Pennslyvania House of Represenatative - Summary and Testimony Dr. Pierre Kory, Pulmonary and Critical Care Medicine Specialist, President and Chief Medical Officer of the Front Line Critical Care Alliance

Summary Points:

- A war on off-patent, FDA approved, inexpensive, safe "repurposed drugs" has been waged by the pharmaceutical industry for decades in an attempt to preserve profits for novel, patented, high profit drugs
- In COVID, this war has accelerated to a degree never witnessed before, with health agencies and pharmaceutical companies purposely either distorting, misrepresenting, or using data to recommend against numerous highly effective repurposed drugs, with the most damaging actions being those against hydroxychloroquine, ivermectin, and more recently fluvoxamine.
    - Part of the actions of this war have consisted of our national health agencies issuing national recommendations against use despite the fact each medicine sits atop either a vast or deep evidence base supporting efficacy.
- Conversely, the currently officially approved drugs by the NIH or FDA, consist nearly solely of high-cost, novel, patented drugs, with highly limited, controversial and weak evidence bases supporting both efficacy and safety, i.e Remdesivir and Molnupiravir, yet they consistently and easily meet approval followed by widespread purchase by our federal government and hospitals
- The only path to reverse the horrifically damaging impacts of this war on repurposed drugs is to take action to support the recent Nebraska Attorney General's opinion supporting the use of "off-label" prescribing by physicians during the pandemic by;
    - Re-establishing the autonomy and duty of physicians to utilize off-label prescribing when they deem it indicated
    - Prevent pharmacists from refusing to fill decades old, FDA approved, off-lable prescribed medications
    - Prevent medical boards or insurance companies for investigating or reprimanding physicians who provide off-label prescriptions to treat this disease.

Until several months ago when the use of monoclonal antibodies by the FDA was approved under emergency use authorization, according to the NIH COVID-19 treatment guidelines, not a single medicine was recommended for the prevention nor early outpatient treatment of COVID-19. In contrast to these agency non-recommendations, over two dozen compounds, many of them off-patient, decades old, proven safe have been shown in numerous trials to be effective in the prevention or treatment of COVID-19. In the case of ivermectin, over 65 controlled studies, many of them randomized, along with many thousands of physicians, have found it to be highly

effective in treatment of COVID-19 given its well-known, proven antiviral or anti-inflammatory properties. My organization, made up of 5 of the most highly published critical care physicians in the world, have long recommended its use in the United States. Instead, these recommendations have been met with attacks and distortions of the science from health agencies, medical boards, and the media. Outside the U.S however, ivermectin is recommended in 39 countries including 28% of the world's population. But not in the U.S.

The reality as to why these medications are ignored and not recommended is quite simple; we live in a healthcare system that is structured to favor novel, highly profitable, pharmaceutically engineered compounds over compounds that have well established safety profiles, yet little profit to be made. This latter class of drugs, known as repurposed drugs, have been the subject of a war by pharmaceutical companies for many decades now. I have had a front-row seat to the latest battles in that war during COVID-19 and it has been one of the most profound sadnesses of my professional career. There are willful distortions of the efficacy data around these safe medications, yet the record is clear, myriad efforts have been made to suppress this evidence of efficacy in an attempt to avoid use of ivermectin, hydroxychloroquine and now fluvoxamine. They are the latest victims in a decades long war by the pharmaceutical industry against repurposed drugs.

VITAMIN D

The first year of the pandemic, in 2020, one of the most absurd curiosity's in the federal health agencies response was their deliberate lack of recommending routine assessments of vitamin D status and or vitamin D supplementation. It is well known that vitamin D deficiency leads to poor outcomes and higher likelihood of contracting COVID-19 disease. The studies demonstrating this now number over 140, repeatedly showing worse outcomes with vitamin D deficiency and greatly improved outcomes with regular Vitamin D therapy. The FDA has known for decades that large portions of the population, including those in the north in low-income neighborhoods, in poverty stricken areas and especially in nursing home residents, vitamin D deficiency is very common. Why did they not recommend a systematic push to correct these deficiencies in order to help patients survive? This was the first concerning inaction of the federal government. Even doctor Anthony Fauci admitted that he regularly takes vitamin D. Yet he did not recommend it to the population. Just last week, a paper showed that if your Vitamin D level is above 50ng/ml, zero mortality's were observed from COVID-19. This is well known by COVID experts. Still no recommendation for Vitamin D supplementation.

HYDROXYCHLOROQUINE

The war on hydroxychloroquine was was won by fraudulent studies that were then later retracted from major impact journals, and by numerous high profile randomized control trials that were designed to fail using inexplicably high doses nearing limits of toxicity and which unsurprisingly lead to worse outcomes in the treatment groups. All of these details are highly referenced in Chapter 1, PART II of the recently published book called "The Real Anthony Fauci – Bill Gates, Big Pharma, and the Global War on Democracy and Public Health".

These trials were focused only on the hospitalized patient which was obviously intended to be able to show a lack of efficacy given that if hydroxychloroquine were to work as an antiviralm it is well known that anti-virals only work early in disease during the viral replicative phase. Yet all the trials were focused on the hospitalized patient. Further our federal government early on in the pandemic restricted hydroxychloroquine only to the hospital. A decision which still troubles me to this day. Once the powers arrayed against repurpose drugs were able to show that the drug at those doses did not work in late phase hospital disease they then concluded that it was ineffective drug and the trials that were designed to study early outpatients were inexplicably discontinued by the NIH despite numerous studies from around the world showing efficacy in early treatment. These actions led the EUA for hydroxychloroquine to be rescinded. Meanwhile doctors around the world and countries around the world which used hydroxychloroquine systematically measured much lower case fatality rates than Western countries in which it was discontinued. Currently based on over 30 controlled trials the signal of efficacy of early outpatient hydroxychloroquine is unassailable. Yet our government still recommends against use and our social media companies censor any mention of its efficacy.

IVERMECTIN

In 2021 the war on Ivermectin began despite (or because of) the fact there are now almost 70 controlled trials, 31 of them are randomized, and 16 of them are double blind prospective randomized controlled trials. Numerous summary meta analysis show consistent benefits in mortality, time to clinical recovery, and time to viral clearance. Large health ministries ivermectin in early treatment programs showed dramatic impacts on the need for hospitalization or death. Uttar Pradesh, a state in northern India of 241 million people, effectively eradicated through the systematic use ivermectin in the prevention and treatment of COVID-19, by having all their health care workers use ivermectin, treating all positive patients with ivermectin, and prophylaxing all household contacts of positive cases with ivermectin. By doing systematic testing, contact tracing, quarantining and treating, in September 2021 they now report almost no active cases in the

majority of the districts in that state. A historic achievement. However, in two major Indian newspaper articles and in the WHO's report praising their achievements and their program, the word ivermectin is not mentioned. Such is the power of the forces against repurposed drugs. Mexico City, and two states in Argentina, (La Pampa and Misiones) also report tightly measured, dramatic impacts in hospitalization and death reductions of their early treatment programs with ivermectin.

Currently the NIH has an official neutral recommendation for ivermectin, defined as "there is insufficient evidence to recommend for or against use". Although they feel there is insufficient recommended evidence to recommend against, the rest of the government's health agencies have strongly advised state health departments, Pharmacy Boards, and all Medical Societies against use. This can be evidenced by the CDC's bulletin out to all the state Department of Health in August which occurred after weekly prescriptions for ivermectin in the United States reached 90,000. Interestingly, this peak in prescriptions was immediately followed by a sharp drop in cases and hospitalizations.

Most concerning, is that the study data supporting ivermectin as a preventative agent is actually the strongest when compared to trials of early and/or late treatment efficacy. The consistent large reductions in the risk of transmission for someone taking ivermectin regularly or semi-regularly are truly astounding. Numerous countries offer regular ivermectin therapy in their frontline health care workers to great effect. Yet in the NIH and WHO documents they state that "they have not reviewed the studies on ivermectin in the prevention of COVID-19". They are ignoring this data for good reason, in order to continue to champion the vaccines as the sole solution to this pandemic as well as to preserve the market for the other oral antivirals that are being tested in the prevention of COVID-19.

Despite these pervasive attacks on such a safe and effective drug in COVID, my own personal experience dates to October of 2020 at the time of my comprehensive review looking at all of the emerging trials (please note that this paper is currently ranked #42 in popularity of any single science paper published in the last 19.6 million papers since 2011). I began to use ivermectin in my practice period since that time and I have consistently witnessed reproducible, temporally-associated improvements in at least one important symptom of COVID-19 whether it be fever, fatigue, chest tightness, cough, or sore throat. Patients who are languishing or worsening over days suddenly change their clinical trajectory to one of rapid improvement. This pattern is one I

have consistently witnessed and is also reported by many of my increasing number of colleagues from around the world who have reached out to me reporting the same observations.

FLUVOXAMINE

The latest battle in the war on repurposed drugs concerns Fluvoxcamine. This is likely the most absurd example. In the spring of 2021, a study reported that within a large French mental hospital, the nurses and doctors were being admitted to the hospital much more frequently than the patients. Using a multivariate analysis they identified that the patients on antidepressants were protected against the more severe outcomes. Subsequent to that study, numerous philanthropic research funders advanced and supported research of the anti-depressant fluvoxamine. First, in a large observation controlled trial and now 2 randomized controlled trials the results showed consistent and profound impacts of fluvoxamine's ability to protect a COVID patient from hospitalization. Despite two large, well-executed, randomized controlled trials, there is a continued lack of approval for use in the U.S of this medication. This is inexcusable. The Infectious Disease Society of America reviewed the studies,

and just last week continued to "recommend against use outside of clinical trials".

NOVEL, PATENTED, PROFITABLE DRUG APPROVALS

Remdesivir

Please recognize that these lack of approvals must be contrasted with the approvals that novel pharmaceutically sponsored, high-cost medications receive. Remdesivir, a drug that failed due to toxicity in the Ebola pandemic met ready approval after one trial showed only a slight reduction in the duration of hospitalization. It is currently the standard of care across the country despite the fact that numerous independent randomized controlled trials have shown that it is either ineffective or shows a trend to increasing harm. Even the World Health Organization does not recommend its use based on their large, multi-center SOLIDARITY trial. The only trials (two) supporting the use of remdesivir were pharmaceutically sponsored trials. A separate 4 "independent" trials done by numerous academic medical centers around the world do not show any efficacy of this drug in the hospitalized patient. This is truly a controversial and likely very harmful drug yet again it is the standard of care in this country. This is the consequence of a healthcare system which is structured to favor pharmaceutically engineered novel and for-profit drugs near at the near-total exclusion of repurposed alternatives.

Molnupiravir

Continuing with this theme, just last week Merck's new oral antiviral agent monupiravir was approved by the FDA despite the panels many concerns about the minimal efficacy and concerns over safety of the drug. It narrowly met approval, yet it clearly will be the standard of care soon even though it cannot to be used by adults who are sexually active and/or of childbearing age without use of contraceptives, indicating the real risk of mutations causing birth defects or cancer. Several other concerns about this approval must be noted; 1) the data from the 2nd half of the trial, after their initial interim analysis showing efficacy, actually found placebo patients to have better outcomes than the treated patients, 2) two trials of the drug in "moderately ill patients" were stopped early due to lack of efficacy, and 3) Merck's trial testing the drug in hospitalized patients was also stopped early for what they described as "business reasons". The discordance in the ease of approval and recommendations of these drugs should alarm all.

Paxlovid

Pfizer recently issued a press release claiming that their new oral antiviral called "Paxlovid" leads to a large reduction in the need for hospitalization (88%) based on one trial. What is alarming about the potential approval of this drug (virtually assured?) is that it relies on a single mechanism of action, that of interrupting an enzyme critical for SARS-CoV-2 replication. Yet, ivermectin is well recognized to not only possess this identical mechanism of action, but also possesses many others as well. So you essentially have a drug that works in one of the well established ways that ivermectin works, and although it shows efficacy it is thought that this narrow action will lead quickly to resistance. Conversely, ivermectin has multiple anti-viral and anti-inflammatory mechanisms such that it is thought to be impervious to resistance. I have no doubt that this new Pfizer drug will readily meet approval.

The war on re-purposed drugs must stop as it is against the public interest. Actions taken to coerce or scare physicians and pharmacists from prescribing or filling off-label, repurposed drugs must stop immediately. The legal and medical evidentiary arguments supporting the need for protections of physicians wishing to prescribe repurposed drugs has been well documented and argued for in a recent opinion issued by the Nebraska Attorney General. Despite this, in many states, medical boards are initiating investigations of physicians who prescribe repurposed drugs like ivermectin.

It is a war that is putting pharmaceutical interests over the public interest. The FDA even argues that off label prescribing should be used when there are no alternatives and/or when the safety and efficacy data is supportive. There are immense data supporting the three repurposed drugs above (and many others). Yet our government, contrary to many governments around the world, is openly attacking, dismissing and distorting the science around these medications. And people are dying as a result due to our doctors being negatively influenced.

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