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VIA E-MAIL

submissions@abim.org

July 8, 2022

Richard J. Baron, M.D.
President & CEO
American Board of Internal Medicine
510 Walnut Street
Suite 1700
Philadelphia, PA 19106-3699

Re: Notice of Potential Disciplinary Sanction
Pierre Kory, M.D.
ABIM AD: 262789

Dear Dr. Baron:

I write on behalf of Pierre Kory, MD in response to the American Board of Internal Medicine ("ABIM" or "Board") letter of May 26, 2022 (hereinafter "Notice") raising concerns that Dr. Kory is spreading medical misinformation regarding the prevention and treatment of COVID-19. That Notice is fatally defective, and, if the Board believes that pursuing the matter is appropriate, it should reissue a proper notice. The Notice is defective because it does not comply with the ABIM's own rules which impose certain requirements including:

In the event ABIM obtains such evidence, it shall so notify the physician in writing. Such notification shall:

- (2) summarize the evidence in ABIM's possession;
- (3) include copies of any documentary evidence in ABIM's possession;
- (4) provide the physician an opportunity to make a written submission to the CCC Disciplinary Sanctions and Appeals, ABIM Policies and Procedures at 18.

The Notice details a number of positions and statements made by Dr. Kory but offers no evidence as to why such positions are inaccurate or constitute misinformation. In order for ABIM to find that any statement of Dr. Kory is misinformation it would, at the very least, need to introduce evidence into the record that could tend to show his statements are inaccurate, and further, rise to the level of misinformation. The Notice must cite and include the documentary evidence of the contrary authorities upon which the Board could so find his statements. The failure of ABIM to refer to any such evidence in the Notice or to attach any documentary

evidence upon which it could base such a finding disallows their introduction into any proceeding and makes it impossible as a matter of law for ABIM to reach such a finding. Proceeding to consider such evidence without having first provided it to Dr. Kory along with the Notice would be a violation of the Board's own rules. It makes it impossible for Dr. Kory to provide a proper response as he is not on notice as to what the basis would be for such an action. The fundamental minimum of due process, as enshrined in the ABIM's Policies and Procedures, is to allow one facing a sanction to confront the evidence against him. What is given in the Notice are his alleged wrongs, which constitute charges, but no evidence against him.¹ The opportunity to provide a response without notice of the authorities or evidence upon which the Board proposes to rely in finding against him is meaningless.

ABIM has instead offered Dr. Kory's statements as if they are self-indicting and so evidently incorrect as to be beyond the need for evidence. While some public health officials have seen their mission as requiring the suppression of minority viewpoints due to a perceived risk of non-compliance with their recommendations,² learned bodies such as this Board perform a different function and must preserve debate. The Board in fact enshrines that view in the very Policy at issue by noting "the importance of legitimate scientific debate." The Board would hopefully recognize the value of ensuring educated voices are free to actively raise alternative views. The fact that the Board believed it could bypass its due process requirements and simply assume the referenced statements constitute sufficient evidence of misinformation, however, suggests in this case it may wish to substitute a narrative for the actual process of science.

¹ We waive any expectation that the Board provide copies of Dr. Kory's own statements. The Notice fails to list or provide any documentary evidence, however, that could be offered to show these statements are incorrect and in fact rise to the level of misinformation. While Committee members can rely to an extent upon their general training and experience, they must nonetheless ground any decision in a review of Agency positions or published studies upon which they would rely in order to create a record beyond the general opinions of Committee members. While this would always be the case, it is especially true here as Dr. Kory has participated in, conducted and reviewed research, critiqued publications on both sides of these issues in detail, presented to and swayed the agencies making public health determinations and has a level of expertise requiring that any findings must be joined at the level of his discourse. A decision cannot be reached by merely adopting a general narrative woven from journal abstracts and commonly held positions that often do not stand up to actual investigation and review.

² A principle concern of public health officials was the use of veterinary forms of ivermectin, use that was unfortunate and ill-advised. Another unfortunate occurrence was that physicians advocating for wider use of human prescribed ivermectin were painted as encouraging patients go outside traditional physician-patient prescribing of human pharmaceuticals, which is largely untrue and certainly not true in Dr. Kory's case.

Dr. Kory has proceeded, with enormous energy and focus, to give voice to the clinical experience of a significant minority of physicians and a considerable body of published scientific evidence. It is particularly inappropriate to frame Dr. Kory's efforts as counter to the public health as his focus has been on the important yet poorly attended task of adding tools to the armamentarium. The biased interpretation of data against repurposed medications has been a great disappointment and educated voices raising that concern are of great value.

However the Board sees this, due process requires that the evidence upon which the Credentials and Certification Committee ("CCC") could conclude that Dr. Kory has been providing misinformation would have to have been provided to him along with the Notice to allow him an opportunity to respond to that evidence. While we respect the knowledge of the Committee members, no committee, merely upon their medical judgment, has sufficient basis to make such a decision. It would require an analysis of documentary evidence at the same level of rigor as that exhibited by Dr. Kory supporting the views to which he is asked to respond.

To be sure the legal issues with the Board's Notice are clear I highlight them throughout this letter:

Lack of Notice: In order to consider pulling a physician's credential in which he has a property or business interest, *see, for e.g., Am. Bd. of Internal Med. v. Muller*, No. 10-CV-2680, 2011 U.S. Dist. LEXIS 25169 (E.D. Pa. Mar. 10, 2011); *Auto. Elec. Serv. Corp. v. Ass'n of Auto. Aftermarket Distribs.*, 747 F. Supp. 1483 (E.D.N.Y. 1990), the physician must have full and proper notice of the nature of the charges and of the evidence which will be used against him. This requirement is not limited to notice of those statements that the Board considers misinformation, but the evidence upon which it proposes to conclude that they are misinformation. Basic due process requirements apply even to a private (non-state) actors who have impacts on member property or business interests. *See for e.g. Chin v. Am. Bd. of Preventive Med., Inc.*, 2015 IL App (1st) 141625-U; *Virgin v. Am. Coll. of Surgeons*, 42 Ill. App. 2d 352, 192 N.E.2d 414 (1963). Such evidence is completely absent from the Board's Notice.

Lack of Evidence Available to the Record: In order to hold a contested consideration of a physician's credential in which he has a vested property interest, the Board must introduce evidence that the statements of concern are in fact misinformation. *Van Daele v. Vinci*, 51 Ill. 2d 389, 282 N.E.2d 728 (1972). This is provided directly in the Boards Policies and Procedures and must be followed. *Int'l Bhd. of Elec. Workers, Local No. 399 v. Zoll*, 135 Ill. App. 3d 910, 90 Ill. Dec. 627, 482 N.E.2d 446 (1985). There is no such reference to any evidence or authority whatsoever. There is therefore no evidence upon which any proceeding could find against Dr. Kory.

Lack of Ability to File a Full Response: While The Board properly provides Dr. Kory an opportunity for a "response," it does not provide him the ability to respond to the grounds

upon which the Board assumes the statements are false. He has thus been deprived of the ability to provide a proper response. *See cases cited supra.*

Evidence of Bias: The presumption that Dr. Kory's statements are so obviously misinformation that no evidence is even necessary demonstrates that the Board has prejudged the matter and is not in a position to fairly consider it.

Dr. Kory's Statements Are Clearly Within the Realm of Legitimate Debate; Evidence to the Contrary Would Have to Have Been Submitted with the Notice

As no effort has been made to provide the authorities upon which the Board proposes Dr. Kory's statements to be found to convey misinformation, until this requirement is fulfilled we are left to imagine upon what grounds the Board purports to rely. The purpose of this discussion is to make clear why such notice is critical before Dr. Kory could submit a full and proper response as well as to make it clear that his statements are part of legitimate public debate.

Public Health Agency/Association Positions: If the Board maintains, for example, that public health agencies have taken express positions contrary to Dr. Kory, it must at the very least introduce detailed evidence as to what those agencies have in fact held as their seeming certainty fades on examination. Perhaps the Board assumes his statements are incorrect given FDA's ivermectin posture even though that Agency has admittedly never conducted an inquiry into nor sees its role as assessing the safety or effectiveness of ivermectin or any other repurposed drugs in the use of COVID 19. What the Agency has done is conduct a manipulative PR campaign mischaracterizing ivermectin as an animal paste and issued messaging contrary to the drugs extensive safety record in human use in order to discourage use, as part of a campaign ostensibly targeting the use of veterinary forms though widely understood as an attack on prescribed human forms. There is no regulatory or scientific basis for that campaign and FDA is currently subject to a federal lawsuit as a result.³ No Agency process providing a basis for this posture was ever conducted and we could demonstrate in detail why it would not be responsible for the Board to rely on the FDA position if relevant.

Perhaps it is based on the CDC's Health Alert regarding the use of ivermectin which is based on inaccurate reporting about Poison Control Center calls and falsely reported hospital admissions to support a health alert that failed to mention a single instance of adverse reactions for prescribed human pharmaceuticals and on a statistical basis for concern that evaporates upon inspection. Or perhaps the Board relies on the numerous associations, such as the AMA, APhA, ASHP and others who merely echoed this advice without conducting original reviews. To all of

³ *Apter et al v. Department Of Health And Human Services et al* 3:22-cv-00184 (Filed 6/2/2022 S.D. Tex.).

these statements we could offer detailed answers but do not at this time because we have not been presented with any statement of basis whatsoever that requires a response.

Perhaps the Board relies upon the National Institutes of Health COVID-19 Panel, which is the only public health agency that has actually conducted a review process of the evidence and which does currently recommend against the use of ivermectin. While disagreement does not, by itself, constitute misinformation and that, at the very least, would require an understanding of Dr. Kory's clearly stated and caveated personal views, the Board should be aware that Dr. Kory's level of acknowledged expertise on the topic resulted not only in an invitation to speak before the NIH COVID-19 panel but in an actual change of their policy. The NIH panel met in mid-January of 2021 with Dr. Kory along with Paul Marik, M.D. (Former Division of Pulmonary and Critical Care Medicine, Eastern Virginia Medical School, Norfolk, VA) on behalf of the Frontline COVID-19 Critical Care Alliance ("FLCCC"). After and as a result of FLCCC's presentation, the NIH elevated ivermectin from its original "do not use" to a "neither recommend for or against" policy, the same policy which at the time referred to monoclonal antibodies, convalescent plasma, and other interventions we are quite certain would not lead the Board to consider sanctioning advocates for those therapies.⁴

The NIH Panel thus acknowledged, until fairly recently (i.e., during most of the time Dr. Kory was making the statements the Board seeks to hold against him) that ivermectin had potential for appropriate physician use by removing the recommendation against use by physicians. We could provide substantial detail that would be useful to the CCC for consideration if presented with a proper Notice that identified the NIH position as a basis for its proposed finding.

There are several consequences of note in the fact that NIH considered that Dr. Kory was an active participant in legitimate debate and possess a high level of expertise on these topics:

Dr. Kory's Expert Status. The Board should take note as it considers how to proceed that Dr. Kory does have internationally recognized expertise specific to the use of repurposed medications for COVID-19. He has conducted a more in-depth study of this issue than even most physicians specializing in the treatment of COVID. In a formal hearing, Dr. Kory would have a right to be admitted himself as an expert witness, *see for e.g. Va. Bd. of Med. v. Zackrison*, 67 Va. App. 461, 796 S.E.2d 866 (2017). (We note there would be many other highly qualified physicians who would be willing to give expert testimony in support.) Given this level of expertise, see attached CV, his opinions should be given serious weight and considered on their merits rather than rejected merely because they are

⁴ The Board would ideally treat situations uniformly; it states in its Policies and Procedures guide at 15 that it will act in such matters in good faith. We would hope that the Board would not position itself as picking and choosing among advocates for similarly situated grades of evidence.

inconsistent with (often misstated) public health narratives.

Continuing with NIH's position, I note that after the completion of the TOGETHER Trial, the NIH panel recommendation reverted somewhat recently and without public input to a "do not use" recommendation. That leads us into the next category of potential evidence upon which the Board, were it to provide proper notice to Dr. Kory, might attempt to rely; selected peer-reviewed, published studies or meta-studies of repurposed drugs for COVID-19.

Published Clinical Research: The TOGETHER Trial is one of the more notable and recent efforts that has been widely promoted as yielding a null result, even though its own authors noted there were potential positive signals in the data.⁵ Dr. Kory and others have published detailed critiques of the treatment protocol tested, study design, analysis of outcomes, financial conflicts of interest and other difficulties. There have, of course, been other studies and meta-studies also finding null results, though often based, as Dr. Kory has noted, upon inadequate dosing, rejection of studies using unreasonable comparator criteria or unevenly applied investigator bias ratings. Null studies are common on many commonly accepted therapeutics and this is hardly dispositive by itself.

There is a substantial body of evidence in support of Dr. Kory's positions regarding the value of ivermectin and other repurposed drugs in COVID-19. Dr. Kory has himself conducted and published peer-reviewed studies⁶ and conducted meta-studies or referenced a large body of

⁵ "Despite the negative results, the researchers did not entirely rule out the possibility that ivermectin might have a place in treating Covid. Among 90 people who were already suffering from severe Covid when they entered the trial, those who tried ivermectin appeared to fare better than did those on the placebo. But the small numbers made it impossible to draw any firm statistical conclusions about ivermectin's benefit. The effect might have been the result of chance. To investigate that result further, the researchers will keep testing ivermectin at higher doses. A new set of volunteers will receive 50 percent more of the drug in each dose and for six days instead of three." <https://www.nytimes.com/2022/06/12/health/ivermectin-covid-recovery-time.html>. Last accessed June 29, 2022). Note that the FLCCC protocol for unresolved cases is five, not three days.

⁶ In response to the allegation regarding the retraction of one of Dr. Kory's articles, originally published in *Journal of Intensive Care Medicine*, that retraction occurred as a result of an unrelated dispute that erupted into litigation with Sentara Norfolk General Hospital and not because of a valid difficulty with the paper. This can be seen in the fact that the same paper was submitted to another journal, passed peer-review despite the concerns that had been raised, and was republished as Kory, P., Meduri, G., Iglesias, J., Varon, J., Cadegiani, F., Marik, P. "MATH+" Multi-Modal Hospital Treatment Protocol for COVID-19 Infection: Clinical and Scientific Rationale. *Journal of Clinical Medicine Research*, North America, 14, feb. 2022.

peer-reviewed studies in support of these positions. See attached CV. Most of these evidentiary materials are readily available online. To conclude that this as misinformation rather than legitimate debate in the face of this level of evidence, it would seem, requires adopting the perverse view that limiting scientific debate serves a public health function. If there is evidence that his materials are inaccurate, made in bad faith or ignorance and are not part of a legitimate public debate, that evidence has not been provided to Dr. Kory.

Given just the information provided here and in Dr. Kory's response should make it clear that this is an issue of professional disagreement and legitimate debate and not one of misinformation.

Confusing Misinformation and Legitimate Debate: The Board's "False or Inaccurate Medical Information" statement begins by stating that "... ABIM recognizes the importance of legitimate scientific debate..." and acknowledges that claims of misinformation must be separated from those engaging scientifically grounded debate. That the Board appears to believe the matters raised by Dr. Kory are so well-settled as to be beyond the necessity of even citation is particularly concerning. Dr. Kory is without question a contributor to active and legitimate scientific debate and the publication record makes it clear that these matters are not settled. Either the Board may be initiating a process that is unable to distinguish between physicians who merely rely upon questionable speculation from those who have been a central participant in an important national discussion, or, of even greater concern, perhaps targeting Dr. Kory precisely because he plays an important role in this debate.

This leads to yet another legal issue that must be addressed, the standards by which disagreements can be adjudged misinformation. Managing the boundary between minority viewpoints and misinformation can be difficult under the best of circumstances, but evaluating information has been sorely tested by the pandemic. In addition to the difficulties presented by evolving clinical experience and inconsistent randomized trials, fair assessments have been hampered by financial, pharmaceutical and other interests. While consensus achieved over sufficient time and evidence is certainly valuable, that has not been achieved here.

Nature of the Standard to be Applied: The Policies and Procedures manual fairly asks for information that is "factual, scientifically grounded, and consensus driven." During the evolving situation of a pandemic, in which large-scale clinical and real-world data is being accumulated and must be assessed in the face of numerous confounding variables, a requirement for "consensus" must be approached in a fashion that does not squelch the voice of experienced physicians.

Response to Notice of Potential Disciplinary Sanction / Pierre Kory, M.D.

Alan Dumoff, Esq.

July 8, 2022

Page 8

Finally, physicians operating in the real world have to balance risks and benefits of available treatments. Little has been available for most of the pandemic, and physicians must deal with serious cases even with vaccination available. The few approved treatments, especially until very recently, have been fraught with difficulties. This must be considered as well, and if the CCC committee wishes to conclude that there are other treatments over the course of Dr. Kory's statements that were superior to and should have been used instead of therapies advocated by Dr. Kory, evidence of that fact needed to have been provided as part of the Notice as well.

In the Alternative, a Discovery Request

We believe it clear beyond doubt that the Board, should it wish to proceed, must reissue it's Notice and include the evidence it wishes to introduce. Should the Board choose to proceed in violation of its own rules we ask that it consider this letter to be a discovery request and immediately forward any and all evidence it intends to be considered by the CCC. If the Board does proceeds to act on this Notice given its defects, my client reserves all rights to recourse in the courts.

If I can assist in facilitating this matter, please do not hesitate to reach out to me.

Sincerely,

A handwritten signature in cursive script that reads "Alan Dumoff".

Alan Dumoff