

September 6, 2023

## RE: **OPEN LETTER<sup>1</sup>** on the Safety and Effectiveness of **COVID-19 Vaccines**

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<sup>1</sup> Also published at <https://hervk102.substack.com/publish/post/136760387>

Dear Patrick,

I would like to take this opportunity to congratulate you on becoming the Executive Director of the Bureau of Biologics, Pharmaceuticals and Self-Care Products. I have always admired your sage and no-nonsense approach to dealing with unacceptable post-marketing risks of new biological therapeutic products. This was witnessed for Raptiva (efalizumab), a monoclonal antibody used in psoriasis patients that became withdrawn from the Canadian, European, and USA<sup>2</sup> markets in 2009. This was due to four cases and **three confirmed deaths** from progressive multifocal encephalopathy (PML, caused by a lytic infection of oligodendrocytes by human polyomavirus, JCV).

I see there have been a lot of changes at the Marketed Health Products Directorate since 2007-2008 when I was seconded to your division to learn about post-market surveillance of newer biological products. This was the best learning experience about the consequences of immunosuppressive monoclonal antibodies to monocytes and how it may lead to increased mortality risks. Presumably other immunosuppressive drugs such as statins or herbal medicines such as turmeric may also convey these increased risks if continued in the longer term. The side effects of immunosuppressive drugs such as Raptiva ranged from the rare and fatal PML cases to the more commonly observed myocardial

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<sup>2</sup> DeFrancesco, L. RIP Raptiva?. *Nat Biotechnol* **27**, 303 (2009). <https://doi.org/10.1038/nbt0409-303>.

infarctions where mortality risks increased proportionately to duration of immunosuppression. You would be happy to know that the knowledge gained from this valuable experience led to the publication of the new immunosenescence paradigm of macrophages in 2015.<sup>3</sup> This novel paradigm attempts to explain how the failed lytic release of HERV-K102 protector particles<sup>4</sup> from foamy macrophages is not only associated with increased risks of tumors and infectious diseases but also chronic diseases including atherosclerosis and cardiovascular disease risks which are linked to aging and/or stress.

I have also noticed that on behalf of the Marketed Health Products Directorate, you attend the monthly National Advisory Committee on Immunization (NACI) meetings, as I once did while Research Manager of the Blood Zoonotics Unit at PHAC. This involvement is pertinent to the issues of the

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<sup>3</sup> Laderoute, MP. A new paradigm about HERV-K102 particle production and blocked release to explain cortisol mediated immunosenescence and age-associated risk of chronic disease. *Discov Med.* 2015 Dec;20(112):379-91.

<sup>4</sup> Discovered at the PHAC and where worldwide patents were applied for by 2006; see Laderoute MP, Giulivi A, Larocque L, et al. The replicative activity of human endogenous retrovirus K102 (HERV-K102) with HIV viremia. *AIDS.* 2007 Nov 30;21(18):2417-24.; Laderoute MP, Larocque LJ, Giulivi A, Diaz-Mitoma F. Further evidence that human endogenous retrovirus K102 is a replication competent foamy virus that may antagonize HIV-1 replication. *Open AIDS J.* 2015 Dec 7;9:112-22. doi: 10.2174/1874613601509010112., and Laderoute MP. Clues to finding correlates of risk/protection for HIV-1 vaccines [version 2; peer review: 2 approved with reservations] *F1000 Research* 2018, 6:868. <https://doi.org/10.12688/f1000research.11818.2>.

post-market **failed** safety and effectiveness of the COVID-19 mRNA vaccines and in my humble opinion, clearly needs a closer inspection and intervention by NACI, PHAC and HC.

If I may, I would like to share the data questioning the safety and effectiveness of the COVID-19 vaccines in general, and more specifically with respect to the safety of the mRNA gene therapy, SARS-CoV-2 spike gene, injections. These mRNA gene therapy products have been marketed in Canada since **September 16, 2021** under the names of COMIRNATY by Pfizer and SPIKEVAX by Moderna. As an immunologist with a history of working with the Brighton Collaboration on vaccine safety, I would hesitate to call these injections 'COVID-19 vaccines' but since they are colloquially known as the mRNA COVID-19 vaccines, this terminology will be reluctantly used here.

## **IgG1/3 Antibodies to Spike Protein ARE Dangerous and Threaten the Safety of COVID-19 Vaccines**

Recently, it was argued that HERV-K102 particle production in foamy macrophages and release by lysis, may form the basis of 'trained INNATE immunity' which seems to provide **the critical interferon based potent INNATE immune protection** against pandemic RNA viruses like SARS-CoV-2 and/or HIV-

1.<sup>5</sup> Indeed, in the latter submitted paper it is argued that the problem of antibody dependent enhancement (**ADE**) of infection into monocytes-macrophages associated with the development of IgG1 and IgG3 antibodies to spike protein *as induced by the COVID-19 vaccines*, annihilates the critical host defense against SARS-CoV-2. Worse yet, this infection of monocytes/macrophages provides an immunologically privileged site for the unimpeded replication of SARS-CoV-2<sup>6</sup> as illustrated in **Figure 1**.

Thus, **ADE** not only antagonises the most critical host defences that provide non-pathogen specific protection mechanisms against emerging and/or pandemic viruses but enhances the production of SARS-CoV-2 virions in an immunologically isolated environment.<sup>6</sup> It likely also enhances macrophage immunosenescence (defined as a failure to release the protector foamy virus HERV-K102 particles by lysis of the foamy macrophages),<sup>3</sup> which contributes to failed immune surveillance against infectious agents and cancers as well as produces an increased risk of chronic disease including cardiovascular.<sup>5</sup> Accordingly, it is easy to see how **ADE** increases the risk of severe disease and

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<sup>5</sup> **Laderoute MP.** Trained immunity involving HERV-K102 activation in foamy macrophages may promote recovery from COVID-19 providing a new innate immunity vaccination paradigm against pandemic RNA viruses. Invited Review *Submitted July 31, 2023* (available upon request).

<sup>6</sup> Dias SSG, Soares VC, Ferreira AC, et al. Lipid droplets fuel SARS-CoV-2 replication and production of inflammatory mediators. *PLoS Pathog.* 2020 Dec 16;16(12):e1009127. doi: 10.1371/journal.ppat.1009127.

mortality pertaining to SARS-CoV-2 infection whether or not the variants cause pneumonia. Thus, adaptive immunity vaccines involving SARS-CoV-2 spike protein have not, cannot, and will not provide a safe and effective solution to the COVID-19 pandemic, which we know well from the attempts to do so for HIV-1, another enveloped RNA pandemic virus.

This then brings us to the issue of what other interventions may reduce severity risks of pandemics (aside from upper respiratory tract sprays and lavages to reduce the inoculum). Remarkably as also captured in [Figure 1](#) adequate plasma levels of vitamin D3 to sufficiently activate the VDR would block this transition<sup>7</sup> from the pro-inflammatory and protector M1-like foamy macrophages to the anti-inflammatory M2-like foamy macrophages that harbour replicating pathogens.<sup>6</sup> Thus, optimal vitamin D3 ([cholecalciferol](#)) blood levels would be expected to greatly reduce the risk of COVID-19 mortality (and probably other infectious diseases including commonly influenza).

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<sup>7</sup> Oh J, Weng S, Felton SK, et al. 1,25(OH)<sub>2</sub> vitamin D inhibits foam cell formation and suppresses macrophage cholesterol uptake in patients with type 2 diabetes mellitus. *Circulation*. 2009 Aug 25;120(8):687-98. doi: 10.1161/CIRCULATIONAHA.109.856070.

Not surprisingly, many knowledgeable scientists and clinicians now believe that ensuring adequate vitamin D3 levels (> 50 ng/mL)<sup>8</sup> is likely better than any vaccine against SARS-CoV-2 (and/or any other pathogen but with the potential exception of HIV-1) especially since the risk of adverse events and **ADE** are negligible for vitamin D3 whether obtained from suntanning (without burning the skin) or via oral supplementation. **Certainly, in preparation for the next pandemic the federal and provincial governments should consider implementing a health care program to provide free access to twice yearly vitamin D3 blood testing as well as consider the sponsorship of free vitamin D3 supplements (cholecalciferol) to those who have less than 50 ng/ml, especially for nursing home residents and those over 50 years of age. A special Task Force to monitor the effectiveness of such a program would be ideal.**

There may be other ways to also help reduce the risks of severe infectious diseases for the Canadian population related to co-morbidities. For example, efforts should be made to protect against chronic disease caused by macrophage immunosenescence.<sup>3</sup> A sign of the latter is hypertension and immunosenescence of macrophages (essentially macrophage dysfunction) increases the risks of

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<sup>8</sup> Borsche L, Glauner B, von Mendel J. COVID-19 mortality risk correlates inversely with vitamin D3 status, and a mortality rate close to zero could theoretically be achieved at 50 ng/ml 25(OH)D3: results of a systematic review and meta-analysis. *Nutrients*. 2021 Oct 14;13(10):3596. doi: 10.3390/nu13103596.

severe viral infections such as severe COVID-19 as well as causes failures of vaccination.<sup>9</sup> The new immunosenescence paradigm<sup>3</sup> suggests the use of ***alpha-fetoprotein antagonists*** such as zinc, 7-keto-DHEA,<sup>10</sup> isoflavonoids and more recently ivermectin<sup>11</sup> to reverse and prevent the immunosenescence of macrophages. Incidentally, immunosuppressive anti-inflammatories would only contribute to the immunosuppression associated with immunosenescence and not its resolution, effectively prolonging chronic diseases. Unfortunately, these common approaches of using anti-inflammatories long term in allopathic

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<sup>9</sup> Cox LS, Bellantuono I, Lord JM, Sapey E, Mannick JB, Partridge L, Gordon AL, Steves CJ, Witham MD. Tackling immunosenescence to improve COVID-19 outcomes and vaccine response in older adults. *Lancet Healthy Longev.* 2020 Nov;1(2):e55-e57. doi: 10.1016/S2666-7568(20)30011-8.

<sup>10</sup> <https://recalls-rappels.canada.ca/en/alert-recall/unauthorized-21st-century-dhea-health-product-seized-moose-jaw-sk-store-labelled-2018> In almost all countries except the U.S., DHEA (prasterone) and metabolites are treated as a controlled anabolic steroid. In the U.S., DHEA is exempt from the Controlled Substances Act, which means it is treated differently from other steroids. DHEA is also allowed in dietary supplements by the Food and Drug Administration (FDA). However, the threat to health in Canada is that DHEA can be converted to testosterone and/or estrogens. Accordingly, one might argue 7-keto-DHEA should be permitted in Canada because it cannot be converted to the sex hormones but would still have the benefits of DHEA. For example, DHEA but not DHEAS binds and inactivates alpha-fetoprotein (AFP).<sup>3</sup> Thus 7-keto-DHEA would likely reverse and prevent macrophage immunosenescence and would help to prepare the population for the next pandemic attack.

<sup>11</sup> Laderoute M. Ivermectin may prevent and reverse immunosenescence by antagonizing alpha-fetoprotein and downmodulating PI3K/Akt/mTOR hyperactivity. *Open Heart.* April 29, 2021. <https://openheart.bmj.com/content/8/1/e001655.responses#ivermectin-may-prevent-and-reverse-immunosenescence-by-antagonizing-alpha-fetoprotein-and-downmodulating-pi3k-akt-mtor-hyperactivity>.



medicine (e.g., statins) and herbal medicine (e.g., turmeric ) might be best avoided to reduce the infectious disease risks during pandemics.<sup>3,12</sup>

As reviewed in reference [5](#), accumulating evidence strongly implies the development especially the **early** development of IgG to spike protein during natural infection (ie., before SARS-CoV-2 was cleared by innate immunity) was associated with severe COVID-19 disease! Thus, *inadvertently*, all the COVID-19 vaccines are marketed based on their ability to generate the dangerous IgG (ie. IgG1 and IgG3) antibodies to spike protein which invariably cause severe COVID-19 disease when SARS-CoV-2 is still circulating in the host. **This provides the first premise for the rejection of the notion that COVID-19 vaccines could be safe and effective (infection and/or mortality).** In other words, such vaccines could only harm individuals and could lead to selection of variants in populations since in fact, these IgG antibodies to spike protein were commonly detected in the upper respiratory tract (URT) moreso after vaccination.<sup>13, 14</sup> The URT is where

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<sup>12</sup> Laderoute M. The paradigm of immunosenescence in atherosclerosis-cardiovascular disease (ASCVD). *Discov Med.* 2020 Jan-Feb;29(156):41-51.

<sup>13</sup> Guerrieri M, Francavilla B, Fiorelli D, et al. Nasal and salivary mucosal humoral immune response elicited by mRNA BNT162b2 COVID-19 vaccine compared to SARS-CoV-2 natural infection. *Vaccines (Basel).* 2021 Dec 18;9(12):1499. doi: 10.3390/vaccines9121499.

<sup>14</sup> Aksyuk AA, Bansal H, Wilkins D, et al. AZD1222-induced nasal antibody responses are shaped by prior SARS-CoV-2 infection and correlate with virologic outcomes in breakthrough infection. *Cell Rep Med.* 2022 Dec 15:100882. doi: 10.1016/j.xcrm.2022.100882.

ADE occurs by conventional means involving FCGR2A as expressed on activated foamy macrophages.<sup>15</sup> These foamy macrophages are known as 'sebocytes' (see ref 5 for more details on these cells) and constitutively produce the protector HERV-K102 particles and release them by lysis in sebaceous glands in the mucosa.<sup>5</sup> Since the transmitted SARS-CoV-2 variants originate in the URT, ADE seems to have contributed to the prolongation of the COVID-19 pandemic through the selection of variants. It is notable that prior to the introduction of the COVID-19 vaccines, there was little selection of immune escape variants.<sup>5</sup> These observations are consistent with the notion that the COVID-19 vaccines likely caused the selection of immune escape variants, such as witnessed for the alpha and then the delta variants in the early months of the mass vaccination campaign.

## **Worldwide Failure to Provide Timely Surveillance for the Safety and Effectiveness of the COVID-19 Vaccines**

Not a single country has provided proper and timely post - Emergency Use Access (EUA) authorization surveillance for the evaluation of the safety and

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<sup>15</sup> Ziegler CGK, Miao VN, Owings AH, et al. Impaired local intrinsic immunity to SARS-CoV-2 infection in severe COVID-19. Cell. 2021 Sep 2;184(18):4713-4733.e22. doi: 10.1016/j.cell.2021.07.023

efficacy of COVID-19 vaccines during the early months of the **experimental** mass vaccination with the gene therapy vehicles which were of dubious safety. It is also incredible that such experimental and dangerous gene therapies were subsequently mandated for travel, schooling and employment with essentially no safety data. Forcing people to be injected with unsafe products goes against the constitution of any democratic country. **There is also a 'glaring' absence of data substantiating benefit over risk of the COVID-19 vaccines as typically established through the assessment of all-cause mortality.<sup>16</sup> This should have been required for the approval of COMIRNATY and SPIKEVAX in Canada which was nevertheless awarded on September 16, 2021 without this critical data.**

Luckily, the UK Office for National Statistics (ONS) released total population mortality raw death counts by vaccination status and mortality rates by vaccination status such as on July 6, 2022.<sup>17</sup> Despite data manipulation for summaries,<sup>18</sup> the listed data enabled the ability to retrospectively assess all-cause

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<sup>16</sup> Graña C, Ghosn L, Evrenoglou T, et al. Efficacy and safety of COVID-19 vaccines. Cochrane Database Syst Rev. 2022 Dec 7;12(12):CD015477. doi: 10.1002/14651858.CD015477.

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<https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsinvolvingcovid19byvaccinationstatusengland/deathsoccurringbetween1january2021and31may2022>.

<sup>18</sup> Fenton, N. E., Neil, M., Craig, C. & McLachlan, S. (2022). "What the ONS Mortality Covid-19 Surveillance Data can tell us about Vaccine Safety and Efficacy", <http://dx.doi.org/10.13140/RG.2.2.30898.07362>

mortality in addition to COVID-19 and non-COVID-19 mortality when comparing ever vaccinated mortality rates to the unvaccinated.

**It should be noted that both Canada and the USA have not released similar mortality data by vaccination status, which probably will never be revealed unless legally demanded through a national inquiry and court order.**

The published mortality rates per 100,000 per year for the ever vaccinated and never vaccinated in this ONS document<sup>17</sup> had been inappropriately manipulated according to Prof. Norman Fenton:

*“Previously discussed explanations for the anomalous differences between non-covid mortality rates in the vaccinated and unvaccinated include miscategorising deaths shortly after vaccination as unvaccinated and omitting completely many vaccinated deaths.”<sup>18</sup>*

Fortunately, the true data could be easily accessed by adding up all the rates for each of the ever-vaccinated categories, providing a new table of interpretable data. This summary data is provided in [Table 1.5](#)

## UK ONS Mortality Data by Vaccination Status<sup>17</sup> Reveals the Pfizer mRNA Vaccine was Neither Safe Nor Effective

As shown in **Table 1**, based on all-cause mortality being over 1 for the ratio of all-cause mortality rates in the ever vaccinated over the unvaccinated except for February 2021, in no other month from January 2021 to May 2022, was there any evidence of post-EUA safety and/or effectiveness. Indeed, the all-cause mortality risk (over 1) was observed in the first month of the program where the elderly had received both doses starting in December 2020. Subsequently, this risk became worse over time largely due to non-COVID-19 mortality which many ascribe to the toxicity and lethality of the spike gene therapy injections,<sup>19</sup> **but also since COVID-19 deaths were elevated by more than two fold by the end of 2021.**

Dr. Peter McCullough and I concurred that, the COVID-19 vaccines should have been **globally halted by the first week in February 2021** having no clear benefit and all risk for mortality when tested in the most susceptible population for the month of January (personal communication). New evidence also confirms the COVID-19 vaccines were failing to prevent infections in early January 2021 in

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<sup>19</sup> Seneff S, Nigh G, Kyriakopoulos AM, McCullough PA. Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and microRNAs. Food Chem Toxicol. 2022 Apr 15;164:113008. doi: 10.1016/j.fct.2022.113008.

the USA.<sup>20</sup> As well, autopsy proven vaccine associated myocardial sudden deaths were proven in 28 of 28 cases of unexpected and sudden deaths following vaccination (usually within one week of the last dose) with the COVID-19 vaccines.<sup>21</sup>

However, like Canada, the UK had problems with supply and had determined earlier that the bulk of the observed protection was afforded by innate immunity related to the first dose.<sup>5</sup> The mRNA vaccine efficacy was estimated at 92-93% following the first dose (provided the infections acquired at the time of vaccination were excluded, ie., those that occurred within the first two weeks).<sup>22</sup> Accordingly the administration of the second dose was deferred in the UK (and Canada) which explains how the COVID-19 mortality rate ratios were favorable for both February and March 2021 (**Table 1**).

For February 2021 over 96% of the vaccinated consisted of mostly elderly persons who only received one dose.<sup>5</sup> As explained elsewhere<sup>5</sup> no spike specific IgG was generated until after the second dose of COVID-19 vaccine. As well, Xu et al, showed that the trained innate immunity which provided the non-specific protection against non-COVID-19 mortality was generated after the first COVID-

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<sup>20</sup> <https://twitter.com/TheChiefNerd/status/1698346313249677355>

<sup>21</sup> Hulscher, N.; Hodkinson, R.; Makis, W.; McCullough, P. Autopsy Proven Fatal COVID-19 Vaccine-Induced Myocarditis. *Preprints* **2023**, 2023071198. <https://doi.org/10.20944/preprints202307.1198.v1>

<sup>22</sup> Showronski DM, De Serres G. Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. Correspondence. *N Engl J Med*. 2021 Feb 17; 384:1576-1578. doi: 10.1056/NEJMc2036242.

19 vaccine dose and was not appreciably affected by the second dose (at least in the period before the dominance of the delta variant).<sup>23</sup> Therefore and importantly, the February 2021 favorable data pertains to **trained innate immunity protection and the lack of IgG1/3 antibodies to spike protein.** For March 2021 in **Table 1**, the fact that the non-COVID-19 mortality ratio was greater than one while the COVID-19 mortality was less than one probably reflects two facts. First the vast majority of the vaccinated by the end of March had still only received one dose. Second, toxic spike protein from the mRNA gene therapy injections lingers in the body for longer than 2 months<sup>19</sup> and could during this period in the elderly, lead to death even after only one dose for those who received the vaccine earlier.<sup>17</sup>

In addition, adding up the raw death counts published by the ONS revealed the following<sup>5</sup> for the 50 years of age and older who were at the greatest risk of death:

1. Overall, there were only 1,455 lives saved from COVID-19 mediated death from January 1, 2021 to May 31, 2022 related to mass vaccination in the

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<sup>23</sup> Xu S, Huang R, Sy LS, et al. COVID-19 vaccination and non-COVID-19 mortality risk — seven integrated health care organizations, United States, December 14, 2020–July 31, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1520–1524. doi: <http://dx.doi.org/10.15585/mmwr.mm7043e2>.

UK and most likely pertained to trained innate immunity and NOT the IgG1 and IgG3 antibodies to spike protein;

2. Most 50 plus vaccinees had 3 doses where the 3<sup>rd</sup> dose was administered in October to December 2021;
3. There were 414,340 excess deaths in the ever vaccinated 50 plus group when compared with the unvaccinated;
4. For each life saved from COVID-19, there was an excess of 285 non-COVID-19 deaths presumably due to the toxicity and lethality of the mRNA spike gene therapy injections (a **remarkably poor risk/benefit ratio**);
5. Overall, in the 50 plus age group from January 1, 2021 to May 31, 2022, death ensued in one in 51 individuals who were injected with at least one dose of the spike mRNA gene therapy vaccines.

How is it that a product that kills one in 51 of the age group most likely to benefit from vaccination (50+ age group) is allowed to remain on the market, let alone be mandated for travel or to continue employment? Raptiva was removed from the international markets due to 3 deaths and here we have solid proof of 414,340 excess deaths in the 50 + age group related to vaccination in the UK alone.



In addition to these fiascos, another line of evidence, excess non-COVID mortality (**Figure 2**) by sex and age for each month of the pandemic<sup>24</sup> has revealed in the under 25 years of age group, there were few if any excess deaths prior to the introduction of the COVID-19 vaccines, but which quickly increased following their introduction into this age group. Many of these deaths could relate to vaccine associated immunodeficiency syndrome (VAIDS).<sup>25</sup> This indicates this population should NEVER have received the COVID-19 vaccines as they were not at any significant risk of COVID-19 severity and death. Many knowledgeable professionals openly opposed the vaccination of children as there were no benefits and all risk. A similar deadly scenario could be painted for mRNA gene therapy exposures during pregnancy and lactation.<sup>26</sup>

As well as shown in **Figure 2**, by June 2022, enhanced **excess non-COVID-19 deaths were observed across all ages** possibly associated with multiple

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<sup>24</sup> <https://twitter.com/OutsideAllan/status/1646813568107511809> The UK Office for Health Improvements and Disparities (UKHID) released a downloadable database on June 8, 2023 [<https://www.gov.uk/government/statistics/excess-mortality-in-england-and-english-regions>] but where charts of the excess mortality data by month, sex and age were compiled and made available by Stuart A @OutsideAllan on twitter on June 8 2023.

<sup>25</sup> Noé A, Dang TD, Axelrad C, Burrell E, Germano S, Elia S, Burgner D, Perrett KP, Curtis N and Messina NL (2023) BNT162b2 COVID-19 vaccination in children alters cytokine responses to heterologous pathogens and Toll-like receptor agonists. *Front. Immunol.* 14:1242380. doi: 10.3389/fimmu.2023.1242380

<sup>26</sup> Thorpe JA, Rogers C, Tankersley S, Redshaw MD, Deskevich MP, Benavides A, McCullough PA. COVID-19 vaccines: the impact on pregnancy outcomes and menstrual function. *J Am Phys Surg* 2023 Spring; Vol 28, Number 1.

booster shots and this continued into May 2023 (ie., the last month reported).

This data is consistent with the notion that the emergency room crisis here in Canada and across the world is likely due to the toxicity and lethality of the COVID-19 vaccines. An immediate remedy would be to prohibit the use of COVID-19 vaccines by taking them off the Canadian market and to issue a moratorium on the use of mRNA technology in clinical trials.

## **Conclusions**

Given that your office has the responsibility to remove from the Canadian market any products where emerging post-market evidence demonstrates the risks do not outweigh the potential benefits, particularly where there are known cases of serious injuries including deaths, I implore you to immediately remove COVID-19 vaccines from the Canadian market while your office preforms a risk assessment. In addition to the Periodic Safety Update Reports (PSURs) that I assume have been submitted on a regular basis, you may need to get a court injunction to force PHAC, Stats Canada or any provincial database to release the data concerning mortality by vaccination status as well as excess mortality by age over the months March 2020 to present. There has been a dearth of reporting serious adverse events of the COVID-19 vaccines including death due to the unusual and unexpected SAEFI reporting structure arranged by PHAC which

appears to sabotage the intended purpose of surveillance for reasons given in the legend to **Figure 3**.<sup>27</sup>

The Government of Canada should consider mandatory autopsies (and sponsoring) for all sudden and unexpected deaths following vaccination which would also determine whether the infectious agent or vaccine caused the death.

It is hoped that Canada will become a world leader in ending the COVID-19 mass vaccination travesty that was based on the unproven and false narrative that the COVID-19 vaccines could be or would be safe or effective. The precautionary principle states the absence of evidence cannot be taken as evidence of the absence of risk.

In short, the mRNA gene therapies masquerading as vaccines have proven to be much more dangerous than previously imagined and under no circumstances should anyone be subject to such unethical medical exposures let alone mandates involving these so-called mRNA vaccines. **There should be an immediate moratorium forbidding the use of these mRNA gene therapies even in clinical trials (analogous to the voluntary moratorium on xenotransplantation clinical trials in Canada).**

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<sup>27</sup> <https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html>

Canada needs to step up to the plate and acknowledge the damage done by the COVID-19 vaccines and other responses to the pandemic. Those who suffered debilitating injuries, death or as professionals who lost their careers or sources of income should be automatically awarded compensation including court orders to have their positions reinstated and to issue backpay.

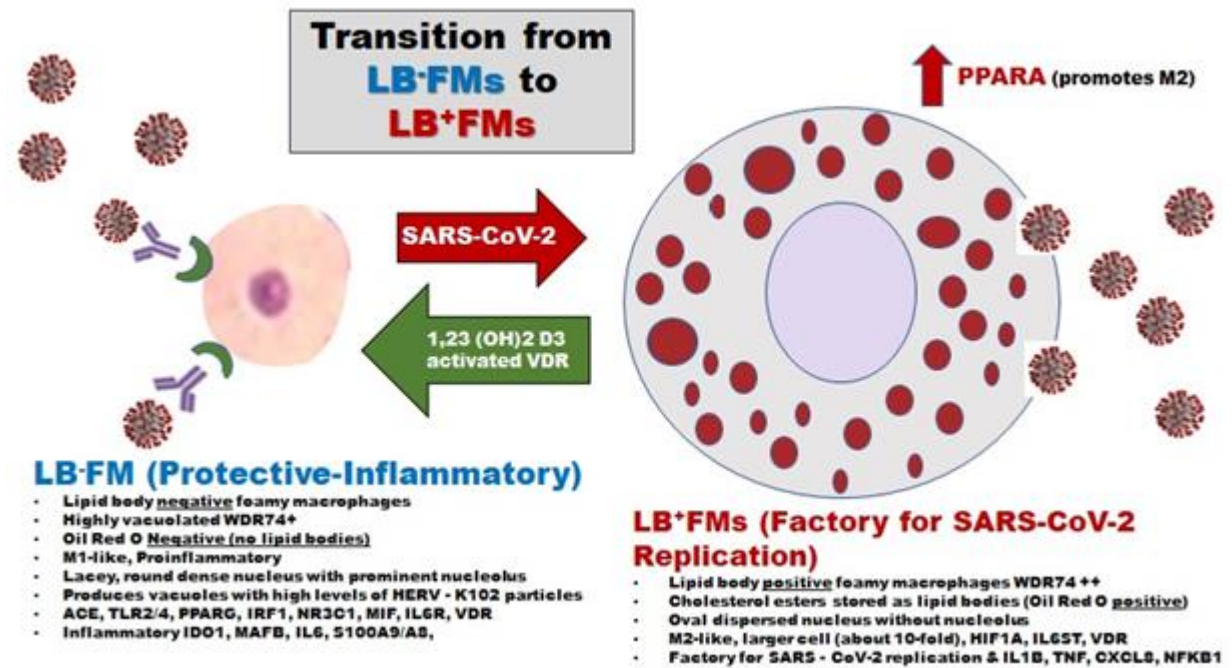
If there is anything I can do with my background, knowledge, and expertise to help you with your post-market COVID-19 vaccine risk assessment, please do not hesitate to ask. I would welcome the opportunity to examine and analyze the COMIRNATY and SPIKEVAX PSURS given my experience with Raptiva.

I hope you and your family are well. If you have any questions do not hesitate to ask.

**Sincerely,**

**Dr. Marian P. Laderoute**, Ph.D. Medical Sciences – Immunology

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**Figure 1.** SARS-CoV-2 Infection by Antibody Dependent Enhancement (ADE) of the Lipid Body Negative Foamy Macrophages (LB<sup>-</sup>FM s) Producing the Protector HERV-K102 Particles Causes the Transition to Lipid Body Positive Foamy Macrophages (LB<sup>+</sup>FM s) Which INSTEAD Becomes a Factory for the Replication of SARS-CoV-2;<sup>6</sup> This Process is Blocked by the Activated Vitamin D3 Receptor (VDR).<sup>7</sup> There are two types of foamy macrophages

in response to pathogens:<sup>28</sup> The LB<sup>-</sup>FM s which produce the protector HERV-K102 particles and

<sup>28</sup> Peyron P, Vaubourgeix J, Poquet Y, et al. Foamy macrophages from tuberculous patients' granulomas constitute a nutrient-rich reservoir for *M. tuberculosis* persistence. PLoS Pathog. 2008 Nov;4(11):e1000204. doi: 10.1371/journal.ppat.1000204.

release them by lysis on day 6-7 and the **LB<sup>+</sup>FMs** in which lipid bodies accumulate in the cytoplasm and strongly stain red for Oil Red O and which tend to harbour pathogens.<sup>6</sup> In

patients with Vitamin D3 levels lower than 50 ng/ml,<sup>8</sup> the entry of SARS-CoV-2 into the protector LB<sup>+</sup>FMs by ADE causes their conversion to lipid body positive foamy macrophages (LB<sup>+</sup>FMs) which become factories for the production of SARS-CoV-2 virions which bud through the cell surface.<sup>6</sup>

Thus, ADE not only antagonises the critical host defence mechanism against pandemic viruses but enhances the production of SARS-CoV-2 virions in an immunologically privileged environment. This is why ADE is so dangerous to infectious disease outcomes.

**% Excess Deaths (Non-COVID-19) by Age Group, Sex & Month (that week ended in)  
England**

Weeks Ending 27Mar20 - 26May23

Source Data:- Office for Health Improvement and Disparities

Graphic:- @OutsideAllan

Year	Month	0-24		25-49		50-64		65-74		75-84		85+		Total
		Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	
2020	3	-10.0%	-23.0%	-2.8%	2.1%	0.2%	-3.7%	-8.4%	-2.0%	-5.5%	-0.6%	-6.3%	-1.8%	-3.8%
2020	4	-5.8%	-20.5%	7.5%	0.2%	12.4%	16.1%	13.4%	18.2%	25.4%	25.9%	40.6%	36.1%	26.9%
2020	5	-15.8%	-12.0%	-1.6%	-2.3%	3.7%	4.9%	-1.8%	-4.2%	-0.5%	-1.8%	10.9%	0.2%	1.9%
2020	6	-23.9%	-21.7%	-8.0%	-7.3%	-6.0%	-2.4%	-3.3%	-8.0%	-8.6%	-10.6%	-11.3%	-13.2%	-9.4%
2020	7	-16.6%	-9.0%	0.7%	0.3%	-6.5%	2.6%	-3.1%	-4.8%	-7.1%	-7.4%	-9.2%	-13.9%	-7.2%
2020	8	1.4%	-1.3%	1.8%	5.9%	2.4%	4.1%	-5.2%	-2.5%	-0.7%	-1.2%	-2.7%	-5.4%	-1.8%
2020	9	-1.4%	-15.4%	5.6%	6.0%	1.6%	5.8%	0.2%	2.4%	0.4%	-0.1%	-2.2%	-1.9%	0.1%
2020	10	-24.0%	-11.4%	2.3%	7.4%	4.1%	4.0%	0.9%	-3.0%	-2.4%	-4.2%	-3.8%	-4.6%	-2.3%
2020	11	-11.3%	-6.1%	3.6%	5.1%	1.9%	5.9%	-7.5%	-2.9%	-8.1%	-7.0%	-7.3%	-10.7%	-5.8%
2020	12	-5.2%	-8.2%	5.5%	6.0%	-5.8%	3.1%	-10.2%	-10.9%	-14.9%	-16.1%	-14.9%	-17.7%	-12.6%
2021	1	-3.1%	-8.1%	0.3%	-11.0%	-10.4%	-6.3%	-17.0%	-16.4%	-19.9%	-23.1%	-22.8%	-26.7%	-20.1%
2021	2	2.0%	4.6%	2.9%	-1.2%	-8.2%	-3.7%	-12.6%	-15.1%	-18.2%	-17.4%	-19.3%	-24.9%	-16.7%
2021	3	16.4%	-1.2%	-4.0%	5.4%	-7.7%	-3.4%	-13.3%	-14.2%	-18.2%	-20.6%	-22.3%	-25.2%	-17.8%
2021	4	-12.5%	-13.8%	2.4%	-5.3%	-5.9%	0.6%	-9.0%	-11.4%	-13.5%	-14.3%	-16.3%	-19.3%	-13.1%
2021	5	-9.0%	7.9%	2.1%	1.2%	-5.6%	3.2%	-10.1%	-7.5%	-8.8%	-7.5%	-10.0%	-10.4%	-7.7%
2021	6	9.3%	3.5%	-2.4%	5.2%	-0.9%	6.6%	-4.6%	-5.0%	-5.1%	-3.3%	-5.6%	-7.2%	-3.9%
2021	7	-7.5%	0.7%	2.4%	3.8%	7.0%	7.2%	0.2%	2.2%	0.7%	1.7%	-0.3%	-2.0%	1.1%
2021	8	-8.3%	-5.6%	-0.5%	2.9%	5.8%	6.8%	5.3%	1.2%	2.7%	0.0%	3.9%	1.2%	2.6%
2021	9	-4.2%	-6.7%	6.2%	5.9%	8.3%	4.8%	7.7%	6.5%	6.0%	4.5%	4.1%	1.2%	4.6%
2021	10	1.0%	5.9%	1.0%	11.8%	9.9%	10.3%	3.5%	3.3%	0.1%	0.9%	1.2%	-0.1%	2.4%
2021	11	10.1%	9.9%	1.0%	3.4%	2.5%	9.0%	6.4%	6.5%	4.5%	0.6%	5.7%	0.1%	3.9%
2021	12	2.2%	5.3%	-4.2%	3.1%	6.8%	6.9%	1.9%	2.0%	0.8%	-3.8%	0.4%	-3.7%	0.0%
2022	1	-10.4%	-9.8%	-2.6%	-9.7%	-8.3%	-4.2%	-14.2%	-12.3%	-14.7%	-17.4%	-20.7%	-23.4%	-16.8%
2022	2	7.5%	16.2%	-2.7%	-4.6%	-3.8%	3.6%	-8.1%	-5.0%	-11.5%	-13.8%	-16.0%	-18.6%	-11.7%
2022	3	10.3%	8.7%	-6.1%	4.4%	-8.3%	3.4%	-7.5%	-6.3%	-9.2%	-12.0%	-14.7%	-15.2%	-10.3%
2022	4	-28.2%	-1.4%	-5.6%	-5.0%	-2.0%	-3.8%	-8.9%	-7.3%	-8.9%	-10.9%	-9.5%	-12.1%	-9.0%
2022	5	-12.3%	6.4%	4.9%	-5.0%	2.5%	8.9%	-0.1%	1.6%	1.7%	2.4%	3.2%	1.4%	2.3%
2022	6	17.9%	16.5%	14.8%	8.1%	18.4%	17.0%	8.9%	9.2%	10.4%	7.5%	8.8%	9.3%	10.0%
2022	7	12.2%	5.5%	6.2%	8.8%	4.6%	11.0%	4.7%	5.5%	7.1%	2.8%	8.3%	6.9%	6.5%
2022	8	10.5%	7.8%	-4.9%	10.2%	17.1%	12.5%	0.2%	7.2%	4.5%	5.6%	10.8%	4.1%	7.1%
2022	9	-0.6%	10.4%	9.5%	8.1%	13.7%	16.9%	7.9%	5.2%	5.8%	6.7%	7.6%	7.5%	7.8%
2022	10	3.9%	5.0%	16.7%	9.2%	11.8%	10.1%	7.5%	6.3%	6.3%	6.4%	9.0%	7.4%	7.9%
2022	11	11.7%	6.7%	7.9%	11.9%	10.5%	13.2%	9.9%	6.8%	2.5%	1.8%	6.6%	1.9%	5.5%
2022	12	26.3%	6.1%	6.3%	4.1%	13.4%	12.4%	6.4%	3.7%	9.6%	-0.5%	7.6%	3.6%	5.9%
2023	1	-4.9%	1.6%	18.4%	4.0%	13.1%	16.2%	7.6%	7.8%	10.4%	2.2%	10.2%	-0.2%	7.1%
2023	2	17.9%	16.7%	7.4%	11.1%	2.7%	11.4%	5.1%	2.7%	0.9%	-3.2%	-2.1%	-7.4%	-0.4%
2023	3	9.1%	13.2%	8.0%	9.1%	3.8%	9.6%	0.6%	-1.6%	-5.8%	-4.6%	-4.5%	-6.8%	-2.7%
2023	4	3.4%	14.9%	4.6%	3.4%	5.3%	11.7%	1.3%	1.5%	-0.1%	-2.0%	-1.8%	-2.0%	0.3%
2023	5	-2.8%	29.5%	16.4%	15.7%	8.2%	16.9%	2.1%	8.6%	5.8%	7.1%	8.3%	3.4%	7.5%



## **Figure 2. UK Non-COVID-19 Excess Mortality by Age, Sex and Month.**<sup>24</sup>

The UK Office for Health Improvements and Disparities (UKHID) released a downloadable database on June 8, 2023

[<https://www.gov.uk/government/statistics/excess-mortality-in-england-and-english-regions>] but where charts of the excess mortality data by month, sex and age were

compiled and made available by Stuart A @OutsideAllan on twitter on June 8 2023.<sup>24</sup>

There were two major periods in the 65 + where trained innate immunity induced by one dose of vaccine (December 2020 to April 2021) or via common exposures to Omicron (January to April 2022) appears to have generated negative excess non-COVID-19 mortality (in dark green).

Note that younger age groups (<65 years of age) exhibited enhanced excess non-COVID-19 mortality potentially related to immunization which began in mid 2021 and may have been also interrupted by exposures to Omicron for the period January to May 2022.

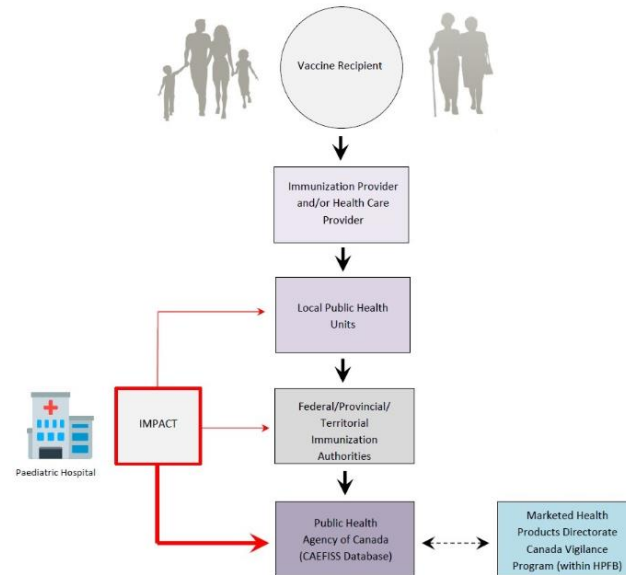
By June 2022 possibly associated with multiple boosters, there was a plethora of non-COVID-19 excess deaths in the UK. It is possible that the excess deaths related to the repeated administration of the COVID-19 vaccines (largely mRNA) might help explain the emergency room crisis witnessed worldwide since June 2022. Therefore, a direct way to curtail this worldwide health care crisis would be to stop using the toxic and deadly COVID-19 vaccines and to ban the mRNA gene therapy technology even for clinical trials.



### Reporting adverse events following immunization

The following diagram depicts how AEFI reports flow from origin (vaccine recipient) to PHAC. CAEFISS includes spontaneous, enhanced and active AEFI reporting processes that are further described below.

Figure 1: Public health reporting pathway for AEFIs to CAEFISS



Abbreviations: IMPACT, Immunization Monitoring Program Active; HPFB, Health Products and Food Branch

### Figure 3. UNUSUAL Vetting of Serious Adverse Events Following COVID-19 Immunization (SAEFCI) with the Absolute Requirement for Initial Reporting by the Doctor Would have Seriously Compromised Surveillance and the Reporting of COVID-19 Vaccine Associated Deaths

Not only would the death reports be delayed by the repeated assessment and uploading at various levels, but without special autopsies that would test for spike protein versus nucleoprotein especially on sudden deaths, it is believed that most of the actual deaths were not reported as:

- 1) there would be no proof that the vaccine caused the death (even though deaths are supposed to be reported even without proven causal association),
- 2) Doctors cannot afford the time to make these reports and have been gaslit into believing the COVID-19 vaccines are safe and effective,
- 3) there was a major disincentive for professionals to report the deaths due to the threat of losing one's license for admitting the COVID-19 vaccines were not safe nor effective.

To date in Canada there are only 4 of 442 deaths that managed to be reported which were accepted as causally related to COVID-19 vaccination.<sup>29</sup> However elsewhere it is estimated that there were at least 30,000 non-COVID-19 DEATHS DUE to vaccination with the COVID-19 vaccines by the end of 2022, that vaccine mortality approached 1% in the elder groups, and the highest peak excess all-cause mortality in Canada in early 2022 occurred following the first booster shot.<sup>30</sup>

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<sup>29</sup> <https://health-infobase.canada.ca/covid-19/vaccine-safety/> accessed September 5, 2023 results to May 26, 2023.

<sup>30</sup> <https://twitter.com/hervk102/status/1667211796405469194>; [https://twitter.com/Inquiry\\_Canada/status/1660643460041326593](https://twitter.com/Inquiry_Canada/status/1660643460041326593); and Dr. Rancourt's testimony can be viewed here: <https://rumble.com/v2ohtte-physicist-dr-denis-rancourt-presents-his-findings-on-all-cause-mortality-ot.html>;

**Table 1. Office for National Statistics (ONS) UK Mortality Rates Per 100,000 Person-Years: Re-Compiled Rate Ratios\* of Ever Vaccinated (Ever Vax) over Unvaccinated (Unvax) January 1, 2021 to May 31, 2022**

		All-Cause Mortality			COVID-19 Mortality			Non-C19 Mortality		
		RATE Unvax	Actual RATE Ever Vax	Ratio of Vax/ Unvax Rates	RATE Unvax	Actual RATE Ever Vax	Ratio of Vax/ Unvax Rates	RATE Unvax	Actual RATE Ever Vax	Ratio of Vax/ Unvax Rates
2021	Jan	2507.6	3483.5	<b>1.39</b>	1187	1526	<b>1.29</b>	1320	1958	<b>1.48</b>
	Feb	5261.5	3205.4	<b>0.61</b>	2174	456.8	<b>0.21</b>	3087	2689	<b>0.87</b>
	Mar	3307.8	4192.7	<b>1.27</b>	591.8	283.9	<b>0.48</b>	2716	3909	<b>1.44</b>
	April	2298.4	5039.7	<b>2.19</b>	145.8	184	<b>1.26</b>	2153	4855	<b>2.25</b>
	May	1718.8	8582.6	<b>4.99</b>	45.5	84.5	<b>1.86</b>	1673	8426	<b>5.04</b>
	June	1589.7	10060	<b>6.33</b>	55.6	87.7	<b>1.58</b>	1534	9916	<b>6.46</b>
	July	1610.7	10307.1	<b>6.40</b>	218.2	224.9	<b>1.03</b>	1392	9960	<b>7.16</b>
	Aug	1711.6	10340.7	<b>6.04</b>	404.2	402.9	<b>1.00</b>	1307	9266	<b>7.09</b>
	Sept	1664.5	8639	<b>5.19</b>	367.8	520.2	<b>1.41</b>	1297	7884	<b>6.08</b>
	Oct	1623.7	12456.3	<b>7.67</b>	322.3	568.6	<b>1.76</b>	1302	11845	<b>9.10</b>
	Nov	1708	15546.6	<b>9.10</b>	421.3	721	<b>1.71</b>	1287	14155	<b>11.00</b>
	Dec	1878.5	16974.3	<b>9.04</b>	520.5	1121.9	<b>2.16</b>	1358	15501	<b>11.41</b>
2022	Jan	1812	19997.9	<b>11.04</b>	584.6	2310.9	<b>3.95</b>	1227	16417	<b>13.38</b>
	Feb	1384.5	12474.4	<b>9.01</b>	258.7	1128.4	<b>4.36</b>	1126	11346	<b>10.08</b>
	Mar	1231.7	10257.2	<b>8.33</b>	183.5	763.6	<b>4.16</b>	1048	9445	<b>9.01</b>
	April	1204.6	12423.2	<b>10.31</b>	204.7	800.8	<b>3.91</b>	1000	11622.4	<b>11.62</b>
	May	872.9	8246	<b>9.45</b>	77.6	261.8	<b>3.37</b>	795	7914	<b>9.95</b>

\*Rates are per 100,000 Person-Years,<sup>17</sup> and were re-compiled where all the rates for ever vaccinated were added up to provide totals. The Ever Vaccinated total mortality rates reported by the ONS were undercalculated (i.e., did not add up) as discussed by Professor Norman Fenton of the UK.<sup>18</sup>