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FLCCC Alliance Response to All National and International Health Agency Recommendations Against Ivermectin in COVID-19

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Despite the rapidly increasing and diverse amounts of medical evidence supporting ivermectin as a life-saving therapy in COVID, multiple national and international health agencies – including but not limited to the World Health Organization, the European Medicines Agency, and the regulatory health agencies of all of North America and Europe – have continued to issue negative recommendations against use of ivermectin in COVID-19.

The FLCCC is one of several groups researching the use of ivermectin in COVID-19, and along with many such groups, we have become increasingly concerned regarding unprecedented, highly irregular, and poorly defended public health agency (PHA) decisions regarding multiple therapeutic agents including that of ivermectin. Many providers, patients, and citizens now openly speculate that these behaviors are consistent with suppression and distortion of the scientific data in order to meet non-scientific (financial and other) objectives. We remind all health care providers and patients that policy decisions must derive from the science with a primary interest in improving public health and not from a predetermined, non-scientific objective. What follows is a detailed and objective analysis of these numerous PHA recommendations.

Agency Concerns: *“Because most of these studies have significant limitations, we cannot draw definitive conclusions on the clinical efficacy of ivermectin for the treatment of COVID-19.”*

FLCCC Response: Guideline officials of numerous leading PHA’s in the US (NIH), UK, Canada, Europe, and the WHO were sent the proceedings of the recent British Ivermectin Recommendation Development effort (BIRD) whereby on February 20, 2021, the results of a comprehensive assessment of the quality of the existing ivermectin trials – conducted according

to a widely accepted protocol consistent with WHO Guideline standard— was presented by the BIRD Technical Working Group to their Recommendation Development Panel.¹ The presentation consisted of the details and results of a systematic review and meta-analysis of 21 randomized controlled trials (RCTs) including over 2,500 patients. The Panel was made up of over 65 general practitioners, specialists, researchers and patient representatives representing over 15 countries from all regions of the world. *Following a guideline development process consistent with the WHO standard*, the BIRD Panel reviewed not only the RCT data, but also a summary of the observational controlled trials (OCT) and the numerous examples of epidemiologic analyses showing the effects of ivermectin distribution campaigns and/or widespread treatment adoption on population-wide rates of excess death.¹ The majority of Panel members (75%) found that the overall certainty of this comprehensive evidence base was overall moderate to high. Importantly, no apparent conflicts of interest were identified amongst the trials. Finally, ***the Panel consensus gave the strongest recommendation option for ivermectin to be adopted in both the prevention and treatment of COVID-19.***

We are severely troubled by the multiple examples of PHA’s failing to openly address the reasons for their discordant conclusions from the now widely known BIRD recommendation as well as to undertake as extensive and proactive an effort as the BIRD or Unitaid research teams. For instance, the Unitaid team identified and established communication with the principal investigators of all 59 active registered, randomized, controlled treatment trials of ivermectin in COVID-19. In this fashion, they were able to receive not only trial results immediately upon completion of each trial, but all the critical details required to accurately assess the quality of the trials. The Unitaid team has also repeatedly offered to share the data they have compiled in their “active” review with any regulatory agency. We have been informed that, as of April 1, 2021, the Unitaid team had results from approximately 24 RCT’s of ivermectin treatment in COVID-19, yet no recent PHA recommendation reflects the data from this number of trial results. The WHO recommendation of March 31, 2021 is most troubling given that they referenced only 16 of the approximately 24 available trial results compiled by the Unitaid team they directly collaborate with.

Further, and perhaps as a direct result of the above, all such PHA recommendations conflict with the findings of benefit reported in multiple published *independent* expert reviews and meta-analyses from across the world including a recent report co-authored by the Nobel Prize winning discoverer of ivermectin, Professor Satoshi Omura. These include:

1. **UK** -British Ivermectin Recommendation Development Panel¹
2. **Spain** – Cabo-Campos et al, Bioaraba Health Research Institute²
3. **Italy** - Nardelli et al. San Raffaele Scientific Institute, Milan, Italy³
4. **US** - Kory P et al. Front Line COVID-19 Critical Care Alliance⁴
5. **Japan** - Yagisawa, M et al. Kitasato Institute, Japan⁵

In particular, the FLCCC’s comprehensive narrative review of ivermectin by Kory et al passed a rigorous peer review performed by 2 career FDA scientists, an expert ICU clinician, and a Senior Scientist/Subject Matter Expert for the Therapeutics Branch of Translational Medicine Division of the Defense Threat Reduction Agency (DTRA) of the Department of Defense. This recently published manuscript, along with the publications from Spain, Italy, Japan, and the UK, and in contrast to all major PHA’s, concluded that the existing evidence base fully supports the immediate global adoption and deployment of ivermectin in the prevention and treatment of COVID-19.

Agency Concerns: The Infectious Disease Society of America (IDSA), a professional society of infectious disease specialists within the US, “recommend against use outside of clinical trials”. Most disturbing, beyond the limited evidence base they included for review, were their “concerns about publication bias, as the available evidence consisted mostly of positive trials of smaller size.” Despite this concern, no mention of any effort to assess for publication bias was done by the IDSA, nor did the IDSA consult with the Unitaid team that had performed the sophisticated “Harbord test for small study effects” and found “no significant risk of publication bias.” Thus, the IDSA erroneously and tragically dismissed an evidence base consisting “mostly of positive trials.”

Agency Concerns: Agencies continue to state the need for “adequately powered, well-designed, and well-conducted clinical trials”

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FLCCC Response: The recent non-evidence-based practice by many PHA's of consistently dismissing all findings from *observational* controlled trials (OCT's) is increasingly described and almost universally accepted. The excessive concerns over possible misinterpretation of such trials due to worries over unmeasured confounders or imbalanced comparison groups has fueled the recent near universal reliance on RCT data alone to inform treatment recommendations. What is shocking is that now, in an almost identical manner, the quality and findings of a large body of *prospective, randomized, controlled trials are being questioned*. This is occurring even though RCT's have long been considered the gold standard of scientific investigation and thus the PHA's refusal to accept these findings are indefensible given that, among the almost two dozen RCTs studying ivermectin in COVID-19, the results from double-blind, single-blind, open label, quasi-randomized, placebo-controlled, or standard of care comparison designs all report consistently similar benefits in clinical outcomes. The known bias against OCT data is exactly why Unitaid/WHO restricted its ivermectin research team to studying results of RCT trials only. Yet, despite their team's compilation of results from almost 24 RCT's, only 16 were referenced in the WHO recommendation and most concerning, only 5 were considered in their estimation of ivermectin's mortality benefit.

The repeated actions by PHA's whereby they include only a limited sample of the existing, publicly available evidence base has led to the ignoring of massive amounts of trials data including thousands of patients. If any and every purported design shortfall of the RCT's is used for either dismissal or weakening of consideration, this "raises the bar" such that almost no studied therapeutic could ever be considered to have proven efficacy. A possible exception appears to be that of a single, massive, impeccably designed and conducted trial performed by a pharmaceutical company or major academic medical center within North America or Europe. Unfortunately, and for increasingly suspect reasons, no such study has yet been completed on ivermectin 16 months into the pandemic. However, even if such a trial had been completed by now, the strength of its findings would not outweigh the current evidence base, given that it derives from a summary of data from many RCTs ("systematic review and meta-analysis data"), long considered the highest

form of medical evidence in support of an intervention, more so than any single—even large—RCT.

FLCCC Response: The persistent PHA practices of selecting only a subset of available medical evidence for ivermectin is common. The last NIH Panel recommendation update on February 12th, where 9 of the 17 RCT results with data on almost 1,100 patients were excluded without explanation, despite having received the results of these trials during an FLCCC/Unitaid presentation to the Panel on January 6, 2021.⁶

- 3 *excluded* RCTs reported statistically significant reductions in mortality
- 4 additional *excluded* RCTs reported statistically significant reductions in viral clearance
- One included RCT was mischaracterized as unblinded when it employed a single-blind design

Further, of the agencies that do consider OCT trials data to be of value, many also *selectively* include only a minority. Using the NIH recommendation from February 12th again as an example;

- 3 *excluded* OCT's reported statistically significant reductions in mortality or viral clearance
- 1 “negative” OCT was included despite numerous and widely criticized design, conduct, and interpretation flaws and the firing of multiple authors and supervisors of the study^{1,2}
- 1 cited OCT (the “ICON” trial published in the high impact journal *Chest* by the American College of Chest Physicians) did not note the investigators' use of multivariate analysis and sophisticated propensity matching techniques considered to match prospective RCT's in accuracy. This was the only trial performed in the United States and it reported a large reduction of mortality in hospitalized patients treated with ivermectin.

The above NIH Panel review must be contrasted with the meta-analyses including over twenty RCTs performed by BIRD and the Unitaid research teams instead that instead find;

¹ <https://wayka.pe/essalud-retira-a-investigadores-tras-estudio-que-advierte-riesgos-en-3-medicamentos-para-covid/>

²

<https://saludconlupa.com/noticias/replica-y-despido-este-es-el-segundo-informe-que-genero-la-salida-de-la-gerenta-de-investigacion-de-essalud/>

- Statistically significant reductions in the **time to viral clearance**
- Statistically significant reductions in the **duration of hospitalization or time to recovery**
- Statistically significant reduction in **mortality rates** (75% absolute reduction in risk of dying)

Agency Concerns: Multiple health agency ivermectin reviews state that the available RCTs are “underpowered” or “small” based on their arbitrary estimation of required size.

FLCCC Response: We are shocked at the need to remind the agencies that, although sample size is an important contributor to statistical “power”, a more determinant variable is the *treatment effect size*. Ivermectin's treatment effects on time to viral clearance, time to clinical recovery, and mortality are of such magnitude that “large” sample sizes are not necessary to ensure the necessary low risk of Type I error. If the entirety of available trial results would be considered, it would be obvious that the majority of these supposedly “small” trials *repeatedly* find differences in outcomes that *reach a high level of statistical significance*. The probability of such findings occurring *repeatedly* among trials from various centers and countries in the absence of a “true” large treatment effect is near nil. Surprisingly, this was first recognized during a January presentation by the lead researcher of Unitaid’s ivermectin team, Dr. Andrew Hill, who said, “**the current calculated probability that ivermectin’s measured effects on survival are due to chance is 1 in 5,000.**” Based on more recent data, the group led by Nobel Prize Winner Satoshi Omura in Japan, wrote “**the probability of ivermectin’s superior clinical performance being false is estimated to be 1 in 4 trillion.**”

Agency Concerns: All agency recommendations oddly provide a detailed summary of ivermectin **RCT trial limitations**, but none similarly detail **the magnitudes or extent of the trial benefits reported**.

FLCCC Response: Again, using the recent NIH panel as an example, among the 8 RCT’s considered, they avoid summarizing that;

- 3 RCTs, (one double-blind, one open-label), with over 600 total patients, reported a statistically significant **reduction in mortality**, while the third found a near statistically significant reduction (p=.052)
- 2 RCTs (one double-blind) found a **statistically significant reduction in time to viral clearance**
- 1 RCT found a **statistically significant reduction in viral load, days of anosmia, and days of cough**
- 1 RCT (double-blind) found a **near statistically significant, large reduction in recovery time**, p=.071
- Further, based on the BIRD meta-analysis, the “number needed to treat” (NNT) to save one life with ivermectin in COVID-19 is 1.5, indicating that of every **nine** patients who would otherwise die from COVID-19, **six** would be saved by treatment with ivermectin. This indicates that ivermectin in COVID-19 to be one of the most powerful interventions in history, even more effective in saving lives than defibrillating a patient with a life-threatening arrhythmia (NNT=2.5). Equally effective is the prevention data finding that the NNT to prevent transmission of the disease is 1.2, indicating that for every **seven** people treated preventively, only **one** would risk falling ill with COVID-19.

Agency Concerns: “the safety of ivermectin in the treatment of COVID-19 has not been established”

FLCCC Response:

- In a recent review of over 350 articles on ivermectin from over the past 35 years and during the over 4 billion doses administered, the prominent French toxicologist Jacques Descotes wrote that, “serious adverse events are unequivocally and exceedingly rare.”⁶
- In the WHO's prior safety analysis from their 2018 *Application for inclusion of ivermectin onto Essential Medicines List for indication of Scabies*; 1) “Over one billion doses have been

given in large-scale prevention programs” and 2) “Adverse events associated with ivermectin treatment. are primarily minor and transient.⁷

FLCCC Response: Given the above unparalleled safety profile along with the large magnitude efficacy being reported, the above PHA’s are adopting increasingly isolated and poorly defensible public health policy positions given the many agencies that have instead adopted recommendations for the use of ivermectin which conflicts with the above North American, European, and International Health Agencies. This rapidly growing list of national and regional health include:

- Slovakia – National Treatment Guideline (1/26/21)
- Bulgaria – Legalized for over-the counter use (2/21)
- Czech Republic – Legalized prescribing (3/12/21)
- Peru – National Treatment Guideline (1/8/21)
- Japan – Tokyo Medical Association (2/9/21)
- Mexico – Institute of Social Security (2/3/21)
- Belize – National Treatment Guideline (12/18/20)
- South Africa – Health Products Regulatory Association (1/27/21)
- Zimbabwe – National Ministry of Health (1/28/21)
- North Macedonia – National Health Minister (1/15/21)
- Uttar Pradesh, India – Treatment Guideline (pop. 234 million -9/3/21)
- State of Bihar, India – Treatment Guideline (pop. 122 million – 8/21)
- Egypt- National Treatment Guideline (11/30/20)
- Guatemala – National Treatment Guideline (1/23/21)
- Nicaragua – National Treatment Guideline (1/25/21)
- State of Chiapas, Mexico (8/1/20)
- Jamaican Medical Association (2/26/20)
- Argentina, 1/3 of territory – States of Pampa, Jujuy, Salta, Tucuman, Misiones, Corrientes (2/26/20)

Agency Concern: Multiple agency reviews report as a limitation the fact that various doses and schedules of ivermectin were used amongst the available trials.

FLCCC Response: We strongly reject this as a “limitation” of the evidence base given that the opposite is true, as it is, in fact, a *strength*. An evidence base consisting of varying treatment regimens allows for the identification of an optimal dosing strategy. Further, Dr. Hill’s data compiled for Unitaid/WHO, has reported a strong dose-response relationship of ivermectin treatment with the time to viral clearance. Such a finding provides yet another pillar of scientific support for the anti-viral efficacy of ivermectin against SARS-CoV2. Despite this, the WHO Guideline indefensibly avoided mention of their own discovery of a dose-response relationship between ivermectin and *time to viral clearance*.

Agency Concerns: On January 6, the FLCCC was asked by the NIH Panel to submit all data on ivermectin as it became available.

FLCCC Response: On January 26, the FLCCC emailed the Panel a recently completed manuscript by the analysts Chamie et al. where they analyzed vast amounts of publicly available (and verifiable) epidemiologic data.⁸ They found conclusive evidence (after ruling out multiple possible confounders) that widespread ivermectin distribution campaigns repeatedly and closely preceded large reductions in both COVID-19 case-fatality rates and “excess deaths” measured in many regions of Peru and other countries.⁷ The FLCCC considers this manuscript to be a historic, landmark paper and a must-read for all public health officials, given that it demonstrates the population-wide role that ivermectin can play in bringing about control of the pandemic. Although no mention of this paper or data was included by the previous NIH, EMA, or other European or North American Agency reviews, we were initially encouraged to learn of the WHO Treatment Guidelines committee request for and receipt of a presentation of these data by the senior author. Disturbingly, no mention of this vast amount of supportive data was mentioned in their March 31, 2021 guideline.

It should also be noted that, since the completion and submission of their Peru analysis manuscript for peer review to a prominent medical journal, Chamie et al have produced numerous other epidemiological analyses finding profound reductions in hospitalizations and case fatality rates after the more recent national or regional adoptions of ivermectin detailed above. A notable example stemmed from the Social Security Institute of Mexico's decision on December 29th, 2020 to adopt a "test and treat" strategy at testing locations. This strategy involved administering a rapid test to all patients, and if positive, the provision of sufficient ivermectin tablets. What followed was a rapid drop in both hospitalizations and death throughout Mexico over the past several months, with very low occupancy in hospitals throughout Mexico, with excess deaths now approaching near pre-pandemic levels.

We are dismayed at the lack of interaction with the Mexico City Health officials overseeing this effort to review these data more fully. We strongly suggest these data be sought and shared more widely via the collaboration of interested health agencies.

Agency Concerns: The agencies continue to post the disproven theory that "ivermectin doses up to 100-fold higher than those approved for use in humans would be required for efficacy."

FLCCC Response: Data proving this statement to be false was presented by Dr. Paul Marik during the FLCCC presentation to the NIH Panel on January 6. This oft-repeated, erroneous theoretical concern, most recently by the EMA, has been fully refuted based on multiple sources of evidence;

- 1) the known poor relevance of inhibitory concentration estimates between cell culture models (in particular monkey kidney cells) and human models
- 2) the unpublished data shared by the scientist Dr. Kylie Wagstaff after the experiment above was repeated using lung alveolar cells which found inhibitory concentrations easily achieved with standard dosing (personal communication, shared with the NIH panel).
- 3) studies showing standard doses can achieve tissue concentrations between 3 -10 times higher than serum, particularly in adipose and lung tissue that highly express ACE-2 receptors

- 4) studies that have identified numerous other mechanisms of action than those theorized in the above experiment using high concentrations (detailed in our recently published scientific review manuscript)
- 5) studies and meta-analyses finding repeated large clinical outcome benefits after standard doses were used thus fully refute the above limitation

Conclusion

In the setting of almost two dozen randomized clinical trials of ivermectin reporting repeated, large, statistically significant benefits in mortality and other important outcomes and the peer-reviewed publication of five independent expert panels from around the world, the question must be asked as to why such a critically and globally important intervention to the ending of a pandemic is being suppressed or dismissed.

These benefits make ivermectin unique amongst COVID-19 therapeutics, given that no other medication has simultaneously shown impacts on prevention of transmission, viral clearance, time to clinical recovery *and* survival. Further, the Unitaid research team findings of dose-dependent impacts on time to viral clearance (an objective outcome), provides an additional, unassailable pillar of evidence that ivermectin has highly potent anti-viral properties. It is impossible to argue of a task more important than globally recognizing that the repeated reductions in morbidity and mortality among the now almost two dozen randomized controlled trials are scientifically valid.

Consistent with the international BIRD consortium, based on the totality of the current evidence base, it is our recommendation that further efforts in planning for or conducting placebo-controlled clinical trials may not only pose serious ethical concerns, but will likely produce redundant data and further delays in the mass deployment of ivermectin that could instead simply and rapidly decrease both case counts and deaths throughout the world. The urgency of recommending ivermectin is particularly acute amongst low- and middle-income countries (LMIC)

given that the mass vaccination strategy embarked upon by all the same agencies referred to in this letter, will take many months if not years to reach LMIC's. These delays combined with an absence of other countermeasures will give the wildtype virus more opportunities to transmit and form escape variants that may compromise the global immunization effort. Therefore, if a highly safe and inexpensive intervention like ivermectin has a reasonable chance of cutting down transmission, it must be deployed without delay.

The FLCCC asks that the health agencies remind themselves of one of their primary purposes – issuing recommendations commensurate with the most updated data, and in the case of ivermectin, those compiled and analyzed by the “active” reviews of expert groups such as the BIRD, FLCCC, and Unitaid teams. We are concerned by the numerous negative agency opinions arguing that “conclusive” data is not available and therefore no recommendation are offered, even weak or less than definitive ones. This stance is both unprecedented and unacceptable given that “definitive” (i.e. a I-A) evidence base is not required to formulate treatment recommendations for a medical therapy. Pretending that overly conclusive evidence is mandatory departs from multiple agency’s established recommendation schemes that purposely allow for recommendations of multiple different strengths, from “strong” to “moderate” to “weak” and based on either “randomized controls trials” to “sub-groups of randomized trials or observational trials” to “expert opinion.” Although the current evidence may not constitute “I-A” level (strongest possible), it clearly meets any number of the other definitive recommendation requirements.

In conclusion, we ask that agencies place a greater effort in further defining the overall quality of the increasing amounts of evidence in support of the efficacy of ivermectin. To say that the existing evidence is *insufficient to recommend for or against* or, worse, *to not use outside the context of a clinical trial* is not correct given the recent conclusions of the BIRD conference Panel’s findings and the near totality of existing trials finding statistically significant benefits in at least one important patient-centered outcome. We are alarmed at the high likelihood that a non-scientific objective explains the reluctance to issue even a weak recommendation for one of history’s safest medicines in the setting of repeated escalations of case counts, hospitalizations, and deaths from COVID-19. In the words of the world expert toxicologist Jacques Descotes, after

recently completing a safety review of over 500 articles on ivermectin, “serious adverse events are unequivocally and exceedingly rare”. In addition, this refusal to recommend departs from several independent expert panels along with the increasing numbers of countries and regional and institutional health ministries that are instead fully adopting ivermectin based on the available evidence. We must remind the agencies that in the absence of even a weak recommendation, most health care providers will be unwilling to prescribe ivermectin despite it being one of the safest medicines in history.

The Front Line COVID-19 Critical Care Alliance

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About the Front Line COVID-19 Critical Care Alliance

The FLCCC Alliance was organized in March 2020 by a group of highly published, world renowned Critical Care physician/scholars – with the academic support of allied physicians from around the world – to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness. Their **MATH+** Hospital Treatment Protocol, introduced in March 2020, has saved thousands of patients who were critically ill with COVID-19. Now, the FLCCC’s new **I-MASK+** Prophylaxis and Early At-Home Outpatient Treatment Protocol with Ivermectin has been released – and is a potential solution to the global pandemic.

For more information: www.flccc.net

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