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January 3, 2022

VIA E-MAIL
sudarsana.srinivasan@ag.ny.gov

Darsana Srinivasan, Esq.
Bureau Chief, Health Care Bureau
Office of New York State Attorney General
28 Liberty Street
New York, NY 10005

Re: Warning letters to physicians regarding prescribing and advertising Ivermectin
Frontline Covid-19 Critical Care Alliance

Dear Ms. Srinivasan:

I write on behalf of the Frontline Covid-19 Critical Care Alliance ("FLCCC" or "Alliance"), a 501(c)(3) organization founded by highly respected and published physicians treating COVID-19 in their offices, hospitals and ICUs in major medical centers since the onset of the pandemic. (*See* extensive material at https://covid19criticalcare.com). As your Office has sent warning letters to a number of physicians associated with FLCCC and its treatment recommendations, we thought it important to reach out directly to address scientific and legal misconceptions with the hope that we can engage in a constructive discussion about FLCCC and physician use of ivermectin as part of its overall protocol.

Sadly, the scientific data supporting the safety and effectiveness of ivermectin as an early intervention in COVID-19 has been clouded by a perfect storm of political controversy, in every sense of that phrase. It has become a hot button for critics who have hijacked the assessment of the science on both sides of the COVID-19 policy divide. Rather than looking at the full spectrum of available data, ivermectin has become a proxy in the debate over pandemic measures and a large body of excellent work has been ignored for unsound reasons. Unfortunately, we have seen regulators and the media perpetuate these narratives rather than examine the facts. Like so many others, we believe your Office has fallen victim to these unscientific and unsupported narratives.

Misrepresentation of the NIH Position

A central concern is that your letters misrepresent the recommendations of the National Institutes of Health ("NIH") regarding the treatment of COVID-19 in a manner consistent with the narrative opposing the use of ivermectin but which is, in fact, false. While your letters claim the NIH has determined there is insufficient data to recommend ivermectin for treatment of

COVID-19 and that physicians should therefore desist from such use, the NIH actually concluded that there is insufficient data to "either recommend for *or against* the use of ivermectin in COVID." One cannot take a statement that something "may or may not be true" and selectively quote one or the other as a finding. It is equally true that the NIH expressly found that there is not enough evidence to recommend *against* the use of ivermectin. Yet your Office bases its cease-and-desist letters precisely on that misrepresentation of NIH's position.

It may be helpful to note that this determination by the NIH was made nearly a year ago, after the very scientific evidence on the FLCCC website that concerns you was personally presented directly to the NIH Covid Panel by FLCCC physicians. The NIH panel met in mid-January of 2021with Paul Marik, M.D. (Former Division of Pulmonary and Critical Care Medicine, Eastern Virginia Medical School, Norfolk, VA) and Pierre Kory, M.D. (Former Chief of the Critical Care Service and Medical Director of the Trauma and Life Support Center at the University of Wisconsin) founding members of the FLCCC Alliance, along with United Kingdom scientist Andrew Hill, M.D., longtime trusted researcher and consultant to the World Health Organization (WHO) (and author of the paper cited below at note 16). After FLCCC's presentation, the NIH immediately elevated ivermectin from a "do not use" to a "neither recommend for or against" policy.[1] While NIH wants to see the results of ongoing trials before a full recommendation,[2] the Panel acknowledged the value of FLCCC's presentation by removing the recommendation *against* use by physicians. By way of reference, until recent specific exceptions were granted, the "neither for or against" category included monoclonal antibodies and convalescent plasma for COVID-19 even though both therapies had been commonly used in COVID-19 treatments without drawing regulatory action. Particularly given the dearth of standard of care options in treating a novel coronavirus, such a neutral finding by the NIH historically places ivermectin's use squarely within the reasonable judgment of the physician. We think if you view the NIH recommendation in this context, both the NIH position and the value of the FLCCC's evidence-based protocols will become more clear.

It is understandable that your Office and other well-intended public officials would misread NIH's conclusions in their good faith efforts to protect the public health in the face of the highly politicized drumbeat against ivermectin. One of those oft repeated drumbeats is that

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[1] https://www.newswise.com/coronavirus/nih-revises-treatment-guidelines-for-ivermectin-for-the-treatment-of-covid

[2] FLCCC has responded in depth to the remaining criticisms the NIH panel had that prevented the recommendation to use: https://covid19criticalcare.com/ wp-content/ uploads/2021/01/FLCCC-Alliance-Response-to-the-NIH-Guideline-Committee-Recommendation-on-Ivermectin-use-in-COVID19-2021-01-18.pdf

"there are no scientific studies that show that ivermectin is safe or effective in the treatment of COVID 19." This is flatly inaccurate as there has long been a substantial body of completed research including peer-reviewed meta-analyses: presently, there are over **71 trials** including **at least 31 randomized controlled trials** showing significant benefit. The studies are summarized at https://c19ivermectin.com and a meta-analysis can be found at https://ivmmeta.com (constantly updated).[3] Currently, over 50,000 patients have been included as study subjects with the overall signal of benefit in important clinical outcomes strongly positive with tight confidence intervals.[4] While there is certainly misunderstanding and controversy around the use of ivermectin.[5] FLCCC has exhaustively reviewed and commented—always based on the *data*--on the concerns that have been raised.[6] [7]

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[3] *See also* Kory, P, Meduri, U, Iglesias, J *et al.* Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19, *Am.J.Therapeutics*. 2021; 28:3 - e299-e318. (Peer reviewed, attached as Exhibit B).

[4] *For e.g., see* Favorable outcome on viral load and culture viability using Ivermectin in early treatment of non-hospitalized patients with mild COVID-19 – A double-blind, randomized placebo-controlled trial. https://www.medrxiv.org/content/10.1101/2021.05.31.21258081v1. (Attached as Exhibit B).

[5] *See for e.g.,* https://www.the-scientist.com/news-opinion/frontiers-removes-controversial-ivermectin-paper-pre-publication-68505

[6] *See for e.g.*, https://covid19criticalcare.com/wp-content/uploads/2021/03/ FLCCC-Statement-on-Weak-Guidance-on-Ivermectin-from-WHO-March-31-2021.pdf;

https://covid19criticalcare.com/wp-content/uploads/2021/03/FLCCC-Alliance-Statement-on-Misleading-FDA-Guidance-on-Ivermectin-March7-2021.pdf;

https://covid19criticalcare.com/wp-content/uploads/2021/03/FLCCC-Alliance-Response-to-the-NIH-Guideline-Committee-Recommendation-on-Ivermectin-use-in-COVID-2-28-21.pdf;

https://covid19criticalcare.com/wp-content/uploads/2021/02/FLCCC-Alliance-Response-to-Merck-statements-on-ivermectin-in-Covid19-Feb7-2021.pdf

[7] It is enlightening to compare the extent of research and effect sizes of ivermectin with that of recently approved Merck's molnupiravir. Note that ivermectin is an inexpensive generic drug, lending it less access to FDA's approval process for a new indication than is available to a pharmaceutical company with a new, patented drug. Indeed, if FLCCC had been able to marshal the resources for FDA approval it would only come many months to years from now, even to

The FDA Position

Your cease and desist letters are also based on the claim that ivermectin is not currently approved by the Food and Drug Administration for the prevention or treatment of COVID-19. But off-label uses of approved drugs are extremely common in medicine and, by itself, provide no basis for an order to cease-and-desist either prescribing or advertising. It is well-settled law that while manufacturers and distributors have limits on speech for off-label claims, that limitation does not apply to physicians.[8] A governmental effort to squelch such statements, where they are in fact supportable as I address in this letter, can in fact be seen as a violation of the First Amendment. *See for e.g. United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Amarin Pharma, Inc. v. United States FDA* , 119 F. Supp. 3d 196, 225-26 (S.D.N.Y. 2015).[9] This is not limited to speech that is non-controversial. Indeed, the fact that there are professional differences of opinion is precisely the circumstance for which these protections are in place. While you are operating from a presumption that ivermectin does not have an appropriate use in COVID-19, this appears to reflect a highly transmissible narrative rather than an independent evaluation by your Office of either the science or public agency positions.

Noting the off-label status of ivermectin's use would certainly be reasonable as an initial observation, if indeed there were a case to make for intervention by your Office. But the implication of your letters that physicians should cease following the evidence and their experience because the indication is not authorized by FDA is neither legally nor historically grounded. Further, there is no basis to rely on the FDA, which has never conducted any formal

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meet the standards for an Emergency Use Authorization. Treating physicians in the room with very ill patients simply cannot and should not wait for that.

[8] "Central to this litigation is that what a manufacturer may lawfully claim that a drug does under the statutory and regulatory scheme, and what a physician may prescribe a drug for, do not match. Once a drug has been approved by the FDA for marketing for any use, the actual prescription choices regarding those drugs are left to the discretion of the physician. *See, e.g.*, 59 Fed. Reg. 59820, 59821 (1994) (noting that the agency has restated this policy on numerous occasions). A physician may prescribe an approved drug for any medical condition, irrespective of whether FDA has determined that the drug is safe and effective with respect to that illness. That physicians may presently prescribe off-label is not in dispute." *Wash. Legal Found. v. Friedman* , 13 F. Supp. 2d 51, 55 (D.D.C. 1998).

[9] "[P]enalizing truthful statements promoting an off-label use "'paternalistically' interferes with the ability of physicians and patients to receive potentially relevant treatment information." *Id.* (quoting *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc*., 425 U.S. 748, 770, 96 S. Ct. 1817, 48 L. Ed. 2d 346 (1976)).

review of the evidence nor published any guidance for comment about ivermectin's use in COVID-19. Only the NIH has done so. The source for FDA's position comes from a consumer-facing page that was developed in response to a concern we share for the use of veterinary forms, as well as other allegedly reported safety concerns I address below. FDA took it upon itself to issue a broader warning, but until a short time ago the FDA page acknowledged that "FDA has not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19...."[10] While this statement curiously has been removed from the FDA website, it remains true. As the Agency has not conducted a formal process of review, the views of its staff merit consideration but aren't findings upon which the Office of the Attorney General may rely.

Support from the Office of the Nebraska Office of the Attorney General

The issue of whether the off-label prescribing of ivermectin for the prevention and treatment of COVID 19 should result in disciplinary actions against physicians was posed to your counterpart in Nebraska, resulting in an exhaustive analytical opinion (Attachment A). This 47 page opinion by Nebraska Attorney General Doug Peterson dated October 14, 2021 concluded: "we find that the available data does not justify filing disciplinary actions against physicians simply because they prescribe ivermectin .... to prevent or treat COVID 19." I highly commend it for your review in its entirety[11] as the opinion offers a careful and comprehensive review of the issues raised in your letters. One of the opinion's useful perspectives is a comparison of the risk profile of ivermectin to other FDA approved drugs for COVID such as Remdesivir which have been scientifically shown to present much higher levels of adverse events. In addition to my letter, my hope is that this report will resolve the questions your Office has about this therapy.

Recommended Use and Public Health Policy

Before addressing the science it is important to put ivermectin prescriptions in context:

First, FLCCC publishes a comprehensive protocol that is meant to work synergistically.[12] Ivermectin is one of a number of evidence-based interventions but is not recommended alone. This protocol has been updated as new information and data become available. The protocol is

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10 *See* archived FDA page from September 1, 2021 at https://web.archive.org/web/20210901003259/https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19

11 Also available at https://ago.nebraska.gov/sites/ago.nebraska.gov/files/docs/opinions/21-017_0.pdf

12 https://covid19criticalcare.com/covid-19-protocols/i-mask-plus-protocol/

designed to work by combining the clinical impacts of a number of different products rather than relying on single ingredients.

Second, FLCCC is a group of well-trained medical physicians (*see* Attachment C) and its goal in the use of ivermectin has been for treating physicians to determine if a prescription is appropriate and for use under medical supervision. The FLCCC has not advocated otherwise and strongly advises against self-prescribing or use of animal forms, though it does advocate to reduce institutional barriers to its use; *ironically, it would be safer, to ensure that the drug is prescribed and used under medical supervision, if physicians were not experiencing barriers and threats of discipline when prescribing it.*

Third, the success of ivermectin requires early intervention before the virus fully takes root. This appears to be almost universally true for antiviral medications. This has been true for the flu, as with Tamiflu, and is also true of the two recent entries in the field by Merck and Pfizer. The push back against use, largely by sources who do not evidence an awareness of the massive body of scientific literature (much of which has been published by FLCCC), has made it difficult for patients to obtain ivermectin at the stage in which it is most useful. Critiques of ivermectin are often based on studies using interventions that were too late, too low in dosing, or on high-profile cases in which ICU patients weeks into the disease (after viral loads were reduced and inflammation had become the problem) were finally given ivermectin and, unsurprisingly, it had little effect. Molnupiravir (recently approved from Merck) and Paxlovid (recently approved from Pfizer) would not fare well in such conditions either. What the evidence shows is that efforts to blockade the early prescribing of ivermectin by a physician properly following a patient is doing real harm and is clearly not in the public interest.

Fourth, FLCCC has offered its protocol in addition to public health measures such as social distancing, the use of masks and vaccination. FLCCC has not suggested to the public or advised physicians to tell their patients that ivermectin, either prophylactically or as an available treatment should substitute for these measures.[13] While we have not investigated physicians that have received your letters and cannot speak to how they practice medicine, your letters do not suggest that your Office has either.

Fifth, as has become even more clear in recent weeks, elimination of COVID-19 is a race against viral evolution. No treatment, vaccine, or intervention is 100% available and effective for all current and future variants. All practical, effective, and safe means should be used. Not doing so increases the risk of COVID-19 becoming endemic and increases mortality, morbidity, and collateral damage.

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13 *See for e.g.* https://covid19criticalcare.com/ivermectin-in-covid-19/faq-on-ivermectin/

Clinical and Epidemiological Evidence for the Use of Ivermectin in COVID-19.

The FLCCC Alliance's work, begun in October 2020 based on a review of recent and rapidly emerging clinical trials evidence, identified the anti-parasitic medicine ivermectin as having highly potent real-world, antiviral and anti-inflammatory properties against SARS-CoV-2 and COVID-19. Further, data from large "natural experiments"– when various regional health ministries and governmental authorities within South American countries initiated "ivermectin distribution" campaigns– revealed temporally associated decreases in case counts and case fatality rates.

The Alliance performed a meta-study and assessment of available studies using the Cochrane Risk of Bias 2.0 tool to assesses trial biases with the grades of "some concern, low, moderate, high, or serious." Although one group of authors assessed many of the trials as having moderate to severe risks of bias, the meta-analyses of these trials by top scientists (including some affiliated with the WHO and other health organizations) enabled a more accurate assessment of the drug's true effects despite individual trial biases. All found consistent benefits amongst the trials. In fact, the consistency of trial results–from sets of randomized and observational controlled trials from varied centers and countries and trial sizes and disease phases–lend even more credibility to the estimates of benefit.[14]

Recent publications of note include a systematic review and meta-analysis by Bryant and Lawrie[15] which found clinically significant reduction in the risk of death and moderate evidence of substantial reductions in illness, and by Hill and Garrat,[16] which in a review of 24 randomized trials found clinically significant reductions in death and inflammatory markers and improvements in clinical recovery.[17] *See also* Kory, P., *ibid*, fn 3 (Attachment B.)

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[14] For more information see https://covid19criticalcare.com/ivermectin-in-covid-19/

[15] Bryant A, Lawrie T *et al*. Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines, *Am. J. Therapeutics* 0, e1-e27 1075-2765 (2021) https://covid19criticalcare.com/wp-content/uploads/2021/06/Ivermectin_for_Prevention_and_Treatment_of.98040.pdf

[16] Hill A, Garrat A, *et al*. *Meta-analysis of randomized trials of ivermectin to treat SARS-CoV-2 infection,* Published by Oxford University Press on behalf of Infectious Diseases Society of America. https://covid19criticalcare.com/wp-content/uploads/2021/07/AndrewHill7-6-21paper.pdf

[17] *See also* Morgenstern J. Redondo J. Olvarria A et al. Ivermectin as a SARS-CoV-2 Pre-Exposure Preventive in Healthcare Workers: a Propensity Score-Matched Retrospective Cohort

In addition to these trials, the epidemiologic data presented by FLCCC may provide the strongest level of medical evidence attainable, as they consist of findings from what should be considered large, real-world "natural experiments" that spontaneously occurred within many cities and regions of the world when local and regional health ministries decided to initiate widespread ivermectin distribution to their citizen populations. The "control groups" in these natural experiments were the neighboring cities and regions that did not employ widespread ivermectin distribution. In the areas with ivermectin use compared to those without, large and temporally associated decreases in case counts and fatalities were found after the ivermectin distribution began. The magnitude and reproducibility from city to city, region to region, and country to country is unassailable. All data were sourced from universally used, publicly available COVID-19 epidemiologic databases. The manuscript by Chamie *et al*, which focuses solely on this data has been refined and reviewed by scientists and researchers under the direction of a dean at a major medical research university. A number of these scientist researchers have joined as co-authors of this historically important manuscript.[18] The FLCCC website contains extensive explanation and citation to the evidence supporting the use of ivermectin in all stages of COVID-19 and provides responses to critiques of that evidence.

Understanding the Ivermectin Critiques

There are clearly substantial differences of professional opinion about the use of ivermectin. FLCCC has exhaustively reviewed and commented on the concerns that have been raised in its FAQ section and elsewhere. For this letter I focus on the most influential meta-study reaching a contrary conclusion, the Cochrane Library Review.[19] While similar methodology was used to that followed by reviewers who reached favorable conclusions, the main differences between these reviews are the criteria for selecting which studies should be included. The Popp Cochrane review only selected 14 of the 31 published studies, rejecting large studies with positive effects on questionable grounds,[20] such as a demand that only studies with PCR testing

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Study Cureus (August 26, 2021) available at: https://covid19criticalcare.com/wp-content/uploads/2021/09/IVM-as-a-Covid-Pre-Exposure-Preventive...pdf

[18] https://covid19criticalcare.com/ivermectin-in-covid-19/epidemiologic-analyses-on-covid19-and-ivermectin/

[19] Popp M, Stegemann M, Metzendorf MI, *et al.* Ivermectin for preventing and treating COVID-19. *Cochrane Database of Systematic Reviews* 2021, Issue 7. Art. No.: CD015017. DOI: 10.1002/14651858.CD015017.pub2.

[20] For a critique of the Popp Cochrane methodology see Fordham E. Lawrie TA. MacGilchrist K. Bryant A. *The uses and abuses of systematic reviews: The case of ivermectin in*

be included even though availability and accuracy varied considerably, especially at the time; inconsistent rejection of comparators; and the exclusion of combination therapies even though that is how ivermectin is actually prescribed in practice. For example, a principal criticism the Popp authors had of favorable studies was inclusion of those that used doxycycline in the intervention arm, complaining that the impacts of doxycycline could not be separately determined. *Ibid*. at 32-33. While there may be some sense to this given complications such as pneumonia, doxycycline has no clinical effect on COVID-19 and thus could not confound the study as a comparator arm.[21]

In five of the studies included in the unfavorable Popp review, subjects only received a single dose,[22] *ibid*, which could not possibly have reached therapeutic levels and are therefore not valid studies. In fact, subjects only received the FLCCC recommended dosing in 5 of the 14 studies. *Ibid*. The study authors expressly state that they were aware of the dosing issue but did not have sufficient information to look at dose-response curves, *ibid.* at 13, yet included low-dose studies in the analysis in any event. *Ibid.* at 17.

Much more can be said, of course, about the science and the nature of these professional differences of opinion. The only reasonable conclusion is that that is what these are, legitimate professional differences of opinion that should be subjected to critique with data, not foregone conclusions. If your Office wants to understand these issues in more detail we would be happy to make arrangements for discussion with FLCCC physicians. However, physicians and scientists should be allowed to make their own determinations in the face of such differences without being subject to legal challenge, particularly when the safety data is properly understood.

The Safety of Ivermectin

The FDA and CDC statements cautioning about ivermectin's safety appear to stem from a mix of concerns that ivermectin has been presented in some lay communities as an alternative to

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W*Covid-19*, pre-publication available at https://osf.io/peqcj/ and with discussion at https://bird-group.org/critique-of-popp-et-al-cochrane-review/

[21] **Error! Main Document Only.**Butler C, Yu, L, Dorward, J et al. Doxycycline for community treatment of suspected COVID-19 in people at high risk of adverse outcomes in the UK (PRINCIPLE): a randomised, controlled, open-label, adaptive platform trial. The Lancet Respiratory Medicine. 9:9, P1010-1020 (Sept 1, 2021) Crossref DOI link: https://doi.org/10.1016/S2213-2600(21)00310-6

[22] These studies gave subtherapeutic levels by infrequent dosing. In one study, they used 0.4 mg/kg but only a single dose. *Ibid.* at 47. Another included study gave a 12 mg dose but only three times over 24 hours. *Ibid.* at 48. Another gave 12 mg once daily over two days. *Ibid.* at 50.

vaccination /public health measures and that some consumers have been self-medicating with animal forms, which were weighed against an expected low level of benefits measured by a selective review of the literature. In this environment, sensationalized media headlines about safety concerns were not analyzed but rather simply spread as part of this narrative. To the extent the concerns relate to unsupervised use of animal forms, they are appropriate. The FDA also oddly chose to discourage interest in properly prescribed ivermectin by warning about potential adverse interactions with other medications, an issue presented by virtually all drugs and routinely considered by prescribing physicians–yet not a particularly significant concern in ivermectin's 40-year history. But it is just one more reason its prescription should be unobstructed to assure use is in medical hands.

The alarms raised about potential for overdosing are not grounded in real concerns as ivermectin is one of the safest drugs known.[23] Studies using ivermectin doses up to 10 times the FDA approved dose of 0.2mg/kg have not been associated with any increased adverse effects. Ivermectin is on the WHO's list of essential medicines, has been given over 4 billion times around the globe and is widely considered a safe drug. According to the WHO, it is safer than both aspirin and Tylenol. Its discoverer was honored with the Nobel prize for its global and historic impacts in eradicating endemic parasitic infections in many parts of the world. The FDA's concern about use of animal drugs is certainly legitimate. FLCCC does not recommend veterinary formulations (nor would any licensed physician) given the lack of safety data around their use.[24]

The risk profile for ivermectin has been driven by and in turn feeds a false media narrative; in New Mexico, for example, two people died from COVID-19 but officials falsely reported they died from ivermectin toxicity, perhaps making assumptions because of alarmist news stories that were circulating. This led the CDC to issue its highest level alert on its network regarding reports of severe illness associated with the use of ivermectin. https://emergency.cdc.gov/han/2021/han00449.asp. Yet that CDC Health Alert, the same one

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[23] *See for e.g.* Kircik LH, Del Rosso JQ, Layton AM, et al. Over 25 *Years of clinical experience with ivermectin: an overview of safety for an increasing number of indications*. J Drugs Dermatol. 2016;15:325–332: Guzzo CA, Furtek CI, Porras AG, et al. . *Safety, tolerability, and pharmacokinetics of escalating high doses of ivermectin in healthy adult subjects*. J Clin Pharmacol. 2002;42:1122–1133.

[24] A summary of FLCCC information about safety can be found at https://covid19criticalcare.com/wp-content/uploads/2021/09/FLCCC-Information-Evidence-for-Safety-of-Ivermectin.pdf

referenced in your letters, contains not a single citation to any instance of harm from a human drug prescribed by a physician.

Citing a 24 fold increase in prescribing from the pre-pandemic baseline, the alert was issued because of a fivefold increase in calls to Poison Control Centers ("NPDS"). Most of these involved patients consuming large amounts of veterinary or unknown forms purchased on the Internet and taken without medical supervision. While claims are circulating that some of these cases were patients taking properly prescribed ivermectin based on statistics from poison control centers and emergency rooms, it is estimated that at least 75% were from self-administered animal drugs.[25]

While a proper analysis of this information isn't readily available, it is useful to note that the NPDS report CDC refers to cites 1,140 reported cases between January 1 and September 21 of 2021. If one extrapolates as a ballpark figure that 75% of these were consumers of the animal drug, then in that eight month period there were 285 calls regarding human drugs, or about 11 per week. According to the CDC health alert, there were approximately 39,000 prescriptions per week at the beginning of 2021 and rising. Poison control calls are not only a *de minimus* number, but looking more closely the NPDS report for ivermectin use in COVID-19,[26] far less than 1% are listed as leading to death (though there is no confirmed case information and it is not clear the NPDS is in a position to distinguish COVID deaths and adverse events from medication). About 2% reported a major effect and 10% a moderate adverse effect. Even assuming these were validly ascribed numbers and extrapolating this 13% apparent effect size to all of the 1,440 reports, there were about 187 cases which reported some level of moderate to serious concern over a time frame in which over one million scripts were written for ivermectin with adverse events reported in roughly 0.019% of cases. Of those, the majority would be from animal forms, leaving an estimate of moderate to severe events with human drugs in the range of 1 in 40,000 prescriptions. The Nebraska Attorney General's Opinion (Attachment A) puts those figures into stark perspective by comparing them with far more numerous adverse events from Remdesivir's use in COVID-19. In short, ivermectin is demonstrably safer than almost every drug, and far safer than the one drug–Remdesivir–that the FDA has approved for use against COVID. Using isolated case reports to support presumptions against ivermectin use is not a valid means of making such determinations.

I am sure this simple analysis leaves something to be desired; for example, it is likely that many scripts were filled to have on hand in the event of potential infection and remain unused,

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25 https://www.npr.org/sections/coronavirus-live-updates/2021/09/04/1034217306/ivermectin-overdose-exposure-cases-poison-control-centers

26 https://piper.filecamp.com/uniq/yyQHzDB8N11tCbpv.pdf

while on the other hand, many of these callers may have suffered nocebo effects in part from all the reporting about the alleged dangers of ivermectin. But this look at the numbers does make the point that relying on hyped news reporting of alleged cases and statistics that make it seem alarming does not in fact demonstrate that the long history of safety for this drug has suddenly changed.

Concluding Thoughts

It is not necessary that you agree that ivermectin is an important drug in managing COVID-19, only that your Office recognize that there is a reasonable basis for its use and there is no basis for the intervention of the Attorney General's office in medical choices made in the face of this level of evidence. We ask that you retract the cease and desist letters intended to restrict the rights of physicians to lawfully discuss this with the public and prescribe ivermectin to their patients.

We believe that the work and position of your Office on this issue is vital and want to be sure that your questions and concerns are addressed. We hope to work with you and if there are reasonable measures that might improve the safety of our communications we would certainly take them into account. We strongly believe that ivermectin, particularly as part of the overall FLCCC protocol, has a vital role to play and that public health policy makers should be helping, not hindering those efforts.

Sincerely,

/s/Alan Dumoff

Alan Dumoff

Attachments

Exhibit A	Nebraska Attorney General Doug Peterson opinion regarding physicians discipline for ivermectin prescribing, October 14, 2020
Exhibit B	Kory, P, Meduri, U, Iglesias, J *et al.* Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19, *Am.J.Therapeutics*. 2021; 28:3 - e299-e318.
Exhibit C	FLCCC's Level of Expertise