TESTIMONY OF PAUL E. MARIK, M.D., FCCP, FCCM
ON BEHALF OF THE FRONT LINE COVID-19 CRITICAL CARE ALLIANCE

In Support of H. B. No. 73

Dave and Angie Patient and Health Provider Protection Act

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before the Health Provider Services Committee

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Submitted by:

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To Chair Al Cutrona, Vice Chair Jennifer Gross and Members of the Committee:

H.B. No. 73, the "Dave and Angie Patient and Health Provider Protection Act," is an important step in allowing doctors to be doctors for the benefit of their patients and to follow the science without fear of improper restrictions by state medical authorities and institutions. Patients should be able to rely upon the physicians they choose, and in critical cases even when hospitalized. In the face of chronic disease for which we have inadequate options, poorly managed conditions such as many cancers, and in response to the novel pandemic, in which for too long there were no recognized answers and even now insufficient data to truly arrive at a definitive standard of care, physicians in clinical practice are an important source of exploration and development of new uses for existing drugs. Repurposed drugs can offer highly cost-effective solutions and have the advantage of well-known safety profiles, such as drug interactions, because they have been in use. Such off-label use is generally recognized by the US Food and Drug Administration ("FDA"). Unfortunately, legal concerns about off-label uses can create unnecessary legal exposure to physicians and restrictions imposed by pharmacies and hospitals that H. B. 73 would address.

I submit this testimony on my own behalf and on behalf of the Front Line Covid-19 Critical Care Alliance ("FLCCC.) (Attachment A: Bios and organizational statement). We appreciate Representative Gross' sponsorship of this bill as it helps to address these problems; one highly concerning instance we have seen is the interference in the practice of medicine during this pandemic. In the case of ivermectin, pharmacies have refused to fill scripts, medical boards have threatened or in some cases taken action against physicians, hospitals have refused access to patients at extreme risk and even prevented their own staff from prescribing ivermectin though they had little else to offer. When professional disagreements or concerns arise, such as when the FDA and CDC issued alerts regarding self-medication with veterinary forms of ivermectin, these were widely taken as setting a standard of care in opposition to physician-prescribed ivermectin in COVID-19. While FDA has clarified that this was not its intent under the pressure of litigation of which I've been a part,[1] they have maintained the same strong implication that this use is improper even though FDA has never studied the matter. There has been a tremendous amount of distortion in the public media about the dangers of ivermectin, encouraged within an echo chamber of federal agencies, professional associations and public.

[1] FDA counsel made this statement November 1, 2022 at oral argument in Apter et al v. HHS, FDA, et al. S. D. Tex. 3:22-cv-00184 (filed 6/6/2022). See for e.g., Henson v. CSC Credit Services, 29 F.3d 280 (7th Cir. 1994). The matter was dismissed on sovereign immunity grounds and the matter is on appeal.

media. State regulators have often followed this lead; the New York Attorney General, as one example, wrote a letter to all the physicians on the FLCCC directory demanding that they cease and desist prescribing ivermectin for COVID-19. One of her points was that it was an off-label use, highlighting that while such use is entirely proper and quite common, the regulatory gap that H. B. 73 clarifies is one that can be abused with unfortunate, real-world consequences.

The focus of the Dave and Angie Patient and Health Provider Protection Act on protecting off-label uses is particularly important across the practice of medicine, not simply in response to this pandemic. The wide adoption of numerous off-label uses initially arise primarily from physician experience. Regulatory exposure should not squelch that development. Nor should patients be put at risk because the State or a medical institution imposes its view over the patient's chosen physician and reasonable course of action simply because of professional disagreement.

Importance of Repurposed Drugs

To briefly highlight the importance of re-purposed drugs, estimates of off-label uses range from 20% to 40% of prescriptions written,[2] depending upon how one counts. Aspirin is used off-label to reduce the risk of heart attack and stroke. Clonidine, a drug that is used to treat high blood pressure is also used off-label to treat a variety of other conditions, including attention deficit hyperactivity disorder (ADHD). Many cancer drugs are used to treat cancers outside of their approved indications and can in fact represent standard of care. Beta-blockers are FDA-approved for the treatment of high blood pressure, but widely recognized by cardiologists as a standard of care for patients with heart failure. Colchicine is indicated for the treatment and prevention of gout, though it is also generally considered first-line treatment for acute pericarditis, as well as preventing recurrent episodes. Amitriptyline, used for treating depression is also prescribed for treating fibromyalgia.

One of the issues in choice of drugs is the built-in presumption that drugs that have been approved by FDA for a specific indication has been shown to be safe and effective and provide the best treatment, which in fact, is not the case. The drug merely has to show some reasonable impact but may in fact have minimal effectiveness and significant safety issues. In COVID-19 treatment, for example, hospitals were pressing Remdesivir on patients even though the World Health Organization advised against it, and it has had limited utility and substantially more adverse effects than ivermectin. To compare safety: there have been 420 U.S. deaths attributed to

[2] *See for e.g.,* https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html

ivermectin over a 20-year period,[3] while there have been 2,014 deaths attributed to Remdesivir[4] though it was only approved by FDA on October 22, 2020, and given to far fewer patients.

As noted by the example of beta-blockers above, the fact that a specific indication has not been approved does not mean such use is improper[5] or inconsistent with the standard of care. The FDA does not set standards of care; professional associations and Ohio public health authorities together have that responsibility. *See Chaney v. Heckler*, 718 F.2d 1174, 1179 (D.C.Cir. 1983) ("FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine.") rev'd on other grounds, 470 U.S. 821 (1985). What is commonly called FDA's "practice of medicine exception" developed from Congress "not want[ing] to interfere with physicians' treatment of their patients." U.S. v. Algon, 879 F.2d 1154 (3d.Cir. 1989).

One way to appreciate the importance of off-label uses is to understand the limitations on approved drugs. That a drug can show some benefit and meet minimal safety standards is sufficient to gain market approval, but by no means suggests that the approved indication will be safely and effectively managed, let alone cured. In 2017, FDA staff did a national survey to determine how well consumers understand the drug approval process, specifically to see if consumers were aware that drug approval only meant that a drug has some utility and does not mean that a disease was fully treatable or that the drug was safe, in order to assess the impact of pharmaceutical advertising.[10] That article recognizes that FDA approval does not necessarily mean the drug will help everyone who uses it, which was widely understood by the public. "However, only 25.1% of respondents knew that FDA approval does not necessarily mean the drug will help most people who use it. Finally, roughly half of respondents (57.1%) knew that FDA approval does not mean that the drug won't harm someone who uses it, and 57.4% knew that FDA approval does not mean that the drug will cure the condition for which it is including new uses from our existing repository of approved drugs, is critical to development

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3 https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4

4 https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4

5 "Once a drug has been approved by the FDA for marketing for any use, the actual prescription choices regarding those drugs are left to the discretion of the physician. *See, e.g.*, 59 Fed. Reg. 59820, 59821 (1994) (noting that the agency has restated this policy on numerous occasions). A physician may prescribe an approved drug for any medical condition, irrespective of whether FDA has determined that the drug is safe and effective with respect to that illness. That physicians may presently prescribe off-label is not in dispute." *Wash. Legal Found. v. Friedman* , 13 F. Supp. 2d 51, 55 (D.D.C. 1998).

and should not be squelched.

Much of the criticism has been with ivermectin for COVID-19, for example, is that its off-label which carries no negative connotation. Allowing such use is particularly important where, as with COVID-19, the only approved drugs were authorized using abbreviated methods, have high risk profiles, and have not been sufficiently studied to become a gold standard against which to judge treatment. At the time, the only approved drug was Remdesivir. To compare safety: there have been 420 U.S. deaths attributed to ivermectin over a 20-year period,[6] while there have been 2,014 deaths attributed to Remdesivir[7] though it was only approved by FDA on October 22, 2020, and given to far fewer patients. Remdesivir, which is considered the "standard of care," was approved contrary to WHO recommendations against its use[8] and a significant body of literature finding its risks outweigh any benefit.[9] This is particularly the case when no approved drugs exist or have yet been sufficiently studied to become a standard of care against which to judge outcomes.

The Professional and Regulatory Problem

The customary allowance for medical professionals to develop lifesaving off-label uses has been seriously challenged by efforts to standardize medicine, remove autonomy from treating physicians, issues which became particularly acute during the pandemic. Public health authorities, spurred on by pharmaceutical companies with deep financial conflicts of interest, moved to denigrate any studies of repurposed drugs for use in COVID-19 as they developed new molecules or vaccines with billion-dollar income streams.

At the same time, this life-saving drug became a victim of a perfect storm of party politics, with political divisions driving the conversation so that the issue of the science quickly became lost and public discussions devolved into which political tribe you belonged. Meanwhile,

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6 https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4

7 https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4

8 https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients#:~:text=WHO%20has%20issued%20a%20conditional,other%20outcomes%20in%20these%20patients.

9 *See for e.g.,* Singh S, Khera D, Chugh A, et al. Efficacy and safety of remdesivir in COVID-19 caused by SARS-CoV-2: a systematic review and meta-analysis. *BMJ Open* 2021;11:e048416. doi: 10.1136/bmjopen-2020-048416

patients suffered, and families bore losses because access to ivermectin was made difficult, which this H. B. 73 is designed to help fix.

Working in inpatient, critical care medicine, this was my first real encounter with the degree to which institutional medicine could veer off course and interfere in good medical judgment. But this has been an eye-opening experience, and I see that issues with regulatory oversight and professional peer pressure to heave to "consensus' medicine is not just a recent issue arising in the pandemic, or that it will be in the next one if we don't learn the right lessons.

The legal problem is that while some off-label uses have developed sufficient publication support to be considered standard of care, many have not. Physicians engaging in such uses are easy targets for regulators as allegedly violating the standard of care. Of the many problems with this situation is that off-label uses of necessity often begin with a few creative physicians who reason, often because of collateral effects seen in patients on the drug, that the benefit of a therapeutic trial in a patient outweighs the risk and gives the drug a try. Exposing physicians to legal risk reduces the availability of important therapies as well as slows that development. Further, the physician knows the patient, the apparent causes of their illness, what has been tried, what they tolerate and a myriad of other factors that regulators penalizing such conduct do not take into account. Cuing up off-label use as a reason to support disciplinary action against responsible physicians has been one of the less remarked tragedies of the institutionalization of medicine, which we have especially seen develop during the pandemic.

Regulatory Challenges: Medical Boards, Hospitals, Pharmacies

One hopes that medical boards will allow reasonable off-label choices to be made and not impose investigation or discipline because they don't recognize a therapy. One also hopes that the various parts of the health care system will operate as a team; when a patient presents a script to their pharmacy or requires hospitalization and an off-label use may help them, there should be cooperation. Concern over legal exposure as a result of off-label use can make it more difficult for physicians, pharmacies and hospitals to work together, and limiting that liability can improve the ability to get important drugs to patients.

Pharmacies

As the pandemic developed and the controversy over ivermectin prescribing grew, national pharmacy chains began to allow and then counsel pharmacists to refuse to fill scripts for COVID-19 and to require ICD-10 diagnostic codes confirming that it was for an indicated use. This put the pharmacies in the business of practicing medicine and, in effect, enforcing a

standard of care determination that it never been properly made by any organization with authority and essentially imposed a blockade against drugs that competed with those in the FDA pipeline.

Hospital Cases

Another very disturbing example of medical interference have been cases where seriously ill patients, for whom no constructive options were available, were nevertheless denied access to ivermectin. There have been a large number of injunctive relief attempts in response to hospital refusals to provide ivermectin for their COVID-19 patients. The FDA Campaign has been frequently cited by courts as a basis for denying relief.

While some state courts have granted requests for an injunction, these cases have universally lost on appeal. This occurred in Ohio in *Smith v. W. Chester Hosp., LLC*, No. CV 2021 08 1206, 2021 Ohio Misc. LEXIS 103, Slip Op. at 5 (Ct. Com. Pl. Sep. 6, 2021). *See also* nationally, *for e.g., Gahl v. Aurora Health Care, Inc.*, 403 Wis. 2d 539, 578 n. 30, 977 N.W.2d 756 (Ct. App. 2022); *Pisano v. Mayo Clinic Fla.*, 333 So. 3d 782, 787 (Fla. Dist. Ct. App. 2022); *DeMarco v. Christiana Care Health Servs*., 263 A.3d 423, 422, 432 (Del. Del. Ch. 2021); *Shoemaker v. UPMC Pinnacle Hosps*., 2022 PA Super 163, 283 A.3d 885; *Abbinanti v. Presence Cent. & Suburban Hosps. Network*, 2021 IL App (2d) 210763, 455 Ill. Dec. 557, 557, 191 N.E.3d 1265; and *Salier v. Walmart, Inc.*, No. 22-CV-0082 (PJS/ECW), 2022 U.S. Dist. LEXIS 148684 (D. Minn. Aug. 19, 2022).

In addition to citing FDA and CDC, a primary issue in these cases was the authority of the hospital to make medical decisions about the patient in their care. This is certainly an important principle, but there are numerous existing distinctions that recognize this cannot be absolute. Right to Try laws, for example, such as H. B. 290, enacted by this body in 2017, recognize that critically ill patients have the right to try drugs that are in the FDA pipeline. This law does not reach ivermectin or other cases of repurposed drugs because the economics required to conduct clinical trials and pay FDA fees, particularly for generic drugs, makes it infeasible to request approval and therefore they are not within the reach of that law.

It is appropriate for the General Assembly to extend the right of patients with the proviso below in such situations to receive medications they are denied solely due to professional disagreement.

Medical Board Matters

One of the difficulties hospital denials have created is the exposure of patient's

physicians, whether established or requested on consult, to discipline by the State Medical Boards. Because outside physicians rarely have privileges at hospitals, these physicians are unlikely to have access to the patient, the entire medical record, or even the attending physician's and are thus placed in Catch-22.

Suggested Amendment

While the language as written is an important step forward, I do believe that a modification would ensure the responsible use of the protections granted in the Act. The Act could be read as written to shield clearly egregious conduct merely because the use was off-label. A fair balancing is needed here, and we suggest several options for the Committee to consider:

x) The prescriber has a reasonable basis for believing that the potential benefit of the prescription outweighs the potential risk, including, without limitation, one or more peer-reviewed published articles, the reported opinions of a minority of physicians, the published opinion of one or more medical/physician organizations, the prescriber's own demonstrable and documented positive outcomes with such prescription or the use of written informed consent that properly sets forth the status of the recommended drug for the indication and its risks and benefits.

- or –

x) A professional occupations board, notwithstanding this section, may take action for a standard of care violation if it can demonstrate by substantial evidence that the prescribing presents risk to the patient that outweigh the potential benefits.

Conclusion

We appreciate the opportunity to present testimony, appreciate the efforts of the Committee, and urge passage of H. B. 73 [with consideration of the amending with our suggested language] to ensure that doctors have the right to practice medicine without undue bureaucratic interference.

ATTACHMENT A

Biographies of Paul Marik, M.D.
Organizational Statement about FLCCC

Paul Marik, MD, FCCM, FCCA, co-founder and chief scientific officer, Frontline COVID-19 Critical Care Alliance (FLCCC)

Dr. Marik has special knowledge and training in a diverse set of medical fields, with specific training in Internal Medicine, Critical Care, Neurocritical Care, Pharmacology, Anesthesia, Nutrition, and Tropical Medicine and Hygiene. Dr. Marik recently retired as a tenured Professor of Medicine and Chief of the Division of Pulmonary and Critical Care Medicine at Eastern Virginia Medical School in Norfolk, Virginia. Dr. Marik has written over 700 peer-reviewed journal articles, 80 book chapters and authored four critical care books. He has been cited over 52 900 times in peer-reviewed publications and has an H-index of 110. He has delivered over 350 lectures at international conferences and visiting professorships. He has received numerous teaching awards, including the National Teacher of the Year award by the American College of Physicians in 2017.

He is the second most published critical care physician in the world and is a world-renowned expert in the management of sepsis – his contributions to the understanding and management of the hemodynamic, fluid, nutritional, and supportive care practices in sepsis have transformed the care of patients throughout the world. He also led the Society of Critical Care Medicine task force on corticosteroids in sepsis. He has already co-authored 10 papers on many therapeutic aspects of COVID-19.

About the Front Line Covid-19 Critical Care Alliance

FLCCC was founded by a group of highly published, world-renowned Critical Care physicians and scholars, including Dr. Kory and Dr. Marik, who have held leadership positions in large medical center ICUs. Its MATH+ Hospital Treatment Protocol was introduced in March 2020 and has saved tens of thousands of patients who were critically ill with COVID-19. The expertise in clinical research can be seen just in the fact FLCCC member physicians have nearly 2,000 published peer-reviewed publications among them. These eminent, well-recognized physicians have extensive experience with COVID-19, and despite being overtime at bedside throughout this emergency, have put remarkable efforts into studying, documenting, and educating the professions and the public about the clinical value of ivermectin in COVID-19.

One of FLCCC's initial efforts, consistent with WHO guidelines, was to explore the re-purposing of existing drugs, an effort that received too little global effort as financial resources focused on developing new patented medications. A rapidly growing published medical evidence base demonstrating ivermectin's unique and highly potent ability to inhibit SARS-CoV-2 replication and to suppress inflammation included not only multiple in-vitro and animal models, but numerous clinical trials from centers and countries around the world showing repeated,

consistent, large magnitude improvements in clinical outcomes when ivermectin is used, not only as a prophylactic agent, but also in mild and moderate cases and even has some positive effects even in severe disease states. FLCCC developed consensus-based standards among its global physician members, issued them for use by interested medical professionals worldwide, and advocated for their adoption and public discussion by physicians who recognize the need to inform the public about the value and availability of ivermectin. The Alliance has the academic support of allied physicians from around the world to research and develop lifesaving protocols for the prevention and treatment of COVID-19 in all stages of illness. The website cites a large number of peer-reviewed publications, some of which were authored by FLCCC's founding physicians.