Rules 53.03 Courts of Justice Act

Court File no. CV-22-00679996-0000

ONTARIO SUPERIOR COURT OF JUSTICE

BETWEEN:

WANH PORTER

Plaintiff

-and-

NORTH YORK GENERAL HOSPITAL

Defendant

EXPERT OPINION REPORT OF DR.

- 1. My name is Dr. . My address is
- I am an Immunotoxicologist and hold a Ph.D. in Biology from the University of Waterloo.
 I am currently an Adjunct Professor at and tenured Professor with the Department of , where I supervised dozens of graduate students.
- 3. I am an active researcher in the field of Immunology, having participated in 12 peerreviewed scientific publications in 2021 and having contributed to 18 scientific articles so far in 2022 that have been submitted for peer-review, accepted but not yet published, or published following peer-review.
- 4. I am a member of four societies, such as the International Society for Developmental Origins of Health and Disease. I received various research grants in the last two years to conduct scientific research, such as a \$210,000 grant from the Natural Sciences and Engineering Research Council of Canada.
- 5. My qualifications are set out in the attached *Curriculum Vitae* marked Schedule A.

- 6. I was instructed by counsel for the Plaintiff to herein provide my expert testimony regarding SARS-CoV-2, COVID-19, how SARS-CoV-2 is transmitted, the mortality of COVID-19, the nature of the COVID vaccines available from Fall of 2021 onward and whether they are experimental, and the efficacy of the COVID vaccines available from Fall 2021 onward. Counsel also instructed me to provide my opinion regarding the issue of workforce COVID-19 vaccination mandates.
- 7. The opinion sought of me is my opinion regarding mandatory workforce COVID-19 vaccination, which is the central issue raised by the Plaintiff in her Claim. Respecting this issue, my opinion is that mandatory workforce COVID-19 vaccination lacked and continues to lack scientific rationale, and produced and continues to produce no clinical benefit.
- In forming my opinion, I assumed the facts as detailed in the Plaintiff's claim, specifically, that the Defendant implemented a mandatory workforce COVID-19 vaccination policy in Fall 2021.
- 9. In preparing this report, I relied on research I had previously done regarding the topics I address in my report and on my research of the sources cited in my report.
- 10. Attached as **Schedule B** is a list of the sources I relied on to prepare this report and which are cited in the footnotes.

I. Severe Acute Respiratory Syndrome - Corona Virus 2

- 11. <u>COronaVIrus Disease 2019</u> (COVID-19) is a symptomatic respiratory illness cause by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- 12. In late 2019, SARS-CoV-2 was first detected and is established as the cause of the disease now designated coronavirus disease 2019 (COVID-19). Approximately 30-40% of persons with SARS-CoV-2 infection are asymptomatic.¹ In those who are symptomatic, there is a

¹ Sah P, Fitzpatrick MC, Zimmer CF, Abdollahi E, Juden-Kelly L, Moghadas SM, Singer BH, Galvani AP. Asymptomatic SARS-CoV-2 infection: A systematic review and meta-analysis. Proc Natl Acad Sci U S A. 2021 Aug 24;118(34):e2109229118. doi: 10.1073/pnas.2109229118.

wide range of illness from those with mild symptoms, such as runny nose, to those with severe disease particularly affecting the respiratory tract, which can result in death, mainly in the elderly with co-morbidities.² Most people with SARS-CoV-2 infection are asymptomatic, or have mild-moderate symptoms not requiring hospitalization. In one study of a relatively healthy population, those with COVID-19 requiring hospital care was < 2%, and the mortality rate was < 0.1%.³

- 13. SARS-CoV-2 is a ribonucleic acid (RNA)-containing virus that has a single positive stranded genome that is around 29,903 nucleotides long. Its genome encodes the information for construction of at least 28 different viral proteins that compose the viral particle. Each protein has an amino acid composition that is dictated by the organization of nucleotide sequences within the SARS-CoV-2 viral genome. The virus is in the coronavirus family, which are all characterized by their crown-like appearance that arise from the arrangement of large spike proteins on their surfaces.
- 14. The spike protein, which is initially constructed as a 1273 amino acid long precursor protein, is clipped into S1 and S2 subunits that remain associated. The S1 subunit harbors a region called the receptor binding domain by which the virus is able to attach to receptors on host cells, including but not limited to, the angiotensin converting enzyme II (ACE-2) protein, to gain access into these cells, where it can replicate. Apart from copies of the membrane and envelope proteins that are also exposed on the surface of the virus, all of the other viral proteins remain buried within the interior of the virus particle.
- 15. In view of the virus surface accessibility and large size of the spike protein, it has been specifically targeted for the production of vaccines that can evoke the adaptive immune system in people to produce two main classes of lymphocytes, *i.e.*, T-cells and B-cells.

Ma Q, Liu J, Liu Q, Kang L, Liu R, Jing W, Wu Y, Liu M. Global Percentage of Asymptomatic SARS-CoV-2 Infections Among the Tested Population and Individuals With Confirmed COVID-19 Diagnosis: A Systematic Review and Metaanalysis. JAMA Netw Open. 2021 Dec 1;4(12):e2137257. doi:10.1001/jamanetworkopen.2021.37257.

² Berlin DA, Gulick RM, Martinez FJ. Severe Covid-19. N Engl J Med. 2020 Dec 17;383(25):2451-2460.

³ Kasper MR, Geibe JR, Sears CL, Riegodedios AJ, Luse T, Von Thun AM, McGinnis MB, Olson N, Houskamp D, Fenequito R, Burgess TH, Armstrong AW, DeLong G, Hawkins RJ, Gillingham BL. An Outbreak of Covid-19 on an Aircraft Carrier. N Engl J Med. 2020 Dec 17;383(25):2417-2426.

16. Some T-cells (*i.e.* cytotoxic T cells) feature antigen-specific receptors (TCRs) that can allow for these lymphocytes to specifically seek out and kill pathogen-infected host cells expressing viral proteins such as the spike protein; the TCR recognizes a tiny and specific part of the viral protein known as an epitope. Most T-cell epitopes are typically linear portions of only 8-25 amino acids long within the structure of a protein, but can also encompass other molecular structures such as found in complex sugars and lipids. T-helper cells are also required to provide help to both cytotoxic T cells and B cells via secretion of cytokines. B-cells express antigen-specific receptors that recognize 3-dimensional epitopes on the foreign agent, and after they become activated by viral proteins, they differentiate into antibody secreting plasma cells. The secreted antibodies bind to a wide range of specific protein epitopes on the surfaces of pathogens, such as SARS-CoV-2, to block viral attachment to host cells, agglutinate the pathogen, or enhance uptake by various phagocytic cells, as well as to effectively serve as beacons for attraction of innate immune cells, such as macrophages, neutrophils and dendritic cells, to directly attack the pathogen along with T-cells.

II. COVID-19: Mortality and Transmission

17. Age is the most important risk factor for COVID-19 mortality. Compared to persons under age 40, persons over the age of 80 have a greater than 300 times chance of dying from COVID-19.⁴ The infection fatality ratio (IFR) in persons over 80 is approximately 1000 times the IFR in those under 20.⁵ In Canada, 61% of COVID-19-related deaths have been

⁴ Williamson EJ, Walker AJ, Bhaskaran K, Bacon S, Bates C, Morton CE, Curtis HJ, Mehrkar A, Evans D, Inglesby P, Cockburn J, McDonald HI, MacKenna B, Tomlinson L, Douglas IJ, Rentsch CT, Mathur R, Wong AYS, Grieve R, Harrison D, Forbes H, Schultze A, Croker R, Parry J, Hester F, Harper S, Perera R, Evans SJW, Smeeth L, Goldacre B. Factors associated with COVID-19-related death using OpenSAFELY. Nature. 2020 Aug;584(7821):430-436.

⁵ Verity R, Okell LC, Dorigatti I, Winskill P, Whittaker C, Imai N, Cuomo-Dannenburg G, Thompson H, Walker PGT, Fu H, Dighe A, Griffin JT, Baguelin M, Bhatia S, Boonyasiri A, Cori A, Cucunubá Z, FitzJohn R, Gaythorpe K, Green W, Hamlet A, Hinsley W, Laydon D, Nedjati-Gilani G, Riley S, van Elsland S, Volz E, Wang H, Wang Y, Xi X, Donnelly CA, Ghani AC, Ferguson NM. Estimates of the severity of coronavirus disease 2019: a model-based analysis. Lancet Infect Dis. 2020 Jun;20(6):669-677.

persons over 80, 82% of deaths have been persons over 70, and 93% of deaths have been persons over $60.^{6}$

- 18. The risk of death due to COVID-19 in persons under age 50 remains small.⁷ In Canada, the risk of death due to COVID-19 in persons < 50 is less than the risk of death due to a motor vehicle fatality.⁸ Globally, excess mortality related to COVID-19 is concentrated in persons over age 60, and particularly in persons over age 75; excess mortality related to COVID-19 was generally not seen in age groups less than age 60.⁹ The attributable mortality due to COVID-19 is similar to influenza in persons aged less than 60.¹⁰ Comorbidities (*i.e.*, diabetes, cardiovascular disease and obesity) are also critical risk factors for COVID-19 disease severity, and these are more common in the elderly.
- 19. Several peer-reviewed systematic reviews and meta-analyses estimate that asymptomatic transmission is 3-25 times lower than symptomatic transmission.¹¹ A very large study in

⁹ Islam N, Shkolnikov VM, Acosta RJ, Klimkin I, Kawachi I, Irizarry RA, Alicandro G, Khunti K, Yates T, Jdanov DA, White M, Lewington S, Lacey B. Excess deaths associated with covid-19 pandemic in 2020: age and sex disaggregated time series analysis in 29 high income countries. BMJ. 2021 May 19;373:n1137. doi: 10.1136/bmj.n1137.

¹⁰ Taniguchi Y, Kuno T, Komiyama J, Adomi M, Suzuki T, Abe T, Ishimaru M, Miyawaki A, Saito M, Ohbe H, Miyamoto Y, Imai S, Kamio T, Tamiya N, Iwagami M. Comparison of patient characteristics and in-hospital mortality between patients with COVID-19 in 2020 and those with influenza in 2017-2020: a multicenter, retrospective cohort study in Japan. Lancet Reg Health West Pac. 2022 Mar;20:100365. doi: 10.1016/j.lanwpc.2021.100365. Staub K, Panczak R, Matthes KL, Floris J, Berlin C, Junker C, Weitkunat R, Mamelund SE, Zwahlen M, Riou J. Historically High Excess Mortality During the COVID-19 Pandemic in Switzerland, Sweden, and Spain. Ann Intern Med. 2022 Feb 1:M21-3824. doi: 10.7326/M21-3824.

⁶ Coronavirus disease 2019 (COVID-19): Epidemiology update, <u>https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html</u> (accessed March 25, 2022)

⁷ Ioannidis JPA, Axfors C, Contopoulos-Ioannidis DG. Population-level COVID-19 mortality risk for non-elderly individuals overall and for non-elderly individuals without underlying diseases in pandemic epicenters. Environ Res. 2020 Sep;188:109890.

⁸ Coronavirus disease 2019 (COVID-19): Epidemiology update, <u>https://health-infobase.canada.ca/covid-</u> <u>19/epidemiological-summary-covid-19-cases.html</u>; <u>https://tc.canada.ca/en/road-transportation/motor-vehicle-</u> <u>safety/canadian-motor-vehicle-traffic-collision-statistics-2018</u>

¹¹ Buitrago-Garcia D, Egli-Gany D, Counotte MJ, Hossmann S, Imeri H, Ipekci AM, Salanti G, Low N. Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: A living systematic review and meta-analysis. PLoS Med. 2020 Sep 22;17(9):e1003346.

Wuhan China of 9,899,828 city residents found 300 asymptomatic cases, but there were no positive tests amongst 1,174 close contacts of asymptomatic cases.¹² Similarly, a very thorough study of 100 cases from Taiwan, found that "none of the 9 asymptomatic case patients transmitted a secondary case."¹³ These studies were done before the Omicron variant became dominant in late December 2021. Omicron and subsequent variants are more transmissible than the already highly transmissible variants of 2020 and 2021, such as Delta. Asymptomatic transmission remains comparatively rare, but all forms of transmissible and less virulent than the previous. None of the vaccines to date prevent transmission, since viral loads are similar between the vaccinated and unvaccinated.¹⁴

20. Household contact is one of the most important modes of transmission. In a meta-analysis of household transmission, which included 54 studies and 77 758 participants,¹⁵ transmission from asymptomatic cases was 0.7% compared to 18% transmission from symptomatic cases. In other words, symptomatic transmission was roughly 25 times higher than asymptomatic transmission. A study from Greece reported the odds of symptomatic

Qiu X, Nergiz AI, Maraolo AE, Bogoch II, Low N, Cevik M. Defining the role of asymptomatic and pre-symptomatic SARS-CoV-2 transmission - a living systematic review. Clin Microbiol Infect. 2021 Jan 20:S1198-743X(21)00038-0.

¹² Cao S, Gan Y, Wang C, Bachmann M, Wei S, Gong J, Huang Y, Wang T, Li L, Lu K, Jiang H, Gong Y, Xu H, Shen X, Tian Q, Lv C, Song F, Yin X, Lu Z. Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. Nat Commun. 2020 Nov 20;11(1):5917.

¹³ Cheng HY, Jian SW, Liu DP, Ng TC, Huang WT, Lin HH; Taiwan COVID-19 Outbreak Investigation Team. Contact Tracing Assessment of COVID-19 Transmission Dynamics in Taiwan and Risk at Different Exposure Periods Before and After Symptom Onset. JAMA Intern Med. 2020 Sep 1;180(9):1156-1163.

¹⁴ Riemersma KK, Grogan BE, Kita-Yarbro A *et al.* (2021 July 31) Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant. *medRxiv*. Published online. doi:10.1101/2021.07.31.21261387.

Byambasuren O, Cardona M, Bell K, Clark J, McLaws M-L, Glasziou P. Estimating the extent of asymptomatic COVID-19 and its potential for community transmission: Systematic review and meta-analysis. JAMMI. 5.4, 2020. 223-234.

Koh WC, Naing L, Chaw L, Rosledzana MA, Alikhan MF, Jamaludin SA, Amin F, Omar A, Shazli A, Griffith M, Pastore R, Wong J. What do we know about SARS-CoV-2 transmission? A systematic review and meta-analysis of the secondary attack rate and associated risk factors. PLoS One. 2020 Oct 8;15(10):e0240205.

¹⁵ Madewell ZJ, Yang Y, Longini IM Jr, Halloran ME, Dean NE. Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis. JAMA Netw Open. 2020 Dec 1;3(12):e2031756.

transmission was 24-27 times greater than asymptomatic transmission.¹⁶ A retrospective contact study from Pakistan estimated the risk of asymptomatic transmission to be 19 times lower than pre-symptomatic transmission.¹⁷

III. The Experimental Nature of the COVID-19 Vaccines

- 21. The four COVID-19 vaccines available to the general public in Canada in the Fall of 2021 and Winter of 2022 were genetic, RNA-based vaccines that use lipid nanoparticle carriers (*i.e.*, Pfizer/BioNTech and Moderna), or adenovirus-based vaccines (*i.e.*, Johnson & Johnson (J&J) and AstraZeneca). In each case, these particular vaccines deliver genetic instructions (RNA or DNA), presumably to deltoid muscle region of the arm at the site of injection, for the production of the spike protein that mimics that of the SARS-CoV-2 virus. An amount of vaccine-induced spike protein is then manufactured by the host cell and presented on the surface of these cells either alone, or displayed on MHC molecules to elicit an inflammatory immune response that culminates in the stimulation and proliferation of T-cells that will seek and destroy host cells expressing spike protein, and B-cells that will produce antibodies that specifically target epitopes on the spike protein.
- 22. Lipid nanoparticles and adenoviruses have been used to deliver drugs and toxins into animals for therapeutic purposes, and even to elicit immune responses.¹⁸ The lipid nanoparticles or genetically engineered adenoviruses normally present the antigen of the pathogen on their own surfaces. However, the combination of the lipid nanoparticles used to get production of a target pathogenic protein on the surface of the body's own cells to

¹⁶ Koureas M, Speletas M, Bogogiannidou Z, Babalis D, Pinakas V, Pinaka O, Komnos A, Tsoutsa S, Papadamou G, Kyritsi MA, Vontas A, Nakoulas V, Sapoynas S, Kanellopoulos N, Kalompatsios D, Papadouli V, Dadouli K, Soteriades S, Mina P, Mouchtouri VA, Anagnostopoulos L, Stamoulis KE, Agorastos K, Petinaki EA, Prezerakos P, Tsiodras S, Hadjichristodoulou C. Transmission Dynamics of SARS-CoV-2 during an Outbreak in a Roma Community in Thessaly, Greece-Control Measures and Lessons Learned. Int J Environ Res Public Health. 2021 Mar 11;18(6):2878. doi: 10.3390/ijerph18062878.

¹⁷ Mahmood M, Ilyas NU, Khan MF, Hasrat MN, Richwagen N. Transmission frequency of COVID-19 through presymptomatic and asymptomatic patients in AJK: a report of 201 cases. Virol J. 2021 Jul 3;18(1):138. doi: 10.1186/s12985-021-01609-w.

¹⁸ Dolgin E. (2021) The tangled history of mRNA vaccines. *Nature*. 597:318-324. <u>https://www.nature.com/articles/d41586-021-02483-w</u>

elicit an immune response against that target remains experimental. Prior to the approvals of these COVID-19 vaccine formulations by the US FDA and Health Canada in the Fall of 2021, no such lipid nanoparticles or adenovirus had been approved for any RNA- or DNA-based vaccine to produce immunity against a pathogen's proteins in humans by specifying their production within the body's own cells.

- 23. These four COVID-19 vaccines were first released for general use in the Canadian population in mid-December 2020 under an Interim Order. In the US, only three of these vaccines (AstraZeneca's adenovirus vaccine was excluded due to safety concerns) were authorized for general use through Emergency Use Authorization (EUA). In Canada, the US and elsewhere, all of these vaccines are actually still in Phase III clinical trials. For example, the Pfizer/BioNTech COVID-19 vaccine, which is the most widely used, is still in Phase III trials, which are not scheduled to be completed until July 30, 2023.¹⁹ The approvals provided by the FDA and Health Canada remain contingent on active and passive monitoring of the efficacy and safety of these non-traditional vaccines. Consequently, these COVID-19 vaccines are still highly experimental in nature.
- 24. Normally, the testing of drugs and vaccines by manufacturers requires pre-clinical trials in at least two different animal models to ensure efficacy and safety. Phase I trials are performed on healthy volunteers to evaluate initial safety concerns. Phase II trials are then undertaken with the main targeted participants with different concentrations of the vaccine to establish an optimum dose, in this case determined by its ability to elicit neutralizing antibody production. Phase III trials are subsequently conducted on a large number of targeted participants in multiple centers to investigate the longer-term efficacy and safety of the tested vaccine at the optimal dose.
- 25. The current continuation of the phase III studies with COVID-19 vaccines has been prompted by several factors, including an unprecedented shortening of the typical testing period of a vaccine from five to ten years, before approval for general release, to under a single year with "Operation Warp Speed" in the US. Phase II and III trials, which instead

¹⁹ Pfizer-BioNTech COVID-19 BNT162b2 Vaccine effectiveness study - Kaiser Permanente Southern California. <u>https://clinicaltrials.gov/ct2/show/NCT04848584</u>

of being conducted over 3 to 5 years normally, were combined, and in less than 6 months were administered to the general population with an Interim Order in Canada and EUA in the US. For example, the phase III clinical studies with the Pfizer/BioNTech vaccine commenced on July 27, 2020, and the vaccine was approved for general use for those over 18 years of age by early December of 2020.

26. Due to the early release of the COVID-19 vaccines, the possibility of missing the occurrence of rare adverse effects (AE) from underpowered clinical trials with low numbers of participants, and their delayed onset were unlikely to be detected until used more widely in populations.²⁰ Analysis of rare and potentially delayed AE are almost impossible in Canada now that less than 15% of the Canadian population remains unvaccinated. Problems like anaphylactic shock (a severe allergic reaction), potentially fatal blood clots from thrombosis and myocarditis were not identified until most of the experimental COVID-19 vaccines were used widely among the public.²¹

IV. The Inefficacy of the COVID-19 Vaccines

A. Relative vs Absolute Risk Reduction

27. In any discussion of efficacy of a vaccine, it is important to understand the concept of relative risk reduction (RRR) and absolute risk reduction (ARR). The AAR represents the difference in rates of an event (*e.g.*, infection) between the experimental group and the control group. It is calculated by subtracting the experimental group event rate from the control group event rate and is usually expressed as a percentage. In contrast, the relative risk reduction (RRR) represents the relative decrease in the risk of an adverse event (AE) in the experimental group compared to the control group. It is calculated by dividing the

²⁰ Di Pasquale A *et al.* (2016) Vaccine safety evaluation: Practical aspects in assessing benefits and risks. *Vaccine* 20;34(52):6672-6680

²¹ Blumenthal KG *et al.* (2021) Acute allergic reactions to mRNA COVID-19 vaccines. *Jama* **325**, 15621565, doi:10.1001/jama.2021.3976.

Selvaraj G, Kaliamurthi S, Peslherbe GH, Wei DQ. (2021) Are the allergic reactions of COVID-19 vaccines caused by mRNA constructs or nanocarriers? *Immunological Insights. Interdisciplinary sciences, computational life sciences* 13, 344-347, doi:10.1007/s12539-021-00438-3

rate of the experimental group by the rate of the control group, and, as with the AAR, is usually expressed as a percentage.

- 28. In a hypothetical example, in a study trial with 100 vaccinated participants, only 1 of them may have become ill (*i.e.*, 0.01), and was not protected by the vaccine from getting sick. In the unvaccinated arm of the trial with 100 more participants, only 2 of them become ill (*i.e.*, 0.02). In this study, the RRR of the vaccine is 50% ((0.01 / 0.02 x 100%), a potentially attractive reduction likely to persuade users to accept the treatment. In contrast, the AAR is merely 1% ((0.02 0.01) x 100%), which means that individuals who did not take the vaccine are still likely to remain free from the disease 98% of the time, as opposed to 99% of the time if they took the vaccine. This may give pause to patients and health professionals when considering the desirability of accepting a new treatment, especially considering the scant safety data. Of note, while the RRR of the first Pfizer/BioNTech trial was 95%, the ARR was only 0.7%, which was calculated by independent investigators but not reported in the original peer-reviewed publication (although the raw data was made available).²²
- 29. Communicating only relative risk can be very misleading, not only to the public, but also to health professionals. As such, the US FDA, in a 2011 report entitled, "Communicating Risks and Benefits: A User's Guide", instructed investigators to, "provide absolute risks, not just relative risks". The guide stated on page 60:

Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. *Thus, an absolute risk format should be used*.²³

²² Brown RB. (2021) Outcome reporting bias in COVID-19 mRNA vaccine clinical trials. *Medicina (Mex)*. 57(3):199. doi:10.3390/medicina57030199

²³ Brewer NT, Downs JS, Fischhoff B, eds. (2011) Communicating risks and benefits: An evidence-based user's guide.:242\ [emphasis added].

B. Fall 2021 and Winter 2022: Delta and Omicron Variants

- 30. Omicron and its subvariants currently remain the dominant COVID-19 variants in Canada. Omicron emerged in early December 2021 in North America and rapidly became the dominant variant by late December 2021, replacing the previously dominant Delta variant. Delta emerged in April 2021 and slowly became dominant by fall 2021 shortly before being replaced by Omicron.
- 31. The Delta variant was highly transmissible and more transmissible than previous variants. Omicron was yet more transmissible, but less severe than Delta. The increase in transmissibility between Delta and Omicron was significant, as reflected in the surge of cases in late 2021 and early 2022. This accords with how SARS-CoV-2 has generally behaved, and with the way many respiratory viruses behave when they first emerge: over time they become even less severe, but even more easily transmitted.²⁴
- 32. The continuation of COVID-19 cases in the fall of 2021, and the 5 to 10-fold increase in cases at the very end of 2021, were due to the Delta and Omicron variants and occurred regardless of the high COVID-19 vaccine uptake amongst Canadians by that period in time. See figure below.

²⁴ Geoghegan JL, Holmes EC. The phylogenomics of evolving virus virulence. Nat Rev Genet. 2018 Dec;19(12):756-769.

Alizon S, Sofonea MT. SARS-CoV-2 virulence evolution: Avirulence theory, immunity and trade-offs. J Evol Biol. 2021 Dec;34(12):1867-1877.

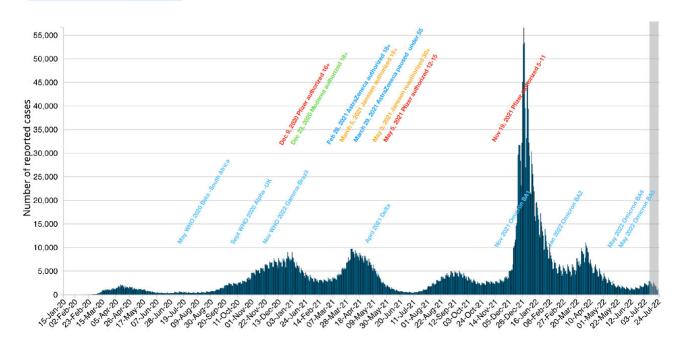


Figure 3. COVID-19 cases (n=3,834,280 1) in Canada by date 2 as of July 29, 2022, 9 am EST (total cases

(Figure generated from https://health-infobase.canada.ca/covid-19/)

33. Mutations in the Omicron variant number about 50, with 32 in the receptor binding domain alone. This is compared to 9-12 mutations in the receptor binding domain of previous variants. The latest estimates of vaccine efficacy in the scientific literature vary widely, but at least one Ontario preprint study on vaccine effectiveness against the Omicron variant shows less than 15% efficacy after two months, and drops to essentially 0% effectiveness around 180 days after the second dose.²⁵ The majority of COVID-19 cases, hospitalizations and ICU admissions have been vaccinated individuals.²⁶

²⁵ Buchan, S. A., Chung, H., Brown, K. A., Austin, P. C., Fell, D. B., Gubbay, J. B., Nasreen, S., Schwartz, K. L., Sundaram, M. E., Tadrous, M., Wilson, K., Wilson, S. E., & Kwong, J. C. (2022). *Effectiveness of COVID-19 vaccines against Omicron or Delta infection*. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.30.21268565</u>

²⁶ COVID-19 Data and Surveillance. Public Health Ontario. Retrieved February 8, 2022, from <u>https://www.publichealthontario.ca/en/data-and-analysis/infectious-disease/covid-19-data-surveillance</u> *Public Health Scotland COVID-19 & Winter Statistical Report.* (2022, February 9). Public Health Scotland, <u>https://web.archive.org/web/20220209174422/https://www.publichealthscotland.scot/media/11619/22-02-09-</u> <u>covid19-winter_publication_report.pdf</u>

- 34. The exact efficacy and duration of vaccine-generated antibodies and broader immune protection against SARS-CoV-2 is currently unknown, but it is much lower than previously thought. The current primary research literature demonstrates a near total lack of effectiveness of the COVID-19 vaccines against the Omicron variant.²⁷
- 35. All currently available COVID-19 vaccines were designed against the original Wuhan strain of SARS-CoV-2 and show little to no efficacy against the Omicron variant.²⁸ This is predictable, and was predicated, due to the nature of the virus, how it mutates over time, especially at suboptimum levels of population immunity, and how these changes permit the virus to effectively evade the vaccines.
- A noteworthy recent Danish study entitled, SARS-CoV-2 Omicron VOC Transmission in Danish Households found 3.66 times higher transmission for "boosted" individuals (3

COVID-19 vaccine surveillance report Week 6. (2022, February 10). UK Health Security Agency, https://web.archive.org/web/20220210161520/https://assets.publishing.service.gov.uk/government/uploads/syst em/uploads/attachment_data/file/1054071/vaccine-surveillance-report-week-6.pdfreport-week-6.pdf

²⁷ Cele, S., Jackson, L., Khan, K., Khoury, D. S., Moyo-Gwete, T., Tegally, H., Scheepers, C., Amoako, D., Karim, F., Bernstein, M., Lustig, G., Archary, D., Smith, M., Ganga, Y., Jule, Z., Reedoy, K., San, J. E., Hwa, S.-H., Giandhari, J., & Blackburn, J. (2021). SARS-CoV-2 Omicron has extensive but incomplete escape of Pfizer BNT162b2 elicited neutralization and requires ACE2 for infection. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.08.21267417</u> Rössler, A., Riepler, L., Bante, D., Laer, D. von, & Kimpel, J. (2021). SARS-CoV-2 B.1.1.529 variant (Omicron) evades neutralization by sera from vaccinated and convalescent individuals. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.08.21267491</u>

Wilhelm, A., Widera, M., Grikscheit, K., Toptan, T., Schenk, B., Pallas, C., Metzler, M., Kohmer, N., Hoehl, S., Helfritz, F. A., Wolf, T., Goetsch, U., & Ciesek, S. (2021). *Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera and monoclonal antibodies*. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.07.21267432</u> Dejnirattisai, W., Shaw, R. H., Supasa, P., Liu, C., Stuart, A. S., Pollard, A. J., Liu, X., Lambe, T., Crook, D., Stuart, D. I., Mongkolsapaya, J., Nguyen-Van-Tam, J. S., Snape, M. D., & Screaton, G. R. (2022). *Reduced neutralisation of SARS-CoV-2 omicron B.1.1.529 variant by post-immunisation serum*. The Lancet, 399(10321), 234–236. https://doi.org/10.1016/s0140-6736(21)02844-0

Ferguson, N., Ghani, A., & Cori, A., *et al.* (2021). *Growth, population distribution and immune escape of the Omicron in England.* Imperial College London. <u>https://doi.org/10.25561/93038</u>

²⁸ Gagne, M., Moliva, J. I., Foulds, K. E., Andrew, S. F., Flynn, B. J., Werner, A. P., Wagner, D. A., Teng, I-Ting., Lin, B. C., Moore, C., Jean-Baptiste, N., Carroll, R., Foster, S. L., Patel, M., Ellis, M., Edara, V.-V., Maldonado, N. V., Minai, M., McCormick, L., & Honeycutt, C. C. (2022). *mRNA-1273 or mRNA-Omicron boost in vaccinated macaques elicits comparable B cell expansion, neutralizing antibodies and protection against Omicron.* bioRxiv. Preprint. https://doi.org/10.1101/2022.02.03.479037

Kannan, S. R., Spratt, A. N., Sharma, K., Chand, H. S., Byrareddy, S. N., & Singh, K. (2022). *Omicron SARS-CoV-2 variant: Unique features and their impact on pre-existing antibodies*. Journal of Autoimmunity, 126, 102779. https://doi.org/10.1016/j.jaut.2021.102779

doses), 2.61 times higher for "fully vaccinated" (2 doses), and only 1.17 times higher for the unvaccinated, when comparing the Omicron to Delta variants.²⁹

- 37. Recent preprint data from CANImmunize in Toronto evaluated vaccine effectiveness (VE) in Canada from December 6 26, 2021 against both the Delta and Omicron variants, as the latter was emerging. They found that, "VE against symptomatic omicron infections was only 36%, 7-59 days after a second dose and provided *no protection after* ≥180 days, but increased to 61% after a third dose" (emphasis added).³⁰ The duration of the efficacy is still unknown at this time, but is expected to be very limited due to emerging evidence from efforts with fourth doses internationally.³¹
- 38. This lack of vaccine effectiveness against the Omicron variant in Canada is consistent with a preliminary report out of Sweden by Sheward *et al* which showed a 40-fold reduction in neutralizing antibody activity against the variant.³² A study reported in the NEJM by Nemet *et al* on December 29, 2021 concluded similarly. The authors stated that although a third dose may improve the vaccination, "even with three vaccine doses, neutralization against the omicron variant was lower (by a factor of 4) than that against the delta variant." (See figure from the publication below). "The durability of the effect of the third dose of vaccine against COVID-19 is yet to be determined."³³

²⁹ Lyngse, F. P., Mortensen, L. H., Denwood, M. J., Christiansen, L. E., Møller, C. H., Skov, R. L., Spiess, K., Fomsgaard, A., Lassaunière, M. M., Rasmussen, M., Stegger, M., Nielsen, C., Sieber, R. N., Cohen, A. S., Møller, F. T., Overvad, M., Mølbak, K., Krause, T. G., & Kirkeby, C. T. (2021). SARS-CoV-2 Omicron VOC Transmission in Danish Households. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.27.21268278</u>

³⁰ Buchan, S. A., Chung, H., Brown, K. A., Austin, P. C., Fell, D. B., Gubbay, J. B., Nasreen, S., Schwartz, K. L., Sundaram, M. E., Tadrous, M., Wilson, K., Wilson, S. E., & Kwong, J. C. (2022). *Effectiveness of COVID-19 vaccines against Omicron or Delta infection*. medRxiv. Preprint. <u>https://doi.org/10.1101/2021.12.30.21268565</u>

³¹ Federman, J. (2022, January 17). *Israel study: 4th vaccine shows limited results with omicron*. AP NEWS. <u>https://apnews.com/article/coronavirus-pandemic-health-middle-east-israel-5da0bbef16209e9c55e48af40248af11</u>

³² Sheward, D., Kim, C., Pankow, A., Castro Dopico, X., Martin, D., Dillner, J., Karlsson Hedestam, G., Albert, J., & Murrell, B. (2021). *Quantification of the neutralization resistance of the Omicron Variant of Concern*. Preprint. https://www.tkbilgin.com/wp-content/uploads/2021/12/ShewardEtAl.pdf

³³ Nemet, I., Kliker, L., Lustig, Y., Zuckerman, N., Erster, O., Cohen, C., Kreiss, Y., Alroy-Preis, S., Regev-Yochay, G., Mendelson, E., & Mandelboim, M. (2021). *Third BNT162b2 Vaccination Neutralization of SARS-CoV-2 Omicron Infection.* New England Journal of Medicine. <u>https://doi.org/10.1056/nejmc2119358</u>

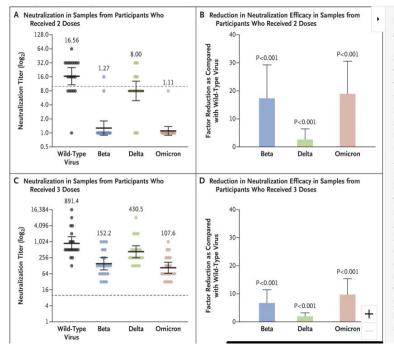


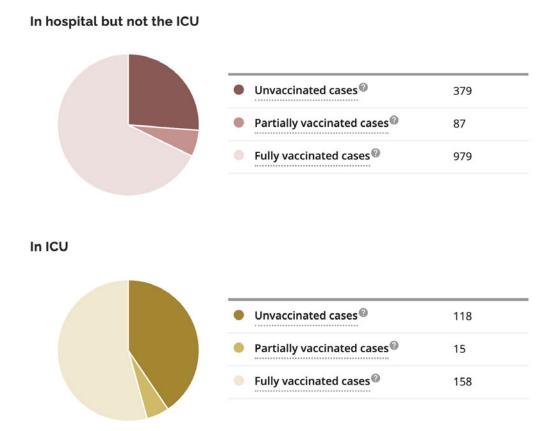
Figure 1. Neutralization Efficiency against Wild-Type Virus and the Beta, Delta, and Omicron Variants of Concern.

Serum samples were obtained from 20 health care workers who had received two doses of the BNT162b2 vaccine (Panels A and B) and from 20 who had receive three doses (Panels C and D). Samples were tested by microneutralization against wild-type severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) an the B.1.351 (beta), B.1.617.2 (delta), and B.1.1.529 (omicron) variants of concern. Dashed lines in Panels A and C indicate the cutoff titer. Geometric mean tite (horizontal lines) with 95% confidence intervals (I bars) are presented, as well as the geometric mean tit value. Dots indicate individual serum samples. The factor reduction as compared with wild-type virus is shown for samples obtained from participants who had received two doses of vaccine (Panel B) and those obtained from participants who had received three doses (Panel D). For these analyses, the mean factor differences between wild-type SARS-CoV-2 and the variants of concern were calculated for each participant; the means of the individual values are shown here. Error bars in Panels B and D indicate the standard error.

C. The Negative Effectiveness of the COVID-19 Vaccines

- 39. Recent data from Ontario and other provinces indicates the development of what is called *negative* vaccine effectiveness. When a population that receives a vaccine becomes *more likely* over time to become infected with the pathogen targeted by the vaccine, that vaccine has induced *negative* efficacy, which is to say it has produced the opposite of the intended effect, rendering the vaccinated more susceptible to infection than the unvaccinated.
- 40. For example, the diagram below taken from an Ontario Government website on February 11, 2022 shows that the COVID-19 vaccinated are at the highest risk of hospitalization including those in ICU.³⁴

³⁴ Hospitalizations | COVID-19 (coronavirus) in Ontario. (2022, February 11). Web.archive.org. https://web.archive.org/web/20220211154925/https://covid-19.ontario.ca/data/hospitalizations



Source: <u>https://web.archive.org/web/20220211154925/https://covid-19.ontario.ca/data/hospitalizations</u>

41. Additional data as graphed below, also derived from the Ontario Government, indicates these trends have continued through May 2022 with those receiving the booster having the highest COVID-19 cases.³⁵ Since only individuals infected with SARS-CoV-2 can transmit the virus causing COVID-19, it means that the most heavily vaccinated are the most highly responsible for transmission.

³⁵ COVID-19 vaccinations data | COVID-19 (coronavirus) in Ontario. (2022, April 30). Web.archive.org. https://web.archive.org/web/20220430131324/https://covid-19.ontario.ca/data



Source: https://web.archive.org/web/20220430131324/https://covid-19.ontario.ca/data

42. The Ontario data is not unique, and an example of data from BC is shown below with a summary table from immunologist and University of British Columbia professor Dr. Stephen Pelech.

					<u>ovia-19-5</u>	urveilla	nce-dashboard ar	id then click o	in the v
ab. The tab	le below summarizes t	he data f	rom these reports	S:					
	1	Vaccinated (Doses 1,2 & 3)				Unvaccinated			
Date	Period of Report	Cases	Hospitalizations	Critical Care	Deaths	Cases	Hospitalizations	Critical Care	Deaths
2022-04-16	March 13 to April 9	5618	735	111	58	914	207	41	16
2022-04-23	March 20 to April 16	6107	840	116	84	965	182	37	10
2022-04-28	March 27 to April 23	6732	1023	132	132	1053	183	34	16
2022-05-05	April 3 to April 30	7276	1200	164	189	1082	216	33	15
Net Change from 2022-04-16		1658	465	53	131	168	9	-8	-1
Net Change (%)		30%	63%	48%	226%	18%	4%	-20%	-6%

Some observations: 1) vaccinated persons account for 93 percent of Covid-19 deaths and have increased 226 percent since March 13th. 2) vaccinated persons account for 87 percent of combined Cases, Hospitalizations and Critical Care.

The most recent Vax Donut Chart is provided:

May 6, 2022 Chart of the Day

💌 < 🕴 Introduction Outcomes by Vax 1 Outcomes by Vax 2 Vax Donut Charts Vax by Age Vax Progress Map Vertical Plots Scatter Plot Ca >



43. The table below shows the COVID-19 case outcomes in Alberta by vaccine status as of January 13, 2022, with the "two dose" group making up the largest percent of cases and hospitalizations.³⁶ Virus transmission is greatest among those infected, which means COVID-19 has been and is transmitted more by vaccinated individuals than unvaccinated.

³⁶ COVID-19 Alberta Statistics. Government of Alberta. Retrieved January 13, 2022, from www.alberta.ca/stats/covid-19-alberta-statistics.html

Table 3. COVID-19 case outcomes in Alberta by vaccine status. Counts are provided for new, active cases, and those currently identified as being hospitalized.

Outcome	Vaccine status	Count (n)	Percent (%)	
New cases	Three doses	830	13.12	
New cases	Two doses	4,015	63.47	
New cases	One dose	301	4.76	
New cases	Unvaccinated	1,180	18.65	
Active cases	Three doses	7,370	11.49	
Active cases	Two doses	43,135	67.26	
Active cases	One dose	2,466	3.85	
Active cases	Unvaccinated	11,158	17.40	
Currently hospitalized	Three doses	150	18.25	
Currently hospitalized	Two doses	334	40.63	
Currently hospitalized	One dose	33	4.01	
Currently hospitalized	Unvaccinated	305	37.10	

Note:

* Vaccine status category is based on protection. Doses administered within 14 days prior to a person's COVID-19 diagnosis are not considered protective; as a result, vaccination categories only include those identified as cases over 14 days past their first or second immunization date.
* Table does not include those with 1 dose. As a result, percentages across rows or columns may not add to 100.

Source: www.alberta.ca/stats/covid-19-alberta-statistics.html

44. Taken together, these data could be an indication of antigenic imprinting (the way in which the viral antigens were first recognized by the immune system inappropriately shapes subsequent immune responses to the live SARS-CoV-2 virus);³⁷ immune exhaustion (multiple boosters with novel genetic vaccines in a relatively short amount of time shuts down the potential immune response upon exposure to the virus);³⁸ antibody-dependent enhancement (neutralizing antibodies generated against the spike protein following vaccination waning quickly, allowing for non-neutralizing antibodies to aid in transport of

³⁷ Wheatley, A. K., Fox, A., Tan, H.-X., Juno, J. A., Davenport, M. P., Subbarao, K., & Kent, S. J. (2021). *Immune imprinting and SARS-CoV-2 vaccine design*. Trends in Immunology, 42(11), 956–959. <u>https://doi.org/10.1016/j.it.2021.09.001</u>

³⁸ Johnson, P. L. F., Kochin, B. F., McAfee, M. S., Stromnes, I. M., Regoes, R. R., Ahmed, R., Blattman, J. N., & Antia, R. (2011). *Vaccination Alters the Balance between Protective Immunity, Exhaustion, Escape, and Death in Chronic Infections*. Journal of Virology, 85(11), 5565–5570. <u>https://doi.org/10.1128/JVI.00166-11</u>

the virus into the host cell);³⁹ or immunological tolerance (the display of foreign spike protein on host cells generated following mRNA-based vaccination producing some form of tolerance rather than protection).⁴⁰

45. Previous attempts at generating gene-based vaccines have resulted in various forms of vaccine-induced disease enhancement. The authors of a recent Nature Review article entitled, *Learning from the Past: Development of Safe and Effective COVID-19 Vaccines* state:

Vaccine-associated disease enhancement in the history of developing vaccines against respiratory syncytial virus, dengue virus, SARS-CoV and Middle East respiratory syndrome coronavirus, highlight the importance of a robust safety and efficacy profile, and present recommendations for preclinical and clinical evaluation of COVID-19 vaccine candidates, as well as for vaccine design and optimization.⁴¹

D. International Observations: Nations with High Vaccine Uptake Have not Experienced a Decrease in Cases

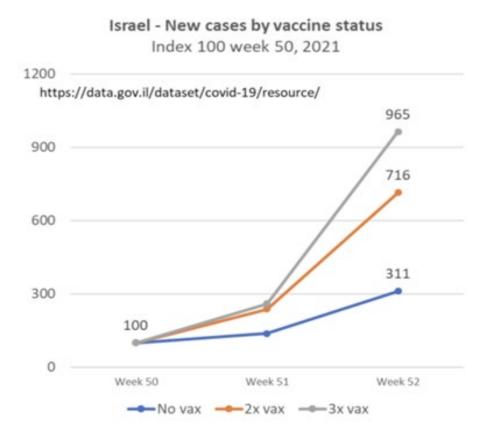
46. Data shows countries with the highest vaccination rates have also recorded the highest case rates in late 2021 into 2022. For example, as seen in the graph below, Israel has recently recorded all-time highs in COVID-19 cases and deaths despite an aggressive vaccination campaign and very high uptake rate of not only the original two doses, but subsequent doses of vaccine as well.⁴²

³⁹ Xu, L., Ma, Z., Li, Y., Pang, Z., & Xiao, S. (2021). *Antibody dependent enhancement: Unavoidable problems in vaccine development*. Advances in Immunology, 151, 99–133. <u>https://doi.org/10.1016/bs.ai.2021.08.003</u>

⁴⁰ EMA regular press briefing on COVID-19. (2022, January 7). European Medicines Agency. <u>https://www.ema.europa.eu/en/events/ema-regular-press-briefing-covid-19-11#event-summary-section</u>

⁴¹ Su, S., Du, L., & Jiang, S. (2020). *Learning from the past: development of safe and effective COVID-19 vaccines.* Nature Reviews Microbiology. <u>https://doi.org/10.1038/s41579-020-00462-y</u>

⁴² Coronavirus in Israel: Ash says COVID-19 likely to never go away. (2022, February 8). The Jerusalem Post. https://www.jpost.com/breaking-news/article-695830



47. Similarly, the nations of Gibraltar, France, and the United Kingdom all experienced significant surges despite ranking near the top of the list for overall vaccine uptake in the Western world. This pattern was observed by Subramanian and Kumar in their research article published September 30, 2021, which revealed that there was no evidence that the COVID-19 vaccination programs had any beneficial effect on case rates using the United States as a case study due to its varied vaccine uptake state-to-state. Further, the authors found a "marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people."⁴³

⁴³ Subramanian, S. V., & Kumar, A. (2021). *Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States*. European Journal of Epidemiology. <u>https://doi.org/10.1007/s10654-021-00808-7</u>

48. According to the UK Health Security Agency COVID-19 Vaccine Surveillance Report, Week 2, Table 12,⁴⁴⁵² in early January in the UK, for persons ages 18 – 69, people vaccinated with 2 doses had over double the positive case reports (per 100k population) compared to the unvaccinated population. For ages 70+, the positive case rate for people with 2 doses is significantly higher than that of unvaccinated people.

V. Conclusion and Opinion

49. No benefit, as far as reducing workplace infection and transmission of COVID-19 was or could have been realized in the Fall of 2021 or Winter of 2022 by requiring all of a workforce to receive the COVID-19 vaccines and excluding all workers who did not receive the COVID-19 vaccines. The evidence also demonstrates vaccinated individuals have been *at least as likely* to develop and transmit COVID-19 as unvaccinated people. In my opinion as a biomedical scientist, this entirely negates any clinical or practical basis for mandated vaccination of a population such as a workforce, *regardless of the nature of the work or who a worker interacts with.*



DR.

⁴⁴ COVID-19 vaccine surveillance report - Week 2. (2022). UK Health Security Agency. <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1047814/Vac</u> <u>cine-surveillance-report-week-2-2022.pdf</u>