Nebraska Attorney General Files Legal Opinion with Dept. of Justice in Support of Off-Label Ivermectin and Hydroxychloroquine for the Prevention and Treatment of COVID

Few subjects have been more controversial than ivermectin and hydroxychloroquine — two long-established, inexpensive medications widely and successfully used in many parts of the world for the prevention and treatment of COVID.

Yet, health care providers across the U.S. are being threatened with discipline for using these off-label medicines for their COVID patients.

On Oct. 15, Nebraska Attorney General (AG) Doug Peterson filed

a legal opinion with the Dept. of Justice stating Nebraska healthcare providers can legally prescribe off-label medications like ivermectin and hydroxychloroquine for the treatment of COVID, so long as they obtain informed consent from the patient.

However, if a healthcare provider neglects to obtain consent, deceives their patients, prescribes excessively high doses or other misconduct – as is the case with any medication – they could be subject to discipline.

The AG's office emphasized it was not recommending any specific treatment for COVID. "That is not our role," Peterson wrote. "Rather, we address only the off-label early treatment options discussed in this opinion and conclude that the available evidence suggests they might work for some people."

Peterson said allowing physicians to consider early treatments will free them to evaluate additional tools that could save lives, keep patients out of hospitals and provide relief for our already strained healthcare system.

Based on an assessment of relevant scientific literature, the opinion was rendered in response to a request by Dannette Smith, CEO of the Nebraska Department of Health and Human Services.

Smith asked the AG's office to look into whether doctors could face discipline or legal action under Nebraska's Uniform Credential Act (UCA) – meant to protect public health, safety and welfare – if they prescribed ivermectin or hydroxychloroquine.

"After receiving your question and conducting our investigation, we have found significant controversy and suspect information about potential COVID-19 treatments," Peterson wrote.

For example, a paper published in the Lancet – one of the most

prestigious medical journals in the world – denounced hydroxychloroquine as dangerous, yet the statistics were flawed and the authors refused to provide analyzed data.

The paper was retracted, but not before countries stopped using the drug, and trials were canceled or interrupted.

"The Lancet's own editor-in-chief admitted that the paper was a 'fabrication,' a 'monumental fraud' and a 'shocking example of research misconduct' in the middle of a global health emergency," Peterson wrote in the opinion.

A recently published paper on COVID recognized that "for reasons that are yet to be clarified," early treatment has not been emphasized despite numerous U.S. healthcare providers advocating for early treatment and "scores of treating and academic physicians" – who have published papers in well-respected journals – urging early interventions.

Peterson cited numerous studies showing ivermectin and hydroxychloroquine reduced mortality by up to 75% or more when used as a preventative or prophylaxis for COVID, suggesting hundreds of thousands of lives could have been saved had the drugs been widely used in America.

"Every citizen – Democrat or Republican – should be grateful for Doug Peterson's thoughtful and courageous counteroffensive against the efforts of Big Pharma, its captive federal regulators, and its media and social media allies to silence doctors and deny Americans life-saving treatments," said Robert F. Kennedy Jr., attorney and chairman of Children's Health Defense.

"We finally have a leader who puts constitutional rights, peer-reviewed science and human health above industry profits. Doug Peterson is uncowed and unbowed – a genuine hero on horseback for all Americans."

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Although the AG's office did not rule out the possibility that other off-label drugs might show promise – either now or in the future – as a prophylaxis or treatment against COVID, it confined its opinion to ivermectin and hydroxychloroquine for the sake of brevity.

Nebraska AG highlights science on ivermectin

In his legal opinion, Peterson concluded evidence showed ivermectin demonstrated striking effectiveness in preventing and treating COVID, and any side effects were primarily minor and transient. "Thus, the UCA does not preclude physicians from considering ivermectin for the prevention or treatment of COVID," Peterson wrote.

In the decade leading up to the COVID pandemic, Peterson found numerous studies showing ivermectin's antiviral activity against several RNA viruses by blocking the nuclear trafficking of viral proteins, adding to 50 years of research confirming ivermectin's antiviral effects.

In addition, safety data for ivermectin showed side effects were "vanishingly small." The latest statistics available through VigiAccess reported only 5,674 adverse drug reactions

to ivermectin between 1992 and Oct. 13, 2021, an "incredibly low" number given that 3.7 billion doses have been administered since the 1980s, Peterson wrote.

Peterson cited several studies showing ivermectin led to improvement of COVID outcomes when used in early treatment or as a prophylaxis, while noting many studies with negative findings of ivermectin "excluded most available evidence," cherry-picked data within studies, misreported data, made unsupported assertions of adverse reactions to ivermectin and had "conclusions that did not follow from evidence."

Peterson also found that epidemiological evidence for ivermectin's effectiveness, derived by analyzing COVID-related data from various states, countries or regions is instructive in the context of a global pandemic.

In one instance, a group of scholars analyzed data comparing COVID rates of countries that routinely administer ivermectin as a prophylaxis and countries that did not. The research showed "countries with routine mass drug administration of prophylactic … ivermectin have a significantly lower incidence of COVID-19."

"This 'highly significant' correlation manifests itself not only 'in a worldwide context' but also when comparing African countries that regularly administer prophylactic 'ivermectin against parasitic infections' and African countries that do not," Peterson wrote. "Based on these results, the researchers surmised that these results may be connected to ivermectin's ability to inhibit SARS-CoV-2 replication, which likely leads to lower infection rates."

Nebraska AG calls out FDA, Fauci on

hypocrisy on ivermectin

Many U.S. health agencies have now addressed the use of ivermectin for COVID. The National Institutes of Health (NIH) has adopted a neutral position, choosing not to recommend for or against the use of ivermectin – a change from its position in January 2021 where it discouraged use of the drug for the treatment of COVID.

Peterson wrote:

"The reason for the change is the NIH recognized several randomized trials and retrospective cohort studies of ivermectin use in patients with COVID-19 have been published in peer-reviewed journals. And some of those studies reported positive outcomes, including shorter time to resolution of disease manifestations that were attributed to COVID-19, greater reduction in inflammatory marker levels, shorter time to viral clearance, [and] lower mortality rates in patients who received ivermectin than in patients who received comparator drugs or placebo."

Yet, on Aug. 29, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases within the NIH, went on CNN and announced "there is no clinical evidence" that ivermectin works for the prevention or treatment of COVID. Fauci went on to reiterate that "there is no evidence whatsoever" that it works.

"This definitive claim directly contradicts the NIH's recognition that 'several randomized trials … published in peer-reviewed journals' have reported data indicating that ivermectin is effective as a COVI D-19 treatment," Peterson wrote.

In March 2021, the FDA posted a webpage, "Why You Should Not Use lvermectin to Treat or Prevent COVID-19."

“Although the FDA’s concern was stories of some people using the animal form of ivermectin or excessive doses of the human form, the title broadly condemned any use of ivermectin in connection with COVID-19,” Peterson wrote. “Yet, there was no basis for its sweeping condemnation.”

Peterson wrote:

“Indeed, the FDA itself acknowledged on that very webpage (and continued to do so until the page changed on September 3, 2021) that the agency had not even ‘reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19.’ But without reviewing the available data, which had long since been available and accumulating, it is unclear what basis the FDA had for denouncing ivermectin as a treatment or prophylaxis for COVID-19.

“On that same webpage, the FDA also declared that ‘[i]vermectin is not an anti-viral (a drug for treating viruses).’ It did so while another one of its webpages simultaneously cited a study in Antiviral Research that identified ivermectin as a medicine ‘previously shown to have broad-spectrum anti-viral activity.’”

“It is telling that the FDA deleted the line about ivermectin not being ‘anti-viral’ when it amended the first webpage on September 3, 2021,” Peterson noted.

Peterson said the FDA’s most controversial statement on ivermectin was made on Aug. 21, when it posted a link on Twitter to its “Why You Should Not Use lvermectin” webpage with this statement: “You are not a horse. You are not a cow. Seriously, y’all. Stop it.”

“This message is troubling not only because it makes light of a serious matter but also because it inaccurately implies that ivermectin is only for horses or cows,” Peterson wrote.

Peterson said the FDA has assailed ivermectin’s safety while

ignoring the fact that physicians routinely prescribe medications for off-label use and that ivermectin is a "particularly well-tolerated medicine with an established safety record."

Peterson added the FDA is ignoring several randomized controlled trials and at least one meta-analysis suggesting ivermectin is effective against COVID. He pointed out the Centers of Disease Control and Prevention has adopted a similar stance – unsupported by scientific evidence – and the media has fueled confusion and misinformation on the drug.

Peterson questions professional associations' stance on ivermectin

Professional associations in the U.S. and internationally have adopted conflicting positions on ivermectin and COVID. The American Medical Association (AMA), American Pharmacists Association (APhA) and American Society of Health-System Pharmacists (ASHP) issued a statement in September strongly opposing the ordering, prescribing or dispensing of ivermectin to prevent or treat COVID outside of a clinical trial.

But their statement relied solely on the FDA's and CDC's suspect positions.

The AMA, APhA and ASHP also mentioned a statement by Merck – the original patent-holder – opposing the use of ivermectin for COVID because of a "concerning lack of safety data in the majority of studies."

"But Merck, of all sources, knows that ivermectin is exceedingly safe, so the absence of safety data in recent studies should not be concerning to the company," Peterson wrote.

Peterson called into question the objectivity of Merck in providing an opinion on ivermectin that U.S. health agencies

are relying upon. “Why would ivermectin’s original patent holder go out of its way to question this medicine by creating the impression that it might not be safe?” Peterson asked. “There are at least two plausible reasons.”

Peterson explained:

“First, ivermectin is no longer under patent, so Merck does not profit from it anymore. That likely explains why Merck declined to ‘conduct clinical trials’ on ivermectin and COVID-19 when given the chance.

“Second, Merck has a significant financial interest in the medical profession rejecting ivermectin as an early treatment for COVID-19. [T]he U.S. government has agreed to pay [Merck] about $1.2 billion for 1.7 million courses of its experimental COVID-19 treatment, if it is proven to work in an ongoing large trial and authorized by U.S. regulators.”

Merck’s treatment is known as “molnupiravir,” and aims to stop COVID from progressing when given early in the course of disease. When Merck announced Oct. 1, that preliminary studies indicated molnupiravir reduced hospitalizations and deaths by half, the drug maker’s stock price immediately jumped to 12.3%.

“Thus, if low-cost ivermectin works better than, or even the same as molnupiravir, that could cost Merck billions of dollars,” Peterson wrote.

Peterson takes on science of hydroxychloroquine

Peterson said based on his review of the evidence, his office did not find clear and convincing evidence that would warrant disciplining physicians who prescribe hydroxychloroquine for the prevention or early treatment of COVID after first obtaining informed patient consent.

Peterson pointed to similar findings with hydroxychloroquine – a less toxic derivative of a medicine named chloroquine – widely used since it was approved by the FDA in 1955 for the treatment of malaria.

Peterson noted that as early as 2004, a lab study revealed chloroquine was "an effective inhibitor of the replication of the severe acute respiratory syndrome coronavirus (SARS-CoV) in vitro" and should "be considered for immediate use in the prevention and treatment of SARS-CoV infections."

In 2005, another study showed chloroquine had strong antiviral effects on SARS-CoV infection and was effective in preventing the spread of SARS-CoV in cell cultures.

Other studies showed hydroxychloroquine exhibited antiviral properties that can inhibit SARS-CoV-2 virus entry, transmission and replication, and contains anti-inflammatory properties that help regulate pro-inflammatory cytokines.

Peterson wrote, "many large observational studies suggest that hydroxychloroquine significantly reduces the risk of hospitalization and death when administered to particularly high-risk outpatients as part of early COVID-19 treatment."

Peterson said the drug is considered to be so safe it can be prescribed for pregnant women, yet during the pandemic, the FDA raised questions about hydroxychloroquine and adverse cardiac events.

These concerns prompted one group of researchers to conduct a systematic review of the hydroxychloroquine safety literature pre-COVID. Their review indicated people taking hydroxychloroquine in appropriate doses "are at very low risk of experiencing cardiac [adverse events], particularly with short-term administration" of the drug.

Researchers noted COVID itself can cause cardiac problems, and

there was no reason "to think the medication itself had changed after 70 years of widespread use," Peterson wrote.

Peterson said one piece of key flawed data had substantially contributed to safety concerns surrounding the drug – the admittedly fraudulent Lancet study that falsely claimed hydroxychloroquine increased the frequency of ventricular arrhythmias when used for the treatment of COVID.

The findings were so startling that major drug trials involving hydroxychloroquine "were immediately halted" and the World Health Organization pressured countries like Indonesia that were widely using hydroxychloroquine to ban it. Some countries, including France, Italy and Belgium, stopped using it for COVID altogether.

Peterson wrote:

"The problem, however, is that the study was based on false data from a company named Surgisphere, whose founder and CEO Sapan Desai was a co-author on the published paper.

"The data were so obviously flawed that journalists and outside researchers began raising concerns within days of the paper's publication. Even the Lancet's editor in chief, Dr. Richard Horton, admitted that the paper was a fabrication, a monumental fraud and a shocking example of research misconduct in the middle of a global health emergency."

Despite calls for the Lancet to provide a full expansion of what happened, the publication declined to provide details for the retraction.

As with ivermectin, the FDA and NIH adopted positions against the use of hydroxychloroquine for COVID – making assertions that were unsupported by data. The AMA, APhA and ASHP, which opposed ivermectin, also resisted hydroxychloroquine for the treatment of COVID.

By contrast, the Association of American Physicians and Surgeons, and other physician groups, support the use of both ivermectin and hydroxychloroquine as an early treatment option for COVID. Peterson cited an article co-authored by more than 50 doctors in Reviews in Cardiovascular Medicine who advocated an early treatment protocol that includes hydroxychloroquine as a key component.

Governing law allows physicians to prescribe ivermectin and hydroxychloroquine, AG says

Neb. Rev. Stat. § 38-179 generally defines unprofessional conduct as a "departure from or failure to conform to the standards of acceptable and prevailing practice of a profession or the ethics of the profession, regardless of whether a person, consumer or entity is injured, or conduct that is likely to deceive or defraud the public or is detrimental to the public interest."

The regulation governing physicians states that unprofessional conduct includes:

"[c]onduct or practice outside the normal standard of care in the State of Nebraska which is or might be harmful or dangerous to the health of the patient or the public, not to include a single act of ordinary negligence."

Peterson said healthcare providers do not violate the standard of care when they choose between two reasonable approaches to medicine.

"Regulations also indicate that physicians may utilize reasonable investigative or unproven therapies that reflect a reasonable approach to medicine so long as physicians obtain written informed patient consent," Peterson wrote.

“Informed consent concerns a doctor’s duty to inform his or her patient, and it includes telling patients about the nature of the pertinent ailment or condition, the risks of the proposed treatment or procedure and the risks of any alternative methods of treatment, including the risks of failing to undergo any treatment at all.”

Peterson said this applies to prescribing medicine for purposes other than uses approved by the FDA, and that doing so falls within the standard of care repeatedly recognized by the courts.

Peterson said the U.S. Supreme Court has also affirmed that “off-label usage of medical devices” is an “accepted and necessary” practice, and the FDA has held the position for decades that “a physician may prescribe [a drug] for uses or in treatment regimens or patient populations that are not included in approved labeling.”

Peterson said the FDA has stated “healthcare providers generally may prescribe [a] drug for an unapproved use when they judge that it is medically appropriate for their patient, and nothing in the federal Food, Drug and Cosmetic Act (“FDCA”) limit[s] the manner in which a physician may use an approved drug.”

In a statement to KETV NewsWatch 7, Nebraska’s Department of Health and Human Services said:

“The Department of Health and Human Services appreciates the AG’s office delivering an opinion on this matter. The document is posted and available to medical providers as they determine appropriate course of treatment for their patients.”