ALAN DUMOFF
Doctor of Law
Master of Social Work

Licensed to practice law in Maryland
and the District of Columbia

30 Windbrooke Circle | Gaithersburg, MD 20879 | (301) 987-0970 | *Fax:* (301) 987-0971 | alandlmc@aol.com

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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:

We appreciate your return correspondence dated February 1, 2022 and took the suggestions for clarifications on the FLCCC website as constructive. While the points you raised we believe were generally consistent with FLCCC's already stated positions, we agreed that these clarifications served a purpose and the changes made are delineated as Attachment A. Your letter acknowledges that the use of ivermectin and other repurposed therapies are the subject of legitimate debate, yet your Office has not only raised cautions about how the evidence should be presented but taken a side in that debate by force of law and threatened to sanction physicians whose trained judgment and clinical experience lead them to conclusions contrary to that of your Office. Given the effort expressed in your letter to encourage careful communication about this topic, which we saw as reasonable and balanced, we raise the question of whether restrictions on practice could be lifted if physicians follow informational guidelines and, where practical, use written informed consent based upon the draft enclosed as Attachment B. Such a negotiated solution would allow your Office to be reassured with regard to potential consumer misperception or disruption of public health messaging while still allowing physicians to practice medicine without unwarranted intrusion.

Your response was completely silent on the cease-and-desist letters that were the subject of our original letter. Your Office has taken its consumer concerns as a basis to overrule learned medical judgment and patient choice by instructing physicians not to prescribe ivermectin to residents of New York. It remains true, however, that NIH, the only public health agency that has conducted a review, expressly found that there was no basis upon which to recommend against the use of ivermectin. While it's true we disagree with NIH to the extent it sat panel members with conflicts of interest and failed to issue a positive recommendation, your Office has not recognized that NIH explicitly found such use is not unreasonable and that your action has no traction in the NIH position you cite. For an Office of the Attorney General to declare any

otherwise lawful prescribing a violation of law is unprecedented and to target physician prescription of ivermectin in COVID-19 in the face of the NIH statement is unsupportable. While your response letter focuses on consumer communication, it conveys several misunderstandings that apparently underlie the prohibition on prescribing and so I address those concerns in the context of your cease-and-desist position.

The Office's Cease-and-Desist Position

First, it is true that some of the studies finding clinical effectiveness for ivermectin in COVID-19 were retracted though you do not allege, nor is it true, that any of the studies FLCCC relies upon were retracted or that the retractions altered the evidentiary landscape. While some retractions occurred under editorial pressure due to the controversy surrounding the issue,[1] the salient point is that these retractions don't support your position, they simply provide a retort. The question is what can be discerned from the large number of properly completed studies and extensive epidemiological evidence. We know from your comments that the FLCCC website was reviewed in some detail, wondered whether the extensive discussion of the evidence and thoughtful analysis of risks of bias, research designs, epidemiological evidence and peer-reviewed published meta-analysis would affect your understanding, and wonder now how the fact that some studies had been retracted seems an answer to what you read on the site.

Second, the alarm over alleged toxicity is inconsistent with substantial evidence of safety. The fivefold increase in calls you cite as if it justifies not only caution but an actual ban is highly misleading. A more fulsome description might be that a 24-fold increase in prescribing resulted in *only* a fivefold increase in calls. To better understand the overall safety signal it is useful to look at absolute numbers in data from the FDA Adverse Events Reporting System (FAERS). While poison control calls and FAERS each suffer from limitations, its notable that reports for products containing ivermectin actually fell slightly in 2020 and 2021, despite increased use and dosing, with a combined total of 503 adverse reports at an annual rate *less* than 2017-2019. Reports did not rise post-COVID-19, but actually *fell.* The media reports about deaths due to

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[1] In this regard I note that another study of ivermectin was published in JAMA on February 18, 2022, concluding that ivermectin was not effective. https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2789362. The actual data in the study does not support that conclusion, as FLCCC has explained in detail at https://flccc.substack.com/p/jama-ignores-peer-reviewed-evidence?s=r and https://pierrekory.substack.com/p/the-disinformation-campaign-against?s=r. Nor does it overcome the totality of evidence that shows otherwise. JAMA, as a matter of editorial policy, has declined to publish any studies whose conclusion correctly states that ivermectin is a valuable drug in COVID-19.

ivermectin use turned out to be false,[2] as did the story about clogged emergency rooms[3], and the two incidents cited on the CDC report raising the concern were particularly egregious cases of misuse which can occur with any medication, in these cases drinking an injectable form prepared for use in cattle and a case of unknown strength purchased on the Internet.[4] Analyzing state-by-state Poison Control Center reports supports the NPR reporting that over 75% of calls were based on self-prescribed animal drugs and that a significant portion of human drug reports involved interactions with other drugs,[5] a universal issue in prescribing which is why it is an important health policy to lift the cease and desist requirement. These are reasons why prescribing should be available unhindered so that physician judgment and human drugs are available and consumers don't turn to unsupervised use.[6]

There have been 393 U.S. deaths attributed to ivermectin over a 20 year period; to provide some context, compare this with over 27,000 deaths from acetaminophen over that same period (though the number of total doses is clearly much larger),[7] or to the 1,612 deaths attributed to Remdesivir[8] (though the number of doses is much smaller!) since it's questionable

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[2] https://rescue.substack.com/p/a-myth-is-born-how-cdc-fda-and-media

[3] https://www.usatoday.com/story/news/factcheck/2021/09/15/fact-check-oklahoma-hospitals-not-backed-up-ivermectin-cases/8271014002/

[4] I note that FLCCC has never provided links to sources of ivermectin or suggested that it be purchased on the Internet.

[5] Using date from The Toxic Exposure Surveillance System (TESS), a uniform data set of US poison centers cases, MedWatch and other sources.

[6] Note that in the recent JAMA study referenced at note 1, of the 241 patients in the ivermectin group there were 4 serious adverse events, compared to 1 in the control group. This is consistent with if not better than seen in trials of many commonly prescribed drugs. The authors don't analyze the statistical significance of any of the adverse events but conclude that the rate of side effects does indicate that it should be taken under medical supervision; banning physicians from prescribing and monitoring the drug only interferes with that goal.

[7] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis

[8] https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis

and recent approval on October 22, 2020.[9] Until ivermectin was suggested to play a major role in the management of COVID-19 in competition with much more profitable drugs in the pipeline, it was widely considered to be an extremely safe drug.[10]

Further, this is not a case in which recognized treatments are being avoided in favor of ivermectin or other FLCCC recommended products. Until recently, there were no approved oral drugs for the outpatient treatment of COVID-19 for which ivermectin substitutes, patients were simply sent home until they required hospitalization. The recent drug approvals, Paxlovid and Molnuparivir, are not yet available in any significant channels nor is there is any post-marketing data available to determine their safety or effectiveness in real world use, a far cry from the extensive data available on ivermectin.

While we don't expect the facts about the treatment or the actual public health agency positions will convince you it has indeed been the best option, it isn't necessary that you agree, only recognize that it is a reasonable and lawful medical choice. There is simply no cause to be found in the bases you cite to substitute your Office's misrepresentation of NIH and over-interpretation of FDA and CDC messaging for the judgment of a treating physician.

The Office's Position about the FLCCC Website

Caveats about what remains to be learned about recent FDA approvals aside, FLCCC does in fact quite firmly believe that ivermectin, particularly when used within the combination protocols described on the site, is "the best tool in fighting COVID-19, that it is a "core medication in the prevention and treatment of COVID-19" and is a "cornerstone" of treatment. There is in fact substantial evidence that "higher doses [of ivermectin] have not only been required but have demonstrated clinical efficacy," as well as safety, and that "Ivermectin should be kept as the cornerstone of COVID-19 treatments and should be given at higher doses in Delta variant infected patients." How it will compare to recently approved drugs or changing variants is as yet unknown but ivermectin remains an important option that should be considered by physicians and about which the public has a right to be informed and have access via prescription. The scientific data discussed on the site is factually accurate and the site does not

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[9] https://www.science.org/content/article/very-very-bad-look-remdesivir-first-fda-approved-covid-19-drug; also note that the WHO found that Remdesivir was not safe and effective for COVID-19 and objected to its approval. https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients. Professional judgments differ on these complex topics, making it a topic ill-suited to treat with such regulatory certainty.

[10] For a discussion of dosing and safety see https://covid19criticalcare.com/wp-content/uploads/2021/09/FLCCC-Information-Evidence-for-Safety-of-Ivermectin.pdf

hide that FLCCC protocols are subject to professional differences of opinion. The statements are certainly not false or misleading, particularly in the absence of any administratively proper public health agency finding that it presents unreasonable dangers that exceed potential benefits. The absence of FDA support, given that it has not reviewed repurposed drugs but is systemically focused only on new drug applications does not turn the direct experience and review of substantial evidence favoring the importance of ivermectin into anything remotely deceptive.

As the FLCCC has never stated that ivermectin was approved by NIH, FDA, CDC or other agency but rather makes it clear that these agencies are in disagreement with its position, its views are not deceptive. Significant resources on the site are devoted to explaining why FLCCC believes those agencies are wrong on the substance and that systemic barriers have blinded the Agency to fair, if indeed any, evaluations of repurposed drugs or of nutrients such as vitamin D or zinc. If the site misled about the status of these drugs, that would indeed be deceptive. But it's hard to imagine any reader coming away with a misimpression on that score. The material on the FLCCC site is a statement of professional opinion about the science underlying ivermectin and other complementary medications, particularly when combined as in the FLCCC protocols, which are not only based upon deeply sourced evidence but are expressions of professional judgment protected by the First Amendment.

Nonetheless, the concerns expressed in your letter clearly deserve consideration and response and did lead to FLCCC making changes in language. Note that FLCCC has never taken the position that consumers should self-medicate with animal drugs. The links about how to get ivermectin you reference refer to physicians and pharmacies that will consider prescribing ivermectin and filling scripts, which is entirely appropriate though we changed the nomenclature as requested. Links to internet or veterinary sources have never been offered. In a Press Release dated March 7, 2021, as one example of FLCCC's policy, the release stated that "We support the FDA's direction that humans should never take medication formulations meant for animals. We also agree that self-dosing of medications without the guidance of a physician is potentially dangerous and could cause serious harm." https://covid19criticalcare.com/wp-content/uploads/2021/03/FLCCC-Alliance-Statement-on-Misleading-FDA-Guidance-on-Ivermectin-March7-2021.pdf

We agree, however, that a clearer statement that consumers should not use animal formulations or self-medicate is reasonable to make and you will see those changes in Attachment A. The site is aimed at professionals and consumers and the statement about composition of liquid veterinary formulations was part of the effort to provide accurate information. It was not FLCCC's intent to suggest, however, that consumers self-medicate and we took that as important feedback.

With regard to referrals to physicians, the site has always informed consumers that the physicians listed on the site make their own decisions among a range of possible therapies, including this notice:

> Ivermectin's use as both a preventative and treatment agent is an important discussion between you and your provider. Our Provider Directory lists a number of providers who support the FLCCC treatment protocols and the wide range of medications included in each. Each provider's care and treatment may vary.

We have endeavored to improve this language, including changing the reference to physicians who "treat COVID-19" rather than "provide ivermectin" as suggested.

Suggested Resolution Regarding the Cease and Desist Letters

Having worked on numerous cases in which medical boards have raised issues with non-standard treatments, the policy under which these cases are often resolved is to ensure informed consent to allow physicians and patients latitude to choose such therapies with an assurance that the patient is aware of the non-standard and controversial nature of the therapy, conflicts over the evidence, what other options might be available including, in this case, all public health measures as well as to understand the potential risks. The concerns raised in your letter can be explained to patients allowing them to make an informed choice with their personal physician who knows their individual circumstances. While off-label use is routine and not a basis to require written informed consent, and while we believe these discussions are in fact routine for physicians who follow FLCCC protocols, providing some formality to the process would assure your Office that patients would make such choices with their physicians with an awareness of these concerns. A proposed draft of informed consent forms are attached for your consideration. (Attachment B).

Proposed Guidelines

As detailed in the attached informed consent form, we would assist the Office by advising physicians in the FLCCC Alliance that they should be sure to do the following when considering a prescription for ivermectin or other off-label drugs for use in COVID-19:

1) advise the patient that the therapy is nonstandard, its use in COVID-19 is controversial, that different authorities have different opinions about whether it should be used, including information about the position of NIH, FDA and CDC.

2) discuss the potential risks of adverse reactions to the medication, including noting the multiple of the customary dosing for the treatment of parasites (as recommended by a minority community of physicians for use in COVID-19) and how that might affect potential adverse effects, including instructions on how the patient should respond should they have any concerns about the medication and reference to https://covid19criticalcare.com/wp-content/uploads/2021/09/FLCCC-Information-Evidence-for-Safety-of-Ivermectin.pdf

3) discuss the risks and benefits of any FDA approved therapies that may be available at that time.

4) caution patients that the use of the medication does not provide a basis for the patient to short cut any of the public health recommended actions such as masking, social distancing, isolation if indicated or appropriate vaccination.

Whatever reservations your Office may have about how FLCCC has addressed the quandary of the gap between the evidence and the hostile policy narrative and barriers to access that erupted toward ivermectin, and indeed toward the very concept of repurposed drugs, patients should not be denied choices made within the treatment relationship with their knowledgeable physician. The Attorney General's Offices of Nebraska, Louisiana, South Carolina and now Oklahoma[11] have moved to expressly protect, rather than interfere, with this right. If a conference call to discuss potential resolution would be helpful we would certainly make the principals available and appreciate the opportunity.

Sincerely,

/ad/
Alan Dumoff

Enclosures
Attachment A – Changes made to the FLCCC website
Attachment B – Proposed written informed consent forms

[11] https://www.usnews.com/news/best-states/oklahoma/articles/2022-02-08/oklahoma-ag-oks-prescribing-ivermectin-hydroxychloroquine