STATE OF MAINE

BOARD OF OSTEOPATHIC LICENSURE

In Re Paul G. Gosselin, D. O.)	SUPPLEMENTAL MOTION
)	TO DISMISS, OR ALTERNATIVELY
Case No. CR2021-49)	FOR STAY OF PROCEEDINGS
)	

Paul G. Gosselin, D.O., by and through his undersigned attorneys, hereby moves for immediate dismissal of these Board proceedings, or alternatively for a stay of the proceedings while he pursues judicial review and relief under 5 M.R.S. § 11001. In support whereof, Dr. Gosselin states as follows:

- 1. On March 2, 2022, Dr. Gosselin filed a Motion to Dismiss these proceedings, alleging *inter alia* that they are a "bad faith prosecution".
- 2. On April 4, 2022, the Hearing Officer issued her recommendation that these proceedings not be dismissed.
- 3. On the eve of the hearing in this matter, the Board has still not ruled on the Motion to Dismiss.
- 4. On April 11, 2022, AAG Andrew Black disclosed communications received from Board Chairman Melissa Michaud, a copy of which is attached as **Exhibit A**. The communications were made in contravention of the Hearing Officer's instruction, contained in her April 13, 2022 Conference Order, that "Board members will be provided the admitted exhibits in advance of the hearing with an instruction that Board Members should not discuss the exhibits or the case with anyone, including each other or Board Staff."

5. In her unauthorized communications, Chairman Michaud states *inter alia*:

I'd like to ask our boards [sic] attorney to consider this upcoming FSMB report to be including as a state exhibit. Its [sic] the New policy on this topic which is very important in regards to this case.

Report of the FSMB Ethics and Professionalism Committee: Professional Expectations Regarding Medical Misinformation and Disinformation: https://www.fsmb.org/siteassets/communications/tab-h2-brd-rpt-22-1-misinformation.pdf

I believe its still in draft form- FSMB HOD meeting is in 3 weeks.

This is the first time that Dr. Gosselin has heard directly from the Board since its November 18, 2021 meeting, at which it decided to pursue him. The recording of that meeting revealed to Dr. Gosselin that the Board's true focus was enforcing the Federation of State Medical Boards ("FSMB") COVID-19 Misinformation Position Statement, and squelching his free speech. Five months later, Chairman Michaud is confirming that the Board's focus has not changed. The filings made in the interval, particularly the Notice of Hearing, which were carefully groomed by counsel, were meant to create the appearance of propriety.

6. Chairman Michaud's statement is a shocking disclosure with effects for the Board's case that are (or should be) catastrophic. It is a candid admission of the fundamental truth of Dr. Gosselin's allegation set forth in his Motion to Dismiss that these proceedings are a "bad faith prosecution" intended to enforce rules published by a private organization lacking any statutory authority to regulate the osteopathic profession in Maine, to harass and punish Dr. Gosselin for the exercise of his 1st Amendment protected free speech rights and physician autonomy, and by making a loud public example of him to deter others in the medical community from similar dissent.¹

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¹ Undersigned counsel have interviewed numerous Maine doctors ready to testify to the reality of the chilling effect and censorship.

- 7. Dr. Gosselin stopped writing COVID-19 vaccine medical exemption letters long ago. He offered to enter into a formal agreement to refrain from doing so in the future, but that offer was rejected. What is this case really about? Chairman Michaud's honest and straightforward communication escaped the careful screening and handling of the AAGs and Board counsel. It removes any shadow of a doubt that, while the Notice of Hearing has been carefully curated by lawyers to reference only medical exemption letters, the Board is really driven by a desire to silence Dr. Gosselin's dissent from the politically approved narratives regarding COVID-19, the COVID-19 vaccines, and alternative treatments. These proceedings are arbitrary, capricious, an abuse of discretion, and exceed the Board's statutory authority.
- 8. The FSMB Report on COVID-19 Misinformation that Chairman Michaud insists is "very important" to this case lists "Scott A. Thomas, DO, Chair, Maine Board of Osteopathic Licensure" as a member of the FSMB Professional and Ethics Committee that authored the report (see p. 14 of the FSMB Report). Further, the FSMB has separately announced on its website both Mr. Thomas' membership of its Professional and Ethics Committee, Melissa Michaud's membership of its Joint Committee with the National Commission on Certification of Physician Assistants, Maroula Gleaton's membership of the FSMB Bylaws Committee and Timothy E. Terranova's membership of the FSMB Education Committee. None of these ties was previously disclosed to Dr. Gosselin. The Osteopathic Board adopted the FSMB's COVID-19 Misinformation Position Statement on January 6, 2022. The Medical Board adopted it on November 22, 2021. The true nature and scope of these and other relationships with the FSMB remains a secret.

² Chairman of the Maine Board of Licensure in Medicine.

³ Member of the Maine Board of Licensure in Medicine.

⁴ https://www.fsmb.org/siteassets/about-fsmb/pdfs/committees.pdf.

- 9. The injury to Dr. Gosselin has been compounded by the denial of his Motion for Voir Dire and Motion for Discovery, both of which were intended, in part, to exfoliate and protect against the due process failures and constitutional violations alleged in his Motion to Dismiss. Both Motions target the Board's communications and coordination with, and the influence of, the FSMB and similar private organizations. The injury is further compounded by the bias of Board member Peter Michaud, and his refusal to recuse himself.
- 10. The administrative process in license disciplinary proceedings has been held to be inadequate as a matter of law to address bad faith prosecutions. In *Bishop v. State Bar of Texas*, 736 F.2d 292, 294 (5th Cir. Tex. 1984), the Fifth Circuit Court of Appeals held that:

Althoughdisciplinary proceedings are capable of deciding constitutional challenges to specific procedures, recourse in those proceedings is not a sufficient avenue to remedy the constitutional injury done by bad faith proceedings themselves. **The right under Shaw is to be free of bad faith charges and proceedings, not to endure them until their speciousness is eventually recognized**. Id. Citing Shaw, supra 467 F.2d at 122 n. 11 and Younger, 401 U.S. at 46, 91 S. Ct. at 751; Wilson [v. Thompson], 593 F.2d at 1375, 1382-83 [(5th Cir., 1979)] (emphasis added).

CONCLUSION

WHEREFORE, for all of the foregoing reasons, Dr. Gosselin respectfully requests that the Board immediately dismiss these proceedings, or alternatively stay them while he pursues judicial review and relief pursuant to 5 M.R.S. § 11001, and in order to avoid compounding the injustices already inflicted upon Dr. Gosselin in this case the Board must do so.

Dated this 13th day of April, 2022.

Respectfully submitted,

David Bauer

F.R. Jerkins (Maine Bar. No. 4667) 97A Exchange Street, Suite 202 Portland, Maine 04101

Telephone: (202) 361-4944 Jenkins@Meridian361.com David E. Bauer (Maine Bar No. 3609) 443 Saint John Street

Portland, ME 04102

Telephone: (207) 400-7867 david.edward.bauer@gmail.com

EXHIBIT A

Subject: FW: State's Exhibits

Date: April 11, 2022 at 9:51 AM

To: Rebekah Smith rsmith@seventreesolutions.com, F. R. Jenkins, Esq. jenkins@meridian361.com, david.edward.bauer

david.edward.bauer@gmail.com

Cc: Strout, Susan E Susan.E.Strout@maine.gov, Johnson, Katie Katie.johnson@maine.gov

Hearing Officer Smith:

We just received the email below. We have not responded to Sue and do not intend to.

Andrew L. Black | Assistant Attorney General Chief, Professional and Financial Regulation Division Office of the Maine Attorney General 6 State House Station | Augusta, ME 04333 (207) 626-8835 (direct dial) | (207) 626-8800 (main office) andrew.black@maine.gov | www.maine.gov/ag



From: Strout, Susan E <Susan.E.Strout@maine.gov>

Sent: Monday, April 11, 2022 9:45 AM

To: Black, Andrew < Andrew. Black@maine.gov>; Johnson, Katie

<Katie.johnson@maine.gov>
Subject: FW: State's Exhibits

Good Morning,

I received this from our Board Chair and told her I would pass it along to you. if I should have cc'd HO Smith, please let me know but I wasn't sure that was necessary until you'd made a determination.

Thanks, Sue

Susan E. Strout, Executive Secretary Maine Board of Osteopathic Licensure 142 State House Station Augusta ME 04333-0142

Tel: 207/446-4205 or 207/287-2480

Fax: 207/536-5811

Web: <u>www.maine.gov/osteo</u>

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AB

From: Melissa Michaud < melissa.michaudpac@gmail.com >

Sent: Saturday, April 09, 2022 7:35 AM

To: Strout, Susan E <Susan.E.Strout@maine.gov>

Subject: Re: State's Exhibits

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sue,

I'd like to ask our boards attorney to consider this upcoming FSMB report to be including as a state exhibit. Its the New policy on this topic which is very important in regards to this case.

Report of the FSMB Ethics and Professionalism Committee: *Professional Expectations Regarding Medical Misinformation and*

*Disinformation:*https://www.fsmb.org/siteassets/communications/tab-h2-brd-rpt-22-1-misinformation.pdf

I believe its still in draft form- FSMB HOD meeting is in 3 weeks.

Melissa Michaud PA-C, BS, MSPAS

On Apr 8, 2022, at 9:44 AM, Strout, Susan E < Susan.E.Strout@maine.gov wrote:

Hi,

HO Smith advises that at this point no one can ask questions or discuss anything with attorneys, other members or her.

Thanks, Sue

From: Melissa Michaud < melissa.michaudpac@gmail.com >

Sent: Friday, April 8, 2022 8:48 AM

To: Strout, Susan E < Susan.E.Strout@maine.gov >

Subject: Re: State's Exhibits

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good Morning Sue,

I would like to ask the hearing officier or attorney representing the board if there will be an additional exhibits or statements regarding the reasons for the licensee's suspension.

His license was suspended based on MRS 2591- Fraud or

deceit/incompetence/unprofessional conduct. I would like to make sure this content will be included. To me this is more about fraudulent letters, than the reasons surrounding vaccines.

Melissa Michaud

Sent from my iPad

On Apr 7, 2022, at 1:29 PM, Strout, Susan E <Susan.E.Strout@maine.gov> wrote:

Good Afternoon,

Below is a link to the Board Staff exhibits for next week. Confidential/identifying information was redacted prior to my receipt.

IMPORTANT INSTRUCTIONS FROM THE HEARING OFFICER:

These exhibits, which have been admitted by the Hearing Officer in the matter of Paul Gosselin, D.O., are being provided in advance of the hearing to facilitate your participation during the hearing. You may not discuss the exhibits, or the case, with anyone, including other Board members or Board staff, in advance of the hearing. If the exhibits are being provided electronically, you may print and mark or notate the exhibits. If you do not have paper copies, you will need to be able to review the exhibits on your device while participating in the Zoom hearing. Regardless of how you access them, you should have the exhibits available to you during the hearing. Thank you.

Any questions for the Hearing Officer must be processed through me – even if you have access to her contact information, please do not reach out to her.

Thanks, Sue

Susan E Strout, Executive Secretary Maine Board of Osteopathic Licensure 142 State House Station Augusta ME 04333-0142

REPORT OF THE BOARD OF DIRECTORS

Subject: Report of the FSMB Ethics and Professionalism Committee:

Professional Expectations Regarding Medical Misinformation and

Disinformation

Referred to: Reference Committee

The Ethics and Professionalism Committee is a standing committee of the Federation of State Medical Boards. The Committee charge, as stated in the FSMB bylaws, is to address ethical and professional issues pertinent to medical regulation.

The 2021-2022 Committee has been tasked with considering the spread of misinformation and disinformation by licensees and providing recommendations on appropriate responses by state medical boards.

In completing its charge, the Committee reviewed information about the origins of the medical misinformation seen today, including misinformation and disinformation that is generated and spread by physicians, vaccine hesitancy on the part of patients, and mistrust in medical and scientific institutions. Two Committee meetings were held where members identified key principles, themes, and issues for inclusion in a committee report that reiterates and expands upon the FSMB's statement about misinformation that was released in July 2021. A draft report was presented to committee members on January 4, 2022, for their review and feedback. Committee feedback was submitted electronically and incorporated into a revised draft.

The draft report provides background information to establish context and inform readers about the FSMB's ongoing work in this area, including the release of its statement about COVID-19 misinformation in July 2021. It then defines "Medical Misinformation," "Disinformation" and "Scientific Evidence" as key terms and explains the foundational principles that apply to sharing information in health care settings. The report then provides considerations regarding medical professionalism and misinformation before offering practice considerations for licensees regarding the conveyance of medical information and how to address misinformation from patients in a clinical setting. Finally, the report provides considerations for state medical boards when regulating the conduct of licensees who spread misinformation.

The draft report was sent to state medical boards on January 18 for their comment. The draft was also sent to all members of the Coalition for Physician Accountability, the Center for Countering Digital Hate, the CEOs of national organizations representing regulatory authorities in several other health professions and a legal expert who has advised the FSMB on constitutional considerations for state medical boards.

Feedback received during the comment period has been incorporated into a revised draft which was considered by the Executive Committee of the FSMB Board of Directors in March 2022.

ITEM FOR ACTION:

The Board of Directors recommends that:

The House of Delegates ADOPT the recommendations contained in the Report of the Ethics and Professionalism Committee: *Professional Expectations Regarding Medical Misinformation and Disinformation*, and the remainder of the Report be filed.

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INTRODUCTION

PROFESSIONAL EXPECTATIONS REGARDING MEDICAL MISINFORMATION AND DISINFORMATION

Report of the FSMB Ethics and Professionalism Committee Submitted to the FSMB House of Delegates, April 2022

Truthful and accurate information is central to the provision of quality medical care. It is instrumental for obtaining informed consent from patients and supports the trust that patients hold in the medical profession. Honesty, truthfulness and transparency are virtues that society expects of all health professionals, and they are traits that are indispensable to physicians carrying out their professional responsibilities and interacting with patients and the public. False information is harmful and dangerous to patients, and to the public trust in the medical profession, especially when licensed physicians disseminate misinformation or disinformation about a disease or illness, including its prevention, management or treatment.

Medical misinformation and disinformation have existed for centuries. However, their impact has been amplified in recent years by technology, e.g., social media, that has facilitated a growing distrust in traditional authorities, including the medical profession. This amplification has not been accompanied by any increase in accountability for those who disseminate the misinformation and disinformation. Prior to the COVID-19 pandemic, misinformation and disinformation regarding the safety and efficacy of vaccines prompted parents to refuse or delay their children receiving scheduled vaccinations, resulting in the reemergence in many parts of the United States of vaccine-preventable diseases like measles. Such misinformed decision-making causes needless harm, including deaths, and erodes the population-level immunity that is necessary to eradicate such infectious diseases.²

Inaccurate information spread by physicians can have pernicious influences on individuals with widespread negative impact,³ especially through the ubiquity of smartphones and other internetconnected devices on wrists, desktops and laptops reaching across thousands of miles to other individuals in an instant. Physicians' status and titles lend credence to their claims. The end result of physician-spread misinformation is often public confusion, 4 further eroding trust in physicians and undermining confidence in the integrity of the medical profession—causing even greater harm to public health. Dissemination of misinformation by physicians leads to harmful

¹ Vaccine Hesitancy Represents Threat to Global Health, KAISER FAMILY FOUNDATION, (Feb 01, 2019), https://www.kff.org/news-summary/vaccine-hesitancy-represents-threat-to-global-health. ² Scott C. Ratzan et al., The Salzburg Statement on Vaccination Acceptance, 24 J. OF HEALTH COMMC'N, (May

³ Carl H. Coleman, Physicians Who Disseminate Medical Misinformation: Testing the Constitutional Limits on Professional Disciplinary Action, FIRST AM. L. REV. (forthcoming 2022), at 2, ("Of particular concern is medical misinformation disseminated by licensed physicians, whose professional credibility gives their voices disproportionate weight.").

⁴ Saswato Ray, What Vaccine Misinformation Really Tells Us. HARV. POL. REV., (August 28, 2021), https://harvardpolitics.com/vaccines-social-media/

consequences in "non-pandemic" circumstances and in a pandemic can raise the stakes and magnify the harms even further, by sowing confusion and reluctance among patients to follow considered and prevailing scientific guidance.⁵

Shortly after the declaration of the COVID-19 pandemic by the World Health Organization on March 11, 2020, the FSMB's Board of Directors adopted a statement in support of the value of face masks to limit the aerosolized transmission of the SARS-CoV2 virus. "Wearing a face covering is a harm-reduction strategy to help limit the spread of COVID-19," the statement said on October 6, 2020, "especially since physical distancing is not possible in health care settings. When seeing patients during in-person clinical encounters, physicians and physician assistants have a professional responsibility to wear a facial covering for their own protection, as well as that of their patients and society as a whole." The statement was prompted by reports from a number of state medical boards receiving complaints regarding physicians and physician assistants failing to wear face coverings during patient care or casting doubt with patients and the public about their effectiveness.⁶

In May of 2021, FSMB Chair Kenneth B. Simons, MD, tasked the FSMB's Ethics and Professionalism Committee with studying the issue of physician misinformation and disinformation in order to provide comprehensive guidance to state medical boards and practicing physicians to better protect patients and promote public health. On July 28, 2021, following a recommendation of the Committee, the FSMB's Board of Directors unanimously approved another statement, this one reminding doctors of their professional responsibilities and the accountability to which they are held, and the potential consequences of activities that puts patients at risk:

"Physicians who generate and spread COVID-19 vaccine misinformation or disinformation are risking disciplinary action by state medical boards, including the suspension or revocation of their medical license. Due to their specialized knowledge and training, licensed physicians possess a high degree of public trust and therefore have a powerful platform in society, whether they recognize it or not. They also have an ethical and professional responsibility to practice medicine in the best interests of their patients and must share information that is factual, scientifically grounded and consensus-driven for the betterment of public health. Spreading inaccurate COVID-19 vaccine information contradicts that responsibility, threatens to further erode public trust in the medical profession and puts all patients at risk."

This report follows months of discussion and deliberation by the Committee and outside experts in law and ethics, and summarizes the Committee's views of misinformation and disinformation. This report offers several recommendations (listed at the end of this guidance for easy reference) for state and territorial medical and osteopathic boards (hereinafter referred to as "state medical boards") to consider as they seek to fulfill their primary and statutory mission to protect the

⁵ The U.S. Surgeon General's Advisory states unequivocally: "Health misinformation is a serious threat to public health" because it "has caused confusion and led people to decline COVID-19 vaccines, reject public health measures such as masking and physical distancing, and use unproven treatments." Vivek H. Murthy, *Confronting Health Misinformation*, OFFICE OF THE SURGEON GENERAL OF THE UNITED STATES, (2021), at 16.

⁶ Knowles H. (December 5, 2020) A doctor derided mask-wearing. His license has been suspended. *The Washington Post*, https://www.washingtonpost.com/nation/2020/12/05/doctor-steven-latulippe-license-suspended/

public, especially in the setting of a global pandemic that – despite the introduction of more than half a dozen vaccines that have helped limit disease severity and death – remains a potent threat across the United States and around the world.

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Section 1: Key Terms

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Medical Misinformation

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Health-related information or claims that are false, inaccurate or misleading, according to the best available scientific evidence at the time.⁷

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Disinformation

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Misinformation that is spread intentionally to serve a malicious purpose, such as financial gain or political advantage.⁸

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Scientific Evidence

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Information from peer-reviewed journals, methodologically-sound clinical trials, nationally or internationally recognized clinical practice guidelines, or other consensus-based documents that receive broad acceptance from the medical and/or scientific communities. Where evidence does not exist in these forms, there must still be a plausible basis in theory or prevailing and consensus-based, peer-acknowledged practice to justify any proposed treatment.

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Section 2: Principles

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Beneficence

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In providing care, proposing treatments to patients or sharing medical advice, physicians must always act in such a way that provides benefit to the patient first, without allowing competing considerations, beliefs or interests to take precedence.

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Non-maleficence

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Physicians have a duty to refrain from acting in a way that harms patients or the public.

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Physicians must remain objective and impartial in the delivery of information and in selecting or curating information that is deemed relevant to patient care and public health. If a treatment is recommended over alternatives, the recommendation must be based in scientific evidence, rather than opinion or motives that do not benefit the patient's health or that of the public. Providing treatment or treatment recommendations that could reasonably be considered below the standard of care puts patients at undue risk. This is fundamentally unjust.

⁷ Office of the U.S. Surgeon General, "A Community Toolkit for Addressing Health Misinformation," 2021.

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Autonomy

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127 128 Physicians have a professional responsibility to respect a patient's right to determine for themselves which treatments or other health decisions are in their best interests. Physicians are encouraged to guide patients towards responsible and beneficent decisions, helping to assess values and preferences, but must not allow their own biases or other non-medical considerations to influence patients' decisions regarding their health.

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While respect for patient autonomy is an essential component of the physician-patient relationship, neither the patient's autonomy, nor the physician's professional autonomy, is absolute. Only reasonable requests on the part of the patient should be granted, and only scientifically justified treatment options should be recommended by the physician.

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Professionalism

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Physicians have a responsibility to approach medical practice in an altruistic manner, placing the needs of their patients and the health of the public above their own goals or motives. This entails a duty to be honest and truthful in all patient interactions, as well as those where the physician is acting or speaking in a professional capacity. This is essential for maintaining trust within the physician-patient relationship and for maintaining society's trust in the medical profession.

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Section 3: Medical Professionalism and Misinformation

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148 149 There are several ethical arguments that support the importance of conveying truthful and accurate information to patients and the public, many of which are referenced in documents such as the American Osteopathic Association's Osteopathic Oath and the American Medical Association's Code of Medical Ethics (revised, 2017). The Declaration of Geneva, adopted by the World Medical Association in 2017, concisely outlines a physician's professional duty and ethical responsibilities.⁹

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In this modern Hippocratic Oath, physicians pledge to:

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Dedicate [their] life to the service of humanity... practice [their] profession with conscience and dignity and in accordance with good medical practice... share [their] medical knowledge for the benefit of the patient and the advancement of healthcare...and not use[their] medical knowledge to violate human rights and civil liberties, even under threat. 10

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Trust and respect are foundational for the physician-patient relationship. These qualities support the physician's duty to act in the patient's best interests and provide decisions and recommendations that aim to benefit them and keep them free from harm. Medical practice is fundamentally about caring for patients, and care cannot be provided safely without respect for

⁹ Parsa-Parsi RW. The Revised Declaration of Geneva: A Modern-Day Physician's Pledge. *JAMA*. 1971–1972 (2017);318(20).

¹⁰ *Id. supra*, note 38.

the inherent value of patients as human beings with dignity and rights. 11 Physicians, therefore, have an ethical duty to honestly inform their patients about potential illnesses and available treatment options. 12

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> Medical professionalism dictates that physicians base the care they provide on the best scientific evidence available at the time, while being truthful and transparent about the sources of their recommendations to foster trust in delivering ethical medical care. While there are gray areas in many aspects of the practice of medicine, which is inherently dynamic and constantly evolving, physicians must exercise care and ensure that any recommendations or prescriptions, especially in a fast-changing pandemic, have a compelling and evidence-based foundation in the medical literature.

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Section 4: Practice Considerations for Licensees

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Physicians regularly make commendable and heroic efforts to protect and enhance the health of their patients, which has been amply demonstrated during the COVID-19 pandemic. The intent of this policy is not to overburden physicians with new or additional requirements but to support their efforts through guidance about how best to carry out their professional responsibilities in combating misinformation and safeguarding public health.

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Conveying Medical Information

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The primary purpose for proposing treatments or conveying medical information and advice about a disease or medical condition must always be to benefit the health of the patient or public. A patient's interests must not be supplanted by the personal goals of the physician, whether they are political, economic or otherwise. Physicians have a duty to "adhere to...professional responsibilities at all times, including in situations that may seem to be outside of the traditional clinical sphere," such as when sharing medical information on social media.¹³

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When medical information is conveyed, whether in a clinical setting or in public through electronic means or otherwise, it must be based upon the best available scientific evidence. Where no such evidence exists, physicians must proceed very cautiously and only when there is a compelling rationale for the proposed treatment and justification of its use in relation to the patient's symptoms or condition. Novel, experimental or unproven interventions should only be considered and proposed when traditional, accepted and proven treatment modalities have been tried and failed. In such instances, there must still be a basis in theory or peer-acknowledged support for such practices. 14 If justification based on scientific evidence is not present, disciplinary action by a state medical board may be warranted. The use of FDA-approved drug products is permissible when such use is based upon scientific evidence or sound medical opinion. Efforts should be made to ensure that information about off-label prescribing is

¹¹ AMA Principles of Medical Ethics.

¹² ABIM Foundation, ACP-ASIM Foundation, and European Federation of Internal Medicine, Medical Professionalism in the New Millennium: A Physician Charter, Annals of Internal Medicine, 5 Feb 2002, Vol. 136, Issue 3, 243-246.

¹³ "Social Media and Electronic Communications," THE FED. STATE. MED. BD. (April 2019), https://www.fsmb.org/siteassets/advocacy/policies/social-media-and-electronic-communications.pdf ¹⁴ Federation of State Medical Boards, Policy on Regenerative and Stem Cell Therapy Practices, 2018.

independently derived, peer reviewed, scientifically sound, truthful and not misleading. 15 Offlabel prescribing of medication, ordinarily permitted by law, is not an appropriate defense or cover for rogue practices occurring without accompanying rationale or justification based in science.

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Standards of care may evolve as novel scientific discoveries occur and as new evidence becomes available. Physicians are expected to be mindful of these evolving standards and avoid making treatment recommendations based on outdated, disproven or otherwise false information.

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In crisis or emergency circumstances, as occurs in a global pandemic or other natural disaster, standards of care may need to be altered to accommodate emergent or urgent circumstances. However, a scientific basis between a condition and proposed treatment is still necessary. Even in the absence of scientific evidence, physicians must not propose treatments that present significant, foreseeable and unjustified or unacceptable risk of harm to patients.

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Patients have a right to be informed about any treatments proposed for them. Physicians have a corresponding duty to clearly convey all relevant information about their proposed treatments, their risks and benefits (including the risks and benefits of not treating them), and reasonable alternatives. Such information must be based on scientific evidence and prevailing standards of care, and duly documented in the medical record. Informed consent fails and a patient's autonomy is negated when the patient consents to a management or treatment plan that is based on misinformation or disinformation.

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Encountering and addressing misinformation in a clinical setting

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Due to the abundance of health-related misinformation that is available to patients online, on television, on radio and in print, physicians are bound to encounter misinformed patients and may face difficulties in convincing patients about the falsity of particular viewpoints regarding the efficacy of certain treatment options. It is noteworthy that public polling continues to demonstrate that doctors are among the most trusted groups 16 and can leverage and increase this trust by engaging respectfully and honestly with patients in conversations that aim to equip them with accurate information.

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244 245 When encountering misinformation in a clinical setting, physicians are encouraged to listen respectfully to their patients before reacting to the information being shared. If a patient feels dismissed when conveying a viewpoint or describing information they have received, this may encourage them to shut down and retreat to what they perceive to be a more accepting community, which may often be where they obtained such misinformation in the first place. Physicians should, therefore, respond at a level that is appropriate for the patient, acknowledge the patient's concerns and engage them in a discussion about their values and health goals. Ideally, the physician will be in a position to help the patient understand that if they value living a healthy life that is free from illness, they ought to also value treatment options that are most

¹⁵ American Medical Association Policy H-120.988: Patient Access to Treatments Prescribed by Their Physicians

¹⁶ University of Chicago Harris School of Public Policy and The Associated Press-NORC Center for Public Affairs Research.

likely to help them achieve these goals. Once a common understanding of patient goals has been established, the patient may be more open to hearing about alternative, better established treatment options from their physician.

Physicians are encouraged to anticipate these difficult conversations by being prepared with easily accessible information for conditions about which patients are frequently misinformed. Options for conveying this information can include pamphlets or handouts in outpatient settings and clinics or links to practice websites. Physicians are also encouraged to maintain their competence and become more knowledgeable of basic principles of statistics, epidemiology, and public health in order to accurately and effectively convey crucial health information to patients, particularly where there may be potential for misinformation.

In addition to requests for treatments based on misinformation, physicians are likely to receive requests from patients for medical exemptions from public health requirements, such as masking or vaccination, that may not be based in medical need. While denying such requests may result in frustrations on the part of the patient and even breakdown of the physician-patient relationship, physicians should not offer exemptions that are not based in medical need or not made within the context of an established physician-patient relationship. Physicians may also receive requests to alter medical records or death certificates in ways that would make them inaccurate, either by removing or adding a diagnosis or cause of death. Such requests violate a physician's ethical and legal duties to accurately document patient encounters or properly certify deaths and should be denied.

Section 5: Considerations for State Medical Boards

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State medical boards have long dealt with complaints about physicians related to false information, false claims of efficacy and false advertising. However, in an age where misinformation can be widely spread online in an instant to a vast number of recipients, boards can expect to receive complaints about misinformation and disinformation with increasing frequency and are encouraged to address complaints expeditiously when there is risk of immediate and widespread harm to public health. A recent survey of state medical boards by the FSMB revealed that two thirds of the 58 state medical boards who responded had seen an increase in complaints about licensees disseminating false or misleading information since the onset of the COVID-19 pandemic.¹⁷

In fulfilment of their mission to protect patients, several state medical boards have already taken disciplinary action against licensees for their role in spreading disinformation and several others are pursuing investigations, though the specifics of those ongoing investigations are not known as they are usually confidential and not made public until a disciplinary action is taken. While some of these investigations may result in further disciplinary actions, some state medical boards have faced criticism from their state government or frustrated segments of the public and media outlets because of certain actions or perception of inaction on their part.

¹⁷ Two-Thirds of State Medical Boards See Increase in COVID-19 Disinformation Complaints, Federation of State Medical Boards, (December 9, 2021), https://www.fsmb.org/advocacy/news-releases/two-thirds-of-state-medicalboards-see-increase-in-covid-19-disinformation-complaints/

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As state medical boards screen and triage complaints about misinformation and disinformation and adjudicate cases, they may have concerns about facing challenges on First Amendment grounds for disciplinary action that restricts a physician's right to speech. In the face of such concerns, the following section outlines several considerations for boards as they consider appropriate regulatory decisions.

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State Medical Practice Acts vary in the ways in which unprofessional conduct is described and by the authority afforded state medical boards to take disciplinary action against licensees for spreading disinformation. Some medical practice acts provide broad latitude to boards in describing grounds for disciplinary action that includes deceit, fraud, intentional misrepresentation, dishonesty and other similar grounds. 18 In some cases, however, boards may be limited to only considering those infractions that occur within the context of a physicianpatient relationship or only during the provision of medical care to patients. In yet other cases, the medical practice act may clearly reference conduct that is likely to "deceive, defraud, or harm the public or any member thereof." A few state statutes include language that explicitly includes conduct or speech which occurs both in private and public.²⁰

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Regardless of varying verbiage in statutes, state medical board expectations of licensees generally are the same regardless of the type of information being conveyed: "Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients."21

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Prohibitions on disseminating misinformation are already expressly written, or implied, in many state statutes regulating the practice of medicine. However, adopting a specific policy on misinformation is encouraged in light of the increased prevalence of, and harm caused by, physician-disseminated misinformation in this ongoing pandemic.

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Additional grounds for disciplinary action that could relate to the dissemination of misinformation but are not necessarily directly related to fraud or deceit could include:

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o Failure to adequately obtain informed consent by not providing adequate or truthful information to patients about proposed treatments

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o Failure to adhere to an applicable standard of care

323 324 Engaging in conduct that is likely to bring the profession into disrepute (unprofessional

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o Engaging in unethical conduct by harming the public²²

¹⁸ See, e.g., Alaska AS§ 08.64.326

¹⁹ Kentucky - KRS 311.595(9) – italics added

²⁰ See, e.g., Louisiana LRS Title 37, Chapter 15: §1285

²¹ Federation of State Medical Boards, "Position Statement on Sale of Goods by Physicians and Physician Advertising," Adopted April, 2017.

²² N.H. Rev. Stat. Ann. § 153-A:13. ("Engaging in unethical conduct including... conduct likely to deceive, defraud, or harm the public.")

 Using experimental forms of therapy without proper informed patient consent, without conforming to generally accepted criteria or standard protocols, or without proper periodic peer review of results²³

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> In assessing a licensee's alleged infraction, state medical boards may wish to consider which factors addressed in the above examples are relevant and addressed in their Medical Practice Acts as bases for imposing disciplinary action. Potential questions and considerations for the board include:

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- o Did the spread of disinformation occur during the course of provision of care or in the context of an established physician-patient relationship?
- o Did the infraction involve conduct on the part of the licensee, or speech only?
- Was the licensee acting in a professional capacity or as a private citizen?
- o Does disinformation (in public or private) indicate high likelihood that the same disinformation is being provided to patients?
- o Did the infraction result in harm to the health of the licensee's patient(s) or did it result in broader harms to the public health?
- Was demonstrable harm involved? Was it direct or indirect harm?
- o Did the licensee knowingly disseminate disinformation? That is, can intent be established?

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State medical boards may also wish to consider whether there may be options available that do not involve disciplinary action but which could help a licensee better understand the ethical basis of their duty to convey accurate information to patients and the public. It may be more effective in certain circumstances to engage licensees in conversation, provide informal and non-public notices and seek educational and remedial options, rather than proceed with disciplinary action. This approach is likely more appropriate in instances where licensees unknowingly spread misinformation without malicious intent.

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There are many ways in which physicians' speech in clinical settings and in public is already subject to reasonable restrictions. To ensure informed consent, many state laws already regulate physician speech and prohibit misinformation. Further, in the interest of patient privacy, HIPAA regulates the types of disclosures physicians can make in the clinic and in public communication. In the interest of consumer protection, the Federal Food, Drug, and Cosmetic Act (FDCA) and the Federal Tort Claims Act (FTCA) restrict health claims made in connection with advertisements for drugs and physician services; both prohibit misinformation in the commercial context.24

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²³ Federation of State Medical Boards, "Guidelines for the Structure and Function of a State Medical and Osteopathic Board,' Adopted May 2021.

²⁴ 15 U.S.C. § 45(a) (The FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce" "misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act."); 21 U.S.C.A. § 331 (THE FDCA prohibits "The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce." Misbranding includes misinformation on the label.

The dissemination of misinformation in the clinic or in public is a clear ethical violation—it endangers public health, undermines the quality of care, and damages the reputation of the medical profession. The harm is even greater when it comes to disinformation, as this implies the physician is knowingly misleading the public for personal gain. A policy which expressly prohibits physicians from disseminating misinformation or engaging in disinformation is thus a reasonable restriction on professional conduct. State medical boards are not ordinarily dissuaded from carrying out their long-held disciplinary procedures. There should not be an exception with respect to the spread of disinformation, particularly when its impact on patients and the health of the public is widespread and severe in an ongoing pandemic that has thus far taken the lives of nearly a million Americans in less than two years.

Section 6: Summary of Recommendations

State Medical Boards

 1. State medical boards are encouraged to adopt a policy that clarifies board expectations regarding the dissemination of misinformation and disinformation by licensees.

2. State medical boards must retain their legislated authority to regulate the professional conduct of licensees in order to effectively protect the public.

3. When adjudicating cases regarding misinformation and disinformation, state medical boards are encouraged to consider the full array of authorized grounds for disciplinary action in their Medical Practice Acts.

4. When appropriate, state medical boards should consider whether there are options that do not involve disciplinary action that could help a licensee understand the ethical basis of their duty to convey accurate information to patients and the public and change or remediate their behavior appropriately.

5. State medical boards should not be dissuaded from carrying out their duty to protect the public by concerns about potential challenges to disciplinary decisions when these decisions are based on sound regulatory considerations for public protection.

Licensees

 Recommendations regarding proposed or potential treatments of a medical illness or condition must be supported by the best available scientific evidence or prevailing scientific consensus.

7. In the absence of available evidence or consensus, physicians must only proceed when there is an appropriate scientific rationale and justification for a proposed treatment, in relation to the patient's symptoms or condition, and the risks and benefits of the approach are understood by the patient in an informed consent that is documented in the medical record. Novel, experimental and unproven interventions should only be proposed when traditional or accepted and proven treatment modalities have been exhausted.

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- 8. Physicians must not propose treatments that present significant, foreseeable and unjustified or unacceptable risk of harm to patients.
- 9. Physicians should be truthful and transparent about the evidential bases for their treatment recommendations, as well as the risks and benefits (including risks and benefits of not treating) and reasonable alternatives to their approach.
- 10. Off-label prescribing of medication, should be based upon scientific evidence or sound medical opinion. Efforts should be made to ensure that information about off-label prescribing is independently derived, peer reviewed, scientifically sound, truthful and not misleading.
- 11. Physicians must not offer exemptions from vaccinations or other preventive measures that are not based in medical need, nor should they acquiesce to patient requests to alter medical records or death certificates in ways that do not accurately reflect patient encounters, diagnoses or treatments.
- 12. Physicians are expected to remain current with evolving scientific evidence and practice standards, and avoid making treatment recommendations based on outdated, disproven or otherwise false information.
- 13. When confronted by misinformed patients, physicians are encouraged to listen respectfully to patients before reacting to the information being shared.
- 14. Physicians should anticipate difficult conversations with patients about controversial topics that are in the news by being prepared with current, evidence-based and easily accessible information for conditions and treatments about which patients may be misinformed.
- 15. Physicians are encouraged to maintain their competence or become knowledgeable in areas such as statistics, epidemiology and principles of public health, either through accredited continuing medical education or other appropriate means, in order to accurately and effectively convey important health information to patients, particularly where there is potential for misinformation.

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