

Ethics, Professionalism and COVID-19

W. Reeves Johnson, Jr., MD, FAAFP
Annual Practice Enhancement Seminar
Tennessee Academy of Family Physicians
TNAFP Office and Virtual
Saturday, March 5, 2022

Ethics, Professionalism and COVID-19

Fellow, Federation of State Medical Boards 2013 - Present

Member, Ethics and Professionalism Committee 2021 - Present

Member, Tennessee Board of Medical Examiners 2013 – 2021

President, 2019-2020

Vice President 2016-2018

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

December 12, 2019 – Cluster of patients in Wuhan China developed shortness of breath and fever.

January 21, 2020 – CDC confirms first case in the USA

January 30, 2020 – World Health Organization (WHO) declares a public health Emergency

February 3, 2020 – USA declares a public health emergency

March 11, 2020 – WHO declares a pandemic

March 13, 2020 – President declares a National Emergency, travel bans begin.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

March 17, 2020 – University of Minnesota begins testing hydroxychloroquine

March 30, 2020 – FDA issues an Emergency Use Authorization (EUA) of hydroxychloroquine

April 29, 2020 – NIH trial shows early promise for Remdesivir

May 1, 2020 – FDA issues an EUA for Remdesivir

June 4, 2020 – Lancet and the NEJM retract studies on hydroxychloroquine

June 18, 2020 – WHO ends study into hydroxychloroquine

June 20 – NIH halts trials of hydroxychloroquine.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

July 9, 2020 – WHO announces COVID-19 can also be spread by airborne transmission in addition to droplet form, can be spread by asymptomatic individuals

July 14, 2020 – Moderna's Vaccine Phase 1 and 2 trials show efficacy

July 22, 2020 – HHS and the DOD partner with Pfizer for delivery of 100M doses of their vaccine in December 2020

July 23, 2020 – NEJM publishes COVID-19 antibodies drop dramatically during the first 3 months of infection

August 11, 2020 – Moderna contracts to deliver 100M doses of its vaccine.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

August 17, 2020 – COVID-19 now the 3rd leading cause of death with deaths exceeding 1000 a day, 5.4M total cases, deaths 8X more common in the US vs. Europe.

August 23, 2020 – FDA issues a EUD for convalescent plasma

August 24, 2020 – JAMA publishes little effect on COVID-19 by remdesivir

August 28, 2020 – first known case of COVID-19 reinfection

September 3, 2020 – steroids - most effective treatment for serious COVID-19

September 15, 2020 – MMWR notes dining out increases infection 2.4X.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

September 28, 2020 – Global COVID-19 deaths exceed 1M

September 29, 2020 – Regeneron monoclonal antibody effective

October 19 – Over 40M cases. 1.1M deaths worldwide, ~20% in the US

October 22, 2020 – FDA approves remdesivir as first COVID-19 treatment

November 9, 2020 – FDA issues EUA for bamlanivimab

November 11, 2020 – *Nature* notes most COVID-19 originates from indoor gatherings

November 23, 2020 – FDA issues EUA for Regeneron monoclonal antibody.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

December 11 and 18, 2020 – FDA issues EUA for Pfizer and Moderna vaccine

December 21, 2020 – new strain found in the UK

December 29, 2020 – UK variant found in US

February 15, 2021 – Various polls note Democrats more likely to receive COVID-19 vaccine: 74-91% vs 51% Republicans

February 19, 2021 – Israel study notes first dose Pfizer vaccine 85% effective after 15-28 days

February 21, 2021 – Israel study finds after 2 doses, Pfizer vaccine ~99% effective at preventing deaths and hospitalizations.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

February 23, 2021 – Pfizer expedites trials for COVID-19 booster

April 1, 2021 – Pfizer phase 3 trial notes vaccine still effective after 6 months

April 16, 2021 – Study notes brain blood clots 95X more likely in those with COVID-19 than those who received the vaccine

April 19 ,2021 – All US adults eligible for the COVID-19 vaccine

April 27, 29, 2021 – CDC relaxes mask guidelines for fully vaccinated while ½ of U.S. states report drops in COVID-19 cases

May 3, 2021 - >20% of new COVID-19 cases in children

May 10, 2021 – FDA issues EUA for Pfizer vaccine in those 12-15 years old.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

May 26, 2021 – Risk of COVID-19 after fully vaccinated: 0.01%

June 23, 2021 – Delta variant advances in the US

June 25, 2021 – Almost all COVID-19 deaths in unvaccinated, breakthrough infections 0.1%

August 3, 2021 – Delta variant affecting ~93% of cases, only 3% in late May

August 12, 2021 – FDA OKs additional vaccine for immunocompromised

September 24, 2021 – additional vaccine recommended for 18-64 years old at increased risk – workplace, LTC, underlying health conditions.

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TIMELINE

American Journal of Managed Care, January 1 and June 3, 2021

November 19, 2021 – FDA, CDC OK boosters for all adults

December 22-23, 2021 – FDA authorizes first 2 oral medications: Paxlovid and molnupiravir

December 27 2021 – CDC shortens time of isolation for asymptomatic cases and quarantine for exposed vaccinated individuals.

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TREATMENTS

Pharmaceutical Journal, December 22, 2021

Antivirals: Remdesivir Chloroquine/hydroxychloroquine
Amodiaquine Artesunate Lopinavir/ritonavir
combination Favipiravir Ribavirin EIDD-2801
Niclosamide Nitazoxanide Oseltamivir Ivermectin AT-527
Molnupiravir PF-07321332

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TREATMENTS

Pharmaceutical Journal, December 22, 2021

Immune modulators: Dexamethasone Hydrocortisone
Convalescent plasma Budesonide (inhaled) AZD7442 Azithromycin
Doxycycline Interferons Tocilizumab Sarilumab Regdanvimab
Canakinumab Anakinra Baricitinib Ruxolitinib Tofacitinib
Acalabrutinib Imatinib Brensocatic Ravulizumab Namilumab
Infliximab Adalimumab Otilimab Medi3506 Monoclonal antibody
cocktail Bamlanivimab (monotherapy) Etesevimab (monotherapy)
Sotrovimab Leronlimab Risankizumab Lenzilumab IMU-838

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TREATMENTS

Pharmaceutical Journal, December 22, 2021

Other or multiple mechanisms: [Colchicine](#) [Dimethyl fumarate](#)
[Angiotensin-converting-enzyme inhibitors/angiotensin II](#)
[receptor blockers](#) [Statins](#) [Aspirin](#) [Clopidogrel](#) [Anticoagulants](#)
[Bemcentinib](#) [Omeprazole](#) [Famotidine](#) [Zilucoplan](#) [Ascorbic](#)
[acid/vitamin C](#) [Vitamin D₃](#) [Aviptadil](#) [Tradipitant](#) [Nitric oxide](#)
[Fluvoxamine](#) [Proxalutamide](#) [Ruconest](#) [TRV027](#) [Ciclesonide](#)

Ethics, Professionalism and COVID-19 TREATMENTS

Pharmaceutical Journal, December 22, 2021

Remdesivir – some efficacy in those with pneumonia needing O₂, WHO: no evidence it improves survival and other outcomes

Hydroxychloroquine – FDA cautioned against it outside of a hospital setting due to risk of heart rhythm problems, several studies: no evidence of benefit

Ivermectin – one study showing benefit was retracted due to suspicion of data manipulation, other studies with conflicting results

Convalescent plasma – studies showing possible benefits are largely case studies, controlled studies showed no benefit

Azithromycin – multiple studies – no benefit.

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Dictionary.com

Misinformation - “false information that is spread, regardless of intent to mislead.” It is simply a term for any kind of wrong or false information

Disinformation - knowingly spreading misinformation.

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Ways mis/dis information has affected the COVID-19 pandemic: *NIH, Z. Gesundh Wiss 2021 Oct.9: 1-10*

Mental health: Uncertainty, panic, anxiety, sleep disorders, depression, suicide

Physical: not slowing down the spread, increased cases, higher mortality, consequences from unproven treatment

Sources: conspiracy theories, social media, medical personnel, political.

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Ways mis/dis information has affected the COVID-19 pandemic: *Gerald Harmon, President, AMA, December 14, 2021*

A recent study by the Johns Hopkins Center for Health Security estimated that false or misleading information continues to inflict between \$50 million and \$300 million in total harm to our nation each and every day since May 2021, when vaccines to prevent COVID-19 became widely available.

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Examples:

The Washington Post, December 15, 2020

America's Frontline Doctors tried to convince Americans that the potential for severe illness from covid-10 was a hoax, in the interest of keeping the U.S. economy open and thus fueling Donald Trump's re-election campaign. Through their social media platforms and rallies, they continue to sow distrust of the Centers for Disease Control and Prevention and dissuade their audiences from following public health guidelines.

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Examples:

The Washington Post, December 15, 2020

Simone Gold one of the founders of America's Frontline Doctors, a California physician and noted advocate of the hydroxychloroquine "cure, continues to spread disinformation, discourage vaccination and promote unproven treatments for covid (for which, NPR noted, she was offering to prescribe via a \$90 telehealth appointment)...

was arrested after Jan. 6, when she participated in the incursion into U.S. Capitol.

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Examples:

The Washington Post, December 6, 2021

An Ohio-based licensed osteopathic physician and anti-vaccine advocate, who gained notoriety for claiming the coronavirus vaccines could leave people “magnetized”

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Examples:

Forbes, June 23, 2021



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Examples:

The Washington Post, December 6, 2021

An Ohio-based licensed osteopathic physician and anti-vaccine advocate, who gained notoriety for claiming the coronavirus vaccines [could leave people “magnetized”](#)

A North Carolina osteopathic physician who has falsely claimed that coronavirus vaccines kill more people than covid-19.

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Ways mis/dis information has affected the COVID-19 pandemic: *NIH, Z. Gesundh Wiss 2021 Oct.9: 1-10*

Other examples: biologic warfare, global conspiracy, 5G networks, man-made, brine mouth rinse, ultraviolet light, garlic or chlorine on the skin, consuming methanol or alcohol, vaccine developed too fast, has a chip, others.

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Top 10 reasons for not getting the COVID-19 Vaccine:

10. It will make you a zombie
9. Vaccines are for dogs
8. It makes you magnetic
7. The vaccine will rub off on others
6. I identify as vaxxed

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Top 10 reasons for not getting the COVID-19 Vaccine:

5. It is not 100% safe
4. It has a tracking device/chip
3. The Plague disappeared without a vaccine
2. It changes your DNA
1. And the number 1 reason...

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Top 10 reasons for not getting the COVID-19 Vaccine:

- 1. It will make you sterile.**

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Federation of State Medical Boards July 29, 2021 statement regarding spreading COVID-19 vaccine misinformation may put medical license at risk

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

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My edit:

"They also have an ethical and professional responsibility to practice medicine in the best interests of their patients. A physician should strive to share information that is factual, scientifically grounded and consensus-driven for the betterment of public health, realizing in some situations, consensus has not been achieved and in these cases, an unbiased presentation of the different scientifically grounded opinions should be provided."

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Other State Medical Board's (SMB) Response:

Federation of State Medical Boards **SURVEY:**

More than two-thirds of the 58 SMBs that responded to the FSMB survey had seen an uptick in complaints.

26% have made or published statements about the dissemination of false or misleading information

A dozen boards, representing roughly 1 in 5 respondents, reported taking some sort of disciplinary action against doctors for spreading false or misleading information.

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Other State Medical Board's (SMB) Response:

The Washington Post, December 6, 2021

The Oregon Medical Board revoked the license of a doctor who refused to follow public health guidelines in his clinic, spread misinformation about masks and overprescribed opioids

A San Francisco doctor who promoted a false conspiracy linking covid-19 with 5G networks surrendered his license to California's medical board

Rhode Island's Board of Medical Licensure suspended the license of a doctor who discouraged patients from getting the coronavirus vaccines.

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The Tennessee Board of Medical Examiners response to COVID-19 mis-/dis-information

At its September 2021 meeting, they heard the office was receiving complaints re COVID-19 and wanted guidance how to proceed with different cases.

- 1) Physician is vaccine hesitant,
- 2) Physician makes up inaccurate facts about the vaccine and advises patients to not get vaccinated, and
- 3) Physician is spreading inaccurate facts about the vaccine and advises patients to not get vaccinated.

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The Tennessee Board of Medical Examiners response to COVID-19 mis-/dis-information

The Board adopted the FSMB Board of Directors position as a policy of this Board

Misinformation would be fleshed out in the investigative process

If the physician has scholarly proof that the information, they are providing is factual then there are no grounds to discipline. However, if the Board identifies misinformation, then the physician could be disciplined

Physicians have always been allowed to discuss their opinions with their patients.

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The Tennessee Board of Medical Examiners response to COVID-19 mis-/dis-information

1. Physician is vaccine hesitant – no investigation, no discipline, the Board doesn't feel like this is practical to enforce. They do feel as though physicians should not be expressing their opinions on hesitancy. These are one-on-one conversations that would be difficult to discipline for. A letter of warning would be appropriate.
2. Physician makes up inaccurate facts about the vaccine and advises patients to not get vaccinated – this should be investigated, this is unprofessional conduct, the office can clearly identify the misinformation being provided and formal discipline is appropriate.
3. Physician is spreading misinformation and advising patients to not get vaccinated – formal discipline is appropriate and the number of people you have reached with the misinformation should be a factor in the level of discipline.

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The Tennessee Board of Medical Examiners response to COVID-19 mis-/dis-information

Received communication from the co-chair of the Tennessee Joint Operations Committee requesting the BME remove the policy from the website or appear before the Committee to explain its action

This from the belief that this new disciplinary offense needed to be by rule, not policy. Any rule must be approved by this Committee

According to a TN BME attorney, she felt this co-chair had no qualms moving forward to dissolving the BME and obtaining new members

December 7, 2021, the BME voted 7-3 to remove the policy from the website but declined to vote to rescind it.

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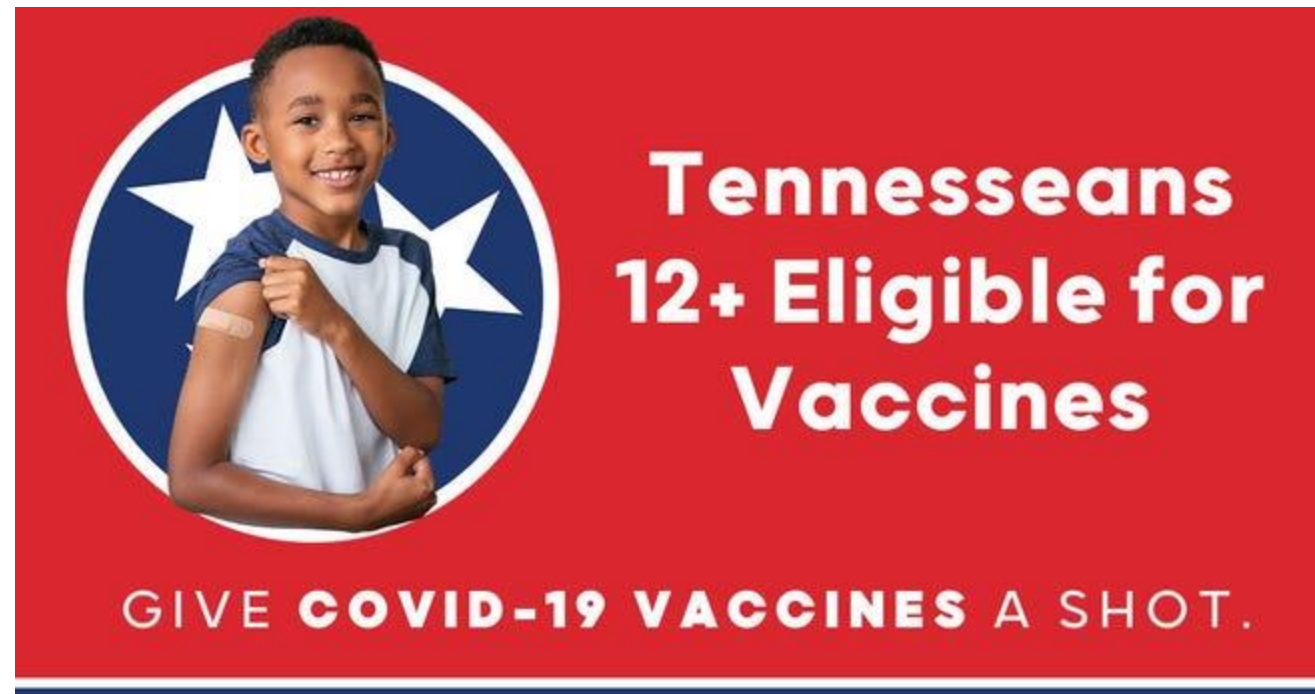
Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Tennessee Lookout, June 17, 2021

June 2015 – Health Commissioner Lisa Piercey called before the
Joint Operations Committee to explain the Department’s targeting
minors for vaccination without parental consent

Concern based on marketing items showing a teenager with a
band-aid on the arm after receiving the vaccine.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Tennessee Lookout, June 17, 2021

This brought on by a memo OK'd by the DOH attorney citing the
Mature Minor Doctrine

Sent to vaccine providers

One recipient upset and posted it on social media.

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Tennessee State Government response to the COVID-19 pandemic and its effect on the practice of medicine.

Dr. Piercey referred to the Mature Minor Doctrine –

Under 7 years old would not be able to make their own health-care decisions.

Between ages 7 and 14, a rebuttable presumption exists that they don't have the capacity to decide about health care without parental consent

Between 14 and 18, young people have the capacity to decide, according to the doctrine, and a physician may treat without parental consent unless it is clear the child is not capable of making the decision.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Dr. Piercey also stated, “Under no circumstance is the department encouraging children to seek out vaccination without parental consent.” “Circumstances (utilizing this Doctrine) would be rare.”

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Comments from Committee members:

“DOH misusing the Doctrine”

“Back off the misunderstanding & misapplication of the Doctrine”

“DOH incredulous encouraging children be vaccinated despite 60%
of the population choosing not to”.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Comments from Committee members:

“majority of adults can reject the vaccine but OK for a 14 year old”

“encouraging a child to go against parent’s wishes”

“DOH and Commissioner come back in July for more discussion
and potential vote on dissolving the DOH”.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Comments from Committee members:

“only the General Assembly can act on the DOH”

motion amended, “DOH to change policy and return in July”

“no evidence that the DOH is targeting minors”.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Tennessean, July 12, 2021

DOH reaction to the June Joint Gov't Ops Committee meeting:

Vaccine events for teens halted

All vaccine communications halted, including notification re
measles vaccine, HPV vaccine, 2nd COVID-19 vaccine, although
some later reinstated

Michelle Fiscus fired.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Public Chapter 6 establishes a new title (14) named COVID-19

Passed during a special session by Legislature October 29, 2021
and signed by our Governor November 12, 2021.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Multiple definitions, including:

Minor

Monoclonal Antibodies

Quarantine

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Actions:

The commissioner of health has the sole authority to determine quarantine guidelines

A local health entity or official, mayor, governmental entity, or school does not have the authority to quarantine a person or private business for purposes of COVID-19

The commissioner may only establish quarantine guidelines by rules.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Actions:

Monoclonal antibodies: a healthcare provider shall exercise independent professional judgment when determining whether to recommend, prescribe, offer, or administer monoclonal antibodies to a patient as a treatment or prophylaxis against COVID-19.

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Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Actions:

Mature minor doctrine. (a) Except as provided in subsection (b), a healthcare provider shall not provide a patient who is a minor with a COVID-19 vaccine without first obtaining written consent from the minor patient's parent or legal guardian

(b) Subsection (a) does not apply if a healthcare provider, in the provider's independent professional judgment, suspects that the minor may be subjected to abuse, as defined in § 37-1-102, by a parent or legal guardian, or may be a dependent and neglected child, as defined in § 37-1-102. If the exception provided in this subsection (b) applies, then the common law applies to the minor's capacity to consent to receiving a COVID-19 vaccine.

Ethics, Professionalism and COVID-19

Tennessee State Government response to the COVID-19 pandemic
and its effect on the practice of medicine.

Actions:

“any disciplinary process, or action taken pursuant to such process, that is implemented by a health-related board regarding the dispensing or prescribing of medication for COVID-19 must be promulgated as a rule.”

Ethics, Professionalism and COVID-19

FSMB's (Draft) Policy Professional Expectations Regarding Medical Misinformation and Disinformation

Truthful and accurate information is central to the provision of quality medical care.

supports the **trust** that patients hold in the medical profession

harmful and dangerous to patients, public health and to the medical profession itself, when licensed physicians **knowingly and maliciously** engage in the **spread of disinformation** and misinformation about a disease or illness, including its prevention, management or treatment

In providing care, proposing treatments to patients or sharing medical advice with the public, **physicians** must **(to the best of their ability)** always **be truthful** and act in such a way that provides **benefit** to the patient or the public first, without allowing competing considerations, beliefs or interests to take precedence **(yet, where consensus is not achieved, provide scientifically relevant alternatives)**.

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FSMB's (Draft) Policy Professional Expectations Regarding Medical Misinformation and Disinformation

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

While there are gray areas in many aspects of the practice of medicine, which is inherently dynamic and constantly evolving, physicians must exercise care and ensure that any **recommendations** or prescriptions, especially in a fast-changing pandemic, have a **compelling and evidence-based foundation** in the **medical literature** (and when this does not exist, present the patient with what are currently **scientifically based options that are currently being evaluated**).

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FSMB's (Draft) Policy Professional Expectations Regarding Medical Misinformation and Disinformation

When **medical information** is conveyed, whether in a clinical setting or in public through electronic means or otherwise, it must be based upon the **best available scientific evidence (at that time)**, or else the standard of care is not met. **Where no such evidence exists**, physicians must **proceed very cautiously** and only when there is a compelling rationale for the proposed treatment and justification of its use in relation to the patient's symptoms or condition

Novel, experimental or unproven interventions should only be **considered and proposed** when **traditional, accepted and proven treatment modalities have been tried and failed**. In such instances, there must still be a basis in **(scientific)** theory or **peer-acknowledged support for such practices**.

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FSMB's (Draft) Policy Professional Expectations Regarding Medical Misinformation and Disinformation

If **justification** based on prevailing **(or legitimate scientific)** evidence is **not present**, **disciplinary action** by a state medical board **may be warranted**. **Off-label prescribing** of medication, ordinarily permitted by law, is **not an appropriate defense** or cover for rogue practices occurring without accompanying rationale or justification based in science

Physicians are expected to **(the best of their ability)** be **mindful of evolving standards of care** and **avoid** making treatment recommendations based on **outdated, disproven or otherwise false information**

Patients have a right to be **fully informed** about any treatments proposed for them. Such information must be **based on scientific evidence and prevailing standards of care**, and duly documented in the medical record. **Informed consent fails** when a patient consents to a management or treatment **plan** that is **based on misinformation or disinformation**.

Ethics, Professionalism and COVID-19

FSMB's (Draft) Policy Professional Expectations Regarding Medical Misinformation and Disinformation

(Regarding) requests for treatments based on misinformation (and/or disinformation), physicians are likely to receive requests from patients for medical exemptions from public health requirements, such as masking or vaccination, that may not be based in medical need. While denying such requests may result in frustrations on the part of the patient and even breakdown of the physician-patient relationship, physicians should not offer exemptions that are not based in medical need or not made within the context of an established physician-patient relationship.

While some might question state medical board authority on First Amendment grounds, the U.S. Supreme Court has previously made clear that “the liberty secured by the Constitution of the United States does not import an absolute right in each person to be at all times, and in all circumstances, wholly freed from restraint.” There are many ways in which physicians’ speech in clinical settings and in public is already subject to reasonable restrictions. In the interest of patient privacy, HIPAA regulates the types of disclosures physicians can make in the clinic and in public communication. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, (1905).

Ethics, Professionalism and COVID-19

FSMB's (Draft) Policy Professional Expectations Regarding Medical Misinformation and Disinformation

Freedom of speech, we hold and restate here, does not imply the freedom to misinform (or disinform). A policy which expressly prohibits physicians from disseminating misinformation or engaging in disinformation is a reasonable restriction on professional conduct

There should not be an exception with respect to the spread of disinformation (and/or misinformation), particularly when its impact on patients and the health of the public is widespread and severe in an ongoing pandemic that has thus far taken the lives of five million individuals in less than two years

When confronted by misinformed (and/or disinformation) patients, physicians are encouraged to listen respectfully to patients before reacting to the information being shared

Physicians should anticipate difficult conversations with patients about controversial topics that are in the news by being prepared with easily accessible information for conditions and treatments about which patients may be misinformed (or disinformed).

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QUESTIONS

W. Reeves Johnson, Jr., MD, FAAFP

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TNAFP Office and Virtually

Saturday, March 5, 2022

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THANK YOU

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Saturday, March 5, 2022