr. Hoffe, page 9, paragraph 46, exhibit "PP")
- 75. The same public health and government officials later admitted that the vaccines do not stop infection, transmission or reinfection, long after vaccine mandates were imposed. The Courts started to recognize this change in messaging and some were even prepared to take judicial notice of this fact. (Parmar, supra at para 109).
- A BC arbitrator held on December 14, 2023 that in the fall of 2021 there was an unexpected and dramatic rise in the number of Covid 19 infections in highly vaccinated countries and it was evident that the vaccines were not working. TC, Local 31 and Purolator Canada Inc. (Moes), Re (at paragraph 10). The arbitrator also found as a result of evidence tendered by the union on behalf of the employees, that studies over time cumulatively revealed by the spring of 2022, a massive drop in 2 dose vaccine effectiveness against infection (at paragraph 12). The union's expert witness Dr. Kaylan testified that this kind of data about the vaccine ineffectiveness over time is the kind of data which would have emerged if the normal clinical trials for new vaccines required for approval by public health authorities had been completed rather than cut off or cut short as they were (paragraph 15).
- 77. The arbitrator noted that much of the evidence presented by the employer, very similar to the facts that the College wishes to have the panel declare judicial notice of, was lacking strong evidentiary value (paragraph 23).
- 78. In this case both the employer, and the union on behalf of its employees, were permitted to tender evidence, including evidence from the union contradicting public health guidance, and both parties were permitted to call expert witnesses challenging the evidence of the opposing party.
- 79. The arbitrator noted that there was a shift in prevailing medical opinion and public health messaging over time because of new facts emerging (paragraph 37).

- 80. The Arbitrator reviewed all of the evidence, including public health announcements, expert testimony that supported and contradicted the public health announcements by government and health regulators, and rendered a decision based on all the evidence presented by both parties that does not align with the current public health guidance by BC's Chief Public Health Officer Dr. Bonnie Henry.
- 81. Dr. Payne notes that a large study across 68 countries and 2947 U.S. counties studied the relationship between the percentage of the population fully vaccinated and new COVID-19 cases. The countries and U.S. counties with the highest vaccination rates had more COVID-19 cases. Similarly, 4 of the 5 U.S. counties with the highest percentage of population fully vaccinated, are listed by the CDC as "high" transmission counties, while 50 "low" transmission counties had only 20% of their population fully vaccinated. (Report of Dr. Payne, page 8)
- 82. On February 5, 2024, the Minister of Health provided an official statement in response to a question posed by MP Mr. Carrie (Oshawa) wherein the Minister confirmed:

At the time of initial authorization of the first COVID-19 vaccines (Pfizer-BioNTech) in December 2020, there was no reported evidence on the efficacy of the authorized COVID-19 vaccine to prevent asymptomatic infection, to reduce viral shedding, or to prevent transmission...

In December 2021, in the context of the circulating Delta (B.1.617.2) variant, evidence was emerging that vaccine effectiveness against SARS-CoV-2 infection and COVID-19 decreases with time after the primary series and there may be some decrease in protection against severe illness (especially in older individuals). Decreasing protection against infection could contribute to increased transmission, since infected individuals may be a source of infection for others. (Appendix 2).

Notice Fact (4) "Vaccines are generally safe and have a low risk of harmful effects, the [sic] especially in children."

- 83. The College relies primarily on statements made by Health Canada, the Public Health Agency of Canada ("PHAC") and the BC Centre for Disease Control ("BCCDC") to support this fact.
- 84. The adverse reaction database for the Covid 19 vaccines developed and maintained by the World Health Organization Collaborating Centre for International Drug Monitoring on behalf of the World Health Organization tells a different story. As of March 11, 2024 WHO has received 5,309,331 reported potential side effects related to the Covid 19 vaccines that are listed by category from 2021 to March 11, 2024. The adverse reports that are relevant to the Citation, and the Particulars Letter that the WHO has listed are:

¹ 39 Akhil Kumar S. V. Subramanian, "Increases in Covid-19 Are Unrelated to Levels of Vaccination across 68 Countries and 2947 Counties in the United States," *European Journal of Epidemiology* 36 (September 30, 2021), http://dx.doi.org/https://doi.org/10.1007/s10654-021-00808-7.

- (a) cardiac disorders 320,015
- (b) congenital, familial and genetic disorders 4142
- (c) immune system disorders 74,480
- (d) nervous system disorders 1,968,133
- (e) pregnancy, puerperium and perinatal conditions 13,750
- (f) reproductive system and breast disorders 275,792
- (g) vascular disorders 239,077.
- 85. The WHO's data also shows that the significant majority of adverse harms reported occurred in persons aged 18 to 64 years of age. (<u>Affidavit #1 Dr. Hoffe</u>, page 14, paragraph 72, exhibit "PPP")
- 86. This is in comparison to the same database which records 325,344 adverse events from 1968 to March 11, 2024 for all flu vaccines. (<u>Affidavit #1 Dr. Hoffe</u>, page 14, paragraph 79, exhibit "WWW")
- 87. The Pfizer Adverse Events Report dated April 30, 2021, which included data from Pfizer's post-market surveillance up to February 28, 2021 that was disclosed by the FDA and Pfizer under compulsion of Court Order, revealed that Pfizer had received 42,086 adverse event reports that included 1223 deaths in less than 3 months after the vaccines entered the market. (Affidavit #1 Dr. Hoffe, paragraph 4, Exhibit "A"),
- 88. Dr. Hoffe created a colour-coded list of the adverse events of special interest detailed by Pfizer in its report that are relevant to the citation showing the numerous and varied adverse events following immunization with the Pfizer vaccine. The colour-coded list makes it much easier to see the adverse events that were listed by Pfizer in their post-market surveillance study. They include numerous neurological side effects (in green), clotting side effects (in blue), death or life-threatening side effects (in red), fertility or pregnancy-related side effects (in pink), myocarditis, pericarditis and endocarditis (in yellow), and risks to children via shedding and otherwise (in orange). A non-exhaustive list of the particular reports of adverse events detailed by Pfizer relevant to the Particulars Letter provided by the College are as follows:
 - (a) acoustic neuritis
 - (b) acquired epileptic aphasia
 - (c) acute disseminated encephalomyelitis
 - (d) acute encephalitis with refractory, repetitive partial seizures
 - (e) acute hemorrhagic leukoencephalitis

- (f) acute hemorrhagic edema of infancy
- (g) acute motor axonal neuropathy
- (h) acute motor-sensory axonal neuropathy
- (i) acute myocardial infarction
- (j) administration site thrombosis
- (k) adrenal thrombosis
- (l) amniotic cavity infection
- (m) anaphylactoid syndrome a pregnancy
- (n) anti-myuelin-associated glycoprotein associated polyneuropathy
- (o) anti-myocardial antibody positive
- (p) anti-neuronal antibody positive
- (q) anti-sperm antibody positive
- (r) aortic embolus
- (s) aortic thrombosis
- (t) arterial bypass thrombosis
- (u) athero-embolism
- (v) atonic seizures
- (w) atypical benign partial epilepsy
- (x) autoimmune demyelinating disease
- (y) autoimmune encephalopathy
- (z) autoimmune myocarditis
- (aa) autoimmune neuropathy
- (bb) autoimmune pericarditis
- (cc) automatism epileptic
- (dd) autonomic nervous system in balance

- (ee) autonomic seizure
- (ff) axonal and demyelinating polyneuropathy
- (gg) axonal neuropathy
- (hh) basilar artery thrombosis
- (ii) benign familial neonatal convulsions
- (jj) brainstem embolism
- (kk) brainstem thrombosis
- (ll) cardiac arrest cardiac failure acute
- (mm) cardiac ventricular thrombosis
- (nn) cardiopulmonary failure
- (oo) cardio-respiratory arrest
- (pp) carotid arterial embolus
- (qq) carotid artery thrombosis
- (rr) cerebellar artery thrombosis
- (ss) cerebellar embolism
- (tt) cerebral artery embolism
- (uu) cerebral artery thrombosis
- (vv) chronic inflammatory demyelinating polyradiculoneuropathy
- (ww) circulatory collapse
- (xx) convulsion in childhood
- (yy) coronary artery disease
- (zz) coronary artery embolism
- (aaa) coronary artery thrombosis
- (bbb) coronary bypass thrombosis
- (ccc) cranial nerve disorder

- (ddd) cranial nerve paralysis (eee) death neonatal (fff) deep vein thrombosis (ggg) deep vein thrombosis postoperative demyelinating polyneuropathy (hhh) demyelination (iii) disseminated intravascular coagulation (jjj) disseminated intravascular coagulation in newborn (kkk) early infantile epileptic encephalopathy with first-suppression (111)embolic stroke (mmm)epilepsy epileptic psychosis (nnn) (000) facial paralysis (ppp) faciobrachial dystonic seizure febrile convulsion (qqq) febrile infection-related epilepsy syndrome (rrr)
 - (ttt) foetal distress syndrome

(sss)

- (uuu) granulocytopena neonatal
- (vvv) Gray matter heterotopia
- (www) Guanase increased; Guillain-Barre syndrome

foaming at mouth focal disc cognitive seizures

- (xxx) infantile genetic agranulocytosis
- (yyy) infantile spasms
- (zzz) juvenile idiopathic arthritis
- (aaaa) juvenile myoclonic epilepsy
- (bbbb) juvenile psoriatic arthritis

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(cccc) juvenile spondyloarthritis
(dddd) low birth weight baby
(eeee) Lupus encephalitis
(ffff) lupus endocarditis
(gggg) Lymphocytopenia neonatal
(hhhh) multiple sclerosis
(iiii)
       multiple sclerosis relapse
(iiii)
       multisystem inflammatory syndrome in children
(kkk) myocardial infarction
(1111)
      myocarditis
(mmmm)
              neonatal Crohn's disease
(nnnn) neonatal epileptic seizure
(0000) neonatal mucocutaneous herpes simplex
(pppp) neonatal pneumonia
(qqqq) neonatal seizure
(rrrr) neutropenia neonatal
(ssss) optic neuritis
       optic neuropathy
(tttt)
(uuuu) ovarian vein thrombosis
(vvvv) pediatric autoimmune
                                 neuropsychiatric disorders
                                                               associated with
       streptococcal infection
(wwww)
              pelvic venous thrombosis
(xxxx) penile vein thrombosis
(yyyy) pericarditis
(zzzz) petite mal epilepsy
(aaaaa) post stroke epilepsy
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(bbbbb) post stroke seizure

(cccc) premature labour

(ddddd) premature menopause

(eeeee) stillbirth

(fffff) still's disease

(ggggg) testicular autoimmunity

(hhhhh) thrombophlebitis neonatal

(iiiii) uncinate fits

(jjjjj) Vasa previa

(kkkk) venous thrombosis neonatal

(IIII) Zeke a virus associated Guillain Barre syndrome.

(Affidavit #1 Dr. Hoffe, paragraph 5, Exhibit "B")

- 89. An official response to a freedom of information request from the BC Ministry of Health confirmed that they were unable to locate any data, records, emails or text messages that proved Dr. Carole Fenton's statement in an April 23, 2021 press release claiming that Covid 19 vaccines were unequivocally safer than Covid 19 infection, nor to show that the vaccines have been demonstrated to be safe and effective through all levels of the clinical trials. (Affidavit #1 Dr. Hoffe page 5, paragraph 22, exhibit "R").
- 90. Dr. Payne highlights in his report the fact that a large portion of adolescents presenting to the Seattle Children's Hospital with Pfizer Covid 19 mRNA vaccine related myopericarditis have persistent late gadolinium enhancement on cardiac MRI. This raises a concern for potential long-term effects as positive late gadolinium enhancement is a powerful prognosticator of adverse outcome and myocarditis. (Report of Dr. Payne, page 16, paragraph 73)
- 91. Dr. Payne confirms that there is an increased risk of pericarditis and myocarditis post vaccine compared to post viral infection. A large population-based Israeli paper recently found that the COVID infection itself, prior to roll-out of the COVID-vaccine, conferred NO increase in the risks of either myocarditis or pericarditis from COVID-19, strongly suggesting that the increases observed in earlier studies were because of the mRNA vaccines, with or without COVID-19 infections as an additional risk in the vaccinated (Page 17)
- 92. Dr. Payne further advises that in a recent paper in Nature revealed a 25% increase in both acute coronary syndrome and cardiac arrest calls in the 16- to 39-year-old age groups

- significantly associated with administration with the first and second doses of the mRNA vaccines but NO association with COVID-19 infection.² (Page 18)
- 93. Dr. Payne further advises that in another very recent autopsy series identified undiagnosed myocarditis as the cause of death among otherwise healthy individuals who "died suddenly" within 20 days following an anti-SARS-Cov-2 genetic vaccine. (Page 18)
- 94. Dr. Payne notes that officials in Finland, Norway, Denmark, Sweden and Iceland have all suspended the use of Moderna vaccine for younger people due to the risk of myocarditis (page 18).
- 95. Dr. Payne confirms that numerous studies have also suggested that the mRNA vaccines including the spike protein that they produce, can impact one's innate immune system negatively, including through immune suppression (page 21)
- 96. Dr. Payne opines that the mRNA lipid nanoparticles based vaccine is highly inflammatory, and it synthetic io9 indivisible lipid component is responsible for the induction of inflammation. Further this platform induces long-term unexpected immunological changes affecting adaptive immune responses and heterologous protection against infection. (Sees page 21)
- 97. Dr. Payne further opines that studies have also indicated that spike protein can interact with tumor suppressor proteins p53 and BRCA, suggesting the possibility of increased cancers and the return of aggressive cancers (page 21)

Particulars Letter (a) the Covid 19 vaccines were experimental at the time Dr. Hoffe made the impugned statements referenced in the Citation and in the Particulars Letter.

- 98. Pfizer's own phase 1, 2 and 3 study, demonstrates that their Covid 19 vaccine was still in clinical trials when they were released to the public and well beyond the date that Dr. Hoffe made his statements. Their own clinical study also shows significant harms experienced by participants in the study, of the nature described by Dr. Hoffe, for which the College says he is guilty of misconduct for repeating.
- 99. Pfizer's Phase 1, 2 3 placebo-controlled randomized blind trial data evaluating the safety, efficacy of the vaccine for healthy individuals confirms at pages 67-69, that they consider a pregnant woman to have been exposed to the Pfizer vaccine through inhalation or skin contact with another person who has been vaccinated. This is often referred to as shedding. Pfizer explains in their study documentation that abnormal pregnancy outcomes are considered serious adverse events such as ectopic pregnancy, spontaneous abortion, intrauterine fetal demise, neonatal death, or congenital anomaly. Pfizer explains at page 69 of their report that exposure is considered to have occurred during breast-feeding if a female participant is found to be breast-feeding while receiving or after discontinuing the

² 87 Christopher L. F. Sun, Eli Jaffe, and Retsef Levi, "Increased Emergency Cardiovascular Events among under-40 Population in Israel During Vaccine Rollout and Third Covid-19 Wave," *Scientific Reports* 12, no. 1 (2022/04/28 2022), http://dx.doi.org/10.1038/s41598-022-10928-z.

- Pfizer vaccine, or through environmental exposure through inhalation or skin contact with someone who has been vaccinated. (<u>Affidavit #1 Dr. Hoffe</u>, paragraph 59, <u>Exhibit "CCC"</u>).
- 100. Both Pfizer and Moderna had ongoing clinical trials to assess the safety and efficacy of their Covid 19 vaccines at the time Dr. Hoffe made his statements, confirming they were still experimental. (<u>Affidavit #1 Dr. Hoffe</u> paragraphs 81-87, Exhibits "<u>YYY</u>", "<u>ZZZ</u>", "<u>AAAA</u>").
- 101. The National Institute of Health through the National Library of Medicine keeps track of completed and ongoing clinical trials related to the Covid 19 vaccines and other drugs. https://clinicaltrials.gov/search?intr=covid19%20vaccine
- 102. There are also a number of clinical studies that are even still going on today including one sponsored by the University of British Columbia, to assess the safety and efficacy of the Covid 19 vaccines. One particular study commenced on June 24, 2022 and is not expected to complete until December 2025. A summary of the study provides "As vaccination against Covid 19 has begun, adverse events to the vaccine, particularly Guillain-Barre (GBS), vaccine -induced immune thrombotic thrombocytopenia (VITT)/thrombosis with thrombocytopenia syndrome (TTS) and myocarditis/pericarditis, after Covid 19 vaccination have been reported worldwide. The objective of the study is to determine if there are specific genetic factors strongly associated with Covid 19 vaccination induced adverse events. The purpose of the study is to reduce the risk of these adverse events through improved understanding of the biology underlying the severe adverse events in the genetic contribution to their cause. No results of this study have been posted to date. (Affidavit #1 Dr. Hoffe paragraphs 88-91, Exhibit "DDDD").

Particulars Letter (b) The long-term consequences of the Covid 19 vaccines are unknown

- 103. The purchase contract between the Government of Canada and Pfizer dated October 26, 2020 was obtained through a freedom of information request. Although heavily redacted, the few paragraphs that remain (page 18 paragraphs 5.4 and 5.5) confirm that Pfizer expressly disclaimed any representations or warranties with respect to the Covid 19 vaccine including any warranties or undertakings as to the merchantability or fitness for a particular purpose of the vaccine. The Government of Canada acknowledged that the materials and components of the vaccine were rapidly developed due to the emergency circumstances of the pandemic and will continue to be studied after provision of the vaccine to the Government. The Government of Canada acknowledged that the long-term effects and efficacy of the vaccine were not currently known and that there may be adverse effects from the vaccine that were not currently known. (Affidavit #1 Dr. Hoffe paragraph 10, Exhibit F)
- 104. Moderna commenced a study to determine the nature of the long-term side effects from their Covid 19 vaccine on December 22, 2021 and which completed on April 28, 2023. Although the study completed nearly a year ago, the results of the study have not been disclosed. (Affidavit #1 Dr. Hoffe, paragraphs 86-87, Exhibit "CCCC").

- 105. Another study which was completed on December 10, 2021 pertained to Covid 19 vaccine -induced transverse myelitis, which is a neurological disorder caused by inflammation of the spinal cord. The overview of the study indicated that some patients receiving the Covid 19 vaccines from AstraZeneca, Pfizer, Moderna and Johnson & Johnson suffered rare but serious adverse events such as transverse myelitis. The results of the study, more than 2 years after the study completed, have not yet been published. (Affidavit #1 Dr. Hoffe, paragraph 85, Exhibit "BBBB").
- 106. The June 14, 2021 report of the House of Commons Standing Committee on Health details the testimony of Dr. Shirin Kaylan, Adjunct Professor of Medicine, University of British Columbia and vice-President, Scientific Innovation, Qu Biologics, where she explained that women have borne the brunt of experiencing more serious adverse events related to the Covid 19 vaccines. She explained that the Covid vaccines deliver genetic material either in the form of DNA or RNA into our cells to make or express viral proteins. She admitted that we have very little, to no knowledge on the long-term safety and efficacy of many aspects of this particular technology especially when they are given in multiple doses. Given this lack of experience she explained, it was very difficult to make well-informed decisions regarding their use.
- 107. Dr. Payne confirms that the Covid vaccines were brought to market extremely quickly and only 6-9 months and that it is therefore impossible to have any long-term safety data in this setting, especially in the context of repeated boosters. Prior to the Covid 19 vaccines, it would usually take 10-12 years to develop a vaccine and test its safety properly, typically longer than 15 years for genetic therapies such as the Covid vaccines.) (Report of Dr. Payne, pages 2-3, paragraph 4)
- 108. Dr. Rose confirms that the different process that was used to manufacture the Pfizer Covid vaccines that were given to the public, namely Process 2, were only tested on 250 individuals between the ages of 16 and 55 years (Report of Dr. Rose, page 25).
 - Particulars Letter (c), (d), (e), (h), (i) and (j) regarding statements made that the Covid vaccines were creating a risk harm related to women's fertility, and effecting women's menstrual cycles
- 109. In an official statement by the Federal Minister of Health on May 25, 2023, the Minister confirmed that:
 - (a) NACI continues to monitor the evidence on the use of Covid 19 vaccines in pregnancy and breast-feeding and will update recommendations as needed.
 - (b) Health Canada and PHAC continue to monitor safety information from various sources including scientific literature, manufacturers and international regulators. If new safety issues are identified, Health Canada takes the appropriate action to ensure that new risks are communicated to Canadians in healthcare professionals.
 - (c) In November 2022, following a review of evidence from clinical trials, observational studies and post-marketing surveillance activities, the

Pharmacovigilance Risk Assessment Committee of the European Medical Association ("EMA-PRAC") concluded that there was "at least a reasonable possibility that heavy menstrual bleeding is causally associated with Cominarty".

- (d) Based on the available evidence, and in the context of the frequency of menstrual irregularities, it is not possible to determine what percentage of Covid 19 mRNA vaccine recipients could experience an increase in menstrual bleeding.
- (e) As part of its ongoing surveillance of Covid 19 vaccine safety, Health Canada is reviewing the peer reviewed article by Dr. James Thorp and Associates (one of Dr. Hoffe's expert witnesses who details this information in his report) in the safety summary reports. Should new safety issues be identified, Health Canada will take appropriate action, including communicating any new risks to Canadians and healthcare professionals. (Affidavit #1 Dr. Hoffe page 15 paragraph 73 exhibit "QQQ")
- 110. The Federal Minister of Health provided an official reply on December 12, 2023 to questions posed by Member of Parliament Mr. Falk (Provencher) where the Minister confirmed the following:
 - (a) none of the Covid 19 vaccine manufacturers sought indications for use in pregnant or lactating women or submitted randomized clinical trial data in pregnant/lactating women for regulatory evaluation. The PCAP product Monographs included statements about the uncertainties related to pregnancy and lactation. (Affidavit #1 Dr. Hoffe page 16 paragraph 76, exhibit "TTT")
- 111. An example where Health Canada and the National Advisory Committee on Immunization ("NACI") make statements in public guidance documents that contradict the official statements from the federal Minister of Health are as follows:
 - In December 2020 NACI recommended against routinely offering Covid 19 vaccines to populations excluded from clinical trials, including pregnant or breast-feeding women, but on May 28, 2021 they changed their public guidance to strongly recommend pregnant or breast-feeding women use the mRNA Covid 19 vaccines. On June 29, 2022 they strongly recommended that pregnant women should be offered a fall Covid 19 booster dose regardless of the number of booster doses previously received. At the date of submission this continues to be NACI's recommendation. (Affidavit of Dr. Hoffe page 7, paragraph 36 Exhibit "FF", bottom of page 2 to top of page 3)
 - The Federal Minister of Health confirmed in the same official statement on December 13, 2023: "Health Canada has not approved any safety claims with regard to pregnant and lactating women." (Inquiry of the Minister of Health for

- Canada December 13, 2023 page 2, last paragraph, Affidavit #1 Dr. Hoffe, para 77, Exhibit "UUU")
- The Federal Minister of Health confirmed in an official statement on December 13, 2023: "As indicated in the specific Product Monographs (for Pfizer and Moderna), it is noted that the safety and efficacy of these vaccines in pregnant women have not yet been established. No indication for use in pregnant or lactating women was sought by the vaccine sponsors or authorized by Health Canada." (Inquiry of the Minister of Health for Canada December 13, 2023 page 2, second paragraph, Affidavit #1 Dr. Hoffe page 16, paragraph 77, Exhibit "UUU"). [Emphasis Added]
- 112. As noted above, and as we will detail below, the product monographs for all of the Covid 19 vaccines confirm that the manufacturers did not have any safety or efficacy data concerning pregnant or lactating women, or whether there would be any harms to fertility, or breast-feeding infants through the vaccine contents being excreted in human breast milk.
- 113. Despite the above, the Minister of Health for the Province of Ontario stated in the provincial legislature on December 9, 2021 that the Covid 19 vaccines were safe for pregnant women and their babies and that this had been accepted by Health Canada. (Affidavit #1 Dr. Hoffe page 6, paragraph 27, exhibit "W")
- 114. Despite the above, Dr. Debra Money of the University of British Columbia stated on global news on May 7, 2021 that the vaccines are safe for pregnant women. (Affidavit #1 Dr. Hoffe page 4, paragraph 18, exhibit "N")
- 115. Despite the above, Dr. Bonnie Henry, Chief Public Health Officer for British Columbia stated in a public address in late 2021 that unequivocally Covid-19 vaccines do not affect fertility. (Affidavit #1 Dr. Hoffe page 6, paragraph 29, exhibit "Y" and exhibit "Z".
- 116. The BC Centre for Disease Control/BC Ministry of Health stated in their April 18, 2023 public health guidance that clinical trials of Covid 19 vaccines all excluded pregnant or breast-feeding women from their trials, although some participants reported pregnancies during the trial. The guidance states that the potential risks of vaccination to pregnant individuals are not clear. The guidance goes on to state that as recommended by NACI, as a matter of informed consent, pregnant women should be counselled about the lack of safety and efficacy data for the currently approved mRNA and adenovirus vaccines in pregnant women. (Affidavit #1 Dr. Hoffe, page 8, paragraph 39, exhibit "II")
- 117. Despite the above, on September 12, 2023 Dr. Theresa Tam, Chief Public Health Officer for Canada, also encouraged pregnant women to get vaccinated with the Covid 19 vaccine. (Affidavit #1 Dr. Hoffe, page 9, paragraph 46, exhibit "PP")
- 118. The College relies on public statements issued by the Society of Obstetricians and Gynecologist of Canada ("SOGC")to support the safety of the Covid 19 vaccines for pregnant women (<u>Application</u> page 38/80, paragraphs (14) and (16) and (17), and while they do point out that the SOGC admits that "while studies to determine if the impact of

Covid 19 vaccine in menstrual cycles are ongoing, and if it does impact the menstrual cycle we would expect it to be limited to one-2 cycles." the College neglects to include the official statement of SOGC regarding their official position on the safety of the Covid 19 vaccines for pregnant and breast-feeding women originally published December 18, 2020 and revised on January 11, 2021. This public statement is more consistent with the product monographs and the Federal Minister of Health's admissions. In its January 11, 2021 official statement, SOGC emphasized that pregnant and breast-feeding women were excluded from the Phase II and Phase III studies for the Pfizer Covid 19 vaccine. They also indicated that until more data was available, the potential risks of vaccination to a pregnant woman and fetus remain unknown. They recommended that pregnant and breast-feeding women who are eligible for the Covid 19 vaccine due to exposure risk, medical status, or other circumstances should be able to make an informed decision by having access to upto-date information about the safety and efficacy of the vaccine (including clear information about the data that they clearly stated is not yet available) and information about the risks of Covid 19 infection for them. (Affidavit #1 Dr. Hoffe, page 3, paragraph 12, exhibit"H"). The public communications by SOGC are contradictory and their reliability is therefore questionable.

- 119. Dr. Jessica Rose confirms that it has been shown in studies from Japan that the lipid nanoparticles used in the modernity and Pfizer vaccines bio distribute and bioaccumulate in various organs. She provides a chart to show which organs seem to be the most affected. The mean total lipid concentration in the ovaries measured 48 hours after injection with the Covid 19 vaccines was one of the highest at 12.3g lipd ug. The concentrations were increasing when the measurements were stopped at 48 hours (Report of Dr. Jessica Rose, page 27)
- 120. Dr. Rose refers to peer-reviewed publications and VAERS data confirming that the data indicates that women are reporting high frequency of miscarriages in the context of Covid 19 vaccines. One recent analysis shows that women exposed to the Covid 19 vaccine just before pregnancy suffered a miscarriage in 32% of the cases. This is twice as high as the upper end of the miscarriage rate before Covid 19 vaccines were available. (Pages 17, 20-21)
- 121. Dr. Pierre Kory reviews the Pfizer report in detail documenting the reports of adverse clinical events during their clinical trials which document that I would have 458 reports of mothers exposed to the vaccine while being pregnant, in 248, and adverse event was reported. 53 of the 248 adverse events involved spontaneous abortion, which they then excluded 17 of them due to having comorbidities or history of spontaneous abortion. (Report of Dr. Kory, page 32 lines 1129-1131)
- 122. Dr. Kory points out that one team of research performed a survey study of the impacts of vaccination on menstruation and quickly received 140,000 reports. Published in Science, they found that 42% of women reported menstral abnormalities related to the Covid 19 vaccines. (Pages 32-33, lines 1133-1170).
- 123. Dr. Kory notes that of the 100 baby/foetal adverse event reports received by Pfizer, 98 of them were reported as serious. The details of the serious harm suffered are reproduced at

- page 37, lines 1211-1221 of Dr. Kory's report. Dr. Kory provides a very detailed assessment of the Pfizer data from their clinical trial at pages 32-41 of his report, which contradicts this Notice Fact (4) and (6).
- 124. Dr. James Thorp opines that the Vaccine Adverse Events Reporting System maintained by the FDA and the CDC documents a clear safety signal for fertility as of May 24, 2023. Dr. Thorp advises that one of the most visible signs of trouble is the much higher volume of reports for infertility, female infertility and male infertility and abnormal fertility tests that were published in VAERS for the Covid 19 injections over a 2-3 year periodcompared to the volume of reports for influenza vaccines and all other vaccines over 33 years of use. The rate of such reports eclipses the rates for all other vaccines by a massive margin. (Report of Dr. Thorp, page 5, lines 125-133)
- 125. Dr. Thorp's own investigational study, which the Federal Minister of Health has said Health Canada is reviewing, compared the number of adverse events reported in VAERS following Covid 19 "vaccination" in pregnancy to adverse events reported following all influenza vaccine since 1998. The results of this investigational retrospective study or catastrophic. The FDA and CDC use a twofold increase as triggering a safety signal, yet Dr. Thorp and Associates found a 57 fold increase in miscarriage, and a 38 fold increase in fetal death (stillbirth) following Covid 19 vaccination when compared to influenza vaccines. 18 distinct adverse event types including abnormal Menzies, and 17 other major pregnancy complications, all exceeded the CDC and FDA safety signals (page 6 lines 142-149).
- 126. Dr. Thorp explains that the 5/50 rule has always been a "rule of thumb". If there are 5 deaths associated with the drug, vaccine or device then a black box warning is issued. If there are 50 deaths the product is immediately removed from the market. The VAERS data has shown that the experimental Covid mRNA gene therapy vaccinations have proven to be harmful by any modern safety standards traditionally applied to other vaccines. (Page 8, lines 155-159)
- 127. Dr. Thorp and Associates conclude that the Covid 19 vaccine -related deaths, fetal malformations, and pregnancy loss are stunning when compared to all other vaccines in the VAERS registry combined, including influenza vaccines and the pertussis vaccines. (Page 8 lines 161-174)
- 128. Particulars Letter (o) shedding is something that comes out of the skin or breath of vaccinated people and can cause bleeding and clotting in non-vaccinated people and can affect menstrual cycles and cause miscarriages as noted by Pfizer in their own study at pages 67 and 68
- 129. The US Department of Health and Human Services, the Food and Drug Administration and the Centre for Biologics Evaluation and Research published an industry guidance in August 2015 for the drug manufacturing industry on how to conduct shedding studies during preclinical and clinical development of their drug products. The report confirms that the term "shedding" means the release of virus or bacteria-based gene therapy products from the patient through one or all of the following ways: feces, urine, saliva,

nasopharyngeal fluids etc., or through the skin. The authors explain that shedding is distinct from biodistribution because the latter describes how a product is spread within the patient's body from the site of administration while the former describes how it is excreted or released from the patient's body. The authors also confirm that shedding raises the possibility of transmission of the virus or bacteria-based gene therapy products from treated to untreated individuals (e.g., close contacts and healthcare professionals). The authors also confirm that transmission could occur if the virus or bacteria-based gene therapy products are shed in the form of intact viruses or bacteria. This guidance indicates that it does not address in this paper, the collection or submission of adverse event information that could be attributed to shedding. Affidavit #1 Dr. Hoffe page 2, paragraph 9, exhibit "E").

- 130. In the Pfizer report referred to by Dr. Hoffe in his impugned statement, the Pfizer Covid19 vaccine is referred to as the "study intervention". An "environmental exposure" to the
 vaccine is defined by Pfizer as a female found to be breast-feeding while having been
 exposed to the vaccine. An example of an environmental exposure during breast-feeding
 is where a female family member or healthcare provider reports that she is breast-feeding
 after having been exposed to the vaccine by inhalation or skin contact (page 69, paragraph
 8.3.5.2 of the Pfizer report). An "occupational exposure" is defined as when a person
 receives unplanned direct contact with the vaccine, which may or may not lead to the
 occurrence of an adverse event or serious adverse event (page 69 paragraph 8.3.5.3 of the
 Pfizer report). (Affidavit #1 Dr. Hoffe, page 11, paragraph 59, Exhibit "CCC").
- 131. At page 67 of the Pfizer report referred to by Dr. Hoffe in his impugned statement, at paragraphs 8.3.5 and 8.3.5.1, it explains that an "exposure during pregnancy" occurs if a female reports that she is pregnant after having been exposed to the vaccine by inhalation or skin contact, or where a male family member or healthcare provider who has been exposed to the vaccine by inhalation or skin contact and then exposes his female partner prior to or around the time of conception. In in either case this event must be reported to Pfizer Safety within 24 hours of the investigator becoming aware of this. At page 69 under paragraph 8.3.5.2, "exposure during breast-feeding" is said to occur if a female participant is found to be breast-feeding while receiving or after discontinuing the vaccine, or if she has been exposed to the vaccine (i.e. environmental exposure) which is when she has been exposed to the vaccine by inhalation or skin contact from a vaccinated person.
- 132. In the Pfizer report, at the top of page 128, Pfizer summarizes the requirements for recording adverse events and reporting serious adverse events which are delineated for 3 types of events. One of the events is exposure to the vaccine during pregnancy or by the infant through breast-feeding, and occupational exposure, which is when a person receives unplanned direct contact with the vaccine through inhalation or skin contact. Women who were pregnant or breast-feeding were excluded from the study (page 42 paragraph 11), but if they came into contact with someone else who had received the vaccine in the manner mentioned above, there was an obligation to report the incident to Pfizer safety.
- 133. Although the Pfizer report does not specifically use the term "shedding" it is clear that is what is being discussed.

- 134. Dr. Jessica Rose reviews peer-reviewed research that confirms that children that have received the Covid 19 vaccines can shed infectious SARS-CoV-2 despite being vaccinated. (Report of Dr. Rose, pages 19 and 20)
- 135. Dr. Pierre Kory explains the science and data behind shedding and confirms that it is a very real phenomenon.
- 136. Particulars Letter (f) (n), (p) the Covid 19 vaccines present safety problems for children in terms of myocarditis, and mortality that are greater than the virus itself
- 137. The Pfizer Adverse Events Report dated April 30, 2021 referenced in detail above confirms that there were a number of serious adverse reactions reported to Pfizer following administration of their vaccine to children and to pregnant women and breast-feeding women.
- 138. Dr. Theresa Tam, Chief Public Health Officer for Canada stated in a June 17, 2021 news broadcast on CTV that the Government was aware of rare cases of myocarditis and pericarditis following receipt of the mRNA vaccines and that they were closely monitoring the emerging evidence. (Affidavit #1 Dr. Hoffe page 5, paragraph 21, exhibit "Q")
- 139. Dr. Bonnie Henry admitted in her public address in late 2021 that the Covid 19 vaccines can cause inflammation of the heart, or the heart muscle or lining of the heart, postvaccination, but indicates that the potential for the side effects is very low. (Affidavit #1 Dr. Hoffe page 6, paragraph 29, exhibit "Y" and exhibit "Z").
- 140. The expert witnesses who have submitted reports on behalf of Dr. Hoffe, detail significant facts, data and studies to support Dr. Hoffe's statements. Their evidence supports the accuracy of Dr. Hoffe's statements and contradict the Notice Facts.
- 141. Dr. Rose notes that in a well referenced study from Japan, after 48 hours, the second-highest accumulation of 24.3 ug lipid equivalent/g after Covid 19 vaccination (next to the ovaries) was found in the liver. She notes that DNA has been discovered in all vials tested to date which leaves the door wide open for the possibility of integration events. It has also been more recently shown in a Nature publication that in vivo frame shifting events occur due to the N1-methylpsudourine substitutions producing off-target proteins in the modified mRNA Covid 19 injectables. These are unknown proteins that are not meant to be produced by the cells of a person. This also raises a plethora of questions pertaining to how these potentially aberrant proteins are affecting the cells. (Report of Dr. Rose Page 28).
- 142. Dr. Rose notes that there are 1077 published papers found when querying myocarditis Covid vaccine in PubMed. She opines that it is well-established that Covid 19 vaccines induced myocarditis in young males. The Vaccine Adverse Events Reporting System in the United States clearly demonstrate the discrepancy between reporting of this problem between first and second doses in 15-year-olds. This trend of vaccine induced myocarditis continues to be revealed in the literature (pages 17-18)
- 143. With respect to Health Canada's recent admission that the Pfizer vaccine is contaminated with DNA fragments called simian virus 40 promoter, after having had this brought to their

attention by Kevin McKernan and Dr. Peter Buckhaults, Dr. Rose notes that DNA fragments of foreign origin transfected into cells in the context of nuclear location sequence (NLS) could result in genomic integration and a plethora of genetic complications including insertional mutagenesis. If this occurs, the Covid 19 vaccines would qualify as gene therapies according to the FDA's definition (pages 24-25).

144. Dr. Rose also confirms that an in-depth review of the literature shows that children were never at significant risk for hospitalization or death from Covid 19 and the research clearly indicates that children develop robust and long-lasting immunity after exposure to the virus. (Pages 19-20)

Particulars Letter (h) the vaccine injuries are significantly underreported

- 145. Pfizer released their Pregnancy and Lactation Cumulative Review on April 20, 2021 containing Pfizer's post-market surveillance data to February 28, 2021. They acknowledge in the report that adverse events following immunization with the vaccine were submitted voluntarily and the magnitude of underreporting was unknown. They identified 673 serious adverse events following immunization up to February 28, 2021. Affidavit #1 Dr. Hoffe, page 5, paragraph 15, <a href="exhibit "K", page 2 first bullet, and para 2)
- 146. Dr. Hoffe's expert witness Dr. Jessica Rose, provides detailed evidence about the reality of the significant underreporting of the adverse events following COVID-19 vaccination making it difficult to determine the true number of adverse events following immunization with the Covid 19 vaccines. (Report of Dr. Rose, pages 9-15)
 - Notice Fact (5) "Infection and transmission of the COVID-19 virus is less likely to occur among fully vaccinated individuals than for those who are unvaccinated; vaccines do not prevent infection, reinfection or transmission but they reduce the severity of symptoms and the risk of bad outcomes.
- 147. Dr. Jessica Rose refers to a peer-reviewed publication in Open Form Infectious Diseases, a study in the Cleveland Clinic of employees showed that "the higher the number of vaccines previously received, the higher the risk of contracting Covid 19." This lack of efficacy of the Covid 19 vaccines in preventing Covid 19 and the harms associated with it, is clearly demonstrated in Figure 1 shown in Doctor Rose's report (Report of Dr. Rose page 8)
- 148. Dr. Rose notes that natural immunity against the virus is established following exposure, and therefore opines that there is no need for prophylaxis in the form of an injection of any kind. Long-lived and robust immunity is precisely what inoculation attempts to mimic (pages 30-31).
- 149. Dr. Payne provided the following facts that contradict Notice Fact (5) in his Report.
 - 30. In Federal Court cross examination on June 3, 2022, Celia Lourenco, the Government of Canada official responsible for approving the COVID genetic vaccines in Canada, admitted that to receive approval, these genetic vaccines needed to achieve only at least 50% relative risk reduction regarding efficacy against infection for at least a short duration

- (i.e. initial trials limited only to 2-months). Absolute risk reduction was not used as part of the approval criteria. "Protection" from severe illness and death were secondary endpoints, and while considered, they were not needed in the approval process. Further, she admitted that she never considered whether the COVID genetic vaccines prevented transmission, as transmission was not an outcome measure that was assessed.³ (Page 8)
- 31. Further, the landmark clinical trials for all the COVID-genetic vaccines in adults and pediatrics were NOT designed or powered to assess for vaccine protection from severe COVID-19 infection outcomes. None of the published trial participants who caught COVID-19 during the trials even required hospital admission. (Page 8)
- 33. A large study across 68 countries and 2947 U.S. counties studied the relationship between the percentage of the population fully vaccinated and new COVID-19 cases. The countries and U.S. counties with the highest vaccination rates had more COVID-19 cases. Similarly, 4 of the 5 U.S. counties with the highest percentage of population fully vaccinated, are listed by the CDC as "high" transmission counties, while 50 "low" transmission counties had only 20% of their population fully vaccinated. (Page 8)
- 150. Dr. McCullough notes that the Covid 19 vaccines failed early in the mass, indiscriminate, mandated campaign. In response to these numerous reports, the CDC announced on May 1, 2021 that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization would be reported. This overt asymptomatic reporting created the false picture of only unvaccinated individuals developing Covid 19, when in reality patients who are fully vaccinated were contracting breakthrough infections resulting in hospitalization and death, except those vaccinated individuals who were previously immune from prior Covid 19 infection. (Report of Dr. McCullough, page 18, lines 340-348)
- Dr. Peter McCullough stated that it is important to recognize that the randomized trials of all COVID-19 vaccines available revealed less than a 1% absolute risk reductions. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9115787/pdf/IERV_0_2067531.pdf. Second, the FDA provided Emergency Use Authorization for the vaccines, not full vaccine approvals. Therefore, the vaccines had not undergone the rigors of regulatory testing. No randomized, placebo-controlled trial of any COVID-19 vaccine has demonstrated statistically significant reductions in hospitalization or death. Interestingly, in the largest clinical trials program reported to date, there were actually more deaths with the Pfizer/BioNTech COVID-19 vaccine than with the placebo. S.J. Thomas, et al., "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months," New Eng. J. Med (Nov. 4, 2021). https://www.nejm.org/doi/10.1056/NEJMoa2110345. (page 34, line 651-661)

³ ₃₇ Federal Court between the Honourable A. Brian Peckford, Leesha Nikkanen, Ken Baigent, Drew Belobaba, Natlkie Grcic, and Aeden Macdonald vs. The Attorney General of Canada. https://www.doakshirreff.com/cross-examination-of-celia-lourenco/

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⁴ 39 Akhil Kumar S. V. Subramanian, "Increases in Covid-19 Are Unrelated to Levels of Vaccination across 68 Countries and 2947 Counties in the United States," *European Journal of Epidemiology* 36 (September 30, 2021), http://dx.doi.org/https://doi.org/10.1007/s10654-021-00808-7.

- 152. Dr. McCullough goes on to state that the SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 17 25 June 2021, 92,056 cases had the Delta variant and 50/7235 fully vaccinated and 44/53,822 of the unvaccinated died. This indicates that the fully vaccinated who contract the Delta variant have an 8.6-fold increased risk for death, (95% CI 5.73-12.91), p < 0.0001, as compared to those who chose to remain unvaccinated, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file364/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf (pages18-19, lines 359-365)
- 153. Dr. McCullough notes that numerous studies have demonstrated that when Covid 19 recovered patients take a Covid 19 vaccination, they can suffer high side effects including hospitalization (page 27, lines 527-528).
- 154. Dr. Steven Pelech challenges the commonly held belief that transmission is less likely among fully vaccinated individuals. Dr. Pelech points to public health data in Alberta and Scotland which show that vaccination was associated with a substantial increase in the likelihood of getting Covid-19 in the first two weeks post-vaccination (Report of Dr. Pelech pages 61-62, paragraph 126).
- 155. Dr. Pelech further points to recent studies showing the negative efficacy of booster Covid-19 vaccines. Not only were boosters not associated with reduced transmission, but studies indicate that the risk of getting Covid-19 increased with each successive vaccination (page 62, paragraph 127, page 78, paragraph 153).
- 156. Dr. Clare Craig notes the case of Gibraltar. Prior to vaccinating its entire population between Jan 9 and March 18, 2021, Gibraltar experienced minimal deaths from Covid-19 precisely 12. However, by the end of 2023 that number exploded to 870 deaths, more than 60 percent of which occurring with several weeks of January 2021. During the same period there was minimal Covid-19 in neighbouring Spain. (Report of Dr. Craig, page 37, lines 866-872)
- 157. Notice Fact (6) "Health Canada has approved COVID vaccines, and regulatory approval is a strong indicator of safety and effectiveness."
- 158. The evidence provided by Dr. Hoffe clearly demonstrates that Health Canada has approved COVID vaccines on the basis that they were safe and efficacious, only to cancel that approval 3 years later when those very same vaccines were found not to be safe.
- 159. Celia Lourenco, the person responsible at Health Canada for approving the Covid 19 Vaccines in Canada submitted a sworn affidavit to the Federal Court of Canada wherein she admitted that the duration of assessment of the safety and efficacy of the Pfizer Moderna vaccines at the time of approval was a median of 2 months. (Affidavit #1 Dr. Hoffe, page 7, paragraph 33, exhibit "CC")
- 160. The BC CDC expressed a high level of concern over the safety of the AstraZeneca Covid 19 vaccine that had been approved by Health Canada, as early as March 25, 2021 in an email to Dr. Bonnie Henry. The particular concerns expressed were the severe nature of

the adverse events following immunization with the AstraZeneca vaccine including high case fatality and sequelae risk, the young age in which these AEFI's were presenting, and the unusual features such that it was determined there was an excess risk associated with the AstraZeneca vaccination. This information was confirmed in emails obtained through a freedom of information request of the BC Ministry of Health. (Affidavit #1 Dr. Hoffe, page 3, paragraph 11, exhibit "G" page 32/59).

- 161. In these same emails between BC public health officials, they discussed their own AEFI summary report as of January 21, 2021, just over one month after the vaccines were made available to the public, which demonstrated AEFI's of 56 in BC, with 18 of them being listed as serious. They also indicated that there was a rate of 46.7 reports of AEFI's associated with Covid 19 vaccines per 100,000 distributed doses.(Affidavit #1 Dr. Hoffe, page 3, paragraph 11, exhibit "G" page 7/59)
- 162. Although Prime Minister Justin Trudeau reiterated on March 15, 2021 that despite alarming safety signals for the AstraZeneca vaccine being recognized in various Canadian provinces and in Europe, he reassured the public that the AstraZeneca vaccine was safe and there was absolutely no risk associated with it. (<u>Affidavit #1 Dr. Hoffe</u>, page 4, paragraph 14, <u>exhibit</u> "J").
- 163. On May 4, 2021, NACI confirmed that information had evolved concerning the safety of the AstraZeneca vaccine and concerning safety signals of harm were emerging including blood clots. NACI confessed that they initially thought the risk of adverse events was one in 1 million but new information suggested it was a 10 fold greater risk, 1 in 100,000. Affidavit #1 Dr. Hoffe, page, 4, paragraph 16, exhibit "L")
- 164. Also on May 4, 2021 Prime Minister Justin Trudeau, and Dominic Cary, Education Minister for New Brunswick contradicted NACI's public messaging and reiterated that all vaccines approved by Health Canada were safe and effective and people should not hesitate to get the AstraZeneca vaccine. Dr. Theresa Tam however, Chief Public Health Officer for Canada expressed that she understood why some individuals would be concerned or frustrated with the news of these safety concerns regarding the AstraZeneca vaccine. She recommended that people should weigh certain factors before considering waiting for Pfizer or Moderna including the risk of blood clots. She advised that further advice on the second AstraZeneca dose would be coming out soon. Affidavit #1 Dr. Hoffe, page, 4, paragraph 17, exhibit "M").
- 165. On May 13, 2021 Dr. Howard Njoo, Canada's Deputy Chief Public Health Officer acknowledged that public health officials in Canada had identified 28 suspected cases of a rare but serious condition called vaccine induced thrombotic thrombocytopenia, or blood clotting that leads to low platelet counts, that included 4 Deaths following vaccination for COVID-19. Alberta, New Brunswick, Nova Scotia, Ontario, Saskatchewan and Québec suspended the use of AstraZeneca as a result. Ontario announced that they felt the incidence of the adverse reaction had now reached 1 in 60,000. Dr. Njoo admitted that the situation with AstraZeneca was evolving, and they were waiting for a determination by Health Canada as well as NACI on the situation with respect to the vaccine induced thrombotic thrombocytopenia. Affidavit #1 Dr. Hoffe, page, 5, paragraph 19, exhibit "O").

- 166. On June 17, 2021, based upon NACI's recommendations, Dr. Theresa Tam, Chief Public Health Officer for Canada, suggested Pfizer and Moderna be offered in preference to AstraZeneca because of concerns over vaccine induced thrombotic thrombocytopenia. She also confirmed that the Government of Canada was aware of rare cases of myocarditis and pericarditis following receipt of the mRNA vaccines, and they were closely monitoring the emerging evidence about these adverse reactions. Affidavit #1 Dr. Hoffe, page 5 paragraph 21, exhibit "Q")
- 167. On September 9, 2022, NACI released their revised public health guidance reminding people administering the Covid 19 vaccines to be aware of the contents of the relevant product monograph and that NACI's public guidance may differ from what was set out in the product monographs of the Canadian manufacturers of the vaccines. NACI emphasized that manufacturers sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monograph. (Affidavit #1 Dr. Hoffe, page 7, paragraph 36, exhibit "FF")
- 168. NACI reiterated on January 12, 2024 that people administering the COVID-19 vaccines need to be aware of the information contained in the product monographs as manufacturers sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monograph. (<u>Affidavit #1 Dr. Hoffe</u>, page 9, paragraph 51, <u>exhibit "UU"</u>)
- 169. The product monograph for the AstraZeneca vaccine with an initial authorization of November 19, 2021 and revised on December 14, 2022 provides the following warnings about the safety of the AstraZeneca vaccine:
 - (a) a combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination
 - (b) there are no safety, immunogenicity or efficacy data to support interchangeability of the vaccine with other Covid 19 vaccines
 - (c) hypersensitivity reactions including anaphylaxis and angioedema have occurred following administration of the vaccine
 - (d) coagulation disorders reported with administration of the vaccine include thromboembolism in combination with thrombocytopenia syndrome, cerebrovascular venous and sinus thrombosis without thrombocytopenia, thrombocytopenia, for which fatal outcomes have been reported.
 - (e) capillary leak syndrome has been observed very rarely following vaccination and is characterized by acute episodes of limb edema, hypotension, chemo concentration and hypoalbuminemia
 - (f) very rare events of demyelinating disorders, such as Guillain-Barre Syndrome and transverse myelitis have been reported following vaccination

- (g) it is unknown whether the vaccine may impact fertility as no data are available in humans
- (h) the safety of the vaccine in pregnant women has not yet been established
- (i) it is unknown whether the vaccine itself is excreted in human breast milk
- (j) non-medicinal ingredients in the vaccine include ethanol, disodium edtate dihydrate, L-histidine, L-histidine, hydrochloride, monohydrate magnesium chloride hexahydrate, polysorbate 80, sodium chloride sucrose and water. (Affidavit #1 Dr. Hoffe, page 11, paragraph 60, exhibit "DDD")
- 170. The Johnson & Johnson COVID-19 vaccine was also approved as being safe and effective by Health Canada. The product monograph for Johnson & Johnson contain similar warnings to the AstraZeneca vaccine. It vaccine was initially authorized by Health Canada on November 23, 2021 and revised on February 16, 2023. The product monograph provides the following information:
 - (a) a combination of thrombosis and thrombocytopenia in some cases accompanied by bleeding has been observed very rarely following vaccination
 - (b) there are no data available on the use of the vaccine to complete a primary vaccination series initiated with another Covid 19 vaccine
 - (c) serious and unexpected adverse events may occur that have not been previously reported
 - (d) anaphylaxis has been reported
 - (e) coagulation disorders that have been reported include thrombosis and thrombocytopenia in as high as one case per 100,000 doses in females ages 30-49 years, with approximately 15% of these cases being fatal
 - (f) immune thrombocytopenia, venous thromboembolism, risk of bleeding, capillary leak syndrome have all been reported following vaccination, very rare events of demyelinating disorders such as Guillian Barre syndrome and transverse myelitis have been reported following vaccination
 - (g) no data are available on fertility in humans
 - (h) there is limited experience with the use of the vaccine in pregnant women it is not known whether the components of the vaccine are excreted in human milk
 - (i) nonmedicinal ingredients in the vaccine include 2-hydroxypropyl-B-cyclodextrin, citric acid monohydrate, ethanol, Hydrochloric acid, polysorbate 80, sodium chloride, sodium hydroxide, trisodium citrate

dihydrate and water. (<u>Affidavit #1 Dr. Hoffe</u>, page 12, paragraph 61, <u>exhibit</u> "EEE")

- 171. Despite the receiving Health Canada's approval, and despite assurances from Prime Minister Justin Trudeau, and other public health officials that the Johnson & Johnson COVID-19 vaccine was safe and effective, Health Canada's authorizations for the public distribution of the Johnson & Johnson and AstraZeneca vaccine were cancelled on June 30, 2023 and December 29, 2023 respectively, due to the safety concerns outlined in the product monographs. (Affidavit #1 Dr. Hoffe, page 8, paragraph 43 exhibit "MM" and page 9 paragraph 49, exhibit "SS")
- 172. The product monographs for Pfizer and Moderna contain similar information to the AstraZeneca and Johnson & Johnson product monographs, and even provide additional warnings, but those products are still currently approved for public consumption.
- 173. The Pfizer product monograph (updated March 21, 2023) states:
 - (a) the safety and efficacy of the vaccine in children under 6 months has not yet been established
 - (b) anaphylaxis has been reported
 - (c) very rare cases of myocarditis and/or pericarditis have been reported following vaccination. Reports of this adverse reaction to the vaccine is lower in 5 through 11-year-olds than it is through 12 through 17-year-olds.
 - (d) It is unknown whether the vaccine has an impact on fertility
 - (e) immunocompromised individuals may have a diminished response to the vaccine
 - (f) safety and efficacy of the vaccine in pregnant women has not yet been established
 - (g) it is unknown whether the vaccine is excreted in human milk and a risk to newborns/infants cannot be excluded

Affidavit #1 Dr. Hoffe, page 14, paragraph 69, exhibit "MMM"

- 174. The Moderna product monograph states:
 - (a) the safety and efficacy of the vaccine for individuals under 6 months of age has not yet been established
 - (b) the vaccine must not be reconstituted, or mixed with other medicinal products or diluted
 - (c) anaphylaxis has been reported

- (d) very rare cases of myocarditis and or pericarditis have been reported during post authorization use. There is an increased risk for myocarditis and pericarditis following vaccination, particularly within the first week following receipt of the 2nd primary series dose or first booster dose in young male adults
- (e) immunocompromised persons may have a diminished immune response to the vaccine
- (f) the safety and efficacy of the vaccine in pregnant women have not yet been established
- (g) it is unknown if the vaccine is excreted in human milk and a risk to newborns/infants cannot be excluded
- (h) overall there was a higher reported rate of solicited adverse reactions in younger age groups
- (i) the following adverse reactions were identified during post-authorization use of the vaccine: immune system disorders including anaphylaxis and hypersensitivity, cardiac disorders such as myocarditis and pericarditis, skin and subcutaneous tissue disorders such as erythema multiforme, acute and delayed uticaria, nervous system disorders including facial paralysis, Bell's Palsy, hypoaesthesia, parasthesia and dizziness. (Affidavit #1 Dr. Hoffe page 13, paragraph 66, exhibit "JJJ" respectively).
- 175. The AstraZeneca and Johnson & Johnson Covid 19 vaccines are not the first drugs that Health Canada has approved as safe and effective that they have later had to withdraw from the market because the contrary actually turned out to be true.
- 176. In the context of considering an application to take judicial notice of the safety and efficacy of the COVID-19 vaccines based upon statements made by Health Canada and other public health officials, the Saskatchewan Court of Appeal had this to say in <u>O.M.S. v. E.J.S. 2023</u> SKCA 8, at para 45:

We also note the existence of easy-to-find case law reports of instances where drug companies have been found to have been brought on the market products that have passed a regulatory process and have been found to be associated with risks that are later determined to have been misdescribed or missed altogether in the product information that accompanies the distribution of the product.

177. One such drug is Vioxx. An article published in the Canadian Medical Association Journal on January 4, 2005 still located on their website, concerns Health Canada's approval in 1999 of Vioxx as a safe and effective medication which was heavily marketed as having a low risk of gastrointestinal bleeding but was withdrawn from the market 4 years later because of an increased risk of cardiovascular disease, mainly myocardial infarction and stroke. It was alleged by the authors of the journal that Health Canada were aware of the

- increased risk of cardiovascular adverse events from the drug long before it was withdrawn from the market. (<u>Affidavit #1 Dr. Hoffe</u> page 2, paragraph 7 <u>exhibit "C"</u>)
- 178. Another such drug is Thalidomide. An article published in the Oxford Academic Journal discussing thalidomide which the authors note was approved by health regulators, including Health Canada, as safe and effective treatment of nausea in pregnant women. It was later discovered that this drug resulted in severe birth defects in thousands of children, and it was ultimately removed from the market about 10 years after it had been approved. (Affidavit #1 Dr. Hoffe page 2, paragraph 8, exhibit "D")
- 179. Dr. Bonnie Henry stated in her public address in late 2021 that unequivocally the Covid 19 vaccines do not change your DNA. (Affidavit #1 Dr. Hoffe page 6, paragraph 29, exhibit "Y" and exhibit "Z")
- 180. On July 28, 2023 Health Canada and the Public Health Agency of Canada admitted in an email to the Epoch Times that it was only after the presence of the SV40 enhancer was raised publicly by Kevin McKernan (one of Dr. Hoffe's expert witnesses) and another independent expert Dr. Phillip Buckhalts, Professor of cancer genomics and director of the Cancer Genetics Lab at the University of South Carolina, that Health Canada went back and looked at the Pfizer application documentation provided to them originally, and confirmed Mr. McKernan and Dr. Buckhaults were correct that the COVID-19 vaccines contained DNA plasmid contamination. Affidavit #1 Dr. Hoffe page 8, paragraph 44, exhibit "NN".
- 181. The Epoch Times subsequently confirmed this in an August 25, 2023 published report. (Affidavit #1 Dr. Hoffe page 8, paragraph 45, Exhibit "OO")
- 182. In an official reply by the Federal Minister of Health on October 27, 2023 to questions posed by Member of Parliament Mr. Carrie (Oshawa) the Minister confirmed that Pfizer used two different manufacturing processes. Process 1 in the clinical trials, and Process 2 in the manufacturing of the vaccines that were given to members of the public:
 - (a) Pfizer's submission provided information that process 1 was used for vaccine development for the clinical trials, and process 2 was used for vaccines that were distributed to the public
 - (b) Health Canada was aware of the presence of residual plasma DNA in the vaccines
 - (c) the simian virus 40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech Covid 19 vaccine.(Affidavit #1 Dr. Hoffe page 15 paragraph 74, exhibit "RRR")
- 183. Although Health Canada maintains that the level of DNA plasmid contamination was within acceptable limits, testing performed by Mr. McKernan and Dr. Buckhaults found otherwise.

- 184. Mr. McKernan, who is the expert who Health Canada admits alerted them to the problem with DNA plasmid contamination of the Covid 19 vaccines, and the presence of the SV40 enhancer in the Covid 19 vaccines, has provided a detailed and thorough report about his own independent research and the risks that this revelation poses to individuals who receive the Covid 19 vaccines.
- 185. Dr. Shirin Kalyan, Adjunct Prof. of Medicine, University of British Columbia and Vice-President, Scientific Innovation, Qu Biologics testified before the Standing Committee on Health in the House of Comments on June 14, 2021 and advised with respect to the vaccines:

The third category is these new cool nucleic acid delivery platforms that we have rolled out, which deliver genetic material either in the form of DNA or RNA into ourselves to make or express viral proteins. We have very little, to no, knowledge on the long-term safety and efficacy of many aspects of this particular technology, especially when these vaccines are given in multiple doses. (Affidavit #1 of Dr. Hoffe page 5, paragraph 20 Exhibit "P".)

- 186. The approval process followed by Health Canada for the COVID-19 vaccines was entirely different from the normal regulatory approval process for other vaccines and unlike the normal approval process Health Canada did not have to conclude that the vaccines were safe or effective or that the benefits outweighed the risks. This reality is fully explained by senior lawyer Shawn Buckley, who practices in the area of Food and drug administration and Health Canada regulatory approvals in his affidavit filed in support of Dr. Hoffe's Response. The significance of this reality cannot be overstated. (Affidavit #1 Shawn Buckley)
- 187. All of the experts who have provided reports on behalf of Dr. Hoffe, document serious concerns about the safety and efficacy of the Covid 19 vaccines and provide peer-reviewed research, and government and real world data to support their assertion.

Notice Facts (7) and (8) Ivermectin is safe for treatment of Covid 19

- 188. The Minister of Health on December 12, 2023 provided and official answers to questions posed by Member of Parliament Mr. Falk (Provencher) which confirms the following:
 - (a) Health Canada did not perform a risk-harm analysis for the use of ivermectin to prevent or treat Covid 19 and only does so if a marketing application for a drug has been submitted by a manufacturer.
 - (b) The Department has not received nor reviewed any scientific evidence for the purpose of determining a benefits, harms, and uncertainties profile on such use. (Affidavit #1 Dr. Hoffe (Affidavit #1 Dr. Hoffe page 16, paragraph 75, exhibit "SSS")
- 189. In an official reply by the Minister of Health on December 13, 2023 to questions posed by Member of Parliament Mr. Epp (Chatham-Kent-Leamington) the Minister confirmed the following:

- (a) the Minister of Health requires a manufacturer to submit an application for approval of a new indication for drug that is already approved for a different indication.
- (b) However, healthcare practitioners may choose to prescribe a drug outside of its approved indication (off-label use). Off-label use falls under the "practice of medicine" and is regulated at the provincial and territorial level. (Affidavit #1 Dr. Hoffe page 17, paragraph 78, exhibit "VVV")
- 190. The answer provided by the Federal Minister of Health confirms that even though ivermectin was not originally authorized for the purpose of treating Covid 19, drugs that have been approved as safe and effective by Health Canada can be prescribed off label by physicians for other uses.
- 191. One reputable source lists 246 studies demonstrating the safety and efficacy of ivermectin as a treatment for Covid 19. 192 of the studies are peer-reviewed with 101 comparing treatment and control groups. (Affidavit #1 Dr. Hoffe page 11, paragraph 58, exhibit "BBB").
- 192. Dr. Pierre Kory, a recognized expert in the field of understanding the science behind the efficacy and safety of using ivermectin to prevent and treat SARS-CoV-2 infection has provided an extensive report with detailed data and scientific research confirming the safety and efficacy of ivermectin in relation to COVID-19. He endorses the above source as a reputable source of information that tracks studies concerning ivermectin along with real-time meta-analysis. (Report of Dr. Kory, page 11 lines 413-414)
- 193. Dr. Kory opines based on his 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, 2024, 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. (Report of Dr. Kory, page 4 lines 140-144)
- 194. Dr. Kory opines that the research shows that the prevention trials found a highly statistically significant 88% reduction in your chance of getting Covid as a result of taking ivermectin, far outperforming what we know of the efficacy of the Covid mRNA vaccines. (Page 9, lines 342-347).
- 195. Dr. Kory confirms 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"

(Page 10, Lines 404-410)

- 196. Dr. Kory gives numerous examples of different countries that trialed ivermectin to treat Covid 19 who had incredibly good success with the treatment and notes that 23 countries, including 39 nongovernmental organizations have now given either partial or full approval for use of ivermectin for treatment and prevention of Covid 19, encompassing 25% of the world's population (page 17, line 604-609)
- 197. Dr. Kory reviews the plethora of studies and data confirming the safety of ivermectin, including the World Health Organization's own data which shows 16 deaths attributed to ivermectin over a 30 year period of regular use. This compared to Remdesivir, strongly recommended by public health officials as a treatment for Covid 19, where there are 11,056 deaths reported after the drug was approved for use on October 22, 2020 and administered to far fewer patients. (Pages 17-22)
- 198. With respect to the use of veterinary sources of ivermectin Dr. Kory opined: 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. (Pages 22-23 line 792-807)

199. Dr. McCullough notes that studies have shown several different treatment methods for Covid 19 which have proven effective. He stated the following: "Even if individuals contract the virus, the treatment of the infection has improved tremendously since the advent of COVID-19. Studies have shown several different treatment methods, which have proven effective. A combination of medications (including hydroxychloroquine, ivermectin, colchicine, budesonide, prednisone, enoxaparin), supported by the Association of American Physicians and Surgeons, for a minimum of five days, and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability), has proven effective. Brian C Procter, Casey Ross, Vanessa Pickard, Erica Smith, Cortney Hanson, Peter A McCullough, Clinical Outcomes After Early Ambulatory Multidrug Therapy for High-risk SARS-CoV-2 (COVID-19) infection, Reviews in Cardiovascular Medicine (December 30, 2021), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited June 26, 2021), summarized in Table 3 below. According to US FDA guidance, we used clinically indicated, medically necessary off-label generic medications in addressing an unmet clinical need, that is, the prevention of COVID-19 hospitalization and death. We found this approach has resulted in an ~85% reduction in hospitalization and death in highrisk individuals presenting with COVID-19.4" (Report of Dr. McCullough, pages 9-10, lines 194-209)

Public Health and Government Officials and the Vaccine Manufacturers Often Don't Agree on the Facts about the Covid-19 vaccines and Public Health Experts Don't Always get it Right

- 200. Danuta Skowroski, lead epidemiologist at the BC CDC, stated on global news on February 19, 2021 that people should only get one dose of the vaccine, contrary to the recommendations of the CEO of Pfizer who was recommending 2 doses of the vaccine.(Affidavit #1 Dr. Hoffe page 4, paragraph 13, exhibit "I")
- 201. Despite NACI and Dr. Tam issuing warnings about concerning safety signals of blood clots related to the AstraZeneca vaccine, Prime Minister Justin Trudeau assured the public that every single vaccine that has been approved by Health Canada is safe and effective. The New Brunswick Education Minister for New Brunswick emphatically told the public that if a vaccine is approved by Health Canada and his Provincial Chief Public Health Officer Dr. Russell and her team, people should "take that shot and ignore NACI..." Affidavit #1 Dr. Hoffe, page 4, paragraph 17, exhibit "M").

- 202. The Ontario and BC public health officials admitted years later that they overestimated the number of people who were in the hospital because of COVID-19 by as much as 46% (Affidavit #1 Dr. Hoffe, page 7, paragraphs 30 and 31, exhibit "AA" and "XXX")
- 203. Dr. Henry states in her most recent October 5, 2023 public health order that, despite our highly vaccinated population in British Columbia, cases, hospitalizations and deaths, from COVID-19 are increasing. Based upon Dr. Henry's statements, one could conclude that vaccination is not effective at preventing these consequences, although she continues to maintain that the vaccines are effective at preventing infection (paras L. and M.) contrary to what most people now understand to be the case. She no longer makes any claims that the vaccines prevent transmission. (Affidavit #1 Dr. Hoffe, Exhibit "QQ").
- 204. It is noteworthy that the decision of the Arbitrator in the <u>December 14, 2023 Puralator</u> decision contradicts current public health guidance by the BC Government and our chief Provincial Health Officer Dr. Bonnie Henry and says the evidence did not justify any mandates after June 30, 2022 at least in part because the vaccines were not stopping infection and transmission. The BC Minister of Health and the BC Chief Provincial Health Officer have made BC the only jurisdiction in North America who believes that we are still in a state of emergency for Covid-19 and have maintained an original 2 dose vaccine mandate for healthcare workers as a result.
- 205. The Government of Saskatchewan revoked the remaining proof of vaccination and testing requirements in Saskatchewan businesses, workplaces and other public venues effective February 14, 2022. (Affidavit #1 Dr. Hoffe page 7, paragraph 32, exhibit "BB")
- 206. The Province of Alberta ended all remaining mandatory public health restrictions for Covid 19 on June 14, 2022. (Affidavit #1 Dr. Hoffe page 7, paragraph 34, exhibit "DD").
- 207. The Government of Canada announced on June 14, 2022 they it was suspending the vaccine mandates for domestic travellers, transportation workers and federal employees. (Affidavit #1 Dr. Hoffe page 7, paragraph 35, exhibit "EE")
- 208. The World Health Organization declared that as of May 5, 2023 that COVID-19 no longer constitutes a public health emergency (Affidavit #1 Dr. Hoffe, page 8, paragraph 42 Exhibit "LL") On May 5, 2023, the BC Minister of Health and Chief Provincial Public Health Officer acknowledged their awareness of this announcement and stated that BC was transitioning out of the emergency phase of COVID-19 and that they would continue to evaluate their ongoing vaccine mandate for healthcare workers (Affidavit #1 Dr. Hoffe, page 8, paragraph 41 Exhibit "KK"). This mandate requires healthcare workers to be vaccinated with two doses of the original vaccine to work in a hospital or facility. This mandate remains in effect. Affidavit #1 Dr. Hoffe, Exhibit "QQ")
- 209. The Department of Homeland Security in the U.S. confirmed as of May 12, 2023 they no longer require non-US travellers into the United States to be fully vaccinated against Covid 19. (Affidavit #1 Dr. Hoffe page 8, paragraph 40, exhibit "JJ")
- 210. Government officials strongly disagree on the public guidance and policy around COVID-19 vaccines. B.C. remains the last province in Canada and only jurisdiction in North

America that continues to ban unvaccinated health care workers from their own healthcare system pursuant to an ongoing declared public state of emergency for COVID-19 by the Chief Public Health Officer Dr. Bonnie Henry as confirmed in her October 5, 2023 public health order. (Affidavit #1 Dr. Hoffe page 9, paragraph 47, exhibit "QQ"). The official leader of the opposition, Kevin Falcon, leader of the B.C. United Party, challenged the B.C. Premier and Minister of Health in the provincial legislature on February 22, 2024 when he said: "B.C. stubbornly clings to its nonsensical and divisive policy. B.C. has long been an outlier. Apparently, the science is different in every other jurisdiction in North America...So my question to the Premier is this, will the Premier finally rehire the healthcare workers that they fired, or will he stubbornly sideline healthcare professionals while BC's healthcare system continues its collapse." (Affidavit #1 Dr. Hoffe page 10, paragraph 53, exhibit "WW")

Interchangeability of the AstraZeneca, Moderna and Pfizer vaccines

- 211. Dr. Teresa Tam advised on June 17, 2021 that the National Advisory Committee on Immunization public guidance had been revised to state that the AstraZeneca, Moderna and Pfizer vaccines are interchangeable. She says they will provide effective protection against infection. She stated that the Government is aware of reports of myocarditis, pericarditis and heart inflammation resulting from the mRNA vaccines and are monitoring it. Affidavit #1 Dr. Hoffe page5, paragraph 21, exhibit "Q")
- 212. The product monographs for AstraZeneca, Moderna and Pfizer contradict Dr. Tam's public health guidance about the interchangeability of the vaccines.
- 213. The AstraZeneca product monograph dated November 19, 2021 and December 14, 2022 provides at page 4, paragraph 4.2:

There are no data available on the interchangeability of VAXZEVRIA with other non ChAdOx1-S (recombinant) COVID-19 vaccines. Affidavit #1 Dr. Hoffe page 11 paragraph 60, exhibit "DDD")

214. At page 7 under the heading "Interchangeability" the product monograph also states:

There are no safety, immunogenicity or efficacy data to support interchangeability of VAXZEVRIA with other non-CHAdOx1-S (recombinant) COVID-19 vaccines.

215. The Moderna product monograph dated September 16, 2021 and revised most recently on October 4, 2023 provide at page 600 paragraph 4.2 as follows:

There are currently no data available from Moderna clinical trials on the interchangeability of SPIKEVAX with other COVID-19 vaccines to complete the primary vaccination series. <u>Affidavit #1 Dr. Hoffe</u> page 13 paragraph 66, <u>exhibit</u> "JJJ")

216. The Pfizer product monograph dated September 16, 2021 and revised on March 21, 2023 provides at page 6 under paragraph 4.2.1 as follows:

There are currently no data available from the Pfizer and BioNTech clinical trials on the interchangeability of COMINARTY with other COVID-19 vaccines to complete the primary vaccination series or for a booster dose. <u>Affidavit #1 Dr. Hoffe</u> page 14 paragraph 69 <u>exhibit "MMM"</u>,

217. And at page 7 under paragraph 4.2.2 Re: individuals aged 5 to less than 12 years of age:

There are no data available on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the primary vaccination series or for a booster dose. Individuals who have received one dose of COMINARTY should receive a second dose of COMINARTY to complete the primary vaccination series and for any additional doses.

Part 2: LEGAL BASIS

Procedural Fairness and the Right to Know the Case to Meet and the Right to be Full Answer and Defence

- 1. It is a fundamental principle of administrative law that a person must know the case they have to meet, and be provided with an opportunity to answer it... As with all principles of procedural fairness, the content of the audi alteram partem rule depends on the context.

 (Nova-BioRubber Green Technologies Inc. v. Investment Agriculture Foundation British
 Columbia 2022 BCCA 247 at para 74; Campbell v. The Bloom Group 2023 BCCA 84 at 48)
- 2. A higher standard of procedural fairness is required when the matter involves professional discipline bodies when the right to continue in one's profession or employment is at stake. Some Courts have noted that a finding of professional misconduct may be more serious than a criminal conviction. A high standard of justice is required when the right to continue in one's profession or employment is at stake and a disciplinary suspension can have grave and permanent consequences upon a professional career.

Sheriff v. Canada (Attorney General) 2006 FCA 139 at paras 29-34; Nguyen v. Chartered Professional Accountants of British Columbia 2018 BCSC 620 at 96; leave to appeal refused 2018 BCCA 299; Oberg v. Saskatchewan (Board of Education of the South East Cornerstone School Division No. 209) 2021 SKCA 28 at paras 80 and 86; The British Columbia College of Nurses and Midwives v. Sean Taylor, unreported, April 24, 2023 at a para 108.

- 3. The Alberta Court of Appeal most recently stated the law as follows:
 - A tribunal that finds itself having to contend with competing versions of events in order to determine whether unprofessional conduct is made out is well-advised to have regard to established principles governing the assessment of evidence. Doing so increases by a measurable degree the reliability of its findings as to whether it is satisfied that it is more likely than not the impugned conduct is made out and whether that conduct warrants disciplinary action.

- While in theory the civil standard of proof in civil cases in which criminal or morally blameworthy conduct is at issue does not change, those who apply it infuse it with sufficient flexibility to take into account the gravity of the allegation and the consequences of a finding adverse to the party the subject of the allegations. This Court has expressly said so: "While disciplinary proceedings of professionals are civil in nature, and the civil burden of proof applies, the fact that a charged member may face serious consequences from a finding of misconduct has prompted the courts to be rigorous in relation to such charges. ... [A]ll ... the elements of the charge must be strictly proven". So has the Supreme Court: "[A] judge should not be unmindful, where appropriate, of inherent probabilities or improbabilities or the seriousness of the allegations of consequences". It is safe to assert that a civil tribunal assessing allegations of criminality or moral wrongdoing will not find against the subject of the allegations in the absence of clear and compelling evidence. (Chartered Professional Accoutnatns of Alberta (Complaints Inquiry Committee) v. Mathison 2024 ABCA 33)
- 4. Dr. Hoffe is entitled to a higher degree of procedural fairness and justice. The College should not be permitted to prevent Dr. Hoffe from contesting the Notice Facts and they should have to prove the facts in the disciplinary hearing through evidence tendered at the hearing that is subject to testing under cross-examination.

5. Allegations of Professional Misconduct is a Strict Liability Offence – Due Diligence is a Defence

- 6. A finding of professional misconduct must be based on actions which would be regarded as disgraceful, dishonourable or unbecoming a member of the profession by that person's fellow members. The offence of professional misconduct is one of strict liability leaving it open to the accused to avoid liability by proving that he took all reasonable care. This involves consideration of what a reasonable man would have done in the circumstances. The defence will be available if the accused reasonably believed in a mistaken set of facts, which, if true, would render the act or omission innocent, or if he took all reasonable steps to avoid the particular event. (Stuart v. BC College of Teachers 2005 BCSC 645 at paras 43-49, and 59).
- 7. The Supreme Court of Canada has confirmed that the standard of proof in a civil matter is a balance of probabilities, but the Court must be mindful of the seriousness of the allegations or consequences and that different levels of scrutiny of the evidence are required depending upon the seriousness of the case. Evidence must always be sufficiently clear, convincing and cogent to satisfy the balance of probabilities test. (F.H. v McDougall, 2008 SCC 53 (CanLII), [2008] 3 SCR 41 at para 40, 45 and 46):
- 8. The College should have to prove the charges in the citation with sufficiently clear, convincing and cogent evidence to satisfy the balance of probabilities test.

The Admissibility of Online or Internet Materials

9. Information obtained from the Internet can be admissible if it is accompanied by indicia of reliability, including, but not limited to:

- (a) whether the information comes from an official website from a well-known organization;
- (b) whether the information is capable of being verified; and
- (c) whether the sources disclose so that the objectivity of the personal organization posting the material can be assessed.

Little or no weight should be given to information found online without careful assessment of its sources, independent corroboration...an assessment of the objectivity of the person placing information online. ((J.N. v. C.G. 2023 ONCA 77 at paras 12 and 13)

10. Dr. Hoffe has presented online materials in this Response that satisfy the above test and can be relied upon by the panel.

The Admissibility of a State Document

- 11. State Documents may be admissible as an exception to the general rule against hearsay as an exception to the general rule against hearsay pursuant to British Columbia's *Evidence Act*, RSBC 1996, c 124.
- 12. <u>Section 25 of the *Evidence Act*</u> provides that:
 - "state document" includes any Act or ordinance enacted or made or purporting to have been enacted or made by a legislature, and any order, regulation, notice, appointment, warrant, licence, certificate, letters patent, official record, rule of court or other instrument issued or made or purporting to have been issued or made under any Act or ordinance so enacted or made or purporting to have been enacted or made, and any official gazette, journal, proclamation, treaty or other public document or act of state issued or made or purporting to have been issued or made.
- 13. Section 25 only speaks to admissibility, and not to what weight a judge must ultimately assign to it. Given the purpose behind section 25 and the public document exception, there is at least an obligation to explain why materials that meet this definition are not trustworthy. (J.N. v. C.G. 2023 ONCA 77 at paras 26 and 28).
- 14. Dr. Hoffe has submitted documents published by government and public health officials that are admissible pursuant to section 25 of the Evidence Act.

Judicial Notice

15. The Supreme Court of Canada held that the law concerning judicial notice is as follows:

The threshold for judicial notice is strict: a court may properly take judicial notice of facts that are either: (1) so notorious or generally accepted as not to be the subject of debate among reasonable persons; or (2) capable of immediate and accurate demonstration by resort to readily accessible sources of <u>indisputable accuracy</u>...

The scientific and statistical nature of much of the information relied upon by the appellant further complicates this case. Expert evidence is by definition neither notorious nor capable of immediate and accurate demonstration. This is why it must be proved through an expert whose qualifications are accepted by the court and who is available for cross-examination.

(R. v. Find 2001 SCC 32 at pages 886, para 48 – Emphasis Added)

- 16. The above criteria are often referred to as the "Morgan criteria" from the article written by Professor E.M. Morgan, "Judicial Notice" (1944) 57 Harv L. Rev 269. (O.M.S. v. E.J.S. 2023 SKCA 8 at paragraph 33).
- 17. The presence of "strong feelings, opinions and beliefs, is not so notorious as to be the subject of judicial notice. (**Find**, supra, at page 873, para 11
- 18. "...the permissible scope of judicial notice should vary according to the nature of the issue under consideration. For example, more stringent proof may be called for of facts that are close to the centre of the controversy between the parties (whether social, legislative or adjudicative) as distinguished from background facts at or near the periphery." (R. v. Spence 2005 SCC 71 at para 60; Kodheir v. Canada 2022 FC 44 at para 27);
- 19. The closer the fact approaches the dispositive issue, the more the court ought to insist on compliance with the stricter Morgan criteria. Thus, in *Find*, the Court's consideration of alleged juror bias arising out of the repellent nature of the offenses against the accused did not relate to the issue of guilt or innocence, and was not "adjudicative" fact in that sense, but nevertheless the Court insisted on compliance with the Morgan criteria because of the centrality of the issue, which was hotly disputed, to the disposition of the appeal. While some learned commentators seek to limit the Morgan criteria to adjudicative facts... I believe the Court's decision in *Find* takes a firmer line. I believe a review of our jurisprudence suggests that the Court will start with the Morgan criteria, whatever may be the type of "fact" that is sought to be judicially noticed. The Morgan criteria represent the gold standard and, if satisfied, the "fact" will be judicially noticed, and that is the end of the matter.

If the Morgan criteria are *not* satisfied, and the fact is "adjudicative" in nature, the fact will *not* be judicially recognized, and that too is the end of the matter. (**R. v. Spence 2005 SCC** 71 at paras 61-62)

20. In the context of a family law case, the Saskatchewan Court of Appeal recently put it this way:

Another principle is that the permissible scope of judicial notice varies "according to the nature of the issue under consideration"... If a particular fact is far removed from the centre of the controversy between the parties, a court ought to ask itself simply whether such a fact would be accepted as such "by reasonable people who have taken the trouble to inform themselves on the topic"..., keeping in mind, of course, that the court must always focus on the precise purpose for which the fact is being used in the case. The closer a particular fact is to the heart of the controversy, the more a court should insist that one of the two Morgan criteria be met before that fact can be properly noticed. If the matter "relates to

- adjudicative issues, the strict Morgan criteria of notorious or indisputable fact govern"....O.M.S. v. E.J.S. 2023 SKCA 8 at para 34.
- 21. Matters that are the proper subject of expert evidence are, by definition, "neither notorious nor capable of immediate and accurate demonstration". That said, recourse to a scientific treaties or textbook may be permissible to prove a fact that is not notorious, but which is capable of immediate and accurate demonstration, if the court can be certain that there will be no conflict between different sources of that kind.... However, the exception to the general rule that judicial notice cannot be taken of matters that require reference to an expert's guidance must be applied only where it is clear that this condition has been met; that is, only where there is well-established, and clearly applicable consensus.(O.M.S. v. E.J.S. 2023 SKCA 8 at paras 34 and 35)
- 22. The Federal Court in **Kodheir v. Canada 2022 FC 44** gave the following examples of facts that were appropriate to take judicial notice of:
 - (a) when driving on St. Catherine St. in Montréal, one will cross Bleury, Jeanne-Mance and St. Urbain Streets in that order. If one is unaware of this, the consultation of a map will readily provide the answer; (para 22)
 - (b) the war in Afghanistan (para 23);
 - (c) radar is used as an instrument of detection and measurement. Its use in air and marine navigation is as widespread as that of the compass (para 24)
 - (d) mobile phone technology requires the use of electromagnetic waves of various frequencies (para 25(
- 23. The Federal Court confirmed that Courts must be careful not to take judicial notice of matters on which science has not reached consensus or which are laden with value judgements, because the need for reliability and trustworthiness increases directly with the centrality of the 'fact' to the disposition of the controversy (**Khodeir**, supra, page 10, paras 26 and 27).
- 24. The Saskatchewan Court of Appeal most recently noted that although many courts in the past have taken judicial notice of the safety and efficacy of the covid 19 vaccines, the view was not unanimous. They also importantly held that in any event, precedent in matters involving judicial notice must be approached cautiously in a context where there is continuing development regarding what facts are notorious and which sources are indisputably accurate. This is nowhere more so the case than with the information surrounding the Covid 19 pandemic, where important aspects of what "everybody knows" today have come to be perceived, at least by some, as suspect or incorrect tomorrow."(O.M.S. v. E.J.S. 2023 SKCA 8 at paras 36 and 37).
- 25. The Saskatchewan Court of Appeal held that the chambers Judge committed an error when he said that he was able to take judicial notice that the Pfizer COVID-19 vaccination was safe and effective for use in people, including both adults and children. The Court of Appeal held that a proper application of the Morgan criteria did not allow for judicial notice

of this fact. The Court of Appeal noted that although the safety and efficacy of the vaccine was not the primary subject of the litigation, it bore heavily on the central matter in dispute, which was whether it was in the best interests of the child to be vaccinated with the vaccine. The Court held that this was an issue in relation to which expert evidence was required, which was amply demonstrated by the fact that the parties presented conflicting expert evidence on the issues which was acknowledged by the Chambers Judge. (O.M.S. v. E.J.S. 2023 SKCA 8 at para 38).

- 26. The Saskatchewan Court of Appeal also addressed the chambers Judge's decision to take judicial notice of the fact that the Pfizer vaccine had been approved by the appropriate government authorities because this fact was in evidence and was uncontested. (O.M.S. v. E.J.S. 2023 SKCA 8 at paras 39 and 40). Similarly, Dr. Hoffe does not contest the facts that Health Canada has approved Covid vaccines and that the Covid vaccines do not prevent infection, reinfection or transmission, and therefore it is unnecessary for the panel to take judicial notice of those facts.
- 27. The Saskatchewan Court of Appeal identified another issue which was whether the Chambers Judge erred in taking judicial notice that because the Pfizer vaccine was government approved, he could take judicial notice that the vaccine was safe and effective. This is precisely what the Colleges asking the panel to do in this case (Application, page 9/80 paragraph 6).
- 28. The Saskatchewan Court of Appeal points out that the regulatory assessment performed by Health Canada of any vaccine, like any other drug, includes the information that accompanies its distribution-most importantly, its product monograph. Part of this is the consumer medication information that must accompany the product when it is distributed relating to such matters as indications and contraindications, side effects or potential side effects and warnings. (O.M.S. v. E.J.S. 2023 SKCA 8 at para 43).
- 29. O.M.S. v. E.J.S. 2023 SKCA 8 has been recently cited with approval in R.v. Zatrepalek 2024 SKCA 27 at 47 and in R. v. Mosquito 2023 SKCA 29 at para 88.
- 30. The only Court in all of the authorities relied upon by the College that appears to have been aware of the unique approval process used by Health Canada for the Covid 19 vaccines, is the Saskatchewan Court of Appeal in O.M.S. v. E.J.S.. In none of the other cases presented by the College, or that we were able to find, was any court presented with the information concerning this unique and very different approval process used for the Covid 19 vaccines, compared to the normal regulatory approval for vaccines and drugs. The importance of this point cannot be overstated.
- 31. The Saskatchewan Court of Appeal in O.M.S., supra, references at paragraph 44 the unique interim order that was authorized by the Minister which set a much lower standard for approval of the COVID-19 vaccines than is normally required. It is not clear if the Court of Appeal fully understood the difference between the requirements of the assessment and analysis required to be undertaken by Health Canada in the normal drug approval process, as compared to the much lower requirements for the assessment and analysis actually undertaken by Health Canada of the Covid 19 vaccines.

32. The Saskatchewan Court of Appeal concludes regardless at para 45:

However, the fact that Health Canada approval of a new drug can only occur if its safety, efficacy and quality have been assessed does not mean that approval constitutes, in and of itself, evidence that would enable a judge to take judicial notice that it is safe and effective. Quite apart from the fact that such a broad and categorical statement has little meaning or utility in a case such as this, regulatory approval means only that Health Canada has determined, based on a risk-benefit analysis, that a drug is sufficiently safe, effective and of sufficient quality to be approved, if it is used in accordance with the approval, including the product monograph, together with any medical advice and monitoring that may be required. While this would always be the case, the limited meaning to be attributed to Health Canada approval in a case of this kind is particularly clear because of the approval that was granted for the Pfizer vaccine. We also note the existence of easy-to-find case law reports of instances where drug companies have been found to have brought on the market products that have passed a regulatory process and have been found to be associated with risks that are later determined to have been misdescribed or missed altogether in the product information that accompanies the distribution of the product.

For these reasons, we find it impossible to say that a conclusion that the Pfizer vaccine is safe because it is government approved is so "notorious are generally accepted is not to be the subject of debate among reasonable persons" or so "capable of immediate and accurate demonstration by resort to readily accessible sources of indisputable accuracy".... In the result, we respectfully conclude that the Chambers Judge erred by taking judicial notice that the Pfizer vaccine was safe and effective on this basis.

(O.M.S. v. E.J.S. 2023 SKCA 8 at paras 39 and 40

- 33. The disciplinary panel in the case of the College of Physicians and Surgeons v. Dr. Trozzi, was also unaware of the significant difference in the criteria required to approve the Covid 19 vaccines as being safe and effective when they decided to rely on Health Canada regulatory approval of the Covid 19 vaccines as evidence of their safety and effectiveness sing party to present qualified expert opinion evidence on the matters in issue. (College of Physicians and Surgeons of Ontario v. Trozzi 2023 ONPSDT 22(at paragraph 90).
- 34. Shawn Buckley, a senior lawyer formerly in British Columbia and more recently now in Alberta, has decades of experience in the area of drug approvals by Health Canada under the Canadian Food and Drugs Act, explains the important difference in the approval criteria for Covid 19 products and the normal approval criteria for drugs in Canada in his Affidavit #1. Mr. Buckley deposes that Health Canada's normal drug approval process for vaccines or any other drug have a minimum of 3 requirements:
 - (a) safety must be proven;
 - (b) efficacy must be proven; and

- (c) it must be clear the benefits of the drug outweigh the risks of a drug intended for use in the general population. (Affidavit #1 Shawn Buckley, paragraph 5)
- 35. Mr. Buckley makes it clear that the normal requirements include high requirements to be met for provable safety and efficacy of the vaccine or drug. If the safety and efficacy profiles of a new drug are not known/established, then there is no approval under the regular new drug approval process. It is only when the safety and efficacy of the new drug is understood that the regulator can then move on to determine whether the benefits of the drug outweigh the risks. (Affidavit #1 Buckley Paragraphs 6-10)
- 36. Mr. Buckley makes it clear that the normal regulatory process was not required, and was not followed, in the approval of the COVID-19 vaccines. Instead, the Minister made an interim order to override the normal regulations requiring detailed safety evidence and substantial evidence of efficacy. The relaxed regulations for the COVID-19 vaccines do not require the Minister to conclude that the benefits of the COVID-19 vaccines outweigh the risks but rather only that he has sufficient evidence to support the conclusion having regard to the uncertainties related to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19. Mr. Buckley points out that without the establishment of the vaccine's safety profile and efficacy profile it is impossible to conclude whether the benefits outweigh the risk. In fact, the Interim Order anticipates that the Minister will have uncertainties. (Affidavit #1 Buckley Paragraphs 12-41)
- 37. Mr. Buckley also deposes that Celia Lourenco of Health Canada, swore an affidavit for the Federal Court in which she outlined the test she used to approve 2 of the Covid 19 vaccines. She confirms Mr. Buckley's statement that safety and efficacy did not need to be proven but only that there was information to support the conclusion that the benefits associated with the Pfizer and Moderna vaccines outweighed the risks, having regard to a shorter term (median of 2 months) follow-up of safety and efficacy at authorization, and the necessity of addressing the urgent public health need related to COVID-19. (Affidavit #1 Shawn Buckley, page 9 paragraphs 42 and 43).
- 38. This evidence makes it clear that Notice Fact 6 (page 9 the Application) that claims the fact that Health Canada approved the vaccines, means that regulatory approval is a strong indicator of safety and effectiveness, is not accurate when it comes to the COVID-19 vaccines because Health Canada used an entirely different set of criteria to approve the COVID-19 vaccines. This difference was not commented upon by any of the courts in the decisions relied upon by the College other than the Saskatchewan Court of Appeal in O.M.S., supra. Even though the Saskatchewan Court of Appeal was aware of the criteria used, it is not clear that they were fully aware of the significant difference between the criteria used to approve the COVID-19 and the normal regulatory approval process. Mr. Buckley explains this difference in detail in his affidavit.
- 39. The Saskatchewan Court of Appeal held: "None of this is to say, of course, that, even in a family law context, the fact of regulatory approval is utterly conclusive as to the question of safety or efficacy, even within the narrow confines of an analysis of a child's best interests. Just as a parent who is called upon to make the decision about the use of a

pharmaceutical product can evaluate information outside of the approved product monograph, it must be open to a parent to lead to admissible evidence to demonstrate that a drug is not safe and effective, whether generally or for the child at issue and that, as a result, neither the parents nor the court can proceed in the usual way based wholly on Health Canada approval and medical advice given on the basis of that approval. Where this occurs, the court must consider all relevant evidence. O.M.S. v. E.J.S. 2023 SKCA 8 at paras 51 and 52.

- 40. The Saskatchewan Court of Appeal also went on to find that the Chambers Judge erred in concluding based upon the expert reports provided by the father, that the Pfizer vaccine was safe and effective because that statement was too sweeping and went beyond the scope of the opinions offered by the 2 experts who offered expert testimony on behalf of the father. The Court found that the expert opinion presented on behalf of the father made it clear that the science and evidence that relate to the Covid 19 pandemic, the virus and the vaccines have evolved and continue to evolve rapidly as does the virus itself. The Court noted that neither of the experts that testified on behalf of the father offered an opinion that the Pfizer vaccine was safe and effective. The Court held that was not surprising as the statement is inconsistent with the reality that safety and efficacy are not absolute concepts. To the contrary, pharmaceutical products carry potential risks of side effects, which must be weighed, in individual cases, hence the potential benefits of the drug. The safety and efficacy of a pharmaceutical is defined with reference to what is identified in its product monograph. As a rule, the safety and efficacy of a pharmaceutical product cannot be discussed in such blunt fashion as to say that it is or is not safe and effective O.M.S. v. E.J.S. 2023 SKCA 8 at paras 58 and 59.
- 41. The Saskatchewan Court of Appeal went on to say that because safety and efficacy are relative concepts, there will generally be more room for expert evidence to assist the court in understanding the implications that flow from the fact that the product has been approved in light of the circumstances of the case, than to challenge the general safety and efficacy of the product itself. O.M.S. v. E.J.S. 2023 SKCA 8 at paras 61.
- 42. Because the mother failed to provide sufficiently compelling evidence to the contrary, the court was entitled to base a decision as to the physical risks and benefits of vaccination on the fact that a vaccine had been approved by Health Canada to be administered in accordance with that approval, together with related medical advice bearing on the question. In this case, there was no evidence of value to the contrary. O.M.S. v. E.J.S. 2023 SKCA 8 at paras 62.
- 43. In another family law case, <u>B.C.J.B. v. E.-R.R.R. 2022 ONCJ 500</u> the father asked the Court to take judicial notice of the facts contained within a number of public health documents from the Government of Ontario, the Government of Canada and the City of Toronto establishing that vaccines are safe and effective. The lower court judge had taken judicial notice of legislative policy regarding pre-Covid immunization reflected in Ontario's Immunization 2020 document, and the Canadian Immunization Guide. The lower court was careful to note that none of the facts contained within these documents disposed of the issue as the court still needed to determine if vaccination was in the specific child's best interests which required additional evidence (para 212). The Court did take

judicial notice that non-Covid vaccines are safe and effective at preventing vaccine preventable diseases but declined to take judicial notice of the safety and efficacy of the Covid vaccine. Instead, the Court relied upon expert evidence presented by both parties to the Court to render its decision.

- 44. The Court in B.C.J.B., supra, beginning at paragraph 214, cites **Inglis v. Inglis 2022 SKCA 82**. a decision of the Saskatchewan Court of Appeal as providing an excellent summary of the wealth of jurisprudence regarding the various findings that courts have made across Canada about the application of judicial notice to the COVID-19 vaccines for children in family law cases. One of the cases referenced by the Saskatchewan Court of Appeal took judicial notice of the risks of the COVID-19 vaccine but also concluded that the COVID-19 vaccines were safe and effective at preventing COVID-19 (something which now, the College admits by their request to take judicial notice of the fact, and that the BC Supreme Court has taken judicial notice of (along with other Courts across the country), that the COVID-19 vaccines do not prevent infection, reinfection or transmission.
- 45. In <u>A.T. v. C.H. 2022 BCPC 121</u> at para 39 point 6), the BC Provincial Court confirms that the fact that other Courts may have taken judicial notice of facts pertaining to the safety and efficacy of the COVID-19 vaccines, and the risks of COVID-19 itself, does not change the fact that these principles may be rebutted by way of compelling evidence to the contrary. Other Courts have also confirmed this principle (K.D.B. v. K.B. 2022 NBQB 074 at para 56; <u>A.C. v. L.L., 2021 ONSC 6530 at para 28</u> and in <u>A.C. v. L.L., 2021 ONSC 6530 at para 28</u>).
- 46. In <u>J.N. v. C.G. 2022 ONSC 1198</u> at para 68 the Court noted in the context of a family law case over a dispute about whether or not the children should be vaccinated for Covid 19:
 - [68] As well, how can you take judicial notice of a moving target?
 - a. During the past 2 years of the pandemic, governments around the world-and within Canada-have constantly changed their health directives about what we should or should not be doing. What works and what doesn't.
 - b. And the changes and uncertainty are accelerating with each passing newscast. Not a day goes by that we do not hear about Covid policies changing and restrictions being lifted.
 - c. Government experts sound so sure of themselves in recommending the current vaccines.
 - d. But they were equally sure when they told us to line up for AstraZeneca. Now they do not even mention that word.
 - e. Even Pfizer has changed its mind. It recently approved vaccines for kids under 5. Then more recently the company changed its mind.
 - f. None of this is meant a criticism. Everyone is doing their best with the new and constantly evolving health crisis.

- g. But how can judges take judicial notice of "facts" where there is no consensus or consistency?
- 47. The Court concluded that the articles from the Internet presented by the mother satisfied the court that a legitimate and highly complex debate exists on the efficacy and utilization of covid vaccines and declined to apply judicial notice as a method of resolving the issue.
- On appeal, the Court of Appeal, noted that the father's chief complaint on appeal was that 48. the motion judge did not properly scrutinize the respondent's evidence and did not consider whether any of it satisfied the threshold criteria governing the admission of expert evidence-including whether the experts were qualified, independent and unbiased. The Court of Appeal concluded that few of the materials presented by the respondent even met the criteria set out in the Internet reliability cases cited by the motion judge as he did not carefully assess its sources or the objectivity of the person placing the information online. The Court of Appeal held that the motions judge failed to assess whether the documents presented were reliable, independent, unbiased and authorized by someone with expertise in the area. The Court of Appeal held that it did not need to decide whether judicial notice should be taken of the public health and government information as the motion judge fell into error in other respects. The Court of Appeal also criticized the motions judge for not considering representations made by the Canadian Pediatric Society which the court held clearly met the criteria necessary to accept Internet information. The Court held that this was a well-known organization, whose objectivity and sources can be readily and easily assessed and the information contained in its documents are capable of verification. Although it was not a government agency, the court should have been comforted knowing that it is opinion was not formulated by a government official, or reliant only on government procured information. The Court of Appeal held that in light of the Court's scepticism of government sources, it was essential that he addressed this issue. (J.N. v. C.G. 2023 ONCA 77 at paras 12, 13,17, 21 and 30).
- 49. The Court of Appeal in J.N. did not take criticize the lower court motions judge for his comments in paragraph 68 referred to above.
- 50. Although the Ontario Court of Appeal mentioned the Saskatchewan Court of Appeal decision in O.M.S., it did so by only referring to one paragraph of that decision. It emphasized that in a family dispute, in most cases, once a drug has been approved, is not necessary for a party to prove, or a court to decide, if an approved drug is safe or efficacious. But rather, in most cases at least, additional evidence is unhelpful because, absent sufficient evidence to the contrary, parents and courts are entitled to decide that a child should be treated with approved medications in accordance with the approval, subject, of course, to any child-specific medical concerns that may be in play, or other relevant factors.(J.N. v. C.G. 2023 ONCA 77 at para 43; leave to appeal dismissed).. [Emphasis added].
- 51. The Ontario Court of Appeal in J.N. did hold, at paragraph 45, contrary to the Saskatchewan Court of Appeal, without mentioning the finding of the Saskatchewan Court of Appeal on the issue, that judicial notice should be taken of regulatory approval of the Covid 19 vaccines and that regulatory approval is a strong indicator of safety and

effectiveness. The Court of appeal in J.N. confirmed that the onus is on the objecting party to show why the child should not receive a Health Canada approved medication, in other words to show why judicial notice should not be taken in this respect. While the Court of Appeal in J.N. recognized the right of an objecting party to be able to present contrary evidence, it is critically important to recognize that the Ontario Court of Appeal in J.N. did not mention that it was aware of the difference in the criteria for regulatory approval by Health Canada of the Covid 19 vaccines compared to normal regulatory approval by Health Canada for all other drugs as explained by Shawn Buckley in his Affidavit #1, and as relied upon by the Saskatchewan Court of Appeal in O.M.S. when they declined to take judicial notice that regulatory approval by Health Canada is a strong indicator of safety and effectiveness. The approach taken by the Saskatchewan Court of Appeal in O.M.S. has been cited with approval by two subsequent Saskatchewan Court of Appeal decisions in 2023 and 2024 as mentioned above.

52. The Ontario Supreme Court, in a family law case, recently recognized that an examination of public health records discloses that the "messaging" of public health has changed over the 3 years that COVID-19 has been with us. Examples given by the Court are as follows:

The consistent messaging virtually from the outset of the Covid 19 outbreak was that vaccines were a panacea and they were essentially the answer to all of the problems related to this disease. What has changed, is that prior to the vaccines being approved and "rolled out" for public use, the "refrain messaging" from public health was that the vaccines would prevent one from contracting Covid 19. ... As referenced in other cases and in public health records, shortly after the Covid 19 vaccines had been approved and rolled out by various governments and people began taking the first dose of vaccine, it became evident that the claim that the vaccine would prevent individuals from getting Covid 19 was not correct. People who had been vaccinated were routinely getting Covid 19 despite the vaccination, contrary to what had been represented by public health would be the case before the vaccine rollout. The public health and government messaging then changed again to claim that while you could get Covid 19 if you were vaccinated, you are at less risk of transmitting Covid 19 to others if you were vaccinated. As time went on, and even after people were encouraged, and in some cases mandated as a requirement of their employment, or to go to a restaurant, or travel, to get a second dose of the vaccine, it became evident that this representation by public health, that being that vaccinated people were less likely to transmit Covid 19, was also false. All of these various iterations for public health authorities can be assessed by checking archival records of public health pronouncements at the time over the last 3 years. The problem for this court and being asked to take judicial notice that the vaccines are "effective" is what the court is being asked to take judicial notice of, is in fact a moving target. What public health authorities say today, is totally different to what public health authorities were saying some months or a year ago... Initially, public health was recommending a single dose of a vaccine. Public health then began to recommend a second dose of the vaccine. Public health recommendations have now further evolved such that booster shots are being recommended every three to six months. For many individuals, public health has now recommended up to 5 doses of the vaccine. Once again, all of this is the subject

of public record. (J.W.T. v. S.E.T. 2023 ONSC 977 at paras 411-422 and 435 to 436).

- The Court in J.W.T., held that the case was distinguishable from the decision in J.N., supra, 53. in that it did not utilize any of the Internet articles relied upon by the mother in J.N. as expert evidence, that the Ontario Court of Appeal determined was not proper evidence. The Court in J.W.T. found that the evidence that was proffered by the dissenting father in this case was sufficient to cause the court to find that it should not take judicial notice of the proclamations of public health authorities that the vaccines are "safe and effective". The Court noted that the court was not deciding that the public health documents are not trustworthy, but only that the objecting party be given an opportunity to call expert evidence to challenge those claims. The court also held that no one can say with certainty what the long-term effects are of these vaccines given that these vaccines have not been administered to any child for a sufficient length of time in order to have empirical evidence on which to base that finding. This court is noted the public health proclamations have been a moving target over the last 3 years and that public health records will show that they continue to be a moving target. Public health proclamations have changed over the last 3 years, and if history is a predictor of the future, they will continue to change over the next months and years. The court addressing at trial this issue will be faced with the public health proclamations that exist at the time of trial which may be different to those that exist today. This Court has made reference to the fact that in taking judicial notice, any court cannot be oblivious to what has transpired in the world and what has been broadly reported in the media. (J.W.T. v. S.E.T. 2023 ONSC 977, paras 615-620, 633-635, 644-648, 653-659).
- 54. The British Columbia Court of Appeal recently held:

[102] It is clear from these cases that judicial notice is not extraordinary, and that it can play an accepted an important role in the litigation process. However, judicial notice operates in the context of an adversarial system. Of critical importance to that system is the long-settled "principle that the opposing party must have the opportunity to challenge all facts that are not self-evidently beyond dispute..." R. v. R.M. 2023 BCCA 455 at para 102.

Conclusion

55. In Dr. Hoffe's case, the Notice Facts are at the centre of the controversy between the parties, and there clearly is not a consensus. Dr. Hoffe has tendered 8 expert reports from qualified experts who directly contest the Notice Facts. The College submits that if they are unsuccessful in their application for judicial notice, they will be relying upon on 2-3 witnesses, 1 expert and "about 6 rebuttal" experts. In addition to presenting qualified expert evidence, Dr. Hoffe has presented in his affidavit evidence from the very Government and Public Health sources that the College relies upon as being indisputably accurate, which demonstrate that these sources have regularly changed what they say the facts are, and often contradict each other and themselves with their public statements as to what they believe the facts are. These are not facts that judicial notice should be taken of.

- 56. There is much robust and passionate debate about the Notice Facts between public health officials, politicians, scientists, researchers, and experts in the applicable disciplines. It is wholly inappropriate to take judicial notice of alleged facts in the circumstances because judicial notice not only dispenses with the proof of a fact, it also forecloses any attempt to present facts to prove the contrary. The College acknowledges this (page 104, paragraph 7 of the Application). After the College has been in possession of Dr. Hoffe's 8 expert reports since January 2024, that contain evidence that directly challenges the veracity of the Notice Facts, they elected to bring an application for judicial notice to prevent those same experts from tendering their expert evidence. To allow this, would constitute a breach of procedural fairness and natural justice, and prevent Dr. Hoffe from making full answer and defence to the College's charges against him.
- 57. Counsel for the College admitted to the panel in the last prehearing conference that their expert witness Dr. Trevor Corneil addresses the Notice Facts in his report. Dr. Hoffe is in possession of this report and can confirm this is true. There is no need, and certainly no justification, for taking judicial notice of these facts if Dr. Corneil offers expert opinion about them in his report.
- 58. In these circumstances, the case authorities make it clear that the College must present in the disciplinary hearing stringent proof of the facts alleged in order justify the charges against Dr. Hoffe in the Citation.
- 59. Dr. Hoffe is entitled to a higher standard of procedural fairness, and a higher standard of justice, and the context of these disciplinary proceedings that have the potential for serious consequences his ability to practice in his profession. He is entitled to provide full answer and defence by tendering witnesses and evidence, including expert evidence, to directly challenge the facts that the College alleges support the charges in the citation. The College should have to prove their case, not have the panel predetermine the case by granting judicial notice of the key elements of the citation.
- 60. Accordingly, Dr. Hoffe respectfully submits that the College's application for judicial notice should be dismissed.

Part 3: MATERIAL TO BE RELIED ON

- 1. Affidavit #1 Dr. Charles Hoffe sworn March 20, 2024
- 2. Affidavit #1 of Shawn Buckley sworn March 18, 2024.
- 3. Report of Dr. Clair Craig dated January 24, 2024.
- 4. Report of Dr. Eric Payne dated January 10, 2024
- 5. Report of Dr. James Thorp dated January 26, 2024
- 6. Report of Dr. Jessica Rose dated January 3, 2024
- 7. Report of Dr. Peter McCullough dated January 26, 2024

- 8. Report of Dr. Pierre Kory dated January 10, 2024
- 9. Report of Dr. Steven Pelech dated January 25, 2024
- 10. Report of Kevin McKernan dated December 21, 2023
- 11. Letter of particulars from Lisa Fong dated January 28, 2022 Appendix 1
- 12. Q-2265 HC Inquiry of Ministry February 5, 2024 Appendix 2

This application has been set by the disciplinary panel for one day on April 19, 2024.

Date: March 22, 2024

Signature of **Lee C. Turner**, lawyer for Respondent, Dr. Charles Hoffe

THIS RESPONSE is Lee C. Turner, of the firm of Doak Shirreff Lawyers LLP, whose place of business and address for service is 200-537 Leon Avenue, British Columbia, V1Y 2A9, Telephone 250.763.4323.