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FLCCC Alliance Statement on the Irregular Actions of Public Health Agencies and the Widespread Disinformation Campaign Against Ivermectin

Introduction

Awareness of ivermectin's efficacy and its adoption by physicians worldwide to successfully treat COVID-19 have grown exponentially over the past several months. Oddly, however, even as the clinical trials data and successful ivermectin treatment experiences continue to mount, so too have the criticisms and outright recommendations *against* the use of ivermectin by the vast majority, though not all, of public health agencies (PHA), concentrated largely in North America and Europe.

The Front Line COVID-19 Critical Care Alliance (FLCCC) and other ivermectin researchers have repeatedly offered expert analyses to respectfully correct and rebut the PHA recommendations, based on our deep study and rapidly accumulated expertise "in the field" on the use of ivermectin to treat COVID-19. These rebuttals were publicized and provided to international media for the education of providers and patients across the world. Our most recent response to the European Medicines Agency (EMA) and others recommendation against use can be found on the FLCCC website here.

In February 2021, the British Ivermectin Recommendation Development (BIRD), an international meeting of physicians, researchers, specialists, and patients, followed a guideline development process consistent with the WHO standard. It reached a consensus recommendation that ivermectin, a verifiably safe and widely available oral medicine, be immediately deployed early and globally. The BIRD group's recommendation rested in part on numerous, well-documented studies reporting that

ivermectin use reduces the risk of contracting COVID-19 by over 90% and mortality by 68% to 91%.

A similar conclusion has also been reached by an increasing number of expert groups from the United Kingdom (UK), Italy, Spain, United States (US), and a group from Japan headed by the Nobel Prize-winning discoverer of Ivermectin, Professor Satoshi Omura. Focused rebuttals that are backed by voluminous research and data have been shared with PHAs over the past months. These include the WHO and many individual members of its guideline development group (GDG), the FDA, and the NIH. However, these PHAs continue to ignore or disingenuously manipulate the data to reach unsupportable recommendations against ivermectin treatment. We are forced to publicly expose what we believe can only be described as a "disinformation" campaign astonishingly waged with full cooperation of those authorities whose mission is to maintain the integrity of scientific research and protect public health.

The following accounting and analysis of the WHO ivermectin panel's highly irregular and inexplicable analysis of the ivermectin evidence supports but one rational explanation: the GDG Panel had a predetermined, nonscientific objective, which is to recommend against ivermectin. This is despite the overwhelming evidence by respected experts calling for its immediate use to stem the pandemic. Additionally, there appears to be a wider effort to employ what are commonly described as "disinformation tactics" in an attempt to counter or suppress any criticism of the irregular activity of the WHO panel.

The WHO Ivermectin Guideline Conflicts with the NIH Recommendation

The FLCCC Alliance is a nonprofit, humanitarian organization made up of renowned, highly published, world-expert clinician-researchers whose sole mission over the past year has been to develop and disseminate the most effective treatment protocols for COVID-19. In the past six months, much of this effort has been centered on disseminating knowledge of our identification of significant randomized, observational, and epidemiologic studies consistently demonstrating the powerful efficacy of ivermectin in the prevention and treatment of COVID-19. Our manuscript detailing the depth and

breadth of this evidence passed a rigorous peer review by senior scientists at the U.S Food and Drug Administration and Defense Threat Reduction Agency. Recently published, our study concludes that, based on the totality of the evidence of efficacy and safety, ivermectin should be immediately deployed to prevent and treat COVID-19 worldwide.

The first "red flag" is the conflict between the March 31, 2021, WHO Ivermectin Panel's "against" recommendation and the NIH's earlier recommendation from February 12th of a more supportive neutral recommendation based on a lower amount of supportive evidence of ivermectin's efficacy at that time.

Two flawed lines of analysis by the WHO appear to account for this inconsistent result:

1) The WHO arbitrarily and severely limited the extent and diversity of study designs considered (e.g., retrospective observational controlled trials (OCT), prospective OCTs, epidemiological, quasi-randomized, randomized, placebo-controlled, etc.).
2) The WHO mischaracterized the overall quality of the trial data to undermine the included studies.

The Severely Limited Extent and Diversity of Ivermectin Data Considered by the WHO's Ivermectin Panel

The WHO Ivermectin Panel *arbitrarily* included only a narrow selection of the available medical studies that their research team had been instructed to collect when formulating their recommendation, with virtually no explanation why they excluded such a voluminous amount of supportive medical evidence. This was made obvious at the outset due to the following:

1) No pre-established protocol for data exclusion was published, which is a clear departure from standard practice in guideline development.
2) The exclusions departed from the WHO's own original search protocol it required of Unitaid's ivermectin research, which collected a much wider array of randomized controlled trials (RCT).

Key Ivermectin Trial Data Excluded from Analysis

1) The WHO excluded all "quasi-randomized" RCTs from consideration (two excluded trials with over 200 patients that reported reductions in mortality).
2) The WHO excluded all RCTs where ivermectin was compared to or given with other medications. Two such trials with over 750 patients reported reductions in mortality.
3) The WHO excluded from consideration 7 of the 23 available ivermectin RCT results. Such irregularities skewed the proper assessment of important outcomes in at least the following ways:
    a) Mortality Assessment
        i) WHO Review: Excluded multiple RCTs such that only 31 total trials deaths occurred; despite this artificially meager sample, an estimate of up to a 91% reduction in the risk of death was found.[1]
        ii) Compared to the BIRD Review: Included 13 RCTs with 107 deaths observed and found a 2.5% mortality with ivermectin vs. 8.9% in controls; estimated reduction in risk of death=68%; highly statistically significant, (p=.007).
    b) Assessment of Impacts on Viral Clearance
        i) WHO Review: 6 RCTs, 625 patients. The Panel avoided mention of the important finding of a strong dose-response in regard to this outcome.
        ii) This action in (i) is indefensible given that their Unitaid research team found that among 13 RCTs, 10 of the 13 reported statistically significant reductions in time to viral clearance, with larger reductions with multiday dosing than single-day, consistent with a profound dose-response relationship.[2]
    c) Adverse Effects
        i) WHO: Only included 3 RCTs studying this outcome. Although no statistical significance was found, the slight imbalance in this limited sample allowed the panel to repeatedly document concerns for "harm" with ivermectin treatment.
        ii) Compare (a) to the WHO's prior safety analysis in their *2018 Application for Inclusion of Ivermectin onto Essential Medicines List for Indication of Scabie*s:
            (1) "Over one billion doses have been given in large-scale prevention programs."

[1] Special emphasis must be placed on this decision; selecting only trials where very few deaths occurred. (n.b., the number of events observed within trials is a primary criterion for judging the "certainty of evidence"). This action provides almost the *entire* basis for the panel's assessment of a "very low certainty of evidence." It is in effect, a "smoking gun," one of the many actions above demonstrating that the primary objective of the Panel was to *recommend against use of ivermectin.*

(2) "*Adverse events* associated with ivermectin treatment. *are primarily minor and transient*."[3]

4) The WHO excluded all RCTs studying the prevention of COVID-19 with ivermectin, without supporting rationale. Three RCTs including almost 800 patients found an over 90% reduction in the risk of infection when ivermectin is taken preventively.[4]
5) The WHO excluded observational controlled trials (OCT), with 14 studies of ivermectin. These included thousands of patients, including those employing propensity matching, a technique shown to lead to similar accuracy as RCTs.
   a) One large, propensity-matched OCT from the US found that ivermectin treatment was associated with a large decrease in mortality.
   b) A summary analysis of the combined data from the 14 available ivermectin OCTs found a large and statistically significant decrease in mortality.
6) The WHO excluded numerous published and posted epidemiologic studies, despite requesting and receiving a presentation of the results from one leading epidemiologic research team. These studies found:
   a) In numerous cities and regions with population-wide ivermectin distribution campaigns, large decreases in both excess deaths and COVID-19 case fatality rates were measured immediately following the campaigns.
   b) Countries with pre-existing ivermectin prophylaxis campaigns against parasites demonstrate significantly lower COVID-19 case counts and deaths compared to neighboring countries without such campaigns.

Assessment of the Quality of the Evidence Base by WHO Guideline Group

The numerous above actions *minimizing the extent of the evidence base* were then compounded by the below efforts to *minimize the quality of the evidence base*:

[2] This omission is the second most important action allowing the panel to find a "very low certainty of evidence," given that, per WHO protocol, if a dose-response relationship is found, the certainty of evidence must be upgraded.

[3] Special emphasis must be placed on the harm of excluding trials data supporting ivermectin in the prevention of COVID-19. If the preventive efficacy of ivermectin were to be known or accepted, this would allow deployment in regions without vaccines.

[4] British Ivermectin Recommendation Development (BIRD) panel (2021). The BIRD Recommendation on the Use of Ivermectin for COVID-19. Full report. https://tinyurl.com/u27ea3y

The WHO mischaracterized the overall quality of the included trials as "low" to "very low," conflicting with numerous independent expert research group findings:

1) An international expert guideline group independently reviewed the BIRD proceeding and instead found the overall quality of trials to be “moderate.”
2) The WHO’s own Unitaid systematic review team currently grade the overall quality as “moderate.”
3) The WHO graded the largest trial it included to support a negative assessment of ivermectin's mortality impacts as “low risk of bias.” A large number of expert reviewers have graded that same trial as “high risk of bias,” detailed in signed by over 100 independent physicians.

We must emphasize this critical fact: If the WHO had more accurately assessed the quality of evidence as “moderate certainty,” consistent with the multiple independent research teams above, ivermectin would instead become the standard of care worldwide, similar to what occurred after the dexamethasone evidence finding decreased mortality was graded as moderate quality, which then led to its immediate global adoption in the treatment of moderate to severe COVID-19 in July of 2020.[5]

Further, The WHO’s own guideline protocol stipulates that *quality assessments should be upgraded* when there is the following:

1) a large magnitude of effect (despite their data estimating a survival benefit of 81%, the low number of studies and events included allowed them to dismiss this finding as “very low certainty”) or;
2) evidence of a dose-response relationship. The WHO shockingly omits the well-publicized reports by their Unitaid research team of a powerful dose-response relationship with viral clearance.

In sum, the WHO’s recommendation that “ivermectin not be used outside clinical trials” is based entirely upon:

1) the dismissal of large amounts of trial data;
2) the inaccurate downgrading of evidence quality; and

[5] The FLCCC Alliance recommended, as well as gave U.S. Senate testimony in support of, the use of corticosteroids in COVID-19 months before this announcement, during the prolonged period when all PHAs recommended against its use.

3) the deliberate omission of a dose-response relationship with viral clearance.

Consequently, these actions formed the basis of their ability to avoid a recommendation for immediate global use.

Even more surprising is that based on their "very low certainty" finding, the panel goes on to "infer" that "most patients would be reluctant to use a medication for which the evidence left high uncertainty regarding effects on outcomes they consider important."

This statement is insupportable in light of the above actions. No patient could ever rationally consent to a trial in which they were acutely ill and would be subject to the possibility of receiving a placebo, once informed of; the large amount of relevant and positive trials that the WHO removed from consideration, their avoidance of reporting a large dose-response relationship, and their widely contradicted "very low certainty" grading of large mortality benefits. Such a trial would result in a historic ethical research violation, causing both a widespread loss of life and a resultant loss of trust in PHAs and research institutions for decades to come.

The many methods employed by the WHO to distort the evidence base and arrive at a non-recommendation are made even more suspicious and questionable by the following:

1) The WHO GDG did not hold a vote on the use of ivermectin. This highly irregular decision was purportedly based on the Ivermectin Panel's "consensus on evidence certainty."
2) Unitaid Sponsors allegedly inserted multiple limitations and weakened the conclusions in the preprint, systematic review manuscript by the Unitaid research team, which has recently led to formal charges of scientific misconduct.
3) Recent WHO whistleblower complaints of external influences in other WHO Covid reports, as well as attempts by massive external funding organizations to increase their influence in formulating WHO policies.
4) The finding of marked differences in the evidence bases used to support prior WHO/BIRD guideline recommendations for ivermectin in other diseases:
    a) WHO: Approved ivermectin in the treatment of scabies based on 10 RCTs that included only 852 patients, despite it being inferior to the standard of care.
    b) FDA: Approved ivermectin in the treatment of strongyloidiasis based on 5 RCTs that included only 591 patients.
    c) BIRD: Approved ivermectin in March, 2021, for the prevention and treatment of COVID-19 based on 21 RCTs and 2,741 patients.

Conclusion

As expert clinician-researchers in society, we are firmly committed to ensuring that public health policy decisions derive from scientific data. Disturbingly, after extensive analysis of the recent WHO ivermectin guideline recommendation, we could not arrive at a credible scientific rationale to explain the numerous irregular, arbitrary, and inconsistent behaviors documented above. Further, after consultation with numerous physicians, guideline reviewers, legal experts, and veteran PHA scientists, we identified two major socio-political-economic forces that serve as the main barrier influences preventing ivermectin's incorporation into public health policy in major parts of the world. They are:

1) the modern structure and function of what we will describe as "Big Science" and;
2) the presence of an active "Political-Economic Disinformation Campaign."

"Big Science"

Also known as "Big RCT Fundamentalism," Big Science reflects a dramatic shift in the practice of modern evidence-based medicine (EBM). Beginning before COVID, it has since rapidly evolved into the current system that more tightly meshes the entities of "Big Pharma," "Big PHA's/Academic Health Centers" (AMC), "Big Journals," "Big Media," and "Big Social Media" into the public health system's efforts at guiding patient care, research and policy.

The structure and function of "Big Science" in COVID-19 is most simply represented as follows:

- Only arbitrarily defined, "large, well-designed" RCTs (Big RCT), generally conducted on North American or European shores, can "prove" the efficacy of a medicine.[6]
- Only Big Pharma/Big PHA/AMCs have the resources/infrastructure to conduct Big-RCTs. (Many equate Big PHA/AMC with Big Pharma, given the funding source of the former.)
- Only Big RCTs by Big Pharma or Big PHA/AMC can publish study findings in high-impact, high-income country medical journals (Big Journals).
- Only medicines supported by Big Journal publications are deemed to have "sufficient evidence" and "proven efficacy" to then be recommended by Big PHAs.[7]
- Only medicines recommended by Big PHAs are covered by "Big Media" or escape censorship on "Big Social Media."

[6] "Large" and "well-designed" are not explicitly or consistently defined given numerous examples of trials in the practice of "Big Science" that are neither large nor well designed.

[7] When applied to medicines without LW-RCTs, appear as "insufficient evidence" and "unproven efficacy."

Conversely, repurposed, off-patient medications such as ivermectin do not attract Big PHA or Big Pharma sponsors to conduct the mandatory Big RCT. Given this structural handicap, many effective medicines including ivermectin are consequently incapable of ever meeting Big PHA standards for approval in such a system. In the case of ivermectin, it is then considered, first by Big PHAs, then throughout Big Media and Big Social media, to be "unproven" given it lacks "sufficient evidence" and is thus heavily censored from public discussion and awareness. Mentions of ivermectin on Big Social Media led to the removal of a popular Facebook group ("Ivermectin MD Team" with over 10,000 followers). Additionally, all YouTube videos mentioning ivermectin in treatment of Covid-19 were removed or demonetized, as well as Twitter pages locked. Further, in Big Media, even the most credentialed independent and expert groups who recommend ivermectin based on a large body of irrefutable evidence are labeled as "controversial" and purveyors of "medical misinformation."

A health system structured to function in this manner is clearly vulnerable to and overly influenced by entities with financial interests. Further, in Covid, such systems have evolved into rigidly operating via top-down edicts and widespread censoring. This allows little ability for emerging scientific developments not funded by Big Pharma to be disseminated from within the system or through media or social media until years later when, and if, a Big RCT is completed. This barrier has presented as an enduring horror throughout the pandemic given the widespread loss of life caused by the systematic withholding of numerous rapidly identified, safe and effective, repurposed medicines for fear of using "unproven therapies" without "sufficient evidence" for use. Alternatively, and for the first time in many physicians' careers, those who seek to treat their patients with such therapies, based on their professional interpretation of the existing evidence are restricted by their employers issuing edicts "from above." They are then forced to follow protocols that rely predominantly on pharmaceutically engineered therapeutics.

It must be recognized that distinct from "regulatory" agencies such as the FDA, whose system often relies upon the primary importance of a "Big RCT," stronger foundations used by PHAs are available. One of the long-standing tenets of modern evidence-based medicine is that the highest form of medical evidence is a "systematic review and meta-analysis" of RCTs and not a sole Big RCT. Disturbingly, not one of the Big PHAs mention this established principle or their long-standing reliance on such evidence-based practices for issuing recommendations. In the case of ivermectin, they willfully ignore the multiple published expert meta-analyses of ivermectin RCTs, including almost two dozen

trials and thousands of patients, reporting consistent reductions in mortality, time to clinical recovery, and time to viral clearance.

These improvements are found consistently and repeatedly, no matter the RCT design, size, or quality, and from varied centers and countries throughout the world. All studies were done without any identified conflict of interest with the vast majority of double-blind, single-blind, quasi-randomized, open-label, standard of care comparison, combination therapy comparisons, etc., reporting benefits. Satoshi Omura, Nobel Prize-winning discoverer of ivermectin, wrote in his team's recent review paper that "*the probability of this judgement on ivermectin's superior clinical performance being false is estimated to be 1 in 4 trillion*." This supports our public warnings against further "placebo-controlled trials" given the near absolute certainty of harm to research subjects included in a placebo Big RCT.

Conversely, despite sitting atop the *highest form of medical evidence*, many non-regulatory Big PHAs around the world cry out for a Big RCT. This is while avoiding the issuance of even one of the several "weaker" recommendation options available to them in the setting of a low-cost, widely available medicine with an unparalleled safety profile and a constantly surging humanitarian crisis, even in the interim. *Insufficient evidence*, *unproven* -- these are comments from WHO, NIH, Europe's EMA, South Africa's SAPHRA, France's ANSM, United Kingdom's MHRA, and Australia's TGA.

Most disturbing to contemplate is our estimation that if the use of penicillin in bacterial infection were to have been tested in these same numbers and types of trials in the 1940s, the graphical display of benefits would look nearly identical to those found with ivermectin. Further, the U.S Cures Act of 2016, "specifically designed to accelerate and bring new innovations and advances faster and more efficiently to the patients who need them" emphasized the importance of using various forms of "real-world evidence" data to aid in regulatory decision-making. We can find no evidence of an organized effort to examine the more than 14, often large OCTs that show evidence of the substantial beneficial use of ivermectin. Further, no PHA has cited the numerous convincing epidemiological analyses that find rapidly falling case fatality rates following ivermectin distribution campaigns.

With the lack of a credible explanation a credible explanation for the absence of even a weak recommendation for ivermectin in the setting of widespread increased death rates from COVID-19, numerous

citizens have speculated that this can only be explained by the presence of an active disinformation campaign by entities with nonscientific and largely financial objectives dependant on the non-recognition of ivermectin's efficacy. We explore the near certainty of this occurring below.

Active Political-Economic "Disinformation" Campaign

"Disinformation" campaigns, best described in the article, "The Disinformation Playbook," are initiated when independent science interferes with or opposes the interests of corporations or policymakers. Although thankfully rare, in certain cases these entities will actively seek to manipulate science and distort the truth about scientific findings that imperil their profit or policy objectives. First developed by the tobacco industry decades ago, these deceptive tactics include the following;

- The Fake: Conduct counterfeit science and try to pass it off as legitimate research.
- The Blitz: Harass scientists speaking out with results inconvenient for industry.
- The Diversion: Manufacture uncertainty about science where little or none exists.
- The Screen: Buy credibility through alliances with academia/professional societies.
- The Fix: Manipulate government processes to influence policy inappropriately.

Numerous examples of the above disinformation tactics by corporations and policymakers, particularly within the pharmaceutical industry, have been documented:

- Georgia Pacific publishing "fake science" on the dangers of asbestos (The Fake)
- Merck manipulating the science around the drug Vioxx (The Fake)
- The NFL intimidating and discrediting scientists reporting link between football and Traumatic Brain Injury (The Blitz)
- GlaxoSmithKline silencing scientists exposing the dangers of Avandia (The Blitz)
- American Chemistry Council sows uncertainty about formaldehyde risks (The Diversion)
- Purdue Pharma partners with academic centers to hide dangers of opioids (The Screen)
- Pfizer pressures FDA to downplay risk of animal drug causing high arsenic (The Fix)

Most worrisome is that ivermectin appears to be up against one of the largest financial and global policy oppositions in modern history, including but not limited to:

- Numerous Big Pharma companies and sovereign nations selling billions of vaccine doses.

  - Scale of market for vaccines now exponentially increasing due to the developing market for "booster shots" against rapidly appearing variants.
  - Big Pharma now promising investors to employ price hikes on vaccines as COVID-19 passes from a "pandemic" to an "endemic."

- Concerns of numerous Big Pharma and Big PHA's that if ivermectin is approved as effective treatment for COVID-19, EUAs for all vaccines would be revoked.
  - Disinformation: FDA posted notices overstating the dangers of ivermectin and against use of ivermectin; despite not having reviewed the trials data.
  - Disinformation: WHO Panel dismisses/ignores most of available evidence base.
  - Disinformation: WHO Panel avoids bringing ivermectin evidence to a vote.
  - Disinformation: Unitaid sponsor influences writing of manuscript conclusions.
  - Disinformation: EMA erroneously claims effective concentrations are unattainable.

- Numerous Big Pharma/Big PHA concerns that ivermectin's potential as an alternative to vaccines may increase vaccine hesitancy and disrupt mass vaccination rollouts.
  - Opponents include large philanthropic sponsors with global vaccination goals.
  - Disinformation: WHO Panel does not review ivermectin prevention trials.

- Numerous Big Pharma company investments in novel, engineered therapies (i.e., oral antivirals by Merck and Pfizer and Gilead) directly compete with ivermectin.
  - Disinformation: Merck places a post on their website, without scientific supporting evidence or named scientist authors that: "No evidence of either a mechanism of action, clinical efficacy or safety in COVID-19 exists."
  - Disinformation: A Merck managing director argues against use in the Philippines by stating: "The levels of evidence do not come up to standards."

- Big Pharma company's (Astra-Zeneca) investment into a long-acting antibody product for prevention and treatment of COVID-19, which competes with ivermectin.
- Numerous Big Pharma's monoclonal antibody products that compete with ivermectin.
- Big Pharma's Remdesivir demand would rapidly decline once hospitalizations were to decrease after ivermectin approval.

Based on the lack of a rational explanation for the above actions by WHO, Merck, FDA, and Unitaid, we conclude that they result from an active disinformation campaign, executed both through the PHA's, media and the WHO Guideline group recommendations. As highly published researchers, we find the allegations of scientific misconduct in the writing of the WHO/United research team's meta-analysis manuscript to be deeply disturbing. It clearly represents a disinformation tactic with an intent to distort and diminish the reporting of a large magnitude benefit on mortality among many hundreds of patients. Further, Merck's demonstrably and blatantly false statements against ivermectin deserve no further discussion. It is yet another entry into the disturbing historical record of actions committed by a Big Pharma entity with the primary intent of protecting profit at the expense of the welfare of global citizens.

For These Compelling and Irrefutable Reasons, The FLCCC Makes a Call to Action

This call to action is no longer just to health authorities, but to citizens everywhere to fight back against these disinformation tactics. We find the advice of the Union of Concerned Scientists (UCS) to be an excellent guide to action in this regard:

Global Citizens

1) Share the playbook with your social media networks when you see new examples like those outlined above.
2) Set the record straight. When you see someone spreading disinformation on a topic, counter it. There are millions around the world who either have studied the data or have experience with the potent efficacy of ivermectin in COVID-19. It is important to correct false assertions.
3) Consider divesting your retirement funds and other investments from companies engaging in disinformation.

Fellow Scientists

1) Become a UCS Network Watchdog to help track and resist attacks on science.
2) If a governmental or NGO scientist**,** report actions that diminish their role in policymaking.

Media

1) Avoid false equivalencies that distort scientific consensus.
2) Correct the record when scientific information is misrepresented, particularly by Big PHA/Big Pharma.
3) Report abuses of science in government.

As an expert group of ivermectin researchers, we are unsure of what else to offer in order to correct or counteract this misrepresentation of an important drug. Our belief is that, of the above actions, the most effective counter to the disinformation campaign would be

that a whistleblower become active from within WHO, the FDA, the NIH, Merck, or Unitaid. This moment in history demands a man or woman with the courage and conviction to step forward. Urgently.

In both the interests of humanity and to motivate and inspire such a citizen of the world, we leave you with the words of Albert Einstein: "***The world will not be destroyed by those who do evil, but by those who watch them and do nothing.***"

Sincerely,

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