CANADIAN COVID CARE ALLIANCE
Alliance canadienne pour la prévention et prise-en-charge de la covid

CCCA

COVID-19 Early Out-Patient Treatment
Pharmaceuticals Task Force
[c/o nakatsuk@queensu.ca]

26 October 2021

To: Canadian Colleges of Physicians & Surgeons
Canadian Colleges of Pharmacy

Re: The inappropriate conduct of Canadian regulatory health agencies

We are writing to express our concerns regarding the conduct of the Canadian professional colleges. Messages to our doctors and pharmacists across this country have stated that ivermectin must not be used in the prevention or treatment of COVID-19.

After reviewing statements and warnings sent to Canadian healthcare professionals, it is clear that you, as a group, have adopted the position taken by Health Canada as published on its website:

"Health Canada is advising Canadians not to use either the veterinary or human drug versions of Ivermectin to prevent or treat COVID-19. There is no evidence that ivermectin in either formulation is safe or effective when used for those purposes. The human version of ivermectin is authorized for sale in Canada only for the treatment of parasitic worm infections in people."

At the same time, the Government of Canada and Health Canada have repeatedly told Canadians that the COVID-19 vaccines are "safe and effective", and this position has been repeated by the Provinces/Territories and the medical regulatory bodies therein. All have supported the concept that, "The most effective strategy for preventing COVID-19 continues to be immunization and all Health Canada approved vaccines provide a high level of protection." For the sake of argument and this letter, let us assume that all the COVID-19 vaccines used in Canada under the Interim Order are "safe and effective."

Below we will outline that ivermectin is safe and effective for COVID-19. It should be part of a multipronged approach to complement the currently employed vaccines, and that Health Canada, along with all of its supporting regulatory agencies, should approve the use of ivermectin to prevent and treat COVID-19.

REGARDING SAFETY OF IVERMECTIN FOR COVID-19

Background: The current evidence provides nothing to suggest that ivermectin is unsafe for use in humans at the dosages prescribed for SARS-CoV-2 **(we do not condone using a veterinary formulation in humans)**. Here is only some of the available information on ivermectin safety:

- A meta-analysis in the Journal of Anti-microbial Chemotherapy examined the safety of high dose ivermectin and concluded safety of ivermectin in high doses seems to be comparable to that of lower doses. (1)

- Safety data of ivermectin in standard doses is widely established; it is on the WHO list of essential medicines.(2)
- Safety of doses up to 10 times the highest FDA approved dose of 200 µg/kg have been well tolerated.(3)
- Adverse events, if they occur, are typically non-severe.(4,5)
- VigiAccess® (6) reporting of adverse events has remained extremely stable for ivermectin over this past year, keeping in mind that millions of doses of ivermectin are being used for SAR-CoV-2 across the globe. The number of adverse event reports for ivermectin was 5663 as of September 26, 2021 cumulative since 1992 (this represents approximately 4 billion doses administered worldwide). In contrast, paracetamol records in VigiAccess retrieved on the same date consist of 168,343 adverse drug reaction records, and COVID-19 vaccines at 2,125,072 adverse drug reaction records.
- An extensive ivermectin safety analysis was published in March, 2021 which uncovered no safety concerns.(7)

Because ivermectin has been used around the world for approximately four decades, we have the benefit of a large amount of data indicating safety in its various applications. Further, it has already proven itself to treat a wide range of diseases.(8,9) We also understand the precautions of using ivermectin in pregnant women, children under 2 years of age, or anyone with a brain injury or meningitis where neurological toxicity may then be a concern. We ascribe to treating the individual patient just as healthcare professionals have always done, considering other medical conditions, warnings, precautions, other medications, and allergies, always, respecting patient autonomy and their ability to accept or refuse treatment while providing informed consent.

Request: We would like you to declare that ivermectin is safe for prevention and treatment of COVID-19. (Ivermectin cannot become unsafe just because it is used off-label for another condition.) If you cannot agree that the human formulation of ivermectin is safe, we ask you to explain why it is unsafe; please cite primary literature for your statements.

REGARDING SAFETY OF VACCINES FOR COVID-19

Question: Do you believe that human use of ivermectin is less safe than the current COVID-19 vaccines?

Background: As noted above, VigiAccess is reporting that the current number of adverse events from the COVID-19 vaccines is over 2,000-fold higher than for ivermectin.

As of September 21, 2021, the VAERS database in the United States has reported 14,925 deaths after administration of COVID-19 vaccines. A large number of severe side effects have also been reported. Since the beginning of the COVID-19 vaccine campaign, the reported deaths from vaccines in the United States have now surpassed the total number of deaths reported to the system from all other vaccines combined in the last 30 years. It is understood these figures do not confirm causality, however because the VAERS system was intended to operate as an early warning system, it is extremely concerning that a detailed investigation does not appear to be currently underway. By way of comparison, the 2018 product

monograph of Merck's ivermectin, known as Stromectol®, states that "There are reports of accidental overdosage of ivermectin, but no fatalities have been attributable to ivermectin overdosing."(10)

We are concerned that in Canada, adverse events from the COVID-19 vaccines are being under-reported. An open letter reported in the Western Standard on September 24th signed by over 3500 Alberta Health Services (AHS) employees expressed that "the vast majority of temporally related adverse events are not being correlated and reported by healthcare workers. If we don't correlate these temporally related events and report them, the data will never be there to accurately assess causality and truly ensure safety…".(11) Even with this in mind, there are currently 197 deaths in Canada after receiving the COVID-19 vaccination, and 5161 serious adverse events following immunization.(12)

Critics seem quick to brush reported vaccine adverse events aside, however we would like to remind you that Canadian professional colleges and health regulatory agencies are in existence to protect the health and safety of the public. We have heard comments about the inaccuracy of VAERS, that a large portion of the reports may have nothing to do with the vaccination, or that people might be filling out adverse events forms to support an "anti-vaccine" agenda. This seems to be without basis, as a preprint study analyzing the first 250 deaths in VAERS found that 72% of reports came from within different levels of the medical system, and that in 86% of the reported deaths the vaccine was the cause of death, possibly the cause of death, or contributed to death.(13) Further, a Harvard study from 2011 indicates that "fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of 'problem' drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative."(14)

REGARDING EFFICACY OF IVERMECTIN FOR COVID-19

Request: We ask that those responsible for evaluating the evidence have clinical expertise and first-hand (i.e., direct-to-patient) experience prescribing early treatment protocols for SARS-CoV-2 before informing policy. And after reviewing the information below (including the references provided), please acknowledge there is evidence to suggest that ivermectin is effective for prevention and treatment of COVID-19.

Background: Upon consultation of the available literature and epidemiological data, there is a large amount of evidence to support the use of ivermectin in early treatment for SARS-CoV-2. The FLCCC is an excellent resource for clinicians to see the summary of available evidence (15, 16) as well as the British Ivermectin Recommendation Development (BIRD) Group.(17) We understand this has been widely debated, and we debate the data among ourselves, including how treatment protocols may need to be adjusted as we encounter new variants. We do not ascribe to the notion that "the science is decided." (the very ideology is antithetical to science). Ivermectin is being actively studied by a Duke University led collaboration (18), and by many others around the globe.

Alberta Health Services has been evaluating multiple studies on ivermectin, and acknowledges even more studies soon to publish findings (19), however the focus on that evaluation seems to neglect important clinical considerations. The notion that only certain large double-blind randomized controlled trials on ivermectin are the only permissible evidence is unfortunately missing the larger clinical picture. Double blind randomized controlled trials still need to be evaluated for critical design flaws *from the perspective of a clinician with expertise in that area*. For example, if patients in a double blind randomized controlled trial were administered ivermectin on an empty stomach for SARS-CoV2, we would not expect much of an efficacy signal because the biodistribution would only be a fraction of what it would be if administered on a full stomach (particularly a fatty meal).

It is also important to note that 31% of clinical practice guidelines for infectious diseases are currently formed using observational studies (20), 10-20% of all prescriptions are prescribed off-label (21), and a Cochrane review from 2014 concluded "there is little evidence for significant effect estimate differences between observational studies and RCTs."(22) Given this information, it is understandable why physicians in our country have deemed it perfectly reasonable during a pandemic to prescribe ivermectin off-label for COVID-19.

Please also appreciate that many of the ivermectin studies have been done by practicing physicians in developing countries using their own personal resources. It is not possible in this context to conduct high-powered randomized clinical trials (RCTs) that Canadian authorities maintain as the standard that must be met.

Furthermore, on October 14, 2021, the State of Nebraska issued a statement: "Allowing physicians to consider these early treatments will free them to evaluate additional tools that could save lives, keep patients out of the hospital, and provide relief for our already strained heathcare system."(23) They concluded that physicians should be allowed "to prescribe ivermectin or hydroxychloroquine to prevent or treat COVID-19." Similarly, the State of Louisiana issued a statement allowing "physicians to prescribe and pharmacists to dispense FDA-approved drugs for off-label use in situations where a physician believes that it is the best treatment option available for a patient suffering from COVID-19."(24) Moreover another highly respected body in the United States, the National Institutes of Health (NIH), has changed its position on ivermectin from "against" to "neither for nor against" in its 2021 January 15th statement (25), and on July 8th NIH gave tacit approval of ivermectin for COVID-19 by including it in Table 2e with a detailed dosing regimen.(26)

REGARDING EFFICACY OF VACCINES FOR COVID-19

Request: We now know that vaccine efficacy wanes over a short period of time, and the vaccines do not provide sterilizing immunity. Please acknowledge the waning efficacy of the current vaccines, and that the vaccines do not prevent infection or transmission.

Background: Waning efficacy is supported by evidence coming out of countries that initiated their vaccine campaigns earlier than Canada. Dr. Sharon Alroy-Preis, Israel's director of public health services, has also voiced concern about the efficacy of the vaccines waning over time. An article from Science magazine reported numbers from Israel up to mid-August as 59% of hospitalizations in the fully vaccinated.(27)

The director of a large hospital in Jerusalem has also publicly stated that 85%-90% of hospitalized patients and deaths are in vaccinated people.(28) Hospitalizations in Israel have risen in July-September 2021 to levels near those previously seen in this pandemic even though nearly 70% of its population was vaccinated.

The Government of Canada acknowledges there are only short-term data on the efficacy of the vaccines and that the "clinical trials of the authorized and available COVID-19 vaccines assessed efficacy against severe COVID-19 disease, but not all provided sufficient data to be able to assess the efficacy against hospitalizations or deaths."(29)

Given these data, we may unfortunately see a growing number of our Canadian hospitalizations occurring in the vaccinated. The open letter posted in the Western Standard from the 3500+ AHS signatories also suggests a shared concern of increasing hospitalizations of the vaccinated as "weeks go by."(11) **Clearly, we need multiple approaches to helping Canadians avoid COVID-19-related hospitalization and death.**

MULTIPLE APPROACHES TO THE PREVENTION AND TREATMENT OF COVID-19

Request: All Canadian healthcare authorities should acknowledge the effectiveness of early out-patient treatment protocols for COVID-19 (including ivermectin) that have been developed by highly credentialed and well-respected clinicians around the globe. They should encourage Canadian physicians to prescribe these protocols when they have deemed it appropriate. Prohibiting treatment is endorsing medical malfeasance; healthcare authorities should not engage in the unprecedented interference of the doctor-patient relationship when individual patient care is required now more than ever.

Background: Ivermectin is often administered as part of early outpatient treatment protocols. Ivermectin, however, is not the only medication that physicians are using to treat patients who have symptoms and/or a diagnosis of COVID-19. Many prominent physicians have developed multi-drug early protocols using different generic medications. Just a few of the physicians are:

- Dr. Peter McCullough
- Dr. Brian Tyson
- Dr. Ira Bernstein
- Dr. Richard Urso
- Dr. Ryan Cole
- Dr. Shankara Chetty
- Dr. George Fareed
- Dr. Pierre Kory
- Dr. Paul Marik

These physicians have treated thousands of patients. They report reduced hospitalizations and deaths from using these medication protocols. Dr. Peter McCullough published his findings at the end of 2020 and the beginning of 2021.(30,31) He also testified at the US Senate regarding early outpatient treatment protocols, noting censorship as a barrier to wide adoption of these protocols.(32) The World Council for

Health recently released a comprehensive and pragmatic guide that describes the possible symptoms and treatment suggestions for home-based care for those with early COVID-19.(33)

There are multiple countries already using ivermectin for both prevention and treatment of SARS-CoV-2. Some of these areas are populous states of India, select regions in the USA, Bangladesh, Mexico, and Japan. Of note, Japan recently announced its need to "greenlight" ivermectin after SARS-CoV-2 cases began soaring despite the high vaccination rate of its population.(34) This is in contrast to the growing number of Scandinavian countries now limiting or halting the use of the Moderna COVID-19 injection (35), and Japan recalling 1.6 million doses of Moderna due to contamination issues.(36)

ADDITIONAL CONSIDERATIONS

Although reluctant to include this section, we found it was unfortunately necessary given the context of our current global situation. Thus, why have safe and efficacious early outpatient treatments not been presented to your memberships?

When investigating the scientific literature and listening to the other physicians and scientists using ivermectin and other early multi-drug treatment protocols, they expressed encountering censorship to an alarming degree, in addition to slander, and "fact-checking" articles that did not accurately fact-check the subject matter. The fact-checking articles focused instead on creating suspicion against the doctors and scientists (who upon investigation were found to be extremely well informed and reputable). We have since then encountered scientists speaking out about "fact checkers", with their opinion that fact checkers are not scientists and in actuality, further act as censors.(37) A short documentary from the BIRD group speaks to the experience of being "fact checked" as well.(38)

Large media outlets have sensationalized the human use of ivermectin with veterinary ivermectin, and there are sparse articles that present an unbiased viewpoint or discussion that we would expect from investigative journalism. The most concerning was a recent article in Rolling Stone that reported a hospital in the United States was overwhelmed by patients that had overdosed on ivermectin to the extent that the hospital could not help other patients. The article turned out to be completely fabricated, however prior to that, it was shared by many other large media outlets.(39) There does seem to be a suppression of the treatment. It's taken many months for the story of Dr. Pierre Kory and the FLCCC to be fairly reported in a relatively small media outlet.(40) Please also keep in mind that we are living in an age where a *Lancet* article was published with findings that treatment with hydroxychloroquine for COVID-19 caused more harm than benefit; however, this article was later retracted (41), unfortunately detracting others from pursuing further scientific study in the meantime. It's extremely unfortunate that humans have resorted to seeking out veterinary ivermectin because rational prescribing and dispensing of the human drug has been suppressed.

SUMMARY

Clinicians in Canada are more than qualified to study the literature and raw data, assess the risk/benefit of potential treatment options, and prescribe off-label as they would for any other condition. We are disappointed the regulatory health agencies assume physicians prescribing ivermectin for COVID-19 are somehow not meeting the expected standards of their profession; we would assume those not working with patients would engage in discussions to learn *from* the physicians. It wasn't so long ago that spirited scientific discourse and respectful debates were not only allowed, but fostered and encouraged by our licensing bodies. Our universities taught all of us to consult the literature, think critically, and apply this to patient care.

It has become increasingly remiss to not offer any strategy for treating COVID-19 in the early stages of the disease. Instead, the current recommendations after a positive test are to isolate and take Tylenol® for pain if necessary. This may be a reasonable strategy for influenza but given the highly destructive potential of SARS-CoV-2 and its variants, this has now become absurd, especially when contrasted against the more robust advice provided by the World Council for Health in its "Early COVID-19 Treatment Guidelines: A Practical Approach to Home-Based Care for Healthy Families."(33)

In fact, only when breathing is severely impaired are patients actively encouraged to seek medical care, and by this point nothing less than emergency medical intervention will suffice. Not only is this an incredibly dispassionate way to practice medicine, but it is also of great cost to our limited community medical services, serving to exhaust both personnel and financial resources unreasonably and unethically.

In no other medical situation would this ever be considered a reasonable standard of care.

Ivermectin is an inexpensive, award-winning medication with antiviral activity, and an excellent safety profile. It has been used across the globe for decades. There is also a strong signal of efficacy supporting its use for SARS-CoV-2 in the current literature and epidemiological data. There is also solid data and clinical experience to suggest that early outpatient treatment protocols involving other generic medications and nutritional supports can reduce hospitalization and death.

To continue to do nothing in this manner is doing harm; it breaks the Hippocratic Oath that every doctor has professionally sworn to uphold.

For the sake of the citizens in your provinces and all Canadians, we call upon you to reconsider your position on the current treatments being offered in this pandemic and let all clinicians know they are free to prescribe ivermectin and other early treatment protocols off-label if they have deemed it appropriate for specific patients. Withholding treatment has already resulted in unnecessary illness and death. Continuing to do so after nearly 16 months of cumulative data is unconscionable.

This letter has been written based on the assumption that you are the decision makers of record. Please clarify if this is incorrect, or if you are simply carrying out orders from a higher authority. We would be most grateful to receive a prompt and commensurate response from you to this letter.

Sincerely,

K. Nakatsu
Kanji Nakatsu
Lead, Pharmaceutical Task Force - CCCA
Professor Emeritus, Pharmacology
Queen's University
nakatsuk@queensu.ca

D. Ross
David Ross FCPA FCA
President,
Canadian Covid Care Alliance
david.ross@canadiancovidcarealliance.org

C. Beveridge
Carole Beveridge
Member, Pharmaceutical Task Force - CCCA
MSc Integrated Healthcare, BSc Phm
cbeveridge@affinityforhealth.ca

K. Levins
Karen Levins
Director,
Canadian Covid Care Alliance
karen@canadiancovidcarealliance.org

S. Pelech
Steven Pelech
Chair, Scientific and Medical Advisory Committee - CCCA
Professor, Medicine, University of
British Columbia
spelech@mail.ubc.ca

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About the Canadian Covid Care Alliance

The Canadian Covid Care Alliance (CCCA) is a group of independent research scientists, doctors, registered nurses and nurse practitioners, and other health care practitioners, as well as lawyers, ethicists and other professionals. The Alliance is dedicated to providing balanced, scientific evidence-based information related to the prevention, tracking and treatment of COVID-19 so that hospitalizations can be reduced, lives saved, and our country safely restored as quickly as possible.

Our representative credentials and expertise within our Alliance include, but are not limited to, the following:

MD, Family Practitioner MD, Coroner RN, Primary Care PhD, Biomedical Research Doctor of Dental Surgery Doctor of Veterinary Medicine	PhD, Immunogenetics PhD, Immunology PhD, Molecular Virology PhD, Viral Immunology PhD, Pharmacology PhD, Biochemistry	PhD, Epidemiology EdD, Psychology DPhil, Bioanalytics PhD, Methodology PhD, Ethics LL.B., B.B.A, Personal Injury	Chiropractic Integrative Medicine Physiotherapy Osteopathy Naturopathy Occupational Therapy

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