CHEMISTRY and CHEMICAL BIOLOGY

McMaster University

15 October, 2021

Dr. Karen Mossman
VP Research, McMaster University

Re: McMaster's Vaccination Policy - COVID-19 Requirements for Employees and Students: A Good Faith Letter in Defense of Research Ethics and Human Dignity

Dear Karen,

As a tenured Professor and bioanalytical chemist in the Department of Chemistry and Chemical Biology with a passion for clinical biomarker discovery, universal newborn screening, and population health, I am writing to you to express my *profound ethical and scientific misgivings* regarding McMaster's Vaccination Policy. I am concerned that the mandate is unnecessary and will not fulfill its stated goals given recent 'real-world' evidence of *waning* vaccine efficacy that does *not* halt viral transmission *nor* prevent infection among the fully vaccinated. Moreover, this callously enforced policy is causing much disruption, division, and distress among vulnerable members of the McMaster community (e.g., women in tenuous positions), including staff resentment (including those whom have been recently coerced to be inoculated to retain their position), a potential loss of talented professionals, and a legal quagmire that may permanently tarnish the reputation of the university. After 18 years of service to McMaster and nearing the peak of my group's research productivity with an extensive array of collaborators from across campus, I am faced with a *severe moral crisis* as the present actions of this institution betray my deeply held convictions related to **biomedical ethics, informed consent, high quality evidence to inform policy, and patient autonomy to make decisions over bodily integrity as opposed to technocratic models of health.** These intellectual virtues and freedoms are now under assault ostensibly to reduce COVID-19 cases and promote health and safety in the workplace, which I assert are *ill-founded and will likely fail despite their best intentions*.

For these reasons, I have decided to *not* disclose my private medical information and vaccination status, and *do not* provide my consent to the University in reviewing a non-medical exemption application or submit to surveillance, and asymptomatic testing that is simply *not* fit for purpose. By doing so, I would only be legitimizing what I consider a deeply flawed, and discriminatory policy. I have strived to diligently fulfill all my workplace obligations during the pandemic, yet I simply *cannot* endorse policies based on segregation, exclusion and stigmatization (*i.e.,* medical apartheid) hastily implemented without transparency or open debate after months of contradictory statements that such policies would *not* be introduced. My decision as a sovereign living human, who exists naturally, constitutes a **conscientious objection to an unethical policy that cannot be medically justified or legally mandated based on recent scientific evidence that is rapidly evolving.** I will strive to apply *the scientific method to disprove* the assumptions claimed in the McMaster's Vaccination Policy, namely: 1. The policy will *mitigate* viral transmission of the SARS-Cov2 Delta variant on campus, 2. The policy will *promote* health and safety in the workplace, and 3. The policy is reasonable and justifiable as a *bona fide job requirement*. The **precautionary principle** implies that the *burden of evidence* is on those proposing new policies without bias or politicization while treating employees with respect and dignity instead of vessels of contagion.

I sincerely urge that members of the McMaster University Vaccine Validation Team (MUVVT) address the *following 6 questions* prior to enforcing draconian policies directly impacting the livelihood of many hardworking employees and their families. I believe that forethought may also reduce potentially grave collateral damage and legal consequences that are preventable if policy makers remain open to dissenting viewpoints even if it may contradict dominant narratives given rapidly evolving scientific evidence.

1. Please explain why *natural immunity* is not considered a viable exemption to vaccination?
There is now irrefutable evidence that natural immunity from prior exposure to SARS-CoV-2 viral infection, or even preexisting immunity to related corona viruses [*Science* **2020**, 374, eabh1823] provides *robust and long-lived immunity* that is comparable and likely superior to vaccine-induced immunity [*BMJ* **2021**; 374, n2101] notably for SARS-CoV-2 variants [*Nature* **2021**; https://doi.org/10.1038/s41586-021-04085-y]. More concerning, COVID-19 recovered patients are prone to a *greater risk* for adverse effects post-vaccination [*Cell Rep.* **2021**;36:109570; *Life* **2021**;11:249]. Why would the MUVVT force COVID-19 recovered individuals (many of whom may have been asymptomatic) to unnecessary risk when they are not a threat to the health and safety of others? If fact, COVID-19 recovered individuals are *less* susceptible to breakthrough infections as compared vaccine-induced immunity for the Delta variant, which would be highly desirable for healthcare workers. In fact, Premier Doug Ford is allowing proof for natural immunity among Ontario MPPs as the National Advisory Committee on Immunization states it is a discretionary recommendation. As a result, omission of natural immunity does *not* constitute a reasonable or medically sound policy as it can only cause unnecessary harm without benefits to McMaster community members.

2. Please provide evidence to support the *current efficacy* of mRNA-based COVID-19 vaccines against the now dominant Delta variant (B.1.617.2) that forms the basis to the university's vaccine mandate.
If McMaster's vaccination policy is *truly* aimed to mitigate viral contagion and promote health and safety of others on campus, could you provide evidence that supports that being 'fully vaccinated' is equivalent to being immune from SARS-CoV-2 infection (i.e., breakthrough cases) notably for the highly transmissible and vaccine-evasive Delta variant. For example, recent data from the US suggests that symptomatic breakthrough infections among fully vaccinated individuals may potentially transmit COVID-19 as *efficiently* as unvaccinated infections [doi: https://doi.org/10.1101/2021.08.19.21262139]. Furthermore, *no* differences exist in *viral load* between vaccinated and unvaccinated, asymptomatic and symptomatic groups [doi: https://doi.org/10.1101/2021.09.28.21264262] rendering vaccine certification and asymptomatic testing of solely unvaccinated individuals completely *without* merit. This rapidly changing landscape highlights the folly of vaccine mandates for experimental biologics that are still undergoing phase 3 clinical trials with poorly understood mechanisms of action. These novel gene-based products are best considered as 'short-lived' therapeutics rather than classic vaccines given their waning protection against infection within a few months. In fact, recent epidemiological data demonstrates a *weak positive correlation* between the fraction of population fully vaccinated and the number of new COVID-19 cases as confirmed across 68 countries as of September 3, 2021 [*Eur. J. Epidemiol.* **2021**. https://doi.org/10.1007/s10654-021-00808-7]. In light of these recent findings, McMaster's vaccine mandate is unreasonable as it may *paradoxically contribute to a greater risk for viral transmission* on campus this winter as fully vaccinated individuals are not tested while potentially having blunted COVID-19 symptoms. At the same time, this policy *unfairly discriminates* against otherwise healthy unvaccinated individuals who are tested biweekly even if asymptomatic, or otherwise banished from campus, or subject to wrongful dismissal. Thus, in my opinion there is **no legitimate public health prerogative** (i.e., protecting others from viral transmission) that can justify the current vaccine policy at McMaster.

3. Please explain why McMaster University is *mandating vaccinations without liability* yet insists that employees take responsibility for assessing the benefits/risks of COVID-19 biological products?

I find it *morally abhorrent* that the institution and policy makers are not accepting liability for any potential vaccine related injuries yet threaten employees with dismissal while using narrowly defined exemptions. This is an authoritarian model for a university to consider as it lacks any meaningful persuasion. The vaccine mandate is particularly egregious given the unacceptably high rate of myocarditis and pericarditis reported for healthy young male adults (1:5000 following a second Moderna dose based on recent estimates from Public Health Ontario) who comprise a major fraction of the McMaster community. Why would the MUVVT actively threaten young males (< 30 years) with expulsion who have a median infection fatality rate (IFR) for COVID-19 of 0.014% [doi: https://doi.org/10.1101/2021.07.08.21260210] while facing an approximate 0.020% risk for vaccine-induced myocarditis (likely underestimated) – not to mention a myriad of other rare yet *proportionally significant* adverse events and unknown long-term effects? In fact, most Scandinavian countries have now restricted the Moderna mRNA inoculation for young adults and totally rescinded vaccine mandates and other ineffective non-pharmaceutical interventions for *an endemic virus*. Vaccine safety is *paramount* when mandating it to low-risk demographics especially if any putative public health benefit related to reducing transmission is now largely *obsolete*. In fact, US data suggests that the Pfizer mRNA biologic product is also temporally associated with elevated risks for myocarditis in young males that is far greater than normal background rates, as well as all other known vaccines [*Curr. Probl. Cardiol.* **2021:** 101011]. Does the university keep track of any vaccine related injuries among staff, faculty and students and update their policy accordingly? Myocarditis is not a minor ailment as it can require hospitalization, lead to heart failure with lifelong consequences. As a result, there is **no legitimate reason** to mandate investigational vaccines on healthy employees without comorbidities given the efficacy and safety of *vitamin D prophylaxis* for boosting immunity and reducing viral infection and COVID-19 disease burden [*Cardiol. J.* **2021** 28:647]; **why is diet/nutrition *not* a core component of your policy?**

4. Please explain why McMaster is explicitly *violating universal principles* of biomedical ethics and human dignity as related to informed consent and experimental medical procedures?

McMaster University has regrettably issued constant threats of loss of livelihood, mobility restrictions, or submission to unapproved testing or disciplinary action for noncompliance that are gross violations of international law, including *Nuremberg Code* (1947, *all 10 points*), the *Declaration of Helsinki* (1964, *articles 13, 16-17, 27, 29, 30, 32*) and the *Universal Declaration on Bioethics and Human Rights* (UNESCO 2005, *articles 3-6*). The latter includes **universal principles** related to human dignity and human rights with the interests and the welfare of the *individual having priority* over the interest of society, and *autonomy of individuals* to make medical decisions and to refuse a treatment *without* disadvantage or prejudice. Obtaining consent through deceptive or forceful means does not legally (or morally) signify consent. These guiding medical principles supersede any provincial 'directives', and there exists *no* notwithstanding clauses for pandemics or governmental emergencies given past human injustices and war atrocities conducted ostensibly for the 'common good'. How can MUVVT defend this overt violation to biomedical ethics and human dignity while treating their employees in such an abusive, disrespectful and patriarchal manner based on a mere directive for a policy from an unaccountable health bureaucrat? This also contradicts McMaster's Strategic Plan for Research (2018-2023, Living Our Core Values) that insists on the primacy of *research ethics.* Does administration at McMaster University now consider that these foundational biomedical ethical principles are no longer valid in a post-COVID-19 era? If so, please provide a *public statement* to disavow them and immediately shut down our reputable research ethic boards (MREB, HiREB) as no longer being essential for future clinical investigations in light of your current policy.

5. Please clarify why rapid antigen tests for COVID-19 are applied *only* to unvaccinated/undisclosed individuals if promoting health and safety in the workplace is the main objective?

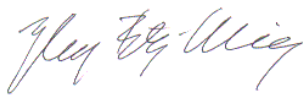
If control of COVID-19 is your policy objective, and the Delta variant is more infectious than the original SARS-CoV-2 viral strain, and, that the fully vaccinated can still contract asymptotic infections that risks them coming to work sick and spreading the virus, why are you *not* currently testing the immune status of *all* staff *regardless* of vaccination status? For example, Cornell University and Harvard University have implemented rapid antigen self-testing for *all* personnel on their campuses given this reality. Also, rapid antigen tests for nasal specimens are a FDA emergency use authorized *in-vitro* diagnostic kit, which have "a potential risk for false negatives with either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations" [https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2]. Public Health Ontario also acknowledges that such point-of-care test kits are *not* a diagnostic result and are also susceptible to false positives, and are best applied when there is a *high pre-test probability* for infection, such as individuals with symptoms or in close contact with confirmed COVID-19 cases that would constitute a reasonable policy. Please provide details regarding the *performance characteristics* of the rapid antigen test kit (Abbott PanBio) for the Delta variant (e.g., positive predictive value), and a rationale on why asymptomatic screening is *unfairly* targeting *only* the unvaccinated. Moreover, workplace testing requires an employee's written informed consent as it violates OHSA policies, which cannot be legally acquired using *coercion* (e.g., threats of job loss) nor applied in a *discriminatory* manner.

6. Please disclose the minutes of meetings and conflicts of interest involving members who formulated the McMaster Vaccination Policy, as well as a formal cost-benefit and job analysis?

Given the impacts that this divisive policy is having among many employees across campus, it is vital that *full transparency* is provided to members of the McMaster community on the decision-making process. Could you please clarify who were the 'McMaster experts' and other influential policy makers while also disclosing any potential financial conflicts of interest. Was a diverse group of researchers offered an opportunity to guide this policy based on the highest quality of evidence, including dissenting voices and individuals with expertise in other relevant domains, such as clinical testing, nutrition and research ethics? Please openly publish a formal *cost-benefit analysis* that 'COVID Safe Passes' (i.e., MacCheck Digital Tool) would effectively *mitigate* viral transmission of the Delta variant and promote health and safety on campus beyond mere assertions that cannot be challenged. Please also provide a *detailed job analysis* that would justify these measures as a *bona fide job requirement* for otherwise healthy personnel in a low-risk university setting who are taking reasonable precautions with existing measures. Also, explain why other major universities in Canada (McGill, UBC) are not implementing vaccines mandates on their employees.

In summary, I sincerely hope that you consider my reasonable critiques to the University's Vaccination Policy in good faith, and re-consider how you enforce these policies in light of emerging scientific evidence.

Sincerely,



Dr. Philip Britz-McKibbin
Professor and Cystic Fibrosis Canada Researcher
Department of Chemistry and Chemical Biology
McMaster University, Hamilton, ON, Canada
Email: britz@mcmaster.ca Webpage: https://britz.mcmaster.ca/