October 11, 2022

From Dr. Marian Laderoute, Ph.D. Medical Sciences-Immunology

hervk102.substack.com

Centers for Disease Control & Prevention October 2022 ACIP Meeting: Docket # CDC-2022-0111-0001 (alternative listing Docket # CDC-2022-0103).

I am an immunologist with experience in biological regulatory approvals, pharmacovigilance, and the prevention of pandemics (National Forum on Xenotransplantation in November 1997) with Health Canada. My last position at the Public Health Agency was Research Manager of the Blood ZOONOTICS UNIT.

I advocate for the testing, evaluation and validation of HERV-K102 as the critical correlate of protection against SARS-CoV-2 as well as the use of safe and effective vaccines. I have no conflicts of interest. International patents/applications for the discovery of HERV-K102 as a protector foamy virus of humans have been abandoned.

I am the lead discoverer from the Public Health Agency of Canada (now retired) of human endogenous retrovirus K102 (HERV-K102) as a replication-competent, non-pathogenic, foamy retrovirus which protects non-specifically against tumors, viruses, and other intracellular pathogens [Laderoute M *et al*., AIDS 2007; Open AIDS J, 2015]. HERV-K102 particle production in monocytes/macrophages generates foamy macrophages (**Figure 1 slide deck**) and is a key component of trained (innate) immunity needed for recovery from SARS-CoV-2 infection [Laderoute M , submitted see abstract **Image 1 in the slide deck**].

The HERV-K102 powerful innate DEFENSE system essentially consists of three parts. First, it involves the HERV-K102 particles which may undergo lytic infection in cells infected with pathogenic viruses (or which are tumor transformed). These particles also enter normal cells but where HERV-K102 merely integrates into genomic DNA. The latter is referred to as 'arming' which is thought to promote quicker and more robust responses upon subsequent exposures and may contribute to the memory response of trained (innate) immunity. The particles which are released from foamy macrophages by lysis trigger T and B cells which recognize and react to HERV-K102 envelope protein (Env). Since HERV-K102 Env becomes expressed on virus infected cells and on tumor cells but NOT normal healthy cells, it serves as an autologous marker of cells set to be destroyed by the HERV-K102 powerful system. Wang-Johanning F et al, JNCI 2012 have proven that the cell surface expression of HERV-K102 Env is a death receptor directly linked to the apoptosis machinery in abnormal cells and does not require complement or cells to complete the death cascade. Both the antibodies and innate T cells to HERV-K102 Env have been shown to clear tumor cells and/or virus infected cells but did not affect normal cells [reviewed in Laderoute M. F1000 Research 2018 https://doi.org/10.12688/f1000research.11818.2].

Because of the cell surface expression of HERV-K102 Env in virus infected cells, 'enveloped' viruses which bud through the cell surface like HIV-1 and SARS-COV-2 likely contain HERV-K102 Env in the particles released from human cells (**Figure 2**). Thus, for these pandemic RNA viruses, the antibodies to HERV-K102 Env can neutralize the virus and thus, contribute to sterile immunity. Sterile immunity has been observed for the commercial sex trade workers that are resistant to HIV-1 acquisition and WHO REMAIN **SERONEGATIVE**. Interestingly, this cohort had a 5-fold increased HERV-K102 genomic DNA provirus copy number over healthy controls which was not found in patients already infected with HIV-1 (**Figure 3)**. Thus, HERV-K102 activity has been correlated with generating sterile immunity *in vivo*.

Accordingly, in theory innate vaccines like BCG vaccines may be useful tools to combat emerging pathogens or pandemics particularly to protect the highest risk groups. For the rest of the population, early treatment of symptomatic individuals with agents known or suspected of enhancing the HERV-K102 protector response (such as ivermectin, zinc, flavonoids, vitamin D etc) would be considered appropriate approaches to containing and ending the pandemic. Along with adoption of healthier life choices and the reduction of stress, these agents could also be used as preventative measures when high levels of the virus are circulating in communities.

Adaptive immunity COVID-19 vaccines particularly those that only use spike as the immunogen are not suited for mass vaccination during a pandemic due to the well-known and highly anticipated problem of antibody dependent enhancement (ADE). ADE mediates infection into ACE2 and TMPRSS2 negative macrophages and thus, obliterates the HERV-K102 protection system leaving the host at very high risk of complications including death. Equally important these COVID-19 vaccines which strongly induce antibodies and neutralizing antibodies with the second dose, provide selection pressure for the emergence and dominance of immune escape variants. This in turn renders the vaccine and the vaccinal antibodies not only obsolete but dangerous to the host. Multiple lines of evidence have implicated the COVID-19 vaccines in the emergence and dominance of immune escape variants such as the alpha and delta variant [Laderoute M, submitted]. Most notably these variants did not exist prior to the introduction of the vaccines (mass vaccinations or related to randomized clinical trials).

It is now well established that antibodies to SARS-CoV-2 spike protein are not protective but caused COVID-19 progression to more severe disease which may include death [Huang et al, 2020; Chen W et al., 2020; Chen S et al, 2020; Hashem et al, 2020; Choteau et al, 2022; Legros et al, 2021; Ren L et al, 2021].

Accordingly on the basis that these antibodies can mediate ADE which can cause progression apparently through ADE entry of SARS-CoV-2 into macrophages [(Ren X et al, Cell, 2021] as well as enhance symptomatic infection rates in vaccinated over unvaccinated through classical ADE involving FCGR2A in the upper respiratory tract [Laderoute M, submitted] means <u>adaptive immunity vaccines are NOT suitable for controlling pandemics.</u>

The evidence in **Table 1** from the UK Office for National Statistics released July 6, 2022 shows from January 1, 2021 to May 31, 2022, that in fact the risks of the vaccines far outweighed the benefits. Indeed these vaccines failed the all-cause mortality test and should have been pulled

from the market around the first week in February. Dr. Peter McCullough concurs with this interpretation of the data in **Table 1**. Further, I have estimated that for every COVID-19 death prevented by the vaccines in the UK up to the end of May 2022, over 200 additional non-COVID-19 deaths occurred due to vaccination. There is no doubt about it that these COVID-19 mRNA and viral vector vaccines are toxic and very dangerous. The VAERS data also confirm this notion for USA citizens.

I have not been able to find equivalent data from the CDC or the USA on the all-cause, COVID-19, and non-COVID-19 mortality rate ratios of the ever vaccinated over the vaccinated. I suspect the data would reflect the same as the UK given that the Pfizer-BioNTech COVID-19 vaccine was dominantly used in both countries.

In summary, I am opposed to adding any and all COVID-19 vaccines to the child/adolescent and adult immunization schedules on the basis that these vaccines are clearly NOT safe NOR effective. Rather they are quite dangerous. In fact, it seems the CDC failed in their due diligence to closely monitor and report outcomes for these COVID-19 vaccines mandated or made available under EUA. The FDA needs to recognize and regulate the COVID-19 mRNA vaccines as gene therapy. Both the FDA and the CDC as well as their advisory committees have been grossly negligent in their role to protect the health of Americans. These might be considered by some as crimes against humanity.