A continuation of a timeline of ivermectin-related events in the COVID-19 pandemic

Mika Turkia

M.Sc., mika.turkia@alumni.helsinki.fi, June 30, 2021

Abstract

This review presents a continuation of a previous timeline that described ivermectin-related events in the COVID-19 pandemic from April 2020 to the end of March 2021. The new timeline covers a period from the beginning of April 2021 to the end of June 2021.

In April 2021, the US National Institutes of Health (NIH) announced a new, large clinical trial including ivermectin, with an estimated study completion date in March 2023. A large national trial was also announced in the Philippines, a 1,160-patient trial in the US, and another trial in Ireland.

Trial results published in the period resembled those of previous trials, not producing clinically meaningful changes to the results of existing meta-analyses. Mainstream press of the high-income countries mostly repeated the same arguments as in the previous period, including the warnings against ivermectin by the European Medicine Agency (EMA) and the World Health Organization (WHO). The sparse and one-sided coverage of ivermectin in the press appeared to result from a program called Trusted News Initiative (TNI). The censorship practices of the social media companies, with policies disallowing expression of views differing from the guidelines of the WHO, continued unchanged, apparently organized under a program called International Fact-Checking Network (IFCN).

In contrast to the previous period – during which groups such as the Front Line COVID-19 Critical Care Alliance (FLCCC) and the British Ivermectin Recommendation Development (BIRD) group attempted to influence the decisions of government agencies – in this period these groups began to bypass the agencies and turn directly to clinicians and the public. FLCCC also published two new protocols, I-MASS for mass immunization, and I-RECOVER for long haul COVID-19 syndrome (LHCS), and a review article which by the end of the period had reached a position in the top 120 of 18 million articles tracked by Altmetric. The BIRD group organized two online conferences on ivermectin and published a meta-analysis which had reached a position in the top 60, respectively.

One of the authors of the in vitro study that initiated the international interest in ivermectin explained that due to, for example, lack of adaptive immune responses in the cell model, their study was unsuitable for making conclusions about in vivo dosing in humans. A review described 20 mechanisms of action of ivermectin in COVID-19.

The parties against and in favor of ivermectin remained in deeply conflicting positions, presenting opposite conclusions on the existing research. The WHO, along with regulatory agencies and national governments of high-income countries, appeared to aim at preserving the value of existing investments in vaccine and investigational therapeutics development, as well as questioning the efficacy and safety of repurposed medicines.

Criticism towards excessive influence of Bill Gates in the WHO emerged during the period, as the largest funder of the WHO appeared to be a group of vaccine promotion and intellectual property rights enforcement oriented organizations founded by Gates. There was a noticeable centralization of power, with the pandemic response largely directed by a few public-private partnerships working on commercializable technologies.

Keywords: *COVID-19, SARS-CoV-2, WHO, ivermectin*

Introduction

Ivermectin is a multifaceted medication invented in collaboration between Japanese professor emeritus Satoshi Ōmura from Kitasato University and US researcher William Campbell from Merck & Co/MSD between 1973 and 1979 [1]; [2]. Each of them received one quarter of the 2015 Nobel Prize in physiology or medicine for their discoveries [3]. Ivermectin is best known as an antiparasitic agent, with approximately four billion doses having been administered since 1981, predominantly in Africa. Merck & Co/MSD's patent expired in most countries in 1996, and ivermectin preparations are currently available internationally from many sources, with the production cost of a single dose estimated to be less than 0.1 US dollars [4].

This article extends the timeline of ivermectin related-events described in a previous preprint available in two versions, March 30, 2021 and April 3, 2021 [5]; [6]. The latter preprint covered the period from April 1, 2020 to March 31, 2021. This preprint extends the timeline to cover April–June 2021, as well as adding a few earlier events. Some caveats of the review are described in the previous preprint. Due to resource limitations, details of many developments are not covered in detail but only mentioned briefly, and omissions have been unavoidable. The focus of this review entails the social, organizational, financial and legal aspects of the situation with ivermectin, with less emphasis placed on presenting clinical trial results and biomedical research.

Some of the main events in the previously covered period from April 2020 to March 2021 were an Australian in vitro study which initiated the interest in ivermectin [7]. This was followed by adoption of ivermectin in several South and Central American countries, the state of Uttar Pradesh in India, and Bangladesh in the second and third quarter of 2020. In late October 2020, the Front Line COVID-19 Critical Care Alliance (FLCCC) published its ivermectin-based outpatient protocol called I-MASK+ [8]; [9]; [10].

A month later, another group called CovidAnalysis begun publishing a meta-analysis of ivermectin trials [11] and a list of ivermectin studies [12]. A main event in December 2020 was the US Senate hearing of Pierre Kory of the FLCCC [13]. The hearing raised interest of Lawrie et al. and Bryant et al. who produced additional meta-analyses [14]; [15]. In conjunction, another group called British Ivermectin Recommendation Development (BIRD) was founded.

Another main event was the introduction of a preprint of a Unitaid/WHO-funded meta-analysis by Hill et al. [16]. Yet another notable event was the publication of an extensive review by a Japanese group including the discoverer of avermectins, the Nobel prize winner Satoshi Ōmura [2]; [17].

In the first quarter of 2021, ivermectin had been adopted in several additional countries including Slovakia as the first European Union member country. However, in March 2021 both the European Medicine Agency (EMA) and the World Health Organization (WHO) advised against the use of ivermectin except in clinical trials, ignoring the various meta-analyses and the results of 26 existing randomized clinical trials, in addition to a similar amount of observational trials and other studies.

The majority of indications and the safety of ivermectin have been described in the previous preprint [6]. In addition, in April 2021 ivermectin was found to effectively inhibit hepatitis E virus replication [18]. There is also a relatively large amount of research about the treatment of cancers with ivermectin [19][20][21][22][23][24][25], including breast cancer [26][27][28][29][30][31][32], ovarian cancer [33][34][35][36][37][38][39], cervical cancer [40], oesophageal squamous cell carcinoma [41], renal cancer [42], glioma [43][44][45], nasopharyngeal carcinoma [46], melanoma [47][48], gastric cancer [49][50], liver cancer [51] and leukemia [52][53] (list from [54]).

Recently, mass distribution of ivermectin has been studied for prophylaxis of malaria [55]; [56]; [57]. Ivermectin has also been found to promote wound healing partly through modulation of the inflammatory process and the levels of transforming growth factor beta 1 (TGF-β1) and vascular endothelial growth factor (VEGF) [58]. Ivermectin has also been proposed for the treatment of autoimmune disorders [59].

Ōmura has characterized ivermectin as "a panacea for resource-poor communities" [60]. Ivermectin has also been said to "continue to surprise and excite scientists, offering more and more promise to help improve global public health by treating a diverse range of diseases, with its unexpected potential as

an antibacterial, antiviral and anti-cancer agent being particularly extraordinary" [61]. Possible issues include environmental toxicity [62]; [63] and the emergence of ivermectin resistance [64].

April 2020

On April 16, Chaccour et al. stated that the recent findings warrant rapidly implemented controlled clinical trials and these trials might open a new field of research on the potential use of avermectins as antivirals but extreme due diligence and regulatory review were needed before testing ivermectin in severe disease. They added that off-label and compassionate use required careful risk–benefit considerations, especially in critically ill patients. The authors suggested trials on early treatment of uncomplicated, low-risk patients [65].

On April 17, a member of the European Parliament asked about the amount of influence of Bill and Melinda Gates Foundation in the WHO [66]; [67].

On April 18, a news report described that in the Dominican Republic, pulmonologist Johnny Tavárez Capellán had carried out an observational trial with 247 patients, observing a favorable response in all cases, with no fatalities [68]; [69].

On April 23, Honduras introduced Catracho, a COVID-19 treatment protocol created by Honduran doctors Óscar Díaz, Fernando Valerio and Miguel Sierra-Hoffman, consisting of colchicine, anti-inflammatories, tocilizumab, ivermectin, anticoagulants, and hydroxychloroquine [70]; [71]; [72].

On April 29, an article by Villar et al. (including Meduri of the FLCCC) provided a rationale for prolonged corticosteroid treatment in COVID-19 [73].

August 2020

On August 2, a news report in a Mexican newspaper described FLCCC's MATH+ inpatient protocol [74].

On August 5, the New York Times wrote about a "civil war in some hospitals" as a result of disagreements on how much freedom should front-line clinicians have in treating COVID-19 patients with unproven drugs [75]. The article described a conflict over care of a patient involved in a clinical trial, where a clinician was pressured by a head researcher to retain the patient following the trial protocol although the clinician considered adhering to the protocol dangerous for the patient in a critical condition. In this case, the researchers compared relying on the clinician's judgment to "witchcraft", insisting the clinician follow the "evidence". The head researcher mentioned his wife had, however, taken hydroxychloroquine for COVID-19 and recovered. Regardless, the head researcher insisted it was essential to rely on research and anything else was witchcraft.

Another researcher who had spent two weeks in one hospital commented that he was "distressed by how quickly doctors were trying untested therapies outside clinical trials. 'I mean, it felt like it wasn't even World War I medicine,' he said. 'It was almost like Civil War-level medicine'". He added that he knew his colleagues had been risking their lives, been overwhelmed by their clinical demands and had no research to rely on but was nonetheless surprised to see many of them making decisions "based on the sort of opinion or written protocol of one or a couple of people that was based on kind of nothing that I could see, other than just, 'This seems like a good idea'". Pierre Kory of the FLCCC commented that "it became like Republicans and Democrats ... the two sides can't talk to each other". After a 6,000-patient trial indicated benefits from corticosteroids [76], one researcher described as a "research purist" commented that the efficacy "is still unknown" and that even one stellar randomized controlled trial does not settle the question of the use of steroids for patients with Covid-19 as "it needs to be replicated". Kory commented that "that's a 6,000-person trial he's discrediting ... that's a person who will never be convinced".

The article also described the editor of the New England Journal of Medicine commenting that the FLCCC's recommendation of corticosteroids in the MATH+ inpatient protocol [77]; [10]; [9] used since January 2020 and made publicly available in the first quarter of 2020 had been just "lucky". He had opposed corticosteroids but had eventually admitted he had been wrong, yet was still frustrated that

doctors were still relying on treatments for which there was no evidence. He had been more positive about tocilizumab for which much less information than that for corticosteroids had been available. He eventually concluded that "I know I seem to be saying opposite things ... I can't argue that I was super rational either".

On August 14, a commentary by Doidge discussed RCT fundamentalism in medicine [78]. He said "the core belief [that only RCTs can decide] is repeated, like a catechism, at times ad nauseam, and contrasting beliefs are treated like heresies. What the RCT fundamentalist is peddling is not a scientific attitude, but rather forcing a tool, the RCT, which was designed for a particular kind of problem to become the only tool we use. In this case, RCT is best understood as standing not for Randomized Control Trials, but rather Rigidly Constrained Thinking". Doidge concluded that "the most prudent option is to allow the professional who knows the patient to have as much flexibility as possible and access to as many medications as possible. If we are to be honest, evidence-based medicine is, in large part, still aspirational. It is an ideal. Clinicians need latitude, and patients assume they have it. But now the RCT fundamentalists are using the absence of RCTs for some drugs to restrict access to them. They have gone too far. This is epistemological hubris, at the expense of lives, and brings to mind the old adage, 'Absence of evidence is not evidence of absence'. As long as we've not got the best studies for all conceivable permutations, medicine will remain both an art and a science".

September 2020

On September 28, a press release about Catracho, the treatment protocol of Honduras, reported that after the introduction of Catracho on April 23, 2020 the hospital mortality rate had decreased from 14.5% to 2.7% by the end of July, 2020 [70]; [71]; [72]. One of the creators of the protocol, Sierra-Hoffman, stated that "I am proud that we can tell the world that Honduras has become part of contemporary world history with golden letters... we have given the world an answer on how to address the virus in critically ill patients, lowering mortality in Honduras, a country with many limitations and with one of the worst prognoses when the pandemic begun ... from a scientific point of view it is a great merit and achievement for humanity". The president of Honduras congratulated the team.

On September 29, a news report from the Dominican Republic described that Dr. José Natalio Redondo had treated at least 6,000 outpatients with ivermectin with promising results [79]. He pointed out the importance of initiating the treatment early.

October 2020

On October 13, Magro et al. published an article describing COVID-19 as a multifaceted viral vasculopathy syndrome [80]; [81]. They described that "each of the cytokines (IL-6, TNF-α, IL-1β, IL-8, and p38) were significantly increased in the endothelia of select extrapulmonary microvascular beds where they each strongly co-localized with the viral spike protein and ACE-2 receptors including the skin". An earlier 2008 study by Zhang et al. [82] had found that "ivermectin improved mouse survival rate induced by a lethal dose of lipopolysaccharides. In addition, ivermectin significantly decreased the production of TNF-α, IL-1ß and IL-6 in vivo and in vitro", matching with the findings of Magro et al.

On October 20, in a video news report, Michael Jacobs, a clinical director of infection in Royal Free Hospital in London, also a co-senior author of WHO's living guideline for COVID-19 therapeutics and an ivermectin panel member responsible for WHO's ivermectin guideline [83], presented the hospital's trial in which volunteers were deliberately exposed to coronavirus in a controlled setting to speed up the development of a successful vaccine [84].

On October 22, Portmann-Baracco et al. commented that "COVID-19 is divided into different phases: asymptomatic, mild symptomatic disease, and severe inflammatory respiratory disease. The first two phases are dependent on viral replication, whereas the latter is attributed to the hyper-inflammatory state called the cytokine storm. Evidence suggests that ivermectin can act at different stages of the disease. Controlled studies must be conducted first to demonstrate the effect of ivermectin against Covid-19, then to determine if this effect is due to its antiviral action and finally to study if its administration is convenient also in hospitalized patients due to its apparent anti-inflammatory effect" [85].

November 2020

An editorial by Abbasi in the British Medical Journal (BMJ) discussed politicization, "corruption" and suppression of science in the context of COVID-19 pandemic [86]. According to the author, the pandemic had unleashed state corruption on a grand scale, with politicians, industry, scientists and health experts participating in an "opportunistic embezzlement" to manipulate the medical-political complex. As examples, the author listed lack of transparency, inappropriate involvement of government advisers in a scientific advisory group, blocking of publication of findings about inadequacy of antibody tests, attempted blocking of a press release of a research paper, competing interests such as shareholding in companies manufacturing tests, treatments and vaccines, and cherry-picking of science to advance anticompetitive practices. The author stated that "suppressing science, whether by delaying publication, cherry picking favorable research, or gagging scientists, is a danger to public health, causing deaths by exposing people to unsafe or ineffective interventions and preventing them from benefiting from better ones. When entangled with commercial decisions it is also maladministration of taxpayers' money. Politicization of science was enthusiastically deployed by some of history's worst autocrats and dictators, and it is now regrettably commonplace in democracies. The medical-political complex tends towards suppression of science to aggrandize and enrich those in power. And as the powerful become more successful, richer, and further intoxicated with power, the inconvenient truths of science are suppressed. When good science is suppressed, people die".

January 2021

On January 9, a newspaper in Peru reported that the former head of state Martín Vizcarra had recommended the use of ivermectin as prevention and treatment despite the absence of scientific evidence, saying that "it does work ... ask those who have had the virus and were treated promptly with ivermectin: the symptoms immediately decreased" [87]. The article mentioned opposition by the US FDA and an analysis of possible therapies carried out by the Pan American Health Organization (PAHO) that had concluded that studies on ivermectin presented "a high risk of bias, very little certainty of the evidence, and that the existing evidence is insufficient to reach a conclusion on its benefits and its damages" (in 2014, PAHO did not concern itself with damages from a mass distribution of ivermectin to 1.4 million schoolchildren in Paraguay [88]). Regardless, local authorities had delivered ivermectin throughout several regions for months, but researchers from a social security scientific evidence generation department had raised alarm about ivermectin's ineffectiveness. The article finished with stating that "without having taken all [opposing] arguments into account, Vizcarra finalized his recommendation as follows: 'I am an engineer, I am not a doctor, but I met with an expert committee which recommended mass distribution. We have to resume prevention'".

On January 27, Bill Gates said that the Coalition for Epidemic Preparedness Innovations (CEPI) had helped fund a number of COVID-19 candidates including the Moderna and Oxford AstraZeneca vaccines, that the United States had included USD 4 billion for Gavi in its latest COVID-19 relief package, and that stopping the next pandemic will require spending tens of billions of dollars per year in for example mega-diagnostic platforms which could test as much as 20 percent of the global population every week [89]. He said one of the most promising COVID-19 therapeutics were monoclonal antibodies which were time-consuming to develop and manufacture. He also stressed the importance of new mRNA vaccines.

On January 29, Joel S. Hirschhorn published an ebook titled "Pandemic blunder: Fauci and public health blocked early home COVID treatment" [90]. The author described the handling of the pandemic as "criminally negligent homicide resulting from intentional actions by myriad government officials". The book concentrated on the actions of the US FDA and NIH. It also analyzed usefulness of RCTs, quoting an article published in the New England Journal of Medicine written by former director of the US Centers of Disease Control and Prevention (CDC) Thomas R. Frieden saying that "elevating RCTs at the expense of other potentially highly valuable sources of data is counterproductive. A better approach is to clarify the health outcome being sought and determine whether existing data are available that can be rigorously and objectively evaluated, independently of or in comparison with data from RCTs, or whether new studies (RCT or otherwise) are needed ... there is no single, best approach to the study of health interventions; clinical and public health decisions are almost always made with imperfect data

... there will always be an argument for more research and for better data, but waiting for more data is often an implicit decision not to act or to act on the basis of past practice rather than best available evidence. The goal must be actionable data – data that are sufficient for clinical and public health action that have been derived openly and objectively and that enable us to say, 'Here's what we recommend and why'" [91]. Hirschhorn added that "many researchers, like [Didier] Raoult [92], opted for observational studies, in which as many patients as possible are treated. This is not a matter of choosing a design that is 'fatally flawed,' it is a matter of choosing a design that is not unnecessarily fatal to the patients. It's not sloppiness (as some of his critics would allege), but being true to the study question as he saw it: how can we save as many lives as possible. These observational studies could begin almost immediately, and didn't require the slow approval process that RCTs require". Hirschorn also noted that "a study showed that 35 percent of the conclusions of the finest RCTs, assessed by peer review and published in the most respected medical journals, could not be replicated on reanalysis of their raw data. Meaning that when researchers gave over their original data sets to another group, they could not come up with the same results 35 percent of the time – in the very best, most-cited journals" [93].

February 2021

On February 5, Schellack et al. described the regulatory framework of South Africa, noting the December 22 decision against ivermectin and the January 27 decision to facilitate a controlled, compassionate access program for it [94].

On February 9, an extension to 'Together' trial led by McMaster University was announced (NCT04727424) [95]; [96]; [97]; [98]. The evaluation of ivermectin was funded by Fast Grants, with the overall trial infrastructure being supported by the Rainwater Foundation. The ivermectin arm was apparently planned to be carried out in Brazil, with a single dose of 18 mg for participants weighing 40-60 kg and 24 mg for participants over 60 kg. The number of participants was expected to be up to 3,200, with results available within three to six months.

March 2021

On March 10, Kern et al. used pharmacokinetic modeling to investigate the dynamic impact of timing and dosing regimens of ivermectin [99]. The authors noted that previous clinical trial results of other drugs had been well explained by these models. In this study the greatest benefits were observed when ivermectin was given immediately at the time of diagnosis. The authors wrote that even interventions with minor antiviral effect may reduce host exposure if timed correctly. In contrast to other modeled drugs for which no effect was observed, ivermectin seemed to be at least partially effective: given on positivity, peak viral load dropped by 0.3-0.6 log units and exposure by 8.8-22.3%.

On March 10, Tarazona et al. prospectively assessed environmental of COVID-19 therapeutic solutions, modeling scenarios for predicting levels of pharmaceuticals ending up in the environment through wastewater treatment plants. Their models predicted a very high impact for ivermectin and azithromycin, even at use levels well below the default value of 1% of the population. The authors said the results highlighted fish sublethal effects as the most sensitive target [100].

On March 12, Czech Republic extended the use of ivermectin from hospitals to all general practitioners and distribution to all pharmacies [101]. For hospitalized patients, a dose of 0.2 mg/kg on days 1, 3 and 5 was administered, with a maximum daily dose of 24 mg. For outpatients, it was administered on days 1 and 3.

On March 16, a Czech newspaper wrote an article clearing "five misunderstandings" about ivermectin, namely that 100 times the standard dosage would be needed, that ivermectin would damage liver and kidneys, that the JAMA study was reliable, that ivermectin was for horses, and that there were no studies about it [102].

On March 16, the National Institutes of Health ACTIV-6 announced a request for implementors for an ACTIV-6 trial of repurposed medicines [103].

On March 16, a news story described some of the background of the adoption of ivermectin in South Africa [104]. A lawyer involved in the process described the compassionate access programme "quite a bureaucratic process, frustrating and completely unworkable" but said the government had agreed to register ivermectin for the treatment of COVID-19 in the next few days, which the lawyer called "a major breakthrough".

On March 16, an article by Thaldar reported that the South African Health Products Regulatory Authority (SAHPRA) had failed to comply with a court order given on February 2, 2021, and therefore broken the law [105]. This had resulted in ivermectin not having been distributed to COVID-19 patients.

On March 23, Michal Rezek, a head of cardioangiology clinic in the Czech Republic, commented that he "does not understand the campaign against ivermectin", most recently demonstrated by the European Medicine Agency's (EMA) decision against it [106]. Rezek said that for the time being, his hospital was continuing its use. In the news report, Rezek refuted EMA's arguments against ivermectin.

On March 23, a group of Brazilian medical associations demanded that drugs with no proven efficacy against COVID-19 should be banned, recommending social distancing and hand washing instead [107].

On March 27, the head of the intensive care unit professor Nathi Mdladla in South Africa said that ivermectin was widely utilized during the first wave. During the second wave in late 2020, authorities noticed this practice and clamped down on it, threatening doctors who had been prescribing it with sanctions. Mdladla believed this response had been unhelpful, and the case was going to appear in a hearing at a high court. Professor Salim Abdool Karim, one of the doctors leading South Africa's coronavirus response, said that the doses being given to people could even be toxic and that "it must be clearly stated that ivermectin does not kill the virus at dosages humans can tolerate. The amount of drug needed to kill the virus is toxic to humans. Whatever it is doing, it is not killing the virus" [108].

On March 27, a Czech expert on clinical studies, Šimon Reich, said that doctors believe in new drugs rather than decades-old antiparasics, and he didn't understand why people were afraid to use old drugs for new diseases [109].

On March 28, a group of British scientists and medical doctors, Health Advisory and Recovery Team (HART), urged the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to consider granting approval for ivermectin [110].

On March 29, Olufemi Emmanuel Babalola, who had organized an ivermectin RCT in Nigeria in May 2020 [111], was interviewed about the use of ivermectin in Nigeria [112]. Babalola stated that for Nigeria's population of 210 million inhabitants, there had been only 2,000 deaths, or 10 deaths per a million inhabitants. In comparison, for France's population of 65.4 million inhabitants and 108,000 deaths, the ratio was 1,650 deaths per a million inhabitants, i.e. over 160 times higher. Nigeria was said to have had a special history with ivermectin due to it having been used for a very long time for the treatment of onchocerciasis (river blindness). More ivermectin had likely been used in Nigeria than in any other country in the world. Babalola claimed the reason for ivermectin not being used in Europe was industry influence and ivermectin's unprofitability in comparison to investigational pharmaceuticals. Babalola claimed Merck & Co/MSD had pressured Nigeria's government not to use ivermectin [113].

On March 30, Wehbe et al. discussed molecular aspects and therapeutic possibilities of repurposing ivermectin for COVID-19 [114].

April 2021

On April 1, an article by Mourya et al. about a retrospective 100-patient trial in India suggested 89% lower risk of no virological cure (10% vs 94%, RR 0.11, $p<0.001$) [115]; [116].

On April 1, a feature by Wadvalla in the BMJ discussed division of the medical community in South Africa [117]. The article described that a lobby group "South Africa Has A Right To Ivermectin" formed on Facebook on January 2, 2021 had reached 72,000 members and was sharing information black market or veterinary ivermectin, reportedly running "an awareness campaign for 'the people's medicine' ", physically distributing pamphlets on the benefits of ivermectin at public spaces throughout the country.

On April 1, a Philippines House of Representatives hearing on March 29 about ivermectin was made available online [118]; [119].

On April 1, a news report by Horowitz pointed out that data by the WHO indicated a 81% reduction in mortality due to ivermectin, yet the WHO recommended against using it [120].

On April 2, a news report by TrialSite News discussed allegations of scientific misconduct related to the recent Unitaid/WHO funded meta-analysis by Hill et al. [121]; [16]. The question was about whether or not a third party not named as an investigator had modified or influenced it to downplay ivermectin's efficacy. The report said a French group, Bon Sens, had sent a demand letter to the University of Liverpool alleging scientific misconduct.

On April 3, an interview of Morteza Shakhsi Niaee, the main researcher in an Iranian clinical trial on ivermectin, discussed the current situation in Iran [122]; [123]; [124]. Niaee stated that "considering the data and the risk-benefit ratio we should spread the word [about ivermectin's efficacy] as much as we can because it is our moral and public responsibility ... we don't know what the result [of this advocacy] will be ... [but] we hope to have a positive influence in the world".

On April 4, Whiteboard Doctor discussed the ivermectin review published on March 24, 2021 by a Japanese group including the discoverer of ivermectin Satoshi Ōmura [125]; [2].

On April 4, a news report by ABC News suggested that unregulated self-medication with a combination of medications or ivermectin had resulted in cases of liver damage in Brazil [126].

On April 4, Daily Mail (UK) wrote that Britain's Health Secretary Matt Hancock was setting up an anti-virals task force to produce a "new innovative coronavirus treatments" with one goal to develop a pill suitable for early outpatient treatment, with details expected to be announced in the coming weeks [127]; [128]. Earlier in February 2021, Hancock had been found guilty of unlawful hiding of information about COVID-19 related government spending [129]. The judge called the act "a historic failure". The anti-virals task force was said to attempt to turn "the latest research on anti-viral therapeutics into approved medical treatments for coronavirus within months". The report referred to UK's "success of the vaccine program" saying it "wants to replicate those achievements with anti-viral drugs". The team was said to be led by a "biochemist turned venture capitalist" Kate Bingham who had previously helped the UK secure agreements for access to 357 million doses of six different vaccines. In 2020, Bingham had served as the Chair of the UK vaccine task force and was currently sitting on the boards of six biotechnology companies [130]; [131].

On April 5, in response to a Brazilian physics professor claiming the meta-analyses produced by the CovidAnalysis group were a scam, a blog post in Portuguese investigated the reliability of them [132]. The author noted that some of the world's most published physicians and researchers had quoted the results of the meta-analyses as valid. A mathematics professor interviewed for the post did not find immediate methodological issues with the meta-analysis. The author had also been in contact with the CovidAnalysis group directly.

On April 6, a news report indicated that after a juridical process the South African Health Products Regulatory Authority (SAHPRA) and parties in favor of using ivermectin for COVID-19 had reached an agreement, according to which registered medical practitioners may prescribe ivermectin for COVID-19 [133].

On April 6, a news report from the Czech Republic mentioned an ongoing observational trial with 100 patients [134]. Asked about the difference between the ivermectin policy of the Czech Republic and the EMA's advice against ivermectin, a head of cardioangiology clinic Michal Rezek commented that the contents of EMA's detailed report were incompatible with the short statement published on the Internet. Rezek said that while EMA admitted the existence of ivermectin studies with positive results they said conclusions could not be made due to ivermectin having been part of a combination of drugs or that the trials had had methodological deficiencies. Rezek said these were just "formal reservations" and that "for them, positive studies are not enough to prove efficacy". Rezek added that EMA's recommendation against ivermectin was not indicated by their not commonly available extensive scientific study. In this background document, EMA rejected positive studies due to their various shortcomings but also stated

that the drug was safe and its efficacy could not be ruled out. Rezek said that "there is no evidence that it did not work".

On April 6, Syed stated that 54 of his previous YouTube videos mentioning ivermectin had been demonetized, and if he would mention ivermectin in his future videos they would be either removed or demonetized [135].

On April 6, an article about a retrospective cohort study by Mokhtari et al. (n=28,759) concluded that early outpatient treatment of mild COVID-19 with hydroxychloroquine (7,295 treated vs 21,464 not treated) reduced the odds of hospitalization by 35.3% (7.2% vs 11.1%, $p<0.001$) and mortality by 69.7% (0.4% vs 1.3%, $p<0.001$) in a six-month follow-up, with no adverse effects [136]; [137].

On April 7, an interview of Tess Lawrie discussed the meta-analysis by Bryant et al. and the meta-analysis by WHO, comparing the two [138]; [15]; [139]. Lawrie mentioned she had not found a protocol for WHO's review. She mentioned discrepancy between which trials had been classified as high risk and low risk of bias.

On April 7, a preprint from Wiseman and Kory discussed the methodology of the clinical trial of Lopez-Medina et al. and concluded that possible clustering and/or drug switching confounding obscured up to 56% of ivermectin's effect [140]; [141]; [142].

On April 7, FLCCC weekly update discussed the situation in Zimbabwe, interviewing Jackie Stone who said ivermectin had "completely changed the landscape for us" with an approximately ten-fold reduction in mortality [143]. Stone had successfully been using colloidal silver, ivermectin and doxycycline protocol for severely hypoxic patients, allowing patients with oxygen saturations under 80% to be treated at home instead of being hospitalized [144]. According to Stone, the components complemented each other. Stone had first been accused of malpractice but later, on January 28, 2021, Zimbabwe had approved ivermectin nationwide [145]; [146]; [147][148][149]. The presentation detailed the various mechanisms of action of ivermectin in each phase of COVID-19, including the role of CD147 receptor [143].

On April 8, an Italian pharmaceutical website updated its guidance on how to legally prescribe ivermectin for COVID-19 in Italy [150].

On April 8, a preprint by Tsegay et al. indicated that ivermectin inhibited 89% of SARS-CoV-2 spike protein binding to ACE2 [151].

On April 8, a statement by the FLCCC Alliance discussed disappointments related to vaccines, suggesting these indicate an increased need for a medication such as ivermectin which has shown efficacy comparable to vaccines [152]. The statement mentioned adoption of ivermectin in several countries and cities including India, Japan and Mexico City, adding that the WHO and NIH have all the data they need to recommend ivermectin to prevent and treat COVID-19.

On April 8, the Washington Post wrote about increased interest in ivermectin in the US, warning that the use of veterinary formulations without knowledge of proper dosing may easily lead to overdosing [153]. A virologist stated that "to my knowledge, there is no data that suggests [ivermectin] is good for Covid-19". The article also mentioned Merck & Co/MSD's statement against ivermectin [154], and a similar statement by the Infectious Diseases Society of America [155]. Next, the article mentioned Kory's argument of ivermectin being a "miracle drug" and his opposition to waiting for data from more trials. The article then discussed the US National Institutes of Health's plan for a large-scale trial of repurposed drugs (possibly including ivermectin, fluvoxamine and famotidine), saying this trial could give a definitive answer to the controversy around ivermectin. Finally, the article mentioned "cautious optimism" raised by the meta-analysis by Hill et al. [16].

On April 8, an editorial in the Wall Street Journal, referring to removals of material describing opinions and actions of elected representatives and their advisers, stated "it's chilling that Google's YouTube, through its 'medical misinformation policy,' appears to be systematically undermining the ability to access material in the public interest" [156].

On April 9, FLCCC Alliance criticized the Washington Post story about not presenting the research data about ivermectin's effectiveness and not discussing the consequences of the prohibitive approach by the government agencies and the censorship of science [157].

On April 9, a US news article titled "Scientists work toward an elusive dream: a simple pill to treat Covid-19" discussed the possibility of a pharmaceutical for early outpatient treatment of COVID-19, stating that the reason for it not existing yet "is not for lack of trying" [158]. The article included an interview of the US National Institutes of Health director Francis Collins who called this kind of pill a "dream", adding that "it's just a damn long pathway ... but I will tell you that this is an extremely high priority for Tony Fauci and Francis Collins and the Biden administration, to work with these companies to try to make sure that we speed this up". Pharmaceuticals in development by Merck & Co/MSD and Ridgeback Biotherapeutics (molnupiravir), Atea Pharmaceuticals (AT-527) and Pfizer (PF-07321332) were mentioned.

On April 9, a news report wrote that a State Supreme Court in New York, US had ordered a hospital to administer four additional doses of ivermectin to a ventilated patient [159].

On April 9, Garcia et al. published a protocol for a randomized clinical trial comparing ivermectin to placebo in early treatment in Peru (SAINT-Peru, NCT04635943) [160].

On April 10, an article about an in silico analysis by Bello found that the in vitro activity of ivermectin may explained by acting as an inhibitor of importin-α, dimeric 3C-like protease, and Nsp9 [161]; [162].

On April 11, the Wall Street Journal published an opinion by Johnson et al., the organizer of US Senate hearings in late 2020 [163]. The authors stated there is already evidence for generics reducing COVID-19 mortality.

On April 11, Evidence-Based Medicine Consultancy Ltd (E-BMC), the research company behind the meta-analyses of Lawrie et al. and Bryant et al., announced that YouTube had blocked video uploads to the company's account until July 10, 2021 [164].

On April 11, an interview of Mary Beth Pfeiffer, an investigative journalist and a contributor to Scientific American, discussed censorship of ivermectin news [165]; [166]. She said the current practices were social media platforms' attempt to be good citizens, and largely a response to the manipulation of social media during the US presidential elections of 2016 which brought on calls of social media to police itself or be regulated. Ironically, however, in this case efforts had backfired. She said there had been "an extremely limited and unfair coverage" of ivermectin in the US and that the during her forty years in journalism, never before had she encountered such censorship. In her opinion, since the beginning of the hydroxychloroquine controversy involving president Trump there had been a bias in the media against early treatment, leading the mainstream media to become very unwilling to conduct proper investigation and act as journalists were supposed to, instead publishing superficial, erroneous articles. Pfeiffer called for a major congress-led investigation on how the pandemic has been handled in the US but added she was not confident there would be anyone able to conduct it properly. She suggested courts as a good starting point for these investigations and demands. Another journalist, Mariam Mia, described the atmosphere surrounding ivermectin journalism being characterized by fear. A South African journalist, Viasen Soobramoney, described they had become unable to publish their stories on social media platforms, leading them to realize the power of these platforms, noting it could lead to scary scenarios. In the discussion it was mentioned that in South Africa, 700 medical doctors had joined together to demand adoption of ivermectin and succeeded.

On April 11, the parliament of Italy voted in favor of early treatments [167].

On April 11, Bisoffi said that an interim analysis of an Italian trial (NCT04438850) had been performed but the decision of the steering committee had been to continue the recruitment, leaving the researchers blind as to the preliminary results (personal communication).

On April 11, a news report discussed the situation in Slovakia, noting that after the official authorization, there was no central plan nor efficient market apparatus in place to efficiently and effectively allocate supplies of ivermectin [168]. Therefore, availability remained an issue, with some Austrian pharmacies said to have turned predatory, marking up the prices. Perhaps 10,000 Slovakians were said to have been treated with ivermectin. Mainstream press was said to avoid the topic or quote physicians with dismissive positions referring to stances of EMA and WHO. Despite the national authorization, Facebook continued to censor local discussions.

On April 12, an article by Saha et al. investigated the binding mechanism of ivermectin with the spike protein of SARs-CoV-2 using three different computational modeling techniques, concluding that ivermectin can be a suitable inhibitor for SARS-CoV-2 to enter into the human cell through hACE2 [169].

On April 12, a news report from Indonesia indicated that the government was finalizing its evaluation of ivermectin [170].

On April 12, a news report from Lucknow, Uttar Pradesh, India stated that Indian states had simply ignored the WHO recommendation against ivermectin [171].

On April 12, a medical doctor suggested that the ivermectin strategy of the pharmaceutical industry was similar to the earlier strategy of the tobacco industry in denying the harms of smoking [172]; [173]; [174]. The author seemed to suggest that the Surgisphere scandal would have been a part of these strategies to resist introduction of early treatments with repurposed medicines. He also seemed to suggest that the WHO, NIH and FDA were involved in these delaying operations.

On April 12, a German magazine Bild wrote about the ivermectin controversy and the refusal of European and German approval authorities to adopt ivermectin, quoting a German immunologist Peter Schleicher saying "it is completely incomprehensible that there is no approval for this in Germany. We would have thousands fewer deaths to mourn" [175].

On April 12, a news report wrote that ivermectin was going to be trialed in Ireland as a part of an international Remap-Cap study [176]. It had already been administered to some critically ill patients before the trial.

On April 12, New Republic published a news report by Zaitchik, titled "How Bill Gates impeded global access to Covid vaccines" [177]. According to Zaitchik, Gates was using his foundation to defend monopoly medicine. Initially in February 2020, a WHO expert group had drafted outlines for pandemic response, assuming that the world would unite against the virus and that intellectual property issues would not be allowed to slow things down. In May 2020, WHO Covid-19 Technology Access Pool (C-TAP) was launched. However in March 2020, Gates had first launched Therapeutics Accelerator, a joint initiative with MasterCard and Wellcome Trust, then in April 2020 a larger initiative inside the WHO called Access to COVID-19 Tools Accelerator (ACT-Accelerator), which was a a public-private partnership based on charity and industry enticements. According to Zaitchik, it "enshrined Gates's long-standing commitment to respecting exclusive intellectual property claims ... [the idea that intellectual property] must be protected, even during a pandemic, carried the enormous weight of Gates's reputation as a wise, beneficent, and prophetic leader ... technically housed within the WHO, the ACT-Accelerator is a Gates operation, top to bottom". It included a vaccine arm called COVID-19 Vaccines Global Access (COVAX) which aimed at providing a small amount of vaccines to low-and-middle-income countries for a lower price [178]. Zaitchik wrote that Gates actively sought to undermine all challenges to his authority and ACT-Accelerator's intellectual property–based charity agenda. Pharmaceutical companies, through International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), strongly supported Gates. C-TAP was manipulatively sidelined in favor of ACT-Accelerator/COVAX which later completely failed to meet its stated goals. Gates also prevented Oxford University's plan to place the rights to its vaccine candidate in the public domain. Subsequently, the rights were sold to Astra Zeneca.

On April 13, an open letter by US doctors described the ivermectin trial by López-Medina et al. published in JAMA on March 4, 2021 as "fatally flawed" [179]; [141].

On April 13, a preprint by Al Sulaiman et al. of a multicenter, non-interventional, retrospective cohort study of 738 critically ill patients at ICUs found a significant association between thiamine use with in-hospital mortality (OR 0.49, 95% CI 0.25-0.97, p=0.04) as well with 30-day ICU mortality (OR 0.45, 95% CI 0.22-0.94, p=0.03). Thiamine also reduced the likelihood to for thrombosis by 81% (OR 0.19, 95% CI 0.04-0.88, p=0.034) [180]. Thiamine is a central component of the FLCCC Alliance's MATH+ hospital treatment protocol [10].

On April 13, Sky News report claimed that the WHO had tried to force a former WHO employee to change a key report to hide the fact that Italy had not updated its pandemic response protocols since 2006 [181]. The employee said the affair has completely undermined WHO's reputation, adding that "I think the problem here is about lack of independence and lack of transparency of the WHO. The

mandate of the organization is to preserve and to promote the health of the entire world. The story that happened shows that the organization is bound by personal interests, government interests, and financial powers". The news report said WHO had refused to help Italian prosecutors investigating Italy's COVID-19 planning, even stating its staff members had immunity from questioning, leaving the prosecution team confused and suspicious. The team said WHO was turning the investigation "into something political".

On April 14, a prophylaxis study in Singapore by Seet et al. indicated that for low-risk patients, a single dose of 0.2 mg/kg (max 12 mg) indicated 49.8% lower risk of severe case compared to vitamin C administration (RR 0.50, p=0.01, n=1,236) (NCT04446104) [182]; [183].

On April 15, website Science-Based Medicine wrote that ivermectin was the new hydroxychloroquine and there was no evidence it could treat COVID-19 [184].

On April 15, at the Medscape website, Vega discussed whether ivermectin or fluvoxamine should be used for outpatients, mentioning studies indicating reduction in mortality in hospitalized patients but no difference in outpatients (in the JAMA study), concluding that the was no indication for routine use of ivermectin in COVID-19, adding that FDA and Merck & Co/MSD had advised against its use [185]. The author was more positive about fluvoxamine for outpatients but concluded that more studies were needed.

On April 15, in Slovakia, a head of intensive care Jakub Hložník described that they had found ivermectin ineffective, stating that their experience confirms the negative opinions of international organizations and the manufacturer [186]. He dismissed the prophylaxis studies done in India as invalid but added there was one "real study published in the prestigious journal JAMA" indicating no effect, stating "this is the most objective study" and that the criticism was about "these people blaming everything" and that in vitro, ivermectin only acts at doses 100 times higher than approved for humans. About the medical profession, he said that "we are not divided. There is a group of doctors who claim to have a cure for COVID-19, and there are the rest of the doctors who are silent because they smile at it or think it is not worth commenting on. We are not inconsistent: look at the opinions of professional companies in which world experts examine how medicines work and what side effects they have". He added that "an atmosphere has been created in which anyone who tells the truth [about ivermectin's ineffectiveness] is attacked for not being able to heal the patients". He said accusations of corruption had "transcended all bounds of decency". About cases, he commented that ivermectin "didn't help at all. There were patients who received ivermectin and then fought for their lives on the ventilator for several more weeks and recovered. If I were like [the ivermectin proponents], I would go to the media and say it was due to ivermectin. But the reality is that this drug did not work at all ... some patients used it at home and ended up in our hospital. If it were so effective, people would not end up with a severe COVID-19 in a hospital despite taking it. That is common sense. You don't need to be a doctor to understand that ... I still don't understand why they attack us when our patients receive the same treatment as in other developed countries ... [allegations about a pharmaceutical lobby] are illogical, because if ivermectin took up, it would become a gold mine for pharmaceutical companies. It would be used by tens or hundreds of millions of people". He said they were mainly using corticosteroids, heparin and vitamins C and D as a supportive treatment, and had tested monoclonal antibodies. Ivermectin was unwise to use "because we don't know how the drug behaves in a COVID-19 patient receiving a number of other medicines" and they had seen cases of ivermectin poisoning. He felt healthcare professionals were spreading misinformation about ivermectin, and added that "it is strange that we have reached a state where ivermectin is being distributed by mayors. It's a prescription drug, not a lentil ... it is a great paradox that people are willing to eat medicines for horses and cattle, but do not want to be vaccinated". The epidemic situation was said to have "improved a bit, thanks to vaccinations and restrictions. But we may read again that it was ivermectin". He also did not believe in the alleged results of Michal Rezek in the Czech Republic.

On April 16, in the Czech Republic, a head of cardioangiology clinic Michal Rezek described that the mortality rate of over one hundred ivermectin-treated inpatients had been around 10 percent, in contrast to a general level of around 20 percent in the Czech Republic [187]. He said a small proportion of patients do not respond to any treatment, and that ivermectin probably has a greater meaning and effect in the outpatient setting and in the early stages of the disease. He said ivermectin is offered to almost everyone in the hospital. He said they don't have convincing results of other antivirals. He added that no-one in the EU has applied for ivermectin's approval for COVID-19 because in order to do that successfully

one would need a large trial with thousands of patients and such large investments are made mainly be pharmaceutical companies expecting future profits. To the question of why ivermectin's role is "desperate", he answered that "I don't know, there are probably more factors ... some doctors simply do not believe in these positive results. Security risks are mentioned, although there is no evidence of harm. The US NIH has stated that there are currently no clear arguments for or against. This is probably the most rational opinion ever issued by an official large institution. They correctly stated that at present the evidence for ivermectin is such that it cannot be clearly stated that it should be recommended because we lack a large placebo-controlled study, but that it cannot be said that it should not be used due to relatively numerous positive results reported in smaller studies". About the WHO decision, Rezek commented that for other medicines that the WHO had recommended against there had been large studies to back up the decision, whereas for ivermectin there had not been such a study. In this respect, the handling of ivermectin had been a deviation from the previous practices. Rezek also mentioned Satoshi Omura had "argued quite convincingly ivermectin should be used and that the data are already sufficient". About COVID-19 in general, Rezek said that "the problem is that we still don't understand the course of the disease: it behaves completely differently from other viral diseases".

On April 16, a scoping review by Bhowmick et al. concluded that evidence is not sufficiently strong to either promote or refute the efficacy of ivermectin, doxycycline, or their combination in COVID-19 management [188]. There were no new safety signals of concern. The quality of studies was said to vary widely, with five studies having a "good" methodological quality [189]; [190]; [191]; [192] and two studies having a "fair" quality [193]; [194].

On April 16, an article by Molento described "unprecedented consequences in Latin America" [195]. The author said endo- and ectoparasites had developed a strong tolerance to ivermectin since the 1980s with increasing reports in the last two decades. The recent COVID-19-related widespread self-medication was said to have been adopted based on false promises against any medical, pharmacological and epidemiological recommendations. The article stated that ivermectin distribution did not result in any modification in the shape of COVID-19 curves when comparing groups of treated and untreated people from the same area, adding that ivermectin might have contributed to a terrible situation in Manaus, with allegedly 90% of patients admitted to the ICU having taken ivermectin as prophylaxis. The author had not seen sound evidence of efficacy and was opposed to communities being used as experimental units, adding that a number of toxic effects had been observed "after 35 consecutive weeks of treatment or even with the use of ten times the antiparasitic therapeutic dose, ... [and] increasing numbers of IVM-related hepatitis (12 cases in 3 months in the state of Bahia)". The article added that livestock released approximately 15 tons of ivermectin per year from fecal elimination in Brazil with an unmeasurable ecotoxicity impact, and assumed that human intake of ivermectin could have a significant additional negative impact to ground water and city reservoirs. The article also noted deficiencies in the individual studies on which the meta-analysis of the CovidAnalysis group was based on. The author concluded that "in Brazil, the use of ivermectin is being regarded as a political fanaticism, which could be punished by international tribunal ... we must condemn its illegitimate and fabricated prescription. Moreover, we should pay attention to the WHO's safety measurements to minimize the virus circulation, and advocate mass vaccination to safeguard the entire region".

On April 16, an opinion published in the Wall Street Journal [196] said: "how shocking it is to read in your editorial that YouTube's standard for medical misinformation is information that contradicts authorities [156]. Modern medicine doesn't believe in authorities but in evidence based on data analyzed from randomized controlled studies. We must never allow anonymous censors to determine what is medical misinformation and cancel scientific inquiry and discussion with which they disagree".

On April 17, a retrospective cohort study by Morgenstern et al. indicated 74.0% lower risk of infection (RR 0.26, p=0.008, n=542) [197]; [198].

On April 17, an open-label nonrandomized case study with 10 ivermectin-treated patients and 15 controls in a French care home suggested (results not statistically significant) 70.0% lower risk of death (10.0% vs 33.3%, RR 0.30, p=0.34) and 55% lower risk of severe disease (30.0% vs 66.7%, RR 0.45, p=0.11) [199]; [200].

On April 17, a presentation by FLCCC's Marik focused on methylprednisolone and ivermectin [201].

On April 18, Salaamedia published a discussion about censorship of science with E. V. Rapiti, Tess Lawrie and Pierre Kory [202].

On April 18, an article by Domingo-Echaburu et al. discussed ivermectin's ecotoxicity [62]. They wrote that available risk assessments confirm extremely high toxicity for invertebrates and that the use of wastewater treatment plant sludge as soil fertilizer in agricultural soils should be approached cautiously.

On April 19, the National Institutes of Health (NIH) announced ACTIV-6 trial intended to compare up to seven repurposed medicines in outpatients with mild to moderate COVID-19 [203]; [103]. It was not announced which medicines would be included in the trial and the trial was not yet registered. The NIH had granted USD 155 million funding for the trial. Enrollment was said to begin in the summer of 2021. The participants were to have had symptoms for no more than seven days. The changes in symptoms were to be assessed over a 14-day period, as well as any hospitalizations and deaths over a 28-day period. Long-term post-COVID-19 symptoms were to be assessed at 90 days.

On April 19, Vanderbilt University Medical Center announced it had been named Data Coordinating Center (DCC) for the ACTIV-6 trial [204].

On April 19, Jackie Stone described in an interview that in Zimbabwe, a group of doctors started ivermectin administration on August 8, 2020. She described that seven previously critical patients and one patient in palliative care suddenly recovered and mortality of her patients dropped to zero [205]; [206]. After two weeks, one 22-bed hospital had become empty. Since the end of August, the information spread on social media. A second wave emerged in January 2021. Official authorization for ivermectin for COVID-19 was granted on January 26, 2021, and by February 26, 2021, COVID-19 mortality in Zimbabwe had dropped to zero.

On April 19, a review by DiNicolantonio et al. suggested that the effectiveness of ivermectin in the cytokine storm phase of COVID-19 may be, at least in part, an anti-inflammatory effect mediated by increased activation of glycine receptors on leukocytes and possibly vascular endothelium [207]; [208].

On April 19, Sky News of Australia reported on ivermectin research, interviewing an Australian parliament member Craig Kelly and showing a recorded statement by Tess Lawrie [209]. Lawrie addressed doctors who had taken the Hippocratic oath, saying they had sworn to do the very best for their patients and that ivermectin was the only thing treating COVID-19 at all stages. She said she had evaluated the evidence properly but for some reason the health authorities had not, asking the doctors to evaluate the evidence themselves. Craig Kelly commented that for over six months he had been "abused and ridiculed" for trying to bring up exactly the same things Lawrie had just stated. The interviewer cited the comment by Peter Schleicher [175] and a statement by professor Robert Clancy saying Kelly had been right to raise awareness about ivermectin and hydroxychloroquine and that due to limitations of vaccines they need to be paired with effective, safe drug treatment [210]; [211]; [212]. Kelly said the national decision against ivermectin was based on eleven studies. Kelly referred to the CovidAnalysis group's meta-analysis, saying 50 of 51 studies indicated "high" efficacy of ivermectin, adding that "bureaucrats had refused to look at the evidence". The report also referred to March 22 article in an UK pharmacy magazine saying "in the UK, the best way forward would be for the MHRA to authorize use of ivermectin for prophylaxis and treatment of Covid-19 on the basis of the published evidence to date" [213]. The report also cited Yale professor Alessandro Santin stating that "ivermectin works ... we must find a way to administer it on a large scale to a lot of people" [214]. Kelly said twelve studies on prophylaxis showed that ivermectin had "close to 90% efficacy which is actually equal or superior to vaccines ... it is the people who are pushing the vaccines who for some reason want to suppress the treatment with ivermectin ... millions of people are dead because of this". The interviewer commented that "there is a lot of dishonesty at work here ... this is frightening, this is disgusting".

On April 19, Frohman et al. published an article about the importance of early treatment, writing that "one very painful outcome of this past year of the pandemic experience is that there has been almost a complete lack of management of those with mild and moderate disease, as well as those wholly asymptomatic. Unfortunately, it is during this initial time, the initial assessment where patients have been summarily told to 'go home and not return until you are more sick', that may represent a time when they are beyond our capability to nurse them back to health, or even to save their lives" [215]. The authors also presented a new early treatment protocol that however did not include ivermectin.

On April 19, a report discussed politicization of ivermectin, mentioning lack of availability of remdesivir and vaccines in resource-limited settings, adoption of ivermectin in Slovakia, the Czech Republic and parts of Latin America, the warnings of FDA, EMA, Merck & Co/MSD and EMA, pro-ivermectin campaign in South Africa, pressure to adopt ivermectin in the Philippines, and the Surgisphere scandal [216]. The author concluded that "consequences of global healthcare inequality are clear: if life-saving vaccines aren't available, people will be driven to take matters into their own hands – with potentially catastrophic results".

On April 20, a news report in the Guardian discussed the new UK antiviral task force, reviewing six medicines (dexamethasone, tocilizumab, budesonide, favipiravir, remdesivir, convalescent plasma) having "shown promise in treating Covid" [217]. Ivermectin was not mentioned.

On April 20, Cochrane Collaboration published a protocol for a systematic review about ivermectin for preventing and treating COVID-19 [218].

On April 21, the State Institute for Drug Control of the Czech Republic was threatening a Czech newspaper with a fine of approximately USD 25,000 for illegal advertising of ivermectin's efficacy by publishing stories with a claim assigned to Paul E. Marik that ivermectin reduced mortality or a claim assigned to Michael Rezek that Czech inpatients had been improved by ivermectin treatment [219]. The threat was described as "shocking" and illegitimate by some parliament members who also accused the Ministry of Health of reluctance in easing patients' access to ivermectin [220].

On April 21, the FLCCC Weekly Update discussed "the WHO's denial of ivermectin: 'Big Science', disinformation and their impacts on human rights", in which "Big Science" represented a concept similar to "Big Pharma" [221]. Kory described how the FLCCC recommendations with regard to COVID-19 had consistently been months to a year ahead of recommendations of other entities, and now wanted to discuss "what we as a group are now finding with our advocacy of good evidence-based medicine: we are now what I think is actually beyond the science. We are running to an area which I knew little about before Covid happened and which I'm quickly becoming an expert on". He said "the WHO most clearly demonstrate what we are up against". According to him, the FLCCC had been accused of spreading misinformation (advocacy of "unproven therapies"). Kory introduced the concept of disinformation to describe the practices of, among others, the WHO. He noted the converging expert opinions from the UK (the BIRD group [222]; [15]), Japan [2], UNITAID/WHO [16] and Spain, in contrast to the opposing recommendations issued by agencies including the European Medicine Agency (EMA), SAHPRA and CADTH. He said the FLCCC had tried to pursue data-based arguments with these organizations but it had been futile. Initially, the FLCCC had assumed the barrier was the "Big Science", a societal constellation that requires that treatments are proven by large RCTs, the fact that only large agencies or pharmaceutical companies are able to finance trials of this magnitude, and premium journals publishing results of these trials and ignoring small clinician-initiated trials, resulting in a monopolization of "serious" science to large, well-funded actors only. Recently in the case of ivermectin, however, the FLCCC had changed its view, no longer seeing the "Big Science" as the only barrier with regard to resistance towards ivermectin. Instead, a more prominent barrier appeared to be a targeted disinformation campaign against ivermectin specifically, pursued predominantly through the WHO.

On corticosteroids, Kory said most hospitals were still adhering to WHO's guidance based on University of Oxford's Recovery dexamethasone trial [76]. According to Kory, it was "an anemic dose" of wrong corticosteroid (FLCCC had recommended methylprednisolone since March 2020). Another mistake had been a dismissal of the role of organizing pneumonia first described in a February 14, 2020 article by Wu et al. [223]. After several rejections, Kory had eventually managed to publish an article on the issue in the BMJ on September 22, 2020 [224]. Later the concept had begun to gain more attention [225]; [226]. He also mentioned the FLCCC had recognized the role of airborne transmission and the roles of vitamins C, D, melatonin, statins, etc., early on in 2020 (in the MATH+ inpatient protocol). In addition, the phase-based nature of COVID-19 had not been recognized [227].

Kory mentioned the US NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership program [228]. According to Kory, one of the partners, the Bill and Melinda Gates foundation, had "an overwhelming policy of global vaccination" and "they essentially represent vaccine manufacturers". ACTIV program had organized six trials on therapeutics [229]. ACTIV-I, had included three patent-protected pharmaceuticals, ACTIV-II ten investigative pharmaceuticals,

ACTIV-III six investigative pharmaceuticals, ACTIV-4 four antithrombotics including aspirin and heparins, ACTIV-5 two investigative monoclonal antibodies, and ACTIV-6 ivermectin. In addition, there had been NIH-funded studies on, for example, remdesivir and convalescent plasma.

On disinformation, Kory said that commonly used tactics included conducting counterfeit science and trying to pass it off as legitimate research, harrassing scientists, manufacturing uncertainty where little or none exists, buying credibility through alliances with academia or professional societies, and manipulating government officials or processes to influence policy. As examples, he mentioned: Merck & Co/MSD obscuring the risks of rofecoxib [230] and GlaxoSmithKline trying to silence a scientist researching the safety of rosiglitazone [231], both of which were later withdrawn from the market; the US opioid crisis having been created or exacerbated by webs of influence woven by several pharmaceutical companies involving health professionals, patient advocacy groups, medical professional societies, research universities, teaching hospitals, public health agencies, policymakers and legislators [232]; Pfizer pressuring FDA to downplay the risks of roxarsone [233]; counterfeit science on the safety of asbestos [234]; tobacco industry practices [235] and a few other examples. About WHO's past track record, Kory commented that "that was then, this is now" and that most of the budget now "has strings attached ... [WHO is] a very compromized organization particularly susceptible to external influences", especially the Bill and Melinda Gates Foundation through Gavi The Vaccine Alliance, CEPI and COVAX. Also, the "revolving door" phenomena was said to have a large effect. According to Kory, the recent failures of the WHO included handling of the Chernobyl (1986) and Fukushima (2011) nuclear disasters, the Ebola epidemic in 2014, the H1N1 pandemic in 2009-2010, and the COVID-19 pandemic. On ivermectin's evidence base, Kory said WHO had failed to publish a pre-established protocol for data exclusion, excluded trials from their original Unitaid search protocol, excluded two quasi-randomized RCTs with lower mortality, two RCTs in which ivermectin was combined with other medications, seven other RCTs, all RCTs about prophylaxis, 13 observational trials with more than 5,500 patients, and numerous epidemiological studies.

Among possible interests against the adoption of ivermectin, Kory said, were in effect everything related to investments in vaccines and investigative pharmaceuticals, including sovereign nations producing them, with "the scale of the market almost incalculable". In closing, Kory asked clinicians to "stop looking for the public health agencies for guidelines ... they don't give expert guidance". He added that it had appeared that the WHO was "accountable to no-one and [for] nothing ... there is no entity above the WHO which can hold the WHO accountable ... it's a bizarre entity ... I don't know how to fix the WHO ... many people have tried in the last 20 years", adding that one way might be to disallow any voluntary contributions.

On April 22, FLCCC's article published as a preprint in 2020 [236], provisionally accepted to Frontiers of Pharmacology, peer-reviewed but subsequently retracted post-peer-review [237]; [238]; [239], was published in American Journal of Therapeutics [240].

On April 22, Philippe Duneton, the chief of Unitaid, the sponsor of the meta-analysis by Hill et al. [16]; [241], said there was a need to "double down on research and development for COVID-19 treatment" [242]. In March 2021, Hill had allegedly said Unitaid had forced him to alter the conclusion of his meta-analysis to state that more research is needed, instead of stating that ivermectin should be adopted based on the current evidence [243]. In the April 22 interview, Duneton said "I think that there is a need ... not just to look [at] old drugs, but to double down [on] the effort in terms of screening of potential new drugs ... people at the beginning thought that it was possible to repurpose drugs, so from hydroxychloroquine, to ivermectin, to colchicine, to remdesivir. A long list. But ... I think that we can say that we don't see a real opportunity with old drugs ... except dexamethasone". However, Unitaid was apparently still including ivermectin in its funded trials "to fill in the gap in evidence". Duneton said "we need to finish the job, because I think that we have seen that people, for whatever good reason, I suspect, want to use drugs without evidence [of benefits]. That's the situation. And I think it's quite important to find out". Duneton was said to "hope for better outcomes for new antivirals in development, such molnupiravir, which is being developed by Ridgeback Biotherapeutics and Merck & Co. and is advancing to Phase 3 trials for outpatient use, along with early-stage antivirals being developed by Pfizer". He also hoped that the second generation of monoclonal antibodies would be efficacious against the new COVID-19 variants and would be easier to administer. Next, the report mentioned an agreement between the Bill and Melinda Gates Foundation and Eli Lilly to develop a monoclonal antibody to treat COVID-19 in low- and middle-income countries. The agreement was said to be a part of the COVID-19 Therapeutics Accelerator, which

worked with but was separate from the ACT Accelerator, of which Unitaid was part. Unitaid was said to typically provide funding for late-stage research and development of new drugs and diagnostics and to bring more affordable formulations to low-and-middle-income countries (LMICs), adding that those efforts "had not been fully maximized". Duneton explained that Unitaid and its partners were working in parallel to ensure access for LMICs when and if new treatments prove to have a significant benefit. "So what kind of incentive, how we can push [for access in LMICs?] Can we organize volume guarantees [the way] we did, for example, for the rapid tests with the Gates Foundation, or incentivize generic manufacturers so we can have access for LMICs in all continents? It's a lot of money, but that's the kind of tool that we need to consider", Duneton said.

On April 22, Indian Council of Medical Research COVID-19 National Task Force published clinical guidance for management of adult COVID-19 patients [244]. For mild disease, as an option "based on low certainty of evidence", the guideline suggested 0.2 mg/kg ivermectin for three days, with the suggestion to avoid it in pregnant and lactating women. For moderate and severe disease the guideline suggested predominantly methylprednisolone and low molecular weight heparin.

On April 22, an opinion by Garegnani et al. stated that research related to ivermectin in COVID-19 has serious methodological limitations resulting in very low certainty of the evidence, and continues to grow [245].

On April 22, a post on the website of Gavi The Vaccine Alliance discussed why ivermectin isn't recommended for use, mentioning the Surgisphere scandal, the case of rejection of FLCCC's article by Frontiers of Pharmacology, the EMA's and NIH's lack of support due to insufficient evidence, and the ongoing Together trial co-sponsored by Bill and Melinda Gates Foundation [246]. The author concluded that "it would therefore be premature to conclude absolutely that ivermectin has no place in COVID-19 treatment. On the basis of current evidence, however, its use cannot be recommended".

On April 24, a full interview of Jackie Stone talking about ivermectin in Zimbabwe was made available [247].

On April 24, Shankara Chetty from South Africa discussed alternative therapy options for COVID-19 [248]. In lymphatic filariasis, host inflammatory responses are due to dying microfilariae [249]. Chetty saw a parallel to inflammatory responses in COVID-19, using ivermectin for immunomodulation of dyspnea which he considered an allergic reaction in the lung due to virus particles [248]. He said there had been no fatalities, no need for oxygenation and no cases of long haul COVID-19 syndrome among his 4,000 patients and that his method "has stood up to the test of time far better than vaccines would". He said in some countries medicine was very regulated with people taught to follow protocols and not to step out of the box. Conversely in India doctors are taught to think outside the box, to try anything, to diagnose patients with their clinical skills, and to only use diagnostic laboratory tests to verify or clarify their clinical diagnosis, never to come to a diagnosis. He also referred to arrogance and snobbery, saying it was difficult to convince someone when they are closed in their ways.

On April 24, a petition to the Government of Canada suggesting adoption of ivermectin for COVID-19 opened on March 25 ended with 4,825 signatures [250].

On April 24 and 25, the BIRD group organized the First International Ivermectin for Covid Conference [251]. The speakers included Mobeen Syed (US), Tess Lawrie (UK), Pierre Kory (US), Hector Carvallo (Argentina), Juan Chamie (US), Andrew Bryant (UK), David Chesler (US), Eli Schwartz (Israel), Wasif Khan (Bangladesh), Manjul Medhi (UK) and Matjaž Zwitter (Slovenia). Syed described five mechanisms of action of ivermectin. Lawrie described the principles of assessment of research evidence, the role of systematic reviews, details of the meta-analyses carried out by the BIRD group [222]; [15] and issues with WHO's meta-analysis. Lawrie referred to the Hippocratic oath and the Helsinki Declaration as fundamental rights of clinicians, adding that BIRD membership was intended for doctors in need of peer support. Chamie compared changes in case fatality ratios of some countries before and after the introduction of ivermectin. Bryant provided an overview of ongoing trials. Chesler described handling of scabies and COVID-19 outbreaks in nursing homes in the United States involving 513 high-risk residents with 309 confirmed COVID-19 cases treated with multi-drug approach (12 mg of ivermectin on days 1 and 8, doxycycline, azithromycin, enoxaparin, zinc, vitamins C and D).

Schwarz described final results of their double-blinded RCT in Israel initiated in March 2020 to study reduction of viral shedding in isolated non-pregnant adult outpatients with mild to moderate or asymptomatic disease. Due to the massive vaccination campaign there was no longer a need for ivermectin treatments in the population; nor, due to lack of patients, was it possible to continue ivermectin studies. Kory discussed recent changes to FLCCC's MATH+ inpatient protocol and the I-MASK+ prophylaxis and early outpatient protocol. Khan described his ivermectin trial conducted in Bangladesh [252]. Carvallo described his experience with ivermectin in long haul COVID-19 syndrome (LHCS). Peers described LHCS as a mast cell activation issue [253]. Mehdi discussed ivermectin in patients at risk of disseminated strongyloides infection. Zwitter discussed medical ethics related to ivermectin in COVID-19.

On April 25, a cluster randomized trial about repurposing ivermectin for outpatients with a mild disease (IVER-Leve) sponsored by the Argentinian Ministry of Public Health completed in Argentina (NCT04784481), indicating that a higher proportion of outpatient discharge was observed in treated patients (98.2% vs 86.1%, p=0.0007) and that the treated patients showed eight times higher chance of discharge (OR 8.71, 95% CI 1.99-38.12. p=0.004) even in the presence of comorbidities [254]; [255]; [256]; [257]; [258]. The authors concluded that the treatment with ivermectin could significantly prevent the evolution to serious stages since no treated patients deteriorated to a severe disease.

On April 25, an letter by Roche et al. stated that despite reported antiviral effects at supratherapeutic doses in vitro, there is neither clinical evidence nor a plausible biologic mechanism to support ivermectin as an effective prophylactic or therapeutic agent against SARS-CoV-2, and that it is important that healthcare professionals understand the lack of evidence for its application to COVID-19, and continue to refute and rebut misleading health information [259].

On April 26, an article about prophylaxis by Bartoszko et al., a group involved with WHO's living guideline, included one trial of ivermectin combined with iota-carrageenan (n=234) [260] and two trials of ivermectin alone (n=540) [261], [262], all compared with standard of care or placebo. The authors concluded that it was highly uncertain whether ivermectin combined with iota-carrageenan or ivermectin alone reduced the risk of SARS-CoV-2 infection [263]. The authors noted that "the data are consistent with three meta-analyses [264]; [265]; [16] and one network meta-analysis [266] evaluating ivermectin as treatment for COVID-19. In contrast with other meta-analyses, we rated the certainty as very low because of serious risk of bias and very serious imprecision".

On April 26, a news report in a Canadian newspaper said Pfizer's was testing its investigational drug PF-07321332, developed from scratch during the current pandemic, which, if successful, could become first-ever COVID-19 outpatient treatment [267]. Pfizer said it had demonstrated potent in vitro antiviral activity against SARS-CoV-2 and it was soon going to be given to 60 volunteers in a phase I trial.

On April 27, the CEO of Pfizer said that an oral drug PF-07321332 for COVID-19 outpatients could be ready by the end of the year 2021. Pfizer had begun an early-stage clinical trial of the oral drug in March 2021. It was working on two antivirals, an oral and an injectable [268]. The report said the drug "could become first-ever home cure for COVID-19 ... for Pfizer and PF-07321332, it is a 'race against time', [a professor in pharmaceutical medicine] said. They not only need to produce a drug that works but need to do it while SARS-CoV- 2 still presents a major public health threat" [267].

On April 27, Merck & Co/MSD announced that it had entered into non-exclusive voluntary licensing agreements for molnupiravir (EIDD-2801/MK-4482), an investigational oral therapeutic intended for treatment of COVID-19 outpatients, with five established Indian generics manufacturers [269].

On April 27, YouTube removed FLCCC's video "WHO's denial of ivermectin: 'Big Science', disinformation and their impacts on human rights" [270].

On April 27, professor Salim Abdool Karim, one of the doctors leading South Africa's coronavirus response with a critical opinion about ivermectin, joined WHO's science council [271].

On April 28 in the Philippines, two lawmakers were planning to distribute three doses of ivermectin at no cost at an event in which those hoping to get ivermectin could present their medical prescriptions or get a prescription from doctors present at the event. FDA director Eric Domingo commented that he had no objection to the plan and that distribution of human-grade ivermectin was allowed as long as it is made by a licensed compounding laboratory with a doctor's prescription and the patients are

checked before issuing a prescription. He added FDA was not for or against any medicine and that it only prohibited unregulated and unregistered drugs. A doctor estimated over 100,000 people were to be given ivermectin over the next few weeks and regularly monitored afterwards. The Philippines Department of Health maintained there was still no concrete evidence of efficacy in mild to moderate COVID-19 [272].

On April 28, an article in The Scientist by Offord discussed events subsequent to the retraction of FLCCC's ivermectin review by Frontiers of Pharmacology in the beginning of March 2021 [273]. The review was intended to be a part of a special issue on drug repurposing for COVID-19, produced by guest editors. Offord wrote that on April 23, following disagreements about other submissions and more than a month of failed negotiations between Frontiers and the guest editors about how to proceed, the editors had followed through on previous threats to resign, while the publisher pulled the special issue page from its website. The editors stated that "the actions of Frontiers in this matter clearly violated well established norms and processes for peer review and publication of scientific works and intellectual contributions ... in our opinion, these unfortunate events constitute gross editorial misconduct" [274].

On April 28, MedPage Today reviewed the history of the development of Merck & Co/MSD's molnupiravir (MK-4482/EIDD-2801) [275].

On April 29, a news report stated that the Christian Social Union in Bavaria (CSU) had called for the federal government in Berlin to help with the adoption of ivermectin [276]. The proposal mentioned that ivermectin had already been adopted in Slovakia as the first EU country, and that two expert groups at the Robert Koch Institute already considered ivermectin a potentially active substance.

On April 30, version 66 of the CovidAnalysis group's meta-analysis of ivermectin studies was made available [277]. 24 peer-reviewed RCTs and observational studies indicated 88% improvement for prophylaxis (RR 0.15, 95% CI 0.05-0.30, n=6,356), 84% improvement for early treatment (RR 0.16, 95% CI 0.08-0.31, n=882), 36% improvement for late treatment (RR 0.64, 95% CI 0.43-0.94, n=1,338), and 72% overall improvement (RR 0.28, 95% CI 0.18-0.41, n=8,576).

On April 30, a preprint by Aguirre-Chang et al. described a therapeutic plan for patients with persistent symptoms [278].

On April 30, an interview with parliamentary managing director of the CSU, Tobias Reiss, called for the authorization of ivermectin in Germany [279]. Reiss mentioned that unlike in the Czech Republic, ivermectin was not discussed in the German media. Reiss also said the FLCCC protocols which included ivermectin were used with favorable results at the Academic Hospital Brothers of Mercy in Munich. Reiss indicated he put more trust in the views of FLCCC, BIRD, and German and Czech scientists using ivermectin than the guidance of EMA and Merck & Co/MSD. According to Reiss, German scientists with experience on ivermectin had stated that "negative evaluations are not based on a thorough analysis of the current state of knowledge". Also Bernhard Seidenath, the chairman of the committee for health and care in the Bavarian state parliament announced CSU had begun campaigning for ivermectin to be trialed for COVID-19 in Germany [280].

In April, Bhorat et al. published a qualitative analysis of seven ivermectin formulations in South Africa indicating that four out of seven formulations contained additional undeclared active pharmaceutical ingredients such as paracetamol, dicyclomine, telmisartan, diclofenac, hydroxyzine, mebeverine, nortriptyline, ornidazole, pregabalin, clopidogrel and etizolam [281].

May 2021

On May 1, a medical doctor using a pseudonym Justus R. Hope published an ebook "Ivermectin for the World" [282]. The book introduced pioneers of early treatments, including George Fareed's, Harvey Risch's, Brian Tyson's and Peter McCullough's experiences with hydroxychloroquine, details of two US Senate hearings about early treatments in 2020, interviews of Pierre Kory and Paul E. Marik, some background of Andrew Hill's meta-analysis, an article about José Natalio Redondo's use of ivermectin in the Dominican Republic, a statement by Jean-Jacques Rajter, articles about court proceedings about ivermectin treatments in the US and in South Africa, an article about YouTube's censorship practices, an open letter and a statement by Lawrie, an article about India, and several other articles.

On May 3, an analysis of the results of early treatment with an ivermectin-based medical kit in Mexico City by Merino et al. indicated a significantly lower hospitalization with ivermectin use, with approximately 70% lower risk of hospitalization [283]; [284].

On May 4, a preprint by Karale et al. describing a systematic review and a meta-analysis of 30 studies indicated an overall mortality benefit (OR 0.39, 95% CI 0.22-0.70) and an even more significant mortality benefit in mild/moderate cases (OR 0.10, 95% CI 0.03-0.33) [285]; [286].

On May 4, an article by Okumuş et al. (the preprint of which had been made available on January 12) about a randomized controlled trial (n=66) about late treatment in Turkey compared low dose hydroxychloroquine, azithromycin and favipiravir with and without ivermectin, indicating 80% lower risk of no virological cure (13% vs 63%, p=0.02) on day 10 (NCT04646109) [287]; [288].

On May 4, MedPage Today discussed cases in the US in which judges had ordered hospitals to give ivermectin to patients despite no evidence of efficacy and even though it wasn't endorsed by federal health agencies [289]. The story mentioned potential side effects of the drug include nausea, vomiting and diarrhea, as well as facial or limb swelling, neurologic adverse events, a sudden drop in blood pressure, and liver injury, according to the FDA, as well as FDA's warning against the use of veterinary forms of ivermectin and its stance that more studies are needed.

On May 4, a news story by Pfeiffer described the situation in the United States where hospitals were refusing to treat patients with ivermectin but in multiple cases, family members of the patients taking the hospitals to courts had resulted in the judges to order the hospitals to use ivermectin for those individual patients [290]. As a reason for their initial refusal, a hospital had stated that ivermectin use was not ethical because it was "not standard of care", in addition to "not being an anti-viral medication". Another had stated that ivermectin was not consistent with their guidelines based on "recommendations of professional societies, international government agencies and infectious disease expert opinions". Asked about a specific patient not having receiving the treatment, a doctor was quoted saying: "That's one life. I have a license to protect".

On May 5, referring to March 2021 guideline by the US National Institutes of Health and the studies by López-Medina et al. and Beltran-Gonzalez et al., the European Centre for Disease Prevention and Control stated that ivermectin had not been shown to be effective against COVID-19 in clinical studies so far as it had not shown any statistically significant difference in neither outpatients with mild disease nor in hospitalized patients with a non-critical disease [291]; [292]; [141]; [293].

On May 5, an in-silico study by Qureshi et al. explored the inhibition of importin-α1 by ivermectin with several computational methods [294].

On May 5, a review by Abdelgawad et al. mentioned that there was no published data about ivermectin's efficacy or safety [295].

On May 6, the president of the Philippines had reportedly ordered a 1,200-patient, six-to-eight month RCT on the efficacy of ivermectin on the early treatment of mild-to-moderate disease [296]; [297]; [298].

On May 6, FLCCC organized an expert panel discussion about standing up for human rights in COVID-19 care [299]. Panel members were Barend Yus (South Africa), Michael Defensor (Philippines), Jackie Stone (Zimbabwe), Ralph C. Lorigo (US) and Jean-Charles Teissedre (France). Kory said that "we are working in a system which is not working for us ... in which therapies are being restricted and deprived from patients ... ivermectin is probably the most absurd example of a system that is completely dysfunctional and failing ... we have to try to figure out how to correct that".

Teissedre, a criminal law attorney working in Bon Sens [300] and also working for an alliance of 500 doctors in favor of ivermectin, had been working on obtaining a recommendation for ivermectin in France since October 2020. The problem was that France and similar countries had "lost their power to decide". It was not a problem of supply or manufacturing but of prescribing and lack of a national guideline. According to Teissedre, creating such a guideline appeared "blocked" by the health authorities which was "difficult to understand", yet in France judges didn't want to legislate on matters that they thought of as science and medicine. The legal action for a guideline had ended unsuccessfully but another legal action for freedom of prescribing was ongoing. In addition, Teissedre was collecting evidence of scientific fraud for a judge to investigate on. Teissedre said the doctors pay attention to national guidelines only; he

added that "maybe they don't read studies, maybe they can't do that, maybe they don't know [how to], it's a big problem" and that "if doctors would be a little bit brave, maybe the pandemic would be over now with ivermectin". He said there is not only the corruption by the industry but also "a psychological problem of the doctors".

Lorigo, an US lawyer, had been litigating against US hospitals in order for patients to obtain ivermectin in hospital settings since January 2021. Utilizing FLCCC research materials he had successfully represented a critical patient in Buffalo [159]; [301], another critical patient in Rochester, and three additional patients, against hospitals refusing to administer ivermectin [302]. Lorigo had not lost a single case, yet hospitals had tried to fight back by saying it was not FDA approved. In the risk versus benefit consideration by the judges, the hospital administration had ended up "out of bullets", Lorigo said.

Yus from AfriForum, a civil rights organization with 280,000 members and a part of the community-based Solidarity movement, described that access to ivermectin in South Africa had been the result of the work of the Solidarity movement and recounted the timeline of ivermectin, started with people using the veterinary form of ivermectin, with South African Health Products Regulatory Authority (SAHPRA) deciding against ivermectin on December 22, Transvaal Agricultural Union of South Africa (TAU SA), a commercial farmers union, requesting an investigation into ivermectin on December 29, SAHPRA announcing on January 6 that it will consider access through Section 21, George Coetzee submitting applications on January 15, Coetzee and AfriForum submitting an urgent court application on January 24, SAHPRA allowing controlled compassionate access on January 27, and the court ordering off-label use of compounded ivermectin for COVID-19 on April 6. Due to lack of general access to human grade ivermectin, the veterinary form was still widely used. Vaccines, even if available, would have been unfeasible in rural areas without electricity. Yus had discussed the possibility of taking the WHO to the International Criminal Court of Hague (ICC) but it had appeared that criminal cases needed to be initiated locally in each country which would take years. Yus said that in order to overcome the resistance on all levels, it was obligatory to organize people into large community-based organizations because those could support major legal cases by crowdfunding. These communities could then balance the interests of governments and large corporations.

Defensor, a Philippines congressman, said there had initially been a crackdown on ivermectin, and at the moment of the discussion, prescribing it was prohibited, with the risk of losing the medical license. Local manufacturers were not allowed to produce ivermectin, thus limiting supply. Remdesivir was used nationwide but ivermectin was allowed in six undisclosed hospitals only. 533 doctors had supported access to ivermectin. The president of the Philippines had noted there must have been a strong reason for the doctors recommending ivermectin to put their reputations on line but the director of the Philippines' FDA had dismissed the president's observation, saying there was "not enough evidence to prove the efficacy of ivermectin". Defensor commented that "Big Pharma will continue to have a hold on our health authorities and the leadership of our medical associations but the people cannot be stopped: they listen, talk, read and watch, and spread the news about ivermectin. Our health authorities have blood in their hands and we will fight them in the massacre of our people". Defensor said doctors in the Philippines were afraid of prescribing ivermectin. The situation had created a black market for ivermectin. Defensor said cases against health authorities were being prepared on remdesivir-related financial corruption.

Stone said that in addition to the mortality being 90% lower with ivermectin, the question had been whether Zimbabwe would have had enough oxygen to be able to follow the WHO guideline on ivermectin. It was not yet in the official national guideline but it was widely used off-label. Stone had been using ivermectin "very publicly" since August 8, 2020, with other doctors joining. As one point, Stone had been arrested (in her words, "ambushed") "for dealing illegal drugs" (ivermectin) after having been reported to medical licensing board by a group of doctors at the moment (Chinese) vaccines were arriving in the country. Stone mentioned Chinese influence in Zimbabwe was huge. On the other hand, based on experience of HIV-1, the authorities had understood that ivermectin was perfect for reducing mutations of SARS-CoV-2, thus supporting efficacy of the vaccine. Stone said they had been using Thomas Borody's "triple therapy" [303] of ivermectin, zinc and doxycycline (a zinc ionophore) to avoid development of ivermectin resistance; Stone said "the whole country knew exactly how to use it". In Zimbabwe, a lot of medications including ivermectin were given over-the-counter by pharmacists, overriding the opposition of medical doctors who had refused to prescribe it. Stone said "the patients had driven this". Stone

had been threatened by expulsion from a national research group if she had mentioned ivermectin there again. Stone wanted to encourage physicians to stand up to the regulators; in her hearing, it had become apparent that her well-prepared legal team had an opportunity to sue the regulator which, after presentation of all the evidence by Stone's team, had become unable to argue against ivermectin.

Kory said that "the fact that we are at war [against COVID-19] and [public health authorities] are putting up these peacetime regulations: it's not how war works. You don't follow peacetime regulations at war ... we all keep talking about guidelines as if the guidelines are how we are going to win this ... NIH guidelines clearly state that they are not mandates ... physicians don't have to follow the guidelines ... they invite you in a shared decision making model to use your expertise, ability, your understanding of the evidence ... you still have autonomy ... many physicians see them as mandates and are very fearful of straying from them ... it's not what those documents are for ... it's time to recognize that and take back some of that autonomy". Kory concluded that "we are progressing ... it's time for civic, social organizations around the world to step up and lead".

On May 6, a preprint by Machanick described the conclusions of the FLCCC's review in the American Journal of Therapeutics [240]; [236] as "a cruel hoax" [304].

On May 6, an article by Shahbaznejad et al. describing a multicenter double-blind randomized controlled trial with 69 hospitalized patients administered a single dose of 0.2 mg/kg of ivermectin in Iran (IRCT20111224008507N3) [305]; [306]. Ivermectin reduced the frequency of lymphopenia, the duration of dyspnea and persistent cough and the mean length of hospital stay. One critical patient in the treatment group died within 24 hours of admission, causing the result to indicate increased mortality for ivermectin.

On May 7, the Bill and Melinda Gates Foundation announced that in contrast to its previous policy on defending COVID-19 vaccine related intellectual property of pharmaceutical companies, it had begun to support a "narrow waiver for COVID-19 vaccines during the pandemic" [307].

On May 7, an editorial by Nardelli et al. presented a meta-analysis of seven ivermectin studies, indicating lower mortality (2% vs 9%, OR 0.19, 95% CI 0.10-0.34, $p<0.01$, n=1,323) [308]. The authors noted that lower mortality may have been due to resolution of Strongyloides hyperinfection. They said that in an emergency situation, the use of a cheap medication without major side effects may be reasonable even if strong verification of its efficacy is still lacking, and that results from the reported trials all point in the same direction and cannot be overlooked.

On May 8, FLCCC announced a new protocol, I-MASS, for mass prophylaxis of populations [309]. For prevention, 18 mg of ivermectin once a week, and 50 µg of vitamin D_3 and a multivitamin daily were suggested. For outpatient treatment, 18 mg of ivermectin daily for five days, 6 mg of melatonin at night for five days, and 80 mg of aspirin daily were suggested. Also, antiseptic mouth wash was suggested three times daily. For post-exposure prevention, 18 mg of ivermectin on days 1 and 3 were suggested.

On May 10, a report stated that the rationale for a decision made in France by French medical authorities to reject ivermectin was undocumented, breaking transparency laws and making it impossible to trace who made the decision and through what kind of process [310]; [311]; [312]; [313]. In response, 1,500 French physicians had signed a letter in protest. The organizer of the protest commented that ivermectin was subject to "special treatment ... the ASNM [French Agency for the Safety of Health Products], WHO, EMA, NIH openly cheat, unscrupulously, with the blessing of so-called democratic governments".

On May 10, an article by Faisal et al. about a RCT with 100 outpatients in Pakistan indicated 68.4% lower risk of no recovery (12.0% vs 38.0%, RR 0.32, $p=0.005$) on days 6-8 (mid-recovery) [314].

On May 10, the state of Goa in India announced ivermectin will be distributed to all adults for prophylaxis [315]. The dosing was said to be 12 mg for five days. Some experts commented that five days was not enough and the medicine should instead be administered continuously until the pandemic was brought under control.

On May 11, the state of Karnataka in India announced one million ivermectin tablets had been procured and their supply was to begin on May 14 [315]. A further 2.5 million tablets were going to be procured for state hospitals.

On May 11, the WHO's chief scientist Soumya Swaminathan reiterated her and the WHO's opposition to India's ivermectin plan, linking to a statement by Merck & Co/MSD claiming there is no evidence of efficacy but considerable safety risks [316]; [154]. The report also said doctors across India were being pressured into giving drugs despite knowing that they are not effective against all forms of COVID-19 and irrespective of the patient's medical history. The head of critical care of one hospital said that there was no evidence and that only two very poor quality studies studies exhibiting a very strong bias existed.

On May 12, in the FLCCC weekly update, Kory again criticized the WHO saying they were hurting the global public health but stated he saw "a sea change" happening, with more attention paid to the failures of public health agencies, this criticism "supercharged" by the publication of the FLCCC's review in the American Journal of Therapeutics which, in about three weeks, had reached a position in the top 250 of over 17,700,000 articles ever tracked by Altmetric, and the first position among approximately 1,200 articles of similar age in all journals [317]. The review was available on PubMed Central (PMC) with PMCID PMC8088823 but could not be found in the PubMed search portal and had no PMID assigned [318].

On May 12, the FLCCC issued a statement "on the irregular actions of public health agencies and the widespread disinformation campaign against ivermectin" [319], detailing flaws in WHO's meta-analysis.

On May 12, a commentary by Bannister stated that an efficient medicine for COVID-19 would halt the international vaccine rollout under Emergency Use Authorization (EUA), endangering the profits of approximately USD 100 billion expected from vaccine sales in 2021 [320]. The author said that the WHO had either made serious mistakes or deliberately undermined early treatment drugs in favor of vaccinations, adding it was a huge windfall for vaccine manufacturers, with Pfizer set to receive approximately USD 70 billion from vaccines over the next five years according to Morgan Stanley. He said that an extension to the Trusted News Initiative (TNI) [321] in December 2020 had led to censorship of early treatments, adding that "almost every media house around the world has contributed to the marginalization of ivermectin".

On May 12, a news report stated that the state of Uttarakhand in India will mass distribute ivermectin as prophylaxis [315]. The dosing for people over 15 was said to be 12 mg twice daily for three days, a total of 72 mg. For children between 10 and 15 years the dosing was half of that. For children between 2 and 10 years ivermectin was to be administered only by prescription, and not administered at all to children below 2 years, pregnant women and people suffering from liver diseases.

On May 13, a news report stated that the state of Odisha in India was to buy 720,000 ivermectin tablets for patients in isolation [322]. Despite the WHO guidance against ivermectin the state health department strongly recommended its use. A prophylaxis trial carried out at the All India Institutes of Medical Sciences (AIIMS) in Odisha in mid-2020 had indicated a 73% reduction of SARS-CoV-2 infection among healthcare workers for the following month after administration of 0.3 mg/kg ivermectin on days 1 and 4 (preprint published on November 3, 2020 [323]; [324], peer-reviewed article published on February 16, 2021 [325]). A local professor commented that "there is no time to wait for a clinical trial during the ongoing emergency situation ... ivermectin is an immune-regulatory and anti-parasite drug. It has few side effects. In the given circumstances, it should continue to be used as certain studies show promising results". The suggested dosing was 12 mg daily for three days.

On May 13, an article by Mahmud et al. described a randomized trial with mild-to-moderate disease treated with a combination of ivermectin and doxycycline with 183 patients in the treatment group and 180 controls (NCT04523831), the results of which were initially published on October 9, 2020 [326]; [327]. According to the CovidAnalysis group, the trial indicated 96% lower risk of no recovery on day 12 (23.0% vs 37.2%, RR 0.04, $p<0.001$), 57% lower risk of disease progression (8.7% vs 17.8%, RR 0.43, $p<0.001$) and 39.0% lower risk of no virological cure (7.7% vs 20.0%, RR 0.61, $p<0.002$) [328].

On May 13, ivermectin was officially included in the ACTIV-6 trial with 15,000 patients (NCT04885530) [329]. The estimated start date was May 2021, the estimated primary completion date December 2022, and the estimated study completion date March 2023.

On May 13, Campbell discussed the plan of the state of Goa in India to distribute prophylactic ivermectin for all adults [330].

On May 13, an interview of Didier Raoult discussed vaccines and corruption [331]; [332]. Raoult noted that among the vaccinated there were fewer hospitalizations but not fewer deaths, adding that because the proportion of asymptomatic carriers remained extremely high the current data did not confirm that vaccines significantly reduced circulation of SARS-CoV-2. Corruption, he said, was as old as the world, and all of the current producers of vaccines had been convicted of corruption: Gilead had been fined USD 97 million, Pfizer USD 60 million, AstraZeneca USD 5.5 million, and also GSK. He described scientific publishing as a profitable business with profits of 35% per year, saying that a significant part of the revenue of premium journals comes directly from pharmaceutical industry, and as soon as a scientific journal reached a large enough audience it became a target of science akin to marketing. Raoult saw it necessary to recreate the seal between public interest activities and the industry, and said he did not think that participating in industry-led trials contributed to knowledge, adding "it is not research to include patients in a trial carried out by the pharmaceutical industry, whose analysis is made by the pharmaceutical industry, whose methodology was decided by the pharmaceutical industry and even the publication of which was written by the pharmaceutical industry and then offered to and accepted in one the biggest journals ... we must return to science that contributes to knowledge ... it is also necessary that ethics committees, rather than looking at the methodology, should ask themselves questions about the ethics of clinical trials".

On May 13, a news report from Hungary described that ivermectin tests in Hungarian hospitals had been going well and in a few months ivermectin would likely be prescribed off-label for COVID-19 outpatients in Hungary. The article said this would be a "major breakthrough", as the pharmaceutical institute had so far explicitly banned anyone from using the drug for COVID-19, with the government even prosecuting a woman who had ordered a dose from South Asia. A local pharmaceutical company was beginning to produce generic ivermectin, and a 70-patient phase II clinical trial managed by the University of Debrecen was ongoing [333].

On May 13, an article by Konne et al. reviewed ivermectin and concluded that it could be a remarkable medical breakthrough for the lasting treatment of COVID-19 [334].

On May 14, Hegazy et al., a group that in 2020 had carried out an ivermectin RCT in Egypt [335]; [261], published a review of ivermectin and suggested that ivermectin could be used for mass chemoprophylaxis of populations with minimal risk [336].

On May 16, a commentary titled "Who's advising WHO on the pandemic?" by a former president of Jamaica Medical Doctors Association criticized WHO for the hypocrisy of claiming to be attempting to save lives and ending the pandemic while at the same time recommending against the use of prophylactic and therapeutic options [337].

On May 17, a news report described a strong disagreement on whether the state of Goa in India should distribute ivermectin against the advice of the WHO [338].

On May 17, a preprint by Bryant et al. provided an updated version of the BIRD group's ivermectin meta-analysis [339]. Twenty-four RCTs involving 3,406 participants met review inclusion. Meta-analysis of 15 trials found ivermectin reduced risk of death by 62% (95% CI 27%-81%) compared with no ivermectin (RR 0.38, 95% CI 0.19-0.73, n=2438, I^2=49%, moderate-certainty evidence). Low-certainty evidence found ivermectin prophylaxis reduced infections by an average 86% (95% CI 79%-91%). Effect estimates for 'improvement' and 'deterioration' clearly favored ivermectin use. Severe adverse events were rare among treatment trials and evidence of no difference was assessed as low certainty. In conclusion, moderate-certainty evidence found large reduction in mortality to be possible.

On May 17, a book chapter by Kapoor et al. reviewing pharmacotherapy for COVID-19 mentioned ivermectin trials in India and Bangladesh [340].

On May 18, a Twitter post by WHO African Region, labeled with "Fact-check" and "ViralFactsAfrica" tags, stated that "ivermectin does not prevent COVID19 and is not an effective treatment for the virus. The medication is used to treat parasitic worms ... Unproven claims about miracle cures for COVID-19 have been around for almost as long as the pandemic. One of these is ivermectin ... it has recently resurfaced in Kenya. But there's no evidence to support the use of ivermectin to prevent or treat COVID-19 ... follow trusted sources like the WHO, Africa CDC and Unicef for the latest COVID-19 info. If you catch the virus, see a health care provider to get approved COVID-19 treatment" [341]. Of tens

of tweets posted by WHO African Region in the latter half of May, a majority concerned vaccines and the COVAX program. WHO African Region also retweeted posts by Gavi The Vaccine Alliance, and by Tedros Adhanom Ghebreyesus which celebrated WHO's partnership with COVAX.

On May 18, the Times (UK) wrote that Bill Gates had sought the help of the convicted sex criminal Jeffrey Epstein to get connected to influential people in order to improve chances of winning the Nobel Peace Prize [342]; [343]. Another report wrote that a former employee had said the prize was "what Bill wants more than anything else in the world" [344].

On May 19, an opinion article by Mookim in Wired magazine wrote about Bill Gates' "vaccine colonialism" and "intellectual property stubbornness", saying "the question is not whether people in rich, Western countries will be prioritized over people in the Global South. Rather, it's whether large Western corporations will benefit to the detriment of people everywhere" [345]. Mookim noted that the Biden administration had recently come out in support of waiving intellectual property rights to coronavirus vaccines, after which the Bill and Melinda Gates Foundation also had reversed course and endorsed the patent waiver [307] but Bill Gates himself had not. The article described that a WHO initiative, a patent-free technology sharing pool C-TAP announced in early 2020 would have removed intellectual property barriers for accessing COVID-19 treatments and vaccines but Gates, "maintaining his steadfast commitment to intellectual property rights", had blocked the plan in order for companies to retain exclusive rights through Gates-initiated COVAX program, regardless of the vaccines and medicines having been developed largely with public funding. Mookim described that COVAX "enshrines monopoly patent rights and relies on the charitable whims of rich countries and pharmaceutical giants ... should we be surprised that a monopolist-turned-philanthropist maintains his commitment to monopoly patent rights as a philanthropist too?" Mookim recounted Gates' anticompetitive practices at Microsoft, calling him a "ruthless monopolist", adding that he "chose to launder his reputation by tried and true philanthropic giving. But as he pivoted to global health, his faith in exclusive IP rights remained unchanged". Mookim also recounted Gates' opposition to generic AIDS medicines for Africa, his two-decade advocation of anticompetitive public health policies, and the Gates Foundation's continuing acquisitions of substantial intellectual property, also throughout the pandemic. In 2020, Gates was said to have leveraged his USD 750 million donation to Oxford University to convince it to not open-license its COVID-19 vaccine. As a result, the rights to the vaccine were sold to AstraZeneca, "with no guarantee of low prices and an extraordinary opportunity for profit".

On May 19, in a FLCCC weekly update, Kory and entrepreneur Steve Kirsch, the founder of an COVID-19 Early Treatment Fund (CETF) [346], discussed early treatments with ivermectin and fluvoxamine [347].

On May 19, an interview of an early outpatient treatments pioneer Peter McCullough, who had already published 40 peer-reviewed articles on COVID-19, described the policy response to the pandemic as "profoundly disturbing" [348]. McCullough described the federal agencies CDC, FDA and NIH as "enormously inept in terms of perceiving what the problem was and in applying any type of judgment or direction to doctors ... what happened was that the doctors were so terribly frightened that they said, 'we are not going to do anything unless we get intellectual support from our associations, from our federal agencies, from our medical societies'. And it was just the opposite of what medicine had always been: early innovation by doctors, empiric treatment, small studies, randomized trials, and then sponsored randomized trials, in that order, and then after large trials, guideline bodies looking at those trials, then federal agencies ... it always started out with early empiricism, then getting to guidelines, years later". He added that "it was a dangerous assumption to assume there is nothing one can do to a fatal infection", that due to poor precautionary measures "every hospitalization in America was a superspreader event", and that "this assumption that there is nothing we can do when giving someone a fatal diagnosis with no instructions led to a massive amplification of cases ... remarkably, not a single academic or community medical center today treats COVID-19 patients as outpatients with the goal of reducing hospitalizations and deaths".

McCullough described US pandemic response as very weak, saying that "to this day, we still have not had a doctor in any position of authority in the United States who has actually ever seen a patient with COVID-19 and treated them ... it is extraordinary ... there was an enormous pressure to suppress early treatments ... the false paper published in the Lancet was extraordinary ... we started to have

an array of incredibly flawed papers publishing exaggerated cardiac effects of hydroxychloroquine ... as the data came out on ivermectin, it became the next drug".

McCullough said that "when the next patient called asking: 'Can you help me?' each doctor had a binary choice, either: 'No, nothing works, there's nothing I can do, just wait until you get hospitalized", or the answer could be: 'You know what, let me try'. And what we found was that this binary choice was the biopsy of who really had courage and excellent clinical judgment. Doctors who were not confident in their clinical judgment quickly said there's nothing they can do and they got into that groupthink. And that could have been over 90% of doctors who had a lack of clinical judgment and a lack of courage. What I found was that those two things are rare ... we have 600,000 dead Americans, the vast majority of whom didn't get an ounce of treatment ... that will go down in history as a shame for our country ... there are many ways to treat this illness ... what I have learnt is that if doctors do almost anything they can reduce hospitalizations and deaths ... the only [reason for the disaster] is that doctors failed to act".

On dismissal of off-label treatments, he said that because of the tremendous fear that settled in, statements from the FDA, NIH and CDC started to take more weight than they ever would have in the past, pharmacies did not dispense prescriptions, and doctors started to get warning letters from medical boards. McCullough said that "we were getting official messages that basically said: don't take care of COVID-19 ... these are codified in policies and emails by major medical organizations ... we have never seen this [before for any other disease] ... there is a term that applies to what's going on, wrongdoing by those in positions of authority: malfeasance". He added that at the same time there were Association of American Physicians and Surgeons (AAPS), FLCCC and BIRD saying "this is wrong; treat patients". He commented that "the reason why you are talking to me today, instead of some FDA official, is because you are getting the sense of reality that this virus is treatable ... we made everything far worse by not treating it, keeping patients in fear and isolation ... we have done multiple things that have promoted hospitalization and excess mortality".

On May 20, an open letter from researchers, medical doctors and NGO representatives to the Ministry of Health of Malaysia presented current research evidence on ivermectin and criticized Malaysia's lack of adoption of it [349].

On May 20, author and journalist Michael Capuzzo called upon journalists to cover ivermectin calling it "a historic opportunity ... for the first time in the long journey from Gutenberg to Google, journalists may be the ones to save the world" [350]. His report covered legal battles in the US about prescribing ivermectin to a couple of hospitalized patients, as well a very extensive coverage of the history of the FLCCC [351]. Capuzzo also claimed that unreported by the press, president Trump had been administered ivermectin at Walter Reed hospital. The report also covered recent experiences in India, quoting an Indian surgeon and hospital owner describing that ivermectin saved India in 2020 after it got official permission in Uttar Pradesh in August followed by many other states but after political changes in January 2021 it started getting "bad propaganda by big pharma and big scientists", leading many doctors to stop using it. That, in turn, led to collapse of prevention and home treatment, seeding the subsequent crisis of overloaded hospitals and many needless deaths in the first half of 2021. The surgeon stated that "we beg health agencies and mainstream media in other countries not to give bad propaganda of ivermectin ... it is saving India and Africa".

On May 21, a news report stated that the University of Minnesota was adding ivermectin to an ongoing outpatient trial with hypoxia, emergency department utilization and post-COVID-19 syndrome prevalence as primary endpoints (NCT04510194) [352]. The trial, with an estimated enrollment of 1,160 patients, included arms for metformin, fluvoxamine, ivermectin, metformin and fluvoxamine, metformin and ivermectin, and placebo. Estimated primary completion date was October 2021 and estimated study completion date December 2021.

On May 23, the First International Ivermectin Summit was organized online by the BIRD group [353]; [354]. The speakers included Martin Gill (South Africa), Jackie Stone (Zimbabwe), Sabine Hazan (US), David Scheim (US), Jennifer Hibberd (Canada), Lucy Kerr (Brazil), Kylie Wagstaff (Australia), Tess Lawrie (UK) and Thomas Borody (Australia).

Gill said the front line doctors are left to what they have, and have to repurpose drugs and come up with protocols that will work. As soon they find one that is working they do a small trial because they need to get information out so that it will be further researched and used around the world. Gill said these small studies are not meant for decision makers but for researchers to have a guideline of what to research. He said the situation with ivermectin was unique due to data on ivermectin being way beyond the point of needing further data since no further data was unlikely to change the conclusion that ivermectin worked so well that it could change the course of the pandemic.

Stone presented her experiences with severe cases and described that early treatment with high doses with titration to effect and with a combination therapy utilizing zinc and doxycycline had improved results in comparison to ivermectin only. She said combination therapy reduced oxygen requirements, an important factor since they often did not have access to oxygen. She said their "hospital at home" approach had resulted in a mortality rate approximately 90% lower than in state hospitals, adding that the mortality rate in moderate to severe inpatients should be less than 1%. She described a few patient cases, stressing the importance of early anticoagulation, aggressive diabetes control, and home nursing on oxygen, adding that the response was a dose dependent. She also said D-dimer was a marker of clot breakdown and an increase in D-dimer indicated recovery instead of deterioration. They had developed a treatment protocol (0.3-0.6 mg/kg ivermectin, ceftriaxone, dexamethasone, zinc, doxycycline, prednisolone, enoxaparin) that had been widely distributed in Zimbabwe so that nurses had learnt to treat patients following the protocol. A January 26, 2021 statement from Zimbabwe Ministry of Health had stated it was important to not deny patients effective treatment regimes. Stone said it was "perhaps time we stood away from what the Northern hemisphere is doing because to be perfectly honest it doesn't really look like it's working".

Hazan said her team had carried out one of the first ivermectin trials. Hazan had used "Ziverdox" protocol consisting of 12 mg of ivermectin on days 1, 4 and 8, 100 mg doxycycline BID, 50 mg of zinc, 3000 IU of vitamin D, and 3,000 mg of vitamin C. Some of her patient cases had been described in the local press [355]. She stressed the importance of "making the patients feel that you are trying to save them" and the importance of combination therapy.

Scheim presented an analysis of ivermectin distribution in Peru, describing that introduction of ivermectin had first caused a 14-fold reduction in excess deaths of people over 60 years old, and subsequent restrictions introduced by a new president had caused a 13-fold increase, respectively. Community mobility, household densities and seropositivity rates were considered as confounding factors. One state without ivermectin distribution differed sharply from states with distribution (74% vs 25% reductions in excess deaths, $p<0.02$).

Hibberd presented world data on ivermectin collected by her and Juan Jose Chamie. According to her, India's second wave started from the city of Mumbai in the state of Maharastra, and from the state of Punjab (originating from Pakistan). Migrant workers fleeing from Mumbai spread the virus especially to the city of Lucknow in the state of Uttar Pradesh. New viral variants were detected in regions where Astra Zeneca vaccinations had been implemented, a pattern also noted for other countries including the UK, South Africa and Brazil. The media represented remdesivir as very effective and ivermectin as unproven and outdated. On April 21, 2021, the national guideline was updated to include ivermectin. Daily death rates stabilized and case counts dropped in Maharastra and Uttar Pradesh. In Tamil Nadu, a state without ivermectin distribution, deaths and case counts had continued increasing. In Mexico, according to Hibberd, the pandemic was under control, with ivermectin being the main factor in enabling that.

Kerr reviewed the pathophysiology of COVID-19 and mechanisms of action of ivermectin. Kerr was the leader of a group "Doctors for Life" with 12,000 members in Brazil. The group was teaching principles of early treatment to clinicians but also in for example factories with lots of workers. The group's protocol was similar to the FLCCC's, with minor differences in dosing. Kerr also stated there had been no issues with using ivermectin for pregnant women and for children over 15 kg.

Wagstaff, one of the authors of the Australian in vitro study published in April 2020 [7], explained that due to for example lack of adaptive immune responses in the cell model, the in vitro study was irrelevant for considerations of dosing in humans, rendering arguments against ivermectin based on the in vitro IC_{50} value groundless. She explained that since ivermectin was a host acting agent it was

working in conjunction with immune system. Therefore, 1:1 ratio of drug to virus was unlikely to be required. Ivermectin also accumulated in the lungs and other tissues. She said they were looking whether ivermectin analogues possessed similar effects.

Lawrie said researchers had a fundamental moral obligation to share preliminary results through pre-publication mechanisms. Journals were not to hinder this sharing of data, and WHO's norms for public health emergencies also encouraged sharing. According to Lawrie, in the case of ivermectin there had been no support to low-and-middle income countries and their clinician-researchers, no editorial support from journals, nor financial support from public health authorities. Instead, the response had been characterized by a systematic denigration of the quality of studies, systematic hindarance to publication, and systematic disinformation and censorship from public health authorities, pharmaceutical companies and the "big tech". In the UK, National Institute for Health and Care Excellence (NICE) had been silent on ivermectin although according to Lawrie evidence for it had existed at every level of the evidence pyramid. In contrast, the use of remdesivir and some other pharmaceuticals had been authorized in the UK on very little evidence. She said the latest meta-analysis by Karale et al. [285] supported the conclusions of the BIRD group. She also mentioned the Catracho protocol of Honduras [70] and the experience of Mexico [284]. International doctors' groups in favor of ivermectin included FLCCC, BIRD, Doctors for Life (Brazil), Canadian Covid Care Alliance, UK Medical Freedom Alliance, Association of American Physicians and Surgeons (AAPS), Ippocrate.org, United Health Alliance, and HART. According to Lawrie, major opponents to ivermectin were the ACT-Accelerator with USD 38.1 billion funding, and the Trusted News Initiative (TNI).

On May 24, a Finnish company Therapeutica Borealis got a US patent for a nasal spray containing ivermectin, hydroxychloroquine and aprotinin, a protease inhibitor [356]. The company said active ingredients were used in a new, targeted manner on the upper respiratory mucous membrane, so that the concentrations of the active ingredients throughout the body remained very low but were sufficient locally to prevent the passage and replication of the virus, making the drug safer and more effective.

On May 24, FLCCC announced that they had been locked out of their Twitter account for "violation of Twitter rules" [357].

On May 24, a Belgian virologist with experience in vaccine research and development in several pharmaceutical companies, the Bill and Melinda Gates Foundation, Gavi The Vaccine Alliance and the WHO, Geert Vanden Bossche, presenting a review of unsolved issues in COVID-19 vaccine related immunology, proposed early multidrug treatment (with e.g. ivermectin as one of the components of an early treatment kit) as a way out of the "mismanaged pandemic" [358]; [359]. Bossche said it was "difficult to imagine how ['updating' vaccines] could solve the problem of immune escape SARS-CoV-2 variants". Bossche referred to a steadily growing community of world-class scientists and experts calling for an immediate halt to the mass vaccination campaigns as the only method. Instead, early treatment proven highly efficient, practical and cost-effective should have been made widely available. He said quick 'updates' of the current Covid-19 vaccines would most likely fail to solve the pandemic because they were still based on an immunological concept and mechanism that didn't address the risk of evolutionary immune escape. He predicted SARS-CoV-2 to become resistant to current vaccines and asked the vaccine community to develop vaccines with a different mechanism of action. Regardless, he predicted that it would be necessary to rely on a short but large scale course of antiviral drug treatment using a compound that can be made available in high quantities at low cost, adding that ivermectin would seemingly qualify. He concluded that "a well-coordinated and targeted drug treatment program could be a game-changer and turn the tide of this pandemic in that it could drastically reduce the chain of viral transmission, not at least in vaccinees. Whether sensibly targeted virucidal chemoprophylaxis will provide populations with sustained protection from COVID-19 in the post-pandemic era and hence, serve as a full-fledged substitute for herd immunity is likely but unproven. Virucidal chemoprophylaxis seems, however, a promising option, the effectiveness of which could rapidly be explored at low cost and without raising the type of safety concerns that are associated with the ongoing mass vaccination campaigns".

On May 24, entrepreneur Steve Kirsch, who had earlier founded a COVID-19 Early Treatment Fund (CETF) which had funded fluvoxamine trials [346], offered an USD 1 million prize for any professor, licensed physician, medical journal editor, NIH or WHO employee, mainstream media reporter, elected official, public health official, or YouTube or Facebook censor who would provide a convincing argument

to a panel of Kirsch-selected judges that the current NIH or WHO recommendations on fluvoxamine or ivermectin were more likely to fit the evidence than recommendations to support the use of both drugs, or who could show that the recommendations were more likely to save more lives than recommending for these drugs [360]. The prize was offered separately for each of the two medicines, making a total of USD 2 million. Kirsch said the evidence for both drugs had been in plain sight for over 7 months, yet Anthony Fauci and Francis Collins (NIH) had remained silent. "If a computer entrepreneur from Silicon Valley can figure all this out seven months ago that it's virtually impossible for these two drugs not to work, why can't the NIH leadership?" Kirsch asked, adding that "why, when David Seftel confirmed the 100% success rate in the original fluvoxamine RCT published in JAMA [on November 12, 2020 [361]; [362]] with a real-world study also with 100% effect size [on February 1, 2021 [363]], did they just ignore it like it never happened? Why didn't they send a team to investigate if there were any biases or confounders? Instead, they just sat back and did nothing when the news came out. There was no investigation. There wasn't even a phone call or email to the investigator. Even after 60 Minutes did a story on this miracle at the racetrack [on CBS News on March 8, 2021 [364]], they still did nothing to investigate. They could have saved hundreds of thousands of lives if they had acted earlier on the evidence that was hiding in plain sight for at least the past 7 months". Kirsch also mentioned that in the beginning of December 2020, the blog platform Medium had, "in response to my efforts to bring this lifesaving advice to the world's attention, suspended my account, removed all the content I had written over the past 7 years, and banned me for life". Kirsch had asked if Medium had any factual information supporting their contention that he was incorrect, to which Medium had responded only that they believed my comments constituted elevated risk because I was making "health claims or advice which, if acted on, are likely to have detrimental health effects on persons or public safety".

On May 24, ivermectin tablets were being sold over-the-counter without prescription nationwide in the Philippines, with the Philippines government funding a clinical trial on the president's order, in parallel with ivermectin distribution to the public [365].

On May 24, in the state of Goa, India, ivermectin tablets promised to health centers and villages, with a value of approximately USD 3,000,000, had reportedly gone missing [366]; [367].

On May 25, a preprint of a meta-analysis by Roman et al. describing a meta-analysis of ten ivermectin trials (n=1,173) utilizing Cochrane tools and GRADE methodology concluded that in comparison to standard of care or placebo, ivermectin did not reduce all-cause mortality, length of stay or viral clearance in RCTs in COVID-19 patients with mostly mild disease, that ivermectin did not have effect on adverse effects or severe adverse effects, and that ivermectin was not a viable option to treat COVID-19 patients [368].

On May 25, data analyst Alvaro Olavarría, the founder of the Tratamiento Temprano ("early treatment") website [369], noted on Twitter that the meta-analysis by Roman et al. had swapped the mortality results of ivermectin and control arms of one of the included RCTs (Niaee et al. [123], n=180) [370]. According to commentators, if the error had been be corrected, the meta-analysis would have indicated a mortality reduction of 66% (p=0.031) [371]. Olavarría claimed the case was "an obvious disinformation campaign by colleagues" [370].

On May 25, the BMJ published an article by Clarke discussing fact-checking health and science on Facebook, saying that Facebook had removed 16 million pieces of its content and added warnings to around 167 million, and that YouTube had removed more than 850,000 videos related to "dangerous or misleading COVID-19 medical information" [372]. The article also mentioned that Facebook and YouTube were relying on third party fact checkers funded by parties such as the Charles Koch Institute related to the billionaire Charles Koch [373]; [374]; [372]. Clarke concluded that the approach taken by social media platforms could ultimately undermine trust in public health, and that in the US, trust in the government and media was already falling.

On May 25, the video of the First International Ivermectin Summit by the BIRD group was removed by YouTube for violating YouTube's Community Guidelines [375].

On May 25, the Indian Bar Association, a lawyers' association in India, sent a legal notice to Soumya Swaminathan, the chief scientist of the WHO [376]; [377]. The 51-page document accused Swaminathan of running a disinformation campaign against ivermectin by deliberate suppression of its effectiveness

despite the existence of large amounts of clinical data, issuing statements in social media and mainstream media to turn the public against the use of ivermectin and to attack the credibility of the Indian Council for Medical Research (ICMR) and All India Institute of Medical Sciences in Delhi (AIIMS) which had included ivermectin in the national guidelines, and abusing her position by repeatedly issuing statements with an intention to mislead and create confusion. The notice also stated that WHO's reports were increasingly seen as biased and lacking in quality, authenticity and rational approach. Copies of the document were sent to the president and the prime minister, governors of all states, and to medical associations and administrative offices.

On May 25, an opinion in a Cyprus newspaper asked about lack of early treatment for COVID-19, especially ivermectin treatment, noting that "to a layman ... the behavior of governments and public-health authorities seems bizarrely wrong, just from a common-sense standpoint ... I try to gauge who's telling the truth by judging their conduct – and so far, the early-treatment proponents are more convincing" [378].

On May 25, University of Minnesota Medical School announced its multi-site clinical trial had received USD 1 million from the Rainwater Charitable Foundation and USD 500,000 from Fast Grants to add ivermectin to their first randomized clinical trial for COVID-19 in the world to include pregnant women [379]; [380]. Fast Grants were supported by Arnold Ventures, The Audacious Project, The Chan Zuckerberg Initiative, John Collison, Patrick Collison, Crankstart, Jack Dorsey, Kim and Scott Farquhar, Paul Graham, Reid Hoffman, Fiona McKean and Tobias Lütke, Yuri and Julia Milner, Elon Musk, Chris and Crystal Sacca, Schmidt Futures, Amazon Web Services and others.

On May 26, an industry report enumerated COVID-19 therapeutics in development in Germany, Austria and Switzerland [381].

On May 26, the preprint of a meta-analysis by Roman et al. was updated to correct an error, yet its conclusions about mortality remained unchanged ("ivermectin did not reduce all-cause mortality", RR 0.37, 95% CI 0.12-1.13) [382]. Commentators on medRxiv and the CovidAnalysis group pointed out additional uncorrected errors in numbers of patients, numbers of events, duration of hospital stay, and events being represented on the wrong side, noting that all errors were in the direction of showing lower than actual efficacy of ivermectin, and adding that the included studies were "cherry-picked" [383].

On May 26, an article by Samaha et al. about a RCT in Lebanon indicated that a single dose of ivermectin lowered the risk of fever on day 3 by 90.9% (2.0% vs 22.0%, RR 0.09, p=0.004 (ChiCTR2000033627) [384]; [385].

On May 26, a patent attorney and a former director of intellectual property at Gilead Sciences Inc., Brian Remy, commenting on an article asking whether "ivermectin is the new penicillin" [386], said that "it's simple, use what works and is the most effective – period" [387]. Remy added that "ivermectin used in combination with other therapeutics is a no-brainer and should be standard of care for COVID-19 ... other viral infections are treated most effectively with combinations (HIV, HCV, etc.). Thus, there is no reason why ivermectin (with a superb safety profile) should not be combined with other generic or patented therapeutics. For example, as a recommended treatment add-on or formulation, unless there are adverse drug interactions, or legitimate IP/patent business reasons – which would be rare for such an old generic drug. The best expert physicians know this and are already doing this (not only with antivirals, but with anti-inflammatories and anticoagulants, with great success, efficacy and safety)". Remy referred to a December 2020 article by McCullough et al. on multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection [388], saying "everyone should be following their lead and approach ... not only would this be good for business and help avoid the criticism, bad PR, and potential civil/criminal liability for censorship, scientific misconduct, etc. etc. for misrepresenting ivermectin and other generics but most importantly it would save countless lives and end this pandemic for good". A few days earlier, Remy had commented that "ivermectin crushes Delhi cases and provides more evidence for a potential win/win solution for patients and companies with non-generic patented therapeutics (criticized for cost, efficacy, etc.), to work on updating their clinical trials/labels to include ivermectin (if possible). For example, as a recommended treatment regimen in the 'Indications and Usage' and 'Dosage and Administration' sections, increasing efficacy by additive (possibly synergistic) effects in a combination approach, maybe even a combination formulation product. It would look great from a PR perspective as well. Just some thoughts. I love it when everybody wins!" [389].

On May 28, a news report in Forbes India said that drugs such as ivermectin continued to be on India's health ministry's treatment protocol despite evidence not inspiring confidence, and that the regulator was approving medicines without following due scientific process, experts had said [390]. According to a director of critical care at a major hospital and a member of state of Maharashtra's COVID-19 task force, only corticosteroids and oxygen were backed by evidence. A pulmonologist said hydroxychloroquine and ivermectin needed to be taken out of the treatment protocol and called for an all-India committee with government, private players and central institutes to finalize treatment protocols. He saw promise in two new antibody cocktails that had recently received emergency use authorizations. These products were said to be priced at approximately USD 900.

On May 29, an Austrian weekly magazine wrote about ivermectin, describing it as having a high efficacy, yet being opposed by WHO and the "mainstream" [391].

On May 29, a news report from Spain interviewed José Muñoz who was initiating an 800-patient clinical trial on ivermectin [392]. Muñoz said they had been trying various drugs for 1.5 years and so far the success had not been equivalent to that of vaccines and that they now wanted to trial high-dose ivermectin.

On May 30, in a blog post citing FLCCC materials, bishop Thomas Schirrmacher, the president of the International Council of the International Society for Human Rights (ISHR) and the secretary general of the World Evangelical Alliance (WEA) which networks churches with 600 million conservative Protestant Christians, stated that ivermectin treatments are safe and effective and could save many lives and speed economic recovery [393].

On May 31, the FLCCC announced it had regained access to its Twitter account but Cision PRWeb and PR NewsWire had announced they would no longer distribute FLCCC's press releases. YouTube had also removed two more videos by FLCCC.

On May 31, version 85 of the CovidAnalysis group's meta-analysis indicated that all 17 RCTs for prophylaxis and early treatment reported positive effects, with an estimated 83% improvement for prophylaxis (RR 0.17, 95% CI 0.05-0.61, n=1,974) and 73% improvement for early treatment (RR 0.27, 95% CI 0.18-0.41, n=1,826) [394]. For late treatment, eleven RCTs indicated 42% improvement (RR 0.58, 95% CI 0.38-0.90, n=1,197). Together, all 28 RCTs indicated 66% improvement (RR 0.34, 95% CI 0.24-0.50, p<0.0001, n=4,997). For mortality, three RCTs about early treatment indicated 83% improvement (RR 0.17, 95% CI 0.03-0.96, n=876), six RCTs about late treatment indicated 62% improvement (RR 0.38, 95% CI 0.17-0.85, n=922). Together, the nine mortality trials indicated 66% improvement (RR 0.34, 95% CI 0.17-0.67, n=1,798). Together, all of the 56 RCTs and observational studies indicated 72% improvement (RR 0.28, 95% CI 0.21-0.36, p=0.00000000000041, n=18,447).

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On June 2, the FLCCC updated its I-MASS protocol intended for mass prophylaxis [395]; [396]. Ivermectin dose for outpatient treatment (daily for five days) was raised from 18 mg to 24 mg.

On June 2, a RCT with 164 patients by Abd-Elsalam et al. failed to produce statistically significant results [397].

On June 3, Wang et al. (a group including Andrew Hill) reviewed production costs of potential repurposed drugs for COVID-19, including dexamethasone, ivermectin, dutasteride, budesonide and colchicine [398]. They indicated that repurposed therapies could be generically manufactured at very low per-course costs, for example USD 0.12 for ivermectin. They concluded that the analyzed drugs were widely available and affordable, and that successful management of COVID-19 required equitable access to treatment for all populations, not just those able to pay high prices.

On June 6, a systematic review and meta-analysis of 19 RCTs with 2,768 patients by Hariyanto et al. indicated that ivermectin was associated with 69% reduction in mortality (RR 0.31, 95% CI 0.15-0.62, p=0.001), 57% reduction in severity of COVID-19 (RR 0.43, 95% CI 0.23-0.81, p=0.008), higher negative test result rate (RR 1.23, 95% CI 1.01-1.51, p=0.04), shorter time to negative test result (mean difference -3.29, 95% CI -5.69 to -0.89, p=0.007), higher symptoms alleviations rate (RR 1.23, 95% CI 1.03-1.46, p=0.02), shorter time to symptoms alleviations (mean difference -0.68, 95% CI -1.07 to -0.29], p = 0.0007)

and shorter time to hospital discharge (mean difference -2.66, 95% CI -4.49 to -0.82], p=0.004) [399]. The authors concluded that more randomized clinical trial studies were still needed to confirm the results.

On June 7, in a blog post in the Science Magazine, Lowe wrote that while it was not important to know the mechanism of action, the trials he had reviewed had used doses far too low in comparison to the required level in vitro [7], the WHO had done a solid job in evaluating the literature [83], the JAMA study [141] had found no benefit, the issue reminded him of the hydroxychloroquine situation, and he was "not having it with people going the conspiracy theory route" [400].

On June 7, the Union Health Ministry and Family Welfare's directorate general of health services (DGHS) issued revised guidelines to stop the use of ivermectin and doxycycline in India [401]. The new guidelines dropped all medicines, except antipyretic and antitussive, for asymptomatic and mild cases, while remdesivir was reserved only for patients hospitalized with moderate or severe disease receiving supplemental oxygen [402]. The guidelines of the Indian Council for Medical Research (ICMR), the country's leading health agency in the fight against COVID-19, remained unchanged, optionally suggesting ivermectin for outpatients.

On June 7, an article by Głuchowska et al. discussed whether parasitic diseases were protective agents or risk factors in COVID-19, noting lower incidence of COVID-19 in most African countries, especially those where malaria is endemic, and speculating that parasites might have also beneficial immunomodulatory effects but also noting that the difference may be due to hydroxychloroquine and chloroquine prophylaxis [403]. They however did not mention the possible effect of ivermectin prophylaxis pointed out by Guerrero et al. [404].

On June 7, in Malaysia, a news report said a complaint had been filed accusing the health minister and the health director-general of refusing to adopt ivermectin for COVID-19 [405].

On June 8, a news report by Birrell discussed conflicts of interest of scientific journals, suggesting that open access journals published by Springer Nature and Elsevier depended on donations of China and access to the Chinese market, which may have led to publication bias [406].

On June 8, in Japan, Constitutional Democrats submitted a bill to the House of Representatives to allow use of existing drugs including ivermectin to treat COVID-19 [407].

On June 9, a news report said the US government had agreed to pay USD 1.2 billion for 1.7 million courses (USD 700 per course) of Merck & Co/MSD's molnupiravir, if it is proven to work in an 1,850-patient trial expected to complete in the fall of 2021, and emergency use authorized by U.S. regulators [408]. Other drugs in development included Pfizer's PF-07321332 and Roche Holding AG's AT-527.

On June 9, the chief minister of the state of Goa in India said that the government of Goa had not purchased a single tablet of ivermectin and that it had been dropped from the treatment protocol, despite an earlier announcement of the Health Ministry on May 10 to distribute it for mass prophylaxis in Goa [409]; [410]. Instead, a plan to vaccinate as many people as possible in the age group 18-44 years was announced [411].

On June 12, an article by Zaheer et al. stated that potential toxicity and careful dosage analyses are urgently required before declaring ivermectin as an anti-SARS-CoV-2 drug candidate [412].

On June 14, a Canadian newspaper published an interview of Edward Mills, the principal investigator in the Canadian Together trial led by McMaster University, with funding for ivermectin and fluvoxamine provided by Fast Grants [413]. Mills discussed the principles and practices of organizing clinical trials and the possible role of repurposed medicines, criticized the FLCCC for overcalling the importance of what they were doing, and held a neutral stance about ivermectin. He expected the ivermectin trial to complete in a few months.

On June 14, an editorial commentary by Siedner introduced a meta-analysis by Hill et al. to be published in the same issue [414]. The meta-analysis was said to include 24 studies and 2,127 participants for mortality outcome. Siedner described the results as "compelling... suggesting a modest to large benefit of a low-cost, widely available, well-tolerated therapy for COVID-19 – a dream scenario – but based on studies with small sample sizes, design flaws, incomplete results, or some combination thereof". He worried about possible "erosion of trust in the scientific community" due to "early support for therapies

prior to a solid evidence base" and stressed the need for larger trials, mentioning that "the best we can do is guess the mechanism of action". He concluded that ivermectin might be best considered as an extremely promising therapy not quite ready for public use; otherwise, there would be "a real risk that the scientific community will once again be bitten by over-enthusiasm and forced to answer to a public that will not be shy about holding us to account".

On June 15, a review by Zaidi et al. provided an extensive review of 20 mechanisms of action of ivermectin for SARS-CoV-2 on four levels: first, direct action on SARS-CoV-2, including action on SARS-CoV-2 cell entry, action on importin superfamily, and action as an ionophore; second, action on host targets important for viral replication, including action as an antiviral, action on viral replication and assembly, action on post-translational processing of viral polyproteins, and action on karyopherin (KPNA/KPNB) receptors; third, action on host targets important for inflammation, including action on interferon (INF) levels, action on toll- like-receptors (TLRs), action on nuclear factor-ϰB (NF-ϰB) pathway, action on the JAK-STAT pathway, PAI-1 and COVID-19 sequelae, action on P21 activated kinase 1 (PAK-1), action on interleukin-6 (IL-6) levels, action on allosteric modulation of P2X4 receptor, action on high mobility group box 1 (HMGB1), action as an immunomodulator on lung tissue and olfaction, and action as an anti-inflammatory; fourth, action on other host targets, including action on plasmin and annexin A2, action on CD147 on the red blood cells, and action on mitochondrial ATP under hypoxia on cardiac function. [415]; [416].

On June 15, an article by Aref et al. about a RCT with ivermectin containing nasal spray in Egypt (n=114) indicated 63.2% lower relative duration of fever (relative time 0.37, p<0.001) and 78.6% lower risk of no virological cure (RR 0.21, p=0.004, 5.3% vs 24.6%) (NCT04716569) [417]; [418].

On June 15, a commentary by Thakur in an Australian newspaper questioned the "lack of alternative treatments" required for emergency authorization of vaccines, suggesting that a significant number of specialists have pointed out benefits of prophylaxis and early treatment with ivermectin [419].

On June 15, adoption of ivermectin had been recently petitioned for in Namibia [420].

On June 15, a news report by NPR wrote about Brazil's use of "unproven drugs" [421].

On June 16, a private clinic was raided in Malaysia for offering ivermectin to COVID-19 patients [422].

On June 16, FLCCC introduced a new protocol, I-RECOVER, for long haul COVID-19 syndrome (LHCS) [423]; [424]. The protocol consisted of an initial therapy with 0.2-0.4 mg/kg of ivermectin for 3-5 days, added with 50 mg of fluvoxamine twice daily for 15 days if the patient was presenting with neurological symptoms. If not all symptoms resolved with ivermectin, an additional corticosteroid protocol was indicated. In case corticosteroids did not produce a resolution, suspected mast cell activation was to be treated with low histamine diet, antihistamines and mast cell stabilizers and possibly other drugs. For all patients, vitamin C, omega-3 fatty acids, atorvastatin and melatonin were suggested.

On June 17, a news story by Zimmer in the New York Times said the U.S. government was to invest USD 3.2 billion to develop antiviral pills for Covid-19 and other viral diseases [425]. The new influx of money was to speed up the clinical trials of a few promising drug candidates which were said to become available by the end of 2021 or in a few years. The mentioned candidates included molnupiravir, AT-527 and PF-07321332. Anthony Fauci commented that "the first drugs for Covid-19 will probably only offer modest benefit against the disease but that would be a good start".

On June 17, an article by Krolewiecki et al. about a proof of concept RCT with 30 patients and 15 controls indicated no difference in clinical outcomes but in patients with higher median plasma ivermectin levels there was a concentration dependent antiviral activity with mean ivermectin plasma concentration levels correlating with viral decay rate (r=0.47, p=0.02) (NCT004381884) [426]; [427]. Due to the small number of patients and controls, the risks of mechanical ventilation and disease progression appeared increased (p=1.00).

On June 17, an article by Bryant et al. presented a meta-analysis of 15 RCTs with 2,438 patients indicating 62% lower risk of death (RR 0.38, 95% CI 0.19-0.73, n=2,438, moderate-certainty evidence) [428]. Also, low-certainty evidence from three trials indicated 86% lower risk of infection in prophylaxis (5.0% vs 29.6%, RR 0.14, 95% CI 79-91%, n=738).

On June 17, an article by Gold et al. suggested that many long haul COVID-19 syndrome (LHCS) symptoms may not be a direct result of the SARS-CoV-2 virus but the result of COVID-19 inflammation-induced Epstein–Barr virus reactivation [429].

On June 18, an analysis by Lind et al. from the COVID-19 response team of the US Centers for Disease Control and Prevention (CDC) analyzed ivermectin prescriptions in the US during the pandemic and found that ivermectin dispensed from outpatient retail pharmacies increased from an average of 3,589 prescriptions per week at the pre-pandemic baseline to a peak of 39,102 prescriptions in the week ending on January 8, 2021 (989% relative percent increase) [430]. The authors stated that clinicians should be aware of the stances of FDA and NIH, and that better trials are needed.

On June 18, an opinion article by Royes discussed the situation in Jamaica, with the government wanting to follow WHO's advice in order to protect the public against possible dangers of ivermectin [431].

On June 18, an opinion article by Gordon discussed the situation in South Africa, indicating that while ivermectin was approved for COVID-19, the process of applying for an individual permit for each patient was unreasonably restrictive and as a result ivermectin was not being widely used [432].

On June 18, in a WHO media briefing, in a reply to a question about the possible relationship between ivermectin home treatment kit distribution in Mexico and the decline in COVID-19 cases and deaths (study by Merino et al. [284]), COVID-19 technical lead Maria Van Kerkhove said that the decline was likely a result of a combination of factors, that WHO only recommends ivermectin in clinical trials, that WHO's clinical management team led by Janet Diaz were constantly looking at all ivermectin studies, there were meta-analyses adding more studies as their results were becoming available, these meta-analyses being updated regularly, and after the meta-analyses providing "robust, comprehensive review" were updated the WHO would be looking at the recommendations again to decide what the guideline development group "can and cannot, should and should not recommend". She said the process was underway and updates would be coming soon [433]. Also the chief scientist Soumya Swaminathan pointed out that epidemiological changes were usually due to combinations of things, never due to a single intervention, and peaks in infections had fallen for various reasons, also in countries not using ivermectin. She said it was important to undertake properly designed studies, adding that "we must have an open mind, and the WHO certainly has an open mind to look at each and every intervention that could be beneficial ... unfortunately there are not very high quality trials yet conducted about the role of ivermectin in either prevention or treatment, and this is what our guideline development group pointed out. When they looked at the meta-analysis, the studies were all very low quality, and therefore what is needed is more evidence ... we encourage more research on this ... the jury is still out on this".

On June 20, a news report by Jaswal analyzed the failure of Goa's ivermectin distribution plan [434]. Earlier, the ICMR had allowed optional use of ivermectin for outpatients with a mild disease. Subsequently, with the intention of prophylaxis, the health minister of Goa had announced a mass distribution of ivermectin. Goa's political opposition soon framed the operation as a financial scam. WHO's chief scientist Swaminathan and a group of prominent medical institutes of hospitals announced ivermectin should only be used in clinical trials. Petitions were filed in the high court against the plan, leading the court to swiftly axe it. Regardless, ivermectin was available over-the-counter in Goa.

On June 20, a news report stated that Goa's directorate of health services has instructed health centres and hospitals across the state to remove ivermectin, zinc and doxycycline tablets from COVID-19 home isolation kits [435].

On June 20, a 16-minute television report on Fox News featured US senator Ron Johnson and FLCCC's Kory presenting their view on ivermectin and censorship. Commenting the week's announcements of US government investing USD 3.2 billion in new antivirals for early treatment, Kory said "they will never develop a drug that is more effective than ivermectin" [436].

On June 22, a systematic review by Murchu et al. about the effectiveness and safety of various pharmacological and nonpharmacological interventions in the ambulatory setting, aimed at preventing severe COVID-19, found very low certainty evidence of effect for ivermectin plus doxycycline and insufficient evidence of effect for ivermectin monotherapy [437].

On June 22, a news report said that the National Agency of Drug and Food Control of Indonesia (Badan POM) had licensed ivermectin for the treatment of COVID-19 [438]. General Moeldoko, the chief of staff of the Executive Office of the President of the Republic of Indonesia, was said to have celebrated the decision. In the previous weeks he had already distributed tens of thousands of doses to various red zone locations.

On June 22, a news report from Argentina described monitoring results of 4,000 patients provided by the ministry of health of the province of Misiones, saying that in comparison to untreated population, ivermectin had reduced hospitalization from 4.7% to 1.2%, and mortality from 1.7% to 0.2% [439]. The effect was dose dependent.

On June 23, a news report said Oxford University was testing ivermectin in its large-scale 'Principle' trial [440]. The intent to include ivermectin in the trial had initially been reported on January 23 [441]; [442].

On June 23, Warren Buffett announced his resignation as the trustee at the Bill and Melinda Gates Foundation, describing his previous role as the trustee as "inactive" [443].

On June 24, emeritus professor Robert Clancy, an immunologist at the University of Newcastle, backed ivermectin as a COVID-19 treatment [444].

On June 24, an article by Yuce et al. determined ivermectin as a M^{pro} inhibitor candidate to be evaluated against SARS-CoV-2 infections [445].

On June 25, an article by Dias de Melo et al. about an animal study showed that standard doses of ivermectin prevented clinical deterioration, reduced olfactory deficit, limited the inflammation of the upper and lower respiratory tracts but had no effect on viral load in the airways in SARS-CoV-2-infected hamsters [446]. It dampened type-I interferon responses, and dramatically reduced the IL-6/IL-10 ratio in lung tissue and promoted macrophage M2 polarization.

On June 25, in a video interview professor of biochemistry and molecular biology Gordan Lauc, an official advisor to the Croatian government on pandemic management strategy, discussed, among other subjects, COVID-19 testing [447]. Lauc commented that he continuously wondered what the reason was for all the fear-inducing propaganda which overestimated mortality, adding that "for example in Croatia I have reasonable influence: I'm a formal advisor of the prime minister. When I look into into this information which is being distributed to the media, most of the times it can be attributed to people who are actually making a lot of profit in this pandemic because this testing industry has become maybe the largest industry in the world. It's a huge amount of tests. Croatia is at the bottom of Europe by the number of tests that we are doing, yet we have already spent maybe USD 250 million on testing. I have a PCR laboratory, I know the technology. The raw cost of testing is virtually zero, so the the kit producers, distributors, laboratories all make a profit. There is a 90% profit margin on all levels. I think this is one of the reasons why people want to keep this going. Because when you have this huge amount of profit just accumulated, you can easily use it to persuade some of the scientists or journalists to go your way. I'm not sure about politicians. I think that every politician wants to be successful. Yet now they all try to strangle their own countries. It is going on with the economies all around Europe and it is going to be a disaster. If you look at what is happening in the US, it is exploding with recovery, and China.. I don't know what will happen to Europe in the end. And we did it to ourselves". The interviewer described the situation as "an unscientific or anti-scientific mass delusion ... people going into politics are not the hardcore nerdy technical types. It's the opposite. We know what their talents are, and they're not technical. So the politicians are ripe to be misled".

On June 25, in a news report, WHO's representative in Malaysia rehearsed WHO's stand on ivermectin: inconclusive evidence of efficacy, very low certainty of this evidence, ivermectin being recommended only in the context of a clinical trial, guidelines being developed by a group of independent experts, trials ongoing, and ivermectin potentially having adverse effects including seizures, coma and even death [448].

On June 25, a survey of 1,055 physicians in 24 states of India indicated that one third had used ivermectin for COVID-19 [449].

On June 26, a news report indicated that the Medicines Control Authority of Zimbabwe (MCAZ) had authorised doctors to prescribe ivermectin for COVID-19, on the condition they record patient symptoms

and adverse effects and report them monthly [450]; [451]; [452]. One interviewed local physician welcomed the regulations but criticized the Medical and Dental Practitioners Council of Zimbabwe (MDPCZ) for arresting a doctor [Jackie Stone] who had been a key figure among early adopters of ivermectin in Zimbabwe. The physician said "many deaths could have been avoided if the regulatory authorities had paid attention to the science as opposed to parroting the WHO and pharmaceutical vested interests", adding that "the evidence has been there for a while and we know ivermectin works from local treatment done by some courageous doctors". He also commented that MCAZ had continuously resisted adoption of ivermectin but had recently been forced to backpedal because of pressure from the government which was seeing the evidence as it had moved out of medical circles into the mainstream. The physician asked why MCAZ had instigated the arrest and humiliation of a doctor despite dozens of studies and a meta-analysis showing ivermectin's efficacy and added that now when Oxford University and the Americans were coming on board, the regulators had suddenly realized the monumental mistake they had made and the risk to their credibility". He said they welcomed the development but were quite disappointed about how studies had previously been ignored and lives lost unnecessarily.

On June 28, a news report indicated an apparent reversal of Zimbabwe's ivermectin policy announced a few days before, saying the health regulator will only allow it for research [453].

On June 28, an article by Roman et al. presented a meta-analysis of ten RCTs including 1,173 patients with mild or moderate disease [368]. The authors wrote that in comparison to standard of care or placebo, ivermectin did not reduce all-cause mortality, length of stay or viral clearance. They concluded that ivermectin was not a viable option to treat COVID-19 patients. The article was based on a previous preprint [382]; [383].

On June 29, Fordham, one of the authors of the March 2021 ivermectin meta-analysis by Bryant et al. [15], discussed their rejected submission of it to Lancet Respiratory Medicine, their earlier attempt to publish it as a Cochrane review, and related issues [454].

On June 30, the latest meta-analysis of 60 ivermectin studies by CovidAnalysis group indicated similar improvements than their March 31 meta-analysis of 49 studies [455]. The improvements in March vs June were 89% vs 85% in prophylaxis, 80% vs 76% in early treatment, 50% vs 46% in late treatment, and 72% vs 71% all together.

Discussion

In the United States and the European Union, most of the year 2020 appeared to have been characterized by an attempt to collect ivermectin-related data. The period from the beginning of November 2020 to the end of March 2021 appeared to be characterized by disputes about interpretation of this data. The change of administration in the United States did not appear to significantly change its ivermectin-related health policy, likely to the disappointment of ivermectin proponents. Beginning from the March 30 guideline decision by the WHO against ivermectin, a period of a kind of trench warfare appeared to emerge. Ivermectin proponents, especially the FLCCC, announced they had resigned their attempts to influence the US National Institutes of Health, the Food and Drugs Agency, the European Medicines Agency and the World Health Organization. Similarly, the BIRD group turned directly to clinicians and the public. Changes to existing treatment protocols were mostly minor. Fluvoxamine emerged as an option and was added to many protocols including the FLCCC's. The FLCCC introduced two new protocols: the I-MASS protocol for mass prophylaxis and the I-RECOVER for long haul COVID-19 syndrome (LHCS). An interesting new development was the recognition of the role of mast cell activation and histamine release in LHCS [456].

The US NIH announced a new trial, ACTIV-6, for repurposed medicines, estimated to finish in March 2023, almost two years in the future, rendering the trial practically irrelevant for the purposes of handling the pandemic. Simultaneously, pharmaceutical companies continued their attempts to finish their trials of new outpatient treatment pharmaceuticals as swiftly as possible, and new projects for the development of such treatments were initiated in the US and the UK.

A third concurrent process was the slower-than-expected progress of vaccination programs. A fourth concurrent process was the adoption of ivermectin in countries outside the US and EU. The countries who

had adopted ivermectin previously, including Slovakia, implicitly disregarded the March 2021 guideline set by the WHO [171]; [457]. India adopted ivermectin nationally after the announcement of the WHO guideline, then mostly dropped it, with the current situation being somewhat unclear. Legal action against the WHO was initiated in India. At the end of the period, Indonesia adopted ivermectin.

With regard to researchers and clinicians, medical professionals whose practices appeared to be predominantly based on following existing regulations and protocols appeared to feel criticism against them unjustified and unfair. Similarly, medical professionals whose interest was in the further development of the protocols felt criticism against them unjustified and unfair. The first group may have perceived the latter group as deviants, whereas the latter group may have perceived the first group as anti-innovative. Presumably, both groups saw each others' practices as somewhat unethical and antisocial. The difference was possibly due to different perspectives on collegiality and the perception of the role of patients. The first group appeared to put more weight on collegial cohesion and rule-adherence, with less weight put on individual patient outcomes, assumedly perceiving that patient outcomes were predominantly the product of the inflexible regulations which lay beyond their responsibility. The second group appeared to put less weight on collegial cohesion and regulations, placing more weight on individual patient outcomes, assumedly perceiving that patient outcomes superseded the rules and that validation of rules was the responsibility of individual clinicians.

With regard to COVID-19, knowledge about the mechanisms and treatments was somewhat scarce especially in the early phase of the pandemic. A recent study described that in such a situation, it would be adaptive to seek further information to resolve uncertainty and obtain a more accurate worldview but biases in such information-seeking behavior could contribute to the maintenance of inaccurate views [458]. The study indicated that more dogmatic individuals were less likely to seek out new information to refine an initial perceptual decision, leading to a reduction in overall belief accuracy despite similar initial decision performance. In addition, dogmatic participants placed less reliance on internal signals of uncertainty, rendering them less likely to seek additional information to update beliefs derived from weak or uncertain initial evidence. Dogmatism is often defined as a viewpoint or system of ideas based on insufficiently examined premises. Thus, differences in openness to research evidence may have been due to differences in personalities and habits which, in turn, may be seen as products of the life experiences (environments) of the individuals, including their medical education.

At times, the views appeared to differ up to a point in which the existence of a shared reality could be questioned, and the practice of presenting opposite conclusions on the same, existing data was in effect making further research irrelevant.

Validity of statistics-based research

In the context of clinical trials, the fundamental validity of the statistics-based research in general is rarely discussed. In 2011, Penston said that the extent and depth of the criticisms of statistics-based research usually comes as a surprise to investigators, doctors and other health care professionals who use the data from large-scale RCTs and epidemiological studies, as they rarely have the time, inclination and skill to read the related literature [459]. He questioned the large size of a study as a sign of strength, saying that as the number of patients recruited to a study increases, statistical significance may be achieved but causal inference is weakened, adding that the source of the problem was the belief that causal relationships of value can be derived from extremely heterogeneous samples. He also said that the methodology of statistics-based research cannot be tested independently of statistics; therefore it is unknown whether the causal inferences drawn from the data of large-scale RCTs and epidemiological studies are valid. According to him, lack of understanding of diseases and the properties of drugs, i.e. ignorance, were driving up the size of studies, and we had witnessed "an inexorable increase in the size of epidemiological studies and RCTs over the past 50 years without any concern for the consequences".

Saint-Mont discussed the effect of randomization, detailing various false assumptions related to it, concluding that randomization does not lift experimental procedures in the medical and social sciences to the level of classical experiments in the natural sciences but may lull researchers into a false sense of security instead [460]. Both Saint-Mont and Penston stressed the importance of the existence of sound background theory as crucial for the success of science. Theory allows for stricter definitions of concepts

and the identification of homogeneous reference classes that ensure regularity and, hence, reliable causal inference. In the context of COVID-19, the FLCCC appeared to present their conclusions more in the context of background theory (especially the MATH+ protocol [77]), while most others appeared to rely more on statistics.

An alternative or adjunct to RCTs to investigate could be causal modeling [461]; [462]; [463]; [464]. According to Sgaier et al., causal modeling allows testing for causality in individuals and population groups faster and more efficiently, along with the ability to unravel the underlying complexity, and allows researchers and program designers to simulate an intervention and infer causality by relying on already available data [461]. Karvanen has provided examples of causal models for a case-control study, a nested case-control study, a clinical trial and a two-stage case-cohort study [463].

Journalistic ethics

With regard to journalistic ethics, the censorship discussion of April 11 appeared to indicate that journalistic principles that should have been self-evident no longer were, such as the responsibility of the media "to tell the truth" [165]. As described already for the period preceding April 2021, the financial press (e.g. the Wall Street Journal [163] and the Financial Express [171]) seemed to be more in favor of repurposed medicines, whereas the generalist press mostly continued to ignore or oppose them [217].

MacLeod has written about practices of the mass media in the United States, stating that corporate shareholders have no interest in the veracity of the news, only in short-term profits, and that reporting that challenges corporate profits is strongly discouraged [465]. A key factor shaping the content of the media is its reliance on advertising from large businesses for revenue. Advertisers wish to appeal to the groups and individuals with a greater spending power and to avoid controversial and critical content. Also, the collapse in advertising revenue in the traditional media has led to an increasing dependence on official sources, government and corporations which effectively subsidize the media by providing free content but expect something in return. In addition, in many cases, journalists are preselected based on their obedience to authority and their credulousness, and they increasingly come from the elite themselves [466]. The media houses also depend on social media for visibility which may be easily denied of them. Yet another factor are ideologies which in the United States were traditionally anti-communist but more recently anti-Trump and anti-Russian, for example. In the US media, ivermectin was often associated with hydroxychloroquine, and hydroxychloroquine with president Trump [467].

The dismissal of ivermectin in the press appeared to be related to the Trusted News Initiative (TNI) founded by Associated Press (AP), Agence France-Presse (AFP), British Broadcasting Corporation (BBC), Canadian Broadcasting Corporation (CBC), European Broadcast Union (EBU), Facebook, Financial Times, First Draft, Google, YouTube, The Hindu, Microsoft, Reuters, Twitter and Washington Post [321]. TNI appeared to function as some kind of peer-to-peer structured censorship mechanism.

Social media fact-checkers

In its COVID-19 medical misinformation policy, YouTube explicitly forbade treatment misinformation including "content that recommends use of ivermectin or hydroxychloroquine for the treatment of COVID-19" and "claims that ivermectin or hydroxychloroquine are effective treatments for COVID-19" [468]. The policy forbade also a large amount of peer-reviewed medical publications, in effect making YouTube an anti-science organization.

In a similar manner the policy forbade "prevention misinformation", explicitly defined as "content that promotes prevention methods that contradict local health authorities or WHO", specifically mentioning "content that recommends use of ivermectin or hydroxychloroquine for the prevention of COVID-19". It also explicitly disallowed discussions of efficacy and possible adverse effects of vaccines which "contradict expert consensus from local health authorities or WHO". Also diagnostic, transmission, social distancing and self-isolation information contradicting local health authorities or WHO were banned. The definitions of "expert" and "consensus" remained undefined, making the policy arbitrary, subsequently making YouTube an unpredictable promoter and enforcer of possibly arbitrary or authoritarian practices. In addition, technically, where local health authorities and WHO disagreed, application of the "or" operator

banned content contradicting with either of them. Therefore in countries such as Slovakia and India, YouTube could not be used for content that recommended either for or against ivermectin for prophylaxis of COVID-19.

Clarke mentioned that YouTube and Facebook were relying on third party fact checkers funded partly by Charles Koch Institute [373]; [374]; [372]. Koch was listed as one of the 18 major funders of Poynter Institute, each with an undisclosed sum of at least USD 50,000, making it impossible to compare funders' contributions [469]; [470]. The International Fact-Checking Network (IFCN) is a unit of the Poynter Institute [471]. In May 2020, Facebook stated that all of its fact-checking partners were certified by IFCN [472]. IFCN stated it led an alliance of over 100 fact-checkers [473]. Poynter Institute described that the alliance was launched in January in response to "rampant misinformation globally" which the WHO classified as an "infodemic", with the alliance "on the front lines in the fight against it".

IFCN and the alliance also maintained a database of checked facts [474]. The database was updated daily, with members collaborating on the "massive crowdsourcing project" by using a shared spreadsheet and instant messaging apps. Poynter said the international collaboration had allowed the members to respond faster and reach larger audiences. All of the over 80 items found in the database with search term "ivermectin" dated between April 2020 and May 2021 were labeled either as no evidence, unproven, exaggerated, misleading, missing context, partly false, or false (the most common label), with two items labeled as explanatory [474]. Most of the items originated from South American partners such as Estadão Verifica in Brazil.

Some of the other major funders of Poynter included Facebook, Google News Initiative [475], Foundation to Promote Open Society (FPOS) of George Soros, a primarily US government funded agency National Endowment for Democracy (NED) [476], Democracy Fund created by eBay founder Pierre Omidyar, funding especially PolitiFact [477], and the Omidyar Network/Luminate also of Omidyar, Craig Newmark Foundation of Craigslist founder Craig Newmark, with at least USD 6 million donated to Poynter Institute [478], and Rita Allen foundation involved in medical research, with its stated goal of "investing in transformative ideas in their earliest stages to promote breakthrough solutions to significant problems" [479].

It was of note that the major funders of Poynter included several individuals who were billionaires. Assumedly, they may have possessed influence over guidelines for what qualified as "facts". While there was not enough information to ascertain whether the observed patterns of social media censorship were related to the values and previously observed practices of the any of the funders specifically, it was also not possible to rule out such influences.

An example may illustrate what kind of issues may arise from the use of donations as a tool for gaining political influence. With regard to funding by Koch, a report by Mayer in the New Yorker described the Koch brothers as "longtime libertarians who believe in drastically lower personal and corporate taxes, minimal social services for the needy, and much less oversight of industry ... their combined fortune of thirty-five billion dollars is exceeded only by those of Bill Gates and Warren Buffett ... many of the organizations funded by the Kochs employ specialists who write position papers that are subsequently quoted by politicians and pundits. David Koch has acknowledged that the family exerts tight ideological control. 'If we're going to give a lot of money, we'll make darn sure they spend it in a way that goes along with our intent ... and if they make a wrong turn and start doing things we don't agree with, we withdraw funding'" [480]; [481].

A republican political consultant commenting Kochs' strategies for opposing climate change related oil industry reforms said that "the key ... was to question the science – a public-relations strategy that the tobacco industry used effectively for years to forestall regulation". As an example of health related interests, David Koch had served on the US National Cancer Advisory Board without disclosing his conflicts of interests as a major producer of formaldehyde, while simultaneously lobbying to prevent the US Environmental Protection Agency (EPA) from classifying formaldehyde as a carcinogen, and funding members of Congress who had stymied the EPA, requiring it to defer new regulations until more studies would be completed.

Mayer's article described Kochs' operations as "covert", referring to David Koch's description of their businesses as "the largest company that you've never heard of". According to SourceWatch, in addition to

denying climate change, other issues on the Kochs' agenda included repealing health reform (Obamacare), dismantling collective bargaining rights, fighting reductions in carbon emissions, keeping corporate money in elections and fighting internet neutrality [482]; [483]. With regard to COVID-19, Koch Industries were producing test kit materials, sanitizers, alerting systems, healthcare IT systems related to COVID-19 diagnostic testing, ventilators, and personal protective equipment [484].

Poynter's largest custom training partners in 2019-2021 included Facebook, Huffington Post, Marketplace, MRC Media, Middle East Broadcasting Networks, National Public Radio (NPR), Newsweek, New York Times, Southern Newspapers Publishers Association, Washington Post, TikTok, USA Today Network, Vice and Voice of America [469].

Academic journals

Regarding the academic journal publisher Frontiers Media SA's, one of the members of its board of directors responsible for the financial and governance oversight of the company was Steve Koltes, founder and co-chairman of CVC Capital Partners Ltd [485]. In 2019, CVC Capital Partners, one of the world's largest private equity and investment advisory firms, was said to have USD 75 billion of assets under management [486]. CVC announced that a group of its executives had helped fund University of Oxford's vaccine research [487]; [488]. CVC had also invested in System C, a company providing key software being used for planning and managing the UK's COVID-19 vaccination programme [489]. The Times described CVC as "powerful, successful and extremely low profile" [490].

In 2015, Frontiers had removed 31 editors after the editors had complained that company staff were interfering with editorial decisions and violating core principles of medical publishing [491].

The WHO

During the period, an intensifying critique of the WHO emerged as a result of the March 2021 ivermectin guideline lacking transparency and breaking established practices of meta-analysis and research. Presenting criticism towards the feasibility of the vaccines-only approach and its possible relationship to financial interests of the pharmaceutical industry, or possible failures of entities such as WHO, FDA, NIH and EMA, has been difficult during the pandemic. Regardless, it is necessary to consider whether funding-related biases might exist with regard to the current practices of these agencies, especially the WHO.

First we may note that the main funders of the WHO for the 2018/2019 biennium were United States (USD 893 million), Bill and Melinda Gates Foundation (USD 531 million), United Kingdom (USD 435 million), Gavi The Vaccine Alliance (USD 371 million), Germany (USD 292 million), Japan (USD 214 million), UN Office for the Coordination of Humanitarian Affairs (UNOCHA) (USD 192 million), Rotary International (USD 143 million), World Bank (USD 133 million), European Commission (USD 131 million), National Philanthropic Trust (USD 108 million), Canada (USD 101 million), China (USD 86 million), Norway (USD 86 million), UN Central Emergency Response (USD 86 million), Sweden (USD 77 million), France (USD 76 million), Kuwait (USD 70 million), Republic of Korea (USD 70 million) and Australia (USD 67 million) [492]; [493]; [494].

The Bill and Melinda Gates Foundation stated that its focus was on vaccine equity [307]. Also Gavi The Vaccine Alliance had been founded by the Bill and Melinda Gates Foundation in 1999, and the Gates foundation had invested a total of USD 4 billion in Gavi [495]. Gavi described the Gates foundation as "a key Gavi partner in vaccine market shaping". The Gates Foundation also had long-term partnerships with Rotary International (polio vaccinations), National Philanthropic Trust, and the World Bank. Together, the USD 902 million contributions of the Gates Foundation and Gavi exceeded the United States contributions of USD 893 million, making the Gates-Gavi cluster the largest funder of the WHO in the 2018/2019 biennium (in April 2020, president Trump announced that US halted funding to the WHO; the effects of this remained unclear [496]; [497]). In addition, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) contributed 33 million. Co-founded by the Bill and Melinda Gates Foundation in 2002, the foundation has contributed a total of USD 2.49 billion to GFATM [498].

Considering the recent USD 4 billion donation by the United States government to Gavi [89], one interpretation of the situation might be that the US outsourced a large part of its public health policy setting to Gavi and, subsequently, to Gates.

Yet another member of the Gates cluster was the Seattle-based PATH (Program for Appropriate Technology in Health), one of the largest nonprofit organizations in global health [499]. In 2021, its website presented with a banner saying "600 million people are vaccinated. 7 billion haven't had a shot. Help PATH today". PATH's CEO Nikolaj Gilbert, previously the global partnerships director for the United Nations Office for Project Services (UNOPS) and an employee of Novo Nordisk, described PATH's priorities: "the partnership with the Bill and Melinda Gates Foundation and the U.S. government has shaped what this organization is all about today ... so one of my key priorities will be to see: how can we sustain and grow those relationships that we have, how can we continue to be the preferred partner for those donors, and how can we also help them with their priorities?" [499].

A 2017 Politico article described Gates as "the world's most powerful doctor", saying his sway over the WHO spurred criticism about misplaced priorities and undue influence [500]; [501]. The article quoted Gates' critics saying that "Gates' priorities have become the WHO's ... he is treated liked a head of state, not only at the WHO, but also at the G20". Top WHO officials were said to have raised concerns that the foundation was distorting research priorities. Over three quarters of the WHO's budget was coming from voluntary contributions which were usually earmarked for specific projects or diseases so that the WHO could not freely decide how to use them. The article stated that the Gates foundation's focus on delivering vaccines and medicines, rather than on building resilient health systems, had drawn criticism. Changes had been made to the WHO's budget approval process to in order to decrease the foundation's influence. Yet a senior fellow for global health at the Council on Foreign Relations commented that "the foundation's impact on the WHO is enormous ... if they weren't there, if they walked away with their money, the deleterious impact would be profound, and everyone is all too aware of that".

Importantly, it should also be noted that the other top 20 funders predominantly represent high-income countries of the North America and Europe. None of the countries that had officially adopted ivermectin country-wide for COVID-19 up to April 2021 were represented [502]. Similarly, Coalition for Epidemic Preparedness Innovations (CEPI), an organization aiming to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks was founded by the governments of Norway and India, Bill and Melinda Gates Foundation, UK Wellcome Trust, and the World Economic Forum [503]. It had later secured financial support from Australia, Austria, Belgium, the Bill and Melinda Gates Foundation, Canada, Denmark, the European Commission, Ethiopia, Finland, Germany, Hungary, Iceland, Indonesia, Italy, Japan, Kuwait, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Romania, Saudi Arabia, Serbia, Singapore, Switzerland, The Republic of Korea, United Kingdom, USAID, and UK Wellcome Trust. Of these countries, as of June 2021, ivermectin had been officially adopted in Mexico, Panama and Indonesia, as well as mixed use or occasional off-label use in some other countries [502].

Additionally, CEPI had received support from undeclared private sector entities as well as public contributions through the UN Foundation COVID-19 Solidarity Response Fund [503]. Each investor was to get one representative to an Investors Council providing guidance and oversight of CEPI activities, with four members serving on the CEPI board. Another entity, a Joint Coordination Group, was intended to discuss how to best enhance CEPI's efforts to deliver and deploy vaccines, and had a role in planning for rapid response to a priority pathogen or an unknown pathogen. The Joint Coordination Group included the WHO, Gavi, European Medicine Agency (EMA), United States Food and Drug Administration Agency (FDA), Médecins Sans Frontières (MSF), UNICEF, International Federation of Red Cross and Red Crescent Societies (IFRC), African Vaccine Regulatory Forum (AVAREF), UK National Institute for Biological Standards and Control (NIBSC) and UK Wellcome Trust. The Wellcome trust had been previously found out to secretly invest in companies that contributed to the same problems the trust said it wanted to solve [504]. The trust's known investments through offshore companies in the Cayman Islands amounted to USD 891 million in 2018.

In 2010, the Bill and Melinda Gates Foundation, Gavi, WHO, US NIH/NIAID, CDC, UNICEF, PAHO and several research organizations launched a Decade of Vaccines collaboration, initiated by the Gates Foundation [505]. The intention was to enable greater coordination across all stakeholder groups –

national governments, multilateral organizations, civil society, the private sector and philanthropic organizations. The five-member leadership council included the director general of WHO, Anthony S. Fauci of the National Institute of Allergy and Infectious Diseases (NIAID), executive director of UNICEF, an representative of African Leaders Malaria Alliance, and the president of global health at the Bill and Melinda Gates Foundation. All the relevant organizations had thus intimately and for the long term participated in the vaccine-centric collaboration initiated by Gates.

According to a recent study, in 2020, governments had spent a total of EUR 93 billion on COVID-19 vaccine and therapeutics development projects, with 95% allocated to vaccines and 5% on therapeutics [506]. 32% of the funds came from the US, 24% from the EU, and 13% from Japan and South Korea (a total of 69%). Only 7% of funds were preferred loans or conventional grants. 93% were advance market commitments (AMCs), i.e. binding agreements to subsidize purchases of vaccine doses prior to availability. Interestingly, 71% of the vaccine funding was allocated to Small and Medium Enterprises (SMEs) and MidCaps, with only 18% allocated to large pharmaceutical manufacturers. The figures did not include private sector investments.

The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership program initiated by the US National Institutes of Health aimed at developing a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines [228]. Its public partners included Biomedical Advanced Research and Development Authority (BARPA), Centers for Disease Control and Prevention (CDC), Department of Defense, Department of Veterans Affairs, European Medicines Agency (EMA), National Institutes of Health (NIH), The Operation (formerly known as Operation Warp Speed), and US Food and Drug Administration (FDA). Industry partners included AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Dewpoint Therapeutics, Eisai, Eli Lilly and Company, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck & Co/MSD, Moderna, Novartis, Novavax, Pfizer, Rhythm Therapeutics, Roche-Genentech, Sanofi, Takeda, and Vir Biotechnology. Nonprofit partners included Bill and Melinda Gates Foundation, Fred Hutchinson Cancer Research Center, Foundation for the National Institutes of Health, and RTI International.

According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), as of February 2021, there were approximately 382 vaccine candidates in development, of which 24 in Phase I, 34 in Phase II and 23 in Phase III [507]. In addition to vaccines, there were over 1,000 clinical trials for therapeutics, of which 190 in Phase III. For example, Eli Lilly and Company and the Bill and Melinda Gates Foundation had entered into an agreement to facilitate access to future Lilly therapeutic antibodies under development, to benefit low- and middle-income countries.

According to Schwab, in five years up to 2020 the Gates Foundation had invested at least USD 250 million in companies that were currently working on COVID-19 vaccines, therapeutics, diagnostics or manufacturing [508]; [509]. Hel also noted that Wellcome Trust had invested at least USD 1.25 billion to COVID-19 related industries [510]. Both funders were thus positioned to potentially gain from the pandemic financially. Wellcome's director had a position on the Scientific Advisory Group for Emergencies advising the UK government on COVID-19, as well as a board seat on the Coalition for Epidemic Preparedness Innovations (CEPI). Earlier, the UK's Scientific Advisory Group for Emergencies had failed to publicly disclose competing interests related to COVID-19. A Canadian professor emeritus of health policy and management commented that the funders were assumedly "acting the way they always have ... looking after their own financial interests [and] pursuing their own privately developed objectives without being responsible to anybody but their own boards of directors". Schwab said that despite the outsize role of the private charities in the pandemic response their financial interests had been little scrutinized, likely because foundations were not subject to the same oversight mechanisms as public institutions. A professor of sociology in the UK commented that the foundations were giving a false ideological impression that they are solving the problem even when they're not.

The Gates foundation had also donated almost USD 2 billion to for-profit businesses, including USD 89 million to Novavax Inc., USD 65 million to GlaxoSmithKline Biologicals, USD 63 million to Evotec and Just Biotherapeutics, USD 61 million to Biologial E. Limited, USD 53 million to LG Chem Ltd., USD 43 million to Dimagi Inc, USD 40 million to Inventprise, USD 38 million to Bharat Biotech International Ltd., USD 37 million to Janssen Vaccines and Prevention BV, and USD 35 million to AJ Vaccines AS [510]. Schwab claimed the foundation was subsidizing private companies' research costs, opening up

markets for their products, and bankrolling their bottom lines. He also claimed the foundation had funded groups pushing for industry-friendly government policies and regulation, including the Drug Information Association. He was also said to have funded nonprofit think tanks and advocacy groups that wanted to limit the role of government or direct its resources toward helping business interests. Schwab also noted that despite having given away USD 23.5 billion in the last five years up to 2020, Bill and Melinda Gates Foundation's income from its investments had exceeded USD 28.5 billion in the same period [510].

Other commentators asked whether the Gates Foundation was addressing or reinforcing systemic problems raised by COVID-19, citing lack of transparency, dogmatic defence of intellectual property rights and monopolies, and intimate involvement with large pharmaceutical corporations as the main issues [511]. A 2016 report by Curtis gave details about Microsoft's tax avoidance practices and its monopolistic nature, the foundation's excessive global influence and support to various questionable practices including industrial agriculture with patented genetically modified seeds, Gates family's "considerable personal access to senior levels of the WHO", Gavi's alleged overpaying for vaccines leading to excessive increases in vaccine prices, Gates' dismissal of the issue, and the foundation's agenda skewing health priorities and distorting health programmes [512]. Curtis wrote that one problem with the foundation's heavy focus on developing new vaccines was that it detracted from other, more vital health priorities such as building resilient public health systems. As a rationale, Gates was said to have provided the following: "Vaccines are an extremely elegant technology. They are inexpensive, they are easy to deliver, and they are proven to protect children from disease. At Microsoft, we dreamed about technologies that were so powerful and yet so simple... all 193 member states, you must make vaccines a central focus of your health systems". Curtis commented that Gates had "a fixation on vaccines". He also claimed the foundation was stifling criticism through its media and NGO influence built on donations. An US professor of media, culture and communications was quoted saying the foundation "wielded enormous propaganda power". A 2009 editorial in the Lancet, describing the foundation's governance principle of being "driven by the interests and passions of the Gates family" as "whimsical", proposed that the foundation should be more transparent and accountable and listen to opinions of external parties [513]; [514].

In April 2020, the Bill and Melinda Gates Foundation awarded a five-year grant of USD 50 million to Unitaid to fight against HIV, tuberculosis and malaria, in addition to previous contributions of USD 100 million since 2006. Unitaid's budget for the year 2021 was approximately USD 32 million [515]. In late 2020, Unitaid partially funded the ivermectin meta-analysis by Hill et al. published as a preprint [16]. This meta-analysis was later ignored by the WHO in its March 2021 decision against the use of ivermectin except in clinical trials [6]. On April 22, the chief of Unitaid stressed the need to increase commercial research and development of new pharmaceuticals for the treatment of COVID-19 [242]. A core function of Unitaid is Medicines Patent Pool, a tool or practice to negotiate patents for low-income countries; this emphasis may have made unpatentable products seem foreign to the organization [516]; [517]. Gates foundation was the chair of Unitaid's Finance and accountability committee and a member of its policy and strategy committee [518].

Comparing the countries most heavily involved in the development and funding of vaccines to the countries with interest in ivermectin it can be noted that the two sets of countries have little overlap. Also, it can be noted that if influence is related to the amount of funding given, the first set of countries likely had more influence in the WHO in comparison to the rest of the countries.

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The WHO, the philanthropic entity Bill and Melinda Gates Foundation, the public-private partnership Gavi The Vaccine Alliance, and the philanthropic-commercial entity CEPI appeared to be strongly interconnected with each other and with high-income nation states. Major financial investments and commitments likely created propensities for various biases and a vulnerability to the sunk cost fallacy [519]. A haphazard or ideological commitment solely to vaccines (95% of government spending) may have overlooked considerations of cost-effectiveness and feasibility, such as vaccines likely being more expensive and more vulnerable to viral variants than repurposed medicines, their long-term safety being unclear, and vaccines likely requiring constant redevelopment and revaccinations, in addition to not being

suitable for self-administration and requiring refrigerated delivery systems. With regard to the sunk cost fallacy, it would be more economical for the governments to reconsider the vaccine and investigative pharmaceuticals dominated pandemic policy and at least adjunct it with broad-spectrum repurposed medicines.

Comparisons to the H1N1 pandemic

After the H1N1 'swine flu' pandemic of 2009-2010, the WHO was accused of malpractice when conflicts of interests of key WHO scientists led to unfeasible WHO recommendations which in turn led to billions of public money spent on inefficacious antivirals for H1N1 influenza [520]; [521]; [522]; [523]. In her book, Abeysinghe has written about the role of the WHO [524]. A review by Andres summarizes key points, including the monopoly of the WHO to declare a pandemic [525]. In the case of H1N1, WHO was retrospectively criticized for unnecessarily declaring a pandemic, as for example the European Centre for Disease Control (ECDC) did not agree that the disease should be qualified as severe (measured by mortality), which at the time was considered a requirement for a pandemic but is no longer mentioned.

At the time, an epidemiologist commented that the WHO, public health officials, virologists and pharmaceutical companies had "built this machine around the impending pandemic ... there's a lot of money involved, and influence, and careers, and entire institutions ... all it took was one of these influenza viruses to mutate to start the machine grinding" [526].

WHO was later criticized by the Council of Europe for giving too much importance to vaccination and for not sufficiently emphasizing other measures such as the use of antivirals even though some arguments suggested that other measures, such as taking antivirals preventively, could be at least as efficacious as vaccines [525]; [521]; [522]. WHO emphasized mass vaccination as the most effective strategy against H1N1 [524]. According to Abeysinghe, this emphasis was a result of the path-dependent institutional reaction of the organization, where prior experience with infectious disease (including notable victories using mass vaccination strategies) resulted in the favoring of this reaction, whereas other potential actions were disregarded or underemphasized.

In June 2010, the rapporteur of Council of Europe Parliamentary Assembly described the acts of the WHO as foolish, saying "this is not going to go away" [524]. The rapporteur assumedly meant the criticism was not going to go away; yet it appears instead that the organizational patterns did not go away, leading the WHO and the national governments to repeat the same issues a decade later in the COVID-19 pandemic.

Legal responsibility of public-private partnerships and the WHO

Clarke has noted that the regulation of global health has partially shifted from the hands of states and international organizations into the hands of public-private partnerships such as Gavi The Vaccine Alliance and the Global Fund [527]; [528]. These partnerships then become capable of also adversely impacting the rights of individuals, leading to concerns of responsibility under international law. However, the private entities in public-private partnerships typically fall outside the framework of responsibility under international law, and thus cannot be held responsible under it. In addition, in certain instances the partnerships have been granted immunity from the jurisdiction of domestic courts. This immunity applies to the staff, funds, properties and assets of these partnerships. The situation regarding Gavi and the Global Fund appeared especially complicated and the legal details were therefore considered out of the scope of this review.

With regard to the WHO, Gostin has described WHO's regulatory powers as extraordinary, noting that it may set regulations on a broad range of health topics including the safety, potency, and advertising of biologicals and pharmaceuticals, and a nomenclature for diseases, causes of death, and public health practices [529]; [530]. These regulations, unlike most international law, are binding on member states unless they proactively "opt out". In addition, also the WHO enjoys several privileges and legal immunities. Regardless of the original purpose of these privileges, the possibility of abuse of these privileges by the WHO also exists. Also here the details were considered out of the scope of this review.

Private philanthropy, society and science

In his recent book, Callahan discussed the role of private philanthropy, noting the rising influence and political significance of elite philanthropy, asking who is making choices over public life and who actually benefits from those choices [531]. Callahan described "today's era of austerity" as a result of an orchestration of the upper class to reduce its taxes and the size of government, even so that in some US states, cuts to higher education specifically helped finance tax reductions for the wealthy and corporations. He noted that in a decade, Bill Gates and Warren Buffett, the main funders of the Bill and Melinda Gates Foundation, had added USD 25 billion and USD 80 billion, respectively, to their wealth, and that the Koch brothers had increased their wealth from USD 9 billion in 2005 to USD 85 billion in 2015.

In a book review, Saunders-Hastings asked whether elite philanthropists are a counterweight to other, self-interested elites or to democracy itself, and noted that the distance between elite "charity" and elite political influence is small and shrinking, and that donors' motivations matter less than the results of their actions [532].

Broad wrote that due to cuts to public funding and increase in private donations, "American science, long a source of national power and pride, is increasingly becoming a private enterprise" and quoted a policy analyst commenting that "the practice of science in the 21st century is becoming shaped less by national priorities or by peer-review groups and more by the particular preferences of individuals with huge amounts of money" [533].

Callahan proposed putting some curbs in place against the private philanthropy, yet noted that foundations and nonprofit trade groups are strongly against any new restrictions, partly due to their dependency on philanthropy. He noted that "rethinking philanthropic freedom is a Pandora's box that almost nobody wants to open", saying the current situation was a result of "yesterday's mantras about philanthropic freedom and the dated regulation upholding it".

Vaccines vs repurposed medicines

In Finland, a team led by two leading Finnish professors, Kari Alitalo and Seppo Ylä-Herttuala, had a patent and intellectual property free adenovirus-based nasal spray COVID-19 vaccine ready in May 2020. Despite taking approximately EUR 18 billion of public debt to mitigate damages caused by societal lockdowns and using hundreds of millions of Euros on diagnostic tests only, the Finnish government refused the approximately EUR 50 million needed to fund a phase III patient trial for the vaccine [534]; [535].

The above case illustrates that the issue at hand is fundamentally not even about vaccines versus repurposed medicines or new pharmaceuticals versus repurposed medicines. Based on this data it is difficult to say whether it is about excessive adherence to inflexible regulations, subconscious biases present in corporate cultures and individuals, intellectual property enforcement, or intentional misleading for profit; likely, it is a mixture of all these factors. Personal biases, organizational cultures and commercial incentives of the vaccine cluster may have lead to attempts to build near-monopolies mass-producing proprietary but inferior products that outcompete more feasible alternatives. In Finland, significantly less interest has been present for any repurposed medicine than for the patent-free vaccine, with the sole exception of the company which developed the ivermectin-containing nasal spray not yet on the market [356].

More generally, the situation may partly be a result of the unprepared and rushed way in which the pandemic has been handled by the governments. Assumedly, from the perspective of governments with 95% of their funding committed to vaccines and international co-operation led by the WHO, paradigm change inducing innovations from outsiders may be perceived as unwanted disturbances. Considering these paradigms, the dismissal of ivermectin might be perceived as cultural discrimination, an instinctive reaction to avoid unfamiliar ideas.

As a result of the chosen policy of vaccines and new pharmaceuticals only, in order to avoid losing the sunk costs and credibility, the interests of the governments and the pharmaceutical industry appeared to align with each other but likely not with the public health interest. The concept of "regulatory capture" may be described as the agencies tasked with protecting the public interest coming to identify with the regulated

industry and protecting its interests against those of the public, with the result of government failing to protect the public [536]. Whether rejection of ivermectin may be seen as an example of "regulatory capture" depends on how the vaccines-only policy was selected: primarily to align with the interests of the pharmaceutical industry, or because a better option could not be imagined. Curiously, options could be imagined early on in many low-income countries, but not in the high-income countries, possibly as a result of "technological capture": when access to advanced technology exists, every problem looks like a problem to be solved with advanced technology, even though such solutions would be suboptimal due to being overly complex and unnecessarily expensive. For example, the idea of spending tens of billions of dollars per year for testing 20 percent of the global population every week assumedly for a single pathogen (SARS-CoV-2) appeared irrational at best [89]. Gates's speeches repeated terms such as "war" and "battle plan" [537]; these talks may easily be interpreted as priming fear in the public. Gates is also famous for regularly predicting the next pandemics [538].

Since the beginning of 2021 at the latest it should have been obvious that the continuing denial of early treatments could not be characterized either as accidental or as a rational choice with respect to public health interest. During the pandemic, a large part of the medical community seemed incapacitated like an old-fashioned military unit lacking leadership. The model based on the fear of losing medical license and an inflexible hierarchical chain of command appeared unsuitable for ensuring proper care of populations.

While denial of treatments for certain illnesses such as drug addictions, post-traumatic stress disorder or "treatment-resistant" depression for years or decades for example by denying funding for the research of psychedelic therapies has become normalized, it was unexpected that in the case of COVID-19 this antisocial behavior on behalf of governments and the pharmaceutical industry would be extended to literally everyone in the world. In a comment suggesting adoption of ivermectin, a patent attorney and a former director of a pharmaceutical company referred to "potential civil/criminal liability for censorship, scientific misconduct for misrepresenting ivermectin and other generics" [387].

The exact causes of the situation remained unclear. Regardless, the consequences remain to be seen and felt. One way forward might entail the majority of governments halting their funding to the WHO in order to dissolve the whole organization which appeared beyond repair. Another necessary change might be the eviction of the so-called philanthropic entities from healthcare contexts. In the long term, another beneficial action might be a worldwide conversion of the pharmaceutical industry into a non-profit operation. Continuing on the current path may result in a further polarization or destabilization of societies.

Near-future objections to adoption of ivermectin will undoubtedly include the possible environmental impacts. In the mid-to-long term, due to the need to reduce water usage and enable better retention of nitrogen, phosphorus and ammonia [539], transition from water based sewer systems to toilet systems not using water and not requiring wastewater processing but utilizing for example composting and new kind of treatments to degrade pharmaceuticals will become inevitable in many areas in any case.

Conclusions

During this period, ivermectin was officially adopted in South Africa but not widely used, adopted but later dropped in most of India, and adopted in Indonesia. In the United States and the United Kingdom, projects with involvement of both the governments and commercial companies were announced for development of new pharmaceuticals for early outpatient treatment of COVID-19, indicating unclear boundaries between these entities. The dismissal of repurposed medicines including ivermectin continued in high-income countries due to very differing views on what constituted evidence of efficacy. The divide between ivermectin proponents and opposers remained mostly unchanged during the period, indicating a stagnated situation.

There was a noticeable centralization of power, with pandemic response and public discussions largely directed by a few organizations that were largely funded by a few billionaires which, in turn, were affected by their own personal preferences and biases such as obsessive-compulsive attachment to testing and new technologies, primarily vaccines. Legal responsibilities of these organizations appeared, in the words of one researcher, "obscure".

Commercial interests appeared to override public health interests during this period. As a result, several low-and-middle-income countries and regions either implicitly or explicitly disregarded the WHO guidance, accelerating an erosion of WHO's credibility.

Abbreviations

SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; COVID-19: coronavirus disease 2019; WHO: World Health Organization; C-TAP: WHO's Covid-19 Technology Access Pool; ACT-Accelerator: Access to COVID-19 Tools Accelerator under WHO; COVAX: COVID-19 Vaccines Global Access, a vaccine arm of ACT-Accelerator; PAHO: Pan American Health Organization; NIH: United States National Institutes of Health; NIAID: National Institute of Allergy and Infectious Diseases; CDC: United States Centers for Disease Control and Prevention; FDA: United States Food and Drug Administration Agency; EMA: European Medicine Agency; CADTH: Canadian Agency for Drugs and Technologies in Health; SAHPRA: South African Health Products Regulatory Authority; ICMR: Indian Council of Medical Research; CEPI: Coalition for Epidemic Preparedness Innovations; Gavi: Global Alliance for Vaccines and Immunization, or Gavi The Vaccine Alliance; IFPMA: International Federation of Pharmaceutical Manufacturers and Associations; TNI: Trusted News Initiative; IFCN: International Fact-Checking Network; JAMA: Journal of American Medical Association; BMJ: British Medical Journal; LMIC: low-or-middle-income country; CSU: Christian Social Union in Bavaria; NGO: non-governmental organization; BIRD: British Ivermectin Recommendation Development Group; FLCCC: Frontline COVID-19 Critical Care Alliance; ICU: intensive care unit; RCT: randomized controlled trial; MEDLINE: Medical Literature Analysis and Retrieval System Online; PubMed: a search engine for the MEDLINE database; NCT: number of clinical trial, a ClinicalTrials.gov identifier; LHCS: long haul COVID-19 syndrome; HCQ: hydroxychloroquine; IVM: ivermectin; mRNA: messenger ribonucleic acid; D-Dimer: a fibrin degradation product; PCR: polymerase chain reaction; IC_{50}: half maximal inhibitory concentration; CFR: case fatality ratio; EUA: Emergency Use Authorization; CD147: Basigin (BSG), or extracellular matrix metalloproteinase inducer (EMMPRIN), or cluster of differentiation 147; RdRp: RNA-dependent RNA polymerase; RR: relative risk, or risk ratio; CI: confidence interval; OR: odds ratio; r: correlation coefficient; p: p-value.

Acknowledgements

The author wishes to thank Simon Barber for a grammar check.

Authors' contributions

The author was responsible for all aspects of the manuscript.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The author declares that he has no competing interests.

Author details

Independent researcher, Helsinki, Finland. ORCID iD: 0000-0002-8575-9838

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