Furman S McDonald, MD, MPH

Senior Vice President for Academic and Medical Affairs

Philadelphia, Pennsylvania, United States

258 followers · 256 connections

Join to view profile

American Board of Internal Medicine

Johns Hopkins Bloomberg School of Public Health

About

Dr. McDonald has extensive experience in Graduate Medical Education, ACGME accreditation, ABIM Certification, epidemiology, biostatistics, and medical education research. He has published more than 100 peer reviewed articles. He is a decorated clinician, educator, and scientist.

Experience

American Board of Internal Medicine

510 Walnut Street | Suite 1700 | Philadelphia, PA | 19106-3699 | 800.441.2246 | www.abim.org | request@abim.org

October 18, 2022 ABIM ID: 136084

Peter McCullough, M.D.
5231 Richard Avenue
Dallas, TX 75206

Personal and Confidential
Sent by Certified Mail

Re: Notice of Recommended Disciplinary Sanction

Dear Dr. McCullough:

The American Board of Internal Medicine (ABIM) provided you notice by letter dated May 26, 2022 (the "Notice") that ABIM's Credentials and Certification Committee (CCC) would consider whether to recommend a disciplinary sanction against you in light of public statements you made about the purported dangers of, or lack of justification for, COVID-19 vaccines.

The CCC met to consider this matter on July 26, 2022. Present for the meeting were Furman S. McDonald, M.D., M.P.H., Senior Vice President for Academic and Medical Affairs, and chair of the CCC; Richard Battaglia, M.D., FACP, Chief Medical Officer; Lorna Lynn, M.D., Vice President, Medical Education Research; Jeffrey Miller, Chief Information Officer; Michael Melfe, Director, Academic Affairs; Ruth Hafer, Credentials and Licensure Manager; Kathryn Ross, Ph.D., Research Associate; and Lauren Duhigg, Senior Research Associate. Also present were Paul Lantieri III and Emilia McKee Vassallo of Ballard Spahr LLP, counsel to ABIM.

Background

You are currently certified by ABIM in Internal Medicine and Cardiovascular Disease.

You have made numerous widely reported and disseminated public statements about the purported dangers of, or lack of justification for, COVID-19 vaccines. In March 10, 2021 testimony before the Texas Senate Committee on Health & Human Services, you stated, among other things, that there is no "scientific, clinical, or safety rationale for ever vaccinating a Covid-recovered patient," and that there is "no scientific rationale" for healthy people under 50 to receive a Covid vaccine. Testimony available at https://www.youtube.com/watch?v=QAHi3lX3oGM. Similarly, you asserted in a national television interview that "[t]here is no reason [people who have previously had COVID-19] should take the vaccine." Transcript of *Ingraham Angle*, Fox News Network, June 29, 2021.

You also have reportedly stated that as many as 50,000 Americans may have died due to Covid-19 vaccines in the first half of 2021. *See, e.g.*, D. Villareal, *7 Doctors at Anti-Vax Summit Catch COVID-19 Despite Touting Ivermectin "Treatment,"* Newsweek, Nov. 23, 2021; K. Krause, *System Sues Vaccine Skeptic*, Dallas Morning News, July 30, 2021; *Alarm Grows as Researchers Warn of Dangers of the COVID-19 Shots*, Mizzima, July 25, 2021. And in another public forum, you reportedly asserted that Covid-19 vaccines are part of "bioterrorism research." *Moscow COVID Delta Response May Shock Government Officials*, Newstex Blogs, The Duran, June 26, 2021.

American Board of Internal Medicine

510 Walnut Street Suite 1700 Philadelphia, PA 19106-3699 800.441.2246 www.abim.org request@abim.org

In addition, in a declaration submitted in support of the plaintiffs in *State of Louisiana, et al. v. Becerra*, No. 3:21-cv-03970-TAD-KDM (W.D. La.), on November 15, 2021 ("*Louisiana* Decl."), you declared – after noting your ABIM certification as part of your background (*Louisiana* Decl. ¶ 4) – that Covid-19 presents a "negligible risk for adults younger than the age of 60" (*Louisiana* Decl. ¶ 9); that "[b]ased on VAERS as of October 29, 2021, there were 18,078 COVID-19 vaccine deaths reported"; and that "COVID-19 mass vaccination is associated with at least a 39-fold increase in annualized vaccine deaths reported to VAERS" (*Louisiana* Decl. ¶ 29).

In response to the Notice, you submitted a letter dated June 14, 2022 "request[ing] prompt dismissal of the matter" or the "right to attend and personally participate and/or have legal counsel represent [you] in the ABIM Credentials and Certification Committee meeting." You included with your letter a "point-by-point declaration" responding to the Notice ("McCullough Decl."). In the McCullough Declaration, you state that you "have been a leader in the medical response to the COVID-19 disaster and have published or been listed on many publications and given testimony before various government bodies. (McCullough Decl. ¶ 5.) Among other things, you discuss and cite purported support for your views of the risks of COVID-19 vaccines (McCullough Decl. ¶ 11-33), and you make a number of statements that echo those you have previously made that are described above. For example, you state that "[t]here is negligible mortality risk [from COVID-19] for adults younger than the age of 50" and that "[t]here is no scientific rationale, medical necessity, or clinical indication for people under age 50 or 60 in general to receive a COVID-19 vaccine" (McCullough Decl. ¶ 8, and p. 18 (Conclusion ¶ 4)), and that "the COVID-19 mass vaccination is associated with at least a massive increase in deaths reported to [the Vaccine Adverse Event Reporting System (VAERS)]" (McCullough Decl. ¶ 23; *see also, e.g.*, McCullough Decl. ¶¶ 24-29 (discussing VAERS and other purported adverse event data in connection with COVID-19 vaccines).

In addition, ABIM received a letter concerning your disciplinary proceeding from United States Senator Ron Johnson, and a letter titled, "Open Letter to the American Board of Medical Specialties and the Federation of State Medical Boards: The destruction of Member Boards' credibility," dated June 26, 2022, with dozens of signatures, "condemn[ing]" the "decision to review" your board certification and others "on the frivolous grounds that they are spreading 'medical misinformation.'"

As set forth in the Notice, ABIM's "False or Inaccurate Medical Information" policy provides:

> While ABIM recognizes the importance of legitimate scientific debate, physicians have an ethical and professional responsibility to provide information that is factual, scientifically grounded, and consensus driven. Providing false or inaccurate information to patients or the public is unprofessional and unethical, and violates the trust that the profession of medicine and the public have in ABIM Board Certification. Therefore, such conduct constitutes grounds for disciplinary sanctions.

(*See* ABIM's Policies & Procedures for Certification (P&P), at p. 19. A printed copy of the P&P was provided with the Notice. The P&P is also available on ABIM's website at http://www.abim.org/about/publications/certification-guides.aspx.)

ABIM's "Disciplinary Sanction and Appeals" policy further provides that ABIM may impose disciplinary sanctions, including the suspension or revocation of board certification or

American Board of Internal Medicine

510 Walnut Street Suite 1700 Philadelphia, PA 19106-3699 800.441.2246 www.abim.org request@abim.org

participation in the certification or Maintenance of Certification processes, invalidation of an examination, or other professional sanctions, if ABIM obtains evidence that in its judgment demonstrates that a candidate or diplomate: (1) has had a license to practice medicine restricted in any jurisdiction, has surrendered a license but continues to hold a valid license in another jurisdiction, or has had one or more licenses suspended or revoked but continues to hold a valid license; (2) engaged in irregular or improper behavior or other misconduct in connection with an ABIM examination; (3) made a material misstatement of fact or omission in connection with ABIM with an application, or misrepresented their board certification or Board Eligibility status with anyone; (4) failed to maintain moral, ethical, or professional behavior satisfactory to ABIM; or (5) engaged in misconduct that adversely affects professional competence or integrity. (P&P at p. 18.)

Decision

As an initial matter, the CCC reviewed your request to participate or be represented by counsel at the meeting of the CCC. The CCC respectfully refers you to the Notice and the other information about ABIM's Disciplinary Sanction and Appeals process set forth in the P&P. The CCC considers documentary evidence and submissions, and physicians who wish to appeal CCC-recommended sanctions have the right of appeal with a hearing before a panel of physicians. (Notice at p. 3; P&P at p. 18; *see also* Appeal Rights, below.)

In its consideration of this matter, the CCC focused particularly on your statements asserting that the mortality risk of COVID-19 is "negligible" for people who are under the ages of 50 or 60, and that there is no medical reason for that population to receive COVID-19 vaccines. (*See* Background, above.) The CCC found that those statements are not factual, scientifically grounded, or consensus driven. Indeed, according to the CDC, from January 1, 2020 to October 8, 2022, more than 71,000 Americans under the age of 50 have died from COVID-19, representing nearly 8% of all deaths for that age group. Moreover, more than 194,000 Americans aged 50 to 64 have died from COVID-19, representing over 12% of all deaths in that age group during the same time period. *See* Centers for Disease Control and Prevention, COVID-19 deaths by sex, age, state, year, and months, https://data.cdc.gov/widgets/9bhg-hcku?mobile_redirect=true (updated as of Oct. 8, 2022).

The CCC also focused on your statements, purportedly relying on VAERS data, suggesting or otherwise insinuating that COVID-19 vaccines themselves have caused or been associated with tens of thousands of deaths that would not have occurred but for the vaccines. The CCC found that those statements are not supported by VAERS data or any other reliable source. Centers for Disease Control and Prevention, COVID-19, Reported Adverse Events, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (updated Oct. 12, 2022) (reporting that "severe reactions after vaccination are rare," and that "[t]he benefits of COVID-19 vaccination continue to outweigh any potential risks"); World Health Organization, Safety of COVID-19 Vaccines, https://www.who.int/news-room/feature-stories/detail/safety-of-covid-19-vaccines (March 31, 2021) (stating that "[b]illions of people have been safely vaccinated against COVID-19," that "mRNA vaccines [for COVID-19] have been rigorously assessed for safety, and clinical trials have shown that they provide a long-lasting immune response," and that "mRNA vaccines are not live virus vaccines and do not interfere with human DNA"). Your suggestions otherwise misrepresent the facts reported in VAERS. Thus, those statements are likewise not factual, scientifically grounded, or consensus driven.

American Board of Internal Medicine

510 Walnut Street | Suite 1700 | Philadelphia, PA | 19106-3699 | 800.141.2246 | www.abim.org | request@abim.org

Nothing in your declaration submitted in response to the Notice, or in the materials submitted to ABIM on your behalf, compels a different conclusion.

For these reasons, the CCC found that you have provided false or inaccurate medical information to the public. By casting doubt on the efficacy of COVID-19 vaccines with such seemingly authoritative statements, made in various official forums and widely reported in various media, your statements pose serious concerns for patient safety. Moreover, they are inimical to the ethics and professionalism standards for board certification.

In light of all the evidence and circumstances, the CCC determined to recommend that your board certifications be revoked.

Appeal Rights

The recommended revocation will become the final decision of ABIM unless you submit a request for an appeal to ABIM in writing on or before ***November 18, 2022***. If you request an appeal, your appeal would be considered by a panel designated by ABIM's Board of Directors (an "Appeal Panel"), which would hold an in-person or telephonic hearing. Appeal panels consist of three independent physicians designated by the Board of Directors, including at least one member of the Board. They have the discretion to affirm, rescind, or modify a recommended sanction, or impose an alternative sanction.

In advance of each appeal hearing, ABIM will provide you and each member of the Appeal Panel with copies of the documentary record for your sanction and appeal proceeding. In its consideration of an appeal of a recommended sanction, an Appeal Panel is not bound by any technical rules of evidence, and it considers any information timely submitted by or on behalf of the physician at any stage of the proceeding, and any other evidence that it deems appropriate.

At the hearing, you and/or your counsel may present information. Subject to the Appeal Panel's discretion, you and/or your counsel may present witnesses, provided that such witnesses were identified in your request for Appeal Panel review. ABIM's counsel may ask questions of you, your counsel, and any witnesses. The Appeal Panel, in its discretion, determines the duration of the hearing. Appeal hearings are transcribed by a professional reporter.

After reaching a decision, an Appeal Panel notifies the physician of its decision in writing. Such written decision includes the factual basis of the decision and a summary of the reason for the decision. The decision of the majority of an appeal panel is a final decision of ABIM.

If you request a hearing before the Appeal Panel, your written request must:

(i) state whether you request an in-person or telephonic hearing;

(ii) state whether you will be represented by counsel at the hearing;

(iii) identify any witnesses you intend to present on your behalf; and

(iv) include any further statement or information that you would like the Appeal Panel to consider.

American Board of Internal Medicine®

510 Walnut Street Suite 1700 Philadelphia, PA 19106-3699 800.441.2246 www.abim.org request@abim.org

If you request a hearing, ABIM will provide notice of the members of the panel and the date, time, and if applicable, place of the hearing at least forty-five days in advance of the hearing.

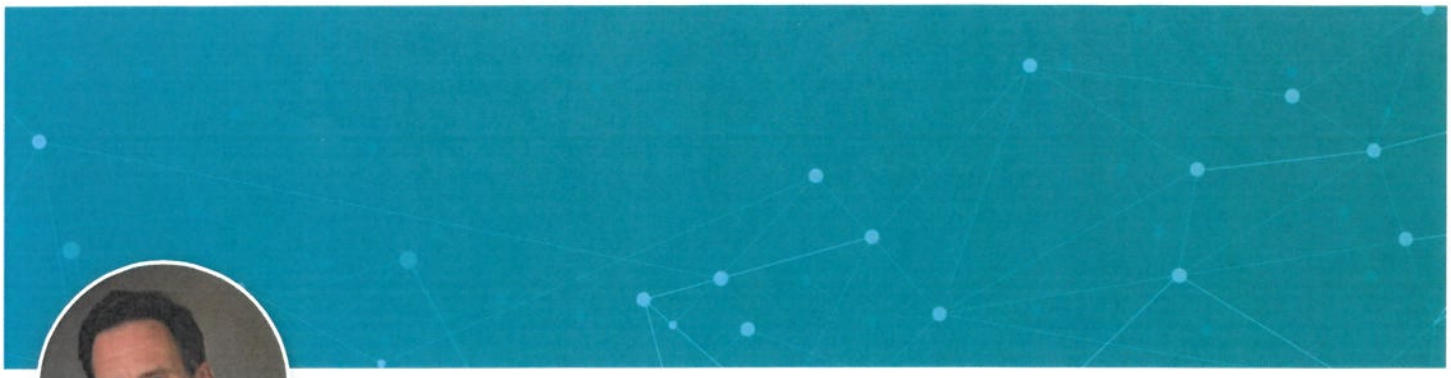
Please address any request for an appeal of the recommended sanction to ABIM at **submissions@abim.org**, and kindly include your six-digit ABIM number.

Please note that a recommended revocation is not final and does not affect your current Board Certification status.

Respectfully,

Furman McDonald

Furman S. McDonald, M.D., M.P.H.
Chair, Credentials and Certification Committee



Richard Baron

President and CEO, American Board of Internal Medicine

Philadelphia, Pennsylvania, United States

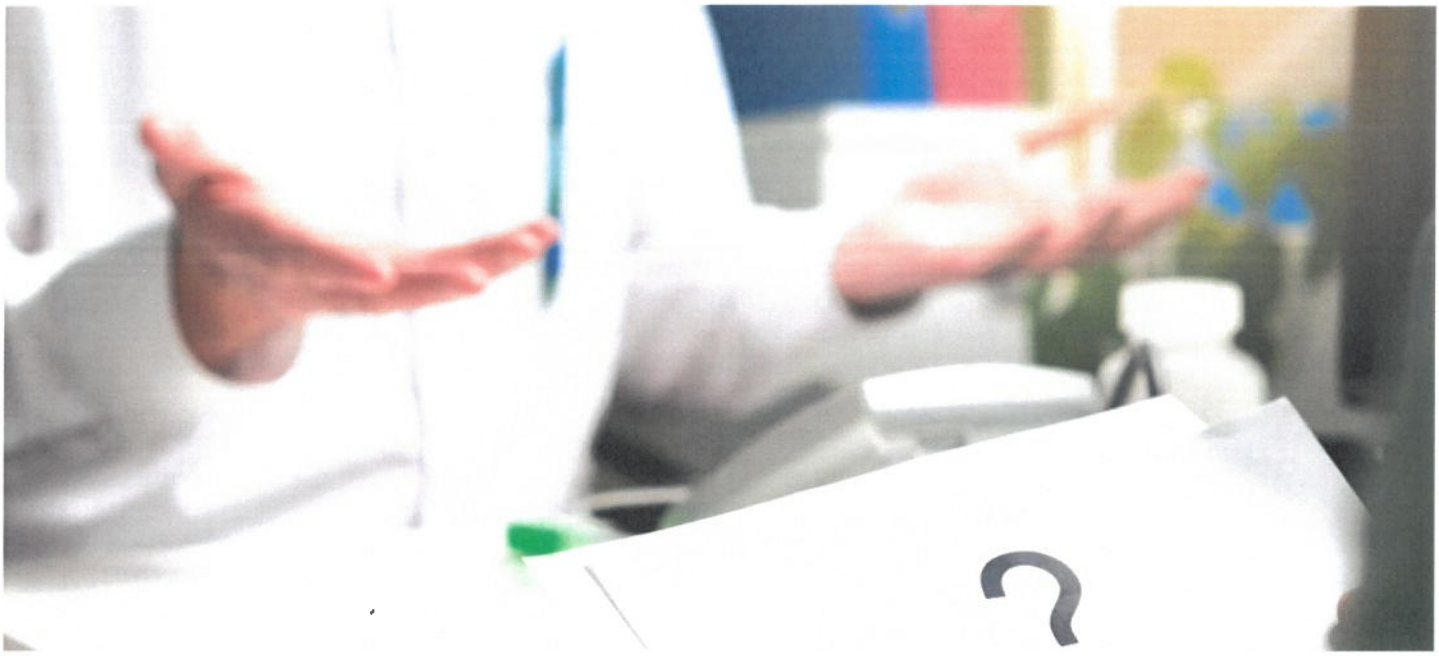
1K followers · 500+ connections

Join to view profile

American Board of Internal Medicine

Yale University School of Medicine

Articles by Richard



Combatting Medical Misinformation

May 18, 2022 | Posted by ABIM | Announcements, News

"Medicine has a truth problem." That is the opening sentence of an article published online today in *The New England Journal of Medicine*, that I coauthored with our Board Chair, Yul D. Ejnes, MD, in which we argue that there must be meaningful consequences for physicians who put patients at risk by spreading medical misinformation.

Claims – for example, that magnets can cure cancer or that children can't spread COVID-19 – that have no credible scientific evidence have caused lasting harm to the public. It is especially damaging when physicians—viewed as trusted authority figures by most people—act against the best interest of patients and the public by spreading false information. We saw medical misinformation accelerate and proliferate during the COVID-19 pandemic to a disturbing level.

The certification credential you hold differentiates you from doctors who have not demonstrated what you have demonstrated: a commitment to know and be guided by current, evidence-based practice. We have heard from many of you – especially those of you directly involved in caring for desperately ill, unvaccinated COVID-19 patients who may have relied on misinformation provided by physicians – that you want your institutions to stand up in support of the evidence-based medicine you practice and the patients you serve. And that is exactly what we are doing.

When ABIM, along with the Boards of Family Medicine and Pediatrics, issued our joint statement last fall warning against the dissemination of misinformation about COVID vaccines, you – the community – responded overwhelmingly positively, with many of you sharing appreciation that your Board was standing up and taking action. That's why we're doing this – in support of you, your colleagues and the vast majority of ABIM certified physicians who have been providing patients with the best possible care and information founded in evidence-based medicine.

And while there are not always right answers in medicine, there are certainly some answers that are clearly wrong. When physicians spread information that is clearly wrong, ABIM has a rigorous, fair and confidential disciplinary process in place to deal with unethical or unprofessional behavior.

We clarified last year that the process could be utilized to determine if the tiny minority of ABIM certified physicians that have spread medical misinformation have jeopardized their certification. More recently, I wrote about the core value of certification to the public, and the deep trust patients place in those who hold our certificate.

To help protect patients and ensure our credential represents knowledgeable, expert physicians, our organization must take meaningful steps to address the spread of false medical information on social media. Thank you for doing all you can to share evidence-based information, and for your ongoing support as we collectively try to stem the tide of misinformation causing unnecessary harm to patients.

ABIM policy on misinformation, Covid misinformation, Slider

YOU MAY ALSO BE INTERESTED IN...

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JULY 7, 2022

Physicians Spreading Misinformation on Social Media — Do Right and Wrong Answers Still Exist in Medicine?

Richard J. Baron, M.D., and Yul D. Ejnes, M.D.

Medicine has a truth problem. In the era of social media and heavily politicized science, "truth" is increasingly crowdsourced: if enough people like, share, or choose to believe something, others will accept it as true. This way of determining "truth" doesn't involve scientific methods; it relies instead on "the wisdom of crowds," which has particular power in a democratic society in which leaders and policies are chosen by the will of the group. Such choices anchor concepts like freedom and liberty. But they may not be helpful in determining whether a building will collapse, whether your brakes will stop your car — or whether a medication or vaccine works.

Growing allegiance to crowd-endorsed "facts" poses a serious challenge for the institutions and structures that the medical enterprise has developed to protect the public and ensure that people can tell who can or cannot be trusted as medical professionals or relied on for scientific knowledge. These structures include comprehensive medical education, licensure, and board certification, and leaders in all these areas are struggling to figure out how to respond to assertions by doctors on social media that are not supported by evidence and may harm patients. The Surgeon General has identified medical misinformation as a major public health threat, and many professional societies, including the American Medical Association, have called for action to combat it.

The issue of what physicians can and cannot say on social media has been hotly debated by legal scholars and in medical journals. Coleman has observed that "professional speech" is a legally contested domain between speech that can be regulated or prohibited by licensing boards and speech protected by the First Amendment. It is also unclear when physicians' speech on social media constitutes "medical practice."[1] Mello has questioned why First Amendment protections should extend to harmful speech that leads to death from preventable disease, when some other forms of speech — such as fraudulent commercial speech, which may be less harmful — are prohibited.[2]

Certifying boards — private, nongovernmental, nonprofit organizations created by the profession to issue voluntary credentials for specialist physicians — are well placed to help address the problem of false information on social media. Though many health care institutions have chosen to mandate board certification as a credential for

employment, certification — unlike a state license — is not legally required in order to practice medicine anywhere in the United States. Becoming certified by the American Board of Internal Medicine (ABIM), the largest board, in internal medicine or one of 21 subspecialties requires passing an exam. And to maintain their certificate, physicians must take and pass exams over the course of their career to demonstrate that they've kept their knowledge current. This requirement helps ensure that physicians are practicing evidence-based medicine supported by the latest peer-reviewed research, with a goal of protecting patient well-being and safety.

Creating these exams involves bringing together academic and practicing expert clinicians from a particular field to write and critique multiple-choice questions that have a single best answer — a process that may provide a useful perspective on somewhat analogous efforts to assess the information that doctors and others disseminate through informal public channels such as social media. The challenge in writing multiple-choice exam questions is not constructing a question with a right answer; rather it's creating the "distractors," the wrong but plausible answers. As anyone who has taken a multiple-choice exam knows, even someone with no knowledge of the relevant field can pass a test when the wrong answers are obviously implausible. An exam question measures something important only if someone acquainted with the field might believe the wrong answers are correct. The expert clinicians spend most of their time debating the distractors: Is that answer really wrong? If anyone around the table can find a valid article that might support the choice of option C as correct, then option C can't be used as a distractor. In these discussions, the experts are guided by peer-reviewed medical literature, not by "prevailing opinion" or what a committee member believes; they don't take polls. They accept the methods underlying scientific studies as a safer guide to practice than the received wisdom, intuition, or even "democratic process." Informed by that literature, they conclude that some answers are definitively wrong.

On July 29, 2021, the Federation of State Medical Boards (FSMB), the umbrella organization of state and territorial licensing boards, issued a policy statement that "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."[3] In September, the ABIM, along with our colleagues at the American Board of Pediatrics and the American Board of Family Medicine, issued a statement supporting the FSMB's position, saying, "We all look to board certified physicians to provide outstanding care and guidance; providing misinformation about a lethal disease is unethical, unprofessional and dangerous."[4] Also in September, the Tennessee Board of Medical Examiners adopted a policy echoing that of the FSMB, which prompted the Tennessee state legislature to pass a law in November prohibiting the licensing board from taking disciplinary action against any doctor for any treatment offered to a patient with Covid. Similar laws are now under consideration in 24 other states.[5]

The ABIM has long had a policy that unprofessional or unethical behavior can lead to revocation of an ABIM certificate. In October, we issued a policy statement making clear that "Providing false or inaccurate information to patients or the public is unprofessional and unethical, and violates the trust that the profession of medicine and the public have in ABIM Board Certification. Therefore, such conduct constitutes grounds for disciplinary sanctions." After we made this statement, we received a number of reports alleging violations of this policy by specific physicians.

Because the credential has substantial importance to our diplomates, and because we always strive for fairness and deliberation, we have a robust disciplinary sanctions and appeals process, giving ample opportunity for physicians facing sanctions to tell their side of the story and to be represented by counsel. We have used this process over the years in response to various cases of unprofessional and unethical conduct, including cheating and criminal and other activity by physicians that may or may not have triggered disciplinary action by state licensing boards. The process sometimes results in the ABIM's temporarily or permanently rescinding certification after review and consideration by panels composed of members of our professional staff and the physician's peers. We have faced — and continue to be engaged in — expensive litigation, defending the integrity of our process in court against various legal challenges. The courts have sup-

ported our right to make judgments about the certification status of physicians to whom we grant the credential.

As the ABIM confronts the danger of medical misinformation, we recognize that there are many clinical issues on which physicians legitimately hold a spectrum of opinions, all supported by evidence; such justifiable positions would not make it as "distractors" on our exam, nor would they meet our definition of "false information," as determined by experts consulting the literature. A whole range of statements with which many — or even most — physicians might disagree would therefore not trigger our disciplinary process. On the other hand, when someone certified by the ABIM says something like "the origin of all coronary heart disease is a clearly reversible arterial scurvy" or "children can't spread Covid" or "vaccines don't prevent Covid deaths or hospitalizations," we are not dealing with valid professional disagreement; we are dealing with wrong answers.

An audio interview with Dr. Baron is available at NEJM.org

With nearly 1 million Americans dead from Covid, and deaths — some of them clearly preventable — continuing at a rate of more than 200,000 per year, it has become imperative for our profession to empower our institutions to signal clearly who is — and who is not — providing evidence-based information. We physicians need to use the institutions we've created for professional self-regulation to maintain public trust by establishing some recognizable boundaries.

There aren't always right answers, but some answers are clearly wrong.

Disclosure forms provided by the authors are available at NEJM.org.

From the American Board of Internal Medicine, Philadelphia (R.J.B., Y.D.E.); and Brown University, Providence, RI (Y.D.E.).

This article was published on May 18, 2022, at NEJM.org.

1. Coleman C. License revocation as a response to physician misinformation: proceed with caution. Health Affairs Forefront, January 5, 2022 (https://www.healthaffairs.org/do/10.1377/forefront.20211227.966736/).
2. Mello MM. Vaccine misinformation and the First Amendment — the price of free speech. JAMA Health Forum 2022;3(3):e220732 (https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790169).
3. Spreading COVID-19 vaccine misinformation may put medical license at risk. Washington, DC: Federation of State Medical Boards, July 29, 2021 (https://www.fsmb.org/advocacy/news-releases/fsmb-spreading-covid-19-vaccine-misinformation-may-put-medical-license-at-risk/).
4. Newton W, Baron RJ, Nichols DG. Joint statement on dissemination of misinformation. Philadelphia: American Board of Internal Medicine, September 9, 2021 (https://www.abim.org/media-center/press-releases/joint-statement-on-dissemination-of-misinformation/).
5. Baron RJ, Emanuel EJ. Politicians should not be deciding what constitutes good medicine. Stat News, March 7, 2022 (https://www.statnews.com/2022/03/07/politicians-should-not-be-deciding-what-constitutes-good-medicine/).

DOI: 10.1056/NEJMp2204813

Institutionalizing Misinformation — The Dietary Supplement Listing Act of 2022

Pieter A. Cohen, M.D., Jerry Avorn, M.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H.

Before the Covid-19 pandemic, 58% of American adults used vitamins, minerals, botanicals, live microorganisms, or other dietary supplements to prevent or treat various conditions, including viral infections, memory loss, and heart disease.[1] Many people have similarly sought out supplements to prevent or treat Covid-19, which contributed to Americans spending an estimated $55 billion on dietary supplements in 2020.

Dietary supplements are often sold alongside over-the-counter medications, but the regulatory frameworks for these products differ substantially. Unlike over-the-counter and prescription drugs, supplements aren't vetted by the Food and Drug Administration (FDA) before being introduced, and their advertising is often deceptive.

The risks associated with supplements are real. A Centers for Disease Control and Prevention study estimated that about 23,000 emergency department visits and more than 2000 hospitalizations each year are attributed to adverse effects of dietary supplements.[2] Other investigators reported that the incidence of liver failure related to dietary supplements increased by a factor of 8 between the passage of the law currently governing these products, the Dietary Supplement Health and Education Act of 1994 (DSHEA), and 2021.[3]

Little is known about which of the tens of thousands of supplement products available for sale

false statements (oral or written) to any government agency and those related to mail and wire fraud — charges for which can be added to liability for any other fraudulent scheme that uses the mail, television, or wire communication (including email) in furtherance of the fraud. In addition, false statements made in connection with the delivery of or payment for health care benefits, items, or services and knowing and willful schemes to defraud any benefit program can be the basis of additional criminal liability.

The Department of Health and Human Services (HHS) can also levy administrative penalties against providers. These penalties include civil monetary penalties (fines based on specific conduct) and what is known in the industry as the "death penalty": exclusion. Excluded clinicians and entities are prohibited from contracting with federal health insurance programs for a set period,[3] depending on the type of violation. Other entities are barred from contracting with excluded providers for health care services; health care organizations should routinely check the list of excluded clinicians and groups to avoid entering into prohibited contracts.

An audio interview with Prof. Buck is available at NEJM.org

In recent years, the HHS Office of Inspector General (OIG) has bolstered enforcement efforts targeting fraud and abuse. For example, the Medicare Fraud Strike Force was created to focus on certain jurisdictions and types of fraud. The OIG also regularly publishes advisory opinions for providers. Areas of focus for the OIG in 2022 included nursing homes, telehealth, fraud related to Covid-19, and managed care.

The enforcement of health care fraud-and-abuse regulation has been aggressive, and statutes could be applied in a draconian manner. Prosecutorial discretion is important, and whether penalties are proportional to the fraud committed, fairly applied, and effective at preventing violations remains an open question. Increased attention and resources and ever-growing complexity in this area make it imperative that providers seek and receive solid legal advice while structuring all kinds of health care business arrangements.

The series editors are Erin C. Fuse Brown, J.D., M.P.H., Aaron S. Kesselheim, M.D., J.D., M.P.H., Debra Malina, Ph.D., Genevra Pittman, M.P.H., and Stephen Morrissey, Ph.D.

Disclosure forms provided by the author are available at NEJM.org.

From the University of Tennessee College of Law, Knoxville.

This article was published on February 18, 2023, at NEJM.org.

1. Department of Justice. Justice Department's False Claims Act settlements and judgments exceed $5.6 billion in fiscal year 2021. February 1, 2022 (https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year).
2. United States v. Lorenzo, 768 F. Supp. 1127 (E.D. Pa. 1991).
3. Centers for Medicare and Medicaid Services. Medicare fraud and abuse: prevent, detect, report. January 2021 (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Abuse-MLN4649244.pdf).

DOI: 10.1056/NEJMp2201628

Protecting the Legitimacy of Medical Expertise

Richard J. Baron, M.D., and Carl H. Coleman, J.D.

Medical licensing gives doctors something uncommon in the United States: monopoly protection precluding unlicensed people from competing to provide services. In upholding the legality of state licensing of doctors in 1889, the Supreme Court observed that because "comparatively few can judge of the qualifications of [a physician's] learning and skill," the public must rely on "the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications."[1] Licensing boards — composed largely of physicians, with some representation from the lay public — therefore have an obligation to ensure that the practitioners they license meet certain minimum standards. Additional privileges are conferred by certifying boards, which provide assurance that the specialized physicians they certify have met professionally determined standards at the end of training and over the course of their career; board certification is commonly relied on as part of hiring and privileging decisions in health care settings.

In response to the Covid-19 pandemic, however, state lawmak-

ers have embraced measures that could seriously undermine boards' ability to carry out these functions. For example, North Dakota has enacted a law prohibiting its board of medicine from disciplining physicians who dispense ivermectin for the treatment of Covid-19,[2] despite extensive evidence that use of the drug for this purpose has no beneficial effect. Legislation in Tennessee prohibits medical boards from disciplining physicians for providing any Covid-related treatment unless they are following a rule that has been approved by the state legislature.[2] Similar legislative proposals have been introduced in at least half of states.[2]

Efforts to limit the powers of licensing boards are the latest example of a larger movement to undermine the concept of expertise and the institutions that validate it. For example, the 2018 federal Right to Try Act gave patients with serious or immediately life-threatening conditions the right to request access to unapproved medications with virtually no oversight by the Food and Drug Administration (FDA). Supporters of the law argued that it was needed because the FDA's expanded-access program delayed patients' access to potentially lifesaving treatments. In reality, the FDA grants virtually all compassionate-use requests within a matter of days. It seems clear that the real motivation behind the law was to chip away at the FDA's role as a gatekeeper.

Some of the most important challenges to expertise are now coming from the judiciary. In 2022, the Supreme Court invalidated the Environmental Protection Agency's Clean Power Plan rule, which was designed to encourage power plants to shift to cleaner renewable-energy sources. Ignoring decades of precedent instructing courts to generally defer to agencies' expert determinations about how to implement their mandates, the Court held in *West Virginia v. Environmental Protection Agency* that agencies may not decide questions of "vast economic and political significance" without specific authorization from Congress. The decision is likely to substantially reduce the authority of subject-matter experts within administrative agencies.

In the context of this broader cultural attack, expertise and authority are increasingly seen as means for elites to establish and support existing hierarchies. There is, of course, some substance to this argument: although orthodox doctors may believe that their dominance and privilege are attributable to the rigor of the methods they use and that other schools of medicine were vanquished because of the superior results achieved by science-based practice, another version of the story sees the suppression of other approaches to healing (e.g., naturopathy, homeopathy, or chiropractic) as the result of ruthless actions by the American Medical Association and other forms of organized medicine. These critiques aren't new; as Lewis Grossman writes in *Choose Your Medicine*, "medical freedom" arguments have long been used to oppose institutions intended to protect consumers, such as medical licensure and the FDA.[3] The difference today is that the anti-expertise perspective has moved into the mainstream. With Google and Amazon having created a world in which people can frictionlessly obtain both information and nearly any product they want, it's not hard to portray expert gatekeepers as barriers to patients' ability to exercise choice.

Perhaps the most substantial threat to expertise is that members of the public are coming to believe that facts don't exist — that all facts are political and therefore a matter of opinion. This mindset is fundamentally incompatible with the scientific practice of medicine, which depends on a shared commitment to backing up hypotheses with empirical evidence. Indeed, modern medicine owes much of its privileged position to a broad acceptance that the methods it uses can be relied on to make medical choices that are likely to do more good than harm.

A 1902 Supreme Court case, *American School of Magnetic Healing v. McAnnulty*, offers an instructive example of what could happen if all medical facts were seen as purely matters of opinion. The American School of Magnetic Healing in Nevada, Missouri, received 3000 pieces of mail every day, largely consisting of checks, money orders, and cash to purchase the healing services that the school advertised in newspapers throughout the United States. Patients who sent payments were instructed to lie down at a specified time wherever they were, and the healers at the magnetic school would, from Nevada, channel the healing energy of the universe into their bodies to heal them.[3] The Post Office Department (which predated the Postal Service) concluded that this practice was a fraudulent operation using the mail and, after a hearing conducted by the postmaster general, stopped delivering

mail to the school. The school sued, and the case went to the Supreme Court, which found in its favor.

Writing for the Court, Justice Rufus Peckham essentially rejected the existence of medical facts. "Just exactly to what extent the mental condition affects the body," he wrote, "no one can accurately and definitely say. . . . Because the [school] might or did claim to be able to effect cures by reason of working upon and affecting the mental powers of the individual . . . who can say that it is a fraud? . . . Those who might deny the existence or virtue of the remedy would only differ in opinion from those who assert it. There is no exact standard of absolute truth by which to prove the assertion false and a fraud."[4] Although this decision was never expressly overruled, both Congress and the courts have since rejected the premise that the efficacy of treatments is purely a matter of opinion.

Differences of opinion within medicine are necessary for progress, and both licensing and certifying boards must therefore be careful to leave room for the expression of divergent views. Moreover, there is ongoing debate regarding the extent to which free-speech protections cover professional speech. But despite the existence of divergent views and areas for legitimate debate, there are some opinions that have been so thoroughly repudiated by existing evidence as to be considered definitively wrong.[5] Constructive debates are possible only within a shared epistemic framework and with a commitment to the idea of verifiable facts. It's incumbent on licensing and certifying boards to defend the existence of facts and to give the public a way to know when practitioners are making claims that are incompatible with reality.

When it comes to disciplining doctors, boards haven't always lived up to public expectations — but that's not a reason they should fall short yet again, especially during a lethal pandemic. Although there are many gray areas in medicine, some propositions are objectively wrong. For example, when a licensed physician insists that viruses don't cause disease or that Covid-19 vaccines magnetize people or connect them to cell towers, professional bodies must be able to take action in support of fact- and evidence-based practice.

The public relies on the medical profession in times of grievous vulnerability and need. For the profession to earn and maintain the public's trust — along with the privileges associated with the status of being licensed practitioners — medical boards must be able to differentiate practitioners who are providing fact-based advice from those who are not.

Disclosure forms provided by the authors are available at NEJM.org.

From the American Board of Internal Medicine and the ABIM Foundation — both in Philadelphia (R.J.B.); and Seton Hall Law School, Newark, NJ (C.H.C.).

This article was published on February 18, 2023, at NEJM.org.

1. Dent v. West Virginia, 129 U.S. 114 (1889).
2. Ollove M. States weigh shielding doctors' COVID misinformation, unproven remedies. Philadelphia: Pew Charitable Trusts, April 6, 2022 (https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/04/06/states-weigh-shielding-doctors-covid-misinformation-unproven-remedies).
3. Grossman LA. Choose your medicine: freedom of therapeutic choice in America. Oxford, UK: Oxford University Press, 2021.
4. American School of Magnetic Healing v. McAnnulty, 187 U.S. 94 (1902).
5. Baron RJ, Ejnes YD. Physicians spreading misinformation on social media — do right and wrong answers still exist in medicine? N Engl J Med 2022;387:1-3.

DOI: 10.1056/NEJMp2214120

The Princess and the He

Brendan M. Reilly, M.D.

It's just us, two old guys in the clinic after hours, so I suspect we're here for the same reason. "Evenin'," he says with a curt New England nod, then gazes down at his sensible shoes — a local guy, not one of those Gucci-loafered leaf-peepers from the city. When the elevator opens on 4, he waves me out first, like he knows where we're going but isn't sure why.

It's a good question. Teach bedside skills to first-year med students? And do it now, in the fall, when their anatomy and physiology courses have just begun? But after a long day in the classroom and labs, they'll have fun percussing and palpating a real person's belly — a "standardized" patient, tonight's "illness script" abdominal pain. They'll bumble and fumble at