

INDIAN BAR ASSOCIATION

(THE ADVOCATES' ASSOCIATION OF INDIA)

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May 25, 2021

LEGAL NOTICE

To

Dr. Soumya Swaminathan

Chief Scientist,

World Health Organisation

Avenue Appia 20

1211 Geneva, Switzerland

Subject: 1. Running a disinformation campaign against Ivermectin by deliberate suppression of effectiveness of drug Ivermectin as prophylaxis and for treatment of COVID-19, despite the existence of large amounts of clinical data compiled and presented by esteemed, highly qualified, experienced medical doctors and scientists.

2. Issuing statements in social media and mainstream media, thereby influencing the public against the use of Ivermectin and attacking the credibility of acclaimed bodies/institutes like ICMR and AIIMS, Delhi, which have included 'Ivermectin' in the 'National Guidelines for COVID-19 management'

Madam,

I, the undersigned, serve the following legal notice upon you:

1. This legal notice is divided in Eight sections:

Sr. Nos	Particulars	Para Nos
1.	Your views and statements against the use	para 2 to 10, para
	of Ivermectin for treatment of COVID-19.	36, 37, 46
2.	Extensive studies and trials that prove	para 11 to 20, para
	effectiveness of Ivermectin in treatment of	30 to 35
	COVID-19.	
3.	Cases in the United States where older	para 21 to 29
	COVID-19 patients who were critically ill,	
	either in comatose state or on ventilators,	
	who have successfully recovered after	
	Ivermectin was included in their line of	
	treatment. Not to miss the crucial role of	
	Courts, who intervened and directed the	
	hospitals to administer Ivermectin on such	
	patients who were at the doorstep of death.	
4.	Cognizance taken of the 'Public Statement'	para 38 to 42
	issued by FLCCC on the Irregular Actions	
	of Public Health Agencies and the	
	Widespread Disinformation Campaign	
	against Ivermectin.	
5.	Ivermectin and 'The National Clinical	para 43 to 45
	Guidelines for Covid-19 management'	
	issued by ICMR.	

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6.	Main grounds for issuance of this legal notice.	para 48 to 57
7.	Falling standards of World Health Organization.	Para 58 to 61
8.	Commendable work by select courageous medical doctors who have lived up to their Hippocratic Oath.	para 62 to 67

2. That, you have tweeted the following on May 10, 2021 on Twitter:

"Safety and efficacy are important when using any drug for a new indication. @WHO recommends against the use of Ivermectin for #COVID19 except within clinical <u>trials https://t.co/dSbDiW5tCW</u> — Soumya Swaminathan (@doctorsoumya) May 10, 2021"

- **3.** That, the above-mentioned tweet came soon after the announcement from the State Health Minister of Goa, India on May 10, 2021 that all the adults in Goa would be given the oral drug **Ivermectin** (hereinafter referred to as '**Ivermectin**') as a prophylactic (Preventive) measure, irrespective of their coronavirus status, in a bid to bring down mortality. He stated that the reason behind such prescription was the study conducted by expert panels from the UK, Italy, Spain and Japan, who found a statistically significant reduction in mortality due to **Ivermectin**.
- **4.** That, you have posted the above tweet in your official capacity as the Chief Scientist at the World Health Organisation (hereinafter referred to as WHO).

- 5. That, you have included a hyperlink in your tweet <u>https://t.co/dSbDiW5t CW</u>, which upon clicking takes the reader to a page on the website of pharmaceutical company Merck, that displays a statement dated February 4, 2021 issued by Merck titled 'Merck Statement on Ivermectin use during Covid Pandemic'. Refer Annexure 1.
- 6. That, you have appeared on YouTube channel MOJO STORY on May 16, 2021, wherein you have been interviewed by Ms. Barkha Dutt in a vlog titled 'Fears of "Prolonged Second Wave" says WHO Chief Scientist on India's COVID Calamity'.

The link to access this vlog is as follows:

https://www.youtube.com/watch?v=N2lNIYXrLlA

That, in this vlog,

At 23:40 markup, Ms. Barkha Dutt has posed a question to you on effectiveness of medicines currently being administered to Covid-19 patients in the absence of vaccines and she specifically asks your views on **Ivermectin** to start with.

At 24:28 markup, you have replied;

"You know, evidence-based guidance and treatment, prevention is really the way to go and what we have tried at the WHO is to update our guidance as often as possible, based on the emerging data. So we have something called like the Living Guideline that we update whenever some new evidence comes out. So we got evidence on Hydroxychloroquine, Lupinavir, Ritonavir, Interferon, Ivermectin , Remdesivir and all of these, the evidence does not support its use, you know, on a wide scale for people infected with SARS CoV-2.

The one drug that has a big mortality benefit is simple Dexamethasone corticosteroids, given at the right stage of the disease because COVID-19 is a viral infection. As of now, we have no anti virals that really act very dramatically on this virus and they would need to be given in the early stage of the disease. We are hoping there are some anti virals in development that will come very soon. So the early stage, you can use monoclonal antibodies, again still under research antivirals and the second phase of the disease that is the anti-inflammatory – that's where the lungs are getting blocked with infection and people's oxygen levels are dropping and that's when steroids help and the anti-inflammatory drugs and the anti-IL-6 inhibitors, they help. That's when patients need oxygen. So what's lifesaving, its oxygen, its corticosteroids given to moderate and severely ill patients and perhaps the anti-IL-6 inhibitors. None of these other drugs which are widely being used including antibiotics has..." (not audible as Ms. Barkha Dutt has *started her next question*)

Ms. Barkha Dutt at **26:24** –...(sound interruption) Azithromycin, **Ivermectin**, Fabiflu that are now being given set base template. You would say none of these need to be given or should be given.

To which you have responded at 26:34 as under;

"<u>There is no evidence that they have any impact on the disease</u> progression so I would rather spend those resources on giving people good quality masks to wear. In the absence of vaccines, masks are the only vaccines. Everybody wears good quality masks, covering their nose and mouth, that is going to make a big difference at the community level

and of course spend resources on ramping up of oxygen and other supplies that you need in the hospital, getting the work force there ready. You will have to supplement the work force because the existing doctors and nurses are not going to be enough to cope with the kind of load that we have seen, so those are the kind of investments that need to be made and you know these drugs really that's not going to be the ones that have an impact."

Ms. Barkha Dutt at 27:30 – Ok I know you are on limited time. I just have one more question on the drugs and then we will do the overall picture. Remdesivir and Plasma Therapy. These are two, again the obsessive things that continue in India. Your last word on those.

To which you have replied at 27:44 as under;

"Again, we had, don't have WHO guidance on plasma therapy but the trial which has just reported, the Recovery trial, in a very large number of patients showed clearly that the plasma therapy is of no benefit. The ICMR trial, many months ago showed the same thing in India. So plasma therapy again, you know, there is poor patient running around trying to get plasma for their relatives. I can understand the desperation, both on the side of patients and the side of doctors, just to do something, do everything possible just to save your loved ones but unfortunately, using these unproven therapies doesn't help, you know to save lives. So what is really critical is the oxygen at the right time and monitoring of people, making sure they get oxygen when they start de-saturating, they get the corticosteroids at the right time, they get the ICU care, the ventilation, the supportive care at the right time, that's really important and I think ongoing research, so again India has large

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number of scientific institutions, there are a number of early leads that different labs are talking about, all of these need to go through the clinical trials and should be tested to see whether they have, we desperately need better treatments for this virus, we don't have and so that should continue. But in the meantime, it is really the approach of testing, identifying people, following them up, monitoring them, getting them into care. Majority of the people will not need to be hospitalized obviously they can be managed at home but the ones who need to must get there and that's the only way to reduce the deaths that we have seen happening now."

- 7. That, your act of posting the said tweet on May 10, 2021 as well as responses to the questions in the interview on MOJO STORY on May 16, 2021 against the use of Ivermectin for treatment of COVID-19, are highly unconscionable, misleading and issued with ulterior purposes and deliberate intention to underplay the effectiveness of Ivermectin in treating the COVID-19 patients as well as its use as a prophylaxis and to dissuade people from using this drug by creating doubts in the minds of people around safety of Ivermectin.
- 8. That, you have deliberately disregarded the fact that there is loads of data to prove that Ivermectin is a safe drug and has no harmful effects in general. The drug Ivermectin which was discovered in 1975, has been around for around 40 years and has also won the Nobel Peace Prize. The 2015 Nobel Prize for medicine and physiology was shared between scientists which included Irish parasitologist William C. Campbell and Japanese microbiologist Satoshi Ōmura for discoveries that led to Ivermectin.

https://www.newscientist.com/article/dn28284-breakthrough-

drugs-for-malaria-and-roundworm-win-medicine-nobel/

- **9.** That, the **Ivermectin** is also recognized by WHO as one of the ten essential medications. Around 3.7 billion dosages of **Ivermectin** have been given out in last 40 years and there is sufficient data to prove its safety. That, you have wilfully ignored the mountains of data that shows that **Ivermectin** is undeniably helpful as prophylactic in preventing contracting COVID-19 and there is compelling evidence of its effectiveness in treating active COVID-19 in hospitalized patients.
- **10.** That, you have intentionally ignored the research undertaken by several doctors, scientists and their associations and alliances, who had started early on the pandemic, fervently searching for medicine/drug that would help in treatment of COVID-19. Their work which includes discussions, paper presentations, data on clinical trials, is readily available on the internet.
 - 11. That, you have deliberately chosen to ignore the work of your own brethren of diligent doctors, physicians and scientists like the 'Front Line COVID 19 Critical Care Alliance' (hereinafter referred to as 'FLCCC') and the British Ivermectin Recommendation Development (hereafter referred to as 'BIRD') Panel
 - **12.** That, FLCCC is an alliance of experienced and esteemed medical doctors and scientists, who have come together at the start of the COVID-19 pandemic and are working tirelessly in conducting research, studies and Randomized Control Trial (hereafter referred to as RCTs).



The website of FLCCC has ocean of information regarding treatment protocols for COVID-19, recommendations from esteemed and experienced medical professionals, testimonies of medical doctors and patients who have benefitted from the work of FCCCL.

https://covid19criticalcare.com/

- **13.** That, the FLCCC team consists of experienced, respectable physicians and scientists who possess wealth of knowledge:
 - 1. Dr. Paul E. Marik, MD
 - 2. Dr. Pierre Kory, MD
 - 3. Dr. G. Umberto Meduri, MD
 - 4. Dr. Joseph Varon, MD
 - 5. Dr. Jose Iglesias, MD
 - 6. Dr. Keith Berkowitz, MD
 - 7. Dr. Fred Wagshul, MD
 - 8. Dr. Scott Mitchell, MBChB
 - 9. Dr. Eivind Vinjevoli, MD
 - 10. Dr. Eric Osgood, M.D.

Their profiles/Curriculum Vitae can be accessed on <u>https://covid19criti</u> calcare.com/about/the-flccc-physicians/

14. That, Dr. Pierre Kory, M.D., M.P.A., has testified twice on behalf of FLCCC, in two senate hearings of United States of America (hereinafter referred to as "US/USA") since the pandemic started. The first one on May 6, 2020 regarding recommendation of Corticosteroids to save lives of critically ill patients. The video of this hearing is available on the FLCCC

website under 'Videos & Press section' and under sub menu 'Official Testimony'.

https://covid19criticalcare.com/videos-and-press/officialtestimony/

The official transcript of this hearing is attached as **Annexure 2**.

- 15. That, Dr. Pierre Kory in his testimony on May 6, 2021 had advanced the case for use of corticosteroids at an appropriate time on critically ill COVID-19 patients, even when all the national and international organisations were against the use of corticosteroids. It is noteworthy that the results of the 'Recovery Trial' which came to be published in November 2020, hailed the effectiveness of Corticosteroids that led to overnight change in the protocol. Sadly, six precious months were lost from the time that Dr. Pierre Kory had testified, till the results of Recovery Trial were published.
- 16. That, Dr. Pierre Kory, on behalf of FLCCC, has testified before the US Senate for the second time on December 8, 2020 regarding the wonder drug <u>Ivermectin and its potential as prophylaxis</u> and also for treating COVID-19 patients. In this testimony, he has justified the use of Ivermectin for treating COVID-19 patients based on 10 RCTs undertaken (at the time he testified). The 28-minute video of his testimony is available on the FCCCL website under 'Videos & Press' section and under sub menu 'Official Testimony'.

https://covid19criticalcare.com/videos-and-press/official-testimony/

The official transcript of this hearing is attached as **Annexure 3**.

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17. That, Dr. Pierre Kory, in the US Senate hearing on December 8, 2020, has expressed his dismay over how some leading public health organisations including US FDA (US Food and Drug Administation), CDC (Centers for Disease Control and Prevention), NIH (National Institute of Health) were losing time in acknowledging the power of Ivermectin in treatment of COVID-19. Dr. Pierre Kory, on behalf of FLCCC, had implored the Senate to have a look at their manuscript which covered the results of 10 Randomised Control Trials.

Refer page 4 of the Annexure 3

18. That, the manuscript of FLCCC has <u>passed a rigorous peer review by senior</u> <u>scientists at the US FDA and Defence Threat Reduction Agency</u>. The same has been published by the '**American Journal of Therapeutics**'

https://eurekalert.org/pub_releases/2021-05/fccc-lpr050621.php

- **19.** That the website of FLCCC has a special page dedicated to the **Ivermectin**. <u>https://covid19criticalcare.com/**Ivermectin** -in-covid-19/</u>
- **20.** That, the BIRD Panel has also conducted expansive studies and trials regarding effectiveness of **Ivermectin** as prophylaxis and for treatment of COVID-19 patients.

BIRD panel includes dozens of multinational scientists and doctors who have discussed the mounting data points and evidence supporting the use of **Ivermectin** in COVID-19 cases. The large, diverse group has reviewed the evidence associated with **Ivermectin** to potentially prevent and treat COVID-19, with a goal of reaching a consensus and making recommendations for further investigation and/or use.

The details of BIRD are available on <u>https://bird-group.org/</u>

Refer Annexure 4 for the details of recommendations by BIRD sent to WHO.

Doctors for Life in Brazil have supported BIRD's position and conclusions that contradict the WHO and claim there is much evidence to recommend Ivermectin for COVID-19, and each postponed day costs many lives.

The document can be accessed by clicking following link: https://bird-group.org/evidence-to-recommend-ivermectin/

BIRD Panel had organized the **FIRST INTERNATIONAL IVERMECTIN FOR COVID CONFERENCE** on 24th and 25th April 2021.

The video is available on following link:

https://bird-group.org/conference-post-event/

Refer Annexure 4 for the details of recommendations by BIRD sent to WHO.

21. That, it is disingenuous of you to have not acknowledged the cases of miraculous recovery of critically ill COVID-19 patients in the US, who were treated with Ivermectin. That, you have wilfully neglected the exemplary work by FLCCC and all such physicians and scientists who have brought back critically ill, comatose and patients on ventilator from the doorsteps of death.

- **22.** That, the patients were saved by the Courts of Law who passed orders to direct the concerned hospitals to administer **Ivermectin**, as US FDA has not yet approved **Ivermectin** for treatment of COVID-19.
- 23. That, <u>Ivermectin has saved the life of one 81 year old male COVID-19</u> <u>patient names John W. Swanson, whose chances of survival were minimal.</u> Refer Annexure 5, a news article in Buffalo News dated April 9, 2021 titled 'Judge orders Batavia hospital to treat coronavirus patient with Ivermectin '

https://buffalonews.com/news/local/judge-orders-batavia-hospital-to-treatcoronavirus-patient-with-**Ivermectin** /article_53c8b32e-996c-11eb-87cf-2bd34f11d3c2.html

The article states;

"Swanson was on a ventilator and "on death's doorstep," at the United Memorial Medical Center when doctors there gave him one dose of Ivermectin on April 1, according to an affidavit filed in court by attorneys for Swanson's wife, Sandra. "After that one dose, he started breathing on his own. He was taken off the ventilator and was making great progress," said attorney Ralph C. Lorigo, who represents the Swanson family with Jon F. Minear. "Then, the hospital refused to give him additional doses." State Supreme Court Justice Frederick J. Marshall issued an order on April 2, directing the hospital to give Swanson four more doses of Ivermectin . As of late Friday afternoon, his attorneys described Swanson as "stable."

24. That, another 80 year old critical COVID-19 patient named Judith Smentkiewicz has had a miraculous recovery from the disease with the help of **Ivermectin**.

Refer Annexure 6, a news article in Buffalo News titled 'After experimental Covid-19 treatment, 80-year-old woman thankful to be home'

https://buffalonews.com/news/local/after-experimental-covid-19treatment-80-year-old-woman-thankful-to-be-home/article_df8ae9da-72e4-11eb-b544-2f9de5ae5d71.html

The article states;

"As Judith Smentkiewicz fought for her life in a local hospital last month, she had no idea that her struggle with Covid-19 was the subject of a heated court battle and stories in the news media. Until a few days ago, the 80-year-old woman was unaware that her family's lawyers had obtained a court order enabling her to receive doses of **Ivermectin**, a drug that has not yet been approved by the federal government as a Covid-19 treatment. Now that she's back at her Cheektowaga home and well on the road to recovery, Smentkiewicz is amazed at everything that happened to her.

Smentkiewicz said she has "absolutely no memory" of a fiveday period when she was on a ventilator at Millard Fillmore Suburban Hospital. According to family members, doctors there told them that her chances of survival were about 20%. "I remember being taken to the hospital in an ambulance on Dec. 31, and being put on a stretcher in a hallway," Smentkiewicz said. "I know they put me on the ventilator that

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day, but I don't remember a single thing that happened until Jan. 4, when I was taken off the ventilator and able to sit up in my bed. I'm kind of glad I don't remember those days." Unapproved by FDA, **Ivermectin** useful as Covid-19 treatment, local doctors say she now knows that her son, Michael, and daughter, Michelle Kulbacki, insisted that doctors give Smentkiewicz **Ivermectin**, a drug that has helped Covid-19 patients in other countries but has not yet been approved as a Covid-19 treatment in the U.

She also realizes that, when doctors were reluctant to give her more than one dose of the drug, her son and daughter hired attorneys Ralph C. Lorigo and Jon F. Minear to get a court order that enabled her to get more doses. <u>On Jan. 8,</u> <u>State Supreme Court Justice Henry J. Nowak ordered the</u> <u>hospital to resume treatment with **Ivermectin**. After that, <u>Smentkiewicz made a strong recovery. She was able to leave</u> <u>the hospital in mid-January.</u></u>

She then spent a month in the Harris Hill Nursing Facility in Amherst, and on Tuesday, she returned home. "I am so appreciative of my family, the lawyers, the judge, the doctors, and all these people who were praying for me and fighting for me," said Smentkiewicz, speaking to a reporter in a strong, clear voice. "I know I had a lot of prayer warriors on my side."

"While she was on the ventilator, we prayed for Mom. We prayed to God, and the answer that came back to us was Ivermectin," Kulbacki said. "My brother was doing some

research on his own and came up with the information about **Ivermectin**. Nothing else was helping our mother. We read that **Ivermectin** was helping other people and had no dangerous side effects. We decided we had to try it." **Kulbacki said her mother made "a complete turnaround"** within days of her first doses of Ivermectin.

Smentkiewicz said she got "very good" care in the hospital and nursing home, and now feels she is "at about 85%" of where she was before she caught the virus. "I'm eating, walking, exercising, getting myself dressed and making my own bed, getting back to normal life little by little," she said. "I feel good, but I get out of breath if I try to do too much. I'm having a little trouble with balance and doing physical therapy twice a week." For years, she has been active as a volunteer at the Chapel in Cheektowaga, where she babysits young children while their parents attend Sunday services. Smentkiewicz said she is anxious to get back to that, and also wants to expand her volunteer activities. "One thing I saw in the nursing home was so many elderly people who just wanted someone to come in, help them open their mail and talk with them for a while," she said. "I think I would like to go in as a volunteer and visit with people who need that." She added that the publicity about her case will encourage families of suffering Covid19 patients to research the possibility of using Ivermectin to treat them.

Doctors recently told The News that **Ivermectin** has helped many patients at two of the region's busiest Covid-19

treatment centers – the Elderwood Health Care facility in Amherst and the McGuire Group's Harris Hill facility. Dr. Thomas Madejski, a former president of the New York State Medical Society, said he has also used **Ivermectin** as an effective treatment for Covid-19 patients in Erie, Niagara and Orleans counties. "It has very benign side effects, and that is one reason I have been offering it to patients," said Madejski, who said he was speaking only for himself, and not for the state medical society. Smentkiewicz said **she has no** way of knowing if Ivermectin is a miracle drug. She said she is thankful she did not become one of the nearly 500,000 Americans killed by Covid-19.

"I can't say it will help everyone, but I definitely believe it helped me, with no side effects," Smentkiewicz said. "I feel that God kept me around for a reason. He had a plan for me," she added. "I believe that part of that plan is to get people to take a closer look at Ivermectin."

25. That, in a third incident, a critically ill COVID-19 68 year old female patient named Nurije Fype, who was in a state of medically induced coma, at the Elmhurst Hospital in a comatose state and who was successful in dodging death due to inclusion of **Ivermectin** in her line of treatment.

Refer Annexure 7, an article published on Medical Brief titled 'US judge orders administration of Ivermectin to comatose patient' dated May 12, 2021:

https://www.medicalbrief.co.za/archives/us-judge-orders-

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administration-of-Ivermectin -to-comatose-patient/

26. That, the case of Nurije Fype is a milestone in success of **Ivermectin** in the treatment of COVID-19. In this case, inspite of the court order to administer **Ivermectin** on Nurije Fype, the hospital had refused to act on the order. This left no option to the family of Nurije Fype but to consider filing a contempt of court petition against the Elmhurst hospital.

The article in Annexure 7 states that;

"At request of her family an Illinois judge has ordered that a comatose woman suffering from COVID-19 to be administered Ivermectin, against the advice of her doctors, reports the Chicago Tribune.

Nurije Fype, 68, has been in intensive care at the hospital since early April and is now on a ventilator, according to testimony at the court hearing. Her daughter, Desareta Fype, is pushing for her mother to receive **Ivermectin**, a medication that the **US Food and Drug Administration** says may be unsafe.

Another federal agency, the National Institutes of Health, has taken a more measured stance, saying that while the drug is well-tolerated when used for its intended purposes, there isn't enough information to allow a recommendation "for or against" using it to treat COVID-19.

Elmhurst Hospital's attorney, Joseph Monahan, said at the hearing none of its doctors would agree to administer **Ivermectin** for COVID-19, and that an internal ethics panel concluded its use couldn't be justified. He argued that judges shouldn't overrule medical decisions.

"(The court) doesn't have the authority to order a medical corporation to use particular medications, particularly when it's an off-label use, particularly when the federal government has said it could be dangerous," he said.

He suggested Desareta Fype could transfer her mother to another facility where doctors would be willing to use the medication, but Judge James Orel seemed astonished at the suggestion. "Let me get this right: The hospital is willing to transfer a woman in a coma with COVID?" he said. "Is that what you're telling me?"

Judge Orel pointed to an affidavit from Fype's physician, Dr William Crevier, in which the doctor said he has used the drug successfully for COVID-19 patients since last year. If Elmhurst Hospital's doctors don't want to use **Ivermectin**, Orel said, they should allow Crevier to administer it.

"Why wouldn't this be tried if she's not improving?" Orel said. "Why does the hospital object to providing this medication? If someone has been in the ICU for a month and not improving, why would the hospital not consider another medication?"

It was still not clear, however, whether the hospital would allow Fype to receive the medication. Orel said he expected the case to head to an appellate court, and when he asked Monahan if the hospital was going to follow his order, the attorney replied, "I will talk to my client."

For more details regarding Court hearing, click on link below;

https://trialsitenews.com/when-nothing-else-works-judges-are-siding-with-Ivermectin/

On May 4, 2021, Judge Orel's response was pointed. "If there's a medicine out there that can assist a patient and nothing else is working and she's regressing to the point of near death, then, yes, I balance the equities." Meaning he weighed the evidence and sided with what many doctors call the "right to try".

This news is covered by FOX 32 News channel and the same can be viewed on following link:

COVID-19 patient shows 'improvement' after receiving Ivermectin following legal battle with hospital'

https://www.youtube.com/watch?v=qEAOICgDYhY

This video features patient Nurije Fype's daughter Desareta Fype and their Attorney Ralph Lorigo.

27. The news related to intervention of court in facilitating the administration of Ivermectin on Nurje Fupe is covered in detail on following websites:

News dated May 1, 2021 titled 'Court Battles Rage to save Lives. Attorney: 'Put Hospital Chief in Jail'

<u>https://www.beckershospitalreview.com/pharmacy/illinois-hospital-gives-</u> <u>covid-19-patient-**Ivermectin** -following-court-order.html</u>

News dated April 16, 2021 titled 'Ivermectin goes to Court and the NIH relaxes its prohibition'

https://www.thedesertreview.com/opinion/letters_to_editor/**Ivermectin** goes-to-court-and-the-nih-relaxes-its-prohibition/article_440b7300-59bf-11eb-b945-4f69ec28f4c0.html

News dated April 21, 2021 titled 'Ivermectin Wins in Court Again: For Human Rights'

https://www.thedesertreview.com/opinion/letters_to_editor/**Ivermectin** wins-in-court-again-for-human-rights/article_98d26958-a13a-11eb-a698-37c06f632875.html

28. That, Dr. Pierre Kory, who has expressed his anguish over refusal by the Elmhurst Hospital to administer **Ivermectin** on Nurije Fupe, despite having a court order and the subsequent consideration to initiate contempt of court proceeding by the patient's family, has been covered by FOX 32 on May 4, 2021and the same can be viewed on following

https://www.youtube.com/watch?v=eEF1eOeRlw0

In this video, Dr. Pierre Kory states;

"They are behaving indefensibly. I think the Judge is dismayed, their horror at what they (hospital) are doing matches mine. It is inexcusable"

https://trialsitenews.com/court-battles-rage-to-save-lives-attorney-puthospital-chief-in-jail/

29. That, there are likely to be more cases of COVID-19 patients having benefitted from using **Ivermectin** in their line of treatment. However, due to stricter laws in the US around patient privacy, not all cases have made to the news and not all patients are forthcoming in sharing the details. But the

testimonies of those who have dodged death and have survived, certainly make a strong case to use **Ivermectin**.

30. That, FLCCC based on its objective studies and RCTs has prevailed upon National Institute of Health (NIH) to change their guidance on **Ivermectin** to 'Neutral' on January 14, 2021, after referencing the increased numbers of clinical trials that have been done with positive results since their last update on August 27. They now recommend neither for nor against the use of **Ivermectin** for COVID-19.

https://www.covid19treatmentguidelines.nih.gov/antiviraltherapy/**Ivermectin** /

31. That, in India, Dr. Surya Kant Tripathi, Head of Respiratory Medicine Department, King George Medical University, Lucknow, along with some other health experts of India, has written a White Paper on **Ivermectin**, in which he has emphasized that this drug reduces the replication rate of the infection by several thousand times.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7434458/

- 32. That, the White paper by Dr. Surya Kant, the studies undertaken by AIIMS
 Bhubaneswar and several other research and studies undertaken by medical doctors and scientists across the globe, have proved Ivermectin to be effective as a prophylaxis and also in the line of treatment for COVID-19.
- **33.** That, the FLCCC in its Press Release on April 29, 2021 titled 'Front Line COVID-19 Critical Care Alliance Statement on New Guidance on

Ivermectin from the All India Institute of Medical Science' has praised the AIIMS for including **Ivermectin** in their national Covid-19 guidelines. FCCL has expressed their gratitude towards AIIMS for having followed the science on **Ivermectin** in creating the new Guidelines.

Refer Annexure 8.

34. That, FLCCC and BIRD have issued a 'Joint Statement on Widespread use of Ivermectin in India for Prevention and Early Treatment' on May 3, 2021.

https://www.einnews.com/pr_news/540334684/medical-organizationsin-the-uk-u-s-join-the-government-of-india-to-recommend-**Ivermectin** -to-end-the-covid-19-crisis

https://covid19criticalcare.com/videos-and-press/flccc-releases/jointstatement-may-03-2021-joint-statement-on-widespread-use-of-**Ivermectin** -in-india-for-prevention-and-early-treatment

Refer Annexure 9.

35. That, the **Ivermectin** has been widely used to treat Covid-19 in South Africa, Czech Republic, Bolivia, Honduras, Peru, Slovakia, Zimbabwe Bangladesh.

The link <u>https://ivmstatus.com/</u> gives pictorial representation of global **Ivermectin** adoption for COVID-19. The status is updated regularly.

36. That, in your interview on Mojo Story on May 16, 2021, while Ms. Barkha Dutt has asked you a pointed question at 22:40 whether to continue using Remdesivir and Ivermectin, you have deliberately misled the audience by

not revealing the mountains of evidence on effectiveness of **Ivermectin**. You, instead of giving a balanced response, that was expected from someone of your stature, have resorted to <u>strawman argument</u> and diverted the attention of people to areas totally unrelated to the specific question posed to you. You have responded by saying;

"There is no evidence that they have any impact on the disease progression so I would rather spend those resources on giving people good quality masks to wear. In the absence of vaccines, masks are the only vaccines. Everybody wears good quality masks, covering their nose and mouth, that is going to make a big difference at the community level and of course spend resources on ramping up of oxygen and other supplies that you need in the hospital, getting the work force there ready. You will have to supplement the work force because the existing doctors and nurses are not going to be enough to cope with the kind of load that we have seen, so those are the kind of investments that need to be made and you know these drugs really that's not going to be the ones that have an impact."

37. That, in the said interview on Mojo Story, you have mentioned about the Living Guidelines issued by WHO on March 31, 2021.

The Living Guideline can be accessed from the website of WHO:

- https://www.who.int/news-room/feature-stories/detail/who-advisesthat-Ivermectin -only-be-used-to-treat-covid-19-within-clinical-trials
- https://www.who.int/publications/i/item/WHO-2019-nCoVtherapeutics-2021.1

Refer Annexure 10 for document titled 'Therapeutics and COVID-19'

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LIVING GUIDELINE DATED MARCH 31, 2021 issued by WHO.

38.<u>MALAFIDES OF 'WHO' IN MISLEADING THE PUBLIC WITH</u> <u>ULTERIOR PURPOSES:</u>

38.1. That, the LIVING GUIDELINE dated March 31, 2021 includes recommendations of WHO on several drugs including **Ivermectin**. The WHO panel has made a recommendation not to use **Ivermectin** in patients with COVID-19 except in the context of a clinical trial.

The document also states the studies and finding of the Global Development Group (GDG), which supposedly served as the rationale for such recommendation regarding **Ivermectin**.

38.2. That, the explanation provided by WHO in the said Living Guideline dated March 31, 2021 is debunked by FLCCC by exposing the severe fallacies and bias on the part of WHO which was pre-determined to block the cheap drug **Ivermectin** from being discovered as effective drug in prevention and treatment of COVID-19.

Refer Annexure 11 - Public Statement dated May 12, 2021 issued by FLCCC titled 'Irregular Actions of Public Health Agencies and the Widespread Disinformation Campaign against Ivermectin'

Refer the following link:

https://covid19criticalcare.com/videos-and-press/flccc-releases/flcccalliance-statement-on-the-irregular-actions-of-public-health-agencies-andthe-widespread-disinformation-campaign-against-ivermectin/

39. That, the para 3 to 8 of the **Public Statement** dated May 12, 2021 issued by FLCCC titled 'Irregular Actions of Public Health Agencies and the Widespread Disinformation Campaign against Ivermectin'

read as under;

"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, placebocontrolled, 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.

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.

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 Scabies:

(1) "Over one billion doses have been given in largescale prevention programs."

(2) "Adverse events associated with **Ivermectin** treatment are primarily minor and transient."

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.

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:

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 an open letter 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.

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

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."

40. That, the said Public Statement also states that (page 2);

"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 Prizewinning 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. <u>These include the WHO and many individual members of its guideline development group</u> (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."

- **41.** That, we as members of public, have taken cognizance of the said Public Statement dated May 12, 2021, issued by FLCCC and we call upon you to provide your response as the Chief Scientist at WHO, to the fallacies pointed out by FLCCC regarding the Living Guideline of WHO dated 31.03.2021 based on the study conducted by Development Guideline Group regarding **Ivermectin**.
- **42.** That, your failure to provide rebuttal to the contents mentioned in **para 39** supra, shall be taken as acceptance of the fallacies in the Living Guideline Report of WHO dated **31.03.2021**.
- **43.** That, 'The Indian Council for Medical Research' (hereafter referred to as ICMR) which is the one of the oldest and largest medical bodies in the world and which is the apex medical research organization, has listed the drug **Ivermectin** as a possible treatment option for mild Covid-19 patient under home isolation in the '**May Do'** category on April 22, 2021. The National Clinical Guidelines for Covid-19 management are developed by All India Institute of Medical Sciences (hereinafter referred to as AIIMS), Delhi and ICMR joint taskforce. Refer **Annexure 12**.
- 44. That, the Ivermectin continues to be part of the National Protocol issued by the ICMR even at the time of drafting this legal notice. Refer Annexure 13 for the National Protocol as updated on May 17, 2021.
- **45.** That, you are a qualified medical doctor possessing the degree of MBBS and MD in Pediatrics from AIIMS Delhi. You have served as Director General of the ICMR and Secretary of the Department of Health Research (Ministry of

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Health and Family Welfare) for the Government of India from August 2015 to November 2017. That, going by your educational qualifications and work experience, you are deemed to be competent enough to understand the significance of statements/protocols/notifications issued by the esteemed organizations of India like ICMR and AIIMS, which you yourself were associated with at some point in time. But you have been repeatedly issuing statements against the use of **Ivermectin** with a malafide intention to misguide, mislead and create confusion in the minds of Indians in order to dissuade us from knowing about **Ivermectin** which has brought back few critically ill COVID-19 patients from the doors of death.

46. That, while you have attached the company statement issued by Merck in your tweet on May 10, 2021, you have intentionally ignored the fact that Merck, which is the manufacturer of **Ivermectin** may have a conflict of interest in issuing the said statement against the use of **Ivermectin** in treatment of COVID-19 as mentioned in para 4, since Merck is in process of making its own COVID-19 drug and that clinical trials for the same are in progress.

Refer the following link:

https://whyy.org/segments/some-doctors-think-theyve-found-acheap-generic-drug-which-treats-covid-19-so-why-hasnt-anyoneheard-of-it/

An excerpt from the above news article titled 'Some doctors think they've found a cheap, generic drug which treats COVID-19. So why hasn't anyone heard of it?' states;

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"Merck, which originally developed **Ivermectin** but whose patent on it expired, does not endorse its use for COVID-19 treatment. In a statement, a Merck representative said that "following detailed review of the evidence available for **Ivermectin** we calculated that the dose required to attain an antiviral effect would significantly exceed the doses known to be safe and well tolerated," referencing the in vitro study. "We therefore concluded that further research to evaluate the clinical potential of **Ivermectin** for the treatment of SARS-CoV-2 was not warranted."

Merck is in the process of developing its own new therapy for COVID-19, which it would presumably patent. It is also involved in vaccine trials."

Merck has issued a statement January 25, 2021 regarding development of its two investigational therapeutic candidates for treatment of COVID 19. Refer **Annexure 14**.

- **47.** That, the **Ivermectin** is off-patent since 1996 and therefore it is available at a cheap rate at present.
- **48.** That, your malafides are proven through your act of attaching the public statement of a pharmaceutical company Merck dated February 4, 2021 instead of the Report of WHO dated March 31, 2021 in your tweet on May 10, 2021. That, you were aware that the said WHO report on Living Guideline dated March 31, 2021 is an eyewash as far as the recommendation on **Ivermectin** is concerned and hence you deliberately attached an older statement of Merck dated February 4, 2021.

- **49.** That, it was your malfeasance reflecting in the tweet on May 10, 2021 against the use of **Ivermectin** in desperate hope to dissuade people of India from discovering the effectiveness of **Ivermectin** and that they keep falling sick and are available as a huge market for several drugs which are being launched now and which are in the pipeline and would be launched soon once the Emergency Use Authorisation (EUA) is granted for their public use.
- **50.** That, you are wilfully speaking against the use of **Ivermectin** for COVID-19 patients as you are aware that in the event of **Ivermectin** being declared as an **'existing and adequate drug'** to treat COVID-19, the Emergency Use Authorisation (EUA) currently granted for variety of vaccines and drugs would stand revoked and this will severely impact the prospects of new vaccines and drugs being manufactured to combat COVID-19.
- **51.** That, you have abused your position as the Chief Scientist at WHO to adversely influence the people including medical doctors and scientists, by trying to impose upon them the fact that WHO does not support the use of **Ivermectin** either as prophylactic or in treatment of COVID-19.
- **52.** It seems that you have deliberately opted for deaths of people to achieve your ulterior goals and this is a sufficient ground for criminal prosecution against you and also for initiating action for revocation of your degrees in medical field.
- **53.** That, it is highly unbecoming of you as a physician and scientist, to insist on Randomized Control Trials amidst pandemic, to ascertain the efficacy of **Ivermectin** in treatment of COVID-19. This is equivalent to you taking a stand

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that allows people to fall sick and probably die of COVID-19, but does not allow them to take a drug which has not only been proven to be safe with no harmful effects, but has also been proved to be effective as prophylaxis and in treatment of COVID-19 in numerous cases across the globe. This is juxtaposed to the fact that precious time was lost in conducting the solidarity trial by WHO that concluded that most of the drugs or therapies did not work viz. Hydroxychloroquine, Remdesivir and the convalescent plasma.

- **54.**You are deliberately ignoring the medical ethics and principles that you are bound to follow;
 - The Declaration of Geneva of the World Medical Association (WMA) binds the physician with the words, "The health and wellbeing of my patient will be my first consideration,"

https://www.wma.net/policies-post/wma-declaration-of-geneva/

2. International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

https://www.wma.net/wp-content/uploads/2006/09/International-Code-of-Medical-Ethics-2006.pdf

3. Article 37 of the WMA declaration of Helsinki, titled: "Unproven Interventions in Clinical Practice" It is paraphrased as "In the treatment of an individual patient, where proven interventions do not exist, a physician may use an unproven intervention if in the physician's judgement it offers hope of saving life, reestablishing health or alleviating suffering

https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf

- **55.** That, you are called upon to read Article 37 of the WMA declaration of Helsinki mentioned in **para 54** supra, at least a hundred times and provide a cogent explanation for:
 - 1. Not supporting the use of **Ivermectin** in treatment of COVID-19, given the fact that **Ivermectin** is proven to be safe with no harmful effects.
 - 2. Ignoring the presence of voluminous data that proves the effectiveness of **Ivermectin**, not to forget the cases where patients have been taken off ventilator soon after **Ivermectin** was administered (Refer para 21 to 28)
- **56.** That, your misleading tweet on May 10, 2021 against the use of **Ivermectin** had the effect of the State of Tamil Nadu withdrawing **Ivermectin** from the protocol on May 11, 2021 just a day after the Tamil Nadu Government had included the same for treatment of COVID-19 patients.

https://science.thewire.in/health/tn-revises-protocols-leaves-out-Ivermectin-for-covid-patients/

57. That, the re-purpose drugs which were included in the solidarity trials like Remdesivir, hydroxychloroquine have proved to be 'Ineffective', so did the convalescent plasma therapy. Your concerns around use of **Ivermectin** for COVID-19 are totally misplaced given the fact that **Ivermectin** has no harmful side effects unlike corticosteroids and Remdesivir. <u>Hence, resistance to use of</u>

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Ivermectin on flimsy grounds and that too by wilfully ignoring the voluminous data that proves the effectiveness of the drug, is not at all tenable, rather it proves your malafides and ulterior purposes.

58. That, the credibility and integrity of WHO has been severely eroded and continues to wane with each passing day due to its miserable failure in handling the pandemic. Also, the reports issued by WHO are increasingly been seen as biased and totally lacking in quality, authenticity and rational approach. The latest the report regarding investigation into the origins of the Corona Virus is also being questioned by the scientists' community. As many as eighteen eminent scientists have written to WHO asking for detailed investigation.

https://www.wsj.com/articles/scientists-call-for-deeper-investigation-intocovid-19-origin-11620928801

The above article states;

"In a letter published Thursday in the journal Science, an international group of <u>18 biologists</u>, immunologists and other scientists criticized the findings of a report released in March by a World Health Organization-led team into the pandemic's origin and called for a more extensive evaluation of the two leading hypotheses: that the pandemic virus entered the human population and began spreading after escaping from a lab or after jumping to humans from infected animals.

TheWHO-led team, which included scientists from China and several other countries, reported no definitive proof of either hypothesis. Yet, the scientists wrote, the team nevertheless concluded that an animal origin for the pandemic was the likelier scenario and devoted only

59. That, the WHO report published in March 2021 regarding the investigation into the origins of Corona virus is found to be severely lacking in many aspects, which is explained in following article;

https://science.thewire.in/the-sciences/scientists-ltter-fuller-investigationorigins-novel-coronavirus-lab-natural-spillover/

The article states;

"This was evidently a comment on the WHO's investigation into the origins of the virus. Under the terms of reference of this investigation, the information, data, and samples for the study's first phase were collected and summarised by a team of Chinese scientists. The rest of the team only built on this analysis, which found no clear evidence either to support a natural spillover or a lab accident. However, the team said a zoonotic spillover from an intermediate host was "likely to very likely," and a laboratory incident was "extremely unlikely".

Even before the WHO report was released in March this year, reports <u>said in November 2020</u> that the WHO had 'ceded' control of the investigation to China in a bid to gain access to the source of coronavirus. The reports argued that the WHO was eager to "win access and coordination" from China but achieved neither."

60. That, several nations are calling out WHO for its falling standards, biased approach and its deliberate acts of omission and commission that are causing loss of human lives.

While the WHO flaunts itself like 'know it all', it is akin to the vain Emperor in new clothes, while the entire world has realized by now that the Emperor (WHO) has no clothes at all.

61. That, you and WHO have misled and misguided all the people throughout the pandemic, starting from the delay in raising alarm soon after SARS-CoV2 was detected in China, your failure to prevail over China in conducting an impartial investigation into the origins of the virus, inordinate time consumed before declaring Remdesivir, Hydroxychloroquine, convalescent plasma as 'ineffective' in treatment of COVID-19, ever changing theories around SARS-CoV2 being transmitted through droplets or it being air borne and many more. The world is gradually waking up to your absurd, arbitrary and fallacious approach in presenting concocted facts as 'scientific approach'. As the famous quote of Abraham Lincoln goes –

"You can fool all the people some of the time and some of the people all the time, but you cannot fool all the people all the time."

62. That, the team of FLCCC have beseeched all countries to use **Ivermectin** which according to them is the only way to end this pandemic.

Refer the article below titled **'immediate global Ivermectin use can end Covid-19 pandemic: Scientists'** published online on The Free Press Journal on May 10, 2021:

<u>https://www.freepressjournal.in/health/immediate-global-**Ivermectin** -<u>use-can-end-covid-19-pandemic-scientists</u></u>

63. That, the article mentioned in para 55 states;

"Peer reviewed by medical experts that included three US government senior scientists and published in the American Journal of Therapeutics, the research is the most comprehensive review of the available data taken from clinical, in vitro, animal, and real-world studies.

Led by the Front Line COVID-19 Critical Care Alliance (FLCCC), a group of medical and scientific experts reviewed published peerreviewed studies, manuscripts, expert meta-analyses, and epidemiological analyses of regions with **Ivermectin** distribution efforts all showing that **Ivermectin** is an effective prophylaxis and treatment for COVID-19.

"We did the work that the medical authorities failed to do, we conducted the most comprehensive review of the available data on Ivermectin," said Pierre Kory, MD, president and chief medical officer of the FLCCC. "We applied the gold standard to qualify the data reviewed before concluding that Ivermectin can end this pandemic."

A focus of the manuscript was on the 27 controlled trials available in January 2021, 15 of which were randomised controlled trials (RCT's). Consistent with numerous meta-analyses of **Ivermectin** RCT's since published by expert panels from the UK, Italy, Spain and Japan, they found large, statistically significant reduction in mortality, time to recovery and viral clearance in Covid-19 patients treated with **Ivermectin**.

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"Our latest research shows, once again, that when the totality of the evidence is examined, there is no doubt that **Ivermectin** is highly effective as a safe prophylaxis and treatment for Covid-19," said Paul E. Marik, founding member of the FLCCC and Chief, Pulmonary and Critical Care Medicine at Eastern Virginia Medical School.

Many regions around the world now recognise that Ivermectin is a powerful prophylaxis and treatment for Covid-19. South Africa, Zimbabwe, Slovakia, Czech Republic, Mexico, and India have approved the drug for use by medical professionals.

<u>The results as seen in this latest study demonstrate that the **Ivermectin** <u>distribution campaigns repeatedly led to "rapid population-wide</u> <u>decreases in morbidity and mortality."</u></u>

"We are calling on regional public health authorities and medical professionals around the world to demand that **Ivermectin** be included in their standard of care right away so we can end this pandemic once and for all," Marik noted."

- **64.** That, the work done by FLCCC, BIRD and similar groups, has ruffled the feathers of many including WHO, whose inefficiencies and failures have been exposed time and again.
- **65.** That, there is a vicious attempt by some individuals including doctors, scientists and leading public health organisations, to suppress all the news regarding effectiveness of Ivermectin. This Syndicate has managed to capture considerable portion of scientific and medical community, who

continuously discredit any reports/news around the effectiveness of **Ivermectin** in treating COvid-19 patients.

Such deliberate actions are explained in detail in the Public Statement by FLCCC (Refer Annexure 11, page 8 to 13)

- **66.** That the FLCCC and BIRD have shown exemplary courage in building a formidable force to tackle the challenges in the form of disinformation, resistance and rebuke from pharma lobbies, powerful health institutions like WHO, NIH, CDC and regulators like US FDA.
- **67.** That, in the time of this crisis, there are few doctors who are living up to their Hippocratic Oath, by putting the patients' interest first and not being complicit in the agenda of spreading disinformation. These brave and courageous doctors, who are morally upright, have chosen to support the truth rather than yielding meekly to authoritative and unscientific mandates.

These doctors are your very own brethren who are highly qualified, experienced and more importantly humane and conscientious.

The FLCCC site has a video dated April 19, 2020 that features following brave doctors, who have been forthcoming in declaring the effectiveness of **Ivermectin:**

- 1. Dr. Paul E. Marik M.D., FCCCM, FCCP Norfolk, Virginia
- 2. Dr. Bruce Boros M.D.

Key West, Florida

3. Dr. Keith Berkowitz – M.D., MBA

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New York

 Dr. Eric Osgood – M.D. Trenton, New Jersey
 Dr. Colleen Aldous – PhD

Durham, South Africa

- 6. Dr. Alexis Lieberman–M.D. Philadelphia, Pennsylvania
- Dr. Randy Grellner M.D.
 Cushing, Oklahoma
- 8. Dr. Jackie Stone M.D. Harare, Zimbabwe
- 9. Dr. Syed Haider M.D.

Asheville, North Carolina

10.Dr. Fred Wagshul – M.D.

Dayton, Ohio

11.Dr. William Crevier – M.D.

Orland Park, Illinois

12.Dr. Arezo Fathie – M.D.

Las Vegas, Nevada

13.Dr. Bruce Patterson – M.D.

Palo Alto, California

14. Dr. Miguel Antonatos – M.D.

Chicago, Illinois

15. Dr. Matt Erickson – M.D.

Gainesville, Florida

16. Dr. Ram Yogendra – M.D.

Pawtucket, Rhode Island 17. Dr. Tess Lawrie – MBBCH, PHD

Bath, United Kingdom

The video can be accessed on <u>https://covid19criticalcare.com/videos-and-</u> press/flccc-alliance-videos/

The description of video reads thus:

<u>They are truly adhering to their Hippocratic Oath and Putting patients – not</u> profits first.

"These brave doctors are rising to the highest ideals of the Hippocratic Oath they took to save the lives of the patients who come into their care. These are the truest heroes of this ruthless pandemic. <u>They have chosen to #followthescienceand save</u> <u>lives—and have refused to be party to the corruption that is</u> <u>endemic among the world's health authorities</u>. There are more brave doctors out there."

That, Dr. Paul E. Marik, towards the end of the video, states the following regarding **Ivermectin**;

"The statistics for us is, we know this can make a difference and save lives. And it seems like nobody really cares and wants to listen to us. We have this massive force that is trying to silence us and yet we feel we can't be silenced. We can't be, because you know the truth will ultimately prevail".

68. That, the Constitution of India, as per Article 51 A (h), casts a solemn duty upon me to develop scientific temper, humanism and the spirit of inquiry and

reform. Therefore, I shall relentlessly pursue and question anything that is found to be unscientific, biased, arbitrary, flawed and irrational, especially in these times when several people are losing their lives, which could have been saved but for the vicious attempts by a few to suppress vital information.

- **69.** That, you are called upon to:
 - (1) Provide your and WHO's response to each and every finding shared by FLCCC in their Public Statement issued on May 12, 2021 regarding the fallacies in the Living Guideline issued by WHO on March 31, 2021
 - (2) Furnish the study papers, research, knowledge resources relied upon by you, based on which, you have tweeted against the use of Ivermectin on May 10, 2021.
 - (3) Explain the rationale for attaching the notification of Merck dated Feb 4, 2021 instead of the Living Guideline issued by WHO on March 31, 2021, in your tweet on May 10, 2021.
 - (4) Explain with facts and figures that support your stand that Ivermectin is not safe.
 - (5) Strictly refrain from sharing your views on Ivermectin for COVID-19 till you address points 1, 2, 3 and 4 above.
- **70.** That, your failure to provide any response or a clear response to all of the points in para 69, shall be deemed as acceptance of all claims and allegations

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against you in this notice and we reserve all the rights to initiate legal action against you, which will be at your peril.

71. This notice is issued by reserving our rights to initiate prosecution under sections 302, 304 (II), 88, 120 (B) and 34 and other provisions of the Indian Penal Code and under Disaster Management Act, 2005 in the appropriate Courts of Law having jurisdiction for each death caused due to your act of commission and omission.

Date: 25.05.2021

Place: Mumbai

Adv. Dipali N. Ojha Head – Legal Cell Indian Bar Association <u>www.indianbarassociation.in</u>

Copy to,

- 1. Hon'ble President of India
- 2. Hon'ble Prime Minister of India
- 3. Hon'ble Governors of all States of India
- 4. Hon'ble Minister of Home Affairs
- 5. Hon'ble Minister of Health and Family Welfare
- 6. The Director, Intelligence Bureau
- 7. The Director, CBI
- 8. Hon'ble Chief Ministers of all States of India

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- 9. The Director General of Indian Council of Medical Research (ICMR)
- 10. The Director, All India Institute of Medical Sciences, Delhi (AIIMS)
- 11. The National President, Indian Medical Association
- 12. The Drugs Controller of India
- 13. The Director, The National Institute of Virology, Pune
- 14. The Chairman, National Medical Commission (NMC)
- 15. South East Asia Office WHO, Delhi, India