2023

Disciplining Doctors: A Call for Caution When Responding to Physicians' Counter-Consensus Speech in the Time of COVID-19

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DISCIPLINING DOCTORS: A CALL FOR CAUTION WHEN RESPONDING TO PHYSICIANS' COUNTER-CONSENSUS SPEECH IN THE TIME OF COVID-19

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The COVID-19 pandemic affected nearly every aspect of life in the United States, including most notably, work-life, home-life, and community-life. During the pandemic, the government took extraordinary steps to try and reduce the spread of the disease by closing businesses, mandating the wearing of masks, and requiring vaccines. Government officials repeatedly justified their actions by

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stating that they were "following the science." However not all members of the scientific/medical community agreed with these actions. Some of these counter-consensus opinions were labeled mis/dis/mal/information.

As the COVID-19 pandemic dragged on, calls to punish doctors for COVID-19 misinformation increased. Some doctors who claimed that mask mandates were ineffective or that the vaccines did not prevent COVID-19 infections or who recommended the use of alternative methods to treat COVID-19 found themselves facing disciplinary investigations. For example, California enacted a law specifically authorizing the state medical licensing board to punish doctors for providing "COVID-19 misinformation" in the context of the doctor–patient relationship. Efforts to punish doctors for their counter-consensus opinions raise several fundamental questions: What restrictions can state medical licensing boards place on doctors' counter-consensus speech? When doctors make statements in the public square about medical controversies are their First Amendment rights different than other citizens? What is the best way to counter incorrect medical information?

Most would likely agree that doctors who make false statements for profit or recklessly provide inaccurate medical advice to patients should be subject to punishment. However, scientific and medical understanding of the COVID-19 virus and how to combat it was in constant flux. Further, scientific consensus appears to have been driven by opinions coming from the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health which suggests an intertwining of politics and medicine. The government agencies tasked with recommending how to combat the pandemic were also the primary sources of medical and scientific truth regarding the pandemic.

This article recommends caution and moderation when disciplining doctors for counter-consensus COVID-19 opinions. First, doctors should not be punished for public statements made outside of the context of the doctor–patient relationship. Punishing doctors for otherwise protected constitutional activity not only infringes on their right to free speech, but also potentially damages the public's trust in the medical community and governmental public health agencies. The better path to successfully combatting inaccurate physician information is with accurate physician information. The truth has ever been more convincing than that which is not true. Second, in the context of the doctor–patient relationship, states, hospitals, and medical associations have an obligation to protect patients and hold doctors to the appropriate medical standards. Thus, doctors can and should be disciplined when they violate their professional obligations while giving advice to patients.

This article recommends, however, caution when disciplining doctors for the advice they give to patients regarding COVID-19. As mentioned, the scientific and medical communities' understanding of COVID-19 has evolved. Opinions that were once thought to be misinformation are now more broadly accepted as true or possibly true. This article recommends an approach to disciplining doctors that analyzes four components related to medical advice or treatment: 1) harmfulness; 2) the presence of fraud, misrepresentation, or coercion; 3) whether there was full and complete informed consent; and 4) did the doctor display the degree of skill and learning employed by a reasonable doctor in a similar circumstance. By analyzing these four elements, doctors who offer earnest, well researched, counter consensus medical advice will avoid discipline, while negligent doctors, offering dangerous and scientifically unsupported opinions will be held accountable.

INTRODUCTION

During 2021, several doctors were investigated by state medical licensing boards because of statements they made regarding COVID-19 prevention and treatment.[1] The statements involved a variety of opinions addressing vaccine safety, mask mandate effectiveness, and COVID-19 treatment.[2] One group of several doctors had a complaint brought against them for publicly recommending the use of alternative treatments like ivermectin for COVID-19.[3] One doctor had

1. *See* Zaz Hollander & Annie Bergman, *Numerous Complaints Filed with State Medical Board over Doctors and Covid-19 Misinformation*, ALASKA DISPATCH NEWS (Nov. 19, 2021), https://www.adn.com/alaska-news/2021/11/19/numerous-complaints-filed-with-state-medical-board-over-doctors-and-covid-19-misinformation/ (discussing several complaints that had been filed against doctors and healthcare providers in Alaska, Oregon, and Washington who made public statements that favored the use of ivermectin to treat COVID-19 and healthcare providers who suggested that masks are ineffective against spreading COVID-19); *see also* Lauren Weber, *Doctors Who Put Lives at Risk With Covid Misinformation Rarely Punished*, WASH. POST (July 26, 2023, 6:00 AM) https://www.washingtonpost.com/health/2023/07/26/covid-misinformation-doctor-discipline/ (detailing multiple instances across the country of doctors who were punished for COVID-19 misinformation and finding "[a]t least 20 doctors nationally were penalized for complaints related to covid misinformation between January 2020 and June 2023, according to board documents . . . . Five of those doctors lost their medical licenses — one had his revoked, while four surrendered theirs."); Davey Alba & Sheera Frenkel, *Calls Grow to Discipline Doctors Spreading Virus Misinformation*, N.Y. TIMES (Aug. 27, 2021), https://www.nytimes.com/2021/08/27/technology/doctors-virus-misinformation.html (noting the growing calls among some medical groups, including the Federation of State Medical Boards, to discipline doctors who share false information such as the popular internet video involving Dr. Daniel Stock testifying before an Indiana school board claiming that COVID-19 vaccines are ineffective and that masks do not help to prevent the spread of COVID-19).

2. *See supra* note 1 and accompanying text.

3. *See* Hollander & Bergman, *supra* note 1.

a complaint brought against them for testifying before the Anchorage Assembly that the "risk of wearing a mask outweighs the benefit" and that vaccines do not prevent infections.[4] These board investigations are consistent with a statement issued by the Federation of State Medical Boards (FSMB) in July 2021.[5] The FSMB made the following statement:

> 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.[6]

Also, on September 30, 2022, Governor Gavin Newson signed a bill into law that was explicitly directed toward COVID-19 misinformation.[7] The law permits the Medical Board of California and the Osteopathic Medical Board of California to discipline doctors who "disseminate misinformation or disinformation related to COVID-19, including false or misleading information regarding the nature and risks of the virus, its prevention, and treatment; and the development,

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4. *Id.*

5. *See* Press Release, Federation of State Medical Boards, FSMB: Spreading COVID-19 Vaccine Misinformation May Put Medical License at Risk (July 29, 2021), https://www.fsmb.org/advocacy/news-releases/fsmb-spreading-covid-19-vaccine-misinformation-may-put-medical-license-at-risk/.

6. *Id.*

7. *See* Jennifer Henderson, *Bill Aimed at Disciplining Docs for COVID Misinfo Approved by California Legislature*, MEDPAGE TODAY, (Aug. 31, 2022), https://www.medpagetoday.com/special-reports/features/100471 (detailing a proposed California bill, known as Assembly Bill 2098, that would authorize the Medical Board of California or the Osteopathic Medical Board of California to take disciplinary action against any doctor who disseminates COVID-19 misinformation or disinformation to a patient in the context of a doctor-patient care relationship). An important limitation on the California bill is that it does not authorize discipline for doctors who make statements outside of the doctor-patient relationship. *See id.* ("The bill does not cover misinformation stated in a public domain, such as on social media . . . .").

safety, and effectiveness of COVID-19 vaccines."[8] The law defined misinformation as "false information that is contradicted by contemporary scientific consensus contrary to the standard of care."[9] California was the first state to pass a law directed specifically at curbing counter-consensus COVID-19 speech by doctors.[10] On October 1, 2023, California repealed the statute.[11]

Threatening to punish healthcare professionals for their counter-consensus views regarding COVID-19 raises several concerns. The combination of the FSMB statement, actions brought against the medical licenses of certain outspoken medical professionals, and California's COVID-19 Misinformation Law were a powerful disincentive to dissenting views when it comes to medical approaches to COVID-19 prevention and treatment. Further, the First Amendment is a consideration when state medical licensing boards take action against medical professionals based on their statements. Moreover, the act of punishing dissenting medical and scientific opinions has the potential to chill valid scientific inquiry and damage the trust between doctors and patients.

If California and other states are to punish doctors for mis/disinformation, who is to be the arbiter of truth? California's law described actionable misinformation as "false information that is contradicted by contemporary scientific consensus contrary to the standard of care."[12] One must ask if there has ever been a scientific or medical advancement that did not, at first, contradict contemporary scientific consensus.[13] As it stands now, it appears that governmental health agencies like the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) are the primary sources hospitals and doctors use for what is correct COVID-19 information.[14] Some hospitals have declared that their COVID-19 therapeutic protocols mirror those of the CDC and NIH.[15] Permitting the government agencies responsible

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8. CAL. BUS. & PROF. CODE § 2270 (2022).

9. *Id.* § 2270(b)(4).

10. *See* Henderson, *supra* note 7 and accompanying text.

11. *See* Jonathan Bilyk, California Quietly Repeals Covid 'Misinfo' Law that Targeted Doctors' Speech Rights, N. Cal. Record (Oct. 2, 2023), https://norcalrecord.com/stories/650040186-california-quietly-repeals-covid-misinfo-law-that-targeted-doctors-speech-rights.

12. CAL. BUS. & PROF. CODE § 2270(b)(4).

13. *See* Whole Woman's Health v. Paxton, 10 F.4th 430, 465–67 (5th Cir. 2021) (Ho, J., concurring) (discussing examples of medical advancements that are accepted today but were viewed as counter consensus when initially suggested).

14. *See infra* note 14 and accompanying text.

15. *See Following Norfolk Doctor's Lead, Other COVID-19 Patients Taking Hospitals to Court to Get Access to Ivermectin*, WTKR (Nov. 15, 2021, 10:00 AM), https://www.wtkr.com/investigations/following-norfolk-doctors-lead-other-covid-19-

for establishing and executing federal public health policy to also be the arbiters of truth when it comes to COVID-19 prevention and treatment seems flawed. The question of permitting government health organizations to determine what is "truth" is even more concerning since much of the debate regarding the response to COVID-19 has taken on a politicized, right-versus-left hue. If there are concerns about allowing the government overly broad powers to limit the speech of doctors, how are we as a society to counter inaccurate COVID-19 information? There is little doubt that there has been a great deal of unsupported "scientific/medical" information—statements like "COVID-19 is no worse than the flu;"[16] "COVID-19 vaccines will magnetize its recipients;"[17] and "the vaccines may sterilize women"[18] all currently lack factual support. So how can society and the medical community counter these sorts of statements when made by doctors? This article seeks to contend with some of these questions.

The article is divided into four sections. The first section will examine some of the major points of disagreement regarding COVID-19 prevention and treatment that have been characterized as misinformation. These points include alleged COVID-19 pandemic dis/misinformation that involves: mask mandate effectiveness, vaccine safety and efficacy, and alternative therapeutic approaches for COVID-19. This section will also discuss how these medical disputes have morphed into political disputes. The second section of the article will discuss some of the traditional mechanisms for disciplining physicians, including disciplinary actions taken at hospitals, state medical licensing boards, and independent medical organizations. The third section will examine the First Amendment

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patients-taking-hospitals-to-court-to-get-access-to-ivermectin ("In a statement sent to us Thursday, Sentara Healthcare said they follow guidance of agencies like the U.S. Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA)[—]all of which currently do not recommend the use of ivermectin as a treatment for COVID-19.").

16. Beatrice Dupuy, *Doctors Falsely Claim Coronavirus No Worse than the Flu*, ASSOCIATED PRESS (Oct. 23, 2020, 12:15 PM), https://apnews.com/article/fact-checking-9573357676.

17. Bruce Y. Lee, *Ohio Doctor Claims COVID-19 Vaccine Magnetizes People, Makes Keys Stick on Forehead*, FORBES (June 10, 2021, 2:26 AM), https://www.forbes.com/sites/brucelee/2021/06/10/ohio-doctor-claims-covid-19-vaccine-magnetizes-people-makes-keys-stick-on-forehead/?sh=4911afae2a34.

18. Mark Brody, Case No. 201841 (R.I. Dep't Health, Bd. of Med. Licensure & Discipline (Apr. 14, 2021) [hereinafter Brody Consent Order], https://health.ri.gov/discipline/MDMarkBrody.pdf (detailing an official reprimand from the medical board to a Rhode Island doctor for sending a letter to all his patients advocating they not take the vaccine because, among other claims, "there exists the possibility of sterilizing all females in the population who receive the vaccination, disrupting recipient's DNA, which controls and regulates who and what we are, and other unpredictable long term health consequences").

limitations on governmental action and how that might be applied to medical mis/disinformation and actions by state medical licensing boards. The fourth section of the article will offer suggestions for responding to counter-consensus COVID-19 pandemic information.

I. COVID-19 MIS/DIS/MALINFORMATION

The COVID-19 pandemic presented unique challenges to public health and our traditional approaches to expressive civil liberties. Our traditional approach to inaccurate information has been to rely on the marketplace of ideas.[19] Inaccurate information is overcome by accurate information and the human desire for the truth.[20] As Aristotle observed over 2000 years ago, it is easier to convince an audience of the accuracy of something that is true than something that is false.[21] But against this traditional approach are the intense challenges created by a deadly pandemic. It can rightly be asked whether during a pandemic we have the time for the marketplace of ideas to work. For over three years the world was disrupted on nearly every level. Millions died, fortunes were lost, and the world collectively waited for the next shoe to drop—when would the next variant evolve and how dangerous would it be? The disruption in the United States was a similar magnitude to war and perhaps beyond. Using CDC data current through August 8, 2023, nearly as many U.S. citizens have died from COVID-19 as service members died in all the United States involved wars since the Revolutionary War combined.[22]

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19. Jill Gordon, *John Stuart Mill and the "Marketplace of Ideas,"* 23 SOC. THEORY & PRAC. 235, 236 (1997) ("[E]veryone comes to the market with his or her ideas, and through discussion everyone exchanges ideas with one another. The ideas or opinions compete with one another, and we have the opportunity to test all of them, weighing one against the other. As rational consumers of ideas, we chose the 'best' among them.").

20. *Id.* at 238 ("Simply put, if the opinion in question might happen to be true, we benefit by allowing it to be expressed freely, thereby putting ourselves in the position of being able to exchange falsity for truth and avoid the presumption of infallibility.").

21. ARISTOTLE, ON RHETORIC: A THEORY OF CIVIL DISCOURSE 35 (George A. Kennedy trans., Oxford Univ. Press 2007).

22. *See* Megan Crigger & Laura Santhanam, *How Many Americans have Died in U.S. Wars?, News Hour*, PBS (May 27, 2019, 12:31 PM) https://www.pbs.org/newshour/nation/many-americans-died-u-s-wars (finding the total number of Americans killed in all our nation's wars, beginning with the Revolutionary War, is more than 1.1 million); *COVID Data Tracker*, CDC, https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://web.archive.org/web/20230808130831/https://covid.cdc.gov/covid-data-tracker/#datatracker-home] (last visited Aug. 8, 2023) (recording 1,136,437 COVID-19 deaths reported in the United States). *But see The Urgent Need for a National Plan to Contain the Coronavirus: Hearing Before the H. Select Subcomm. On the Coronavirus Crisis*, 116th Cong. 50 (2020) (statement of Robert R. Redfield, M.D, Director, Centers

Further, some have argued that social media, like Facebook and X (formerly Twitter), have skewed the marketplace of ideas such that fringe or unscientific theories have been able to garner a huge following.[23] Justice Arthur Goldberg famously noted that the United States Constitution "is not a suicide pact."[24] Others have observed that no constitutional protection is absolute.[25] Some might argue that the need for unity, the need for collective action (e.g., vaccination), and the need for the public to have accurate information must be prioritized over traditional approaches to freedom of speech.[26]

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for Disease Control and Prevention) (responding to questions about inflated death numbers due to financial incentives to hospitals, including an instance where the Colorado Governor had to remove 12 percent of deaths following an investigation, Dr. Redfield commented, "I think you're correct, in that we've seen this in other disease processes too . . . . I do think, though, when it comes to hospital reimbursement issues for individuals that get discharged, there could be some play in that for sure."); Chris Talgo, *Is U.S. COVID-19 Death Count Inflated?*, HILL (Sept. 3, 2020, 8:00 AM), https://thehill.com/opinion/healthcare/514915-is-us-covid-19-death-count-inflated/ (discussing the concerns around inflated death toll numbers by reporting on "several stories in which people with COVID-19 had deadly heart attacks, yet these cases were coded as COVID-19 deaths" and "a Florida man who died in a motorcycle crash happened to also have COVID-19 at the time, yet was coded as having died from COVID-19, not because of the motorcycle accident"); David Leonhardt, *A Positive Covid Milestone*, N.Y. TIMES (July 17, 2023), https://www.nytimes.com/2023/07/17/briefing/covid.html ("The official number is probably an exaggeration because it includes some people who had [the] virus when they died even though it was not the underlying cause of death. Other C.D.C. data suggests that almost one-third of official recent Covid deaths have fallen into this category. A study published in the journal Clinical Infectious Diseases came to similar conclusions.").

23. *See* Brandy Zadrozny, *YouTube, Facebook Split on Removal of Doctors' Viral Coronavirus Videos*, NBC NEWS, (Apr. 29, 2020, 12:14 PM), https://www.nbcnews.com/tech/tech-news/youtube-facebook-split-removal-doctors-viral-coronavirus-videos-n1195276 (analyzing the difficulty in "moderating high-stakes misinformation as it goes viral, especially when the source is considered an expert."). *But see* Editorial, *Fauci's Direct Line to Zuck Proves Facebook COVID Censorship Was All About Power, Not Public Health*, N.Y. POST (Sept. 9, 2022, 4:59 PM), https://nypost.com/2022/09/09/faucis-direct-line-to-zuck-proves-facebook-covid-censorship-was-all-about-power/ ("Recent filings from a lawsuit by the Louisiana and Missouri attorneys general against the Biden administration reveal that Facebook head Mark Zuckerberg gave Dr. Anthony Fauci his personal phone number shortly before the platform started to crack down on alleged COVID misinformation.").

24. Kennedy v. Mendoza-Martinez, 372 U.S. 144, 160 (1963).

25. Ruth Marcus, *Will the Supreme Court Let Texas's Latest Assault on Women's Rights Proceed?*, *Opinions*, WASH. POST (Apr. 12, 2020, 6:54 PM), https://www.washingtonpost.com/opinions/will-the-supreme-court-let-conservatives-use-the-pandemic-to-trample-abortion-rights/2020/04/12/c0b860ac-7cfc-11ea-9040-68981f488eed_story.html ("No constitutional right is absolute; the Constitution, we are told, is not a suicide pact. In a pandemic, otherwise sacrosanct rights must yield to the common good.").

26. *See* Christa Case Bryant, *Free Speech in a Pandemic: Congress Wrestles with Drawing a Line*, CHRISTIAN SCI. MONITOR (Sept. 8, 2021),

Below I will discuss some common allegations of inaccurate information regarding COVID-19. As mentioned, this alleged inaccurate information has been given a variety of descriptive terms, including misinformation, disinformation, and malinformation.[27] Each of these descriptors conveys an increasing degree of culpability.[28] Misinformation simply describes the idea of inaccurate information.[29] Disinformation has a darker meaning.[30] According to the Merriam-Webster Dictionary, disinformation means: "[F]alse information deliberately and often covertly spread (as by the planting of rumors) in order to influence public opinion or obscure the truth."[31] Disinformation is a term traditionally used when discussing military campaigns or strategic misdirection between rival countries.[32] Finally, malinformation appears to be a relatively new term used to describe "when genuine information is shared to cause harm, often by moving information designed to stay private into the public sphere."[33] Others have suggested that malinformation could be used to describe "the use of facts deliberately out of context with an intent to mislead."[34]

Although it is certainly possible that individuals, organizations, and even governments could be engaging in disinformation and malinformation regarding COVID-19, the focus of efforts to discipline doctors during the COVID-19 pandemic appears to have been on

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https://www.csmonitor.com/USA/Politics/2021/0908/Free-speech-in-a-pandemic-Congress-wrestles-with-drawing-a-line (quoting Senator Ben Ray Lujan of New Mexico, who co-sponsored a bill that would increase social media platform liability for disseminating misinformation about the pandemic, as saying, "I'm on the side of trying to save people's lives and make sure that companies are not profiting off of spreading dangerous misinformation.").

27. *See Information Campaigns and COVID-19 Vaccine Messaging: Applying Lessons Learned from the 2020 Election*, NAT'L GOVERNORS ASS'N (Aug. 3, 2021), https://www.nga.org/wp-content/uploads/2021/07/Information-Campaigns-and-COVID-19-Vaccine-Messaging-Applying-Lessons-Learned-from-the-2020-Election.pdf (analyzing the types of false information campaigns that were pervasive throughout the pandemic).

28. *Id.*

29. *Id.* ("Misinformation refers to false information shared inadvertently or without harmful intent . . . .").

30. *Id.* ("[D]isinformation refers to the deliberate creation of inaccurate information for malicious purposes . . . .").

31. *Disinformation*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/disinformation (last visited Oct. 28, 2023).

32. *See id.* (noting the first known use of the term "disinformation" was in 1939 when a writer described Nazi intelligence activities).

33. Clair Wardle, *Information Disorder: Toward an Interdisciplinary Framework for Research and Policy Making* (Council Eur. Rep. No. DGI (2017)09), Sept. 27, 2017, https://rm.coe.int/information-disorder-toward-an-interdisciplinary-framework-for-researc/168076277c.

34. *See supra* note 27 and accompanying text.

misinformation.[35] One editorial, written by Dr. Matthew K. Wynia, the Director of the Center for Bioethics and Humanities at the University of Colorado's Anschutz Medical Campus, seems to capture this sentiment.[36] Dr. Wynia's editorial compares some of the medical professionals offering counter-consensus views regarding the pandemic to snake oil salesmen.[37] The difference that Dr. Wynia suggests is that:

> [M]ore often than not, today's COVID quacks appear to believe the stories they tell. Most are not getting rich off the pandemic, and we can presume they are being honest when they claim to be frustrated by the lack of mainstream acceptance of their fringe ideas. Many have convinced themselves they are saving lives by standing up to a medical establishment they view as ignorant or corrupt.
>
> In other words, they are misguided but most are not *intentionally* hurting anyone, because their beliefs are sincere.[38]

Although the disagreements regarding COVID-19 within the medical community and broader society are many, this article specifically addresses three areas of disagreement. Those areas are: do mask mandates help to reduce the spread of COVID-19 enough to justify their use; how safe and effective are the COVID-19 vaccines; and what treatments are effective against COVID-19?

A. *To Mandate Masks or Not to Mandate Masks*

The effectiveness of mask mandates in countering the spread of COVID-19 has been, and continues to be, a matter of disagreement.[39]

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35. *See* Brody Consent Order, *supra* note 18 and accompanying text.

36. Matthew K. Wynia, *Medicine Must Sanction the COVID Quacks*, MEDPAGE TODAY (Oct. 17, 2021), https://www.medpagetoday.com/opinion/second-opinions/95085 ("When significant harms are arising due to a doctor's persistent and demonstrably false beliefs, good intentions and sincerity in holding the false beliefs no longer matter.").

37. *Id.*

38. *Id.*

39. *See* Tom Jefferson et al., *Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses*, COCHRANE DATABASE OF SYST. REV., Jan. 30, 2023. This study is sometimes referred to as the Cochrane Study. The Cochrane Study analyzed seventy-eight randomized controlled trials (RCT) to determine the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses. *Id.* at 1–2. Of the seventy-eight RCTs, six were conducted during

Right from the beginning of the pandemic, the question of mask effectiveness was front and center.[40] In February 2020, the Surgeon General of the United States tweeted the following message: "Seriously people. STOP BUYING MASKS! They are NOT effective in preventing general public from catching #Coronavirus."[41] In March

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the COVID-19 pandemic. *Id.* at 2. The authors' conclusions were that wearing masks in the community was probably not effective at reducing the spread of respiratory infection:

> We included 12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community). Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence. Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence). Harms were rarely measured and poorly reported (very low-certainty evidence).

Id.; *see also* Mark Loeb et. al, *Medical Masks Versus N95 Respirators for Preventing COVID-19 Among Health Care Workers: A Randomized Trial*, 175 ANNALS OF INTERNAL MED. 1629, 1634 (2022) ("[I]n the intention-to-treat analysis, RT-PCR-confirmed COVID-19 occurred in 52 of 497 (10.46%) [participants] in the medical mask group versus 47 of 507 (9.27%) in the N95 respirator group . . . ."); Joel Zinberg, *COMMENTARY: Do Masks Work to Stop Virus Spread?*, LAS VEGAS REV. J. (May 7, 2022, 9:00 PM), https://www.reviewjournal.com/opinion/commentary-do-masks-work-to-stop-virus-spread-2573085/ ("A recent review of the literature reported two randomized controlled clinical trials of the effectiveness of masking in COVID-19. One failed to demonstrate a statistically significant benefit. The second found small, marginally statistically significant reductions in viral transmission for surgical masks but not for cloth masks. Thirteen of 14 tests assessing mask-wearing in non-COVID respiratory infections failed to find a statistically significant benefit. Randomized controlled clinical trials are the gold standard in medical research because randomization minimizes the effect of unmeasured confounding variables and researcher bias that can occur in observational studies."). *But see How We Know Masks, Even the Cloth Ones, Reduce the Spread of COVID-19*, NEWS TRIB. (Apr. 26, 2022, 4:00 AM), https://www.newstribune.com/news/2022/apr/26/how-we-know-masks-even-the-cloth-ones-reduce-the/ (reporting on a study that showed that compared to non-mask wearers, those wearing an N95 or KN95 had an 83 percent lower positive rate, those wearing a surgical mask had a 66 percent lower positivity rate, but "[t]he impact of cloth masks . . . was not statistically significant" due to the small sample size).

40. *See* Zinberg, *supra* note 39 (noting that while the CDC and other health organizations eventually pushed for masking, "[e]arly in the pandemic, the Centers for Disease Control and Prevention, the World Health Organization, British health authorities and the European Center for Disease Prevention and Control all refrained from recommending widespread mask usage, often discouraging it.").

2020, Dr. Anthony Fauci famously stated on 60 Minutes that, for healthy Americans, masks were not necessary.[42] Less than a month later the Centers for Disease Control began recommending that masks be worn in public.[43] After the CDC began recommending masks, mask mandates were not far behind.[44] Once mask mandates were in place, the move to silence those who believed mask mandates were ineffective began.[45] Particular attention was focused on silencing

41. Leah Asmelash, *The Surgeon General Wants Americans to Stop Buying Face Masks, CNN Health*, CNN (Mar. 2, 2020, 9:38 AM), https://www.cnn.com/2020/02/29/health/face-masks-coronavirus-surgeon-general-trnd/index.html (noting Adams further informed Americans that "[w]ashing your hands, staying home when sick and other 'everyday preventive actions' are the best protections," along with getting "a flu shot, as fewer flu patients means more resources to fight the coronavirus.").

42. *60 Minutes: Covid-19, Fiona Hill, Elfstedentocht* (CBS television broadcast Mar. 8, 2020), https://www.cbs.com/shows/video/LJTjRQI4s6cYb1MJhZ9DzXrwCKM7Mw17/ ("When you're in the middle of an outbreak, wearing a mask might make people feel a little bit better and it might even block a droplet, but it's not providing the perfect protection that people think that it is."). It is important to view Dr. Fauci's comments in the context of the interview. Dr. Fauci does not recommend against wearing masks—rather, at the time of the interview, he stated it was unnecessary for healthy individuals. *Id.* Perhaps most relevant to this article's discussion is the fact that Dr. Fauci appears to question the effectiveness of masks. *Id.* That being said, even as early as March 2020, Dr. Fauci was recommending masks for health care professionals and sick individuals. *See* Brit McCandless Farmer, *March 2020: Dr. Anthony Fauci Talks with Dr. Jon LaPook About COVID-19*, CBS NEWS (Mar. 8, 2020, 7:02 PM), https://www.cbsnews.com/news/preventing-coronovirus-facemask-60-minutes-2020-3-08/ (quoting Dr. Fauci saying, "It could lead to a shortage of masks for people who really need it," in response to surge in prices as healthy people buy masks).

43. See Alexi Cohan, Timeline: Changes to CDC Mask Guidelines Since the *Pandemic Began*, BOS. HERALD (July 27, 2021, 5:54 PM), https://www.bostonherald.com/2021/07/27/timeline-changes-to-cdc-mask-guidelines-since-the-pandemic-began/ (documenting the CDC and other government officials' shift in the masking policy from general members of the public do not need them in January of 2020 to official calls and mandates for masking by July 2020).

44. *See* Kaylyn Kluck, *Northeast Tennessee County Mayors Extend Mask Mandates as COVID-19 Case Numbers Worsen*, WJHL (Aug. 3, 2020, 6:40 PM), https://www.wjhl.com/local-coronavirus-coverage/northeast-tennessee-county-mayors-extend-mask-mandates-as-covid-19-case-numbers-worsen/ (discussing four Tennessee counties extending their mask mandates beyond the expected expiration date); *see also* Amelia Schafer, *Students React to Lack of State Mask Mandate in Iowa*, SIMPSONIAN (Sept. 9, 2020), https://thesimpsonian.com/30571/news/students-react-to-lack-of-state-mask-mandate-in-iowa/ (discussing how Iowa's refusal to enforce mask mandate created confusion and concern for students returning to campus from a state like Oregon, which implemented strict mask mandates).

45. *See* Allan Smith, *Twitter Removes Tweet From Top Trump COVID-19 Adviser Saying Masks Don't Work*, NBC NEWS (Oct. 18, 2020, 3:27 PM), https://www.nbcnews.com/politics/donald-trump/twitter-removes-tweet-top-trump-covid-adviser-saying-masks-don-n1243841 ("Twitter on Sunday removed a tweet from one of President Donald Trump's top Covid-19 advisers, which falsely claimed that masks don't work to prevent the spread of coronavirus."); Joe Walsh, *Rand Paul Suspended From YouTube Over Covid Claims*, FORBES (Aug. 11, 2021, 4:31 PM), https://www.forbes.com/sites/joewalsh/2021/08/10/rand-paul-suspended-from-

doctors who asserted that masks do not work.[46] The changing guidance from the CDC and Dr. Fauci continued for two years.[47] Although the changes in mask guidance were often tied to the rise and fall of COVID-19 cases,[48] it also appeared that other non-scientific factors were influencing the guidance.[49] Particularly, Dr. Fauci suggested he did not recommend wearing masks to save protective masks for medical professionals.[50] Today, several studies support that mask mandates are effective at reducing the spread of COVID-19,[51]

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youtube-over-covid-claims/?sh=21059ba11971#open-web-0 ("YouTube said [Kentucky Senator] Paul's video [stating cloth masks don't work] violated its Covid-19 medical misinformation rules, which ban users from claiming that masks are ineffective at preventing the coronavirus from spreading.").

46. Richard A. Friedman, *We Must Do More to Stop Dangerous Doctors in a* Pandemic, Opinion, N.Y. TIMES (Dec. 11, 2020), https://www.nytimes.com/2020/12/11/opinion/scott-atlas-doctors-misinformation.html ("It's bad enough when our political leaders promote quack theories about the coronavirus and its treatment. But what do we do about the doctors who enable them and use their medical authority to promote pseudoscience? Take Scott Atlas, a former Stanford University radiologist with no training or expertise in public health or infectious diseases. As President Trump's special adviser on the coronavirus, he cast doubt on the efficacy of face masks, long after science had confirmed their efficacy. He was a staunch proponent of herd immunity — a recommendation that would almost certainly have resulted in vast mortality. And on Dec. 8, Senator Ron Johnson, Republican of Wisconsin, known for his allegiance to fringe theories, called two doctors with such beliefs to testify before his committee. One was Ramin Oskoui, a cardiologist in Washington who said that 'masks do not work' and that 'social distancing doesn't work.' In fact, there is indisputable scientific evidence that both are effective in preventing or limiting the spread of the coronavirus.").

47. *See* Deborah Netburn, *A Timeline of the CDC's Advice on Face Masks*, L.A. TIMES (July 27, 2021, 4:47 PM), https://www.latimes.com/science/story/2021-07-27/timeline-cdc-mask-guidance-during-covid-19-pandemic (detailing masking requirements' "many twists and turns since the early days of the pandemic" up through July 27, 2021).

48. *See id.* ("CDC recommends that fully vaccinated people return to wearing masks indoors in parts of the U.S. where the coronavirus is surging.").

49. *See infra* note 49 and accompanying text.

50. Victor Davis Hanson, *The Ignoble Lie*, INDEP. INST. (Nov. 1, 2021), https://www.independent.org/news/article.asp?id=13839 ("Fauci said he misled the country about mask-wearing during the pandemic by claiming they were of little use. But he argued that he lied in order that the public not make a run on masks, deplete the supply, and thus rob medical professionals of protective equipment. Fauci also told "noble" lies about the likely percentage of the public needing to be vaccinated to achieve herd immunity. He kept raising the bar—from 60-70 percent to 75-80 percent, to 85 percent. Apparently, Fauci feared a lower figure, even if accurate, might lull people into complacency about getting inoculated. Fauci also lied about his own role in routing U.S. aid money to subsidize gain-of-function viral research at the Wuhan virology lab—the likely birthplace of COVID-19.").

51. *See* Jeremy Howard et al., *An Evidence Review of Face Masks Against COVID-19*, 118 PROC. NAT'L ACAD. SCI. U.S., Jan. 11, 2021, at 9 ("Models suggest that public mask wearing is most effective at reducing spread of the virus when compliance is high."); Jerry T. J. Ju et al., *Face Masks Against COVID-19: Standards, Efficacy,*

while other studies, including a meta analysis by the highly respected Cochrane Library,[52] suggest that mask mandates have little or no impact on the spread of COVID-19.[53]

B. *The Wisdom of Vaccination*

Perhaps the most contentious medical issue during the pandemic was related to vaccination.[54] The politicization of the debate over

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Testing and Decontamination Methods, 292 ADVANCES IN COLLOID & INTERFACE SCI., Apr. 27, 2021, at 16 ("Despite their shortcomings, community-based research has demonstrated the efficacy of cloth masks in slowing down the spread of COVID-19.").

52. *See* Tom Jefferson et al., *supra* note 39 and accompanying text.

53. *See* Bret Stephens, *The Mask Mandates Did Nothing. Will Any Lessons Be Learned?*, *Opinion*, N.Y. TIMES (Feb. 21, 2023), https://www.nytimes.com/2023/02/21/opinion/do-mask-mandates-work.html ("The most rigorous and comprehensive analysis of scientific studies conducted on the efficacy of masks for reducing the spread of respiratory illnesses — including Covid-19 — was published late last month. Its conclusions, said Tom Jefferson, the Oxford epidemiologist who is its lead author, were unambiguous. 'There is just no evidence that they' — masks — 'make any difference,' he told the journalist Maryanne Demasi. 'Full stop.' But, wait, hold on. What about N-95 masks, as opposed to lower-quality surgical or cloth masks? 'Makes no difference none of it,' said Jefferson. What about the studies that initially persuaded policymakers to impose mask mandates? 'They were convinced by nonrandomized studies, flawed observational studies.' What about the utility of masks in conjunction with other preventive measures, such as hand hygiene, physical distancing or air filtration? 'There's no evidence that many of these things make any difference.'"); *see also* Zinberg, *supra* note 39; Steve Scauzillo, *Mask Mandate Didn't Work Against COVID-19 in LA, Say Doctors from USC and UCLA*, L.A. DAILY NEWS (Aug. 15, 2022, 5:45 AM), https://www.dailynews.com/2022/08/13/doctors-from-usc-ucla-say-mask-mandates-for-covid-19-not-effective-as-mask-debate-goes-on/ (detailing a letter requesting an end to mask mandates sent from top doctors in California to Los Angeles County's Board of Supervisors citing "the county's statistics, and studies in Europe and some U.S. states, showing that after mask mandates were imposed, transmission of COVID-19 did not slow down."); Scott Balsitis et al., *Bringing Back a Mask Mandate in Los Angeles County is Unjustified*, ORANGE CNTY. REG. (July 22, 2022, 6:24 PM), https://www.ocregister.com/2022/07/22/bringing-back-a-mask-mandate-in-los-angeles-county-is-unjustified/ ("Exhaustive tracking of in-school COVID spread was indistinguishable with and without student mask use in studies in Spain, a conclusion repeated in two separate COVID waves. Studies of student masking with control groups in Georgia, North Dakota, Finland and the UK have all found the same lack of clear benefit. One randomized controlled trial showed no significant benefit to the mask wearer, and a second randomized trial found a slight benefit (and only in older adults) that was not reproduced with a different analysis of the same data.").

54. *See* Katie Camero, *UCLA Doctor 'Willing to Lose Everything' Escorted From Work For Refusing COVID Vaccine*, SACRAMENTO BEE (Oct. 10, 2021, 8:34 AM), https://www.sacbee.com/news/coronavirus/article254829122.html (detailing a doctor being escorted out of the hospital for refusing California's requirement that "all health care workers in California are required to have received their second shot of the two-dose Pfizer or Moderna vaccines, or the one-dose Johnson & Johnson vaccine, by [September 30, 2021].").

vaccines was nearly immediate.[55] During his presidency, Donald Trump celebrated Operation Warp Speed[56] as a historic achievement and after leaving office he encouraged the public to get vaccinated and boosted.[57] President Biden suggested that getting vaccinated was a patriotic duty.[58] During the 2020 presidential campaign, candidates including Vice President Joseph Biden and Senator Kamala Harris raised concerns that the Trump administration was rushing the vaccine to the public.[59] According to then-candidate Biden:

> Americans have had to endure President Trump's incompetence and dishonesty when it comes to testing and personal protective equipment. We can't afford to repeat those fiascos when it comes to a vaccine. . . . Let me be clear, I trust vaccines. I trust scientists. But I don't trust Donald Trump, and at this moment, the American people can't either.[60]

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55. *See* Dr. Joel Zinberg, *It Seems Clear Dems Pressured the FDA to Delay the COVID Vaccine to Hurt Trump*, N.Y. POST (Sept. 13, 2022, 10:14 AM), https://nypost.com/2022/09/12/it-seems-clear-dems-pressured-the-fda-to-delay-the-covid-vaccine-to-hurt-trump/ (asserting the delays and push to release the COVID vaccine until directly after the 2020 presidential election was directly tied to Democrats and the FDA seeking to hamper President Trump's reelection efforts).

56. *Remarks by President Trump at the Operation Warp Speed Vaccine Summit*, NAT'L ARCHIVES (Dec. 8, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-operation-warp-speed-vaccine-summit/#:~:text=And%20we%20were%20very%2C%20very,in%20this%20extraordin ary%20American%20initiative ("Before Operation Warp speed, the typical timeframe for development and approval, as you know, could be infinity. And we were very, very happy that we were able to get things done at a level that nobody has ever seen before. The gold standard vaccine has been done in less than nine months.").

57. *See* Meridith McGraw, *Trump Encourages Americans to Get the Covid Vaccine*, POLITICO (Mar. 16, 2021, 8:42 PM), https://www.politico.com/news/2021/03/16/trump-americans-covid-vaccine-476479 (detailing Former President Trump's interview with Maria Bartiromo on Fox News where he recommended Americans get the vaccine and that it was safe to do so).

58. *See* Sheryl Gay Stolberg, *Former Biden Advisers Urge a Pandemic Strategy for the 'New Normal'*, N.Y. TIMES (JAN. 6, 2022), https://www.nytimes.com/2022/01/06/us/politics/former-biden-advisers-pandemic-strategy.html (quoting President Biden encouraging Americans to get vaccinated by saying, "I honest to God believe it's your patriotic duty.").

59. *See* Kendall Karson et al., *Biden: 'I Trust Vaccines. I Trust Scientists. But I Don't Trust Donald Trump'*, ABC NEWS (Sept. 16, 2020, 6:11 PM), https://abcnews.go.com/Politics/biden-speak-vaccine-politics-center-stage-process/story?id=73047767 ("[Kamala] Harris has also said flatly that she would not take Trump's word on the safety and efficacy of a COVID-19 vaccine.").

60. *Remarks by Vice President Joe Biden After a Vaccine Briefing in Wilmington, Delaware*, AM. PRESIDENCY PROJECT (Sept. 16, 2020), https://www.presidency.ucsb.edu/documents/remarks-vice-president-joe-biden-after-vaccine-briefing-wilmington-delaware.

Although candidates Joseph Biden and Kamala Harris made clear they broadly trusted vaccines and scientists, they suggested that the Trump administration's lack of transparency raised concerns about the safety or effectiveness of the COVID-19 vaccine.[61] Within months of being elected the shoe was on the other foot and it was the transparency of the Biden administration that was being questioned.[62] Less than a year after being elected, the Biden administration's FDA asserted in court documents that it needed fifty-five years before responding fully to a Freedom of Information Act (FOIA) request regarding COVID-19 vaccine data.[63] A short time later, the FDA sought to extend that delay by another twenty years.[64]

The COVID-19 vaccination debate added heat to the long-simmering controversy involving the relationship between childhood vaccinations and autism.[65] Thus, stark lines of division were already present even before COVID-19 was a household word. These lines of division had well-established labels—anti-vaxxers on one side and Big Pharma on the other.[66] The title anti-vaxxer carried with it an anti-

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61. *See* Alice Miranda Ollstein, *On Coronavirus Vaccines, Biden Says He'll Trust Scientists, Not Trump*, POLITICO (Sept. 16, 2020, 6:42 PM), https://www.politico.com/news/2020/09/16/joe-biden-coronavirus-vaccine-trump-416420 (quoting then-Vice President Biden calling for "'total transparency' from the drug companies developing the vaccine and the rank-and-file scientists at the [FDA] and the [CDC] so that the public can vet political officials' claims."); *see also* Karson et al., *supra* note 59 and accompanying text.

62. *See* Jenna Greene, *Wait What? FDA Wants 55 Years to Process FOIA Request over Vaccine Data*, REUTERS (Nov. 18, 2021, 4:31 PM), https://www.reuters.com/legal/government/wait-what-fda-wants-55-years-process-foia-request-over-vaccine-data-2021-11-18/ (noting if the FDA is granted fifty-five years to release FOIA information, "plaintiffs Public Health and Medical Professionals for Transparency can expect to see the full record in 2076.").

63. *Id.*

64. *Compare* Greene, supra note 62 and accompanying text toJenna Greene, *'Paramount Importance': Judge Orders FDA to Hasten Release of Pfizer Vaccine Docs*, REUTERS (Jan. 7, 2022, 12:51 PM), https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/ (noting that a ruling by a Texas District Court Judge accelerating the FDA's FOIA document release timeline means "all the Pfizer vaccine data should be public by the end of the summer rather than, say, the year 2097.").

65. *See Discussing Vaccines and Autism*, SW. AUTISM RSCH. & RES. CENT., https://www.autismcenter.org/discussing-vaccines-and-autism (last visited Nov. 10, 2022) ("Some parents of children with ASD wonder whether a link exists between autism and vaccines. The concern first started with the MMR vaccine, an immunization against measles, mumps, and rubella. Some parents believe this vaccine causes the onset of autism.").

66. *See* Soumya Karlamangla, *Once Known for Vaccine Skeptics, Marin Now Tells Them 'You're Not Welcome'*, N.Y. TIMES (Oct. 2, 2022), https://www.nytimes.com/2022/10/02/us/covid-vaccine-marin-california.html ("For more than a decade, few places in the nation were associated with anti-vaccine

science/flat earth connotation.[67] The popular view of an anti-vaxxer suggests an uneducated person who is irresponsibly putting the rest of the population at risk by allowing themselves or their children to be a vector for a dangerous disease.[68] Big Pharma, on the other hand, describes a corporate monolith that has extended its influence into doctor's offices, media outlets, and political bodies.[69] The recent catastrophes involving large pharmaceutical companies like Pfizer, Merck, Johnson & Johnson, and others linked to the opioid epidemic and medications like Vioxx, supported the narrative that Big Pharma was not to be trusted.[70]

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movements as much as Marin County . . . a highly educated, affluent community with low childhood vaccination rates, driven by a contingent of liberal parents skeptical of traditional medicine."); *see also infra* note 65 and accompanying text.

67. John P. Moore, *Op-Ed: The Anti-vax Movement Was Already Getting Scary. COVID Supercharged It*, L.A. TIMES (Feb. 25, 2022, 3:00 AM), https://www.latimes.com/opinion/story/2022-02-25/covid-anti-vax-childhood-vaccination-measles-mumps ("The anti-vax movement has never been based on science. . . . They claim that any opposition to their propaganda must be proof of 'deep state' or 'big pharma' corruption of science and public policy. It's a tired playbook, but it resonates with people whose psychological states leave them susceptible to believing conspiracy theories. One study found that people who believe '9/11 truther' theories are more likely than average to also believe COVID-19 vaccines are dangerous.").

68. *See* Paul Krugman, *What To Do With Our Pandemic Anger, Opinion*, N.Y. TIMES (Feb. 7, 2022), https://www.nytimes.com/2022/02/07/opinion/covid-unvaccinated-anger.html ("[T]hose who refuse to take basic COVID precautions [including mask wearing and vaccinations] are, at best, being selfish — ignoring the welfare and comfort of their fellow citizens. At worst, they're engaged in deliberate aggression — putting others at risk to make a point."); Andrea Stanley, *People Are Hiding That Their Unvaccinated Loved Ones Died of COVID*, ATLANTIC (Jan. 18, 2022), https://www.theatlantic.com/family/archive/2022/01/unvaccinated-covid-deaths-secret-grief/621269/ (discussing how compassion online for COVID victims has now turned to vitriol and scorn in the wake of the vaccine roll out).

69. *See* Abbey Meller & Hauwa Ahmed, *How Big Pharma Reaps Profits While Hurting Everyday Americans*, CTR. FOR AM. PROGRESS (Aug. 30, 2019), https://www.americanprogress.org/article/big-pharma-reaps-profits-hurting-everyday-americans/ ("The pharmaceutical industry leverages Washington's culture of corruption to increase profits while everyday Americans suffer from high drug prices.").

70. *See* Lena Groeger, *Big Pharma's Big Fines*, PROPUBLICA (Feb. 24, 2014), https://projects.propublica.org/graphics/bigpharma (documenting major settlements among eleven leading pharmaceutical companies showcasing that these companies have "agreed to pay over $13 billion to resolve U.S. Department of Justice allegations of fraudulent marketing practices"); *see also* Brian Mann, *4 U.S. Companies Will Pay $26 Billion to Settle Claims They Fueled the Opioid Crisis*, NPR (Feb. 25, 2022, 7:39 AM), https://www.npr.org/2022/02/25/1082901958/opioid-settlement-johnson-26-billion ("This settlement resolves thousands of civil lawsuits filed against the companies beginning in 2014 by local and state governments as well as Native American tribes nationwide.").

During the pandemic, a majority of the medical community has agreed that the COVID-19 vaccines are safe and effective,[71] while a smaller, and sometimes vocal, group of physicians has disagreed.[72] This aspect of the COVID-19 response controversy has often been cast in binary terms—the shots are either a universal good or a universal bad.

Time and study have softened some of the bright lines of the debate. In January 2023, the CDC recommended all individuals over the age of six months be vaccinated.[73] However, some doctors have

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71. *See AMA Covid-19 Guide: Background/Messaging on Vaccines, Vaccine Clinical Trials & Combatting Vaccine Misinformation*, AM. MED. ASS'N, Winter 2021, at 1, https://www.ama-assn.org/system/files/2021-02/covid-19-vaccine-guide-english.pdf (establishing clear, direct guidance, data, and talking points for physicians to promote the "safety and efficacy of COVID-19 vaccines as they become available for public use" to both the media and patients); Nirbachita Biswas et al., *The Nature and Extent of COVID-19 Vaccination Hesitancy in Healthcare Workers*, 46 J. CMTY. HEALTH 1244, 1245 (Apr. 20, 2021) ("The prevalence of COVID-19 vaccination hesitancy worldwide in healthcare workers ranged from 4.3 to 72% (average rate of 22.51% . . . across [all] studies with [76,471] participants."). Vaccine safety, efficacy, and potential side effects were top reasons for COVID-19 vaccination hesitancy in healthcare workers. *Id.* at 1249.

72. *See* Peter McCullough, M.D., *Dr. McCullough with Sara Gonzales, Blaze Media: Perfidious Vaccination Tactics*, RUMBLE (July 27, 2022), https://rumble.com/v1dv5on-dr.-mccullough-with-sara-gonzales-blaze-media-perfidious-vaccination-tactic.html (questioning the safety and efficacy of the COVID vaccine); *Newsmax Medical Guests Tell Viewers Not to Take the COVID-19 Vaccines, Saying They're Ineffective and Unsafe*, MEDIA MATTERS FOR AM. (June, 15, 2022, 10:03 AM), https://www.mediamatters.org/newsmax/newsmax-medical-guests-tell-viewers-not-take-covid-19-vaccines-saying-theyre-ineffective ("We should decline all boosters at this point in time, drop all mandates . . . the data on the vaccines . . . are so terrible and the fact that there are still mandates in place — the science has long departed from any rationale for continuing this vaccine campaign."). *But see* Berkeley Lovelace, Jr., *Myocarditis After Covid Vaccination: Research on Possible Long-Term Risks Underway*, NBC NEWS (Nov. 12, 2022, 7:00 AM), https://www.nbcnews.com/health/health-news/myocarditis-covid-vaccine-research-long-term-effects-rcna55666 ("Both Pfizer and Moderna are launching clinical trials to track health issues — if any — in the years following a diagnosis of vaccine-associated heart problems in teens and young adults.").

73. *See Stay Up To Date With Vaccines,* CDC (Sep. 15, 2023), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html [https://web.archive.org/web/20230917052315/https://www.cdc.gov/coronavirus/20 19-ncov/vaccines/stay-up-to-date.html] (recommending everyone stay up to date with COVID-19 vaccination, including all primary series doses and boosters for their age group which includes one updated dose for everyone aged 5 years and older if it has been at least 2 months since their last dose, and for children aged 6 months–4 years who completed the Moderna primary series and if it has been at least 2 months since their last dose); Lauren Gardner, *CDC Advisors Recommend Adding Covid Shots to Routine Immunization Schedules for Kids, Adults*, POLITICO (Oct. 20, 2022, 1:51 PM), https://www.politico.com/news/2022/10/20/cdc-advisers-recommend-adding-covid-shots-to-routine-schedules-for-kids-adults-00062739 ("The CDC's independent vaccine advisers voted 15-0 Thursday to add most

come to question the wisdom of COVID-19 vaccination for the young.[74] A recent article by doctors from several medical schools and universities argues against mandated booster vaccinations of college-age adults.[75] According to the authors, based on CDC data,

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COVID-19 vaccines offered in the U.S. to the childhood, adolescent and adult immunization schedules.").

74. *See* Jon Miltimore, *England Refuses to Offer COVID Shots to Kids Under 12, While U.S. Cities Mandate Them. Who's Right?*, FEE STORIES (Sept. 14, 2022), https://fee.org/articles/england-refuses-to-offer-covid-shots-to-kids-under-12-while-us-cities-mandate-them-who-s-right/ ("[T]he [UK Health Security Agency's] decision puts England in line with several other European Countries—including Sweden, Finland, Norway, and Denmark—that do not offer or recommend mRNA vaccines to healthy young children."). Over the course of the pandemic, the position of various countries regarding vaccination of the young has changed. For example, in the UK, as of June 21, 2023, the policy was changed to say:

> The NHS is offering coronavirus (COVID-19) vaccines to children aged 5 to 11 years. Experts have advised that parents of all children aged 5 to 11 years should be offered the chance to have their child vaccinated. Vaccination is particularly important for children who have health conditions that put them at high risk from COVID-19, as the benefits are greater.

A Guide for Parents of Children Aged 5 to 11, UK HEALTH SEC. AGENCY (updated June 21, 2023), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachm ent_data/file/1095990/COVID-19-guide-for-parents-of-children-aged-5-11-years.pdf. *See also* Dr. John Campbell, *Adverse Vaccine Events in 5 to 11 Year Olds*, YOUTUBE (July 21, 2022), https://www.youtube.com/watch?v=uIFSvnB1WlQ (interpreting an article from the New England Journal of Medicine regarding vaccination of children for COVID-19 in Singapore, which according to Dr. Campbell suggested that healthy children 5 to 11 should not be vaccinated). *But see* Leo Benedictus, *Youtuber Misinterprets Covid-19 Vaccine Evidence on Children from Singapore*, FULL FACT (Aug. 12, 2022), https://fullfact.org/health/john-campbell-youtube-singapore-children/ (criticizing Dr. Campbell's interpretation of the study and asserting Dr. Campbell oversimplified and incorrectly described the study). It is noteworthy that the authors of the study in the New England Journal of Medicine did not reach the same conclusion as Dr. Campbell. *See* Sharon H.X. Tan et al., *Effectiveness of BNT162b2 Vaccine Against Omicron in Children 5 to 11 Years of Age*, 387 NEW ENG. J. MED. 525, 531 (2022) ("[D]uring a period when the omicron variant was predominant, BNT162b2 vaccination reduced the risks of SARS-CoV-2 infection and Covid-19–related hospitalization among children 5 to 11 years of age.").

75. *See* Kevin Bardosh et al., *COVID-19 Vaccine Boosters for Young Adults: A Risk Benefit Assessment and Ethical Analysis of Mandate Policies at Universities*, J. MED. ETHICS, Dec. 5, 2022, at 1 ("Two main factors continue to drive scientific controversy: a lack of evidence that booster doses provide a meaningful reduction in hospitalization risk among healthy adolescents and young adults, and mounting evidence that widespread prior infection confers significant protection against hospitalization due to (re)infection.").

vaccination of this group of the population is not justified.[76] As recently as September 2022, an article in the New England Journal of Medicine suggested a more nuanced approach to boosters than that recommended by the CDC.[77] At the time the FDA approved the omicron-specific boosters for the Moderna and Pfizer COVID-19 vaccines,[78] some doctors, including a member of the independent review panel for the FDA, issued statements recommending against the omicron-specific vaccination because of inadequate data from clinical testing.[79] The Florida Surgeon General recommended that males 18–39 not get the COVID mRNA vaccine based on concerns that

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76. *Id.* ("University booster mandates are unethical because they: (1) are not based on an updated (Omicron era) stratified risk-benefit assessment for this age group; (2) may result in a net harm to healthy young adults; (3) are not proportionate: expected harms are not outweighed by public health benefits given modest and transient effectiveness of vaccines against transmission; (4) violate the reciprocity principle because serious vaccine-related harms are not reliably compensated due to gaps in vaccine injury schemes; and (5) may result in wider social harms. We consider counterarguments including efforts to increase safety on campus but find these are fraught with limitations and little scientific support.").

77. Dan H. Barouch, *Covid-19 Vaccines—Immunity, Variants, Boosters*, 387 NEW ENG. J. MED. 1011–20 (Sept. 15, 2022) ("Plans for boosters should therefore be based on robust scientific data that show substantial and sustained increases in prevention of severe disease rather than on short-term increases in neutralizing antibody titers. Enhanced community engagement and implementation research may also reduce vaccine misinformation. Ideally, Covid-19 boosters should be recommended no more than annually and preferably less frequently, and a diversity of booster options should be available to the public. The use of vaccine platforms with improved durability would be highly desirable."). This recommendation is different from the guidance provided by the CDC: "[V]accine recommendations are different depending on your age, the vaccine you first received, and time since last dose." Gabor David Kelen, M.D. & Lisa Maragakis, M.D., M.P.H. *COVID-19 Vaccine: What You Need to Know*, Hopkins Med., https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-19-vaccine-what-you-need-to-know (last updated Nov. 1, 2022). "[P]eople who are moderately or severely immunocompromised" have different recommendations for COVID-19 vaccines. *Id.* For an adult 18–49 who has been vaccinated but not boosted, the CDC webpage recommends a booster six months after receiving the initial vaccinations. Press Release, *CDC Statement on ACIP Booster Recommendations*, CDC (Sept. 24, 2021), https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html.

78. *See* Lauran Neergaard, *FDA Approves Updated COVID Booster Shots That Target Omicron*, PBS NEWS HOUR (Aug. 31, 2022, 1:37 PM), https://www.pbs.org/newshour/health/fda-approves-updated-covid-booster-shots-that-target-omicron ("'One needs to refresh the immune system with what is actually circulating,' [FDA vaccine chief Dr. Peter Marks] said. That's why FDA also is no longer authorizing boosters made with the original recipe for those 12 and older.").

79. *See* Liz Essley Whyte, *Latest Covid Boosters Are Set to Roll Out Before Human Testing Is Completed*, WALL ST. J. (Aug. 28, 2022, 5:30 AM), https://www.wsj.com/articles/latest-covid-boosters-are-set-to-roll-out-before-human-testing-is-completed-11661679003 ("'I'm uncomfortable that we would move forward—that we would give millions or tens of millions of doses to people—based on mouse data,' said Paul Offit, an FDA adviser and director of the Vaccine Education Center at Children's Hospital of Philadelphia.").

the cost/benefits analysis for individuals in that sex and age demographic did not favor vaccination.[80]

Throughout the pandemic, claims and counterclaims have been made. Some who were opposed to vaccine mandates suggest that an increase in excess deaths in the United States and other highly vaccinated countries is attributable to adverse side effects from the vaccine.[81] Those who favor vaccine mandates have suggested that the unvaccinated are the reason COVID-19 has been so successful in mutating and thereby defeating the vaccines.[82] At the time of the writing of this article, the best evidence available supports that the COVID-19 vaccines[83] confer powerful immune benefits but that

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80. *See Guidance for mRNA COVID-19 Vaccines*, FLA. HEALTH (Oct. 7, 2022), https://floridahealthcovid19.gov/wp-content/uploads/2022/10/20221007-guidance-mrna-covid19-vaccines-doc.pdf?utm_medium=email&utm_source=govdelivery ("With a high level of global immunity to COVID-19, the benefit of vaccination is likely outweighed by this abnormally high risk of cardiac related death among men in this age group.").

81. *See Viral Claims Are Blaming a Surge in Excess Deaths in Europe on Vaccines. But Experts Say That's Not the Case*, ABC NEWS (Sept. 1, 2022, 9:27 PM), https://www.abc.net.au/news/2022-09-02/fact-check-excess-deaths-europe-not-vaccines/101394264 (debunking a widespread social media claim from a Swedish blogger that implied a link between COVID vaccines and a 542% increase in deaths of children aged 0–14 in Europe); *Fact Check—No Evidence That People Aged 25–44 Experienced an 84% Increase in Excess Mortality Due to COVID Vaccine Rollout*, REUTERS (Mar. 25, 2022, 10:47 AM), https://www.reuters.com/article/factcheck-excess-mortality-idUSL2N2VS1BI (analyzing social media claims that the increase in excess deaths in the US was linked to the COVID vaccines and explaining that the increase in excess deaths was neither as high as 84% nor attributable to the COVID vaccines).

82. *See* Roz Plater, *Unvaccinated People Are Increasing the Chances for More Coronavirus Variants — Here's How*, HEALTHLINE (Aug. 10, 2021), https://www.healthline.com/health-news/unvaccinated-people-are-increasing-the-chances-for-more-coronavirus-variants-heres-how ("'[Unvaccinated people] play a huge role. If everyone is vaccinated, eventually infections drop to zero and so do variants,' [Dr. Purvi] Parikh said. 'But if the virus has an easy host, such as an unvaccinated individual, then it is easy for it to mutate into a more contagious and virulent form.'"). *But see* Anika Singanayagam et al., *Community Transmission and Viral Load Kinetics of the SARS-CoV-2 Delta (B.1.617.2) Variant in Vaccinated and Unvaccinated Individuals in the UK: A Prospective, Longitudinal, Cohort Study*, 22 LANCET 183, 183 (2021) ("[F]ully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."); McKenzie Beard, *Covid Is No Longer Mainly a Pandemic of the Unvaccinated. Here's Why*, WASH. POST (Nov. 23, 2022, 7:46 AM), https://www.washingtonpost.com/politics/2022/11/23/vaccinated-people-now-make-up-majority-covid-deaths/ (noting that in September 2021, vaccinated individuals accounted for 23% of COVID-19 death, by January and February of 2022, that number had increased to 42%, and in August of 2022, 58% of all COVID-19 deaths were individuals who had been vaccinated or boosted).

83. The article is specifically referring to the three vaccines that were initially approved by the FDA and are listed in the CDC tracker to denote vaccinated status. They are: Pfizer, Moderna, and Johnson & Johnson. *COVID Data Tracker*, *COVID-19*

benefit wanes over time (as does natural immunity).[84] The data reported to the Vaccine Adverse Event Reporting System (VAERS) suggests that there are rare adverse events associated with the COVID-19 vaccines.[85] At least one study found that some of the most

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Vaccine Effectiveness Update, CDC (Aug. 31, 2023), https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness.

84. *See* Nick Andrews et al., *Covid-19 Vaccine Effectiveness Against the Omicron (B.1.1.529) Variant*, 386 NEW ENG. J. MED. 1532, 1532 (2022) ("Primary immunization with two doses of ChAdOx1 nCoV-19 or BNT162b2 vaccine provided limited protection against symptomatic disease caused by the omicron variant. A BNT162b2 or mRNA-1273 booster after either the ChAdOx1 nCoV-29 or BNT162b2 primary course substantially increased protection, but that protection waned over time."); *see also Stay Up to Date with COVID-19 Vaccines*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html [https://web.archive.org/web/20230125112104/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html] (last updated Jan. 25, 2023) (noting for the Moderna booster, the CDC recommended that everyone 6 months and older receive a booster).

85. *See* Wenxin Guo et al., *Profiling COVID-19 Vaccine Adverse Events by Statistical and Ontological Analysis of VAERS Case Reports*, 13 FRONTIER PHARMACOLOGY, June 24, 2022, at 1 (examining the VAERS reports regarding the Pfizer, Moderna, and Jansen vaccines and finding in "VAERS data as of 31 December 2021, 96 [adverse events] were found to be statistically significantly associated with the Pfizer-BioNTech, Moderna, and/or Janssen COVID-19 vaccines."). Interpreting data from VAERS system is difficult. VAERS reports are unverified reports of adverse events. *Vaccine Adverse Event Reporting System (VAERS)*, CDC, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (last visited June 7, 2023) ("VAERS accepts and analyzes reports of possible health problems—also called 'adverse events'—after vaccination. As an early warning system, VAERS cannot prove that a vaccine caused a problem. Specifically, a report to VAERS does not mean that a vaccine caused an adverse event. But VAERS can give CDC and FDA important information. If it looks as though a vaccine might be causing a problem, FDA and CDC will investigate further and take action if needed.") (emphasis original); *Guide to Interpreting VAERS Data*, VAERS, https://vaers.hhs.gov/data/dataguide.html (last visited Nov. 16, 2022) ("'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events. The degree of underreporting varies widely. As an example, a great many of the millions of vaccinations administered each year by injection cause soreness, but relatively few of these episodes lead to a VAERS report. Physicians and patients understand that minor side effects of vaccinations often include this kind of discomfort, as well as low fevers. On the other hand, more serious and unexpected medical events are probably more likely to be reported than minor ones, especially when they occur soon after vaccination, even if they may be coincidental and related to other causes."); Fernando P. Polack et al., *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*, 383 NEW ENG. J. MED. 2603, 2603 (2020) (finding the Pfizer vaccine was effective against COVID-19 and had no more adverse side effects than other viral vaccines); Edson D. Moreira, Jr. et al., *Safety and Efficacy of a Third Dose of BNT162b2 Covid-19 Vaccine*, 386 NEW ENG. J. MED. 1910, 1918 (2022) (finding patients who received a third booster suffered no new or different adverse side effects than those from the original vaccine series). *But see* Lovelace, Jr., *supra* note 72 and accompanying text; Dror Mevorach et. al., *Myocarditis*

highly-publicized serious side effects, like pericarditis and myocarditis,[86] occur at a higher rate as a result of COVID-19 infection than from COVID-19 vaccines.[87]

Many medical experts have acknowledged that some of what the scientific community thought was true regarding COVID-19 was not.[88] Although the CDC's statistics note a many times greater likelihood of hospitalization of an unvaccinated individual versus a vaccinated and boosted individual,[89] gone are the days where the government claims, "You're not going to get COVID if you have these

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After BNT162b2 and mRNA Vaccine Against COVID-19 in Israel, 385 NEW ENG. J. MED. 2140, 2149 (Dec. 2, 2021) ("On the basis of data from an Israeli national database, the incidence of myocarditis after two doses of the BNT162b2 mRNA vaccine was low but higher than the incidence among unvaccinated persons and among historical controls. The risk of myocarditis was driven primarily by the increased incidence after the second dose of vaccine and in young male recipients.").

86. *See CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older*, FDA (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older ("Rapid-response investigation of the signal in the [CDC's Vaccine Safety Datalink] raised a question of whether people 65 and older who have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent were more likely to have an ischemic stroke in the 21 days following vaccination compared with days 22-42 following vaccination."); *see also Myocarditis and Pericarditis Considerations*, CDC, https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html (last viewed Sept. 29, 2022) ("Cases of myocarditis and pericarditis have rarely been observed following receipt of COVID-19 vaccines used in the United States. Evidence from multiple monitoring systems in the United States and around the globe support a causal association between mRNA COVID-19 vaccines (i.e., Moderna or Pfizer-BioNTech) and myocarditis and pericarditis.").

87. *See* Martina Patone et al., *Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex*, 146 CIRCULATION 743, 743 (2022) ("The risk of myocarditis is greater after SARS-CoV-2 infection than after COVID-19 vaccination and remains modest after sequential doses including a booster . . . . However, the risk of myocarditis after vaccination is higher in younger men, particularly after a second dose of the mRNA-1273 vaccine.").

88. *See* Michael Merschel, *Rethinking What You Thought You Knew About COVID-19 Reinfections*, AM. HEART ASS'N (July 20, 2022), https://www.heart.org/en/news/2022/07/20/rethink-what-you-thought-you-knew-about-covid-19-reinfection (discussing how understandings of COVID-19 have evolved and changed, resulting in the need for people to remain up to date on the most recent COVID-19 data).

89. *See Covid Data Tracker-Report*, CDC (last visited Nov. 16, 2022) ("In August 2022, compared to people who are up to date with COVID-19 vaccinations, monthly rates of COVID-19-associated hospitalizations were 5.2x higher in unvaccinated adults ages 18 years and older."); *see Covid Data Tracker-Report*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/hospitalizations-by-vaccination-status-report.pdf (last visited Feb. 4, 2023) ("In November 2022, compared to adults ages 18 years and older who received an updated COVID-19 bivalent booster dose, monthly rates of COVID-19 associated hospitalizations were 16.0x higher in unvaccinated and 2.7x higher in vaccinated adults without an updated booster.").

vaccines."[90] Also, gone are the claims that COVID-19 is a pandemic of the unvaccinated.[91] A recent study on the CDC website noted that between March 2022 and May 2022, approximately 72% of the population that was studied and required hospitalization due to COVID-19 had at least the first course of vaccinations, and 44% had been boosted.[92] Perhaps both assertions were more politics than science.

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90. President Joseph Biden stated in a CNN Town Hall Meeting, "'If you're vaccinated, you're not going to be hospitalized, you're not going to be in an ICU unit, and you are not going to die. . . . [Y]ou're not going to get COVID if you have these vaccinations." Paige Levin, *Watch the Entire CNN Town Hall With President Joe Biden*, CNN (July 21, 2021, 10:50 PM) (transcript available at http://www.cnn.com/TRANSCRIPTS/2107/21/se.01.html), https://www.cnn.com/2021/07/21/politics/full-president-joe-biden-cnn-town-hall-july-l), 21/index.html. *But see* Kashmira Gander, *Fact Check: Did Joe Biden Spread Misinformation on COVID Vaccines?*, NEWSWEEK (July 22, 2021, 11:50 AM), https://www.newsweek.com/fact-check-joe-biden-spread-misinformation-covid-vaccines-1612181 ("Joe Biden spread misinformation about COVID vaccines at a CNN town hall on Wednesday. It is not true that people vaccinated against COVID will not get the disease, be hospitalized, end up in an ICU, or die because of it. As evidenced by CDC data, these occurrences are rare.").

91. *See* President Joe Biden, Remarks on Fighting the COVID-19 Pandemic (Sept. 9, 2021) (transcript available at https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/) ("While the vaccines provide strong protections for the vaccinated, we read about, we hear about, and we see the stories of hospitalized people, people on their death beds, among the unvaccinated over the past few weeks. This is a pandemic of the unvaccinated."). *But see* Aaron Blake, *Yes, It's Still a Pandemic of the Unvaccinated — Arguably Even More So Now*, WASH. POST (Feb. 3, 2022, 5:23 PM), https://www.washingtonpost.com/politics/2022/02/03/yes-its-still-pandemic-unvaccinated-arguably-even-more-so-now/ ("The most recent data suggests those who continue to eschew the vaccines, despite everything, are likely to drive the death toll even more."). *But see* Brian Myers, *Opinion: The False 'Pandemic of the Unvaccinated' Motto Did Lasting Harm*, DES MOINES REG. (Apr. 17, 2022, 8:32 AM), https://www.desmoinesregister.com/story/opinion/columnists/iowa-view/2022/04/17/covid-pandemic-unvaccinated-motto-false-lasting-harm/7320097001/ (discussing the data showing that breakthrough infections, which were supposed to be rare, are actually common).

92. *See* Fiona P. Havers et al., *Laboratory-Confirmed COVID-19–Associated Hospitalizations Among Adults During SARS-CoV-2 Omicron BA.2 Variant Predominance — COVID-19–Associated Hospitalization Surveillance Network, 14 States, June 20, 2021–May 31, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. 1085, 1088 (2022).

C. *Alternative Treatments: Ivermectin, Hydroxychloroquine and Fluvoxamine*

Before the vaccine controversy there was hydroxychloroquine and ivermectin, and later there was fluvoxamine.[93] As each proposed therapeutic was considered, the NIH, CDC, and FDA determined the drug was either ineffective or the evidence to support its use was inadequate.[94] Often, there was disagreement between the doctors and researchers.[95] Those who favored some of these alternative treatments were declared promoters of COVID-19 misinformation.[96] Some studies supporting a positive effect of a drug were withdrawn

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93. *See* Luc Berlivet & Ilana Löwy, *Hydroxychloroquine Controversies: Clinical Trials, Epistemology, and the Democratization of Science*, 34 MED. ANTHROPOLOGY Q. 525, 525 (2020) ("The claim that anti-malaria drug, chloroquine and hydroxychloroquine, can cure COVID-19 became a focus of fierce political battles that pitted promoters of these pharmaceuticals, Presidents Bolsonaro and Trump among them, against 'medical elites.'"); *see also* Leon Caly et al., *The FDA-Approved Drug Ivermectin Inhibits the Replication of SARS-CoV-2 in Vitro*, 178 ANTIVIRAL RSCH., June 2020, at 1 ("Ivermectin, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity *in vitro*, is an inhibitor of the causative virus (SARS-CoV-2) . . . . Ivermectin therefore warrants further investigation for possible benefits in humans.").

94. *See Hydroxychloroquine Does Not Benefit Adults Hospitalized with COVID-19*, NAT'L INST. HEALTH (Nov. 9, 2020), https://www.nih.gov/news-events/news-releases/hydroxychloroquine-does-not-benefit-adults-hospitalized-covid-19 ("[Hydroxychloroquine] provides no clinical benefit to hospitalized patients. Though found not to cause harm, early findings in June when the trial was stopped indicated that the drug was not improving outcomes in COVID-19 patients."); *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19*, FDA (Dec. 10, 2021), https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 ("The FDA has not authorized or approved ivermectin for use in preventing or treating COVID-19 in humans or animals. . . . Currently available data do not show ivermectin is effective against COVID-19."); *Fluvoxamine*, NAT'L INST. HEALTH (DEC. 16, 2021), https://www.covid19treatmentguidelines.nih.gov/therapies/miscellaneous-drugs/fluvoxamine/ (recommending against the use of fluvoxamine for COVID-19, concluding, "[t]here is insufficient evidence for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of fluvoxamine for the treatment of COVID-19.").

95. *See* Hayden Sparks, *Texas Doctors Promote Hydroxychloroquine, Blast Texas Medical Board on Virtual Town Hall*, TEXAN (Aug. 12, 2020), https://thetexan.news/texas-doctors-promote-hydroxychloroquine-blast-texas-medical-board-on-virtual-town-hall/ ("[S]everal practicing physicians promoted the benefits of early intervention coronavirus treatments, including hydroxychloroquine and budesonide therapy, and criticized the Texas Medical Board for allegedly deterring doctors from caring for their patients suffering from COVID-19.").

96. *See* Victoria Knight, *Will Doctors Who Are Spreading COVID-19 Misinformation Ever Face Penalty?*, TIME (Sept. 20, 2021, 3:10 PM), https://time.com/6099700/covid-doctors-misinformation/ (discussing several doctors who are part of the "Disinformation Dozen," a group ranked for spreading COVID-19 misinformation online, including promoting hydroxychloroquine as a cure).

after publication.[97] In another circumstance, the NIH rejected the conclusions of researchers who found a positive effect from fluvoxamine for fighting COVID-19.[98]

Those who argue that drugs like ivermectin, fluvoxamine, and hydroxychloroquine have been unreasonably dismissed, often claim there has been unequal treatment when these drugs are compared to remdesivir. Remdesivir was the first anti-COVID-19 therapeutic fully approved by the FDA.[99] Although remdesivir was approved by the FDA for emergency use and then received full approval, the World Health Organization initially did not recommend the drug for the treatment of COVID-19 and later only recommended it in limited circumstances.[100] The data regarding remdesivir is mixed. Several studies have found a beneficial effect, especially if given early in the treatment of COVID-19.[101] However, other studies have found little to no statistically significant benefit of remdesivir.[102] In addition to

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97. Charles Piller, *Many Scientists Citing Two Scandalous COVID-19 Papers Ignore Their Retractions*, SCI. (Jan. 15, 2021), https://www.science.org/content/article/many-scientists-citing-two-scandalous-covid-19-papers-ignore-their-retractions "Both of the retracted COVID-19 papers, one in *The New England Journal of Medicine* (NEJM) and the other in *The Lancet*, were based on what appeared to be a huge database of patient records compiled from hospitals worldwide by Surgisphere, a small company operated by vascular surgeon Sapan Desai, who was a co-author on each article.").

98. See infra note 159 and accompanying text.

99. See Press Release, FDA, FDA Approves First Treatment for COVID-19 (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19 ("The approval of Veklury [remdesivir] was supported by the agency's analysis of data from three randomized, controlled clinical trials that included patients hospitalized with mild-to-severe COVID-19.").

100. *See Therapeutics and COVID-19: Living Guideline*, WORLD HEALTH ORG. (Sept. 16, 2022), https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.5 (altering its recommendations regarding remdesivir from "conditional recommendation against. . . in patients with non-severe COVID-19 at the highest risk of hospitalization" to "conditional recommendation *for* the use of remdesivir in patients with *severe* COVID-19, and a conditional recommendation *against* the use of remdesivir in patients with *critical* COVID-19 (first published 20 November 2020, updated 22 April 2022, updated 16 Sept. 2022)").

101. *See* Mulugeta T. Angamo et al., *Efficacy and Safety of Remdesivir in Hospitalised COVID-19 Patients: A Systematic Review and Meta-Analysis*, 50 INFECTION 27, 27 (2021) ("Despite conditional recommendation against its use, remdesivir could still be effective in early clinical improvement; reduction of early mortality and avoiding high-flow supplemental oxygen and invasive mechanical ventilation among hospitalized COVID-19 patients."); Robert L. Gottlieb et al., *Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients*, 386 NEW ENG. J. MED. 305, 305 (2022) ("Among nonhospitalized patients who were at high risk of COVID-19 progression, a 3-day course of remdesivir had an acceptable safety profile and resulted in an 87% lower risk of hospitalization or death than placebo.").

102. *See* Yeming Wang et al., *Remdesivir in Adults with Severe COVID-19: A Randomised, Double-Blind, Placebo-Controlled, Multicentre Trial*, 395 LANCET 1569, 1569 (2020) ("In this study of adult patients admitted to hospital for severe COVID-

drugs like remdesivir, the medical community and pharmaceutical industry have continued searching for new COVID-19 treatment options.[103]

1. Ivermectin

The use of ivermectin to treat COVID-19 was perhaps the most hotly contested medical issue regarding alternative COVID-19 treatments.[104] Beginning in April 2020, news stories reported that an Australian study found ivermectin might be an effective treatment for COVID-19.[105] Since those stories, the NIH, CDC, and FDA have all issued statements regarding the drug and COVID-19. The NIH guidance has shifted during the pandemic from neutral to against the

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19, remdesivir was not associated with statistically significant clinical benefits. However, the numerical reduction in time to clinical improvement in those treated earlier requires confirmation in larger studies."); Suzana E. Tanni et al., *Use of Remdesivir in Patients with COVID-19: A Systematic Review and Meta-Analysis,* 48 J. BRAZ. PNEUMOL, Feb. 2, 2022, at 11, https://www.scielo.br/j/jbpneu/a/zQ3HjwfmqfkDsRpB4PxL9nr/?format=pdf&lang=en ("[R]emdesivir had no effect on reducing mortality, the use of mechanical ventilation/ECMO, or severe adverse events in hospitalized patients with moderate to severe COVID-19. However, we identified increased rates of clinical improvement and recovery in those patients."); Michael E. Ohl et al., *Association of Remdesivir Treatment With Survival and Length of Hospital Stay Among US Veterans Hospitalized With COVID-19,* 4 JAMA NETWORK OPEN, July 15, 2021, at 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781959 ("[R]emdesivir therapy was not associated with improved 30-day survival but was associated with a significant increase in median time to hospital discharge. . . . The findings suggest that routine use of remdesivir may be associated with increased use of hospital beds but not with improvements in survival.").

103. *But see* John Lauerman, *Merck Covid Drug Linked to New Virus Mutations, Study Says,* BLOOMBERG (Feb. 1, 2023), https://www.msn.com/en-us/money/other/merck-covid-drug-linked-to-new-virus-mutations-study-says/ar-AA170cuh?ocid=msedgdhp&pc=U531&cvid=bb21d1834f5b486790c1fadf476ce705 ("Merck & Co's Covid-19 pill is giving rise to new mutations of the virus in some patients, according to a study that underscores the risk of trying to intentionally alter the pathogen's genetic code.").

104. *See* David Robinson, *Here's Who Prescribed Ivermectin to Treat Severely Ill COVID-19 Patients in NY Hospitals,* LOHUD (Oct. 21 2021, 5:01 AM), https://www.lohud.com/story/news/coronavirus/2021/10/21/heres-who-prescribed-ivermectin-covid-patients-ny-hospitals/8526574002/ ("[I]vermectin is the latest drug to be promoted by some health providers—and vaccine skeptics and celebrities—as a potential COVID-19 treatment, despite federal regulators warning against self-medicating with the unapproved drug.").

105. *See* Caly et al., *supra* note 93 and accompanying text; Jay Bhatt & Lucien Bruggeman, *Head Lice Drug Emerges as Potential Coronavirus Treatment, Studies Show,* ABC (Apr. 14, 2020, 4:03 AM), https://abcnews.go.com/Health/head-lice-drug-emerges-potential-coronavirus-treatment-studies/story?id=70119724 ("The coronavirus is not a parasite, but experts suggest that the drug essentially treats it like one and blocks the viral RNA from invading healthy cells. Unable to enter the cell, the RNA is slowed from replicating, giving the patient's immune system more time to fight it off.").

use of ivermectin.[106] On April 10, 2020, the FDA issued a warning that it was

> [C]oncerned about the health of consumers who may self-medicate by taking ivermectin products intended for animals, thinking they can be a substitute for ivermectin intended for humans. . . . People should never take animal drugs, as the FDA has only evaluated their safety and effectiveness in the particular animal species for which they are labeled. These animal drugs can cause serious harm in people. People should not take any form of ivermectin unless it has been prescribed to them by a licensed health care provider and is obtained through a legitimate source.[107]

Once ivermectin was identified as a potential tool in the fight against COVID-19, several studies were initiated; unfortunately, one of those studies relied on data secured from a company called Surgisphere.[108]

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106. *See Ivermectin, Coronavirus Disease 2019 (COVID-19) Treatment Guidelines*, NAT'L INST. HEALTH, Feb. 11, 2021, at 104 [hereinafter *Ivermectin I*], https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-02-11-2021.pdf ("There are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of ivermectin for the treatment of COVID-19. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19."); *Ivermectin*, NAT'L INST. HEALTH (Mar. 6, 2023) [hereinafter *Ivermectin II*], https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/ ("The Panel recommends against the use of ivermectin for the treatment of COVID-19.").

107. Ronnie Das, *Health Officials Warn Public Not to Use Heartworm Disease Medicine for Animals as Treatment for COVID-19 in Humans*, WRBL (Apr. 22, 2020, 11:09 AM), https://www.wrbl.com/news/health/coronavirus/health-officials-warn-public-not-to-use-heartworm-disease-medicine-for-animals-as-treatment-for-covid-19-in-humans/; *see also Ivermectin Intended for Animals: Letter to Stakeholders—Do Not Use in Humans as a Treatment for COVID-19*, FDA (Apr. 10, 2020), https://www.fda.gov/safety/medical-product-safety-information/ivermectin-intended-animals-letter-stakeholders-do-not-use-humans-treatment-covid-19.

108. *See* Catherine Offord, *The Surgisphere Scandal: What Went Wrong?*, SCIENTIST (Oct. 1, 2020), https://www.the-scientist.com/features/the-surgisphere-scandal-what-went-wrong--67955; ("It sounds absurd that an obscure US company with a hastily constructed website could have driven international health policy and brought major clinical trials to a halt within the span of a few weeks. Yet that's what happened earlier this year, when Illinois-based Surgisphere Corporation began a publishing spree that would trigger one of the largest scientific scandals of the COVID-19 pandemic to date."); *see also* Amit M. Patel et al., *Ivermectin in Covid-19 Related Critical Illness*, https://www.isglobal.org/documents/10179/6022921/Patel+et+al.+2020+version+1.pdf (retracted from publication).

In May 2020, the Lancet and the New England Journal of Medicine had to retract two studies examining repurposed drugs to fight COVID-19 due to questions about data collection[109]—Surgisphere was the medical data collection company used in both articles.[110] A third study, asserting that ivermectin was highly effective at reducing COVID-19 mortality, was also retracted because it was based on information collected by Surgisphere.[111] In July 2020, the World Health Organization issued a statement that ivermectin was not effective against COVID-19.[112] In March 2021, that statement was amended to recommend ivermectin to treat COVID-19 only in clinical trials.[113] In 2021, the NIH issued the following statement:

> [T]here is insufficient evidence for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of ivermectin for the treatment of COVID-19. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19.[114]

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109. *See* Charles Piller & Kelly Servick, *Two Elite Medical Journals Retract Coronavirus Papers Over Data Integrity Questions*, SCI. (June 4, 2020), https://www.science.org/content/article/two-elite-medical-journals-retract-coronavirus-papers-over-data-integrity-questions ("In the first big research scandal of the COVID-19 era, *The Lancet* and *The New England Journal of Medicine* (*NEJM*) today retracted two high-profile papers after a company declined to make the underlying data for both available for an independent audit. . . ."); *see also* Jared S. Hopkins & Russell Gold, *Hydroxychloroquine Studies Tied to Data Firm Surgisphere Retracted*, WALL ST. J. (June 5, 2020, 9:22 AM), https://www.wsj.com/articles/authors-retract-study-that-found-risks-of-using-antimalaria-drug-against-covid-19-11591299329 ("Three authors involved in Lancet article that drew scrutiny said they couldn't get full data set behind study; an article in the New England Journal of Medicine was also retracted.").

110. *See* Piller & Servick, *supra* note 109 ("Three authors on the *Lancet* paper requested the retraction, after initiating an independent review of the raw hospital patient data summarized and provided by Surgisphere, a small Chicago-based company operated by Sapan Desai, the fourth author of the study.").

111. *Id.*

112. *See supra* note 100, at 95 ("[R]ecommendation not to use ivermectin in patients with COVID-19 except in the context of a clinical trial (published 31 March 2021).").

113. *See WHO Advises That Ivermectin Only Be Used to Treat COVID-19 Within Clinical Trials*, WORLD HEALTH ORG. (Mar. 31, 2021), https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials (advising ivermectin should only be used in the context of clinical trials but "[t]he panel did not look at the use of ivermectin to prevent COVID-19, which is outside of scope of the current guidelines.").

114. *Ivermectin I*, *supra* note 106 and accompanying text.

In April 2022, the NIH updated its recommendation and came out against the use of ivermectin to treat COVID-19 except in clinical trials.[115]

The American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists issued a joint statement declaring that they "strongly oppose the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial."[116] The FDA issued a warning on its webpage with a picture of a horse entitled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19."[117] The article explains that ivermectin is a common animal de-wormer as well as used in humans to treat parasitic infections.[118] The article notes that ivermectin has not been approved by the FDA for the treatment or prevention of COVID-19 and the best approach for prevention is to get vaccinated.[119]

Two studies are of particular note. In February 2022, an article was published in the Journal of the American Medical Association.[120] That study examined the effect of ivermectin on COVID-19 disease progression in patients with mild to moderate COVID-19 and other

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115. Kelly Jones, *No The National Institutes of Health Didn't Approve Ivermectin As a COVID-19 Treatment*, WCNC (Sept. 19, 2022, 5:16 PM), https://www.wcnc.com/article/news/verify/coronavirus-verify/no-the-national-institutes-of-health-didnt-approve-ivermectin-as-a-covid-19-treatment-fact-check/536-141ec9bf-7b1e-422d-8a19-155ff75b8f58 (quoting the NIH as saying,"[a]lthough there have been many ivermectin studies, only a few trials have been adequately powered, well-designed, and well-conducted. More recent clinical trials address the limitations of earlier studies but fail to show clear evidence that ivermectin reduces time to recovery or prevents COVID-19 disease progression.").

116. Press Release, Am. Med. Ass'n, *AMA, APhA, ASHP Statement on Ending Use of Ivermectin to Treat COVID-19* (Sept. 1, 2021) [hereinafter AMA Press Release], https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19.

117. *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19*, *supra* note 94.

118. *Id.*

119. *Id. But see Coronavirus Outbreak: Can Anti-Parasite Drug Ivermectin Kill COVID-19? Know More*, FREE PRESS J. (Apr. 4, 2020, 10:43 AM), https://www.freepressjournal.in/world/coronavirus-outbreak-can-anti-parasite-drug-ivermectin-kill-covid-19-know-more ("Monash Biomedicine Discovery Institute's Dr. Kyle Wagstaff said that they had found that a single dose could essentially remove all viral RNA (effectively removed all genetic material of the virus) by 48 hours and that even at 24 hours there was a really significant reduction in it . . . .").

120. Steven Chee Loon Lim et al., *Efficacy of Ivermectin Treatment on Disease Progression Among Adults with Mild to Moderate COVID-19 and Comorbidities: The I-TECH Randomized Clinical Trial*, 184 JAMA INTERN MED. 426, 434 (2022) ("In this randomized clinical trial of high-risk patients with mild to moderate COVID-19, ivermectin treatment during early illness did not prevent progression to severe disease. The study findings do not support the use of ivermectin for patients with COVID-19.").

comorbidities.[121] The study included just under 500 participants and found no clinically significant benefit to ivermectin.[122] A larger, and more impactful, study was published in the New England Journal of Medicine in March of 2022, which also found no clinically significant benefit of ivermectin in treating COVID-19.[123] That study included 3,515 participants.[124]

Despite this evidence, a number of doctors disagree with the conclusion that ivermectin is ineffective against COVID-19. Several of these doctors have organized and created a group called the Front Line COVID-19 Critical Care Alliance (FLCCC).[125] The FLCCC argues that ivermectin is an effective treatment, both to prevent and to treat COVID-19.[126] In support of its position, the FLCCC cites ninety-eight studies that in the aggregate include tens of thousands of participants.[127] As mentioned above, the debate about ivermectin's use as a treatment for COVID-19 began when studies,[128] according to the NIH, suggested "ivermectin acts by inhibiting the host importin alpha/beta-1 nuclear transport proteins, which are part of a key intracellular transport process that viruses hijack to enhance infection by suppressing the host's antiviral response."[129] Further, the FLCCC has argued that countries or regions that have used ivermectin, like India, Peru, and Argentina,[130] demonstrate a clear

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121. *Id.*

122. *Id.*

123. Gilmar Reis et al., *Effect of Early Treatment with Ivermectin Among Patients with COVID-19*, 286 NEW ENGL. J. MED. 1721, 1721 (2022) ("Treatment with ivermectin did not result in a lower incidence of medical admission to a hospital due to progression of COVID-19 or of prolonged emergency department observation among outpatient with an early diagnosis of COVID-19.").

124. *Id.*

125. *Ivermectin*, FRONT LINE COVID-19 CRITICAL CARE ALL. [hereinafter *Ivermectin III*], https://covid19criticalcare.com/ivermectin/ (last visited June 14, 2023) ("A growing evidence base of dozens of studies around the world demonstrate ivermectin's unique and highly potent ability to inhibit SARS-CoV-2 replication and aid in recovery from COVID-19. Based on this evidence, and on first-hand clinical observations, the FLCCC recommends its use, as part of a combination therapy, in all stages of COVID-19.").

126. *Id.*

127. *Id.* (citing "98 studies from 1067 scientists, 135,958 patients in 27 countries.").

128. *See* Sundy N. Y. Yang et al., *The Broad Spectrum Antiviral Ivermectin Targets the Host Nuclear Transport Importin α/β1 Heterodimer*, 177 ANTIVIRAL RSCH., Feb. 28, 2020, at 2; *see also* A.P. Arevalo et al., *Ivermectin Reduces Coronavirus Infection in Vivo: A Mouse Experimental Model*, 11 SCI. REP., Mar. 30, 2021, at 1; *see also* Caly et al., *supra* note 93 and accompanying text.

129. *Ivermectin I*, *supra* note 106 and accompanying text.

130. *See Epidemiological Analyses on Ivermectin in COVID-19*, FRONT LINE COVID-19 CRITICAL CARE ALL. (Dec. 4, 2022),https://covid19criticalcare.com/ivermectin-in-covid-19/epidemiologic-analyses-on-covid19-and-ivermectin/.

causal connection between the use of ivermectin and reductions in cases of COVID-19, hospitalizations, and deaths from COVID-19.[131] Some of the most striking statistics offered by the FLCCC in support of its position come from Uttar Pradesh, India.[132] Uttar Pradesh is home to over 220 million individuals.[133] At the peak of the second wave of COVID-19, the minister for Medical and Health, Family Welfare, and Maternal and Child Welfare of the Uttar Pradesh government reported approximately 350 deaths a day due to COVID-19.[134] As of September 28, 2021, Uttar Pradesh had 177 active cases in the entire region.[135] Doctors from the FLCCC assert that a significant part of Uttar Pradesh's success in combatting COVID-19 was due to its aggressive early intervention on cases, which included the use of ivermectin in combination with other medications.[136] It should be noted that some argue that the success of Uttar Pradesh, India is not related to the use of ivermectin.[137] It is also noteworthy that the Indian Council of Medical Research does not recommend ivermectin to treat COVID-19.[138]

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131. *Id.*

132. *See Joint Statement on Widespread Use of Ivermectin in India*, FRONT LINE COVID-19 CRITICAL CARE ALL. (May 3, 2021), https://covid19criticalcare.com/joint-statement-on-widespread-use-of-ivermectin-in-india-for-prevention-and-early-treatment/.

133. *See* Soutik Biswas & Aparna Alluri, *Uttar Pradesh Bill: The Myth of India's Population Explosion*, BBC NEWS (July 13, 2021), https://www.bbc.com/news/world-asia-india-57801764 (noting Uttar Pradesh is India's most populated state).

134. *See* Govindraj Ethiraj, *After the Covid-19 Crisis, How Has Uttar Pradesh's Health Strategy Changed?*, SCROLL INDIA (Oct. 2, 2021, 9:30 PM), https://scroll.in/article/1006641/after-the-covid-19-crisis-how-has-uttar-pradeshs-health-strategy-changed.

135. *Id.*

136. *But see* Terry K., *WND Parrots COVID Vaccine Misinformer*, CONWEBBLOG (Oct. 14, 2021, 1:49 AM), https://conwebwatch.tripod.com/blog/index.blog/2378048/wnd-parrots-covid-vaccine-misinformer/ (offering explanations other than the use of ivermectin to explain the rapid improvement in Uttar Pradesh regarding COVID-19); Linda Qiu, *Fact-Checking Joe Rogan's Interview with Robert Malone That Caused an Uproar*, N.Y. TIMES (June 22, 2023), https://www.nytimes.com/2022/02/08/arts/music/fact-check-joe-rogan-robert-malone.html ("Promoters of ivermectin often cite Uttar Pradesh's low death toll as proof of the drug's efficacy, but experts say there is no proof of that causal link. It is also worth noting that researchers have questioned the reliability of data from Uttar Pradesh.").

137. *See* Craig Jones, *Success of Ivermectin in Preventing COVID-19 in India Has Not Been Proven*, NEWSWISE (Nov. 22, 2021, 9:00 AM), https://www.newswise.com/factcheck/success-of-ivermectin-in-preventing-covid-19-in-india-has-not-been-proven/?article_id=761091 ("While cases appear to have fallen in Uttar Pradesh as well as most locations in India, it's not clear why. Many other factors, including immunity from a previous infection, vaccination, and lockdowns, likely helped reduce the number of cases.").

138. *Id.*

Although the debate over the use of ivermectin to treat COVID-19 continues, it seems to have moved into a less intense phase. Given the outcome of several large, double-blind placebo-controlled studies, it seems more and more of the medical and broader communities are convinced that ivermectin is not effective against COVID-19.[139] A small number of doctors, however, remain convinced of its efficacy and continue to advocate for its use.[140] Also, several states have introduced legislation to either prevent disciplinary action against doctors who prescribe ivermectin for COVID-19 or to make ivermectin more freely available.[141]

2. Hydroxychloroquine

Perhaps no drug has come out of the COVID-19 pandemic worse off than hydroxychloroquine. It may have been due to the rush to find a quick solution to the pandemic or because former President Trump suggested it was a miracle drug well before any vigorous clinical

139. *See* Reis et al., *supra* note 123 and accompanying text.

140. *See* Aria Bendix, *The Ivermectin Battle Isn't Over: COVID-19 Doctors Are Prescribing the Drug in Plain Sight*, BUS. INSIDER (Feb. 12, 2022, 8:59 AM), https://www.businessinsider.com/doctors-prescribing-ivermectin-covid-misinformation-2022-2 (detailing the author's own doctor prescribing ivermectin for her COVID-19 diagnosis in addition to other doctors and groups that continue to believe in the efficacy of ivermectin).

141.*See* Jason Alatidd, *Anti-Vaccine, Anti-Quarantine, Pro-Ivermectin Bills Advanced by Kansas Public Health Politicians*, TOPEKA CAP. J. (Mar. 17, 2022, 2:18 PM), https://www.cjonline.com/story/news/healthcare/2022/03/17/897meric-legislators-advance-anti-vax-bills-covid-vaccines-quarantine-orders-ivermectin-hcq/7074540001/ ("Senators tasked with directing public health policy have advanced plans to promote unproven drugs for COVID-19 treatment, discourage child wellness vaccines and strip health officers of quarantine powers."); Siobhan Benham & S. Nicole Condodemetraky, *Sustain Governor's Veto of Ivermectin Bill, Op-eds*, N.H. UNION LEADER, (Sept. 13 2022), https://www.unionleader.com/opinion/op-eds/897merica-benham-s-nicole-condodemetraky-sustain-governors-veto-of-ivermectin-billarticle_c00f8171-efc5-5f91-afae-6d573c3b2237.html ("The N.H. Nurse Practitioner Association (NHNPA), representing licensed prescribers working in the state of New Hampshire, stands in strong support of Governor Chris Sununu's veto of HB 1022, permitting pharmacists to dispense the drug Ivermectin by means of a standing order."); Adrianna Rodriguez, *Lawmakers Push Legislation to Protect Doctors who Prescribe Ivermectin for COVID-19. Can They Do That?*, USA TODAY (Mar. 10, 2022, 5:02 AM), https://www.usatoday.com/story/news/health/2022/03/10/covid-ivermectin-bill-dozens-states-push-laws-protect-doctors/9356967002/?gnt-cfr=1 ("Dozens of state lawmakers push bills that would make it easier for doctors prescribe ivermectin for COVID-19 . . . .").

testing was completed.[142] Regardless, hydroxychloroquine is now synonymous with the politicization of medicine.[143]

The path of hydroxychloroquine from savior to villain is strange. Hydroxychloroquine is an FDA-approved antimalarial drug[144] that showed some possible value as an anti-COVID-19 therapy in in-vitro (in glass) studies.[145] As one article points out, it was at this point that the cart got "before the horse."[146] Rather than waiting for animal studies to be completed, the push for clinical trials was made and numerous studies began.[147]

The FDA approved the use of hydroxychloroquine for the treatment of COVID-19 on an emergency-use basis on March 28,

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142. *See* Joe Palca, *Trump Tells the Story of a 'Miracle' Cure For COVID-19. But Was It?*, *Coronavirus Updates*, NPR (Apr. 7, 2020, 8:35 PM), https://www.npr.org/sections/coronavirus-live-updates/2020/04/07/829302545/trump-tells-the-story-of-a-miracle-cure-for-covid-19-but-was-it ("'Four hours later [after taking Hydroxychloroquine], she awoke and she said, I feel better,' Trump recalled. 'And then, shortly thereafter, she felt great. The way she spoke . . . it was like a miracle. And this was not a fan of mine, but she's a fan of mine now.'").

143. *Id.*; Julia Carrie Wong, *Hydroxychloroquine: How an Unproven Drug Became Trump's Coronavirus 'Miracle Cure'*, GUARDIAN (Apr. 7, 2020, 01:00 AM), https://www.theguardian.com/world/2020/apr/06/hydroxychloroquine-trump-coronavirus-drug ("The story of how hydroxychloroquine was anointed the Trump administration's miracle drug for the coronavirus pandemic is a distinctly modern tale of misinformation within a global information ecosystem beset by widespread uncertainty, fear, media fragmentation and hyper-partisanship. Belief in the drug's potential to cure patients infected with the virus followed an extraordinary trajectory from a small study conducted in France (Trump's 'very good test') to Silicon Valley social media influencers, Fox News and the largest bully pulpit: the White House.").

144. *See Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication—FDA Cautions Against Use Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm* Problems, FDA (Apr. 24, 2020), https://www.fda.gov/safety/medical-product-safety-information/hydroxychloroquine-or-chloroquine-covid-19-drug-safety-communication-fda-cautions-against-use (detailing that Hydroxychloroquine and chloroquine are FDA-approved to treat or prevent malaria).

145. *See COVID-19: Evidence Based Medicine: Hydroxychloroquine*, UNIV. OF MINN. (June 5, 2020), https://covidebm.umn.edu/evidence-based-therapies/hydroxychloroquine ("Hydroxychloroquine has been found to have in-vitro antiviral activity against SARS-CoV-2."). *But see* Ilan S. Schwartz et al., *Hydroxychloroquine for COVID-19: The Curtains Close on a Comedy of Errors*, 11 LANCET REG'L HEALTH, May 5, 2022, at 1 ("[M]ost outpatient trials failed to enroll to completion, and none were independently large enough to definitely refute a small benefit in this setting.").

146. Schwartz et al., *supra* note 145 and accompanying text.

147. *Id.*

2020.[148] By June 2020, the FDA removed the emergency-use authorization.[149] On June 15, 2020, the FDA stated,

> Recent results from a large randomized clinical trial in hospitalized patients, a population similar to the population for which chloroquine and hydroxychloroquine were authorized for emergency use, demonstrated that hydroxychloroquine showed no benefit on mortality or in speeding recovery. This outcome was consistent with other new data, including data showing that the suggested dosing regimens for chloroquine and hydroxychloroquine are unlikely to kill or inhibit the virus that causes COVID-19.[150]

It is perhaps understandable that there was a rush to approve hydroxychloroquine for COVID-19. As of March 28, 2020, COVID-19 had infected over 120,000 people in the United States in a matter of two or three months.[151] Also, as of March 2020, no effective treatment was in existence and vaccines were just an idea.[152]

3. Fluvoxamine

One of the more recent alternative drugs to be considered for the treatment of COVID-19 is fluvoxamine. Fluvoxamine is used to treat obsessive-compulsive disorders and depression.[153] The drug received

148. Letter from Denise M. Hinton, Chief Scientist, FDA, to Dr. Rick Bright, Dir. of Biomedical Advanced Rsch. and Dev. Auth., Off. of Assistant Sec'y for Preparedness and Response, HHS (Mar. 28, 2020), https://www.fda.gov/media/136534/download (revoked).

149. Press Release, FDA, Coronavirus (Covid-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine (June 15, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and.

150. *Id.*

151. *See* CDC COVID-19 Response Team, *Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 — United States, February 12–March 28, 2020*, 69 MORBIDITY AND MORTALITY WKLY. REP. 382, 382 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm (documenting 122,653 COVID-19 cases by March 28, 2020).

152. *See* Denise Grady, *Trial of Coronavirus Vaccine Made by Moderna Begins in Seattle*, N.Y. TIMES (July 14, 2020), https://www.nytimes.com/2020/03/16/health/coronavirus-vaccine.html ("The first testing in humans of an experimental vaccine for the new coronavirus began on Monday, the National Institute of Allergy and Infectious Disease announced.").

153. *See Fluvoxamine, COVID-19 Treatment Guidelines*, NAT'L INST. HEALTH

FDA approval in the 1980s and has a long and well-documented history as a safe medication.[154] Researchers theorize that fluvoxamine is helpful as a treatment for COVID-19 because it acts as an anti-inflammatory when taken early in the disease process.[155]

At least three studies have found that fluvoxamine has a clinically significant effect as a treatment for COVID-19.[156] One of those studies, the TOGETHER study, involved just under 1,500 patients in Brazil.[157] Researchers stated:

> Our trial has found that fluvoxamine, an inexpensive existing drug, reduces the need for advanced disease care in this high-risk population. A 10-day course of fluvoxamine costs approximately US$4 even in well-resourced settings. Our study compares favorably with the treatment effects of more expensive treatments including monoclonal antibodies for outpatient treatment.[158]

The study also found "the absolute number of serious adverse events associated with fluvoxamine was lower than for placebo."[159] It is noteworthy that the researchers who conducted the TOGETHER study regarding fluvoxamine also examined ivermectin. The

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(Dec. 16, 2021), https://www.covid19treatmentguidelines.nih.gov/therapies/immunomodulators/fluvoxamine/ ("Fluvoxamine is a selective serotonin reuptake inhibitor (SSRI) that is approved by the Food and Drug Administration (FDA) for the treatment of obsessive-compulsive disorder and is used for other conditions, including depression.").

154. *See* Michael Hiltzik, *Column: With Fluvoxamine, Doctors Find an Old Drug That May Actually Work Against COVID-19*, L.A. TIMES (Aug. 21, 2021, 12:33 PM), https://www.latimes.com/business/story/2021-08-18/fluvoxamine-covid.

155. *Id.* ("Several clinical trials, including a large trial with 1,500 test subjects, indicate that the drug may help COVID-19 patients in the early stages of the disease stay out of the hospital and avoid long hours under the eyes of emergency room physicians."); *see also* Todd C. Lee et al., *Fluvoxamine for Outpatient Management of COVID-19 to Prevent Hospitalization: A Systematic Review and Meta-Analysis*, 5 JAMA NETWORK OPEN, Apr. 6, 2022, at 2, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2790742 ("One such medication is fluvoxamine, which is a selective serotonin reuptake inhibitor (SSRI) that is also a potent activator of the sigma-1 receptor which decreases inflammation via reducing endoplasmic reticulum stress.").

156. *See* Hiltzik, *supra* note 154 and accompanying text.

157. Gilmar Reis et al., *Effect of Early Treatment with Fluvoxamine on Risk of Emergency Care and Hospitalization Among Patients with COVID-19: The TOGETHER Randomised, Platform Clinical Trial*, 10 LANCET GLOB. HEALTH E42, E42 (2022) ("Treatment with fluvoxamine . . . among high-risk outpatients with early diagnosed COVID-19 reduced the need for hospitalization defined as retention in a COVID-19 emergency setting or transfer to a tertiary hospital.")

158. *Id.*

159. *Id.*

ivermectin study was published in the New England Journal of Medicine and found no clinically significant benefit to the drug.[160]

Although a few studies have found a benefit to fluvoxamine, the NIH guidance is that "[t]here is insufficient evidence for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of fluvoxamine for the treatment of COVID-19."[161] The NIH points out weaknesses in how the TOGETHER study assessed favorable outcomes.[162]

II. TRADITIONAL METHODS OF DISCIPLINING DOCTORS

Disciplinary action against doctors can take several forms. A doctor may face an investigation and adverse action from a hospital where they have hospital privileges, the specialty boards and organizations they are members of, and a state medical board where the doctor is licensed to practice.[163] Although this amount of oversight

160. Reis et al., *supra* note 123 and accompanying text.

161. Reis et al., *supra* note 157 and accompanying text.

162. *Id.* ("While fluvoxamine treatment significantly reduced the primary composite outcome in the TOGETHER trial (i.e., retention in the emergency department for >6 hours or admission to a tertiary hospital), the difference in hospitalizations between arms was not significant. Defining the clinical relevance of the >6 hour emergency department observation time endpoint is difficult, especially its applicability to practice settings in different countries. Moreover, the endpoint has not been used in other studies of interventions for nonhospitalized patients at high risk for hospitalization and death. While a per-protocol analysis found a significant treatment effect for mortality in patients taking >80% of possible doses (assessed by patient self-report), no such benefit was found in the primary ITT analysis. The 80% threshold has no clear justification, and only 74% of participants in the fluvoxamine arm reached this level of adherence. Since per-protocol analyses are not randomized comparisons, they can introduce bias when adherence is associated with factors that influence the outcome; this bias cannot be excluded in this study. Notably, mortality in the placebo arm was substantially higher in those with ≤80% adherence than in those with >80% adherence, suggesting that factors other than adherence differed in the per-protocol population. Finally, including only participants who could tolerate fluvoxamine does not reflect the actual effectiveness of the drug, since intolerance and adherence appeared to be related.").

163. Although action by specialty boards is uncommon, two doctors, Dr. Peter McCullough and Dr. Pierre Cory, associated with counter-majority COVID-19 views were investigated by the American Board of Internal Medicine (ABIM). *See* Debra Heine, *American Board of Internal Medicine Threatens to Revoke Medical Licenses from COVID Docs Peter McCullough and Pierre Kory*, TENN. STAR (June 23, 2022), https://tennesseestar.com/news/901merican-board-of-internal-medicine-threatens-to-revoke-medical-licenses-from-covid-docs-peter-mccullough-and-pierre-kory/admin/2022/06/23/ (explaining that Dr. McCullough had his board certification in internal medicine and cardiology revoked); Susan Berry, *COVID Early Treatment Champion Dr. Peter McCullough Files to Dismiss His Decertification by American Board of Internal Medicine for Speaking Truth About mRNA Shots*, TENN. STAR (Nov. 9, 2022), https://tennesseestar.com/news/covid-early-treatment-champion-dr-peter-mccullough-files-to-dismiss-his-decertification-by-american-

might seem extensive, it is broadly believed that doctors face too little disciplinary action rather than too much.[164] Further, the variability of disciplinary action by state medical boards has been a point of concern. One study observed that there were as many as four times the disciplinary actions per capita in some states than in others.[165]

A. *Hospitals*

Every hospital that receives Medicare or Medicaid funding and is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is required to create rules that ensure doctors holding clinical privileges are accountable to the hospital for the quality of care the doctor provides to their patients.[166] Thus, each hospital is required to create rules governing the granting, reviewing, and removing of clinical privileges.[167] Medical staff by-laws generally govern the review of clinician privileges and the procedures that must be followed when some adverse action is initiated regarding a physician's privileges.

Hospitals may take disciplinary action regarding a doctor's privileges for a variety of reasons.[168] Particularly relevant to this article are disciplinary actions directed toward physicians who refuse

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board-of-internal-medicine-for-speaking-truth-about-mrna-shots/sberry/2022/11/09/ (reporting the American Board of Internal Medicine (ABIM) "stripped [Dr. McCullough] of his board certifications in internal medicine and cardiology because of his testimony in Senate subcommittee hearings regarding the risks of the COVID-19 'vaccines'[—]information that countered that of the federal government."). It is noteworthy that the title of the June 23, 2022, article described above is somewhat misleading. The ABIM can sanction its members by removing their certification, but it cannot revoke a medical license. *See* AM. BD. OF INTERNAL MED., POLICIES & PROCS. FOR CERTIFICATION 17 (2022), https://www.abim.org/Media/splbmcpe/policies-and-procedures.pdf ("ABIM will suspend or revoke a Board Certification of any diplomate who has a license that is suspended, revoked, surrendered or restricted (whether voluntarily or otherwise) so as to prohibit the practice of clinical medicine in one or more jurisdictions, and no valid license in any other jurisdiction.").

164. *See* Adam M. Gershowitz, *The Opioid Doctors: Is Losing Your License a Sufficient Penalty for Dealing Drugs?*, 72 HASTINGS L.J. 871, 879 (2021) ("In short, conventional wisdom in the medical community is that medical boards are under-disciplining physicians.").

165. Kara Gavin, *For Doctors Behaving Badly, Punishments Vary by State*, MICH. MED. (Mar. 24, 2016, 8:00 AM), https://labblog.uofmhealth.org/industry-dx/for-doctors-behaving-badly-punishments-vary-by-state ("[S]ince there probably isn't a fourfold difference in the actual behavior of doctors, the reason for this difference lies in the wide variation between states in their regulations, procedures and resources for punishing doctors who do wrong.").

166. ANNE M. DELLINGER, HEALTH CARE FACILITIES LAW: CRITICAL ISSUES FOR HOSPITALS, HMOS, AND EXTENDED CARE FACILITIES 5–8 (1991).

167. *Id.* at 6–8.

168. *Id.* at 24–27.

to follow hospital rules[169] or engage in incompetent practice.[170] In pursuing disciplinary action against a doctor, hospitals are required to provide physicians a fair degree of due process (notice of a proposed action and hearing, the right to a hearing, to present witnesses and cross-examine witnesses, the right to present evidence and to make a written statement after all the evidence has been presented, among other rights).[171]

There are several circumstances in which a hospital could consider disciplinary action regarding a doctor's COVID-19 care of a patient. Some hospitals have established treatment guidelines about COVID-19.[172] A doctor who insists on not following those guidelines could lead to action regarding that doctor's privileges in the hospital.[173] Further, if a doctor provided COVID-19 care that did not comply with the standard of care, that too could be the basis of hospital disciplinary action. Recently, a hospital in Houston, Texas suspended one of its doctors' privileges for her social media posts regarding COVID-19 vaccinations and treatment.[174]

Actions that affect a doctor's privileges at one hospital reverberate beyond that facility. In 1986, Congress passed the Health Care

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169. *Id.* at 26.

170. *Id.* at 27.

171. *Id.* at 44 (noting these due process rights are set out in the Health Care Quality Improvement Act).

172. *See e.g., Mount Sinai Health System Treatment Guidance for SARS-CoV-2 Infection (COVID-19)*, MOUNT SINAI HEALTH SYS. (July 14, 2023), https://www.mountsinai.org/files/MSHealth/Assets/HS/About/Coronavirus/Mount-Sinai-Health-System-Treatment-Guidelines-for-COVID-Updated.pdf (listing treatment options depending on symptom and medications that are not currently recommended to treat COVID-19).

173. Marik v. Sentara Healthcare, 109 Va. Cir. 88, 94–95 (Va. Cir. Ct. 2021) ("Marik alleges that if he violates the Guidelines, he could be disciplined, have his Sentara hospital privileges revoked, and/or be subject to a medical malpractice suit. At the Hearing, Bundy, Sentara's Chief Quality and Safety Officer, admitted that if Marik violated the Guidelines, his hospital privileges could be at risk. The Court finds that Marik has alleged a sufficiently concrete and imminent injury. Specifically, the Court finds—based on the evidence presented—that Marik could be subject to discipline and perhaps lose his hospital privileges if he does not comply with the Guidelines.").

174. Julian Gill, *Houston Methodist Suspends River Oaks Doctor for Spreading COVID Misinformation*, HOUS. CHRON. (Nov. 12, 2021), https://www.houstonchronicle.com/news/houston-texas/health/article/Houston-Methodist-suspends-River-Oaks-doctor-for-16615892.php ("'Dr. Mary Bowden, who recently joined the medical staff at Houston Methodist Hospital, is using her social media accounts to express her personal and political opinions about the COVID-19 vaccine and treatments,' Houston Methodist said in a statement. 'These opinions, which are harmful to the community, do not reflect reliable medical evidence or the values of Houston Methodist, where we have treated more than 25,000 COVID-19 inpatients, and where all our employees and physicians are vaccinated to protect our patients.'").

Quality Improvement Act.[175] The Act provided, among other provisions, that when an adverse action is taken by a hospital against a doctor's privileges that action must be reported to the National Practitioner Data Bank.[176] Hospitals in the United States have access to the database and usually review it before hiring doctors.[177] Thus, an adverse action against a doctor's hospital privileges can adversely impact that doctor for years to come.

B. *State Medical Licensing Boards*

Each state has the power to regulate the practice of medicine as part of its power to "protect the health and welfare of its citizens."[178] This power to regulate includes the power to license and discipline doctors.[179] Every state and the District of Columbia has a medical licensing board. These boards typically investigate and, when necessary, discipline its doctors.[180] Investigations frequently occur as a result of a complaint filed regarding a physician, but some boards are permitted to initiate investigations without a complaint.[181] The

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175. Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101–11152 (2018); *see also* Susan L. Horner, *The Health Care Quality Improvement Act of 1986: Its History, Provisions, Applications and Implications*, 16 AM. J.L. & MED. 453, 495 (1990) (collecting the history of the Act and the subsequent responses "made by the courts, hospitals, physicians, peer review groups and finally Congress.").

176. 42 U.S.C. § 11131–11133; Yann H.H. van Geertruyden, *The Fox Guarding the Henhouse: How the Health Care Quality Improvement Act of 1986 and State Peer Review Protection State Statutes Have Helped Protect Bad Faith Peer Review in the Medical Community*, 18 J. CONTEMP. HEALTH L. & POL'Y 239, 257 (2001) ("Once a report has been submitted to the [National Practitioner Data Bank Report], whether legitimate or not, any hospital at which the reprimanded physician attempts to obtain privileges will be notified of the adverse action. Due to the reporting requirements of the NPDB, the reviewed physician is essentially 'blacklisted' in both the community where he or she practices, as well as other communities in which the physician may wish to practice.").

177. *See* van Geertruyden, *supra* note 176, at 257 ("Under the HCQIA, hospitals have an affirmative duty to query the NPDB when a physician applies for medical staff privileges or requests clinical privileges."); *see also* 42 U.S.C. § 11135(a)(2) (requiring hospitals to check the NPDB for any updates on all their staff every two years).

178. S. SANDY SANBAR ET AL., LEGAL MEDICINE 10 (S. Sandy Sanbar et al. eds., 7th ed. 2007).

179. *Id.* at 10–16.

180. *See* Milton Heumann et al., *Prescribing Justice: The Law and Politics of Discipne for Physician Felony Offenders*, 17 BOS. U. PUB. INT. L.J. 1, 7 (2007) ("Typically, such boards handle the licensing of physicians, the investigation of complaints, physician discipline, and where appropriate, the rehabilitation of offending physicians.").

181. *Id.* at 10 ("[R]ather than constantly revising schemes of regulation pertaining to particular procedures, states have regulated with a 'circular process of defining the scope of licensure,' whereby state medical licensing laws 'avoid defining allowable

grounds for disciplining a doctor will vary from state to state, but common bases include malpractice, improper prescribing of controlled substances, unprofessional conduct, and alcohol or drug dependency.[182]

Since a doctor's ability to practice medicine involves an important right, doctors who face formal disciplinary actions are entitled to significant due process.[183] Some state medical boards have a fairly elaborate process that also involves lawyers from the state attorney general's office.[184] A board's power to take adverse action can include no action, a reprimand, requiring additional training, probation, suspension, and revocation of a license.[185] While doctors are typically permitted to appeal the decisions of state medical boards, judicial reviews of those administrative actions usually only inquires into whether "the administrative agency acted arbitrarily, capriciously, or fraudulently."[186] Like adverse actions taken by a hospital, adverse actions taken by a state medical board must be reported to the National Practitioner Data Bank.[187]

C. *Private Medical Associations*

It is uncommon for doctors in the United States to complete medical school and residency and then simply begin to practice medicine. Most medical school graduates pursue some additional board certification.[188] Although the focus of board certification is to

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practice in terms of specific procedures or methods of practice,' opting instead to define the practice of medicine more generally.").

182. *See* SANBAR, *supra* note 178, at 12 ("Grounds for discipline of the medical licensee are generally set forth in statutes as 'unprofessional conduct' or violations of the Medical Practice Act.").

183. *Id.* at 13 (listing due process before a board as including, but not limited to "[p]roper notice of charges, notice of hearing before a properly constituted tribunal, the right to cross-examine and produce witnesses, and the right to a full consideration and fair determination based on the facts").

184. *See* Heumann et al., *supra* note 180, at 12–16 (providing a thorough discussion of the New Jersey Board of Medical Examiners procedures for addressing allegations of physician misconduct).

185. *See* SANBAR, *supra* note 178, at 13–14.

186. *Id.* at 14.

187. *See* Gershowitz, *supra* note 164 (observing that even though the federal government maintains the national data bank, some states fail to regularly review the information in the data repository).

188. *See* Donna B. Jeffe et al., *Which U.S. Medical Graduates Plan to Become Specialty-Board Certified? Analysis of the 1997–2004 National Association of American Medical Colleges Graduation Questionnaire Database*, 81 J. ACAD. MED. S98, S98 (2006) ("The proportion of 108,408 graduates planning specialty-board certification decreased from 97.3% in 1997 to 88.4% in 2004.").

demonstrate a higher level of skill and medical understanding,[189] it is also an important stepping stone in a doctor's career. In fact, some Health Management Organizations in the past have required board certification when hiring new doctors.[190]

There are twenty-four different board certifications listed on the American Board of Medical Specialties.[191] Each board is an independent organization that has its own policies, requirements, and procedures for securing and maintaining board certification.[192] For instance, the American Board of Internal Medicine (ABIM) has among its policies guidance on disciplinary action and appeals.[193] According to that policy, board-certified physicians can have their certification suspended or revoked for a variety of reasons, including "(4) fail[ing] to maintain moral, ethical or professional behavior satisfactory to ABIM; or (5) engag[ing] in misconduct that adversely affects professional competence or integrity."[194] The due process available to a physician facing disciplinary action by the ABIM includes many of the same rights as actions before state medical boards.[195]

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189. *See* Elaine Cox, *Board Certification for Doctors: What Does It Really Mean?*, U.S. NEWS HEALTH (Apr. 26, 2017), https://health.usnews.com/health-care/for-better/articles/2017-04-26/board-certification-for-doctors-what-does-it-really-mean ("Board certification . . . implies that the practitioner has gone above and beyond that minimal standard in a particular specialty or subspecialty by way of extra education and study, and has passed a test to prove it.").

190. Asha P. Wallace, *HMOs and Physicians Without Board Certifications*, 328 NEW ENG. J. MED. 1501, 1501 (1993) ("When managed care first appeared, [Health Maintenance Organizations] enlisted physicians and then used these rosters to market their plans. Concurrently, they developed credentialing criteria, which typically included information on training and licensure, board certification, and malpractice experience. Then HMOs began to emphasize in their marketing that they had only board-certified physicians on their panels, implying that this restriction defined a better plan.").

191. *See What is ABMS Board Certification?*, AM. BD. OF MED. SPECIALTIES, https://www.abms.org/board-certification/ (last visited Nov. 22, 2022) ("The 24 ABMS Member Boards are independent organizations entrusted to evaluate physicians' and medical specialists' knowledge, skill, and judgment and grant board certification to the individuals who complete board specific requirements including medical licensure, residency/fellowship training, program director attestation, and passing a rigorous exam.").

192. *Id.*

193. *See General Policies: Disciplinary Sanctions and Appeals*, AM. BD. INTERNAL MED., https://www.abim.org/certification/policies/general-policies (last visited Sept. 14, 2023).

194. *Id.*

195. *Id.*

III. THE FIRST AMENDMENT, DOCTORS, AND "PROFESSIONAL SPEECH"

The current debate involving disciplinary actions against doctors for COVID-19-related speech is the most recent controversy regarding physician speech. However, efforts to limit or require doctors or healthcare facilities to engage in certain speech have long been the subject of numerous court cases and several Supreme Court decisions. Can the state require doctors to make certain statements to patients considering an elective abortion?[196] Can the state prevent doctors from making certain statements to minors regarding gender reassignment?[197] Can the state prevent doctors from making statements to minors regarding the alteration of the minor's sexual orientation?[198] Each of these questions, like the COVID-19 question, involves compelled or prohibited professional speech. One aspect of the COVID-19 speech question that is somewhat distinct is the effort to control physician speech beyond the strict boundaries of the doctor-patient relationship.[199]

The United States Supreme Court has issued several important decisions recently regarding professional speech. The case most recent and relevant to this discussion is *National Institute of Family & Life Advocates. v. Becerra*.[200] In *Becerra*, the Court heard a challenge to California's Reproductive Freedom, Accountability, Comprehensive

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196. *See* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 882 (1992) (plurality opinion) ("If the information the State requires to be made available to the woman is truthful and not misleading, the requirement may be permissible."), *overruled by* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022).

197. *See* Dara Kam, *Florida's Transgender Treatment Rule Is in Effect, but Legal Challenges Are Planned*, HEALTH NEWS FLA. (Aug. 22, 2022, 8:36 AM), https://health.wusf.usf.edu/health-news-florida/2022-08-22/floridas-transgender-treatment-rule-will-face-a-legal-fight ("The Florida Board of Medicine, at the behest of the state Department of Health, is exploring a rule that would ban doctors from providing gender-affirming care, such as puberty blockers, hormone therapy and surgery, to youths."); Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *38 (E.D. Ark. June 20, 2023) ("[T]he Court finds that the State has failed to prove that its interests in the safety of Arkansas adolescents from gender transitioning procedures or the medical community's ethical decline are compelling, genuine, or even rational. Act 626 violates Dr. Stambough's rights under the First Amendment.").

198. *See* Claudia E. Haupt, *Professional Speech*, 125 YALE L.J. 1238, 1240 n.2 (2016) ("*See* Pickup v. Brown (*Pickup I*), 740 F.3d 1042 (9th Cir. 2013) (upholding the California law prohibiting licensed mental health providers from providing SOCE therapy to children under eighteen against a First Amendment challenge), *aff'd, remanded, and reh'g denied*, 740 F.3d 1208 (9th Cir. 2014), *cert. denied*, 134 S. Ct. 2871 (2014); . . . *see also* Doe v. Christie, 33 F. Supp. 3d 518 (D.N.J. 2014) (same).").

199. *See* Gill, note 174 and accompanying text; *see also* Weber, *supra* note 1 ("Two-thirds of state medical boards reported increased complaints 'related to licensee dissemination of false or misleading information' . . . .").

200. Nat'l Inst. of Family & Life Advoc. v. Becerra, 138 S. Ct. 2361, 2361 (2018).

Care, and Transparency Act (FACT Act).[201] The California law required clinics that principally served pregnant women to provide notices informing them of free or low-cost pregnancy services, including abortions.[202] The FACT Act primarily focused on regulating pregnancy crisis centers in California.[203] These crisis centers were pro-life organizations advocating non-abortion options to pregnant women.[204] The plaintiffs in the case argued that the FACT Act violated their First Amendment rights by compelling government-sanctioned speech.[205] The District Court hearing the case denied the plaintiffs' request for an injunction and the Ninth Circuit upheld that conclusion.[206] The Ninth Circuit concluded that the plaintiffs were unlikely to win their case on the merits because the restriction they complained of involved professional speech and was thus subject to a lower level of scrutiny.[207] A majority of the Supreme Court disagreed.[208]

Writing for a majority of the Court, Justice Thomas began by noting that the speech regulation at issue in the case was content-based.[209] Because the plaintiffs were "compel[ed] to speak a particular message," such notices "'alte[red] the content of [their] speech.'"[210] Next, Justice Thomas observed that there were only two circumstances where content-based professional speech was afforded less protection than the traditional standard of strict scrutiny.[211] Those two circumstances involve professionals disclosing "factual, noncontroversial information in their commercial speech,"[212] and "professional conduct, even though that conduct incidentally involves speech."[213] Ultimately, a majority of the Court found that the speech involved in *Becerra* did not fall under either of the two circumstances that permitted a lower level of scrutiny.[214] Thus, when the majority

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201. *Id.* at 2368.
202. *Id.*
203. *Id.*
204. *Id.*
205. *Id.* at 2370.
206. *Id.*
207. *Id.*
208. *Id.*
209. *Id.* at 2371.
210. *Id.* (quoting Riley v. Nat'l Fed'n of Blind of N.C., Inc., 487 U.S. 781, 795 (1988)).
211. *Id.* at 2372 (noting neither "turned on the fact that professionals were speaking.").
212. *Id.*; *see e.g.*, Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio, 471 U.S. 626, 651 (1985); Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 455–56 (1978).
213. *Becerra*, 138 S. Ct. at 2372; *see e.g.*, *Ohralik*, 436 U.S. at 456; *Casey*, 505 U.S. at 884.
214. *Becerra*, 138 S. Ct. at 2372 ("[N]either line of precedents is implicated here.").

applied the more restrictive standard of strict scrutiny, it found the FACT Act violated the plaintiffs' First Amendment rights.[215]

In the context of the current COVID-19 misinformation debate, the professional conduct exception to the general rule seems most relevant. In *Becerra*, Justice Thomas cites *Ohraklik v. State Bar Association Ohio*[216] and *Planned Parenthood of Southeastern Pennsylvania v. Casey* as representative of the exception.[217]

When looking at these various cases together a picture emerges—professional speech is "subject to reasonable licensing and regulation by the state."[218] In *Casey*, the Supreme Court found there was no First Amendment violation in requiring doctors to inform patients seeking an abortion:

> Except in a medical emergency, the statute requires that at least 24 hours before performing an abortion a physician inform the woman of the nature of the procedure, the health risks of the abortion and of childbirth, and the "probable gestational age of the unborn child." The physician or a qualified nonphysician must inform the woman of the availability of printed materials published by the State describing the fetus and providing information about medical assistance for childbirth, information about child support from the father, and a list of agencies which provide adoption and other services as alternatives to abortion. An abortion may not be performed unless the woman certifies in writing that she has been informed of the availability of these printed materials and has been provided them if she chooses to view them.[219]

The *Casey* Court describes the compelled speech provision as a reasonable regulation by the state by connecting the above

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215. *Id.* at 2375 ("In sum, neither California nor the Ninth Circuit has identified a persuasive reason for treating professional speech as a unique category that is exempt from ordinary First Amendment principles. We do not foreclose the possibility that some such reason exists. We need not do so because the licensed notice cannot survive even intermediate scrutiny.").

216. *Ohralik*, 436 U.S. at 456.

217. *Casey*, 505 U.S. at 884.

218. *See id.*

219. *Id.* at 881. It is worth noting that the Pennsylvania statute at issue in Casey had an escape clause to the mandatory disclosure that allowed a doctor to not provide the required information "'if he or she can demonstrate by a preponderance of the evidence, that he or she reasonably believed that furnishing the information would have resulted in a severely adverse effect on the physical or mental health of the patient.' 18 Pa. Cons. Stat. § 3205 (1990)." *Id.* at 883–84.

information to the doctor's obligation of ensuring they have informed consent before performing any medical procedure.[220] *Casey* overruled two prior decisions regarding compelled professional speech involving abortion: *Thornburgh v. American College of Obstetricians and Gynecologists*[221] and *City of Akron v. Akron Center For Reproductive Health*.[222] The *Casey* Court stated:

> To the extent *Akron I* and *Thornburgh* find a constitutional violation when the government requires, as it does here, the giving of truthful, non-misleading information about the nature of the procedure, the attendant health risks and those of childbirth, and the "probable gestational age" of the fetus, those cases go too far, are inconsistent with *Roe*'s acknowledgment of an important interest in potential life, and are overruled.[223]

Although states can impose restrictions or requirements on speech based on the right to regulate professions, those limitations are only an "incidental burden on protected expression."[224]

In *Becerra*, the Supreme Court rejected a broad First Amendment exception for professional speech.[225] Based on this holding, a degree of parsing appears necessary before going further. The effort to discipline doctors for COVID-19 misinformation seems to fall into two broad categories: medical advice given by a doctor to a patient; and public statements made in conferences, social media, newspapers, televised interviews, or testimony that is not made in the context of a

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220. *Id.* at 881.

221. Thornburg v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747, 763–65, 767, 769, 771–72 (1986), *overruled by* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

222. City of Akron v. Akron Ctr. for Reproductive Health, 462 U.S. 416, 438–39, 441–42, 448, 450–52 (1982), *overruled by* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

223. *Casey*, 505 U.S. at 882.

224. Sorrell v. IMS Health, Inc., 564 U.S. 552, 567 (2011).

225. Nat'l Inst. of Family & Life Advoc. v. Becerra, 138 S. Ct. 2361, 2375 (2018) (citations omitted) ("'Professional speech' is also a difficult category to define with precision. As defined by the courts of appeals, the professional-speech doctrine would cover a wide array of individuals—doctors, lawyers, nurses, physical therapists, truck drivers, bartenders, barbers, and many others. One court of appeals even applied it to fortune tellers. All that is required to make something a 'profession,' according to these courts, is that it involves personalized services and requires a professional license from the State. But that gives the States unfettered power to reduce a group's First Amendment rights by simply imposing a licensing requirement. States cannot choose the protection that speech receives under the First Amendment, as that would give them a powerful tool to impose 'invidious discrimination of disfavored subjects.'").

doctor-patient relationship.[226] The distinction between these two categories is significant. The capacity of the state to restrict or require speech from doctors would seem to be at its apogee in the context of the doctor-patient relationship—particularly when regulating informed consent. Conversely, the state's power to limit the speech of doctors would seem weakest when the doctor is making a statement in a public forum, outside of the doctor-patient relationship.

Although a distinction can be drawn between the two categories of professional speech, it should not be forgotten that there is the possibility of some overlap between public statements made by doctors and advice given by a doctor to individual patients. For example, doctors making a public statement trade, to one degree or another, on their status as a doctor. Further, there is the danger that a physician making a broad public statement could be misunderstood by members of the public to be giving individual medical advice.

Several articles have discussed the difficulty in distinguishing conduct and speech in the context of a professional relationship.[227] Despite this challenge, some areas of professional conduct by physicians would seem to fall clearly in or out of the speech as conduct category. For example, a physician engaging in casual conversation with a patient about a non-health-related topic would be engaging in non-conduct speech. A doctor explaining to a patient her recommendation regarding a medical course of action would be

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226. A third category of speech can be imagined as purely private non-professional conversations. This category would involve statements made by a doctor to friends and family without any representations that the doctor's statements represent a professional opinion. An example might be a pathologist who in casual conversation tells a neighbor that because the pathologist had a bad reaction to his first COVID-19 vaccine, the pathologist does not plan on getting another. Such a casual conversation, without the suggestion of a medical opinion or advice, would seem to be outside the realm of a disciplinary action. It is also worth noting that none of the groups seeking to discipline COVID-19 misinformation appear to be attempting to reach such trivial personal communications. Rather, the focus appears to be on communications with individual patients or statements made to the public often via social media.

227. *See* Patrick Bannon, *Intermediate Scrutiny vs. the "Labeling Game" Approach:* King v. Governor of New Jersey *and the Benefits of Applying Heightened Scrutiny to Professional Speech*, 23 J.L. & POL'Y 649, 655 (2015) (criticizing the Supreme Court's "undoubtedly incomplete definition of professional speech" and arguing a better solution was put forth by the Third Circuit court in *King v. Governor of New Jersey*, 767 F.3d 216 (3d Cir. 2014)); John S. Ehrett, *Speak No Evil, Do No Harm: A New Legal Standard for Professional Speech Regulation*, 2018 U. ILL. L. REV. ONLINE 184, 191 (2018) (advocating for a new standard to determine what is and is not considered professional speech); Erika Schutzman, Note, *We Need Professional Help: Advocating for a Consistent Standard of Review When Regulations of Professional Speech Implicate the First Amendment*, 56 B.C. L. REV. 2019, 2038 (2015) ("Although to some courts '[i]t is clear that individuals do not surrender their First Amendment rights entirely when they speak as professionals,' other courts have chosen to offer essentially no protection to speech that occurs in the context of a professional relationship.").

engaging in conduct-based speech. The Supreme Court has said as much in *Becerra*.[228] Because physicians have a professional obligation to ensure they have received informed consent from their patients, the communication necessary to satisfy that professional obligation is subject to a lesser standard of review than strict scrutiny.[229]

For a doctor providing a patient medical advice regarding COVID-19, as with any medical care, informed consent is critical. Further, given the diversity of information available regarding the wearing of masks, vaccines and boosters, and therapeutic care for patients with COVID-19, a well-informed patient is especially necessary to ensure autonomous decision making.[230] Thus, state medical licensing boards have a role in responding to allegations that a doctor has failed to meet his or her professional obligation in this regard. A brief review of the past year's decisions of two state licensing boards—Virginia and North Carolina—reveals that violations of informed consent do make up part of the disciplinary actions taken by those boards.[231]

IV. A RECOMMENDATION

Balancing the relevant competing interests involved in disciplining doctors who offer minority or even fringe opinions

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228. *See Becerra*, 138 S. Ct. at 2373; *see also* J. Aidan Lang, Note, *The Right to Remain Silent: Abortion and Compelled Physician Speech*, 62 B.C. L. REV. 2091, 2142 (2021).

229. *See* FAY A. ROZOVSKY, CONSENT TO TREATMENT: A PRACTICAL GUIDE 1–11 (Wolters Kluwer, 5th ed. 2014).

230. The purpose of informed consent in the United States is to ensure that patients are making well informed decisions about their own medical care. Thus, informed consent fulfills one of the four pillars of modern medical ethics—autonomy. *See Opinion 2.1.1 Informed Consent, Consent, Communication & Decision Making*, AMA CODE MED. ETHICS, https://www.ama-assn.org/delivering-care/ethics/informed-consent (last visited Nov. 28, 2022) (noting doctors are expected to inform patients of "the diagnosis (when known); the nature and purpose of recommended interventions; [and] the burdens, risks, and expected benefits of all options, including foregoing treatment").

231. *See* William Lafayette Doss, III, M.D, Case Nos. 198327, 192010, 186401, 183820, 182240, (Va. Bd. of Med. July 8, 2022) [hereinafter Doss Consent Order], https://www.dhp.virginia.gov/Notices/Medicine/0101053048/0101053048Order07082022.pdf (disciplining Dr. Doss for failure to provide adequate information to patients regarding certain prescribed medications); Letter of Concern from N.C. Med. Bd. to Winifred Owumi, M.D. (Nov. 29, 2021), https://ncmb.blob.core.windows.net/prod/204870/Owumi%20-%20Executed%20PubLOC%20-%2011.29.2021-fba8e03a-74c9-43f1-93f2-290011e6d630.pdf?sv=2019-07-07&sr=c&sig=KeQFxayA6FHDhCSD7gi6j3bAh9zIf52hjk9alAau1yM%3D&st=2023-10-29T16%3A15%3A39Z&se=2023-10-29T17%3A30%3A39Z&sp=r (detailing in their letter, which qualifies as an adverse action, Dr. Winifred Owumi's failing to secure appropriate informed consent from the parents of a child she conducted a circumcision upon).

regarding COVID-19 is difficult. The controversy raises issues involving public safety, freedom of speech, the proper role of the state in regulating the practice of medicine, allowing dissenting voices in the scientific and medical communities, the doctor-patient relationship, and patient autonomy. The recommendation offered in this article seeks to balance these interests. As suggested above, efforts to address physician speech and COVID-19 information can be divided into two categories: doctor speech as conduct and doctor speech as speech.

A. *Doctor Speech As Conduct*

As noted in *Becerra*, limitations on doctor-patient communication about informed consent are neither new nor particularly controversial. The state's interest in protecting the public and ensuring that doctors fulfill their professional obligations are part of why this type of speech is subject to a lower level of scrutiny by courts.[232] Thus, when states like California pass statutes like the COVID-19 Misinformation Act,[233] where the law is limited to regulating speech in the context of the doctor-patient relationship, the state has the greatest likelihood of its law surviving legal scrutiny.[234] That being said, a doctor's obligations under the doctrine of informed consent are more detailed than simply stating the scientific consensus. Doctors are expected to explain to patients their treatment options, the risks and benefits associated with each option, and the risks and benefits associated with taking no action.[235] It is important to keep in mind that the object of informed consent is that the patient has all the information necessary to make an informed, independent choice.[236] To support this discussion we can imagine several factual scenarios. Below I discuss two that deal with the decision to receive a COVID-19 vaccination. Informed consent in the context of vaccination

232. *See Becerra*, 138 S. Ct. at 2373 (citation omitted) ("[T]he requirement that a doctor obtain informed consent to perform an operation is 'firmly entrenched in American tort law.'").

233. *See supra* notes 7–11 and accompanying text.

234. *See* McDonald v. Lawson, No. 822-cv-01805-FWS-ADS, 2022 WL 18145254, at *14 (C.D. Cal. Dec. 28, 2022) (finding the act was within the state's power to regulate the practice of medicine and medical treatments). *But see* Hoeg v. Newsom, No. 2:22-CV-01980 WBS AC, 2023 WL 414258, at *12 (E.D. Cal. Jan. 25, 2023) (finding the plaintiffs would likely succeed in challenging the act under the vagueness doctrine).

235. *See Opinion 2.1.1 Informed Consent*, *supra* note 230 and accompanying text.

236. *See* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 881–86 (1992) (plurality opinion) (detailing the importance of fully informing a woman considering an abortion).

is not as straightforward as in other contexts like surgery.[237] In the vaccination context, public health is an added consideration. Despite this added consideration, informed consent is still required.[238]

Scenario One. In 2022, a patient goes to their doctor and asks whether the doctor recommends the now-available omicron-specific COVID-19 vaccine. Let us also suppose the doctor is concerned that the booster has not completed human clinical trials. Further, because the patient seeking the advice is a young male (twenty years old), has no comorbidities, and has already had COVID-19 during the omicron surge, the doctor does not favor the patient receiving the vaccine at this time. Also, for the sake of this hypothetical, let us assume the CDC and NIH recommend that all eligible individuals get the omicron-specific booster, and the patient is eligible.

Scenario Two. A patient goes to their doctor for an annual examination and has not received a COVID-19 vaccination. The patient is a seventy-two-year-old male and has several comorbidities that would make him particularly susceptible to COVID-19. The patient has refused the vaccine because he fears that the mRNA vaccine will alter his DNA and because the patient is convinced that COVID-19 is no worse than the average flu.

In both scenarios, the doctor would have an obligation to educate the patient regarding their treatment options. The doctor's advice would, at a minimum, have to meet the standard of care for advising their patients of COVID-19 treatments. Thus, in both scenarios, the doctor should advise both patients that vaccination is recommended by the CDC and NIH and explain the benefits and risks of vaccination. However, given the doctrine of informed consent is directed toward patients making well-informed, autonomous decisions about their health, it would be both acceptable and appropriate for the doctor to provide both patients with more information. For example, in the first scenario, so long as the doctor had an evidenced-based foundation for his or her recommendation, the doctor could advise the patient to wait on the omicron-specific booster and then explain the basis for the recommendation. Thus, we could envision a doctor explaining to the patient that the CDC and NIH both recommend that eligible individuals receive the booster why those organizations have made that recommendation and the evidence the recommendation is based on. Further, the doctor ought to explain to the patient the potential

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237. *See* Dorit Rubinstein Reiss & Nili Karako-Eyal, *Informed Consent to Vaccination: Theoretical, Legal, and Empirical Insights*, 45 AM. J.L. MED. 357, 358 (2019) ("The public health aspect of vaccines imposes constraints absent in other contexts. When public health is at risk, the individual right to autonomy may be restricted through legal rules aimed to support vaccination rates.").

238. *See id.* at 391 (detailing consent to vaccinations within the United States and analyzing the caselaw and statutory requirements).

adverse events associated with the vaccine and the rates of those events in individuals in a similar medical circumstance as the patient. The doctor could then explain why, in this patient's specific circumstance, the doctor is recommending against getting the booster at this time. The doctor should then explain the risks associated with not being boosted for an individual in the patient's medical circumstances. It would be wise for the doctor to also point out that several scientific studies have acknowledged that both natural and vaccine-acquired immunity wane over time.

With regard to the second scenario, we would expect that in addition to advising the patient that he should receive the COVID-19 vaccine, the doctor would do more. It would be consistent with the goals of informed consent that the doctor explain to the patient the currently available evidence that contradicts the patient's beliefs regarding COVID-19 and the vaccine. For patients to make truly autonomous decisions, they require evidence-based data. With regard to the patient's belief that COVID-19 is no more dangerous than the flu, the doctor could explain that deaths attributed to the flu in the United States from 2010 to 2020 were between 12,000 and 52,000 annually.[239] The CDC estimate for COVID-19 deaths from 2020 to November 2022 was over 1 million.[240] Further, it would seem appropriate to advise the patient that individuals in his particular age demographic who are unvaccinated are particularly vulnerable to infection, hospitalization, and death.[241] With regard to the patient's concern about an alteration of DNA due to the COVID-19 vaccine, the doctor might explain that there are no studies demonstrating that the COVID-19 vaccine alters the patient's DNA. Further, the doctor could explain how mRNA vaccines work and why this does not affect a patient's DNA. Once again, this approach facilitates the patient's informed, autonomous decision regarding treatment.

1. The Chelation Therapy Model

When looking at other medical controversies that might provide some guidance for how the medical and legal community could

239. *See Burden of Flu, Influenza (Flu)*, CDC, https://www.cdc.gov/flu/about/burden/index.html (last visited Nov. 29, 2022) ("CDC estimates that flu has resulted in 9 million–41 million illnesses, 140,000–710,000 hospitalizations and 12,000–52,000 deaths annually between 2010 and 2020.").

240. *See COVID Data Tracker*, CDC, https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://web.archive.org/web/20221129083125/https://covid.cdc.gov/covid-data-tracker/#cases-deaths-testing-trends] (last visited Nov. 29, 2022). *But see* Beard, *supra* note 82 and accompanying text.

241. *See* Beard *supra* note 82 (recognizing that the elderly are at the greatest risk of dying from a COVID-19 infection).

approach counter-orthodox medical opinions in the context of the doctor-patient relationship, chelation therapy for arteriosclerosis might be helpful.[242] Chelation therapy is an FDA-approved medical treatment used primarily to remove toxic metals from the body.[243] Chelation "is a chemical process in which a substance is used to bind metals or minerals so they can be excreted from the body."[244] In addition to being used to treat heavy metal poisoning, since the 1950s a small minority of doctors in the United States have used the therapy to treat arteriosclerosis,[245] Chelation therapy is not approved by the FDA for this purpose.[246] Further, it is not approved by Medicare for reimbursement if used to treat arteriosclerosis.[247] Arteriosclerosis is the most common form of heart disease and causes approximately

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242. In some of the footnotes in this section the term arteriosclerosis is used and at other times atherosclerosis. For example, the court in *State Bd. of Med. Exam'r of Fla. v. Rogers*, 387 So. 2d 937, 938 (Fla. 1980), uses the term arteriosclerosis and the court in *State Bd. Of Registration for the Healing Arts v. McDonagh*, 123 S.W.3d 146, 149 (Mo. 2003), uses the term atherosclerosis. The reason the courts use different terms is likely because atherosclerosis is a specific kind or type of arteriosclerosis. *See* Cheryl Whitten, *What Is the Difference Between Atherosclerosis and Arteriosclerosis?*, WEBMD, https://www.webmd.com/heart-disease/difference-between-atherosclerosis-arteriosclerosis (last visited Nov. 29, 2022) ("Arteriosclerosis is the general name for a group of conditions that cause arteries to become thick and stiff.").

243. *See Questions and Answers on Unapproved Chelation Products*, FDA, https://www.fda.gov/drugs/medication-health-fraud/questions-and-answers-unapproved-chelation-products (last visited Nov. 29, 2022) ("In medicine, chelation has been used for treatment of metal poisoning . . . . All FDA-approved chelation therapy products require a prescription because they can only be used safely under the supervision of a healthcare practitioner."); *see also* Villarruz-Sulit et al, *infra* note 287 and accompanying text.

244. *Chelation for Coronary Heart Disease: What You Need to Know*, NAT'L INST. HEALTH, https://www.nccih.nih.gov/health/chelation-for-coronary-heart-disease-what-you-need-to-know (last visited Nov. 22, 2022).

245. *See id.* ("When it's used as a complementary treatment for heart disease, a health care provider administers a solution of disodium EDTA in a series of infusions through the veins.").

246. *See id.* ("The use of EDTA chelation for heart disease has not been approved by the FDA").

247. *Chelation Therapy for Treatment of Arteriosclerosis*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=86&ncdver=1 (last visited Oct. 29, 2023) ("EDTA [Ethylenediamine-Tetra-Acetic Acid] chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered[.] Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section."); United States v. Lawrence, 405 F. 3d 888, 894 (10th Cir. 2005) ("Although chelation therapy is generally not covered by Medicare, Lawrence submitted bills to Medicare indicating the clinic had performed a form of intravenous therapy which was covered by Medicare.").

370,000 deaths a year in the United States.[248] The use of chelation for arteriosclerosis is very controversial[249]—a majority of the medical community does not think chelation therapy is an effective treatment for arteriosclerosis. As a result, some doctors who have recommended and provided chelation therapy to their patients have faced disciplinary actions before their state medical boards. Discussed below are two such cases. It is possible that the chelation debate could provide a template for reviewing the actions of doctors who recommend alternative COVID-19 treatment approaches.

The first case is *State Board Medical Examiners v. Rogers.*[250] In *Rogers,* the defendant was a practicing physician in Florida who offered his patients chelation therapy for arteriosclerosis.[251] Dr. Rogers's local medical board received a letter from the adult daughter of one of Dr. Rogers's patients asking the board about Dr. Rogers's use of chelation therapy.[252] The local medical board conducted an investigation and ultimately issued an order to Dr. Rogers to discontinue the therapy.[253] The doctor refused and the matter was taken up by the state medical board.[254] After holding a hearing, the hearing officer recommended that Dr. Rogers receive a reprimand, be placed on probation for one year, and be directed by the state Medical Board to stop providing chelation therapy to patients to treat arteriosclerosis.[255] The Board approved the hearing officer's recommendation and Dr. Rogers appealed the decision to the First District Court of Appeals of Florida.[256] The district court overturned

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248. *See* Roma Pahwa & Ishwarlal Jialal, *Atherosclerosis*, NIH: NAT'L LIBR. MED. (Aug. 8, 2023), https://www.ncbi.nlm.nih.gov/books/NBK507799/ ("Atherosclerosis is a chronic inflammatory disease of the arteries and is the underlying cause of about 50% of all deaths in westernized society.").

249. Kaye L. Rathmann & Larry K. Golightly, *Chelation Therapy of Atherosclerosis*, 18 DRUG INTELL. CLINICAL PHARM. 1000 (Dec. 1984) (arguing that evidence of chelation therapy's beneficial effect for the treatment of atherosclerosis is lacking). In fact, many studies that have examined chelation therapy in relation to atherosclerosis have found the treatment was ineffective. *See* Villarruz-Sulit et al., *infra* note 287 (finding the data that chelation therapy helps with heart disease inconclusive). *But see Chelation for Coronary Heart Disease: What You Need to Know*, *supra* note 244 (discussing a large-scale study sponsored by the National Center for Complementary and Integrative Health and the National Heart, Lung, and Blood Institute that demonstrated a modest improvement for patients with atherosclerosis who underwent chelation therapy; however, only patients with diabetes demonstrated these improvements).

250. State Bd. of Med. Exam'r of Fla. v. Rogers, 387 So. 2d 937 (Fla. 1980).

251. *Id.* at 937–38.

252. Rogers v. State Bd. of Med. Exam'rs of Fla., 371 So. 2d 1037, 1038 (Fla. Dist. Ct. App. 1979).

253. *Id.*

254. *Id.*

255. *Id.*

256. *Id.*

the decision of the Medical Board.[257] The Florida State Board of Medicine appealed,[258] and the Florida Supreme Court upheld the decision of the lower appellate court.[259]

The Florida Supreme Court held that the state Medical Board had engaged in the arbitrary and unreasonable exercise of its power.[260] The court focused on several factors including the lack of any evidence that chelation therapy was harmful; Dr. Rogers had not defrauded, misled, coerced, or overreached; and Dr. Rogers allowed patients to make their own choices as to whether to undergo the treatment after full disclosure regarding the disagreement within the medical community.[261] The court stated:

> Under the particular facts of this case, we conclude that the Board's action unreasonably interferes with Dr. Rogers' right to practice medicine by curtailing the exercise of his professional judgment to administer chelation therapy. The record before us fails to evidence harmfulness as a reasonable basis for the Board's action in restricting use of this treatment.[262]

The second case is *State Board of Registration for the Healing Arts v. McDonagh*.[263] The factual and legal issues in *McDonagh* are complicated. Dr. McDonagh, like Dr. Rogers, believed that chelation therapy was helpful to patients with arteriosclerosis and had been treating patients with that therapy for many years.[264] Between 1989 and 2001, the State Board of Registration for the Healing Arts had shifted its views on chelation therapy and its use in the treatment of arteriosclerosis.[265] Up to 1989, the Board seemed ambivalent regarding the treatment.[266] In 1989, however, the Board conducted an in-depth examination of the treatment but never issued any new rules or regulations.[267] In 1992 and 1994, two large, well-designed studies concluded that chelation therapy provided no benefit for the treatment of arteriosclerosis.[268] In response to these studies, the American Medical Association issued a statement concluding that

257. *Id.* at 1042.
258. State Bd. of Med. Exam'r of Fla. v. Rogers, 387 So. 2d 937 (Fla. 1980).
259. *Id.*
260. *Id.*
261. *Id.* at 939.
262. *Id.*
263. State Bd. of Registration for the Healing Arts v. McDonagh, 123 S.W.3d 146 (Mo. 2003).
264. *Id.* at 149–52.
265. *Id.* at 150.
266. *Id.*
267. *Id.*
268. *Id.*

there was no scientific evidence supporting the use of chelation therapy for arteriosclerosis, and shortly thereafter the Missouri Board of Registration for the Healing Arts issued a similar statement.[269] Dr. McDonagh nonetheless continued to treat patients with chelation therapy.[270]

The Board filed two separate disciplinary actions against Dr. McDonagh; one was dismissed and the other proceeded to a hearing.[271] The Board's second action included thirteen counts.[272] Among the charges were allegations that Dr. McDonagh had "endanger[ed] . . . the health of patients through the inappropriate provision of chelation therapy" and that he "misrepresented the efficacy of this therapy for atherosclerosis."[273] A hearing was held before an administrative law judge, and the judge ruled in Dr. McDonagh's favor.[274] The Board appealed the decision to the state circuit court, which upheld the administrative law judge's decision.[275] The Board then appealed the matter to the state supreme court—the case was reversed and remanded.[276]

The Missouri Supreme Court returned the case to the administrative law judge because the expert testimony relied upon the incorrect legal standard for medical negligence.[277] Particularly relevant is the Missouri Supreme Court's discussion of the standard to be applied to whether Dr. McDonagh had failed "to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of the applicant's or licensee's profession."[278] The Board argued that "Dr. McDonagh is negligent if he treats his patients in a way other than the treatment generally offered by doctors in the field."[279] Further, since most doctors do not use chelation therapy to treat atherosclerosis, Dr. McDonagh must have been negligent.[280] The Missouri Supreme Court rejected this approach.[281] Instead, a majority of the court stated:

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269. *Id.*

270. *Id.* ("In spite of these developments, neither the FDA, the AMA or the Board banned the use of chelation therapy to treat vascular disease, and Dr. McDonagh continued to prescribe and administer the therapy in his practice.").

271. *Id.* at 151.

272. *Id.*

273. *Id.*

274. *Id.*

275. *Id.*

276. *Id.* at 160.

277. *Id.* at 160.

278. *Id.* at 158.

279. *Id.*

280. *Id.*

281. *Id.* at 159 ("Neither party's argument is correct . . . . The relevant standard of care for discipline for repeated negligence is necessarily that set out in the statute addressing that conduct.").

> As the issue here is the treatment of persons with vascular disease, the appropriate standard of care *is that used by doctors treating persons with vascular disease*.
>
> Application of this standard does not merely require a determination of what treatment is most popular. Were that the only determinant of skill and learning, any physician who used a medicine for off-label purposes, or who pursued unconventional courses of treatment, could be found to have engaged in repeated negligence and be subject to discipline. This would not be consistent with section 490.065.
>
> Rather the statute requires only what it says—that Dr. McDonagh use that degree of skill and learning used by members of the profession in similar circumstances. By analogy, one doctor may use medicine to treat heart problems while another might [choose] to perform a by pass and a third to perform angioplasty, yet all three may be applying the requisite degree of skill and learning. That they came to differing conclusions by applying that skill and learning does not make one negligent and one non-negligent.[282]

Judge Michael A. Wolff concurred in part and dissented in part.[283] The judge suggested that the Board drop its action against Dr. McDonagh.[284] In offering this suggestion, the judge asked, "Is the healing arts board's use of section 334.100, which prescribes discipline for repeated acts of 'negligence,' an inappropriate use of the disciplinary process to impose the board's sense of orthodoxy?"[285]

When *Rogers* and *McDonagh* are considered together several factors can be distilled that might be useful for state medical boards addressing counter-consensus approaches to COVID-19. Those factors are: 1) harmfulness; 2) the presence of fraud, misrepresentation, or coercion; 3) whether there was full and complete informed consent; and 4) did the doctor display the degree of skill and learning employed by a reasonable doctor in a similar circumstance.[286] This proposed

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282. *Id.*

283. *Id.* at 160 (Wolff, J., concurring in part, dissenting in part).

284. *Id.*

285. *Id.* at 162.

286. *See* State Bd. of Med. Exam'r of Fla. v. Rogers, 387 So. 2d 937, 939 (Fla. 1980) (listing the district court's considerations and conclusions).

approach would require a case-by-case analysis for each specific allegation regarding misconduct by doctors in providing information and care to their patients.

It is important to note that the application of this standard could support disciplinary action against a doctor using chelation therapy.[287] In *Rogers*, for example, the relevant court found discipline was not supported, but given different evidence or facts, discipline might have been justified.[288] Whether chelation therapy is harmful was poorly supported in *Rogers*, but evidence may reveal a significant harm from this unconventional treatment.[289] In *Sletten v. Briggs*, the North Dakota Supreme Court upheld a state medical board's suspension of a doctor's license for the use of chelation therapy.[290] Although the North Dakota Supreme Court seemed more deferential to the state medical license board than the courts in *Rogers* and *McDonagh*, the hearing before the licensing board led to the conclusion that chelation therapy does pose a risk of harm.[291]

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287. *See* Sletten v. Briggs, 448 N.W. 2d 607, 611 (N.D. 1989) (upholding the state medical board's decision to suspend a doctor's license for using chelation therapy where the Board found such treatment was associated with renal failure and electrolyte imbalance). Although the North Dakota Supreme Court upheld the medical board's decision, the issues in the case were more complicated than in *Rogers* and *McDonagh*. Dr. Briggs had entered into a settlement stipulation of a prior complaint to the Board which gave significant discretion to the Board regarding alleged future violations by Dr. Briggs. *Id.* at 608–09.

288. *See Rogers*, 387 So. 2d at 939 ("Under the particular facts of this case, we conclude that the Board's action unreasonably interferes with Dr. Rogers' right to practice medicine by curtailing the exercise of his professional judgment to administer chelation therapy."); *McDonagh*, 123 S.W.3d at 159 ("[I]f Dr. McDonagh's treatment, . . . demonstrates the application of the degree of skill and learning ordinarily used by members of his profession, then it is not a basis for discipline under the statute, even if other doctors would apply these facts to reach a different result.").

289. *See* Maria Vanessa Villarruz-Sulit et al., *Chelation Therapy for Atherosclerotic Cardiovascular Disease*, COCHRANE DATABASE SYST. REV., May 5, 2020, at 16, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7198985/pdf/CD002785.pdf ("In addition, the proper recording and reporting of safety issues or adverse events should always be part of research involving novel treatments such as this. In as much as benefits need to be reported, there is always a need to balance it with any risk present.").

290. *See Sletten*, 448 N.W.2d at 611.

291. *Id.* at 608 ("The therapy consists of an intravenous infusion of three grams of a chemical called EDTA three times a week . . . . The potential problems associated with this procedure include renal failure and electrolyte imbalance . . . ."). It is important to note that several state medical boards have taken actions against medical doctors who administer chelation therapy for conditions other than heavy metal poisoning. *See e.g.*, Geier v. Maryland State Bd. of Physicians, 116 A.3d 1026, 1032 (Md. 2015) (using chelation therapy to treat precocious puberty and autism). Although these cases include chelation therapy, they also frequently involve allegations of other misconduct, making it difficult to parse out the role of chelation therapy in the

To illustrate how these factors might be applied, we can return to the first fact scenario regarding COVID-19 vaccinations. In that scenario, the doctor recommended that his 20-year-old healthy male patient delay taking an omicron booster.[292] Here, the first question is whether this advice is harmful. That is perhaps the most difficult question to answer. Although some healthy young people have gotten very ill and died from COVID-19, those cases are exceedingly rare.[293] The CDC has estimated that fewer than 600 males between the ages of 5 and 18 have died from COVID-19 in the United States.[294] Further, the likelihood of a healthy, young, vaccinated individual who has already had COVID-19 during the omicron surge dying is also rare.[295] Although the current data regarding adverse reactions to COVID-19 boosters indicates that boosters are no more likely to cause a serious adverse reaction than the original vaccine (and those serious adverse reactions are extremely rare),[296] rare risks are not *no* risks.

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disciplinary action. *See e.g., id.* at 1030 (observing that the doctor did not obtain informed consent and falsified records); DeHart v. State Bd. of Registration in Podiatry, 293 N.W.2d 806, 808 (Mich. Ct. App. 1980) (finding a podiatrist's use of chelation constituted "practice of medicine" under the statute so his standard of care should have been that of a physician not a podiatrist).

292. *See supra* Part IV.A.

293. *See Deaths by Sex, Ages 0–18* Years, CDC, https://data.cdc.gov/NCHS/Deaths-by-Sex-Ages-0-18-years/xa4b-4pzv (last visited July 27, 2023) (according to the most recent CDC data, approximately 588 males between the ages of 5 and 18 have died from COVID-19 between January 2020 and June 2023).

294. *See id.* Although the number of deaths from COVID-19 among males 5–18 in the U.S. is very low, death is not the only serious adverse outcome associated with COVID-19—hospitalization, pericarditis, myocarditis, and "long Covid" are all possibilities. *See* Olga Vera-Lastra et al., *Myopericarditis as a Manifestation of Long COVID Syndrome*, 13 CUREUS, Nov. 10, 2021, at 4–5 (reporting on a young patient who presented symptoms of "chest pain, dyspnea, and tachycardia after the acute phase of COVID-19 infection" and finding it likely that a "healthy patient who exhibits mild symptoms of COVID-19 may present long COVID" including myopericarditis).

295. Although individuals who have been infected with COVID-19 have a degree of immunity, that immunity will wane—just as it does with vaccine immunity. Furthermore, research supports that the omicron variant of COVID-19 has a much higher reinfection rate than earlier variants. *See* Osman Özüdoğru et al., *SARS CoV-2 Reinfection Rate is Higher in the Omicron Variant Than in the Alpha and Delta Variants*, 192 IR. J. MED. SCI. 751, 755 (2023) ("[T]he variant with the highest reinfection rate in our study is the currently dominant Omicron variant (13.0%). Of those with a reinfection period of 3–6 months, 11 (8.8%) had Alpha variant, 9 (7.2%) Delta variant, and 105 (84.0%) Omicron variant.").

296. *See* Moreira, Jr. et al., *supra* note 85, at 1918 ("In our phase 3 trial, which included more than 10,000 participants, a third 30-μg dose of BNT162b2 administered a median of 10.8 months after the second dose was safe and effective. The safety profile was consistent with the results of previous trials, and reactogenicity was similar to that after the second dose. No new safety signals were identified, and no cases of myocarditis or pericarditis were reported."); Natacha Buergin et al., *Sex-Specific Differences in Myocardial Injury Incidence After COVID-19 mRNA-1273 Booster Vaccination*, EUR. J. HEART FAILURE, July 20, 2023, at 1 (concluding "mRNA-1273

Researchers from several medical schools and universities recently published an article raising concerns about the risk-benefit calculation regarding boosters and young adults.[297] In our fact pattern, full and complete informed consent is envisioned such that the patient has all the relevant information regarding his options before deciding whether to follow the doctor's recommendation. Finally, did the doctor employ the degree of skill and learning as used by reasonable members of the profession in a similar circumstance? Some might argue our first scenario doctor did not employ the degree of skill and learning of a reasonable doctor in a similar circumstance because most physicians are recommending the omicron-specific booster for their young patients. However, following the logic of *McDonagh*, the question is not what treatments most doctors recommend, rather, the question is whether the doctor employed the proper level of skill and learning in providing advice. Provided the doctor has engaged in an evidence-based approach to the advice he has given, then it can be argued that the doctor met this requirement.

What might be an example of a failure to meet the standards suggested above? We can consider the disciplinary action taken against Dr. Mark Brody by the Rhode Island Board of Medical Licensure and Discipline.[298] In Dr. Brody's case it was alleged, and admitted at the hearing, that before the release of the COVID-19 vaccines in 2020, Dr. Brody sent a letter to his patients informing them that he would not be administering any vaccinations.[299] It was further alleged that the letter sent by the doctor advised patients to "not accept the coronavirus vaccine at the time, regardless of who the manufacturer is, and what you may be told by those who may want to persuade you to take it."[300] Further, the doctor stated that "there exists the possibility of sterilizing all females in the population who receive the vaccination, disrupting recipient's DNA, which controls and regulates who and what we are, and other unpredictable long-term health consequences."[301] When asked by the Medical Board for

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vaccine-associated myocardial injury was more common than previously thought, being mild and transient, and more frequent in women versus men. The possible protective role of IFN-λ1(IL-29) and GM-CSF warrant further studies.").

297. *See* Bardosh, *supra* note 75 and accompanying text; Fatma Khaled, *Top Florida Doctor Warns Young Men COVID Vaccines Pose 'High Risk' of Death*, NEWSWEEK (Oct. 9, 2022, 5:46 PM), https://www.newsweek.com/top-florida-doctor-warns-young-men-covid-vaccines-pose-high-risk-death-1750150 ("'Based on currently available data, patients should be informed of the possible cardiac complications that can arise after receiving a mRNA COVID-19 vaccine. With a high level of global immunity to COVID-19, the benefit of vaccination is likely outweighed by this abnormally high risk of cardiac related death among men in this age group' . . . .").

298. *See* Brody Consent Order, *supra* note 18 and accompanying text.

299. *Id.* at 1–2.

300. *Id.* at 2.

301. *Id.*

the evidence on which he based his advice, Dr. Brody was unable to cite any peer-reviewed studies or medically trustworthy sources.[302] Rather, the doctor cited media reports.[303]

Applying the standards suggested by this article, disciplinary action seems necessary. Dr. Brody's letter presented a high potential for a real and direct threat to the health of his patients. The wholesale recommendation to all his patients to not receive a COVID-19 vaccination posed a serious health risk, especially to Dr. Brody's older patients and those with illnesses or conditions that placed them at higher risk of becoming seriously ill from COVID-19. Dr. Brody's statement could also run afoul of the second factor described above. Although the statement may not represent fraud (a purposely deceptive act) or coercion, it could qualify as a misrepresentation given the negligent character of the comments. Third, Dr. Brody's comments fail by a significant degree to meet the standards of informed consent. By refusing to offer any information regarding the benefits of receiving the vaccine, or accurately discussing the scientific evidence regarding adverse reactions to the vaccine, the doctor has failed to fulfill this obligation. Finally, given that the doctor did not rely on any scientific or medical evidence before advising all his patients to refuse the COVID-19 vaccine, and that he offered this advice without consideration of patients' individual circumstances, Dr. Brody did not employ the degree of skill and learning as used by reasonable members of the profession in a similar circumstance. The Rhode Island Board of Medical Licensure and Discipline entered a consent order in which Dr. Brody agreed to accept a disciplinary reprimand and other actions dictated by the Board.[304]

2. A Recommendation for Restraint

As noted above, in some circumstances state medical licensing boards have the power to discipline doctors who offer medical advice to patients that is counter to mainstream approaches to COVID-19. When determining whether to discipline a doctor, due consideration ought to be given to the potential second-order effects that discipline might have. For example, the California Anti-Misinformation statute authorized the discipline of doctors for information shared as part of the doctor-patient relationship that is not supported by scientific consensus.[305] Such a law has the potential to chill legitimate doctor-patient communication, reduce trust between doctors and patients,

302. *Id.*
303. *Id.*
304. *Id.* at 7–9.
305. *See supra* notes 7–11 and accompanying text.

and cause patients to follow the dangerous path of self-care and self-medication.

By way of example, we can consider the ivermectin debate. As mentioned above, early in the pandemic, ivermectin was considered as a possible treatment/prophylactic for COVID-19.[306] Although the drug had and still has its advocates, several studies, including two large double-blinded placebo-controlled studies published in the New England Journal of Medicine and the Journal of the American Medical Association have found no statically significant benefit in the treatment of COVID-19.[307] Based on these studies, most in the medical community will not prescribe ivermectin for patients with COVID-19. Some doctors still prescribe ivermectin.[308] Several doctors who did prescribe ivermectin have faced investigations by their state medical licensing boards.[309] Also, many pharmacists would not fill ivermectin prescriptions if they were for the treatment of COVID-19.[310]

After ivermectin was suggested as a potential prophylactic or treatment for COVID-19, several news stories reported that individuals were self-medicating with veterinary ivermectin.[311] Ivermectin was first used in the United States as an animal anti-parasitic and is a common veterinary medication at stores that sell farming equipment and animal grain.[312] Reports surfaced of increased calls to poison control lines relating to individuals who took an accidental overdose of veterinary ivermectin.[313]

Generally, a doctor can not be compelled to provide a patient with a medication they do not believe will work. Further, if a doctor does prescribe ivermectin to treat COVID-19, any disciplinary action should involve a thorough examination of the safety of the particular treatment and the particular patient. Although serious adverse side

306. *See* Caly et al., *supra* note 93 and accompanying text.

307. *See* Lim et al., *supra* note 120 and accompanying text; *see also* Reis et al., *supra* note 123 and accompanying text.

308. *See Ivermectin III*, supra note 125 and accompanying text.

309. *See* Heine, *supra* note 163 and accompanying text.

310. *See* AMA Press Release, *supra* note 116 and accompanying text.

311. *See* Liz Ahlberg Touchstone, *Can People Take a Livestock Drug to Treat a Deadly Virus?*, ILL. NEWS BUREAU (Sept. 2, 2021, 10:00 AM), https://news.illinois.edu/view/6367/737643427 ("Demand has surged for ivermectin, a drug widely given to horses and cows to treat worms and other parasitic infections, as a possible treatment or preventative for COVID-19. Some seekers have turned to over-the-counter animal formulations . . . resulting in a spike in calls to poison control centers.").

312. *Id.*

313. *Id.*

effects have been linked to ivermectin, they are rare.[314] Even the TOGETHER study published in the New England Journal of Medicine, which found ivermectin was not effective against COVID-19, found no statistically significant difference in adverse events between the members of the study receiving ivermectin versus a placebo.[315] Given the safety profile of ivermectin[316] and the evidence suggesting its possible benefit, a doctor might wish to prescribe the drug. Assuming the doctor has secured full and complete informed consent and has otherwise met the standard of care, punishing that doctor may do more harm than good. If members of the public believe that physicians are being prevented from sharing their actual professional opinions for fear of being punished, trust between patients and doctors will inevitably be harmed.[317] Further, the likelihood of individuals self-medicating with dangerous substitutes will increase.[318] In addition to dangerous self-care, patients may lose

314. *See* Courtney Temple et al., Correspondence, *Toxic Effects from Ivermectin Use Associated with Prevention and Treatment of COVID-19*, 385 NEW ENG. J. MED. 2197 (2021) ("There is insufficient evidence to support the use of ivermectin to treat or prevent Covid-19, and improper use, as well as the possible occurrence of medication interactions, may result in serious side effects requiring hospitalization"); Eloise Baudou et al., Correspondence, *Serious Ivermectin Toxicity and Human ABCB1 Nonsense Mutations*, 383 NEW ENG. J. MED. 787 (2020) (discussing a thirteen-year-old boy's serious side effects following treatment for an unknown ailment with ivermectin). Finally, even those who have urged caution regarding ivermectin's use against COVID-19 have accepted the strong safety profile of the drug. *See* Jérémy T. Campillo et al., *Serious Adverse Reactions Associated with Ivermectin: A Systematic Pharmacovigilance Study in Sub-Saharan Africa and in the Rest of the World*, PLOS NEGLECTED TROPICAL DISEASES, April 20, 2021, at 2 ("While our results do not put in question ivermectin's excellent safety profile, they show that as for all drugs, appropriate pharmacovigilance for adverse reactions is indicated.").

315. *See* Lim et al., *supra* note 120 and accompanying text.

316. *See Ivermectin II*, *supra* note 106 (listing potential side effects such as dizziness, pruritus (itching), nausea, or diarrhea). The website goes on to state:

> Neurological adverse effects have been reported with the use of ivermectin for the treatment of onchocerciasis and other parasitic diseases, but it is not clear whether these adverse effects were caused by ivermectin or the underlying conditions.

Id. But see Temple et al., *supra* note 314 and accompanying text; Baudou et al., *supra* note 314 and accompanying text. Finally, even those who have urged caution regarding ivermectin's use against COVID-19 have accepted the strong safety profile of the drug; Jérémy T. Campillo et al, supra note 314 and accompanying text.

317. Brian Kennedy et al., *Americans' Trust in Scientists, Other Groups Declines*, PEW RSCH. (Feb. 15, 2022), https://www.pewresearch.org/science/2022/02/15/americans-trust-in-scientists-other-groups-declines ("Overall, 29% of U.S. adults say they have a great deal of confidence in medical scientists to act in the best interests of the public, down from 40% who said this in November 2020. Similarly, the share with a great deal of confidence in scientists to act in the public's best interests is down by 10 percentage points (from 39% to 29%), according to a new Pew Research Center survey.").

318. *See* Touchstone, *supra* note 311 and accompanying text.

faith in their doctors more broadly.[319] Patients may conclude that if they cannot trust their doctor regarding ivermectin, perhaps they cannot trust their doctor regarding vaccination, masks, or any other COVID-19 related care.[320] If doctors are allowed to offer counter-consensus opinions (provided the opinions do not violate the principles described above), patients can be more confident that their doctor's opinions comply with the larger medical community. Thus, if a patient knows their doctor feels free to recommend ivermectin if she thinks it would be of value, that patient is more likely to trust their doctor when she says not to take the drug because it will not help.

B. *Professional Speech as Speech*

As discussed in the introduction, efforts to discipline medical doctors for their minority-held beliefs regarding COVID-19 extend beyond opinions expressed in the context of the doctor-patient relationship. In fact, it is likely that it is the public statements of doctors (on social media, YouTube, in newspapers, on television, and even at medical conferences) that create the greatest concern.[321] Despite the call by some to punish these doctors or prevent them from expressing their minority-held COVID-19 beliefs,[322] state action through medical licensing boards will face First Amendment challenges. In *Becerra*, the Supreme Court appears to have resolved the question of whether there is a "professional speech" exception to the usual standards regarding the First Amendment.[323] The Court explained that other than professional commercial speech or professional speech as conduct, there is no "professional speech" exception to the usual rules of the First Amendment.[324]

In the commercial speech context, the Supreme Court has established a lower level of scrutiny for laws that require "professionals to disclose factual, noncontroversial information in

319. *See* Mikkael Sekeres, *The Pandemic Has Eroded Our Trust in Doctors*, SALON (Oct. 31, 2021, 10:00 AM), https://www.salon.com/2021/10/31/trust-in-doctors-eroded/ ("Trust in medicine has taken a hit over the past year-and-a-half as we've reacted in real time to what we've defined as truth in a quickly moving pandemic, and in an era in which information is disseminated quickly.").

320. *See id.* ("Is it any wonder that some vaccine hesitancy can be attributed to suspicion of information about the safety and efficacy of the vaccine — information provided by the same healthcare authorities who first insisted that masks weren't important?").

321. *See* Gill, *supra* note 174 and accompanying text.

322. *See* Wynia, *supra* note 36 and accompanying text.

323. Nat'l Inst. of Family & Life Advoc. v. Becerra, 138 S. Ct. 2361, 2371–72 (2018) ("But this court has not recognized 'professional speech' as a separate category of speech. Speech is not unprotected merely because it is uttered by 'professionals.'").

324. *Id.*

their 'commercial speech.'"[325] Although some of the doctors making counter-consensus statements regarding COVID-19 may be engaging in commercial speech, this would appear to be the exception.[326] Thus, statements by doctors that are advertisements could be more freely regulated, but statements of opinion that are not tied to a commercial endeavor would not.[327]

With regard to physician professional speech as conduct, courts distinguish between statements made in the treatment of a patient and public statements unrelated to the care of a particular individual. A recent case decided by the Ninth Circuit, *Pickup v. Brown*,[328] illustrates this point nicely.

In *Pickup*, the Ninth Circuit considered a First Amendment challenge to a recent California law that "banned state-licensed mental health providers from engaging in sexual orientation change efforts with patients under the age of 18 years of age."[329] The law further held that state-licensed mental health providers who violated the new law would face discipline by the state licensing authority.[330] The court ultimately upheld the statute, ruling that it did not violate the plaintiff's First Amendment rights.[331] When determining whether the California law ran afoul of the First Amendment, the court suggested that professional speech could be envisioned as running along a continuum.[332] The court explained:

> At one end of the continuum, where a professional is engaged in a public dialogue, First Amendment protection is at its greatest. Thus, for example, a doctor who publicly advocates a treatment that the medical establishment considers outside the mainstream, or even dangerous, is entitled to robust protection under

325. *Id.* at 2372.

326. *But see* Michelle R. Smith et al., *Anti-Vaccine Chiropractors Are Rising Source of Spreading COVID-19 Misinformation*, FOX 13 TAMPA BAY (Oct. 11. 2021, 5:27 PM), https://www.fox13news.com/news/anti-vaccine-chiropractors-are-rising-source-of-spreading-covid-19-misinformation ("The AP also found some chiropractors were selling anti-vaccine ads on Facebook and Instagram, including one in California who pushed a link to a disinformation-filled video series about vaccines that AP previously reported has paid out millions to affiliates who helped sell the product.").

327. *See* Sorrell v. IMS Health, Inc., 564 U.S. 552, 567 (2011) ("[T]he First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech.").

328. Pickup v. Brown, 740 F.3d 1208 (9th Cir. 2014).

329. *Id.* at 1221.

330. *Id.* at 1223.

331. *Id.* at 1229 (The bill regulates "professional *conduct*, where the state's power is great, even though such regulation may have an incidental effect on speech.").

332. *Id.* at 1227.

> the First Amendment—just as any person is—even though the state has the power to regulate medicine.[333]

The *Pickup* court's statement above has been echoed in other cases and by several legal scholars.[334] Thus, when doctors make a public statement, even public statements regarding medicine, they enjoy the same First Amendment rights to freedom of speech as any other citizen.

1. Medical Speech as a Political Tool

It is an unfortunate fact that from time to time medicine and science become politicized. A few courts have commented on this phenomenon.[335] Since the beginning of the pandemic, political figures

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333. *Id.*

334. The *Pickup* court cites to the decisions of other court cases that stand for the proposition that the state is no more able to limit doctors' public statements regarding medical opinions than it can any private citizen so long as the statements are made outside of a doctor-patient relationship. *See* Snyder v. Phelps, 562 U.S. 443, 451 (2011) ("Speech on matters of public concern is at the heart of the First Amendment's protection.") (internal quotation marks, brackets, and ellipsis omitted); Bailey v. Huggins Diagnostic Rehab. Ctr., Inc., 952 P.2d 768 (Colo. Ct. App. 1997) (finding that the First Amendment prevents a dentist from being held liable for statements made while promoting his book, even though the statements are counter to current medical opinion); *See also* Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech*, 2007 U. ILL. L. REV. 939, (2007); Haupt, *supra* note 198, at 1254–55 (quoting Lowe v. SEC, 472 U.S. 181, 232 (1985) (White, J., concurring)) ("The line between the professional's private speech and professional speech, then, can be drawn by considering the presence or absence of a professional-client relationship. 'Where the personal nexus between professional and client does not exist, and a speaker does not purport to be exercising judgment on behalf of any particular individual with whose circumstances he is directly acquainted,' the speaker is not engaged in professional speech. When the professional's advice is distributed generally or to the public at large, outside of the professional-client relationship, it is most likely not professional speech. Investment advice distributed to the general public, for example, does not constitute professional speech; nor do books on how to avoid probate, diet plans, or mushroom guides, even though inaccurate information so disseminated may be harmful. When professionals speak in such a manner, they act as ordinary citizens participating in public discourse and accordingly enjoy ordinary First Amendment protection.").

335. Nat'l Inst. of Family & Life Advoc. v. Becerra, 138 S. Ct. 2361, 2374 (2018) ("Take medicine, for example. 'Doctors help patients make deeply personal decisions, and their candor is crucial.' *Wollschlaeger v. Governor of Florida*, 848 F. 3d 1293, 1328 ([11th Cir.] 2017) (en banc) (W. Pryor, J. concurring). Throughout history, governments have 'manipulat[ed] the content of doctor-patient discourse' to increase state power and suppress minorities: 'For example, during the Cultural Revolution, Chinese physicians were dispatched to the countryside to convince peasants to use contraception. In the 1930s, the Soviet government expedited completion of a construction project on the Siberian railroad by ordering doctors to both reject requests for medical leave from work and conceal this government order from their patients. In

have used doctors and scientists to advance their objectives. Former President Trump established daily briefings from the COVID-19 Task Force, led by Vice President Mike Pence.[336] The task force included Dr. Anthony Fauci, Dr. Deborah Birx, and Dr. Robert Redfield.[337] Subsequently, Dr. Scott Atlas was also appointed to the Task Force.[338] Some have argued that President Trump's choice to appoint Dr. Atlas to his COVID-19 Task Force was politically motivated.[339] Senator Rand Paul and Dr. Fauci have clashed repeatedly during Senate Hearings regarding the government's response to COVID-19.[340] The

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Nazi Germany, the Third Reich systematically violated the separation between state ideology and medical discourse. German physicians were taught that they owed a higher duty to the "health of the Volk" than to the health of individual patients. Recently, Nicolae Ceausescu's strategy to increase the Romanian birth rate included prohibitions against giving advice to patients about the use of birth control devices and disseminating information about the use of condoms as a means of preventing the transmission of AIDS.' [Paula] Berg, *Toward a First Amendment Theory of Doctor-Patient Discourse and the Right To Receive Unbiased Medical Advice*, 74 B.U. L. REV. 201, 201-202 (1994) (footnotes omitted)."); Whole Woman's Health v. Paxton, 10 F.4th 430, 467 (5th Cir. 2021) ("[S]ome academics have even begun to wonder whether '[s]cience . . . can no longer be construed simply as the ideal of the quest for truth (i.e., pure science).'") (Owen, C.J., concurring); Fabrice Jotterand, *The Politicization of Science and Technology: Its Implications for Nanotechnology*, 34 J.L. MED. & ETHICS 658, 658–61 (2006) (citations omitted) ("Science, through its technological applications, has become the source of economic power and, by extension, political power. As a result, science, with its political implications, has entered what [one scholar] calls the era of 'post-academic' science. And the role played by cultural-political factors in scientific research lies at the basis of a shift in how scientific inquiry is conducted.").

336. Brian Padden, *Coronavirus Fears Could Become Defining US Election Issue*, VOA NEWS (Mar. 5, 2020, 8:51 PM), https://www.voanews.com/a/science-health_coronavirus-outbreak_coronavirus-fears-could-become-defining-us-election-issue/6185357.html ("Public confidence in Trump's presidency could hinge on whether his administration can calm growing coronavirus fears.").

337. *Id.*

338. Cristina Cabrera, *Trump's Fav Advisor Brushes off Redfield and Fauci: 'I'm Not Here to Make Friends'*, TALKING POINTS MEMO (Sept. 29, 2020, 9:54 AM), https://talkingpointsmemo.com/news/trumps-fav-covid-adviser-brushes-off-redfield-and-fauci-im-not-here-to-make-friends.

339. *Id.* ("Dr. Scott Atlas, a member of the White House COVID-19 task force who is infamous for parroting Trump-friendly but scientifically dubious talking points about the pandemic . . . .").

340. *See Fauci Urges Caution on Schools, Warns Against 'Cavalier' Idea That Children Are Immune from COVID-19*, FOX 5 WASH. D.C. (May 13, 2020), https://www.fox5dc.com/news/fauci-urges-caution-on-schools-warns-against-cavalier-idea-that-children-are-immune-from-covid-19 ("Speaking at a Tuesday Senate hearing, Dr. Anthony Fauci had a sharp retort for Sen. Rand Paul after the Kentucky Republican said that Fauci was not the 'end all' in knowledge about the coronavirus, and that it's 'kind of ridiculous' to suggest children should be kept out of school in fall."); Sheryl Gay Stolberg, *Trump May Reject Tougher F.D.A. Vaccine Standards, Calling Them 'Political'*, N.Y. TIMES, (Sept. 24, 2020),

COVID-19 pandemic and how the United States government has responded to the crisis are political. Because of that, permitting all citizens, even doctors with potentially harmful views, to have a full right to freedom of speech is necessary. The Supreme Court has repeatedly stated that at the core of the First Amendment's protections is the citizens' right to express their political or ideological beliefs.[341] In *West Virginia State Board v. Barnette*,[342] Justice Jackson wrote:

> If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics,

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https://www.nytimes.com/2020/09/23/us/politics/coronavirus-science.html ("At one point, Senator Rand Paul, Republican of Kentucky, upbraided Dr. Fauci for favoring an 'economic lockdown' — Dr. Fauci insisted he had said no such thing — and suggested, without evidence, that spread of the virus had slowed in New York because 'they have enough immunity to actually stop it.'"). *But see* Allie Hogan, *Dr. Fauci Says He Recommended a Nationwide Shutdown to Trump Early On*, YAHOO! (Oct. 7, 2020), https://www.yahoo.com/video/dr-fauci-says-recommended-nationwide-144411296.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAAMjNofwzhla1-Tk78c7NII1tws5a_8FhWgX5M16iI-FtN_YEF_ElugqhPsZzGw0OYNq9tQcgyNstDtsNM2HYM48J2fx6PJJM7ahmIIRvoMnh_GXqWIOZUW1zpGIA3jFrEGZxvq5_oYGwOg673tXJO_2IEIvI-7lzUopShukohTuZ ("When it became clear that we had community spread in the country, with a few cases of community spread—this was way before there was a major explosion like we saw in the Northeastern corridor driven by New York City metropolitan area—I recommended to the president that we shut the country down,' said Fauci."); Aidin Vaziri, *Coronavirus Live Updates: The Race Between Variants and Vaccines is Heating Up. Can the Bay Area Pull Ahead?*, S.F. CHRON. (Mar. 19, 2021, 01:09PM), https://www.sfchronicle.com/local/article/The-race-between-variants-and-vaccines-is-heating-16037147.php [https://plus.lexis.com/api/permalink/c452d67c-7108-49e3-adc3-3c9a85ab690d/?context=1530671] ("In the latest testy public exchange between Dr. Anthony Fauci and Sen. Rand Paul, R-Ken., Paul accused the nation's top infectious disease expert Thursday of wearing a mask for 'theater,' and claimed masks are not needed after vaccination. 'You've been vaccinated, and you parade around in two masks for show. You can't get it again,' Paul said during a Senate hearing. Fauci shot back: 'Can I just state for the record that masks are not theater . . . I totally disagree with you.' He said masks are still important in view of unknown potential of coronavirus variants that are spreading. It's also not known how long vaccine protection lasts.").

341. *See The First Amendment: Categories of Speech*, CONG. RSCH. SERV., Jan. 16, 2019, at 1, https://crsreports.congress.gov/product/pdf/IF/IF11072 ("The Supreme Court has long considered political and ideological speech to be at the core of the First Amendment, including speech concerning 'politics, nationalism, religion, or other matters of opinion.' *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). Political speech can take other forms beyond the written or spoken word, such as money, e.g., *Buckley v. Valeo*, 424 U.S. 1 (1976) (per curium), or symbolic acts, e.g., *Texas v. Johnson*, 491 U.S. 397 (1989). A government regulation that implicates political or ideological speech generally receives strict scrutiny in the courts, whereby the government must show that the law is narrowly tailored to achieve a compelling government interest.").

342. West Virginia State Bd. v. Barnette, 319 U.S. 624 (1943).

> nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein. If there are any circumstances which permit an exception, they do not now occur to us.[343]

2. Limiting Professional Speech May Have an Adverse Effect

Numerous media outlets, medical doctors, and academics have pointed out the dangers associated with COVID-19 misinformation. It would be wrong to underestimate the danger posed by misinformation. Doctors dispensing opinions, like Dr. Brody, have the potential to influence patients or the public. That influence could prove deadly. However, is silencing the Dr. Brodys of the world a successful tactic for ensuring that members of the public make medical decisions based on the best available information? Perhaps not.

As the effort to punish doctors for COVID-19 misinformation has intensified, so have the claims of a broad-based conspiracy to silence doctors who speak the truth. By attempting to silence doctors offering medical opinions unsupported by scientifically valid methods, those seeking to counter misinformation may proliferate it. To those suspicious of governmental mandates and the influence of pharmaceutical companies, the effort to silence doctors offering counter-consensus views of COVID-19 origins and treatment looks too much like an effort to bury the truth.[344] Thus, even the most outrageous, inaccurate, or fanciful opinions take on a hue of legitimacy they would not otherwise have. When doctors offering counter-consensus opinions are silenced, every time the CDC, FDA, or NIH changes COVID-19 guidance to suggest that counter-consensus views were correct, produces a great cry of "I told you so."[345] This further fuels the belief that the truth is known and being silenced. It further creates resistance that could cost lives.

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343. *Id.* at 642.

344. *See supra* note 23 and accompanying text; *see also* Steven Hatfill, *Why Is the Media Suppressing Information About Hydroxychloroquine's Effectiveness Against COVID?*, FEDERALIST (Aug. 20, 2020), https://thefederalist.com/2020/08/20/why-is-the-media-suppressing-information-about-hydroxychloroquines-effectiveness-against-covid/ (countering multiple Washington Post stories which labeled any use or push for Hydroxychloroquine as a therapy or treatment for COVID as "fringe doctors spouting dangerous falsehoods.").

345. *See* Elle Purnell, *Media, CDC Quietly Admit 3 COVID Truths After 2 Years of Lies. Did They Think We Wouldn't Notice?*, FEDERALIST (Jan. 10, 2022), https://thefederalist.com/2022/01/10/media-cdc-quietly-admit-3-covid-truths-after-2-years-of-lies-did-they-think-we-wouldnt-notice/ ("Over the weekend, Centers for Disease Control and Prevention Director Rochelle Walensky appeared on numerous news shows and bluntly admitted some big truths that critics of COVID mania have been saying all along.").

C. *A Return to the Marketplace Theory*

So, if counter-consensus public statements by physicians regarding COVID-19 are protected by the First Amendment and, even if they could be silenced, the result might be worse than allowing inaccurate statements to continue, what is to be done? Perhaps the best path is to contest counter-consensus theories in the arena of public opinion.[346] Several sources have raised the concern that a small number of medical doctors have developed an outsized voice about COVID-19 information.[347] Doctors like Pierre Cory, Peter McCullough, and Robert Malone have reached millions of United States citizens and convinced them, to one degree or another, to not trust the mainstream medical community's recommendations regarding COVID-19. Each of these doctors has appeared in television interviews, YouTube videos, medical conferences, and print interviews. The mainstream medical community should engage in the same approach and convince the public of the error in these doctors' reasoning. Even better would be a series of open debates between doctors from the CDC, NIH, and FDA and counter-consensus medical experts.

Recently, Joe Rogan, a very popular podcast personality, offered to host a debate between Democratic Presidential Candidate Robert Kennedy Jr. and Dr. Peter Hotez regarding vaccines.[348] Candidate Kennedy accepted the challenge and Dr. Hotez declined.[349] Dr. Hotez explained his decision to decline the invitation in an interview that

346. *See* Gordon, *supra* notes 19–20 and accompanying text.

347. *See* Benedictus, *supra* note 74 and accompanying text; Hollander & Bergman, *supra* note 1 and accompanying text.

348. Jeremy Littau, *Social Media Has Collapsed Good Debate*, ATLANTIC (June 24, 2023), https://www.theatlantic.com/technology/archive/2023/06/joe-rogan-rfk-jr-interview-debate/674515/ ("Last weekend, the vaccine scientist Peter Hotez criticized the influential podcaster Joe Rogan for hosting Robert F. Kennedy Jr., lamenting the fact that a podcast with millions of listeners lent its megaphone to a notorious spreader of vaccine misinformation. In response, Rogan challenged Hotez to come on his show and debate RFK Jr. with no time limit, offering to donate $100,000 to charity as an incentive. Although Hotez declined, RFK Jr. graciously accepted, leading Elon Musk to muse that Hotez was scared of debate. Given the audiences that Rogan and Musk command and the following that RFK Jr. has cultivated, the tweets sparked a kind of pressure campaign that ratcheted up quickly.").

349. See Dr. Thomas K. Lew, Joe Rogan, RFK Jr. Don't Get It: Vaccine Science Isn't Up for Debate, USA TODAY (June 25, 2023, 5:06 AM), https://www.usatoday.com/story/opinion/voices/2023/06/25/rogan-debate-challenge-shows-why-covid-misinformation-thrives/70347479007/ ("The premise that scientific data needs to win over the masses to be true is flawed. Science is science, and objective data that can be reliably reproduced is true whether people believe it or not.").

was published on the American Medical Association webpage.[350] In the interview, Dr. Hotez stated, "[T]wo reasons for [declining the debate]. I think, one, as I often like to say, science is not something, typically, that we work through a debate mechanism, right? . . . And then, there's the particular problem of RFK, Jr."[351] Dr. Hotez discusses the typical mechanisms by which scientific and medical ideas are advanced—through medical papers that are peer-reviewed and through medical conferences.[352] Regardless of whether debate is part of medical and scientific advancement, which itself seems open to challenge, convincing the public of the correctness of a particular public health approach is perfectly suited to debate. Perhaps Dr. Hotez would not be the ideal individual to represent the pro-vaccine view, particularly if his past dealings with Candidate Kennedy would interfere with an informative discussion on vaccines, but surely some individuals are.

Dr. Hotez's position was echoed in an article in USA Today. The writer states,"[T]he whole premise that scientific data needs to win over the masses to be true is flawed. Science is science, and objective data that can be reliably reproduced is true whether people believe it or not."[353] The author's assertion is misdirected. No one would argue that scientific truth is determined by acceptance. Truth is truth whether it is believed or not. It has been true for all of human history that certain germs cause disease.[354] However, it was not until the nineteenth century that germ theory gained acceptance.[355] If scientists and doctors wish people to follow their advice, then they

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350. *See Dr. Peter Hotez on the Anti-science Movement and Declining Joe Rogan's Debate Challenge*, AM. MED. ASS'N (July 13, 2023) https://www.ama-assn.org/delivering-care/public-health/dr-peter-hotez-anti-science-movement-and-declining-joe-rogan-s-debate (providing a full transcript of Dr. Hotez's comments on the Joe Rogan vaccine debate invitation).

351. *Id.*

352. *Id.* ("We write our papers, submit them to journals like the *Journal of the American Medical Association*, JAMA. And it gets peer-reviewed, sometimes rejected, requests for major revisions—and so that's our currency. We work through scientifically peer-reviewed papers. And also, meetings—again, like the AMA meeting. Right? That's why we have it—so biomedical scientists like myself can present in front of critical audiences—sometimes favorable, sometimes critical—so you can go back to your lab and fix potential problems. So, there is a way of doing it. It's not typically done through debate. As I like to say, you debate 18th-century Enlightenment philosophy and talk about Rousseau versus Bishop, Berkeley versus Hume or you debate politics. But science, we don't typically debate.").

353. *See* Lew, *supra* note 347 and accompanying text.

354. *See A Theory of Germs*, NIH: NAT'L LIBR. MED., https://www.ncbi.nlm.nih.gov/books/NBK24649/ ((last visited Aug. 7, 2023) ("It seems impossible that people once believed that foul odors could create disease or that 'evil spirits' could cause a person to become ill.").

355. *See* Nancy J. Tomes, *American Attitudes Toward the Germ Theory of Disease: Phyllis Allen Richmond Revisited*, 52 J. HIST. MED. 17, 18–20 (1997) (detailing the history and advancement of germ theory in the United States).

have to convince people that they are correct. The author of the USA Today piece raises the valid concern that Robert Kennedy Jr. is a skilled oral advocate, in effect, a professional debater.[356] If a doctor were to engage in a debate with Mr. Kennedy, the doctor might lose simply because Mr. Kennedy is a better orator. Despite this danger, debate or open discussion of contrary views is how the public is moved to accept or deny a particular view or position. Rather than turning down the debate, perhaps a better course would be to have a properly educated professional advocate square off with Mr. Kennedy.

Other steps could enhance a marketplace approach to convincing the public that the mainstream medical community is correct. Removing the appearance of financial incentives provided by the pharmaceutical industry to doctors, hospitals, and government agencies could help convince more individuals to accept the recommendations of public health experts.[357] The term "regulatory capture" is frequently used to describe when "a political or regulatory body is acquired, or 'captured,' by the industry which the body is intended to regulate."[358] Concerns have been raised as to regulatory capture by large pharmaceutical companies of the usual mechanisms that might restrain, regulate, or investigate them. A few examples include pharmaceutical companies sponsoring news programs,[359] paying academic medical researchers for consultation,[360] and

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356. *See* Lew, *supra* note 349 and accompanying text.

357. Laura Karas, *FDA's Revolving Door: Reckoning and Reform*, 34 STAN. L. & POL'Y REV. 1, 2 (2023) ("The frequency and fluidity with which government employees alternate between public-serving roles and private-sector roles, sometimes but not always representational in nature, remain an enduring cause of consternation and mistrust.").

358. Jack Brown, *A Blind Eye: How the Rational Basis Test Incentivizes Regulatory Capture in Occupational Licensing*, 17 J.L. ECON. & POL'Y 135, 138 (2022).

359. Kim C. Budak et al., *Advertiser Spending on Primetime News Throughout the Coronavirus Pandemic*, UNIV. TEX. AT AUSTIN: CTR. FOR MEDIA ENGAGEMENT (Mar. 14, 2022), https://mediaengagement.org/research/ad-spending-on-primetime-news-coronavirus/ (breaking down advertising on the major news networks during the pandemic).

360. *See* Marcia Angell, *Big Pharma Bad Medicine*, BOS. REV. (May 1, 2010), https://www.bostonreview.net/forum/angell-big-pharma-bad-medicine/ (detailing the author's belief that academic and pharmaceutical companies are too financially intertwined). Angell goes on to state:

> Among the many letters I received in response, two were especially pointed. One asked rhetorically, 'Is academic medicine for sale? These days, *everything* is for sale.' The second went further: 'Is academic medicine for sale? No. The current owner is very happy with it.' The author didn't feel he had to say who the current owner was. The boundaries between academic medicine—medical schools, teaching hospitals, and their faculty—and the pharmaceutical industry have been dissolving since the 1980s, and the important

financial entanglement between the pharmaceutical industry, the FDA,[361] and the CDC.[362] Steps like creating more stringent post-employment limitations on FDA and CDC employees[363] and restrictions on individual academic medical researchers receiving payment[364] from pharmaceutical companies could help reduce the appearance of regulatory capture and bias.

Additionally, a vigorous emphasis by public health governmental agencies on conveying accurate information is critical to reinforcing confidence in those institutions. When the public perceives that the spokesperson for a particular agency has been incorrect or untruthful, the impact can be significant. Dr. Fauci was the face of the government's COVID-19 response for over two years. Public trust in Dr. Fauci waned.[365] Although that waning trust is likely due in part

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> differences between their missions are becoming blurred. Medical research, education, and clinical practice have suffered as a result.

Id.

361. *See* Miriam Fauzia, *Fact Check: Some, But Not All, of the FDA's Funding Comes From the Companies Whose Products It Approves*, USA TODAY (Aug. 27, 2021, 12:02 PM), https://www.usatoday.com/story/news/factcheck/2021/08/27/fact-check-some-fdas-budget-does-come-industry-funding/5572076001/ ("About 45% of the FDA's budget, or $2.7 billion, comes from industry user fees, according to a fact sheet released by the FDA in November 2020. The other 55%, or $3.2 billion, comes from federal funding."). Some of the financial entanglement is actually beneficial to taxpayers. Part of the FDA's funding comes from companies that apply to have their drugs approved. *Id.* The sum is paid whether the drug is approved or not. *See* C. Michael White, *Why Is the FDA Funded in Part By the Companies It Regulates?*, CONVERSATION (May 13, 2021, 8:43 AM), https://theconversation.com/why-is-the-fda-funded-in-part-by-the-companies-it-regulates-160444 ("Manufacturers pay these fees when submitting applications to the FDA for drug review and annual user fees based on the number of approved drugs they have on the market."). Despite the absence of a short-term financial motive for the FDA to approve drugs, the arrangement does entangle the FDA's interests with the interests of drug companies.

362. *See* Jeffrey Mervis, *U.S. Lawmakers Want NIH and CDC Foundations to Say More About Donors*, SCI. (June 29, 2018), https://www.science.org/content/article/us-lawmakers-want-nih-and-cdc-foundations-say-more-about-donors ("The CDC Foundation has come under fire in recent years for how it has handled corporate donations, and as a result has severed connections with some donors.").

363. *See* Karas, *supra* note 357, at 56–57 ("A flat prohibition for a period of time on senior FDA officials' employment in industry is likely to face the familiar charges that individuals will be deterred from entering government service, private interests in gainful employment will be unduly trammeled, and agency-industry cooperation will suffer.").

364. *See* Angell, *supra* note 360 ("Increasingly, industry is setting the research agenda in academic centers, and that agenda has more to do with industry's mission than with the mission of the academy. . . . Moreover, drug companies often contract with academic researchers to carry out studies for almost entirely commercial purposes.").

365. *Compare* Nadav Gavrielov, *Trust in Health Agencies and Fauci Remains Strong, a Poll Finds, but Personal Doctors Score Higher*, N.Y. TIMES (July 26, 2021), https://www.nytimes.com/2021/07/21/us/fauci-cdc-covid-misinfo.html ("In a telephone

to "COVID-19 fatigue," some is also likely due to missteps that caused some to question Dr. Fauci's credibility.[366] In particular, Dr. Fauci's changing positions on masks at the beginning of the pandemic and reasons on when herd immunity would be achieved are frequently cited to doubt his credibility.[367]

Greater transparency might also enhance trust in public health institutions. Candidate Biden raised questions regarding the transparency of the production of the COVID-19 vaccines.[368] President Biden can enhance public trust in the program by accelerating the disclosure of as much COVID-19 data as possible.

Finally, efforts should be made to disentangle large pharmaceutical companies from COVID-19 treatment studies. Former President Trump touted his successful incorporation of private-sector pharmaceutical companies into the government's pandemic response, but with that incorporation came suspicion. Because large pharmaceutical companies have made billions off of the COVID-19 pandemic, many are suspicious of information or studies in which large pharmaceutical companies have had a hand.[369] These

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poll of 1,719 adults, 76 percent reported being somewhat or very confident in the trustworthiness of information about Covid-19 from the Centers for Disease Control and Prevention, and 77 percent expressed the same confidence about the Food and Drug Administration. Both results, from a survey conducted from June 2 to 22, were largely unchanged from an April poll."), *with* Katie Smith, *NewsNation Poll: Voters' Trust in Biden, Health Officials Eroding*, NEWSNATION (updated Jan. 14, 2022, 6:06 AM), https://www.newsnationnow.com/polls/newsnation-poll-voters-trust-in-biden-health-officials-eroding/ (when 1,000 registered voters were polled and asked "who they trusted, only 31 percent chose Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Disease; and 16 percent chose Biden, according to the NewsNation poll"). *See also* James Hamblin, *Can Public Health Be Saved?*, *Opinion*, N.Y. TIMES (May 12, 2022), https://www.nytimes.com/2022/03/12/opinion/public-health-trust.html ("As of this January, trust in the C.D.C. had plummeted. At the beginning of the pandemic, 69 percent of Americans believed what they heard from the agency, according to an NBC News poll. Now that has fallen to 44 percent. The numbers for Dr. Anthony Fauci have also substantially declined, despite his decades of government service under seven presidents and attempts to remove himself from political rhetoric.").

366. *See* Tristan Justice, *How Anthony Fauci Made Himself the Face of America's Institutional Decay*, FEDERALIST (May 27, 2021), https://thefederalist.com/2021/05/27/how-anthony-fauci-made-himself-the-face-of-americas-institutional-decay/ ("As the face of the masks, the face of the lockdowns, and possibly even the face of the pandemic, Fauci also became the face of accelerating institutional decay, a political figure whose abject dismissal of alternative strategies amid high-stakes crises left a nation weaker and more divided than in decades.").

367. *See* Marty Makary, *Dr. Fauci's Legacy*, FREE PRESS (Aug. 24, 2022), https://www.commonsense.news/p/dr-faucis-legacy (detailing Dr. Fauci's conflicting policies and statements on school closures, masks, and herd immunity).

368. *See* Ollstein, *supra* note 61 and accompanying text.

369. *See* Sydney Lupkin, *COVID Vaccines Are Set to Be Among the Most Lucrative Pharmaceutical Product Ever, Medical Treatments*, NPR (Nov. 24, 2021, 4:26 PM),

suggestions are intended to rebut what might be thought of as "low-hanging fruit" arguments for those offering counter-consensus COVID-19 opinions.

Likely, a certain segment of the population will not be convinced by such steps. Some individuals simply will not be moved, regardless of the quality of evidence offered or the arguments made. But these are not the individuals that are moved by misinformation in the first place. Perhaps misinformation may confirm a view held by that segment of the population, but it does not create the belief. The group that misinformation can impact are those that are undecided, and argumentation is the best way to lead them to a decision. If the mainstream medical community's position is the most correct, it will be able to move those who are undecided to action. If the mainstream medical community cannot move those who are undecided, then it should reformulate its argument or reflect on the correctness of its position.

CONCLUSION

Choosing the correct response to the opinions of doctors who hold counter-consensus views on COVID-19 is challenging. The response must be attuned to a constantly changing landscape of information and accept that what science and medicine do not know regarding COVID-19 remains substantial. It should be tempered in such a way as to cause the least amount of interference with the doctor-patient relationship. When the response comes from organizations associated with state governments, it must avoid interfering with doctors' rights to freedom of speech under the First Amendment.[370] Finally, the

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https://www.npr.org/2021/11/24/1059041725/covid-vaccines-are-set-to-be-among-the-most-lucrative-pharmaceutical-products-ev ("This year, Pfizer expects to bring in $36 billion from worldwide sales of its COVID-19 vaccine. That would shatter the previous record in annual sales for a single pharmaceutical product—about $20 billion for the anti-inflammatory drug Humira—and make the Pfizer vaccine the bestselling pharmaceutical product ever."); Kevin Dunleavy, *Just How Much COVID-19 Vaccine Money is on the Table? A Whopping $157B Through 2025, Report Says*, FIERCE PHARMA (Apr. 29, 2021, 7:35 AM), https://www.fiercepharma.com/pharma/how-much-covid-19-vaccine-money-table-157b-through-2025-analyst ("In its annual forecast for global drug spending, the IQVIA Institute for Human Data Science put the figure at $157 billion through 2025.").

370. The absence of state action would preclude a First Amendment claim. *See* Dimarco v. Rome Hosp., No. 88-CV-1258, 1991 U.S. Dist. LEXIS 16603, at *9 (N.D.N.Y. June 29, 1991) ("A private defendant acts under color of state law for purposes of § 1983 when he is a willful participant in joint action with the State or its agents.") (internal quotations and citations omitted)); Santos v. Maldonado, Civil No. 09-1850 (FAB/BJM), 2011 U.S. Dist. LEXIS 116141, at *39 (D.P.R. July 1, 2011) ("Plaintiffs' final cause of action claims that defendants, *i.e.*, a private institution and its employees, violated plaintiffs' First Amendment speech and association rights.

response must seek to protect the health and welfare of the public. That protection is best achieved by disciplining doctors who, in the context of the doctor-patient relationship, give advice that is harmful, incorrect, and fails to demonstrate the skill and learning of a reasonable physician in a similar circumstance. Such discipline can be taken by state actors like medical licensing boards, public hospitals, or private organizations. When doctors engage in counter-consensus speech in the public square a different tact is needed. The best approach is to offer more speech—not less. Engage the counter-consensus opinions in the arena of the marketplace of ideas. Adopt means and methods that ensure the persuasive voice of the majority of the medical community is heard. Remove the "low hanging fruit" arguments of governmental concealment or pharmaceutical interference, by maximizing transparency of COVID-19 information and disentangling pharmaceutical interests from studies examining the safety and effectiveness of vaccines and COVID-19 treatments.

'Obviously, only the government can violate First Amendment rights,' so, absent any allegation whatsoever of state action, this claim should be dismissed." (quoting McGuire v. Reilly, 386 F.3d 45, 60 (1st Cir. 2004))); Braswell v. Haywood Reg. Med. Ctr., 234 Fed. Appx. 47, 52 (4th Cir. 2007) (discussing the resolution of First Amendment claims by doctors at a public hospital).