Rule 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. JULIE PONESSE

My name is Dr. Julie Ponesse. My address is a second provide this opinion voluntarily, based upon my personal knowledge, education, facts, and experience.

- 2. I have a Ph.D. in Ethics and Ancient Philosophy from the University of Western Ontario. I also have a Masters of Philosophy with Collaborative Specialization in Bioethics from the Joint Centre for Bioethics at the University of Toronto and a Diploma in Ethics from the Kennedy Institute of Ethics at Georgetown University. My qualifications are set out in the attached *Curriculum Vitae* marked **Schedule A**.
- 3. My areas of research and teaching specialization include Ethical Theory, Applied Ethics (Health Care Ethics, in particular), and Ancient Philosophy (especially Aristotle's virtue ethics). I have published and taught in each of these areas including Health Care Ethics courses with a significant History of Medicine component (including the history of pharmacology and the regulatory capture that has become part of the relationship between the pharmaceutical industry and the public and private bodies meant to regulate them). I am competent to testify as an ethical expert to the facts and matters set forth herein.

- 4. I am well versed in the fundamental principles of contemporary bioethics and in the balancing of these in the context of public health, including an understanding of the thresholds that must be met in order to justify vaccination mandates, which limit personal rights and freedoms for the sake of the collective good. I am well versed in the ethical dimensions of voluntary informed consent in the context of health care, and of the international and national documents which aim to protect persons from the risks of health care (including but not limited to the Universal Declaration on Bioethics and Human Rights, The World Medical Association Declaration of Helsinki, The World Medical Association International Code of Medical Ethics, the Nuremberg Code, and the Code of Ethics of the Canadian Medical Association). I also have a background in the History of Medicine, which offers a number of examples of the importance of the priority of autonomous, free, and informed medical choice, the sanctity of the physician-patient relationship, and the human costs of compulsory medical intervention and pharmaceutical decision-making incentivized by profit.
- 5. I was instructed by counsel for the Plaintiff to herein provide my expert opinion regarding the ethical dimensions, including the potential harms and costs, of imposing a COVID-19 vaccination mandate on health care employees, especially with regard to Mrs. Porter's situation. Counsel also instructed me to explain the distinction between mere choice and free choice in health care ethics.
- 6. My opinion is that mandatory workforce COVID-19 vaccination does not produce demonstrated benefit over costs and, therefore, lacks ethical justification, including in the context of a health care workforce and regardless of whether the mandated workforce vaccination is universally enforced or *bona fide* requests for statutory human rights accommodation are granted. For greater clarity, subsumed in this opinion is the opinion that there lacks the ethical justification required to deny accommodation of a health care worker who is religiously compelled to not receive the COVID-19 vaccines.
- 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 or around the fall of 2021.

I. Introduction: Balancing the Collective Good with Limitations on Personal Autonomy

- 9. The ethics of mandated vaccination is largely the ethics of public health. At its core, public health is concerned with promoting and protecting the health of populations, broadly understood. While the focus of clinical practice is on the health of individuals, public health is committed to advancing health at the level of groups or populations. In other words, in clinical practice, health is a private good; in public health, it is a public good. The former is conceptually simpler because only the individual's own choices, deeply held beliefs, medical history, prognosis, etc. are what matters.
- 10. But in public health, private medical choices must be considered in relation to one another, and conflicts between them often cannot be perfectly resolved. Public health ethics recognizes that what happens to us and what we do often has an effect on others, and that we very often succeed or fail together.
- 11. More broadly, this is the foundation of community and statehood, and the undergirding of our moral obligations to one another. There is a camaraderie in this, a comfort in knowing that one's life is interwoven with others and that we may not be alone or unique in our suffering. But it also imposes a heavy burden of responsibility to ensure that our actions thoughtfully take into consideration their impact on others.
- 12. Improvements to our polices surrounding public smoking reflect this idea. Unlike the use of certain recreational drugs that primarily impact only the user (MDMA and Ketamine, for example), cigarette smoking has well-documented deleterious effects on those around us (namely "second-hand" smokers). Choosing to smoke a cigarette in a restaurant or at the entrance to a public building has such a negative and unmitigable effect on non-smokers who use those spaces, and which is not offset by considerable benefit to the user, that we consider prohibitions on smoking in those areas to be a justified limitation on autonomous action.
- 13. The existence of a universal health care system funded through taxes further complicates this situation. Even behaviours that do not directly impact others but which are costly for

our health care system, and therefore indirectly costly for others, become reasonable subjects of policy restrictions when all of society is asked to bear the burden of personal costly choices. And so what might seem like the private choice to wear a seatbelt, for example, becomes a question of public health in a system in which others will suffer from the potentially costly lifestyle choices of individuals because of limited health care resources being directed to managing the effects of those choices.

- 14. But not all cases which pose tensions between private choices and public effects are so easy to resolve. Some personal choices which potentially threaten others are of great benefit to the individual, and sometimes the supposed or presumed threat of those choices to others is not clearly understood or easily demonstrated. (Sometimes, for example, time is needed to know the true effects of our choices on others and so evaluations of those effects in the moment cannot be more than educated estimations.)
- 15. Furthermore, it is sometimes impossible to perfectly resolve the tension between autonomous action and the collective good. Sometimes there is a moral remainder, the sum of the morally regrettable costs that may result from an otherwise defensible decision such as the sacrifice of one person for many.¹
- 16. Further still, autonomous choices are not always popular choices—those the majority of persons in a given society would make. But this is an inherent and therefore unavoidable feature of a pluralistic society, which aims to allow for the greatest sphere possible for the respect of choices which might not be our own. This respect is essential for pluralism to function on pain of losing the grounds for respecting choice at all.
- 17. Public health, for this reason, cannot be an elimination exercise, one which systematically disregards the validity of unpopular choices. It must be an exercise in balancing: balancing the respect for autonomy and personal decision-making against the effects those decisions can have on others. As moral philosopher William Frankena said, a moral person's actual duty is determined by weighing and balancing all competing *prima facie* duties in a particular case.

¹ Williams, Bernard. "Ethical Consistency." Problems of the Self. Cambridge University Press, 1973. p. 166.

- 18. A COVID-19 vaccination mandate is a "textbook" case in point of a public health policy that requires this kind of balancing. Mandates aimed at protecting public health are, in principle, ethically justified, but only to the extent and insofar as they create a favourable risk/benefit ratio with respect to the public good and are appropriately balanced with considerations of their effects on personal autonomy and safety. However, because autonomy is a *prima facie* good, and fundamental to the project of democracy, it must be carefully considered as to when, to what degree, and under what conditions autonomy is restricted. Not just any public (or majority) request to infringe on another's personal decision-making will suffice.
- 19. The following kinds of questions are relevant to the task of balancing: What sacrifices can we expect individuals to make to satisfy public health interests? What sacrifices can we expect individuals to make to satisfy the public's expectations with respect to health? What threshold of benefit must be met in order to justify limitations on a person's private choices? What is the scope of the onus on the part of a mandating body to provide accommodations for those seeking an exemption from the relevant mandate? What are the costs of too quickly denying these exemptions?
- 20. These are only some of the relevant questions when it comes to assessing the ethical soundness of a vaccination mandate. Much balancing is required in public health ethics, and it is almost inevitable that public health policies will come at the cost of some personal rights and freedoms. The challenge is to determine when those limitations are justified and when are they an unjustifiable 'step too far'.

II. The Conditions Precedent to Justify a COVID-19 Vaccine Mandate from a Cost-Benefit Perspective

21. First to consider is what conditions must be met for a vaccine mandate to be ethically justified. Pandemics pose a unique ethical challenge because what one person does potentially affects others, and the effects of one person's actions on others can be grave and substantial. And this is especially true for health care workers. For this reason, there is some historical precedent for mandating vaccines for health care workers (vaccination

against serious diseases such as diphtheria, polio, mumps, and measles for health care workers—common by the beginning of the 20th century—is a good example).

22. However, we need to be careful not to assume that the mere existence of an inoculation to address a transmittable virus means that intervention is capable of preventing disease transmission or that it ought to be mandated for health care workers. The following non-exhaustive list establishes three conditions all of which must be met if the threshold is to be met for ethically justifying a COVID-19 vaccination mandate for health care workers. These three conditions taken together represent the absolute minimum requirements a vaccine mandate must meet to possibly be regarded as ethically acceptable. There are other considerations, such as whether the disease in question can be effectively and affordably treated, which it would appear COVID-19 arguably is with the use of common supplements and medications such as Ivermectin and Zinc.²

A. Morbidity and Mortality

23. For a vaccine mandate to be ethically justified, the disease for which vaccination is mandated must be a highly virulent pathogen which is a significant cause of morbidity and mortality, posing a substantial threat to all persons. Historical data indicate the mortality rate from various major smallpox outbreaks, for example, is approximately 30%.³ Ebola is also a highly virulent pathogen with an infection fatality rate (IFR) of approximately 50% and is capable of inducing a lethal hemorrhagic fever.⁴

² Front Line COVID-19 Critical Care Alliance. Prevention and Treatment Protocols for COVID-19. https://covid19criticalcare.com/covid-19-protocols/. Accessed October 2, 2021.

³ Though the case-fatality rate differs for the different forms of smallpox, it was approximately 30% overall in unvaccinated individuals. <u>https://www.cdc.gov/smallpox/clinicians/clinical-disease.html</u>. Accessed October 1, 2021.

⁴ Zampieri, Carisa, Nancy Sullivan and Gary Nabel. "Immunology of Highly Virulent Pathogens." *Nature Immunology*, vol. 8. 2007, pp. 1159-1164. <u>https://www.nature.com/articles/ni1519/</u>

24. COVID-19, on the other hand, has an exceedingly low IFR, estimated by the CDC to be 0.002807% for all age groups.⁵ It was widely known by mid-2021 that the IFR for COVID-19 was well below 0.5% and would only continue to decrease over time. The virulence of different pathogens (Smallpox, Ebola and SARS-CoV-2) vary dramatically, which calls into question the "threshold" for actual morbidity and mortality needed to justify mandating vaccination for health care workers. COVID-19 is, by comparison, not a highly virulent pathogen, and therefore does not meet the epidemiological threshold for morbidity and mortality to ethically justify mandating vaccination for health care workers.

B. Whether or Not the Vaccine is Sterilizing

- **25.** Since justifying a vaccination mandate depends largely on the effectiveness of the vaccine, and vaccine effectiveness depends largely on its sterilizing capabilities, whether or not the vaccine is sterilizing or non-sterilizing (i.e., "leaky") is crucial to determining the ethical justification of the mandate. Vaccine mandates are based on the assumption the vaccines prevent transmission of the pathogen.
- 26. A good example of this is mandatory vaccination for the Hepatitis B virus. However, the Hepatitis B vaccine is notably dissimilar to the COVID-19 vaccines in every feature. Unlike the latter, the Hepatitis B vaccine is a sterilizing vaccine that provides the recipient with robust and durable immunity from a chronic, often devastating, illness. Even then, antibodies are checked before and after a series of injections to prevent unnecessary inoculation.
- **27.** In contrast to a traditional sterilizing vaccine, the COVID-19 vaccines are non-sterilizing. Therefore, COVID-19 vaccinated persons still become infected with, and transmit, the

⁵ <u>https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html</u>. Accessed March 21, 2023. Other sources report similar findings. A recent study in *The Lancet*, for example, estimates COVID's IFR to range from 0.0023% (for a healthy 7-year-old) to 1.0035% (for a healthy 60-year-old), with most of those infected experiencing only minor symptoms (COVID-19 Forecasting Team [2022, Feb 16], Variation in the COVID-19 infection-fatality ratio by age, time, and geography during the pre-vaccine era: a systematic analysis. <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02867-1/fulltext</u>) Accessed March 21, 2023. To put this into some perspective, the COVID-19 IFR in people <65 years old was, at the height of the pandemic, equivalent to the mortality rate from driving between 4 and 82 miles per day (an average of 13 countries evaluated). Joffe, A. R. (2021, Feb 26) COVID-19: Rethinking the lockdown groupthink. Front Public Health. <u>https://doi.org/10.3389/fpubh.2021.625778</u>. Accessed March 21, 2023.

virus. And, since the COVID-19 vaccines do not prevent transmission, they must be regarded as akin to personal treatment *and not a public health measure*.

C. Whether the Vaccine is Experimental or Proven Over Time to be Safe

- 28. The ethical validity of a COVID-19 vaccination mandate also depends on the risks from the disease balanced against the risks from the vaccine used to prevent it. The novel nature of the COVID-19 vaccines put health care workers and professionals in an extremely difficult position. With knowledge of the effects of the COVID-19 vaccines limited to only a number of months, the decision to mandate the COVID vaccines for all employees of an institution or organization is one fraught with uncertainty.
- 29. When vaccination benefits are known to be high (because the vaccine effectively prevents infection and transmission of a disease with a significant IFR), and the risks from vaccination have shown themselves to be low, mandating vaccination may be justified. Another way to say this is that a vaccination mandate might be ethically justified if it does not produce disproportionate harms (harms which are equal to or greater than those from the disease it is supposed to treat). According to psychopharmacologist David Healy, "A core feature of healthcare is that a medicine should not produce disproportionate problems; a sleeping pill should not cause peripheral neuropathy or birth defects."⁶
- 30. The four COVID-19 vaccines available to the general public in Canada in the fall of 2021 and winter of 2022 were genetic, mRNA-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), first released for general use in the Canadian population in mid-December 2020 under an Interim Order. These vaccines utilize novel technology and are still in Phase III clinical trials.⁷ They are therefore fairly described as "experimental".

⁶ Healy, David. "Shifting Vaccine Confidence." *Dr. David Healy*. <u>https://davidhealy.org/shifting-vaccine-confidence/</u>. Accessed October 1, 2021.

⁷ Pfizer-BioNTech COVID-19 BNT162b2 Vaccine effectiveness study - Kaiser Permanente Southern California. <u>https://clinicaltrials.gov/ct2/show/NCT04848584</u>

- 31. Much debate has ensued over whether or not the COVID vaccines are truly novel or truly experimental and, if they are, whether or not this creates a medical and moral cost. It is well known in the medical community that the proper testing of vaccines typically takes many years, not months. The mRNA technology had not, prior to 2020, been used in a prophylactic drug and so long-term side effects were, in principle, impossible to ascertain. Furthermore, unlike a drug formulated at a known dose, the mRNA to be injected produces proteins the quality and quantity of which were largely unknown. Since these, and other unknowns enhance risk, the participant cannot be said to give truly *informed* consent in the way they could for a non-investigational pharmaceutical product.
- 32. This is not, by itself, a reason to distrust a pharmaceutical product since, arguably, advances could have been made in the development process. However, there is precedent, even in recent history, to expect and require a novel vaccine to prove itself before releasing it without a making a full and transparent explanation of its possible harms a key aspect of the consent process *and certainly before mandating it*.
- 33. For example, one year after novel vaccines were manufactured and released on an expedited basis to address the threat of the 2009 H1N1 swine flu, post-marketing reports of narcolepsy emerged in some Pandemrix vaccine recipients. However, it would take a further seven years—and a lawsuit—to discover internal pharmacovigilance reports by the manufacturer which indicated that problems with the vaccine's safety had actually been produced in real time during the pandemic.⁸
- 34. In the context of the many times in recent history a new medical intervention, endorsed and promoted by government and private enterprise alike, turned out to actually be very dangerous and harmful, it was reasonable to have concerns in the fall of 2021 about the safety of the COVID vaccines. From an ethical perspective, the relevant issue is not whether the COVID vaccines have proven themselves to be safe (which, now, in 2023, it is apparent they are not); the point is there was insufficient evidence and inadequate scientific

⁸ Doshi P. Pandemrix vaccine: why was the public not told of early warning signs? <u>BMJ2018;362:k3948doi:10.1136/bmj.k3948</u>. Accessed March 21, 2021.

certainty regarding the safety of the COVID-19 vaccines to justify mandating them in the fall of 2021.

- 35. Health care workers, in particular, are aware of the risks associated with medical research and that the long-term harms of some pharmaceuticals are often not known until many years down the road. (Some of the injuries to the kidneys, heart, reproductive organs, ears and eyes caused by thalidomide, for example, were not discovered until a decade later.) Given the lack of general public awareness that the COVID-19 vaccines came to market under emergency use authorizations, and the fact COVID-19 vaccination consent forms do not reflect the ethical protections for research participants, genuine, fully informed consent was not actually possible for the COVID-19 vaccines.
- 36. Since the risk from COVID-19 decreases drastically as age decreases, the longer-term effects of the vaccines on the lower age groups will increase their risk-benefit ratio, perhaps substantially. Health care workers in the 25-34 age group, for example, will be more vulnerable to disproportionate harms from the vaccine mandate than those in the 65+ group. And, one might argue, they have the most to lose if affected by a vaccine injury since they are at the beginning of their lives and careers, may have young families to support, etc.
- 37. Regardless of how the mass COVID-19 vaccination program has played out, the fact the COVID-19 vaccines were still very new, experimental, and rushed to market in late 2020, making them more potentially dangerous because many of the possible effects were then unknown, was a good enough reason to question their safety. Conceptually, it's easy to assume that similarly named things (e.g., "vaccines") will have similar properties. To return to the topic of the Hep-B and Smallpox vaccines, it is easy to import their successful history into our ways of thinking about new "vaccines" to come to market. However, the Hep-B and Smallpox vaccines have now been tested and observed for decades. Even if we assume COVID-19 had comparable morbidity and mortality (which it did not) and the COVID-19 vaccines were sterilizing (which they were not), it would have remained ethically unacceptable to mandate the COVID-19 vaccines when they were on the market for less than one year.

- 38. Strangely, and perhaps ironically, COVID-19 vaccine mandates did not become a widelyadopted policy until many months after the COVID-19 vaccines became available, that was, until the months of September 2021 – January 2022. The COVID-19 vaccines were generally first available to select populations, including health care workers, in December 2020. By August 2021, after eight months of observational data accumulated, it became evident—at least to anyone who would have exercised reasonable diligence at the time to inform themselves—that the vaccines were not sterilizing and not likely to become sterilizing. Yet, instead of immediately mandating the vaccines once they were available and pursuant to the *promise* they would be sterilizing, the mandates were only implemented *after* data showed they were *not* sterilizing.
- 39. In summary, because COVID-19 has a comparatively low IFR, the COVID-19 vaccines are non-sterilizing, and the COVID-19 vaccines were, in the fall of 2021, experimental, the high threshold of benefit over harm has not been established. It may be ethical to mandate vaccination for health care workers when, at a minimum, the risk of harm to patients is significant, the vaccines are proven to be sterilizing, and the vaccines are proven *over time* to be safe. This was not the case of COVID-19 vaccination mandates in the year 2021: COVID-19 did not pose a significant threat of morbidity and mortality to most people; the COVID-19 vaccines were non-sterilizing, and their safety profile was not yet sufficiently known, which was a function of their experimental nature. It was therefore medically and morally unethical for the Defendant to mandate COVID-19 vaccination for health care workers such as Mrs. Porter.

III. Nonmaleficence and Harm (to Others and to Oneself)

40. The prevailing ethical narrative of the COVID-19 pandemic is collectivist and utilitarian in nature, which states that the right action is the one that will bring about the greatest good for the largest number of people. "We're all in this together" and "do your part" messaging is evidence of this mindset. This is the reasoning behind the strongest argument made by COVID-19 vaccine mandate proponents: insofar as vaccines prevent transmission and thereby reduce harm to others, restrictions on individual freedom are viewed as ethically

justifiable.⁹ It is important to note that the obligation to others based on a possible reduction of harm is based on the harm principle, or the principle of nonmaleficence ("first do no harm"), which states that we have a negative ethical and legal duty to avoid harm to others, *not a positive duty to create benefit for others*.¹⁰ The principle of nonmaleficence also requires us to consider what harms to individuals can be allowed, and even endorsed, by collectivist public health decision-making, and the magnitude of the collateral damage for individuals in the pursuit of the end. To the degree the harm principle requires us to mitigate individual freedom for the sake of reducing harm to others, it also requires us to mitigate individual harm in the pursuit of ostensibly reducing harm to others.

- 41. In practice, the harm principle means avoiding anything which is *unnecessarily* or *unjustifiably* harmful. Living in society with one another, especially when it comes to transmissible viruses, carries some risk, to greater and lesser degrees at different times. But the key consideration is whether the level of harm is proportionate: a policy must be expected to produce public health benefits that outweigh relevant harms, including harms related to coercion, undue pressure, and other forms of freedom restriction.
- 42. Since health care workers are in a unique position to be infected and transmit viruses to patients, their families, and the public generally (a kind of harm), mandating COVID-19 vaccination for health care workers would seem to be a justified way to dramatically reduce the possibility of harm to others. However, the force of protecting the public good becomes less compelling when the principle of nonmaleficence is applied to the particular health care worker herself, and as data confirms the known latent risks associated with novel and experimental vaccines such as the COVID-19 vaccines.¹¹

⁹ World Health Organization. COVID-19 and mandatory vaccination: Ethical considerations: policy brief. May 30, 2022. Available at COVID-19 and mandatory vaccination: Ethical considerations (who.int). Accessed on August 20, 2022.

¹⁰ Beauchamp, Tom, and James Childress. *Principles of Biomedical Ethics*. 8th ed., Oxford University Press, 2019.

¹¹ Adverse events including deaths from the COVID vaccines are already 1000% higher than prior years. <u>https://wonder.cdc.gov/controller/datarequest/D8</u>; <u>https://cf5e727d-d02d-4d71-89ff</u> <u>9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6fbc5935da07322.pdf</u>

- 43. Vaccines occasionally cause adverse events for otherwise healthy people. However small the risk, the fact that there is *some* risk to a person who would have avoided the risk without the vaccine, obligates us to ensure this potential harm is offset by a particularly high magnitude of benefit. In the case of the COVID-19 vaccines, adverse events include myocarditis, stroke, heart attack, Bell's palsy, severe menstrual problems, increased risk of developing "turbo" cancers, neurological conditions, and immune system damage, some of which lead to death. Some of these risks and adverse events were known in the fall of 2021, while others were reasonably foreseeable as being the possible side effects of an experimental vaccine that is, by virtue of its experimental nature, more likely to carry risks.
- 44. What we have learned since 2021 shows that the vaccines are doing exactly what the clinical trials indicated they would do, which is fail to prevent transmission and increase morbidity and mortality in the vaccine group. As a paper by some of the world's top scientists and bioethicists shows, 22,000 30,000 healthy adults aged 18-29 would need to be boosted with an mRNA vaccine to prevent one COVID-19 hospitalization and that, to prevent that one hospitalization, there would be 18-98 serious adverse events.¹² We also learned that vaccination appears to confer, at best, modest protection against longer-term sequelae.¹³ We learned that countries with the highest vaccination rates have the highest COVID and death rates. And we saw a 40% rise in all-cause mortality, a super-disaster given that a 10% rise is a once in 200-year disastrous event. Most of this was reasonably foreseeable in the fall of 2021 with the information available at that time.
- 45. It may be objected that infectious pathogens also kill people, which is certainly true, but these two categories of deaths *are not ethically equivalent*. Infection with a pathogen for which there exists a vaccine is not mandated, whereas deaths resulting from mandatory vaccination are mandated deaths, a harming of some people for the prospective benefit of the majority. Critically, any discrimination against the unvaccinated (or a privileged treatment of the vaccinated) amounts to a violation of the rights to bodily autonomy,

¹² <u>https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4206070#</u>

¹³Al-Aly, Z., Bowe, B. & Xie, Y. Long COVID after breakthrough SARS-CoV-2 infection. *Nat Med.* 2022;28:1461–1467. <u>https://doi.org/10.1038/s41591-022-01840-0</u>

equality, and even life (since a small percentage of the targeted population are expected to die as a result of this coercive treatment).

IV. Autonomy, Medical Decision-Making, and Informed Consent

- 36. While it is not clear COVID-19 vaccination mandates, generally, are supported even on a cost-benefit analysis, the obligation to weigh a potential net benefit from the mandate against autonomy makes it even more difficult to show that such mandates are ethically justified.
- 37. We have heard a lot about autonomy over the last three years, but rarely in favourable terms. The term has been used, and perhaps overused and even misused, to the point that we are becoming desensitized to its meaning and significance. But if we are to understand how to balance it with the collective good, and why it is incumbent on us to do so, then it is worth pausing to consider what it means.
- 38. Autonomy, from the Greek for "self" and "rule," refers to the right of an individual to make informed, voluntary choices under the influence of as little bias, coercion or duress as possible. Tom Beauchamp and James Childress, long regarded as the "fathers of bioethics," describe it in the following way:

"Personal autonomy is, at minimum, self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice. The autonomous individual acts freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and sets its policies. A person of diminished autonomy, by contrast, is in some respect controlled by others or incapable of deliberating or acting on the basis of his or her desires and plans."¹⁴

39. In health care ethics, a patient's autonomy is one of four irreducible and non-fungible duties. In fact, each of the four principles of bioethics—autonomy, nonmaleficence, beneficence, and justice—are taken to be *prima facie* principles. As such, as ethicist W.D.

¹⁴Beauchamp, T.L. and J.F. Childress: 2001, *Principles of Biomedical Ethics* (5th ed.). New York: Oxford University Press. p. 58.

Ross explains, these are duties that are binding or obligatory, other things being equal.¹⁵ Each of these obligations may yield to a more pressing duty (such as when two or more principles conflict with one another as in the smoking example above). This is why discussions of balancing, and not justifications for negating, occupy so much attention in the literature. What it means for autonomy to be a *prima facie* duty is that, in the face of no other sufficiently compelling claim, we have a duty to respect it. An individual's autonomy, in other words, must be respected unless the value of a competing claim is undeniable.

- 40. Those who give priority to the collective good (because, quite likely, of a deeper commitment to the principle of justice) will be unpersuaded by appeals to the importance of autonomy, but they will also be unlikely to be persuaded by many other traditional bioethical commitments (respect for persons, consent, the avoidance of coercion, etc.). There are, of course, arguments that can be made about why autonomy is instrumentally valuable, why a life in which we are unable to make and act on our decisions undermines our physical and mental health, and our happiness and overall well-being. But, in my opinion as an ethicist, autonomy has value over and above this kind of instrumental value because it is constitutive of what it means to be human.
- 41. Bodily autonomy is a constitutive condition of our existence as rational agents. It reflects the fact that personhood is defined largely by our unique set of deeply held beliefs and values (religious, spiritual, ethical, political, scientific, etc.) and on our ability to act on these. Being able to maintain consistency between our beliefs and our actions is essential to integrity, to maintaining the wholeness of our person. *Losing autonomy, and therefore integrity, is tantamount to losing something essential to what makes life worth living*. Autonomy is, therefore, a necessary condition of a good life, and is arguably as valuable as being alive itself. What underpins the idea that autonomy is a *prima facie* good is that, as J. Markovits writes, "I must see myself as having unconditional value—as being an end in myself and the condition of the value of my chosen ends—in virtue of my capacity to bestow worth on my ends by rationally choosing them."¹⁶ The inability to rationally

¹⁵ Ross, W.D. The Right and the Good, Oxford: Oxford University Press, 1930. p. 20

¹⁶ Markovits J. *Moral reason*. Oxford: Oxford University Press, 2014.

choose and act on one's ends has a corruptible effect on personal integrity and therefore identity.

- 42. Every violation of bodily autonomy is, therefore, a partial destruction of individual agency which amounts to a partial destruction of life. Furthermore, violations of autonomy constitute real and immediate harms, and are therefore more ontologically significant than the *risk* of harm to others associated with many personal health care choices.
- 43. It is important to note that autonomy is related to freedom, but distinct from it in that the latter concerns the ability to act without external or internal constraints and also with sufficient resources and power to make one's desires effective. Autonomy, on the other hand, concerns the independence and authenticity of our deeply held beliefs and desires (values, emotions, etc.) that move us to act in the first place. Autonomy reflects who we are, how we prioritize competing values and interests, and who and what we aim to be. This point must be acknowledged to emphasize the importance of autonomy to maintaining our identity-defining beliefs and desires, including those about our health.
- 44. Autonomy's *prima facie* value demands that any time autonomy is encroached on, an argument is needed to show that the relevant restrictions on our freedom are reasonably necessary to preserve something of comparable or greater value. In the case of vaccine mandates, the conscientious objector is at risk of losing not just bodily integrity, though that is a serious enough loss in itself, but also the loss of the integrity of one's constitution created by acting against one's deeply held beliefs and values. Therefore, we must consider whether an individual's possible contribution to herd immunity, for example, offsets the harm of coercively depriving a person of bodily autonomy with respect to a potentially life changing or otherwise irreversible decision about self-constitution.

45. Respect for personal autonomy has, for the above reasons, become the cornerstone of medical legislation, and bioethical codes and documents. Consider the following examples:

- "The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected." (*The Universal Declaration on Bioethics and Human Rights (2005), Article 5*).
- "The interests and welfare of the human being shall prevail over the sole interest of society or science." (*The European Council's Convention for the Protection of Human Rights and Dignity of the Human Being*).
- "Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health." (*The European Charter of Patients' Rights*)
- "The primary duty of the physician is to promote the health and well-being of individual patients... The physician must provide care with the utmost respect for human life and dignity, and for the autonomy and rights of the patient." (*World Medical Association International Code of Medical Ethics*)
- "The patient-physician relationship is at the heart of the practice of medicine. It is a relationship of trust that recognizes the inherent vulnerability of the patient even as the patient is an active participant in their own care. The physician owes a duty of loyalty to protect and further the patient's best interests and goals of care by using the physician's expertise, knowledge, and prudent clinical judgment." (*The Canadian Medical Association's Code of Ethics*).
- "To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments." (*National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974, part B 1*).
- 46. While the instruments and declarations above tend to focus on the duties of physicians to patients, and while the COVID-19 narrative has notably displaced the physician-patient

relationship with the state-patient relationship, each of the main health care ethics instruments gives lexical priority to the rights of individual patients over the group, and to respect for patient autonomy as fundamental and primary to the practice of medicine. This does not mean that consideration of the effects of one's health care choices on populations should be disregarded, but that to do so without careful consideration of reasons is to ignore the irreducible priority of individual patients' rights.

- 47. For this reason, vaccination mandates, which systematically disregard individual bodily autonomy for the sake of the ostensible collective good (and typically without allowances for exemption on the basis of conscientious objections) run roughshod over a longstanding and carefully articulated system of health care ethics. This is an additional reason why requests for exemptions on the basis of statutory human rights protections must be very seriously considered and weighed against the possible benefits of their denial.
- 48. How does autonomy relate to the ethics of COVID-19 vaccination? The moral obligation to vaccinate is a powerful part of the COVID-19 narrative, creating a presumption that a person's primary moral obligation is to become vaccinated for the sake of others. As an article in the New York Times from May 2021 stated, "It is a moment of both obligation and opportunity."¹⁷ And the Canadian Medical Association lists vaccination as a physician's obligation of non-maleficence to patients. (Whether COVID-19 vaccines fulfill this obligation in practice is another matter.) Underlying this presumption is the idea that our personal freedom to accept or refuse a medical intervention (such as vaccination) has a lower moral status than the potential benefits of vaccination to others. Conscientious or religious objections to vaccination mandates are typically dismissed because, while we might recognize that autonomy has some value, we assume that, in situations of crisis, autonomy has less lexical moral priority than the utilitarian value of actions that may benefit others. If autonomy does have less moral value, then this is a notable departure from the history of health care ethics which gives irreducible moral priority to *each* of the four principles. And again, if a decision favours justice over autonomy, the moral remainder should be regarded as regrettable rather than justifiably ignored.

¹⁷ <u>https://www.nytimes.com/2021/05/14/opinion/biden-covid-vaccines-world-india.html.</u>

- 49. It is worth noting the inherent subjectivity of the way autonomy must be respected. The communication process involved in a physician obtaining informed consent, for example, must be compassionate and respectful of the patient's unique values, even if they differ from those of the health care provider, public health policy makers, or even the standard goals of biomedicine. Support for autonomous medical decision-making must occur within the context of the patient-doctor relationship in which there is an implicit covenant and bilateral trust between the doctor and patient.
- 50. The concept of moral decision-making assumes that rational agents are capable of making informed and voluntary choices. With respect to health care decisions, respect for autonomy reflects the recognition that persons have the capacity to act intentionally, with understanding, and without controlling influences that would mitigate against free and voluntary acts. This principle is the basis for the practice of "informed consent" in the physician-patient relationship.
- 51. This crucial element of informed consent that has been overlooked the last three years is that it is not about what is best from an objective point of view. Consent is, by nature, personal and subjective. It is about a particular person's deeply held beliefs and values, and should reflect the risks *that* particular person is willing to take. When it comes to making health care decisions, individuals tend to differ in their assessment of risk, for example. Some will opt to take a chance while others will not. Risk averseness depends on many factors including one's life experience, age and gender, personality, health status, life plans, the existence of family and other personal relationships, and religious and conscientious beliefs, etc. A person with end-stage cancer may be more willing to participate in a cancer drug trial with unknown or known severe side effects. A person with a young family may be less likely to take on risks that threaten their employment status. Applying a rule that forces all of us to behave in the same way, assuming the same level of risk, is an affront to personal autonomy and is likely to generate much reasonable resistance. Judge Corkery made this point in a case involving a 12-year-old trying to resist her father's request to be vaccinated when he wrote: "Even if I were to take judicial notice

of the "safety" and "efficacy" of the vaccine, I still have no basis for assessing what that means for *this* child."¹⁸

- 52. Furthermore, informed consent depends on many variables and comes in degrees, as does the voluntariness of choice. Dynamic informed consent becomes more necessary the riskier the intervention, the more it is high-impact (e.g. a definitive "critical life choice"), the more it is value-laden and controversial, the more private the area of the body that the intervention directly affects, and the more conflicted the practitioner or the recipient. The need for informed consent is, in other words, scalar. COVID-19 vaccination is a risky intervention; it is also a high-impact, critical life choice which is deeply value-laden given creed-based beliefs such as Mrs. Porter's.
- 53. Autonomy also circumscribes the role of others who might influence the patient to make a decision that does not reflect their own wishes or best interests. In clinical practice, unthinking acquiescence to public health legislation which is presented as being for the sake of the public good, but which is against the patient's choice and/or the physician's clinical judgment about what is in the patient's best interest, is an abrogation of the duty of health care providers.
- 54. In summary, while balancing the four central principles of bioethics—autonomy, nonmaleficence, beneficence and justice—when they conflict can be difficult, the *prima facie* nature of each obligates us to consider what conditions must be met before it becomes reasonable to limit personal autonomy when it conflicts with other principles (the obligation to prevent harm to others, for example).

¹⁸ <u>M.M. v W.A.K., 2022 ONSC 4580</u>, at paragraph 43 [emphasis original].

V. Choice and Coercion

- 54. According to Tom Beauchamp and James Childress (the "fathers of bioethics"), autonomy "is undermined by coercion, persuasion, and manipulation"¹⁹ and the "underlying principle and justification of informed consent requirements... is a moral principle of respect for autonomy."²⁰ To make a voluntary choice is, at minimum, to do what one would do in the absence of coercion, persuasion, or manipulation. It is especially important that individuals make health care choices based on the perceived intrinsic value of those choices and not for extrinsic reasons. It is important a person's decision to undergo surgery, for example, be on account of the inherent benefits of the surgery itself and not because of extrinsic reasons such as financial gain, public pressure, or pressure from a doctor.
- 55. Furthermore, it is important to think about autonomy as creating both 'negative' and 'positive' duties. The negative duty refers to what we must *not* do: autonomous actions should not be subject to controlling constraints by others. But this is not enough. Autonomy also requires the respectful disclosure of information so people can make a full and free choice. Respecting autonomy isn't just about obtaining permission; it is about empowering a person to make her own decision so there is confidence their choice is as free and reflective of their identity as possible under the circumstances.
- 56. The moral concept of autonomy has, historically, been important to the courts of Ontario. In 1991, Justice Robins of the Ontario Court of Appeal stated:

The right to determine what shall, or shall not, be done with one's own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law. This right underlies the doctrine of informed consent. With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self-determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the

¹⁹ Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 4th ed. New York, NY: Oxford University Press; 1994. p. 58.

²⁰ Faden, Ruth and Beauchamp, Tom. *A History and Theory of Informed Consent*. New York: Oxford University Press, 1986. p. 216.

doctor, who ultimately must decide if treatment - any treatment - is to be administered. $^{21}\,$

- 57. It is often underappreciated the degree to which vaccine mandates are inevitably coercive. Consider the fact such mandates divide the mandated into three groups: (1) Those who would have done what the mandate demands even without it (making the mandate unnecessary); (2) Those who will not do what the mandate demands even with it (making the mandate ineffective); and (3) Those who choose to do what the mandate demands only because of it (which makes their choice coerced).
- 58. When an employee is mandated to receive a vaccination to which she objects, that employee is economically coerced to participate in an activity where some percentage of employees are expected to be harmed 'in the course of employment' as a direct result of the mandated activity. To whatever degree they might be justified, employment vaccine mandates are, by definition, coercive health care policies. They impose a consequence on persons who, in the absence of the threat of the loss of employment, would not voluntarily choose vaccination (if the person would voluntarily agree to vaccination, the mandate would not be necessary.)
- 59. Since maintaining one's employment is at least partly a financial interest, vaccine mandates financially incentivize one's health care choice to be vaccinated (and perhaps to quite a significant degree if the consequence is loss of employment altogether, as in the case of Mrs. Porter). So, the question becomes when, if ever, is it ethically justified to financially incentivize a person's medical decision-making, contravening a person's own autonomous choice?
- 60. The issue of coercion highlights the moral difference between *mere choice* and *free choice*. Some choices are, in fact, coercive in nature. These type of choices, while logically involving choice because more than one option may be chosen, cannot be said to be free or voluntary.

²¹ *Fleming v Reid*, [1991] O.J. No. 1083, at paragraph 33.

- 61. A surprising and disappointing feature of most, if not all, court decisions regarding COVID-19 vaccine mandates is a closing of the moral space between free, informed choice on the one hand, and forced action on the other, even to the point of defining non-physical coercion out of existence.
- 62. Consider, for example, the recent case of *Hawke v Western University*, in which five Western University students challenged the University's COVID-19 vaccine mandate. Among other things, the students claimed the University's COVID-19 vaccine requirement was coercive, forcing upon students a choice between the two undesirable alternatives of either receiving into their body an injection they did not want or abandoning their postsecondary studies. However, in her judgment, Justice Tranquilli rejected this claim by stating:

I do not agree with the applicants' characterization of the Policy as being "coercive" in nature. I do not accept the Policy will "force" members of the university community to disclose their personal information. The Policy forces individuals to choose between two alternatives, even if they like neither option. The choice is the individual's to make. Each choice comes with its own consequences. That is the nature of choices[.]²²

63. Many similar cases involving COVID-related mandates have failed for the same reason: because judges deny the coercive nature of the mandates. The judges in these cases take for granted that mandates simply offer a choice, the consequences of which may both be undesirable for some choosers. It is important, therefore, to consider what are the likely consequences of eliminating the moral space between free, voluntary choice and strict physical force (someone who is stronger than you using your hand to slap someone else, for example).

²² <u>Hawke v Western University</u>, 2022 ONSC 5243, at paragraph 71.

64. Bioethics literature is very clear medical coercion is a direct affront to free, voluntary consent. Coercion is present when a person is literally able to select from more than one option but she feels pressure or duress in doing so. For example, in its guidebook for physicians on consent, the Canadian Medical Protective Association stated:

Patients must always be free to consent to or refuse treatment, and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated.

physicians should be more than usually careful to assure themselves patients are in full agreement with what has been suggested, that there has been no coercion and that the will of other persons has not been imposed on the patient."²³

- 65. More generally, the literature also recognizes this difference between mere choice and free choice. Mere choice is when it is literally possible to select from more than one option, however undesirable each of those options may be. If someone holds a gun to your head with the demand that you turn over your wallet, you can literally choose to surrender your wallet or not. In cases like this, it is possible to choose between more than one alternative, even though the consequences of both are undesirable.
- 66. Consider also the following two health care examples. Suppose your physician withholds pharmaceutical products until you submit to perform sexual acts. You can choose to refuse the sexual act and do without the drug or, conversely, accept the drug and submit to the sexual act. Is your choice free of coercion? Or consider a poor person who knows that his only way to gain access to an expensive life-saving drug is to participate in a risky study where the drug is provided free of charge. He is not, strictly speaking, forced to participate but, because none of the options available to him are decent, his consent is involuntary and the trial is unethical.
- 67. Perhaps for these reasons, the avoidance of coercion is treated as even more important than consent in medical ethics. For example, research with no consent is permissible under certain conditions but the use of coercion is always impermissible. This is because

²³ <u>https://www.cmpa-acpm.ca/en/advice-publications/handbooks/consent-a-guide-for-canadian-physicians</u>

coercion undermines the voluntariness of a person's decision whether to enroll in research and, therefore, is frequently inconsistent with valid consent. Coercion involves person A proposing to render person B significantly worse off if B does not do what A wants. While coercion increases—sometimes dramatically—the costs of selecting one option over another, it does not eliminate choice altogether. One can still choose. But coercion violates respect for autonomy to a greater extent than does the use of deception or simply using people without their knowledge.

- 68. Health care ethics, and practical ethics more generally, has recognized that we can do better than dissect the terrain of choice as bluntly as Justice Tranquilli did in *Hawke v Western University*, and that a more nuanced understanding of the conditions that make our choices free versus constrained is ethically required. If our choices are to be truly free and expressive of who we are as persons, we require dynamic choice, choice situations which do not threaten what is constitutive of who we are. Fully free autonomous choice has come to be the gold standard of choice in health care ethics. We now recognize that the lack of decent alternatives to accepting a bad offer, the so-called "no choice" situation, makes us forced or compelled to choose the offer, and therefore undermines voluntariness, and should be avoided whenever possible. While in these cases, indecent alternatives are open to us, this is also true in "your money or your life" situations in which the option of dying is possible. But we would not say that anyone who gives up their money to avoid dying has done so freely and as a representation of their deeply held beliefs and values. These are cases of coercion and, as such, occupy the moral space between physical force and actual free choice.
- 69. The mere presence of a choice that did not involve physical force does not therefore indicate the presence of free choice. Medical consent must be free—non-coerced—in order to be valid. Without it, we have no rights at all; every other right can be subverted by medical coercion. Mrs. Porter, like all other persons subject to a vaccine mandate, is able to choose. But her choice was not free or voluntary, it was a mere choice—a coerced choice—because it was a choice between violating her sincerely held religious beliefs or losing a job she both derived meaning from and depending upon for income. From an

[25]

ethical perspective, it is unreasonable, indeed unintelligible, to characterize such a choice as somehow a non-coercive choice.

- 70. As Heuston and Buckley put it: "A man cannot be said to be 'willing' unless he is in a position to choose freely; and freedom of choice predicates the absence from his mind of any feeling of constraint interfering with the freedom of his will."²⁴ A "feeling of constraint" so as to "interfere with the freedom of a person's will" can arise in a number of situations not involving force, threats of force, fraud, or incapacity. The concept of consent as it operates in tort law is based on a presumption of individual autonomy and free will. It is presumed that the individual has real freedom to choose to consent or not. This presumption, however, is untenable in certain circumstances. A position of relative weakness can, in some circumstances, interfere with the freedom of a person's will. Our notion of free choice must, therefore, be modified to appreciate the power relationship between the parties.
- 71. Heuston and Buckley elaborate that an assumption of individual autonomy and free will is also the underlying premise of contract law, which has evolved in such a way that it recognizes that contracting parties do not always have equality in their bargaining strength. The doctrines of duress, undue influence, and unconscionability have arisen to protect the vulnerable when they are in a relationship of unequal power. For reasons of public policy, the law will not always hold weaker parties to the bargains they make.
- 72. And Professor Klippert, in his book *Unjust Enrichment* (1983), refers to duress, undue influence, and unconscionability as "justice factors."²⁵ He lumps these together under the general term "coercion" and states that, "In essence the common thread is an illegitimate use of power or unlawful pressure which vitiates a person's freedom of choice." In a situation where an individual is induced to enter into an unconscionable transaction

²⁴ Heuston, R.F.V. and Buckley, R.A. *Salmond and Heuston on the Law of Torts,* 19th ed. Sweet & Maxwell, 1987, pp. 564-65.

²⁵ Klippert, G. B. Unjust Enrichment. 1983. p. 156.

because of an inequitable disparity in bargaining strength, it cannot be said that the individual's act is voluntary.

- 73. If the "justice factor" of unconscionability and duress is used to address the issue of voluntariness in the laws of contract and tort, then it seems reasonable that it be invoked to assess the issue of voluntariness when it comes to the choice to comply with or refuse to comply with vaccination mandates. The principles that have been developed in the area of contract law to negate the legal effectiveness of certain contracts provide a useful framework for the evaluation of the level of freedom and coercion present in cases of mandated health care procedures such as Mrs. Porter's.
- 74. Eliminating the possibility of coercion in vaccine mandate cases risks eliminating all recognition of coercion except in scenarios involving physical force. Consider the case of *Norberg v Wynrib*,²⁶ which concerns the power dynamic impacting consent to sexual activities in the health care setting. Dr. Wynrib suggested to Ms. Norberg that she could receive painkillers only if she submitted to sexual activities with him. Ms. Norberg submitted but eventually sued Dr. Wynrib for, among other things, the tort of battery in relation to the sexual activities. The doctor advanced the defence of consent. The Supreme Court of British Columbia dismissed her claim, finding that she had given implied consent to the sexual activities because she never said she did not want to perform the acts. Eventually a majority of the Supreme Court of Canada ruled in Mrs. Norberg's favour, recognizing the power relationship between the parties. The Court found Ms. Norberg's consent had been vitiated in the exploitative circumstances of her drug addiction and total dependence on the doctor to obtain more drugs.
- 75. Norberg v Wynrib reveals the importance of creating moral space that exists between physical force at one end of a spectrum and uncoerced, freely-chosen consent at the other. The mere fact Ms. Norberg was able to choose access to drugs on condition of sex was not enough to make her choice *free*. It was a choice that severely compromised who she was as

²⁶ [1992] 2 S.C.R. 226.

a person (constitutive) because of the way the doctor framed the choice. As the Supreme Court stated:

The concept of consent as it operates in tort law is based on a presumption of individual autonomy and free will. *In some circumstances, a position of relative weakness can interfere with the freedom of a person's will.* Accordingly, our notion of consent must involve an appreciation of the power relationship between the parties.²⁷

VI. Conclusion

81. Vaccine mandates are largely about balancing two of the four *prima facie* bioethics principles: autonomy and justice considerations for others. Neither of these can simply be ignored in favour of the other but must be balanced. Considerations relevant to the balancing involve the conditions that must be met to establish a threshold of clear benefit versus harm, the reasons for respecting personal autonomy, and the costs of eliminating an understanding of the coercive nature of mandates. Mandatory workforce COVID-19 vaccination, especially when coupled with a refusal to accommodate sincere conscientious objectors such as Mrs. Porter, does not produce demonstrated benefit over costs and, therefore, lacks ethical justification, including in the context of a health care workforce.

DATE: March 24, 2023

DR. JULIE PONESSE

²⁷ Norberg v Wynrib, at paragraph 27 [emphasis added].